

COMPILATION OF VARIOUS LEGAL PROVISIONS ON COMPULSORY LICENSES AND
GOVERNMENT USE

COMPILATION DE DISPOSITIONS JURIDIQUES SUR LES LICENCES OBLIGATOIRES ET
L'UTILISATION PAR LES POUVOIRS PUBLICS

COMPILACIÓN DE DIVERSAS DISPOSICIONES LEGALES SOBRE LICENCIAS OBLIGATORIAS Y
EXPLOTACIÓN POR EL GOBIERNO

تجميع مختلف الأحكام القانونية بشأن التراخيص الإجبارية والاستخدام الحكومي

强制许可各种法律规定及政府使用情况汇编

КОМПИЛЯЦИЯ РАЗЛИЧНЫХ ПРАВОВЫХ ПОЛОЖЕНИЙ О ПРИНУДИТЕЛЬНЫХ ЛИЦЕНЗИЯХ
И ИСПОЛЬЗОВАНИИ В ГОСУДАРСТВЕННЫХ ЦЕЛЯХ

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ALBANIA

Law No. 9947 of July 7, 2008, on Industrial Property (as amended up to Law No. 55/2014 of May 29, 2014)

Articles 50 and 51

Article 50 Compulsory Licenses

1. On request, the court is entitled to grant a compulsory license to any Person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent in the Republic of Albania when he meets all the requirements defined in the implementing regulation of this Law, provided that:

- a) four years have expired from the filing of the application and three years have expired from the grant of the patent;
- b) the patent owner has not exploited the patent on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction.
- c) the Person requesting the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and if such efforts have not been successful within a reasonable period of time.

2. Based on the request, for a non-exclusive use of the patent protected invention or the plant species protected by this right, the court is entitled to grant a compulsory licence in respect of a first patent to the patent owner or right holder on the plant species, who cannot use the second patent or right on a plant species without infringing the first patent, by making a payment established by an expert appointed by the court, provided that:

- a) the invention claimed in the second patent or the protected plant species involves a technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- b) they have requested to the patent or right holder on the plant species, the right to be provided with a contractual licence and have not been provided with the same.”

2/a. The court, for a non-exclusive use of the protected invention, takes any measure it deems necessary to verify the existence of such a situation.

2/b. In the case of a compulsory licence, as provided under paragraph 2 of this Article, the owner of the first patent or the holder of the right on a plant species shall be entitled to use the subsequent patented invention or protected plant species under a combined licence on reasonable terms.

3. On request, the court is entitled to grant a compulsory license in respect of patents and supplementary protection certificates relating to the manufacture and sell of pharmaceutical products, when such products are intended for export to importing countries in need of such products in order to address public health problems, subject to the implementing regulation.

4. The type of use covered and the conditions to be met shall be specified by the court. The following conditions shall apply:

- a) The scope and duration of the exploitation shall be limited to the purpose for which it was authorized;
- b) The exploitation shall be non-exclusive;
- c) The exploitation shall be non-assignable. In the case of a compulsory licence, as provided by paragraph 2 of this Article, the authorised exploitation regarding the first patent shall be non-assignable, except with the assignment of the second patent or plant species.
- c) The amount of products manufactured under the license shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of products manufactured under other compulsory licenses granted elsewhere.

5. The exploitation shall be authorized, above all, to supply the market of the Republic of Albania, except in the case provided in paragraph 3 of this article.

6. A compulsory license shall be valid until the end of the time period designated by the court or until the end of the term of the patent. However, the court may, on reasoned request, decide to cancel the authorization, subject to adequate protection of the legitimate interests of the Persons so authorized, if and when the circumstances which led to it cease to exist and are unlikely to recur.

7. Compulsory licenses shall be registered in the patent register.

8. The owner of the patent shall be entitled to adequate compensation for a compulsory license, taking into account the economic value of the authorization. When the parties do not agree, the amount of this compensation shall be set by the court.

9. The holder of a compulsory license may renounce at it at any time. If the holder does not begin exploitation within one year from the final grant of the compulsory license, the owner of the patent may claim for the compulsory license to be modified or annulled.

10. The requirements of paragraphs 1(c) and 5 of this article shall not be applicable when such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account of in determining the amount of remuneration in such cases. The court shall have the authority to refuse termination of an authorization if the conditions that led to such authorization are likely to recur.

Article 51 Exploitation by the Government or Third Parties Authorized by the Government

1. When the interests of essential defense or national security require it, the Minister of Defense or the Minister of Health may, even without the approval of the owner of the patent or the applicant, by a notification in the GDPT Gazette, authorize a governmental agency or a specific Person to make, use or sell the invention for which the patent application was submitted, or the patent was granted, subject to payment of equitable remuneration to the owner of the patent or to the patent applicant. The owner of the patent or the patent applicant shall be notified as soon as possible.

2. An appeal to the court can be taken against the decision of the Minister of Defense or the Minister of Health.

ALGERIA

Loi n° 03-19 du 9 Ramadhan 1424 correspondant au 4 novembre 2003 portant approbation de l'ordonnance n° 03-07 du 19 Joumada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention

Articles 38-49

38. Toute personne peut, à tout moment après l'expiration d'un délai de quatre (4) années à compter de la date de dépôt de la demande d'un brevet ou de trois (3) années à compter de la date de délivrance du brevet d'invention, obtenir auprès du service compétent, une licence d'exploitation pour cause de défaut ou d'insuffisance d'exploitation.

Pour l'appréciation du délai cité à l'alinéa ci-dessus, le service compétent appliquera celui qui expire le plus tard.

La licence obligatoire ne peut être accordée par le service compétent, qu'après vérification de la réalité du défaut ou de l'insuffisance d'exploitation et s'il n'existe pas de circonstances qui justifient ce défaut ou cette insuffisance d'exploitation de l'invention brevetée.

39. Toute personne demandant une licence obligatoire conformément aux articles 38 et 47 de la présente ordonnance, doit apporter la justification qu'elle s'est préalablement adressée au titulaire du brevet d'invention et n'a pu obtenir de lui une licence contractuelle à des conditions équitables.

40. La licence obligatoire, visée à l'article 38 ci-dessus, ne peut être accordée qu'à un requérant présentant les garanties nécessaires à une exploitation apte à remédier aux déficiences qui en ont motivé l'octroi.

41. La licence obligatoire est accordée moyennant une indemnisation adéquate, selon le cas d'espèce, compte tenu de la valeur économique de la licence.

42. La licence obligatoire ne peut être transmise qu'avec la partie de l'entreprise ou du fonds de commerce qui en a la jouissance. Une telle transmission ne peut être effectuée qu'avec l'autorisation du service compétent.

43. La licence obligatoire ou la transmission de licence obligatoire doit être inscrite auprès du service compétent moyennant le paiement de la taxe prescrite.

44. Sur requête du titulaire du brevet d'invention ou du bénéficiaire de la licence obligatoire, le service compétent peut modifier la décision d'octroi de la licence obligatoire dans la mesure où des faits nouveaux justifient une telle modification en particulier lorsque le titulaire du brevet accorde des licences contractuelles à des conditions plus avantageuses pour le licencié contractuel.

45. Sans préjudice des dispositions du dernier alinéa du présent article et sur demande du titulaire du brevet d'invention, la licence obligatoire peut être retirée par le service compétent dans les cas suivants;

1°) si les conditions qui justifient l'octroi de la licence obligatoire ont cessé d'exister,

2°) si le bénéficiaire de la licence obligatoire ne satisfait plus aux conditions fixées.

Le service compétent ne retire pas la licence obligatoire s'il acquiert la conviction qu'il existe des circonstances qui justifient le maintien de la licence et en particulier dans le cas visé au point 1) ci-dessus, lorsque le bénéficiaire de la licence exploite industriellement l'invention brevetée ou a fait des préparatifs sérieux en vue de cette exploitation industrielle.

46. La demande de licence obligatoire d'un brevet d'invention qui doit faire l'objet de la justification prévue à l'article 39 ci-dessus, est formulée auprès du service compétent. Le service compétent convoque et entend le demandeur et le titulaire du brevet ou leurs représentants.

Si le service compétent accorde la licence obligatoire, il doit en fixer les conditions en précisant notamment sa durée et, sauf accord entre les parties, le montant de l'indemnisation due au titulaire du brevet, sans préjudice, dans ce dernier cas, du recours auprès de la juridiction compétente qui statue en premier et dernier ressort.

Les dispositions du présent article s'appliquent au cas de transmission de la licence obligatoire d'un brevet d'invention tel que prévu à l'article 42 de la présente ordonnance.

47. Si une invention protégée par un brevet d'invention ne peut être exploitée sans qu'il soit porté atteinte aux droits découlant d'un brevet d'invention antérieur, il peut être accordé, sur demande, une licence obligatoire au titulaire du brevet d'invention ultérieur.

Une telle licence sera accordée dans la mesure nécessaire à l'exploitation de l'invention, pour autant que celle-ci présente un progrès technique notable et soit d'un intérêt économique important, par rapport à l'invention objet du brevet antérieur.

Le titulaire du brevet antérieur a droit à une licence réciproque, à des conditions raisonnables, pour utiliser l'invention objet du brevet ultérieur.

48. La licence obligatoire visée à l'article 38 ci-dessus sera non exclusive et aura principalement pour objet l'approvisionnement du marché national.

49. Une licence obligatoire peut être accordée à tout moment par le ministre chargé de la propriété industrielle à un service de l'État ou à un tiers désigné par le ministre, pour une demande de brevet ou pour un brevet d'invention, dans l'un des cas suivants :

- 1) Lorsque l'intérêt public, en particulier la sécurité nationale, la nutrition, la santé ou le développement d'autres secteurs de l'économie nationale l'exige, et notamment lorsque la fixation, pour les produits pharmaceutiques brevetés, de prix excessifs ou discriminatoires par rapport aux prix moyens du marché;
- 2) Lorsqu'un organe judiciaire ou administratif juge que la manière dont le titulaire du brevet ou son preneur de licence exploite l'invention est anticoncurrentielle et lorsque le ministre chargé de la propriété industrielle est convaincu que l'exploitation de l'invention en application du présent alinéa, permettra de remédier à cette pratique.

ANDORRA

Law on Patents (dated 10/06/1999)

Article 34

Article 34 - Compulsory licenses

(1) Any person who proves his ability to work the patented invention in Andorra, after the expiration of a period of four years from the filing date of the application or three years from the grant of the patent, whichever is later, may institute legal proceedings in front of the Civil Court to request a the grant of a compulsory license to exploit the patented invention if it is not worked or is insufficiently worked in Andorra.

(2) The scope and duration of any compulsory license shall be limited to the purpose for which it is granted, and such license shall be

- (a) non-exclusive,
- (b) non-assignable, except with that part of the enterprise or goodwill which enjoys such authorization,
- (c) granted exclusively for the supply of the domestic market.

(3) The grant of a compulsory license shall be subject to the payment of adequate remuneration to the proprietor of the patent. Such license may only be granted if, prior, the person requesting it has made efforts to obtain authorization from the proprietor on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

(4) A compulsory license shall not be granted if the Judicial Authority determines that circumstances exist which justify the non-working or insufficient working of the patented invention in Andorra, and in particular if the product covered by the patent is put on the market in Andorra in sufficient quantity to satisfy the needs in Andorra.

(5) Proceedings mentioned in paragraph (1) shall follow the “procediment abreujat” (summary procedure) and therefore the Court shall give both the proprietor of the patent and the person requesting such license an adequate opportunity to present arguments.

(6) The proprietor of a patent may institute legal proceedings in front of the Civil Court requesting the revocation of a compulsory license when the circumstances which led to its granting cease to exist and are unlikely to recur. The Court shall take into account the legitimate interests of the proprietor of the patent and of the licensee.

ANTIGUA AND BARBUDA

Patents Act, 2018

Sections 34 and 35

34. Exploitation by Government or person authorized thereby

(1) Where –

(a) the public interest, in particular, national security, nutrition, health, or the development of other vital sectors of the national economy so requires; or

(b) the Minister has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and he is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice, the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Minister’s authorisation, as determined in the said decision, and, where a decision has been taken under subsection (1) (b), the need to correct anti-competitive practices.

(3) The Minister shall make his decision after hearing the owner of the patent and any interested person.

(4) A request for the Minister’s authorisation to exploit a patented invention shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorisation, a request for a contractual licence, but that that person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(5) Subsection (4) shall not apply in cases of:

(a) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the Minister’s decision as soon as reasonably practicable;

(b) public non-commercial use, and

(c) anti-competitive practices determined as such by the Minister in accordance with subsection (1) b).

(6) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorised for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anticompetitive, and if the Minister is satisfied that the issuance of the non-voluntary licence would remedy such practice.

(7) The authorisation shall not exclude:

- (a) the conclusion of licence contracts by the owner of the patent; or
- (b) the continued exercise, by the owner of the patent, of his rights under section 32.

(8) Where a third person has been designated by the Minister, the authorisation may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(9) The exploitation of the patented invention by the Government agency or third person designated by the Minister shall be predominantly for the supply of the market in Antigua and Barbuda.

(10) Upon the request of the owner of the patent, of the Government agency or of the third person authorised to exploit the patented invention, the Minister may, after hearing the parties, vary the terms of the decision authorising the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(11) Upon the request of the owner of the patent, the Minister shall terminate the authorisation if he is satisfied, after hearing the parties, that the circumstances which led to his decision have ceased to exist and are unlikely to recur, or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(12) Notwithstanding subsection (11), the Minister shall not terminate the authorisation if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.

35. Compulsory Licenses

Where –

- (a) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- (b) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or
- (c) the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or
- (d) the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in the territory of Antigua and Barbuda, either through manufacture in Antigua and Barbuda, or through importation; or
- (e) when a patent (the “second patent”) claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in a patent (the “first patent”) without infringing which the second patent cannot be exploited;

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. Each request for a compulsory license shall be considered by the Minister on its individual merits. The exploitation of the invention shall be limited to the purpose for which it was licensed and shall be subject to the payment to the said owner of an adequate remuneration in the circumstances of each case, taking into account the economic value of the Minister’s decision, as determined in the said decision, and, where a decision has been taken under item (b) of this section, the need to correct anti-competitive practices. The Minister shall take his decision after hearing the owner of the patent and any interested person if they wish to be heard.

(2) The public interest according to subsection (1) (a) includes public health problems such as HIV, tuberculosis, malaria and other epidemics. Therefore, the Minister in the case of national emergency or other circumstances of extreme urgency has the authority to grant a compulsory license or authorize a public noncommercial use for the importation of a pharmaceutical product, a product produced by a patented process or a process of making a pharmaceutical product provided an alternative process of making the same product is not known or not available, under the terms and conditions contained in Article 31 bis of the TRIPS Agreement, the Annex to the Agreement and the Appendix to the Annex.

(3) A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(4), before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.

(4) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(5) Upon the request of the owner of the patent, the Minister shall –

- (a) terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision;
- (b) notwithstanding paragraph (a) of this subsection, not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1) (b) if and when the conditions which led to such compulsory license are likely to recur.

(6) The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(7) The compulsory license shall always be non-exclusive. Therefore, it shall not exclude:

- (a) the exploitation of the invention by the patent owner himself, either through manufacture in Antigua and Barbuda or through importation or both; and
- (b) the conclusion of license contracts by the owner of the patent; and
- (c) the continued exercise, by the owner of the patent, of his rights as stated in section 32 of this Act.

(8) A request for the compulsory license shall be addressed to the Minister and shall be accompanied by the following:

- (a) evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. Unless the particular circumstances of the case show otherwise, a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time;

(b) evidence concerning a previous attempt of obtaining a voluntary license, under section 37 subsection (1) shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

(9) The exploitation of the invention by the Government agency or third person licensed by the Minister shall be predominantly for the supply of the market in Antigua and Barbuda, except, when it is permitted to remedy a practice determined to be anticompetitive according subsection (1) (2); or when the compulsory license concerns a patent claiming a pharmaceutical product or a process of making a pharmaceutical product, and the purpose of the license is to export the patented products or the products manufactured by the patented process for an importing Member with no or with insufficient manufacturing capacity, in accordance with the terms and conditions of Article 31 bis of the TRIPS Agreement.

(10) Where a compulsory license is granted under subsection (1) (e):

- (a) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
- (b) the license of the first patent shall be non-assignable except with the assignment of the second patent.

(11) The provisions of this article shall apply, where appropriate, and *mutatis mutandis*, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.

(12) Any decision by the Minister as regards a request for a compulsory license or a compulsory license granted, including the decision relating to the remuneration, may be subject to an appeal by the patent applicant or owner or by the requesting party, in accordance with section 63 of this Act.

(13) Adequate remuneration of compulsory license under subsection 2 shall take place only in the exporting country according to Article 31 bis (2) of the TRIPS Agreement.

ARGENTINA

Ley N° 24.481 de 30 marzo de 1995, de Patentes de Invención y Modelos de Utilidad (con las modificaciones introducidas hasta el Decreto N° 27/2018 de 10 de enero de 2018)

Articles 42-50

CAPITULO VII

OTROS USOS SIN AUTORIZACION DEL TITULAR DE LA PATENTE

ARTICULO 42. — Cuando un potencial usuario haya intentado obtener la concesión de una licencia del titular de una patente en términos y condiciones comerciales razonables en los términos del artículo 43 y tales intentos no hayan surtido efecto luego de transcurrido un plazo de CIENTO CINCUENTA (150) días corridos contados desde la fecha en que se solicitó la respectiva licencia, el INSTITUTO NACIONAL DE LA PROPIEDAD INDUSTRIAL, podrá permitir otros usos de esa patente sin autorización de su titular. Sin perjuicio de lo mencionado precedentemente, se deberá dar comunicación a las autoridades creadas por la Ley N 22.262 o la que la modifique o sustituya, que tutela la libre competencia a los efectos que correspondiere.

ARTICULO 43. — Transcurridos TRES (3) años desde la concesión de la patente, o UATRO (4) desde la presentación de la solicitud, si la invención no ha sido explotada, salvo fuerza mayor o no se hayan realizado preparativos efectivos y serios para explotar la invención objeto de la patente o cuando la explotación de ésta haya sido interrumpida durante más de UN (1) año, cualquier persona podrá solicitar autorización para usar la invención sin autorización de su titular.

Se considerarán como fuerza mayor, además de las legalmente reconocidas como tales, las dificultades objetivas de carácter técnico legal, tales como la demora en obtener el registro en Organismos Públicos para la autorización para la comercialización, ajenas a la voluntad del titular de la patente, que hagan imposible la explotación del invento. La falta de recursos económicos o la falta de viabilidad económica de la explotación no constituirán por sí solos circunstancias justificativas.

EL INSTITUTO NACIONAL DE LA PROPIEDAD INDUSTRIAL notificará al titular de la patente el incumplimiento de lo prescrito en el primer párrafo antes de otorgar el uso de la patente sin su autorización.

La autoridad de aplicación previa audiencia de las partes y si ellas no se pusieran de acuerdo, fijará una remuneración razonable que percibirá el titular de la patente, la que será establecida según circunstancias propias de cada caso y habida cuenta del valor económico de la autorización, teniendo presente la tasa de regalías promedio para el sector de que se trate en contratos de licencias comerciales entre partes independientes. Las decisiones referentes a la concesión de estos usos deberán ser adoptadas dentro de los NOVENTA (90) días hábiles de presentada la solicitud y ellas serán apelables por ante la Justicia Federal en lo Civil y Comercial. La sustanciación del recurso no tendrá efectos suspensivos.

ARTICULO 44. — Será otorgado el derecho de explotación conferido por una patente, sin autorización de su titular, cuando la autoridad competente haya determinado que el titular de la patente ha incurrido en prácticas anticompetitivas. En estos casos, sin perjuicio de los recursos que le competan al titular de la patente, la concesión se efectuará sin necesidad de aplicar el procedimiento establecido en el artículo 42.

A los fines de la presente ley, se considerarán prácticas anticompetitivas, entre otras, las siguientes:

- a) La fijación de precios comparativamente excesivos, respecto de la media del mercado o discriminatorios de los productos patentados; en particular cuando existan ofertas de abastecimiento del mercado a precios significativamente inferiores a los ofrecidos por el titular de la patente para el mismo producto;
- b) La negativa de abastecer al mercado local en condiciones comerciales razonables;
- c) El entorpecimiento de actividades comerciales o productivas;
- d) Todo otro acto que se encuadre en las conductas consideradas punibles por la Ley N 22.262 o la que la reemplace o sustituya.

ARTICULO 45. — EL PODER EJECUTIVO NACIONAL podrá por motivos de emergencia sanitaria o seguridad nacional disponer la explotación de ciertas patentes mediante el otorgamiento del derecho de explotación conferido por una patente; su alcance y duración se limitará a los fines de la concesión.

ARTICULO 46. — Se concederá el uso sin autorización del titular de la patente para permitir la explotación de una patente —segunda patente— que no pueda ser explotada sin infringir otra patente —primera patente— siempre que se cumplan las siguientes condiciones:

- a) Que la invención reivindicada en la segunda patente suponga un avance técnico significativo de una importancia económica considerable, con respecto a la invención reivindicada en la primera patente;
- b) Que el titular de la primera patente tenga derecho a obtener una licencia cruzada en condiciones razonables para explotar la invención reivindicada en la segunda patente, y
- c) Que no pueda cederse el uso autorizado de la primera patente sin la cesión de la segunda patente.

ARTICULO 47. — Cuando se permitan otros usos sin autorización del titular de la patente, se observarán las siguientes disposiciones:

- a) La autorización de dichos usos la efectuará el INSTITUTO NACIONAL DE LA PROPIEDAD INDUSTRIAL;
- b) La autorización de dichos usos será considerada en función de las circunstancias propias de cada caso;
- c) Para los usos contemplados en el artículo 43 y/o 46 previo a su concesión el potencial usuario deberá haber intentado obtener la autorización del titular de los derechos en término y condiciones comerciales conforme al artículo 43 y esos intentos no hubieren surtido efectos en el plazo dispuesto por el artículo 42. En el caso de uso público no comercial, cuando el gobierno o el contratista, sin hacer una búsqueda de patentes, sepa o tenga motivos demostrables para saber que una patente válida es o será utilizada por o para el gobierno, se informará sin demoras a su titular;
- d) La autorización se extenderá a las patentes relativas a los componentes y procesos de fabricación que permitan su explotación;
- e) Esos usos serán de carácter no exclusivo;
- f) No podrán cederse, salvo con aquella parte de la empresa o de su activo intangible que la integre;
- g) Se autorizarán para abastecer principalmente al mercado interno, salvo en los casos dispuestos en los artículos 44 y 45;
- h) El titular de los derechos percibirá una remuneración razonable según las circunstancias propias de cada caso, habida cuenta del valor económico de la autorización, siguiendo el procedimiento del artículo 43; al determinar el importe de las remuneraciones en los casos en que los usos se hubieran autorizado para poner remedio a prácticas anticompetitivas se tendrá en cuenta la necesidad de corregir dichas prácticas y se podrá negar la revocación de la autorización si se estima que es probable que en las condiciones que dieron lugar a la licencia se repitan;
- i) Para los usos establecidos en el artículo 45 y para todo otro uso no contemplado, su alcance y duración se limitará a los fines para los que hayan sido autorizados y podrán retirarse si las circunstancias que dieron origen a esa autorización se han extinguido y no sea probable que vuelvan a surgir, estando el INSTITUTO NACIONAL DE LA PROPIEDAD INDUSTRIAL facultado para examinar, previa petición fundada, si dichas circunstancias siguen existiendo. Al dejarse sin efecto estos usos se deberán tener en cuenta los intereses legítimos de las personas que hubieran recibido dicha autorización. Si se tratara de tecnología de semiconductores, sólo podrá hacerse de ella un uso público no comercial o utilizarse para rectificar una práctica declarada contraria a la competencia tras un procedimiento judicial o administrativo.

ARTICULO 48. — En todos los casos las decisiones relativas a los usos no autorizados por el titular de la patente estarán sujetos a revisión judicial, como asimismo lo relativo a la remuneración que corresponda cuando ésta sea procedente.

ARTICULO 49. — Los recursos que se interpusieran con motivo de actos administrativos relacionados con el otorgamiento de los usos previstos en el presente capítulo, no tendrán efectos suspensivos.

ARTICULO 50. — Quien solicite alguno de los usos de este Capítulo deberá tener capacidad económica para realizar una explotación eficiente de la invención patentada y disponer de un establecimiento habilitado al efecto por la autoridad competente.

ARMENIA

Law of the Republic of Armenia of June 10, 2008, on Inventions, Utility Models and Industrial Designs

Articles 69-71

Article 69. Compulsory License

(1) Any person or the Republic of Armenia may, without the consent of the patent owner (rightholder), use the protected invention, utility model or industrial design (compulsory license) by court decision where:

- (a) the public interest demands, in particular, national security, nutrition, health or the development of other vital sectors so requires;
- (b) it is determined that the owner of the patent or his licensee abuses the patent rights, in particular where the manner of exploitation, contrary to the adopted regulations, restrains competition;
- (c) the invention, utility model, industrial design has not been used or has been used unconscientiously during the period of 4 years from filing the application or 3 years from granting patent (certificate) (the later filing date shall be applied).

(2) The court shall grant compulsory licenses under paragraph (1) of this Article with regard to given circumstances and after hearing the right holder.

(3) Compulsory licenses under paragraph (1) of this Article shall be granted provided that the person filing the request proves that he has made efforts to conclude a license contract with the rightholder on reasonable commercial terms and that such efforts failed to succeed within a reasonable period of time.

(4) Paragraph (3) of this Article shall not apply if a state of war or emergency has been declared.

Article 70. Conditions for Granting Compulsory Licenses

(1) Compulsory licenses under Article 69 shall be granted under the following conditions:

- (a) scope and duration shall be limited with regard to their purposes;
- (b) they shall be only non-exclusive;
- (c) they may not be transferred to third parties, with the exception of the licensee enterprise or business;
- (d) they shall be granted primarily for the suffice of the internal market demand.

(2) Where a patent, hereinafter referred to as “the second patent”, cannot be exploited without infringing another patent, hereinafter referred to as “the first patent”, the following conditions, in addition to paragraph (1) above, for the grant of compulsory license in respect of the first patent it is necessary that:

- (a) the invention protected by the second patent shall involve a technical advance of considerable economic significance compared to the invention protected by the first patent;
- (b) the owner of the first patent shall, under reasonable conditions, be entitled to a cross-license to use the invention protected by the second patent;

(c) the use authorized in respect of the first patent shall be transferred by the person having the compulsory license only with the simultaneous transfer of the company's part, where the use of the mentioned subject matter is realized.

(3) The compulsory license is recognized as expired by the court decision:
(a) if the circumstances which led to it have been eliminated and are unlikely to recur;
(b) after receiving compulsory license the license-holder didn't undertake the necessary preparatory work to use it during one-year period.

(4) In the case of semiconductor technologies a compulsory license may be granted only by the State for exclusively non-commercial use as well by judicial or administrative authorities for prevention of unfair competition.

Article 71. Remuneration for Compulsory Licenses

(1) A compulsory license shall be granted to the owners of patents against equitable remuneration.

(2) The amount of the remuneration shall be determined with regard to the circumstances of each case and taking into account the economic significance of such an authorization.

AUSTRALIA

Sections 132A-136M and 163-170 of Patents Act 1990 (consolidated as of August 25, 2018)

Section 12.1 of Patents Regulations 1991 (consolidated as of October 17, 2018)

132A Simplified outline of this Chapter

This Chapter provides for court orders requiring the grant of compulsory licences in respect of patented inventions.

Special provision is made for compulsory licences to exploit patented pharmaceutical inventions. This is to enable the manufacture of a pharmaceutical product in Australia for export to an eligible importing country, to address public health problems in that country.

This Chapter also provides generally for the surrender of patents, and for court orders revoking patents.

132B Simplified outline of this Part

The Federal Court may make an order under this Part requiring the grant of a compulsory licence to work a patented invention.

The court may order a compulsory licence to be granted if the reasonable requirements of the public are not being met with respect to a patented invention.

The reasonable requirements of the public relate, broadly speaking, to whether Australian trade or industry is unreasonably affected by the actions of the patentee in relation to the manufacture or licensing of the invention (or the carrying on of a patented process).

The court may also order a compulsory licence to be granted if the patentee has engaged in restrictive trade practices in connection with the patent under the Competition and Consumer Act 2010 or under an application law (within the meaning of that Act).

The court may order a patent to be revoked after an order for a compulsory licence has been made (on the same grounds that apply to an order for a compulsory licence).

The patentee must be paid an agreed amount of remuneration, or an amount of remuneration determined by the court.

133 Compulsory licenses-general

(1) Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.

Note: For compulsory licences for the manufacture and export of patented pharmaceutical inventions to eligible importing countries, see Part 3. However, Part 3 does not prevent a compulsory licence from being ordered under this Part in relation to such an invention (see section 136C).

(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.

(2) After hearing the application, the court may make the order if satisfied that:

(a) all the following conditions exist:

- (i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;
- (ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;
- (iii) the patentee has given no satisfactory reason for failing to exploit the patent; or

(b) the patentee has contravened, or is contravening, Part IV of the *Competition and Consumer Act 2010* or an application law (as defined in section 150A of that Act) in connection with the patent.

(3) An order must direct that the licence:

(a) is not to give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention; and

(b) is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;

and may direct that the licence is to be granted on any other terms specified in the order.

(3B) If the patented invention cannot be worked by the applicant without his or her infringing another patent:

(a) the court is to make the order only if the court is further satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention (other invention) to which the other patent relates; and

(b) the court must further order that the patentee of the other invention:

(i) must grant to the applicant a licence to work the other invention insofar as is necessary to work the patented invention; and

(ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the patented invention; and

(c) the court must direct that the licence granted by the patentee of the other invention may be assigned by the applicant:

(i) only if he or she assigns the licence granted in respect of the patented invention; and

(ii) only to the assignee of that licence.

(4) An order operates, without prejudice to any other method of enforcement, as if it were embodied in a deed granting a licence and executed by the patentee and all other necessary parties.

(5) The patentee is to be paid in respect of a licence granted to the applicant under an order:
(a) such amount as is agreed between the patentee and the applicant; or
(b) if paragraph (a) does not apply—such amount as is determined by the Federal Court to be just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act).

(6) The patentee or the Federal Court may revoke the licence if:
(a) the patentee and the licensee are agreed, or the court on application made by either party finds, that the circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur; and
(b) the legitimate interests of the licensee are not likely to be adversely affected by the revocation.

134 Revocation of patents after grant of compulsory licence

(1) Where a compulsory licence relating to a patent is granted, an interested person may apply to the Federal Court, after the end of the prescribed period, for an order revoking the patent.

(2) After hearing the application, the court may make the order if satisfied that:

(a) both:

(i) the reasonable requirements of the public with respect to the patented invention have not been satisfied; and

(ii) the patentee has given no satisfactory reason for failing to exploit the patent; or

(b) the patentee is contravening Part IV of the Competition and Consumer Act 2010 or an application law (as defined in section 150A of that Act) in connection with the patent.

135 Reasonable requirements of the public.

(1) For the purposes of sections 133 and 134, the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:

(a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:

(i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or

(ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or

(iii) to carry on the patented process to a reasonable extent; or

(iv) to grant licences on reasonable terms; or

(b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or

(c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.

(2) If, where paragraph (1)(c) applies, the court is satisfied that the time that has elapsed since the patent was sealed has, because of the nature of the invention or some other cause, been insufficient to enable the invention to be worked in Australia on a commercial scale, the court may adjourn the hearing of the application for the period that the court thinks sufficient for that purpose.

Chapter 17 of the Patents Act 1990 relates to The Crown. Sections 163 – 172 are relevant to this question.

[...]

136B Simplified outline of this Part

The Federal Court may make an order under this Part requiring the grant of a compulsory licence to exploit a patented pharmaceutical invention for manufacture and export to an eligible importing country.

The court may order a compulsory licence to be granted if the proposed use of the pharmaceutical product is to address a public health issue in the eligible importing country:

- (a) in a national emergency (or other extremely urgent circumstances); or
- (b) by the public non-commercial use of the product.

The order may be amended or revoked by another order of the court.

The patentee must be paid an agreed amount of remuneration, or an amount of remuneration determined by the court.

136C Relationship between Parts 2 and 3

This Part does not prevent a compulsory licence from being ordered under Part 2 in relation to a patented pharmaceutical invention.

Division 2—Patented pharmaceutical invention compulsory licences

136D PPI compulsory licences—applications for orders

Application for order

(1) A person (the **PPI order applicant**) may apply to the Federal Court for an order (the **PPI order**) under section 136E requiring the patentee of a patented pharmaceutical invention to grant the PPI order applicant a licence (a **PPI compulsory licence**) to exploit the invention to the extent necessary for the purposes of manufacturing a pharmaceutical product in Australia for export to an eligible importing country.

Note 1: A patented pharmaceutical invention may be a patented product or a patented process: see the definition of patented pharmaceutical invention in Schedule 1.

Note 2: For remuneration in respect of a licence, see section 136J.

(2) However, a person cannot apply for an order in respect of an innovation patent unless the patent has been certified. Statement—eligible importing country

Statement—eligible importing country

(3) An application must include a copy of a statement made by or on behalf of, and with the authorisation of, the eligible importing country to the effect that it will take reasonable measures within its means, proportionate to its administrative capacities and to the risk of trade diversion, to prevent re-exportation from its territory of a pharmaceutical product imported into its territory in accordance with a PPI compulsory licence.

Statement—importer

(4) If the pharmaceutical product is to be imported on behalf of, and with the authorisation of, the eligible importing country, an application must also include a copy of a statement made by the importer to the effect that it will take reasonable measures within its means to prevent the pharmaceutical product from being used other than in accordance with a PPI compulsory licence.

Parties

- (5) The following are parties to proceedings on an application under this section:
- (a) the PPI order applicant;
 - (b) the patentee;
 - (c) any person claiming an interest in the patent as exclusive licensee or otherwise;
 - (d) at the option of the eligible importing country—that country.

136E PPI compulsory licences—orders

- (1) After hearing an application for a PPI order under section 136D, the Federal Court may, subject to this Part, make the order sought if the court is satisfied of all of the following matters:
- (a) the application is made in good faith;
 - (b) the pharmaceutical product is to be imported:
 - (i) by the eligible importing country; or
 - (ii) by a person (the **third party importer**) on behalf of, and with the authorisation of, the eligible importing country;
 - (c) the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country:
 - (i) in circumstances of national emergency or other circumstances of extreme urgency; or
 - (ii) in other circumstances—by the public non-commercial use of the pharmaceutical product;
 - (d) exploiting the patented pharmaceutical invention is necessary to enable the import and proposed use of the pharmaceutical product as mentioned in paragraphs (b) and (c);
 - (e) if subparagraph (c)(ii) applies:
 - (i) the PPI order applicant has given the patentee a notice in the approved form seeking from the patentee an authorisation to exploit the patented pharmaceutical invention for public non-commercial use; and
 - (ii) during the 30 days beginning when the notice was given, the PPI order applicant has tried, without success, to obtain such an authorisation from the patentee on reasonable terms and conditions;
 - (f) the notification requirements prescribed by regulation in relation to the importation of the pharmaceutical product into the eligible importing country have been complied with;
 - (g) the PPI order applicant, the eligible importing country and, if there is a third party importer, that importer, will take reasonable measures to prevent a pharmaceutical product that is exported from Australia in accordance with a PPI compulsory licence from being used for a purpose other than the purpose of addressing the public health problem mentioned in paragraph (c).

(2) Without limiting the matters that the court may take into account in deciding whether it is satisfied of a matter mentioned in subsection (1), the court must take into account any matters prescribed by regulation.

- (3) A regulation made for the purposes of paragraph (1)(f) may:
- (a) without limiting subsection 33(3A) of the *Acts Interpretation Act 1901*, prescribe different notification requirements for the importation of pharmaceutical products into eligible importing countries of different kinds; and
 - (b) despite subsection 14(2) of the *Legislation Act 2003*, refer to eligible importing countries (or different kinds of eligible importing countries) by applying, adopting or incorporating, with or without modification, any matter contained in any other instrument or other writing as in force or existing from time to time.

136F PPI compulsory licences—terms

- (1) A PPI order must direct that the PPI compulsory licence is granted on the following terms:
- (a) no more than the quantity of the pharmaceutical product that is determined by the Federal Court to be necessary to meet the needs of the eligible importing country is manufactured;

- (b) the entirety of the pharmaceutical product manufactured for that purpose is exported to that country;
- (c) the pharmaceutical product is labelled and marked in accordance with the regulations;
- (d) before shipment of the pharmaceutical product begins, the shipment information prescribed by regulation is made available on a website by, or on behalf of, the licensee for a minimum period prescribed by regulation;
- (e) the duration of the licence is only for the period of time determined by the Federal Court to be necessary to address the public health problem concerned;
- (f) the licence does not give the licensee, or a person authorised by the licensee, the exclusive right to exploit the patented pharmaceutical invention;
- (g) the licence is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;
- (h) the licensee must give the Commissioner the information prescribed by regulation in relation to the licence in accordance with the regulations.

(2) A PPI order may also direct that the licence is to be granted on any other terms specified in the order, including terms covering:

- (a) other requirements relating to the labelling and marking of the pharmaceutical product; and
- (b) other information to be made available by the licensee and the way in which it is to be made available.

(3) However, a term specified in a PPI order must not be inconsistent with any regulations prescribed for the purposes of paragraph (1)(c), (d) or (h).

136G PPI compulsory licences—amendment

Application for order

(1) A person may apply to the Federal Court for an order amending any of the following terms of a PPI compulsory licence:

- (a) the quantity of the pharmaceutical product concerned;
- (b) how the pharmaceutical product is labelled and marked;
- (c) the duration of the licence;
- (d) the information that is to be made available by the licensee and the way it is to be made available.

Note: For remuneration in respect of the licence as amended, see section 136J.

Order

(2) The court may make the order sought in relation to a term if it is satisfied that:

- (a) it is just to do so in all the circumstances; and
- (b) the legitimate interests of the following are not likely to be adversely affected by the amendment of the term:
 - (i) the patentee;
 - (ii) any person claiming an interest in the patent as exclusive licensee or otherwise;
 - (iii) the licensee;
 - (iv) the eligible importing country.

(3) However, an amended term must not be inconsistent with any regulations prescribed for the purposes of paragraph 136F(1)(c), (d) or (h).

Parties

(4) The following are parties to any proceedings under this section:

- (a) the applicant under subsection (1);
- (b) the patentee;
- (c) any person claiming an interest in the patent as exclusive licensee or otherwise;
- (d) the licensee;

(e) at the option of the eligible importing country—that country.

136H PPI compulsory licences—revocation

Application

(1) A person may apply to the Federal Court for an order revoking a PPI compulsory licence.

Note: For remuneration in respect of the use of a PPI compulsory licence while it is in force, see section 136J.

Federal Court may revoke licence

(2) The Federal Court may make the order sought if the court is satisfied that:

(a) one or more of the following applies:

(i) the substantive circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur;

(ii) the licensee has not complied with the terms of the licence;

(iii) if an amount of remuneration has been agreed or determined under section 136J—the amount has not been paid within the time agreed or determined; and

(b) the legitimate interests of the licensee or the eligible importing country are not likely to be adversely affected by the revocation.

Parties

(3) The following are parties to any proceedings under this section:

(a) the applicant for revocation;

(b) the licensee;

(c) at the option of the eligible importing country—that country.

136J PPI compulsory licences—remuneration

Working out amount of remuneration

(1) The patentee is to be paid an amount agreed or determined under subsection (3) in respect of the use of a patented pharmaceutical invention authorised by a PPI compulsory licence.

(2) For the purposes of subsection (1), the use of a patented pharmaceutical invention authorised by the PPI compulsory licence is:

(a) while it is in force—the use authorised by the licence as granted and as amended (from time to time) under section 136G; or

(b) if it has ceased to be in force (whether because it was revoked or otherwise)—the actual use of the patented pharmaceutical invention under the licence while it was in force.

(3) For the purposes of subsection (1), the amount is:

(a) an amount agreed between the patentee and the PPI order applicant, licensee or former licensee (as the case requires); or

(b) if paragraph (a) does not apply—an amount determined by the Federal Court to be adequate remuneration taking into account the economic value to the eligible importing country of the use of the patented pharmaceutical invention authorised by the PPI compulsory licence.

Application to make or amend a determination

(4) A person may apply to the Federal Court:

(a) to make a determination under paragraph (3)(b); or

(b) to amend a determination made under that paragraph.

Note: Grounds for an application under paragraph (b) may include the fact that the terms of the PPI compulsory licence have been amended, or the licence has been revoked.

Parties

(5) The following are parties to any proceedings under this section:

- (a) the applicant for the determination or the amendment of the determination;
- (b) the PPI order applicant;
- (c) the licensee;
- (d) the patentee of the patented pharmaceutical invention;
- (e) any person claiming an interest in the patent as exclusive licensee or otherwise.

Can PPI be exploited if remuneration is not agreed or determined?

(6) To avoid doubt, if the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country in circumstances of national emergency or other circumstances of extreme urgency, the licensee may exploit a patented pharmaceutical invention under a PPI compulsory licence, as granted or amended (as the case may be), whether or not an amount has been agreed or determined under this section.

(7) However, if the proposed use of the pharmaceutical product is to address a public health problem in the eligible importing country in other circumstances, by the public non-commercial use of the pharmaceutical product, the licensee must not exploit a patented pharmaceutical invention under a PPI compulsory licence unless an amount has been agreed or determined under this section.

Can PPI compulsory licence be revoked if remuneration is not agreed or determined?

(8) To avoid doubt, a PPI compulsory licence may be revoked whether or not an amount has been agreed or determined under this section.

Division 4—General

136K PPI compulsory licences—nature of orders

Without prejudice to any other method of enforcement, a PPI order operates as if it were embodied in a deed granting or amending a licence and executed by the patentee and all other necessary parties.

136L PPI compulsory licences—consistency of orders with international agreements

A PPI order must not be made that is inconsistent with a treaty between the Commonwealth and a foreign country.

136M PPI compulsory licences—applications heard together

Nothing in this Part prevents the Federal Court from dealing with the following applications together:

- (a) applications for different PPI orders, or for the amendment or revocation of such orders;
- (b) applications for determinations under paragraph 136J(3)(b) for remuneration in relation to different PPI compulsory licences, or for the amendment of such determinations.

[...]

163. Exploitation of inventions by Crown

(1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:

- (a) if the application is pending-of the nominated person's rights in the invention; or
- (b) if a patent has been granted for the invention-of the patent.

(2) A person may be authorised for the purposes of subsection (1):
(a) before or after any act for which the authorisation is given has been done; and
(b) before or after a patent has been granted for the invention; and
(c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.

(3) Subject to section 168, an invention is taken for the purposes of this Part to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia.

164 Nominated person or patentee to be informed of exploitation

As soon as practicable after an invention has been exploited under subsection 163 (1), the relevant authority must inform the applicant and the nominated person, or the patentee, of the exploitation and give him or her any information about the exploitation that he or she from time to time reasonably requires, unless it appears to the relevant authority that it would be contrary to the public interest to do so.

165 Remuneration and terms for exploitation

[...]

(2) The terms for the exploitation of the invention (including terms concerning the remuneration payable to the nominated person or the patentee) are such terms as are agreed, or determined by a method agreed, between the relevant authority and the nominated person or the patentee or, in the absence of agreement, as are determined by a prescribed court on the application of either party.

(3) For the purposes of subsection (2), the terms, or the method, may be agreed before, during or after the exploitation.

(4) When fixing the terms, the court may take into account any compensation that a person interested in the invention or the patent has received, directly or indirectly, for the invention from the relevant authority.

165A Exploitation of invention to cease under court order

(1) A prescribed court may, on the application of the nominated person or the patentee, declare that the exploitation of the invention by the Commonwealth or the State is not, or is no longer, necessary for the proper provision of services of the Commonwealth or of the State if the court is satisfied that, in all the circumstances of the case, it is fair and reasonable to make the declaration.

(2) The court may further order that the Commonwealth or the State is to cease to exploit the invention:

(a) on and from the day specified in the order; and
(b) subject to any conditions specified in the order. In making the order, the court is to ensure that the legitimate interests of the Commonwealth or of the State are not adversely affected by the order.

166 Previous agreements inoperative

An agreement or licence (whether made or given before or after the commencement of this Act) fixing the terms on which a person other than the Commonwealth or a State may exploit an invention is inoperative with respect to the exploitation, after the commencement of this Act, of the invention under subsection 163 (1), unless the agreement or licence has been approved:

- (a) if the relevant authority is the Commonwealth-by the Minister; or
- (b) if the relevant authority is a State-by the Attorney-General of the State.

167 Sale of products

(1) The right to exploit an invention under subsection 163 (1) includes the right to sell products made in exercise of that right.

(2) Where under subsection 163 (1) the sale of products is not an infringement of:

(a) a patent; or

(b) a nominated person's rights in the products;

the buyer, and any person claiming through the buyer, is entitled to deal with the products as if the relevant authority were the patentee or the nominated person.

168 Supply of products by Commonwealth to foreign countries

Where the Commonwealth has made an agreement with a foreign country to supply to that country products required for the defence of the country:

(a) the use of a product or process by the Commonwealth, or by a person authorised in writing by the Commonwealth, for the supply of that product is to be taken, for the purposes of this Chapter, to be use of the product or process by the Commonwealth for the services of the Commonwealth; and

(b) the Commonwealth or the authorised person may sell those products to the country under the agreement; and

(c) the Commonwealth or the authorised person may sell to any person any of the products that are not required for the purpose for which they were made.

169 Declarations that inventions have been exploited

(1) Subject to subsection (4), a patentee who considers that the patented invention has been exploited under subsection 163 (1) may apply to a prescribed court for a declaration to that effect.

(2) In proceedings under subsection (1):

(a) the alleged relevant authority is the defendant; and

(b) the alleged relevant authority may apply by way of counter-claim in the proceedings, for the revocation of the patent.

(3) The provisions of this Act relating to the revocation of patents apply, with the necessary changes, to a counter-claim.

(4) An application under subsection (1) in respect of an innovation patent cannot be made unless the patent has been certified.

170 Sale of forfeited articles

Nothing in this Chapter affects the right of the Commonwealth or a State, or of a person deriving title directly or indirectly from the Commonwealth or a State, to sell or use an article forfeited under a law of the Commonwealth or the State.

171 Acquisition of inventions or patents by Commonwealth

(1) The Governor-General may direct that a patent, or an invention that is the subject of a patent application, be acquired by the Commonwealth.

(2) When a direction is given, all rights in respect of the patent or the invention are, by force of this subsection, transferred to and vested in the Commonwealth.

(3) Notice of the acquisition must be:

- (a) given to the applicant and the nominated person, or the patentee; and
- (b) published in the Official Journal and the Gazette unless, in the case of the acquisition of an invention that is the subject of an application for a patent, a prohibition order, or an order under section 152, is in force in respect of the application.

(4) The Commonwealth must pay a compensable person such compensation as is agreed between the Commonwealth and the person or, in the absence of agreement, as is determined by a prescribed court on the application of either of them.

172 Assignment of invention to Commonwealth

(1) An inventor, or an inventor's successor in title, may assign the invention, and any patent granted or to be granted for the invention, to the Commonwealth.

(2) The assignment and all covenants and agreements in the assignment are valid and effectual, even if valuable consideration has not been given for the assignment, and may be enforced by proceedings in the name of the Minister.

Part 1—Compulsory licences (general)

12.1 Applications for orders for compulsory licences

(1) For the purposes of subsection 133(1) of the Act, the period of 3 years after the date of granting of the patent to which the application relates is prescribed.

(2) An applicant must lodge with the Registrar of the Federal Court:

- (a) a copy of the application that includes:
 - (i) the name and address of the applicant; and
 - (ii) the address for service in relation to the application; and
 - (iii) the identity of the patent; and
 - (iv) if the applicant relies on the ground mentioned in paragraph 133(2)(a) of the Act—facts supporting the assertion that the reasonable requirements of the public with respect to the patented invention have not been satisfied; and
 - (iva) if the applicant relies on the ground mentioned in paragraph 133(2)(b) of the Act—facts supporting the assertion that the patentee has contravened, or is contravening, Part IV of the Trade Practices Act 1974 or an application law (as defined in section 150A of that Act) in connection with the patent; and
 - (v) for an innovation patent—the date that the patent was certified; and
- (b) a declaration by the applicant to the effect that the facts in the statement are true to the best of the knowledge of the applicant.

(2A) For subparagraph (2)(a)(ii), the address for service must be an address that is mentioned in Rules made by the Federal Court for the service of the application, as in force from time to time.

Note: In a transitional period after this subregulation commences, there may be different Rules made by the Federal Court to deal with suitable addresses for service in particular circumstances.

(3) The applicant must:

- (a) serve a copy of the application and declaration on the patentee and any other person who claims an interest in the patent as soon as practicable after lodgment; and
- (b) lodge with the Registrar notice of the date when, and the place where, he or she complied with paragraph (a).

(4) For subregulation (3), the applicant must serve the copy in accordance with Rules made by the Federal Court for the service of the application and declaration, as in force from time to time.

Note: In a transitional period after this subregulation commences, there may be different Rules made by the Federal Court to deal with service in particular circumstances.

AUSTRIA

Patentgesetz 1970 (zuletzt geändert durch das Bundesgesetz BGB1. I. Nr. 37/2018)

Sections 36 and 37

Zwangslizenzen

§ 36. (1) Kann eine patentierte Erfindung nicht verwertet werden, ohne eine mit besserem Zeitrang

patentierte Erfindung (älteres Patent) zu verletzen, hat der Inhaber des jüngeren Patent Anspruch auf eine nicht ausschließliche Lizenz an dem älteren Patent, wenn die mit dem jüngeren Patent geschützte Erfindung gegenüber der mit dem älteren Patent geschützten Erfindung einen wichtigen technischen Fortschritt von erheblicher wirtschaftlicher Bedeutung darstellt. Im Falle der Lizenzeinräumung hat auch der Inhaber des älteren Patent Anspruch auf eine nicht ausschließliche Lizenz am jüngeren Patent.

(2) Kann ein Pflanzenzüchter ein Sortenschutzrecht nicht erhalten oder verwerten, ohne eine mit besserem Zeitrang patentierte Erfindung (älteres Patent) zu verletzen, hat er Anspruch auf eine nicht ausschließliche Lizenz an dem Patent, soweit die Pflanzensorte einen bedeutenden technischen Fortschritt von erheblichem wirtschaftlichen Interesse gegenüber der patentgeschützten Erfindung darstellt und soweit diese Lizenz zur Verwertung der zu schützenden Pflanzensorte erforderlich ist.

(3) Wird dem Inhaber eines Patent für eine biotechnologische Erfindung eine nicht ausschließliche Lizenz für eine durch ein mit besserem Zeitrang erteiltes Sortenschutzrecht (älteres Sortenschutzrecht) geschützte Pflanzensorte erteilt, weil er die biotechnologische Erfindung nicht verwerten kann, ohne ein älteres Sortenschutzrecht zu verletzen, dann hat der Inhaber des älteren Sortenschutzrechtes Anspruch auf eine nicht ausschließliche Lizenz an dem jüngeren Patent zur Verwertung der geschützten Erfindung.

(4) Wird eine patentierte Erfindung im Inland nicht in angemessenem Umfang ausgeübt, wobei die Ausübung auch durch Import erfolgen kann, und hat der Patentinhaber nicht alles zu einer solchen Ausübung Erforderliche unternommen, so hat jedermann für seinen Betrieb Anspruch auf eine nicht ausschließliche Lizenz an dem Patent, es sei denn, der Patentinhaber weist nach, daß die Ausübung der Erfindung im Inland wegen der der Ausübung entgegenstehenden Schwierigkeiten nicht oder nicht in größerem Umfang zumutbar ist, als dies geschehen ist.

(5) Ist die Erteilung einer Lizenz an einer patentierten Erfindung im öffentlichen Interesse geboten, hat jedermann für seinen Betrieb Anspruch auf eine nicht ausschließliche Lizenz an der Erfindung. Der diesbezügliche Anspruch der Bundesverwaltung ist hingegen an keinen Betrieb gebunden.

§ 37. (1) Verweigert der zur Einräumung einer Lizenz gemäß § 36 Berechtigte deren Einräumung, obwohl sich der Lizenzwerber bemüht hat, die Zustimmung innerhalb einer angemessenen Frist zu angemessenen geschäftsüblichen Bedingungen zu erhalten, so entscheidet auf Antrag des Lizenzwerbers das Patentamt in dem für die Anfechtung von Patenten vorgeschriebenen Verfahren. Im Fall der Lizenzeinräumung ist eine angemessene Vergütung zu bestimmen, wobei der wirtschaftliche Wert der Lizenz in Betracht zu ziehen ist. Die gegebenenfalls erforderliche Sicherstellung sowie die sonstigen Bedingungen der Benützung sind unter Berücksichtigung der Natur der Erfindung und der Umstände des Falles festzusetzen. Umfang und Dauer der Lizenz gemäß § 36 werden vorwiegend für die Versorgung des inländischen Marktes gestattet und sind auf den Zweck zu begrenzen, der sie erforderlich gemacht hat. Im Falle der Halbleitertechnik kann die Lizenz nur für den öffentlichen, nicht gewerblichen Gebrauch oder um eine in einem Gerichts- oder Verwaltungsverfahren festgestellte wettbewerbswidrige Praxis abzustellen, eingeräumt werden.

(2) Die Einräumung einer Lizenz gemäß § 36 Abs. 4 kann erst vier Jahre nach der Anmeldung oder drei Jahre nach der Kundmachung der Erteilung des Patentbeschlusses, an dem die Lizenz begehrt wird, beantragt werden; maßgebend ist diejenige Frist, die zuletzt abläuft.

(3) Vom Erfordernis der Einholung der Zustimmung des zur Einräumung einer Lizenz Berechtigten kann im Fall des § 36 Abs. 5 bei Vorliegen eines nationalen Notstandes oder sonstiger Umstände von äußerster Dringlichkeit abgesehen werden. In diesem Fall ist durch Zwischenentscheidung eine vorläufige Bewilligung zur Benützung der Erfindung zu erteilen.

(4) Eine gemäß Abs. 1 eingeräumte Lizenz ist vorbehaltlich eines angemessenen Schutzes der berechtigten Interessen der ermächtigten Personen auf Antrag aufzuheben, wenn und sofern die Umstände, die zu ihr geführt haben, zu bestehen aufhören und wahrscheinlich nicht wieder eintreten. Das Patentamt entscheidet über diesen Antrag in dem für die Anfechtung von Patenten vorgeschriebenen Verfahren.

(5) Bei Verfahren über die Einräumung oder Aufhebung von Lizenzen gemäß § 36 Abs. 2 und 3 hat jedem Senat der Nichtigkeitsabteilung ein Mitglied anzugehören, das auf Vorschlag des Bundesministers für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft vom Bundesminister für Verkehr, Innovation und Technologie ernannt worden ist.

AZERBAIJAN

The Law of Azerbaijan Republic "On Patent" 2009

Articles 18 and 20

Article 18. Using of the subject matter of industrial property without consent of patent owner With the objectives of safeguarding the interests of national security respective body of executive power has the right of giving his consent on use of the subject matter of industrial property without the consent of patent owner. In this case remuneration compensation is paid to patent owner. In the case when the patent owner is not satisfied with the amount of

compensation, he may appeal to the Court in an order established by legislation the Republic of Azerbaijan.

Article 20. Compulsory license concerning granted of right on use

1. Where the owner of a patent or his right successor does not use the subject matter of industrial property within 3 years time from the date a patent is granted without any valid reason and does not made serious preparation to use or suspend more than 3 years and refuses from grant the license after termination of this period, any legal entity or natural person may appeal to the Court with a request for the grant compulsory license on use the subject matter of industrial property.

Compulsory license shall be of non-exclusive character. Where in the licensee does not use compulsory license within the period of 2 years from the date of obtaining, the owner of patent may appeal the Court for cancellation of the license in an order established by the legislation. Relations between patent owner and person obtained the compulsory license from the date of granting of compulsory license considered equal to the relations between licensor and licensee established by the present Law.

2. If a patent owner is not able to exploit the subject matter of industrial property without infringing the rights of another patent owner, he shall be entitled to require the latter to conclude with him a license agreement. Litigations concerning this problem consider by the Court proceedings in an order established by legislation.

BAHRAIN

Law No. 1 of 2004 on Patents and Utility Models

Articles 24-27

Chapter (4) Compulsory licensing for exploiting a patent

Article (24)

The Minister of Trade may issue compulsory non-exclusive licensing for the exploitation of the patents in the following cases:

a. National emergencies, persisting necessity or for the purposes of noncommercial public utility provided that the patentee shall be informed of that, when possible, after granting the license.

b. Where the owner has not exploited the patented invention or has insufficiently exploited it with respect to the needs of local market in the Kingdom at reasonable prices –taking into account the counterpart prices prevalent in other countries - within three years of the date of patent registration or four years of the filing application whichever is longer. Should the Ministry of Trade deem that despite the lapse of the period stated in this clause that failure to exploit the subject invention is due to reasons that are beyond the control of the patentee, it may grant him a grace period not exceeding two years to exploit the patented invention completely or otherwise the Ministry may issue a compulsory license for any person whom the patentee either denied licensing for exploitation or bound it to unfair commercial terms.

c. Where the exploitation of a patent that implies a technical progress that is of great significance to industry cannot be exploited without the exploitation of another patent, the patentee of the first patent may be granted a compulsory licensing for exploiting the other patent in which case abandonment of the licensed exploitation shall not take place without the abandonment of the first patent. The patentee of the other patent, in return, shall have the right to get a compulsory licensing to exploit the first patent with reasonable terms.

d. In case the patentee is exercising his rights in such a manner that would prevent others from engaging in fair competition.

Article (25)

The following shall be taken into consideration upon granting compulsory licenses:

- a. Each application for a license shall be decided separately for its specific conditions and circumstances, following the payment of the due fees.
- b. The license shall only be granted for meeting the demand in the local market.
- c. The applicant for a license shall be able to seriously exploit the patent through a firm established in the Kingdom.
- d. The applicant shall have tried to obtain a license from the patentee under reasonable commercial remuneration and conditions but did not reach an agreement during a reasonable period of time, notwithstanding the case stipulated in item (a) of the previous article.
- e. The applicant for a compulsory licensing shall undertake that the scope and duration of the license shall be limited to the purpose for which it is granted by the licensing decision.
- f. Should the invention relate to “semi-conductors” technologies, licensing shall only be permitted for public, general, and non-commercial purposes, or to rectify practices proven to be anticompetitive.
- g. The licensee shall not assign the license of exploiting the patented invention except to the firm concerned with this exploitation or to the part related to the exploitation of the patent subject to the prior approval by the Ministry of Trade.
- h. The patentee shall receive an equitable remuneration which takes into account the economic value of the license. It shall also be taken into consideration the necessity of rectifying anticompetitive practices –if they exist- when estimating the remuneration value.
- i. The terms prescribed in items (b) and (d) shall not apply in the case of licensing issued to rectify practices deemed to be constraining fair competition.
- j. The Minister of Trade of his own motion or upon request of those concerned amends the licensing terms should the conditions for which a license has been given change.

Article (26)

The competent authority at the Ministry of Trade shall provide the patentee with a copy of the licensing application –in cases other than the one stipulated in item (a) of Article (24) of this law, in which case the patentee may submit to the competent authority a written response to the application subject to the periods and procedures defined by the Executive By-laws. In all cases, the Minister shall issue a decision to either accept or reject the application or keep the application pending on some requirements he stipulates and in all cases the Ministry shall be committed to notify the patentee and the license applicant of its decision within thirty days of issuance thereof. Such decision shall be recorded in the patent register and shall be published in the manner prescribed by the Executive By-laws.

Article (27)

The Minister of Trade may, of his own motion or upon request from the patentee, terminate the license before it expires in the following cases:

- a. Lapse of the reasons that led to license him provided that it is likely that these reasons will not arise again, in the case of which an adequate protection shall be granted to the legal interests of the licensee, subject to the conditions and procedures prescribed by the Executive By-laws.
- b. Failure on the part of the licensee to exploit the license within two years of the licensing date.
- c. Licensee violation of any condition according for which the license was given, or failure to undertake the obligations stipulated in this law and the decisions issued in the implementation thereof.

BANGLADESH

The Patents and Designs Act (Act No. II of 1911) (2003)

Sections 22 and 23A

Section 22 - Compulsory Licenses and Revocation

22. (1) Any person interested may present a petition to the Government which shall be left at the Department of Patents, Designs and Trade Marks, together with the prescribed fee, alleging that the demand for a patented article in Bangladesh is not being met to an adequate extent and on reasonable terms and praying for the grant of a compulsory license, or, in the alternative, for the revocation of the patent.

(2) The Government shall consider the petition, and if the parties do not come to an arrangement between themselves the Government may, as it thinks fit either dispose of the petition itself or refer it to the High Court Division for decision.

(3) The provisions of sub-section (4) of section 15, prescribing the procedure to be followed in the case of references to the Court under that section, shall apply in the case of references made to the Court under this section.

(4) If the Government is of opinion, or, where a reference has been made under subsection (2) to the High Court Division, that Court finds that the demand for the patented article in Bangladesh is not being met to an adequate extent and on reasonable terms, the patentee may be ordered to grant licenses on such terms as the Government or the High Court Division, as the case may be, may think just, or, if the Government or the High Court Division is of opinion that the demand will not be adequately met by the grant of licenses, the patent may be revoked by order of the Government or the High Court Division: Provided that an order of revocation shall not be made before the expiration of four years from the date of the patent, or if the patentee gives satisfactory reasons for his default.

(5) For the purposes of this section the demand for a patented article shall not be deemed to have been met to an adequate extent and on reasonable terms-

(a) if by reason of the default of the patentee to manufacture to an adequate extent and supply on reasonable terms the patented article, or any parts thereof which are necessary for its efficient working, or to carry on the patented process to an adequate extent or to grant licenses on reasonable terms, any existing trade or industry or the establishment of any new trade or industry in Bangladesh is unfairly prejudiced,; or

(b) if any trade or industry in Bangladesh is unfairly prejudiced by the conditions attached by the patentee to the purchase, hire or use of the patented article or to the using or working of the patented process.

Revocation of patents worked outside Bangladesh

23. (1) At any time not less than four years after the date of a patent granted under this Act, any person may apply to the Government for relief under this section on the ground that the patented article or process is manufactured or carried on exclusively or mainly outside Bangladesh.

(2) The Government shall consider the application, and, if after inquiry it is satisfied-

(a) that the allegations contained therein are correct; and

(b) that the applicant is prepared, and is in a position, to manufacture or carry on the patented article or process in Bangladesh; and

(c) that the patentee refuses to grant a license on reasonable terms,

then, subject to the provisions of this section, and unless the patentee proves that the patented article or process is manufactured or carried on to an adequate extent in Bangladesh, or gives satisfactory reasons why the article or process is not so manufactured or carried on, the Government may make an order-

(a) revoking the patent either-

(i) forthwith; or

(ii) after such reasonable interval as may be specified in the order, unless in the meantime it is shown to its satisfaction that the patented article or process is manufactured or carried on within Bangladesh to an adequate extent; or

(b) ordering the patentee to grant a license to the applicant which may be a license exclusive to him or otherwise as the Government may direct.

(3) No order revoking a patent shall be made under the last sub-section which is at variance with any treaty, convention, arrangement or engagement with any foreign country

(4) The Government may, on the application of the patentee, extend the time limited in any order made under sub-section (2), clause (ii), for such period not exceeding two years as it may specify in a subsequent order, or revoke any order made under sub-section (2), clause (ii), or any subsequent order if sufficient cause is in its opinion shown by the patentee.

Operation of order under section 22 or section 23

[23A. An order of the High Court Division under section 22 or of the Government under section 22 or section 23, directing the grant of any license shall, without prejudice to any other method of enforcement, operate as if it were embodied in a deed granting a license and executed by the patentee and all other necessary parties.]

BARBADOS

Patents Act, 2001 (Cap. 314) (as amended by Act No. 2 of 2006)

Sections 49 and 50

Use by Government or third party

49. (1) Where Exploitation by Crown, government

(a) the exploitation within Barbados of an invention protected by agency or patent is, in the opinion of the Minister, necessary

(i) in the interests of national security;

(ii) in the interests of national health;

(iii) in the interests of national nutrition;

(iv) in the interests of the development of an essential sector of the economy of Barbados; or

(v) for other public interests;

(b) the High Court has determined that the manner of exploitation by the owner of a patent or his licensee is anti-competitive,

the Minister may, without the consent of the owner of the patent, but subject to the payment of a reasonable amount for its exploitation, authorize by order the exploitation of the invention in Barbados by the Crown, by a government agency or by any person named in the order.

(2) Before the Minister makes an order under subsection (1),

(a) the views of the Director must be obtained regarding the use of the invention;

(b) the owner of the patent for the invention, and, where there is a licence-contract, his licensee, must be notified of the Minister's intention to make an order under subsection (1).

(3) All persons who have been notified under subsection (2), and any other interested persons shall, together with any person whose participation the Minister considers desirable, be invited by the Minister to a hearing concerning authorisation of the exploitation of the invention.

(4) In determining a reasonable amount of payment under subsection (1), the Minister shall take into account the economic value of the use of the patented invention and the need to correct anti-competitive practices.

(5) A request for the Minister's authorisation must be accompanied by evidence that the owner of the patent has received, from the person seeking the authorisation, a request for a contractual licence, but that that person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(6) The following exceptions are applicable:

(a) subsections (2), (3) and (5) do not apply where a state of emergency has been declared pursuant to any enactment, or in other circumstances of extreme national urgency, but in any such case, the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable;

(b) subsection (5) does not apply where the use is for public non-commercial purposes; and

(c) subsection (3) does not apply where the High Court has determined that the manner of exploitation by the owner of a patent or his licensee is anti-competitive.

(7) The exploitation of a patented invention in the field of semiconductor technology shall only be authorised either for public non-commercial use or where the High Court has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Minister is satisfied that the grant of the authorisation would remedy such practice.

(8) The authorisation shall not exclude

(a) the conclusion of licence-contracts by the owner of the patent; or

(b) the continued exercise by the owner of the patent of his rights under section 5(2).

(9) Where a third party has been designated by the Minister, the authorisation may only be transferred with the enterprise or business of that party or with the part of the enterprise or business within which the patented invention is being exploited.

(10) The exploitation of the invention by the Crown, government agency or third person referred to in subsection (1), shall be predominantly for the supply of the market in Barbados and shall be limited to the purposes for which it was authorised.

(11) The Minister may, upon the request of the owner of the patent, the Crown, government agency or the third person referred to in subsection (1), after hearing the parties, if any or both of them wish to be heard, vary the terms of the decision authorising the exploitation of the patented invention, to the extent that changed circumstances justify such variation.

(12) Upon the request of the owner of the patent, the Minister shall terminate the authorisation if he is satisfied, after hearing the parties, if any or both of them wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur, or that the Crown, government agency or third person referred to in subsection (1) has failed to comply with the terms of the decision.

(13) Notwithstanding subsection (12), the Minister shall not terminate the authorisation if he is satisfied that the need for adequate protection of the legitimate interests of the Crown, government agency or third person justifies the maintenance in force of the decision.

(14) A person aggrieved by a decision of the Minister under subsection (1), (11) or (12) may appeal to a Judge in chambers.

Non-voluntary licences

50. (1) After the expiration of a period of 4 years from the date of voluntary filing of the patent application or 3 years from the date of the grant of licences, the patent, whichever period expires last, any person interested may apply to the High Court for the grant of a non-voluntary licence under a patent, on the ground that the patented invention is not exploited or is insufficiently exploited by working the invention locally or by importation in Barbados.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the High Court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Barbados.

(3) The High Court shall make an order setting out

- (a) the scope and function of the licence;
- (b) the time limit within which the licensee shall begin to exploit the patented invention; and
- (c) the amount to be paid to the owner of the patent and the conditions of payment.

(4) Any person to whom a licence is granted under this section, shall exploit the patented invention in Barbados in accordance with the terms of the order under subsection (3), and shall exploit the patented invention sufficiently.

(5) Where

- (a) the invention claimed in a patent (in this section referred to as the “later patent”) cannot be exploited in Barbados without infringing a patent granted on the basis of an application benefiting from an earlier application (in this section referred to as the “earlier patent”); and
- (b) the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the High Court may, upon the request of the owner of the later patent, issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is granted under subsection (5), the High Court shall, upon the request of the owner of the earlier patent, issue a non-voluntary licence in respect of the later patent.

(7) In the case of the grant of a non-voluntary licence under subsection (5), subsection (3) applies, *mutatis mutandis*, with the exception that no time limit need be fixed.

(8) In the case of a non-voluntary licence issued under subsection (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence granted under subsection (6), only with the earlier patent.

(9) A licence granted under this section

- (a) is not exclusive;
- (b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and
- (c) is limited to the supply of the patented invention predominantly in Barbados.

(10) Where the High Court is satisfied that the grounds on which any licence granted under this section have ceased to exist, it may, on the application of any interested party, terminate such licence.

(11) Any person to whom a licence is granted under this section shall pay such remuneration to the owner of the patent as may be agreed, or as may be determined by a method agreed upon between that person and the owner of the patent or, in default of agreement, as is determined by the High Court on the application of either party.

(12) A licence shall not be granted under this section unless the person applying for the licence, having taken all reasonable steps to do so, has been unable to obtain a licence or to obtain a licence on reasonable terms from the owner of the patent.

(13) A licence shall not be granted under this section in respect of a patent relating to an integrated circuit.

(14) A non-voluntary licence granted under this section is subject to payment of the prescribed fee.

BELARUS

Law of the Republic of Belarus No. 160-Z of December 16, 2002, on Patents for Inventions, Utility Models, Industrial Designs (as amended up Law No. 328-Z of December 22, 2011)

Article 38

Compulsory Licensing

38. Where the owner of a patent has failed to use or has insufficiently used an invention within five years or a utility model or an industrial design within three years following the date of the grant of the patent, any person who wishes to use the patented invention, utility model or industrial design and is in a position to do so, but with whom the owner of the patent has refused to conclude a licensing agreement, may apply to the courts for the grant of a non-exclusive compulsory license. The court shall grant a compulsory license and shall lay down the limits on the use of the invention, utility model or industrial design, as also the amount, dates and procedure for the payment of royalties, unless the owner of the patent is able to prove that the failure to use or the insufficient use of the invention, utility model or industrial design is justified by legitimate reasons.

BELGIUM

Code of Economic Law 2018

Articles XI.37 to XI.46

Art. XI.37. [§ 1er. Le ministre peut octroyer, conformément aux articles XI.40 à XI.42, une licence d'exploitation d'une invention couverte par un brevet :

1° lorsqu'un délai de quatre années à compter de la date de dépôt de la demande de brevet, ou de trois années à compter de la délivrance du brevet, le délai qui expire le plus tard devant être appliqué, s'est écoulé sans que l'invention brevetée soit exploitée par importation ou une fabrication sérieuse et continue en Belgique et sans que le titulaire du brevet justifie son inaction par des excuses légitimes.

Dans le cas d'un brevet ayant pour objet une machine, la fabrication sérieuse et continue en Belgique par le titulaire du brevet de produits obtenus à l'aide de cette machine peut être considérée comme valant exploitation de l'invention brevetée en Belgique lorsque cette

fabrication apparaît comme plus importante pour l'économie du pays que celle de la machine elle-même.

Une licence obligatoire pour défaut ou insuffisance d'exploitation ne sera accordée qu'à condition que la licence soit octroyée principalement pour l'approvisionnement du marché national.

2° lorsqu'une invention, couverte par un brevet appartenant au demandeur de la licence, ne peut être exploitée sans porter atteinte aux droits attachés à un brevet issu d'un dépôt antérieur et pour autant que le brevet dépendant permette un progrès technique important, d'un intérêt économique considérable, par rapport à l'invention revendiquée dans le brevet dominant et à condition que la licence soit octroyée principalement pour l'approvisionnement du marché national;

3° lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger et pour autant que la variété représente un progrès technique important d'un intérêt économique considérable par rapport à l'invention revendiquée dans le brevet et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national;

4° au titulaire d'un droit d'obtention végétale, lorsque le titulaire d'un brevet concernant une invention

biotechnologique a, conformément aux dispositions de la loi sur la protection des obtentions végétales, obtenu une licence obligatoire pour l'exploitation non-exclusive de la variété végétale protégée par ce droit d'obtention végétale parce qu'il ne peut exploiter l'invention biotechnologique sans porter atteinte à ce droit d'obtention végétale antérieur et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national.

Dans le cas de la technologie des semi-conducteurs telle que définie dans la directive 87/54 du Conseil du 16 décembre 1986, les licences visées au 1° et au 2° du présent paragraphe ne peuvent être accordées que si elles sont destinées à remédier à une pratique dont il a été déterminé, à l'issue d'une procédure judiciaire ou administrative, qu'elle est anticoncurrentielle.]

§ 2. Le demandeur de la licence doit établir:

1) dans les cas visés au paragraphe précédent :

- a) que le titulaire du brevet tombe sous l'application de l'une de ces dispositions;
- b) qu'il s'est vainement adressé au titulaire du brevet pour obtenir une licence à l'amiable;

2) en outre, si la licence est réclamée par application du 1° du paragraphe précédent, qu'il disposerait, dans l'hypothèse où la licence lui serait octroyée, des moyens nécessaires pour assurer une fabrication sérieuse et continue en Belgique d'après l'invention brevetée.

§ 3. Toute action en contrefaçon d'une invention couverte par un brevet dont une licence obligatoire est demandée et intentée contre le demandeur d'une telle licence suspend la procédure d'octroi de la licence jusqu'au moment où le jugement ou l'arrêt acquiert force de chose jugée. Si la contrefaçon est établie, la demande de licence obligatoire est rejetée.

§ 4. Est réservée l'application des lois prévoyant l'octroi de licences d'exploitation d'inventions brevetées en des matières spéciales, notamment la défense nationale et l'énergie nucléaire.]

Art. XI.38. [§ 1er. Dans l'intérêt de la santé publique, le Roi peut, par arrêté délibéré en Conseil des ministres, octroyer une licence d'exploitation et d'application d'une invention couverte par un brevet pour :

- a) un médicament, un dispositif médical, un dispositif médical ou un produit de diagnostic, un produit thérapeutique dérivé ou à combiner;
- b) la méthode ou le produit nécessaire pour la production d'un ou plusieurs produits mentionnés sous a);
- c) une méthode de diagnostic appliquée en dehors du corps humain ou animal.

§ 2. Le demandeur de la licence obligatoire doit établir qu'il dispose, dans le cas où la licence obligatoire lui serait octroyée, des moyens ou de l'intention loyale d'obtenir les moyens qui sont nécessaires pour la fabrication et/ou l'application sérieuse et continue en Belgique de l'invention brevetée.

§ 3. Toute procédure concernant une action en contrefaçon d'une invention couverte par un brevet pour lequel une licence obligatoire pour des raisons de santé publique a été demandée et qui est intentée contre le demandeur d'une telle licence, est suspendue en ce qui concerne la question de la contrefaçon jusqu'au moment où une décision concernant la licence obligatoire est prise par le Roi conformément au paragraphe 1er.

§ 4. Les licences octroyées en application du présent article ne sont pas exclusives.

§ 5. La licence obligatoire peut être limitée dans le temps ou en ce qui concerne son champ d'application.

§ 6. Le demandeur d'une licence obligatoire soumet sa demande au ministre et adresse une copie de celle-ci au Comité consultatif de Bioéthique.

Le ministre transmet la demande dans un délai de dix jours au Comité consultatif de Bioéthique. Durant le même délai, le ministre informe le titulaire du brevet qui fait l'objet d'une demande de licence obligatoire, du contenu de la demande et l'invite à faire connaître son point de vue concernant l'octroi possible d'une licence obligatoire ainsi que ses observations relatives à une rémunération raisonnable au cas où une licence obligatoire serait accordée, dans un délai d'un mois au Comité consultatif de Bioéthique avec une copie à lui-même.

Le Comité consultatif de Bioéthique soumet au ministre un avis motivé et non contraignant sur le bien-fondé de la demande.

Dans un délai de trois mois après réception de l'avis du Comité consultatif de Bioéthique, le ministre soumet, pour délibération au Conseil des ministres, un projet d'arrêté royal motivé sur le bien-fondé de la demande. Le ministre soumet également une proposition de rémunération pour le titulaire du brevet.

Si le Roi décide, conformément au paragraphe 1er, d'octroyer la licence obligatoire, Il détermine le cas échéant, par arrêté délibéré en Conseil des ministres, la durée, le champ d'application et les autres conditions d'exploitation de cette licence. Les conditions d'exploitation fixent également la rémunération afférente à l'exploitation de l'invention brevetée durant la procédure d'octroi de la licence.

En cas de crise de santé publique et sur proposition du ministre ayant la santé publique dans ses attributions, le Roi peut, par arrêté délibéré en Conseil des ministres, prendre des mesures en vue d'accélérer la procédure mentionnée dans le présent paragraphe. Il peut, le cas échéant, prévoir que l'avis du Comité consultatif de Bioéthique ne doit pas être obtenu, afin d'accélérer la procédure de prise d'octroi de licence.

Les décisions prises dans le cadre des procédures visées aux alinéas précédents sont publiées au Moniteur belge et mentionnées au Recueil.

La licence obligatoire produit ses effets à compter du jour de l'exploitation et au plus tôt à dater de la demande de la licence obligatoire.

§ 7. Une rémunération raisonnable doit être versée par le demandeur de la licence pour l'utilisation de l'invention brevetée durant la période entre la demande de licence obligatoire

pour des raisons de santé publique et l'arrêté royal qui octroie la licence obligatoire. Dans ce cas, le Roi fixe le montant de la rémunération, par arrêté délibéré en Conseil des ministres.

§ 8. Dès l'octroi de la licence obligatoire, les rapports entre le titulaire du brevet et le licencié sont assimilés, sauf dérogations décidées en vertu du paragraphe 6, à ceux existant entre un concédant et un licencié contractuels.

§ 9. L'octroi de la licence obligatoire, ainsi que les décisions s'y rapportant, sont inscrites au registre.

§ 10. Pour autant que des éléments nouveaux soient intervenus, le Roi peut, par arrêté délibéré en Conseil des ministres, à la requête du titulaire du brevet ou du licencié et conformément aux procédures prévues par le paragraphe 6, procéder à la révision de ce qui a été décidé en ce qui concerne leurs obligations réciproques et, le cas échéant, les conditions d'exploitation.

§ 11. A la demande de tout intéressé et après avoir à nouveau pris connaissance de l'avis du Comité consultatif de Bioéthique, le Roi peut, par arrêté délibéré en Conseil des ministres, retirer la licence obligatoire octroyée pour des raisons de santé publique si, après l'expiration du délai fixé pour l'exploitation, le licencié n'a pas exploité en Belgique l'invention brevetée par une fabrication sérieuse et continue.

L'arrêté de retrait est publié par extrait au Moniteur belge et mentionné au Recueil.

§ 12. Les articles XI.37, XI.40 à XI.46 ne s'appliquent pas à la licence obligatoire visée au présent article. Les dispositions du présent article ne s'appliquent pas aux licences obligatoires visées par les articles XI.37, XI.40 à XI.46.]

Art. XI.39. [§ 1er. Sans préjudice du paragraphe 2, le Roi est l'autorité compétente au sens de l'article 2.4. du Règlement (CE) N° 816/2006 du Parlement européen et du Conseil du 17 mai 2006 concernant l'octroi de licences obligatoires pour des brevets visant la fabrication de produits pharmaceutiques destinés à l'exportation vers des pays connaissant des problèmes de santé publique.

Les décisions relatives à l'octroi, à la révision, au rejet et au retrait d'une licence obligatoire sont prises par arrêté délibéré en Conseil des ministres.

§ 2. Le Roi peut désigner les autorités belges compétentes pour mettre en oeuvre les articles 6.1, 7, 14, 16.1, alinéa 2, 16.3 et 16.4 du Règlement (CE) N° 816/2006.

§ 3. Le Roi est habilité à fixer des exigences purement formelles ou administratives nécessaires pour le traitement efficace des demandes de licence obligatoire visées par le Règlement (CE) N° 816/2006.

§ 4. Les articles XI.37, XI.38 et XI.40 à XI.46 ne s'appliquent pas à la licence obligatoire visée au présent article. Les dispositions du présent article ne s'appliquent pas aux licences obligatoires visées aux articles XI.37, XI.38 et XI.40 à XI.46.]

Art. XI.40. [§ 1er. Les licences obligatoires octroyées par application de l'article XI.37 ne sont pas exclusives.

§ 2. Sans préjudice du deuxième alinéa de l'article XI.37, § 1er, 1°, la licence octroyée par application dudit 1° du paragraphe 1er, ne confère au licencié que le droit d'exploiter l'invention brevetée par fabrication sérieuse et continue en Belgique. Le ministre fixe le délai dans lequel

une telle fabrication doit être réalisée, cette fabrication impliquant l'application intégrale du procédé éventuellement revendiqué dans le brevet.

La licence obligatoire peut être limitée dans le temps ou à une partie seulement de l'invention lorsque celle-ci permet la réalisation d'autres fabricats que ceux requis pour satisfaire les besoins dont question à l'article XI.37, § 1er.

Dès l'octroi de la licence obligatoire, les rapports entre le titulaire du brevet et le licencié sont assimilés, sauf dérogations prévues par l'arrêté de l'octroi, à ceux existant entre un concédant et un licencié contractuels.

§ 3. La licence octroyée par application de l'article XI.37, § 1er, 2°, est limitée à la partie de l'invention couverte par le brevet dominant dont l'utilisation est indispensable pour l'exploitation de l'invention brevetée dépendante et ne permet cette utilisation qu'en liaison avec ladite exploitation.

Le troisième alinéa du paragraphe 2 est applicable à la licence obligatoire.

Le titulaire du brevet auquel la licence obligatoire est imposée peut, si les deux inventions se rapportent au même genre d'industrie, se faire octroyer à son tour une licence du brevet dont le demandeur de la licence obligatoire s'est prévalu.

§ 4. La licence octroyée en application de l'article XI.37, § 1er, 3° ou 4°, est limitée à la partie de l'invention couverte par le brevet dominant dont l'utilisation est indispensable pour l'exploitation de l'invention brevetée dépendante ou de la variété protégée par le droit d'obtention végétale dépendante et ne permet cette utilisation qu'en liaison avec ladite exploitation.

Le troisième alinéa du paragraphe 2 est applicable à la licence obligatoire octroyée en application de l'article XI.37, § 1er, 3° ou 4°.]

Art. XI.41. [1 § 1er. Dans les cas visés à l'article XI.37, § 1er, le ministre octroie les licences obligatoires sur requête.

§ 2. La requête est transmise par le ministre à la Commission des licences obligatoires afin que celle-ci entende les intéressés, les concilie s'il se peut et, dans le cas contraire, lui donne un avis motivé sur le bien-fondé de la demande. La Commission joint à son avis le dossier de l'affaire.

Le ministre décide de la suite à réserver à la requête et notifie sa décision aux intéressés par envoi recommandé.

§ 3. Dans les cas visés à l'article XI.37, § 1er, 2° et 3°, la demande de licence obligatoire est déclarée fondée si le titulaire du brevet dominant ne conteste ni la dépendance du brevet ou du droit d'obtention végétale du demandeur de la licence, ni sa validité, ni le fait que l'invention ou la variété permet un progrès technique important, d'un intérêt économique considérable, par rapport à l'invention revendiquée dans le brevet.

§ 4. Le fait pour le titulaire du brevet antérieur de nier la dépendance du brevet ou du droit d'obtention végétale du demandeur de la licence emporte de plein droit pour ce dernier l'autorisation d'exploiter l'invention décrite dans son propre brevet ou dans son droit d'obtention végétale ainsi que l'invention dite dominante sans pouvoir de ce chef être poursuivi en contrefaçon par le titulaire du brevet antérieur.

La contestation de la validité du brevet ou du droit d'obtention végétale dépendant suspend la procédure administrative relative à la reconnaissance du bien-fondé de la demande de licence, à condition, soit qu'une action en nullité dudit brevet ou droit d'obtention végétale soit déjà introduite devant l'autorité compétente par le titulaire du brevet dominant, soit que celui-ci cite le demandeur de la licence devant le tribunal dans les deux mois de la notification qui lui a été faite du dépôt de la demande de licence.

La contestation du progrès technique important, d'un intérêt économique considérable du brevet ou du droit d'obtention végétale dépendant par rapport à l'invention décrite dans le brevet dominant suspend la procédure administrative relative à la reconnaissance du bien-fondé de la demande de licence, à condition que le titulaire du brevet dominant introduise, dans les deux mois de la notification qui lui a été faite du dépôt de la demande de licence, une requête au tribunal siégeant comme en référé. La décision judiciaire n'est pas susceptible d'appel ou d'opposition.

L'inobservation du délai prévu aux deux alinéas précédents entraîne forclusion du droit du titulaire du brevet dominant de faire valoir sa contestation devant le tribunal.]

Art. XI.42. [1 § 1er. Dans les quatre mois de la notification de la décision, le titulaire du brevet et le demandeur de licence concluent une convention écrite concernant leurs droits et leurs obligations réciproques. Le ministre en est informé. A défaut d'une convention dans le délai susvisé, les droits et les obligations réciproques seront fixés par le tribunal siégeant comme en référé, sur citation de la partie la plus diligente.

Une copie du jugement définitif est immédiatement transmise au ministre par le greffier.

La fixation des obligations des parties comprendra en tout cas une rémunération adéquate compte tenu de la valeur économique de la licence.

§ 2. Le ministre octroie la licence par un arrêté motivé.

La licence obligatoire et les décisions s'y rapportant sont inscrites au registre.

L'arrêté est publié au Moniteur belge et mentionné au Recueil.]

Art. XI.43. [§ 1er. Il est institué auprès du SPF Economie une Commission des licences obligatoires qui a pour mission d'accomplir les tâches qui lui sont dévolues par les articles XI.41, XI.44 et XI.45.

La Commission est composée de dix membres nommés par le ministre.

Huit membres sont désignés sur proposition des organisations représentatives de l'industrie, de l'agriculture, du commerce, des petites et moyennes entreprises industrielles et des consommateurs.

Les organisations visées à l'alinéa précédent sont désignées par le ministre.

Deux membres sont désignés parmi les membres du Conseil de la Propriété intellectuelle. Ils restent membres de la Commission pour la durée de leur mandat au sein de celle-ci, indépendamment de leur qualité de membre dudit Conseil.

Le mandat de membre de la Commission est d'une durée de six ans. Il est renouvelable.

La Commission est présidée par un de ses membres, désigné par le ministre pour un terme de trois ans renouvelable.

Les avis sont adoptés par consensus. A défaut de consensus, l'avis reprend les différentes opinions.

Le Roi détermine les modalités de fonctionnement et d'organisation de la Commission.

La Commission élabore son règlement d'ordre intérieur. Celui-ci entre en vigueur après approbation du ministre.

§ 2. Lorsque le ministre est saisi d'une requête en vue de l'octroi d'une licence obligatoire, il désigne auprès de la Commission un ou plusieurs agents qualifiés, choisis parmi les fonctionnaires du SPF Economie.

La Commission définit la mission des agents visés à l'alinéa 1er et fixe les modalités en vertu desquelles ces agents lui rendent compte de leur mission. La Commission précise les conditions de transmission des documents visés à l'alinéa 4, en vue d'assurer la protection des renseignements confidentiels.

Les agents commissionnés par le ministre sont compétents pour recueillir tous renseignements, recevoir toutes dépositions ou tous témoignages écrits ou oraux qu'ils estiment nécessaires à l'accomplissement de leur mission.

Dans l'exercice de leurs fonctions, ces agents peuvent :

1° moyennant un avertissement préalable d'au moins cinq jours ouvrables ou sans avertissement préalable s'ils ont des raisons de croire qu'il existe un risque de destruction de pièces utiles à l'instruction de la demande de licence obligatoire, pénétrer, pendant les heures habituelles d'ouverture ou de travail, dans les bureaux, locaux, ateliers, bâtiments, cours adjacentes et enclos, dont l'accès est nécessaire à l'accomplissement de leur mission;

2° faire toutes les constatations utiles, se faire produire, sur première réquisition et sans déplacement, les documents, pièces ou livres nécessaires à leurs recherches et constatations et en prendre copie;

3° prélever des échantillons, suivant les modes et les conditions déterminés par le Roi;

4° saisir, contre récépissé, les documents visés au point 2 qui sont nécessaires à l'accomplissement de leur mission;

5° commettre des experts dont ils déterminent la mission, suivant les conditions déterminées par le Roi.

A défaut de confirmation par le Président de la Commission dans les quinze jours, la saisie est levée de plein droit. La personne entre les mains de laquelle les objets sont saisis peut en être constituée gardien judiciaire. Le président de la Commission peut donner mainlevée de la saisie qu'il a confirmée, le cas échéant sur requête du propriétaire des objets saisis adressée à la Commission.

Moyennant un avertissement préalable d'au moins cinq jours ouvrables ou sans avertissement préalable s'ils ont des raisons de croire qu'il existe un risque de destruction de pièces utiles à l'instruction de la demande de licence obligatoire, les agents commissionnés peuvent visiter les locaux habités avec l'autorisation préalable du Président du tribunal de commerce. Les visites dans les locaux habités doivent s'effectuer entre huit et dix-huit heures et être faites conjointement par deux agents au moins.

Dans l'exercice de leur mission, ils peuvent requérir l'assistance des services de police.

Les agents commissionnés exercent les pouvoirs qui leur sont accordés par le présent article sous la surveillance du procureur général, sans préjudice de leur subordination à l'égard de leurs supérieurs dans l'administration.

§ 3. Les agents commissionnés à cet effet remettent leur rapport à la Commission. La Commission n'émet son avis qu'après avoir entendu le titulaire du brevet et la personne qui requiert ou a obtenu la licence obligatoire.

Ces personnes peuvent se faire assister ou représenter, soit par un avocat, soit par une personne que la Commission agréée spécialement dans chaque affaire. La Commission entend également les experts et les personnes qu'elle juge utile d'interroger. Elle peut charger les agents commissionnés de procéder à un complément d'information et de remettre un rapport complémentaire.

Un mois au moins avant la date de sa réunion, la Commission avise par envoi recommandé les personnes qui doivent être entendues au cours de cette réunion. En cas d'urgence, le délai est réduit de moitié.

§ 4. Les frais de fonctionnement de la Commission sont à charge du budget du SPF Economie.]

Art. XI.44. [Pour autant que des éléments nouveaux soient intervenus, il peut être procédé, à la requête du titulaire du brevet ou du licencié, à la révision des décisions prises en ce qui concerne leurs obligations réciproques et, le cas échéant, les conditions d'exploitation. La compétence de révision appartient à l'autorité de qui la décision émane et la procédure à suivre est la même que celle qui est prévue pour conduire à la décision soumise à révision.]

Art. XI.45. [1 § 1er. A la demande du titulaire du brevet, le ministre retire la licence obligatoire s'il résulte d'un jugement coulé en force de chose jugée que le licencié s'est rendu coupable à l'égard du titulaire du brevet d'un acte illicite ou qu'il a manqué à ses obligations.

§ 2. A la demande de tout intéressé, le ministre peut retirer la licence obligatoire concédée pour défaut d'exploitation si, à l'expiration du délai fixé par le ministre pour l'exploitation, le licencié n'a pas assuré en Belgique une exploitation de l'invention brevetée par une fabrication sérieuse et continue.

§ 3. Les décisions de retrait sont soumises par le ministre, pour avis, à la Commission des licences obligatoires.

Le retrait fait l'objet d'une décision motivée. Celle-ci mentionne le cas échéant la raison pour laquelle l'avis de la Commission n'a pas été suivi.

L'arrêté de retrait est publié par extrait au Moniteur belge et mentionné au Recueil.]

Art. XI.46. [Le titulaire d'une licence obligatoire ne peut transférer par cession ou sous-licence à des tiers les droits attachés à la licence qu'avec la partie de l'entreprise ou du fonds de commerce affectée à l'exploitation de la licence et sous réserve que les licences octroyées par application de l'article XI.37, § 1er, 2°, ne sont cessibles qu'avec le brevet dépendant.

L'article XI.51 est applicable par analogie.]

Art. XI.47. [1 § 1er. Le brevet s'éteint au terme de la vingtième année à compter du jour du dépôt de la demande, sous réserve du paiement des taxes annuelles visées à l'article XI.48.

§ 2. Dans le cas prévu à l'article XI.23, § 8, la demande de brevet cesse de produire ses effets, sous réserve du paiement des taxes annuelles, à l'expiration du délai prescrit pour le paiement de la taxe de recherche, si cette taxe n'a pas été acquittée.]

BELIZE

Patents Act (Cap. 253, Revised Version 2000)

Sections 38 and 39

Non-Voluntary Licences

38. (1) At any time after the expiration of four years from the date of filing of a patent application or three years from the date of the grant of a patent, whichever happens later, any interested person may apply to the Court for the grant of a non-voluntary licence under the patent on the grounds that the patented invention is not being exploited or is being insufficiently exploited by working the invention in Belize, or by importation into Belize.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Belize.

(3) The Court shall, where it grants a non-voluntary licence, fix:-

- (a) the scope and function of the licence;
- (b) the time limit within which the licensee must begin to exploit the patented invention; and
- (c) the amount of the remuneration to be paid to the owner of the patent, and the conditions of the payment thereof.

(4) The beneficiary of the non-voluntary licence shall:-

- (a) have the right to exploit the patented invention in Belize in accordance with the Court's order;

- (b) commence the exploitation of the patented invention within the time stipulated in the said order; and
(c) thereafter, exploit the patented invention sufficiently.

(5) Where the invention claimed in a patent (referred to in this section as a “later patent”) cannot be exploited in Belize without infringing a patent granted on the basis of an application benefiting from an earlier filing, or, where appropriate, priority date (referred to in this section as an “earlier patent”), and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Court may, upon the application of the owner of the later patent, issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is issued in accordance with subsection (5), the Court shall, upon the application of the owner of the earlier patent, issue a non-voluntary licence in respect of the later patent.

(7) In the case of an application for the issuance of a non-voluntary licence in accordance with subsections (5) and (6), subsection (3) shall apply mutatis mutandis, except that no time limit need be fixed by the Court.

(8) In the case of a non-voluntary licence issued under subsection (1), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (5), only with the earlier patent.

(9) An application for a non-voluntary licence shall be subject to payment of the prescribed fee.

(10) No licence shall be granted under this section in respect of a patented invention in the field of semi-conductor technology.

(11) Section 35(2) to (12), and 62 (2) shall apply mutatis mutandis.

Exercise of powers on applications under section 38

39. The powers of the Court on an application under section 38 shall be exercised with a view to ensuring that the inventor or other person beneficially entitled to a patent receives adequate remuneration having regard to the economic value of the licence.

BHUTAN

The Industrial Property Act of the Kingdom of Bhutan of 2001

Section 15

Exploitation by Government or Person thereby Authorized

15. (1) Where:

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- (ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice: the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The

exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices. The Minister shall take his decision after hearing the owner of the patent and any interested person if they wish to be heard.

(2) Upon request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(3) (a) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.

BOLIVIA (PLURINATIONAL STATE OF)

Decision No. 486 of 14/09/ 2000 of the Commission of the Andean Community - Common Industrial Property Regime (Cartagena Agreement)

(Refer to ANDEAN Community below.)

BOSNIA AND HERZEGOVINA

Law on Patents

Articles 79 and 80

Article 79 (Compulsory License)

(1) If the right holder refuses to assign the right to the economic exploitation of a protected invention in Bosnia and Herzegovina or imposes unreasonable conditions for such an assignment without having made effective and serious preparations for the exploitation thereof in Bosnia and Herzegovina, the Court of Bosnia and Herzegovina may grant a compulsory license at the request of an interested party. In such a case, the right holder shall be informed of the grant of the compulsory license within a shortest possible time limit.

(2) The request for the grant of a compulsory license referred to in paragraph (1) of this Article may be filed after the expiration of the four-year period from the filing date of a patent application or after the expiration of the three-year time limit from the date of the grant of a patent, whichever of these two time limits expires later.

(3) A compulsory license may be granted only if the person filing the request referred to in paragraph (2) of this Article unsuccessfully attempted, within a reasonable period of time, to obtain authorization from the patent holder for the exploitation of the protected invention on reasonable commercial terms and conditions.

(4) A compulsory license may not be granted if the patent holder proves the existence of legitimate reasons justifying non-exploitation or insufficient exploitation of the protected invention.

(5) At a reasoned request, the Court of Bosnia and Herzegovina may grant a compulsory license for somebody else's patent to the patent holder who cannot exploit his protected invention without infringing somebody else's patent.

(6) The compulsory license referred to in paragraph (5) of this Article may be granted, provided that: a) a patent owned by the person filing the request referred to in paragraph (2) of this Article involves an important technological advance, which is of considerable economic significance in relation to the invention protected by the patent for which the grant of a compulsory license is requested. b) the holder of the patent for which the grant of a compulsory license is requested is entitled to a cross license on reasonable terms and conditions.

(7) A compulsory license may not be exclusive, and the scope and duration thereof shall be exclusively limited to the purpose for which it was granted.

(8) A compulsory license may be transferred only together with the production plant or the part thereof in which the invention for which it was granted is exploited.

(9) A compulsory license shall be authorized primarily for the purpose of supplying domestic market, unless it is necessary to correct the practices determined in a judicial or administrative process to be uncompetitive .

(10) At a reasoned request of an interested party, the Court of Bosnia and Herzegovina shall cancel a compulsory license if and when the circumstances which led to the authorization thereof cease to exist and are unlikely to recur, but provided that the legitimate rights of the licensee are protected.

(11) The patent holder shall be entitled to remuneration taking into account the economic value of a license and the need for correcting uncompetitive practices.

(12) The compulsory license referred to in paragraph (5) of this Article shall be nontransferable, except in the case of simultaneous transfer of the patent for which it was granted. (13) The provisions of paragraphs (5), (6) and (12) of this Article shall apply mutatis mutandis to the right to protection of a plant variety.

Article 80 (Compulsory License in Public Interest)

(1) The Council of Ministers of Bosnia and Herzegovina (hereinafter referred to as the Council of Ministers) may grant a compulsory license if the exploitation of the invention protected by a patent is necessary due to national emergencies for the purpose of:

- a) State security,
- b) protection of public interest in the field of health and nutrition,
- c) protection and improvement of human environment,
- d) special interest in a particular branch of economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive.

(2) In the case of semi-conductor technology, a compulsory license may be granted only in the cases referred to in paragraph (1) of this Article.

(3) The provision of paragraph (3) of Article 79 of this Law shall not apply in the cases referred to in paragraph (1) of this Article.

BOTSWANA

Industrial Property Act, 2010 (Act No. 8 of 2010)

Section 31-35

Compulsory licences in the public interest or for competition

31. (1) The Minister may, without the consent or authority of the patentee and after giving a hearing to the patentee and any other interested party, authorise a Government agency, other person or body to exploit the patented invention on the payment of adequate remuneration to the patentee where —

- (a) it is in the public interest to do so for purposes of national security, nutrition, health, development of other vital sectors of the national economy, social service; or
- (b) a court or administrative body has determined that the manner of exploitation of the invention by the patentee is anti-competitive or constitutes an abuse of the patent.

(2) In the determination of adequate remuneration under subsection (1), the Minister shall take into account the economic value of the exploitation of the patented invention and the need for the elimination of anti-competitive practices.

(3) The exploitation of the patented invention under subsection (1) shall be for the supply of the domestic market in Botswana only, except where paragraph 1 or 3 of Article 31bis of the TRIPS Agreement applies.

(4) Upon request by the patentee, a Government agency, other person or body authorised to exploit a patented invention under subsection (1), the Minister may, after hearing the parties, vary the terms of the decision authorising the exploitation of the patented invention as circumstances may justify.

(5) The Minister may revoke a decision made under subsection (1) where, after hearing all the parties he or she is satisfied that the circumstances which led to his or her decision have ceased to exist and are not likely to recur, or that the agency, person or body has failed to comply with the terms of the decision.

(6) Notwithstanding the provisions of subsection (5), the Minister shall not terminate the authorisation to exploit the patent if he or she is satisfied that public interest as referred to in subsection (1) justifies the maintenance of his or her decision.

(7) Where a third party has been designated by the Minister to exploit a patent under this section, such exploitation may be transferred only within the enterprise or business within which the patented invention is being exploited.

(8) The authorisation to exploit a patent under this section shall not exclude —

- (a) the right by the patentee to grant a licence to another person to exploit the patent; or
- (b) the continued exercise, by the patentee, of his or her rights under section 24 (2).

(9) A request to the Minister under subsection (4) by an agency, other person or body for an authorisation to exploit a patent under this section shall be accompanied by evidence that the patentee has received, from the person seeking the authorisation, a request for a contractual licence, and that such person has been unable, within a reasonable time, to obtain the licence on reasonable commercial terms and conditions.

(10) Subsection (9) shall not apply in cases of national emergency or other circumstances of extreme urgency, nor in the cases mentioned in subsection (1) (a).

(11) Where a competition authority has determined that the manner of exploitation of a patent in the field of semi-conductor technology is anticompetitive, the Minister shall authorise the issuance of a compulsory licence if he or she is satisfied that the issuance of a compulsory licence would remedy such practice.

(12) Any person who is aggrieved by a decision of the Minister under this section may appeal to the High Court against that decision.

Importation of patented products by Government or third party

32. (1) Subject to section 31, the Minister may issue a licence to a Government agency or any authorised person for the importation of patented products such as generic pharmaceutical products from any legitimate alternative foreign source without the approval of the patentee where —

(a) it is in the public interest to do so for purposes of national security, nutrition, health, development of other vital sectors of the national economy, social service; or

(b) the market for the patented product is not being supplied in sufficient quantities or on reasonable terms in relation to market demand.

(2) The importation of the patented product by a Government agency or any authorised person shall be solely for public non-commercial use within Botswana, except where paragraph 1 or 3 of Article 31bis of the TRIPS Agreement is applicable.

(3) A licence issued under subsection (1) shall include the name of the pharmaceutical product and an estimate of the quantities of the pharmaceutical product to be imported during the term of the licence: Provided that the estimate shall not limit the quantity of the pharmaceutical product required to address the public health problem that the importation seeks to address.

(4) Where in respect of the pharmaceutical product referred to in subsection (1) a compulsory licence has been granted in the exporting country under the system set out in Article 31bis of the TRIPS Agreement and the Annex thereto, and remuneration for the licence has been paid accordingly in the exporting country, the obligation to pay remuneration for the compulsory licence to import that product into Botswana shall not apply.

Compulsory licences for failure to exploit patent

33. (1) At any time after the expiration of three years from the date of the grant of a patent or four years from the filing date of the application, whichever occurs later, any person may apply to the High Court for an order to be granted a licence under the patent on the grounds that a market for the patent is not being supplied, or is not being supplied on reasonable terms, in Botswana.

(2) Notwithstanding the provisions of subsection (1) an order to issue a compulsory licence shall not be granted if the patentee satisfies the High Court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patent.

(3) Where the High Court grants an order for the issue of a compulsory licence under this section, it shall —

(a) set out the scope and function of the licence;

(b) fix the time limit for the exploitation of the patent; and

(c) set out the conditions and amount of remuneration to be paid to the patentee.

(4) A request for the issue of a compulsory licence shall be made in the prescribed form subject to payment of the prescribed fees.

Licences in respect of dependent patents

34. (1) If the exploitation of a patent (in this section referred to as “the later patent”) is dependent upon the obtaining of a licence under an earlier patent, the patentee in respect of the later patent may apply to the High Court for an order to be issued a licence to exploit the earlier patent, and the order may be granted on such conditions as may be imposed, including a condition that such licence may be used only for the purpose of permitting the later patent to be exploited.

(2) The Court shall not grant an order under this section unless the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent.

(3) Where a holder of a plant variety right cannot exploit his or her right without infringing a prior patent, the holder may apply for a compulsory licence for the non-exclusive use of that patent, to the extent necessary to allow the exploitation of the plant variety right.

(4) Where a patentee of a biotechnological invention cannot exploit the patent without infringing a prior plant variety right, the patentee may apply for a compulsory licence for the non-exclusive use of the plant variety right, to the extent necessary to allow the exploitation of such patent.

(5) The High Court may, on an application made to it by the patentee in respect of an earlier patent or plant breeder’s right, as the case may be, grant an order for the issue of a licence to use the invention claimed in the later patent or plant breeder’s right.

(6) A licence granted under this section shall not be transferable except in conjunction with the transfer of the licence in respect of the later patent.

(7) The provisions of section 31 (1) regarding the remuneration due to the owner of the patent shall apply to licences issued under this section.

Termination of contracts relating to licences

35. Any contract relating to a licence to exploit a patent shall terminate on the date on which the patent under which the licence was granted expires, is revoked or otherwise ceases to protect such invention.

BRAZIL

Law No. 9.279 of May 14, 1996 (Law on Industrial Property)

Articles 68-72

68. The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

(1) The following also occasion a compulsory license:

I. non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the

patented process, except cases where this is not economically feasible, when importation shall be permitted; or

II. commercialization that does not satisfy the needs of the market.

(2) A license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent, that shall be destined predominantly for the domestic market, in which case the exception contained in Item I of the previous Paragraph shall be extinguished.

(3) In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the provisions of Article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent.

(4) In the case of importation to exploit a patent and in the case of importation as provided for in the preceding Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.

(5) The compulsory license that is the subject of Paragraph 1 shall only be required when 3 (three) years have elapsed since the patent was granted.

69. A compulsory license shall not be granted if, on the date of the application, the titleholder:

I. justifies the non-use based on legitimate reasons;

II. proves that serious and effective preparations for exploitation have been made;

III. justifies the failure to manufacture or to market on grounds of an obstacle of legal nature;

70. The compulsory license shall also be granted when all the following circumstances apply:

I. there is a situation of dependency of one patent with regard to another;

II. the object of the dependent patent constitutes a substantial technical progress with regard to the earlier patent; and

III. the titleholder fails to reach agreement with the patentholder of the dependent patent on the exploitation of the earlier patent.

(1) For the purposes of this Article, a dependent patent is considered to be a patent whose exploitation necessarily depends on the use of the object of an earlier patent.

(2) For purposes of this Article, a process patent may be considered dependent on the respective product patent, and likewise, a product patent may be dependent on a process patent.

(3) The patentholder licensed pursuant to the provisions of this Article shall have the right to a crossed compulsory license on the dependent patent.

71. In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patentholder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio, without prejudice to the rights of the respective titleholder.

Sole Paragraph. The act of granting the license shall establish its term and the possibility of extension.

72. Compulsory licenses shall always be granted on a non-exclusive basis, and sublicensing shall not be permitted.

BRUNEI DARUSSALAM

Patents Order, 2011

Sections 55-63

PART XI

LICENCES OF RIGHT AND COMPULSORY LICENCES

Licences of right.

55. (1) At any time after the grant of a patent, its proprietor may apply to the Registrar for an entry to be made in the register to the effect that licences under the patent are to be available as of right.

(2) Where an application under subsection (1) is made, the Registrar shall give notice of the application to any person registered as having a right in or under the patent and, if satisfied that the proprietor of the patent is not precluded by contract from granting licences under the patent, the Registrar shall make that entry.

(3) Where an entry under subsection (2) is made in respect of a patent-

(a) any person shall, at any time after the entry is made, be entitled as of right to a licence under the patent on such terms as may be settled by agreement or in default of agreement by the Registrar on the application of the proprietor of the patent or the person requiring the licence;

(b) the Registrar may, on the application of the holder of any licence granted under the patent before the entry was made, order the licence to be exchanged for a licence of right on terms so settled;

(c) if, in proceedings for infringement of the patent, the defendant undertakes to take a licence on such terms, no injunction shall be granted against him and the amount (if any) recoverable against him by way of damages shall not exceed twice the amount which would have been payable by him as licensee if such a licence on those terms had been granted before the earliest infringement; and

(d) the renewal fee payable in respect of the patent after the date of the entry shall be half the fee which would be payable if the entry had not been made.

(4) An undertaking under subsection (3)(c) may be given at any time before final order in the proceedings, without any admission of liability.

(5) The licensee under a licence of right may (unless, in the case of a licence the terms of which are settled by agreement, the licence otherwise expressly provides) request the proprietor of the patent to take proceedings to prevent any infringement of the patent.

(6) If the proprietor refuses or neglects to take proceedings under subsection (5) within 2 months after being so requested, the licensee may institute proceedings for the infringement in his own name as if he were the proprietor, making the proprietor a defendant.

(7) A proprietor so added as defendant shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

Cancellation of entry made under section 55.

56. (1) At any time after an entry has been made under section 55 in respect of a patent, the proprietor of the patent may apply to the Registrar for cancellation of the entry.

(2) Where an application under subsection (1) is made and the balance paid of all renewal fees which would have been payable if the entry had not been made, the Registrar may cancel the entry if satisfied that there is no existing licence under the patent or that all licensees under the patent consent to the application.

(3) Within the prescribed period after an entry had been made under section 55 in respect of a patent, any person who claims that the proprietor of the patent is, and was at the time of the entry, precluded by a contract in which the claimant is interested from granting licences under the patent may apply to the Registrar for cancellation of the entry.

- (4) Where the Registrar is satisfied, on an application under subsection (3), that the proprietor of the patent is and was so precluded, he shall cancel the entry.
- (5) The proprietor shall be liable to pay, within a period specified by the Registrar, a sum equal to the balance of all renewal fees which would have been payable if the entry had not been made, and the patent shall cease to have effect at the expiration of that period if that sum is not so paid.
- (6) Where an entry is cancelled under this section, the rights and liabilities of the proprietor of the patent shall after the cancellation be the same as if the entry had not been made.
- (7) Where an application has been made under this section-
- (a) in the case of an application under subsection (1), any person; and
- (b) in the case of an application under subsection (3), the proprietor of the patent, may, within the prescribed period, give notice to the Registrar of opposition to the cancellation.
- (8) The Registrar shall, in considering the application made under this section, determine whether the opposition is justified.

Compulsory licences.

57. (1) Any interested person may apply to the court for the grant of a licence under a patent on the ground that the grant of the licence is necessary to remedy an anti-competitive practice.
- (2) Without prejudice to the generality of subsection (1), the court may determine that the grant of a licence is necessary to remedy an anti-competitive practice if -
- (a) there is a market for the patented invention in Brunei Darussalam;
- (b) that market -
- (i) is not being supplied; or
- (ii) is not being supplied on reasonable terms; and
- (c) the court is of the view that the proprietor of the patent has no valid reason for failing to supply that market with the patented invention, whether directly or through a licensee, on reasonable terms.
- (3) Subject to this section, if the court is satisfied that the ground referred to in subsection (1) is established, the court may make an order for the grant of a licence in accordance with the application upon such terms as the court thinks fit.
- (4) A licence granted under this section-
- (a) is not exclusive; and
- (b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used.
- (5) Any licence granted under this section may, on the application of any interested party, be terminated by the court where the court is satisfied that the ground upon which the licence was granted has ceased to exist and is unlikely to recur.
- (6) Where a licence is granted under this section to any person, the person shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed between the person and the patentee or, in default of agreement, as is determined by the court on the application of the person or the patentee.
- (7) The powers of the court on an application under this section shall be exercised with a view to securing that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the economic value of the licence.
- (8) No order shall be made in pursuance of any application under this section which would be at variance with any treaty or international convention relating to patents to which Brunei Darussalam is a party.

PART XII

USE OF PATENTED INVENTIONS FOR SERVICES OF GOVERNMENT

Use of patented inventions by Government and authorised parties.

58. (1) Subject to sections 61, 62 and 63, but notwithstanding any other section of this Order, the Government and any party authorised in writing by the Government may do anything in relation to a patented invention -
- (a) for a public non-commercial purpose; or

(b) for or during a national emergency or other circumstances of extreme urgency, and anything done by virtue of this section shall not amount to an infringement of the patent.

(2) Without prejudice to the generality of subsection (1) subject to sections 61, 62 and 63, but notwithstanding any other section of this Order, the Government and any party authorised in writing by the Government may import any relevant health product, and do anything in relation to any relevant health product so imported, for or during a national emergency or other circumstances

of extreme urgency, if the Government has given the Council for TRIPS a relevant notification in relation to the relevant health product.

(3) For the purposes of this section and section 59-

(a) any use of an invention for the supply to the government of any country outside Brunei Darussalam, in pursuance of any agreement or arrangement between the Government of His Majesty the Sultan and Yang Di-Pertuan and the government of that country, of articles required for the defence of that country shall be deemed to be a use of the invention for a public non-commercial purpose; and

(b) the power of the Government or any party authorised by the Government to do anything in accordance with this section shall not, in the case of a patent relating to an integrated circuit, extend to sale of the invention to the public.

(4) The purchaser of any article sold in the exercise of the powers conferred by this section, and any person claiming through the purchaser, shall have power to deal with it in the same manner as if the patent were held on behalf of the Government.

(5) In this section -

“integrated circuit” means a product, in its final or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in and on, or in or on, a piece of material and which is intended to perform an electronic function;

“relevant notification” means a notification that satisfies the requirements of

(a) paragraph 2(a) of the ‘ Doha Declaration Implementation Decision; or

(b) paragraph 2(a) of the Annex to the TRIPS Agreement.

Rights of third parties in respect of Government use.

59. (1) In relation to [a] anything done in accordance with section 58 by the Government or any party authorised in writing by the Government; or

(b) anything done to the order of the Government-

(i) for a public non-commercial purpose; or

(ii) for or during a national emergency or other circumstances of extreme urgency, by the proprietor of a patent in respect of the patented invention or by the proprietor of an application for a patent in respect of the invention for which the application has been filed and is still pending, the provisions of any licence, assignment or agreement to which this subsection applies shall, subject to sections 61, 62 and 63, be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use.

(2) The reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(3) Subsection (1) shall apply to any licence, assignment or agreement which is made, whether before or after the date of commencement of this Order, between (on the one hand) any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and (on the other hand) any person other than the Government.

References of disputes as to Government use.

60. (1) Any dispute as to the exercise by the Government or a party authorised by the Government of the powers conferred by, or as to the terms for doing anything in accordance with, section 58 may be referred to the court by either party to the dispute after a patent has been granted for the invention.

(2) In determining any dispute referred to the court under this section, the court shall have regard to

(a) any benefit or compensation that the patentee of the invention may have received, or may be entitled to receive, directly or indirectly, from the Government or any party authorised by the Government in respect of the patented invention; and

(b) the need to ensure that the patentee shall receive reasonable remuneration having regard to the economic value of the patented invention.

(3) If the validity of a patent is put in issue in proceedings under this section and it is found that the patent is only partially valid, the court may, subject to subsection (4), grant relief to the proprietor of the patent in respect of that part of the patent which is found to be valid and to have been used in

accordance with section 58.

(4) Where in any such proceedings it is found that a patent is only partially valid, the court shall not grant relief by way of costs or expenses except where the proprietor of the patent proves that the specification of the patent was framed in good faith and with reasonable skill and knowledge, and in that event the court may grant relief in respect of that part of the patent which is valid and has been

so used, subject to the discretion of the court as to costs and expenses.

(5) As a condition of any such relief, the court may direct that the specification of the patent shall be amended to its satisfaction upon an application made for that purpose under section 80, and an application may be so made accordingly, whether or not all other issues in the proceedings have been determined.

(6) In any proceedings under this section, the court may at any time order the whole proceedings or any question or issue of fact arising in them to be referred, on such terms as the court may direct, to an arbitrator; and references to the court in this section shall be construed accordingly.

(7) One of the 2 or more joint proprietors of a patent or an application for a patent may, without the concurrence of the others, refer a dispute to the court under this section, but shall not do so unless the others are made parties to the proceedings; but any of the others if made a defendant shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

Nature and scope of rights under section 58.

61. (1) The right to use a patented invention under section 58 -

(a) is not exclusive;

(b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and

(c) is, notwithstanding section 58(2) (a), limited to the supply of the patented invention predominantly in Brunei Darussalam by the Government or a party authorised by the Government under that section.

(2) The right under section 58 to use a relevant health product which is imported under section 58(2) does not include a right to export the relevant health product.

(3) The right to use a patented invention under section 58 may, on the application of any interested party, be terminated by the court, where the court is satisfied that the circumstances that gave rise to the right to use the patented invention have ceased to exist and are unlikely to recur.

(4) Where the court has terminated the right under section 58 to use a patented invention, the court may make such consequential orders as it thinks necessary.

Duty to inform patentee.

62. (1) Where any thing set out in section 64(1) is done in relation to a patented invention by the Government or a party authorised in writing by the Government for a public non-commercial purpose, the Government department that did or authorised the doing of the thing shall inform the patentee promptly of the doing of the thing.

(2) Where any thing set out in section 64(1) is done in relation to a patented invention by the Government or a party authorised in writing by the Government for or during a national emergency or other circumstances of extreme urgency, the Government department that did or authorised the doing of the thing shall, as soon as reasonably practicable, inform the patentee of the doing of the thing.

Patentee entitled to remuneration.

63. (1) Subject to subsection (2), where an act is done under section 58, the Government shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed, between the Government and the patentee having regard to the economic value of the patented invention or as may, in default of agreement, be determined by the court under section 60.

(2) No remuneration shall be payable under subsection (1) in respect of the import or subsequent use under section 58(2) of any relevant health product, if the patentee has received or will receive any other remuneration in respect of that relevant health product.

BULGARIA

Law on Patents and Utility Model Registration (as amended up to 2012)

Articles 32 and 32a

Принудителна лицензия

Чл. 32. (1) (Изм. - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Когато заинтересовано лице е направило неуспешни опити да получи договорна лицензия от притежателя при справедливи условия, лицето може да поиска от Патентното ведомство да предостави в негова полза принудителна лицензия за използване на това изобретение, ако е налице поне едно от следните условия:

1. изобретението не е било използвано в продължение на 4 години от подаването на заявката за патент или на три години от издаването на патента, като се прилага срокът, който изтича по-късно;
2. в сроковете по т. 1 изобретението не е било използвано в достатъчна степен за задоволяване на националния пазар, освен ако притежателят докаже уважителна причина за това.

(2) Молителят по предходната алинея трябва да докаже, че е в състояние да използва изобретението в рамките на исканата принудителна лицензия.

(3) (Нова - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Извън случаите по ал. 1, принудителна лицензия може да се предостави, когато общественият интерес налага това, без да са водени преговори с притежателя на права върху защитеното с патент изобретение.

(4) (Предишна ал. 3, изм. - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Принудителна лицензия може да се предостави в полза на притежател, чието изобретение е предмет на по-късен патент и влиза в обхвата на друг по-ранен патент, ако притежателят на по-ранния патент отказва да предостави лицензия при справедливи условия, когато изобретението - предмет на по-късния патент, представлява важен технически прогрес от съществено икономическо значение в сравнение с изобретението - предмет на по-ранния патент. Притежателят на по-ранния патент има право на кръстосана лицензия при разумни условия за използване на изобретението, претендирано в по-късния патент.

- (5) (Предишна ал. 4, - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Принудителната лицензия може да бъде само неизключителна. Тя може да бъде прехвърлена само заедно с предприятието, в което се използва изобретението - предмет на такава лицензия.
- (6) (Предишна ал. 5, - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Принудителната лицензия може да бъде прекратена, ако получателят в едногодишен срок от предоставянето ѝ не е пристъпил към подготовка за използване на изобретението. Във всички случаи принудителната лицензия се прекратява, ако в двегодишен срок от предоставянето ѝ получателят не е започнал да използва изобретението.
- (7) (Нова - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Обхватът на принудителната лицензия се определя от целта, за която тя е предоставена.
- (8) (Предишна ал. 6 - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Принудителна лицензия не се предоставя в полза на нарушител на патента.
- (9) (Предишна ал. 7 - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) В двустранни и многостранни договори, по които страна е Република България, могат да се предвидят и други условия за предоставяне на принудителна лицензия за патентоприетатели от държавите, участващи в такива договори.
- (10) (Нова - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Получателят на принудителна лицензия дължи на притежателя на патента възнаграждение.
- (11) (Нова - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Принудителната лицензия се прекратява, когато отпадне основанието за нея.
- (12) (Нова - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) Редът за предоставяне и прекратяване на принудителна лицензия се определя с наредбата по чл. 55, ал. 3.

Принудителна кръстосана лицензия

Чл. 32а. (Нов - ДВ, бр. 64 от 2006 г., в сила от 09.11.2006 г.) (1) Когато селекционер не може да придобие или да ползва право върху сорт растение, без да наруши по-ранен патент, той може да поиска принудителна лицензия за неизключително използване на изобретението, защитено с патента, доколкото лицензията е необходима за използването на сорта растение за целите на правната му закрила, при условие че за това бъде заплатено съответно възнаграждение.

Когато такава лицензия бъде предоставена, притежателят на патента има право да получи

кръстосана лицензия за използване на защитения сорт при справедливи условия.

(2) Когато притежател на патент за биотехнологично изобретение не може да го ползва, без да наруши по-ранно право върху сорт растение, той може да поиска принудителна лицензия за неизключително използване на защитения сорт растение, при условие че за това бъде заплатено съответно възнаграждение. Когато такава лицензия бъде предоставена, притежателят на защитения сорт има право да получи кръстосана лицензия за използване на изобретението при справедливи условия.

(3) Лицето, поискало издаване на принудителна лицензия по ал. 1 или 2, трябва да докаже, че:

1. е направило безуспешен опит да получи договорна лицензия от притежателя на патента или на сорта растение;
2. сортът растение или изобретението представляват значителен технически прогрес от съществен икономически интерес в сравнение с изобретението - предмет на патента, или защитения сорт растение.

BURKINA FASO

See Articles 46 to 56 of Annex I of *Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), February 24, 1999)*

BURUNDI

Law No. 1/13 of July 28, 2009, on Industrial Property in Burundi

Articles 78-102

Chapter VII: Compulsory and non-voluntary licenses

Section 1: Compulsory licenses for failure to work

Article 78: At the request of any interested person or the Public Prosecutor's Office, submitted after the expiration of a period of four years as from the date of filing of the patent application or three years as from the grant of the patent, it being necessary to apply the period which expires last, a compulsory or non-voluntary license may be granted if one or more of the following conditions has been met:

1. The public interest, in particular national security, nutrition, health or the development of other vital sectors of the national economy, so requires;
2. A judicial or administrative body has deemed that the way in which the patent holder or his licensee are exploiting the invention is abusive, anti-competitive or fails to meet reasonable conditions of demand for the protected product in sufficient quality and quantity;
3. The refusal of the patent holder to grant licenses on reasonable commercial conditions and terms;
4. The establishment or development of industrial or commercial activities suffers unfair or substantial damage.

Nevertheless, a compulsory license may not be granted if the patent holder gives legitimate grounds to justify his failure to work the invention.

Section 2: Compulsory licenses for dependent patents

Article 79: In the event that an invention protected by a patent cannot be used without infringing the rights attached to a prior patent whose holder refuses to authorize use on reasonable commercial conditions and procedures, the holder of the subsequent patent may obtain a non-voluntary license from the court for such use, on the same conditions as those which apply to the non-voluntary licenses granted under Article 78 as well as on the following additional conditions:

1. The invention claimed in the subsequent patent represents significant technical progress of considerable economic interest in relation to the invention claimed in the prior patent;
2. The holder of the prior patent is entitled to a reciprocal license on reasonable conditions to use the claimed invention;
3. The use authorized in relation to the prior patent shall be non-transferable unless the subsequent patent is assigned as well.

Section 3: Compulsory licenses granted by the Minister responsible for trade

Article 80: The Minister may decide that, even without the consent of the patent holder, a State service or a third party designated by him may exploit the invention.

Every request for compulsory licensing shall be examined by the Minister on its own merits. Exploitation of the invention shall be limited to the purposes for which the license was granted and shall be subject to the payment, to the patent holder, of appropriate compensation according

to the case at hand, in view of the economic value of the Minister's decision, as it is determined in said decision and, if the decision is taken on the basis of a court judgment, in view of the need to correct anti-competitive practices.

The Minister shall take his decision after hearing the patent holder and any interested persons, if they wish to be heard.

Article 81: Decisions relating to compensation for a compulsory license covering a patent claiming a pharmaceutical product or manufacturing process for a pharmaceutical product must take into consideration, as the case may be, the procedures and conditions set in the decision of the WTO General Council of August 30, 2003, if no other process for manufacturing the same product is known or available.

Article 82: The Minister may, at the patent holder's request and after hearing the parties, modify the terms of the decision authorizing the exploitation of the patented invention insofar as a change in circumstances warrants such modification.

Article 83: The Minister shall put an end to the compulsory license, at the patent holder's request, if he is convinced that the circumstances which led him to take his decision have ceased to obtain and shall not reoccur or that the State service or third party appointed by him has failed to respect the terms of the decision.

Article 84: The compulsory license may only be transferred with the firm or goodwill of this person or with the part of the firm or goodwill within which the patented invention is exploited.

Article 85: The compulsory license shall always be non-exclusive. As a result, it shall not prohibit: - exploitation of the invention by the patent holder himself, either by manufacturing in Burundi, by import, or by both means; - signature of licensing contracts by the patent holder; - continued exercise, by the patent holder, of the rights granted to him.

Article 86: A request for a compulsory license must be addressed to the Minister responsible for trade.

It must be accompanied by proof indicating that the patent holder has refused to grant the applicant a contractual license on reasonable conditions and procedures and within a reasonable time frame.

Save in exceptional circumstances, the maximum period shall be six months between the date on which the patent holder was informed of the request for a voluntary license and the date on which the applicant was informed by the patent holder of the final decision to reject the proposal.

Article 87: Evidence of an attempt to obtain a voluntary license, as defined by Article 86, shall not be required in case of a national emergency or in other situations of extreme urgency, in case of non-commercial public use or if the license is granted to remedy a practice that has been recognized as anti-competitive at the conclusion of judicial or administrative proceedings.

Notwithstanding, in such a case, the patent holder must be informed of the decision taken.

Article 88: Exploitation of the invention by the State service or the third party to which/whom the Minister has granted a license must be primarily aimed at supplying the market in Burundi, unless the compulsory license concerns a patent relating to a pharmaceutical product or a manufacturing process for a pharmaceutical product, provided that no other process for manufacturing same product is known or available and that the license is for the export of patented products or products manufactured by means of the patented process in a foreign

territory or country with non-existent or insufficient manufacturing capacities, in accordance with the procedures set by the decision of the WTO General Council dated August 30, 2003.

Article 89: Compulsory licenses for the exploitation of inventions in the field of semiconductor technology shall only be granted for non-commercial public use or if an administrative or judicial body has ruled that the way in which the patented invention is exploited by the patent holder or his licensee is anti-competitive.

Article 90: In the event that a compulsory license is granted under Article 80, the holder of the first patent shall be entitled to a reciprocal license, on terms to be determined in the regulations, to exploit the invention claimed in the second patent.

The license granted for the first patent may not be assigned unless the second patent is assigned.

Section 4: Grant of a compulsory license by the courts

Article 91: Requests for the grant of a compulsory license shall be filed with the commercial court of the patentee's domicile, or if the patentee is domiciled abroad, with the court of the place where domicile has been elected or an agent authorized for filing purposes.

The patent holder or his agent shall be notified of the request within eight days at the latest.

Article 92: The request must contain:

- the name and address of the applicant;
- the title of the patented invention and the patent number for which the compulsory license is sought;
- proof that the industrial exploitation of the patented invention does not meet reasonable conditions of demand for the protected product;
- proof that the applicant first wrote by registered letter to the patent holder asking him for a contractual license, but was not able to obtain such a license from him on commercial conditions and procedures within a reasonable time frame;
- proof that the applicant is capable of industrially exploiting the patented invention.

Article 93: The court hearing the matter shall examine whether the request for the grant of a compulsory license meets the conditions set out in this Chapter. After examining the case, the court shall take a decision to grant or refuse the non-voluntary license.

Article 94: In the event that the compulsory license is granted, the court's decision shall specify:

1. The field of application of the license, that is, the acts it covers and its period of validity, it being understood that a non-compulsory license does not cover the act of importing;
2. The fee due from the beneficiary of the license to the patent holder, in the absence of an agreement between the parties. This fee must be fair and may be subject to judicial review.

Article 95: The court shall notify the decision to the Industrial Property Director, the applicant and the patent holder. This same decision shall be brought to the attention of any beneficiary of a license whose name appears in the special patent register, by the Industrial Property Director. This decision shall be the subject of publication in the Official Journal of Burundi and on the Internet site of the Ministry responsible for trade.

Section 5: Appeals against decisions to grant a compulsory license

Article 96: The patent holder, the holder of a license whose name appears in the special patent register or any person who has requested the grant of a compulsory license may, within a period of one month, as from notification, lodge an appeal against the decision handed down by the first judge with the next higher legal instance.

Article 97: Appeals lodged against a decision to grant a compulsory license shall stay its execution. Decisions handed down on appeals shall be forwarded to the Industrial Property Director with a view to their publication.

Section 6: Rights and obligations of compulsory license holders

Article 98: Compulsory licenses shall authorize their holder to exploit a patented invention, in accordance with the conditions set by the court.

Article 99: The grant of a compulsory license shall not affect the licensing contracts or compulsory licenses in force and shall not preclude the signing of other licensing contracts or the grant of other non-voluntary licenses. Nevertheless, the patentee may not sign licensing agreements on more favorable terms than those of the compulsory licenses.

Section 7. Limitations on compulsory licenses

Article 100: The holder of the compulsory license may not, without the patent holder's consent, authorize a third party to perform the acts which fall within the field of application of his non-voluntary license. Notwithstanding the provisions of Article 84, a compulsory license may be transmitted with the license holder's establishment or with the part of this establishment which exploits the patented invention.

Section 8. Modification and withdrawal of the compulsory license

Article 101: At the request of the patent holder or compulsory license holder, the competent court may amend the decision to grant the compulsory license in the event that new facts so warrant.

Article 102: The court shall withdraw the compulsory license at the patent holder's request in one of the following cases:

1. the reasons for its granting have ceased to obtain;
2. the compulsory license holder has not respected the license's field of application;
3. the compulsory license holder is in arrears with the payment of the fee provided for in Article 94.

CABO VERDE

Industrial Property Code (approved by Decree-Law No. 4/2007 of August 20, 2007)

Articles 50 - 60

Article 50

Compulsory working

1. The patentee shall be required to work the patented invention, directly or through third parties and to commercialize the results obtained in order to satisfy the needs of the national market.
2. The working must commence within four years of the patent application, or within three years from the date of grant.

Article 51

Nondiscrimination

The enjoyment of patent rights shall not be subject to any form of discrimination, based on the place of the invention, technological field and the fact that the products are produced locally or

imported from any Member State of international organizations of which Cape Verde is a member.

Article 52

Expropriation for public interest

Any patent may be legally expropriated for public good, through payment of fair compensation, if the need to disclose the invention, or to make it available for use by public bodies, so demands.

Article 53

Compulsory licensing

1. Compulsory licenses relating to a specific patent shall be granted in any of the following cases:
 - (a) nonworking or insufficient working of the patented invention;
 - (b) interdependence of patents;
 - (c) existence of public interest grounds.
2. The scope and duration of such licenses shall be limited to the purposes for which they are granted and they shall be predominantly used to supply the domestic market.
3. Compulsory licenses shall not be exclusive and may only be transmitted with the part of the company or establishment that works them.
4. Compulsory licenses may only be granted if the interested claimant has made efforts to obtain a contractual license from the patent holder on acceptable commercial terms within a reasonable period.
5. Compulsory licenses may be revoked, without prejudice to the adequate protection of the legitimate interests of the respective owners, if and when the circumstances, which gave rise to them, cease to exist or are unlikely to be repeated.
6. If a patent has as its subject matter semiconductor technology, compulsory licenses may only be granted for non-commercial public interest purposes.
7. The owner of the licensed patent shall be entitled to fair and adequate compensation, taking into account the economic value of the license, with the right to appeal the decision which grants or refuses it, in accordance with the law.

Article 54

License issued for nonworking of the invention

1. When the deadlines referred to in paragraph 2 of Article 50 have elapsed, the patentee who, without due cause or legal basis, does not work an invention, directly or through a license, or does not do so in such a way as to meet domestic needs, may be obliged to grant the license to work the invention.
2. In addition, a patentee who ceases to work it for three consecutive years, without just cause or legal grounds, may be obliged to grant the working license for the invention.
3. Due cause shall be deemed to be objective difficulties of a technical or legal nature, independent of the will and situation of the patentee, that make it impossible to work or sufficiently work the invention.

Article 55

Non-obligation to grant a license

While a compulsory license remains in force, the patentee may not be compelled to grant another.

Article 56

Cancellation of the license

A compulsory license may be cancelled if the licensee does not work the license in such a way as to meet domestic needs.

Article 57

Dependent licenses

1. If it is not possible to work an invention protected by a patent without infringing the rights conferred by an earlier patent, and both the inventions are used for different industrial purposes, a license may be granted only if the essential nature of the first invention for the working of the second is proven and to the extent necessary therefor; the first patent owner shall have the right to fair compensation.
2. If inventions protected by dependent patents are used for the same industrial purposes and a compulsory license is granted in favor of the owner of the dependent patents, the owner of the earlier patent may also request the grant of a compulsory license against the later patent.
3. If the subject matter of an invention is a process for the preparation of a chemical, pharmaceutical or food product protected by a patent that is in force and if this process patent represents a considerable technical advance in relation to the earlier patent, both the owner of the process patent and the owner of the product patent shall have the right to request a compulsory license against the patent of the other owner.
4. If the person obtaining a plant variety is unable to obtain or exploit a plant variety right without violating a previous patent, he may request a compulsory license for the non exclusive exploitation of the invention protected by the patent, in so far as that license is necessary for the exploitation of the same plant variety, in exchange for the payment of adequate remuneration.
5. As long as a license of the type set out in the previous paragraph is granted, the patent owner shall have the right to a reciprocal license, under reasonable conditions, to use that protected variety.
6. If the owner of a patent, related to a biotechnology invention, is unable to exploit it without violating a previous plant variety right in a variety, he may request a compulsory license for the nonexclusive exploitation of the protected variety through that variety right, in exchange for the payment of adequate compensation.
7. As long as a license of the type set out in the previous paragraph is granted, the patentee shall have the right to a reciprocal license, under reasonable conditions, to use that protected variety.
8. The applicants for the licenses referred to in paragraphs 4 and 6 must prove that:
 - (a) they tried, in vain, to obtain a contractual license from the owner of the patent or the plant variety right;
 - (b) the plant variety, or invention, represents significant technical progress, of considerable economic interest, in relation to the invention claimed in the patent or the plant variety to be protected.
9. The provisions of this Article shall apply, equally, as long as one of the inventions is protected by a patent and the other by a utility model.

Article 58

Public interest

1. The patentee may be compelled to grant a license for the working of the respective invention for reasons of public interest.
2. Grounds for public interest shall be deemed to exist if at the start, the increase or the spread of working of the invention, or the improvement of the conditions in which such working takes place, are of paramount importance to public health or for national defense.
3. It shall be considered equally that there are public interest reasons when there is nonworking and insufficient quality or quantity of working which may cause serious harm to national economic or technological development.
4. The grant of the license on the grounds of public interest shall fall within the remit of the Government, through the Ministry responsible for that area of Industry.

Article 59

Applications for compulsory licenses

1. Compulsory licenses must be requested from the organization responsible for industrial property, and the applicant must submit the forms of proof which substantiate his application.

2. Requests for compulsory licenses shall be examined in the order in which they are received by the services.
3. On receipt of the request for a compulsory license, the organization responsible for industrial property shall notify the patentee that, within two months, he should state what he sees fit and submit the respective proof.
4. The organization responsible for industrial property shall evaluate the statements of the parties and the exploitation guarantees of the invention offered by the applicant for the compulsory license and shall decide, within two months, if this should be granted or not.
5. If the decision is positive, it shall notify both parties so that, within one month, both designated experts who, in conjunction with the expert designated by the organization responsible for industrial property, agree, within two months, the conditions of the compulsory license and the compensation to be paid to the patentee.

Article 60

Notification of and appeal against grant or refusal of the license

1. The grant or refusal of the license and the respective conditions of the working shall be notified to both parties.
2. The decision shall be subject to appeal to be lodged with the competent court, in accordance with the law.
3. A decision in favor of the grant must be recorded with the organization responsible for industrial property.
4. An extract from the register referred to in the preceding paragraph shall be published in the Industrial Property Gazette.

CAMBODIA

Law on Patents, Utility Models and Industrial Designs

Articles 47-64

SECTION 11 Exploitation by Government or Person thereby Authorized

Article 47.- The Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention where:

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- (ii) a judicial body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive.

The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Minister's authorization, as determined in the said authorization.

The Minister shall take his decision after hearing the owner of the patent and any interested person if they wish to be heard.

Article 48.- Upon request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

Article 49.- Upon request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances of items (i) and (ii) in the 1st paragraph of Article 47 of this Law which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

Notwithstanding the 1st paragraph of this Article, the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.

Article 50.- Where a third person has been designated by the Minister, the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

Article 51.- The authorization shall not exclude:

- (i) the conclusion of license contracts by the owner of the patent or the continued exercise, by the owner of the patent, of his rights under Article 42 of this Law; or
- (ii) the issuance of a non-voluntary license under Section 12 of Chapter 2 of this Law.

Article 52.- A request for the Minister's authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time. The 1st paragraph of this Article shall not apply in cases of:

- (i) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable;
- (ii) public non-commercial use; and
- (iii) anti-competitive practices determined as such by a judicial body in accordance with Article 47 of this Law.

Article 53.- The exploitation of the invention by the Government agency or third person designated by the Minister shall be predominantly for the supply of the market in the Kingdom of Cambodia.

Article 54.- The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized for public non-commercial use.

Where a judicial body has determined that the manner of exploitation of the patented invention in the field of semi-conductor by the owner of the patent or his licensee, is anti-competitive, the Minister may issue a non-voluntary license to remedy such practice.

Article 55.- The decisions of the Minister under Section 11 of Chapter 2 of this Law may be the subject of an appeal before the competent Court.

SECTION 12 Non-Voluntary Licenses

Article 56.- On the request, made to the Minister after the expiration of a period of four (4) years from the date of filing of the patent application or three (3) years from the date of the grant of the patent, whichever period expires last, the Minister may issue a non-voluntary license if he is satisfied that the patented invention is not exploited or is insufficiently exploited in the Kingdom of Cambodia.

Notwithstanding the 1st paragraph of this Article, a non-voluntary license shall not be issued if the owner of the patent satisfies the Minister that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention.

Article 57.- The decision issuing the non-voluntary license shall fix:

- (i) the scope and the function of the license;
- (ii) the time limit within which the licensee must begin to exploit the patented invention; and
- (iii) the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

Article 58.- The beneficiary of the non-voluntary license shall have the right to exploit the patented invention in the Kingdom of Cambodia according to the terms set out in the decision issuing the license, shall commence the exploitation of the patented invention within the time limit fixed in the said decision and, thereafter, shall exploit the patented invention sufficiently.

Article 59.- Where the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Minister, upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.

Article 60.- Where a non-voluntary license is issued under Article 59 of this Law, the Minister, upon the request of the owner of the earlier patent, shall issue a non-voluntary license in respect of the later patent.

Article 61.- In the case of a request for the issuance of non-voluntary license under Articles 59 and 60, Article 57 of this Law shall apply *mutatis mutandis* with the proviso that no time limit needs to be fixed.

Article 62.- In the case of a non-voluntary license issued under Article 59 of this Law, the transfer may be made only with the later patent, or, in the case of a non-voluntary license issued under Article 60 of this Law, only with the earlier patent.

Article 63.- The request for the issuance of a non-voluntary license shall be subject to payment of the prescribed fee, as referred to in Article 130 of this Law.

Article 64.- The 2nd paragraph of Article 47 to Article 55 of this Law shall apply *mutatis mutandis* for Section 12 of Chapter 2 of this Law.

CANADA

Patent Act (R.S.C., 1985, c. P-4) (as amended up to December 13, 2018)

Sections 19, 21 and 65

Government may apply to use patented invention

19 (1) Subject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government.

Terms of use

(2) Subject to section 19.1, the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner considers expedient but the Commissioner shall settle those terms in accordance with the following principles:

(a) the scope and duration of the use shall be limited to the purpose for which the use is authorized;

- (b) the use authorized shall be non-exclusive; and
- (c) any use shall be authorized predominantly to supply the domestic market.

Notice

(3) The Commissioner shall notify the patentee of any use of the patented invention that is authorized under this section.

Payment of remuneration

(4) Where the use of the patented invention is authorized, the authorized user shall pay to the patentee such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization.

Termination of authorization

(5) The Commissioner may, on application by the patentee and after giving all concerned parties an opportunity to be heard, terminate the authorization if the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user.

Authorization not transferable

(6) An authorization granted under this section is not transferable.

Conditions for authorizing use

19.1 (1) The Commissioner may not authorize the use of a patented invention under section 19 unless the applicant establishes that

- (a) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and
- (b) its efforts have not been successful within a reasonable period.

Exception

(2) Subsection (1) does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

Prescribed uses

(3) The Commissioner may not, under section 19, authorize any use that is a prescribed use unless the proposed user complies with the prescribed conditions.

Limitation on use of semi-conductor technology

(4) The Commissioner may not, under section 19, authorize any use of semi-conductor technology other than a public non-commercial use.

Appeal

19.2 Any decision made by the Commissioner under section 19 or 19.1 is subject to appeal to the Federal Court.

Regulations

19.3 (1) The Governor in Council may make regulations for the purpose of implementing, in relation to patents, Article 1720 of the Agreement.

Definition of Agreement

(2) In subsection (1), Agreement has the same meaning as in subsection 2(1) of the North American Free Trade Agreement Implementation Act.

Use of Patents for International Humanitarian Purposes to Address Public Health Problems

Purpose

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Definitions

21.02 The definitions in this section apply in this section and in sections 21.03 to 21.19.

authorization means an authorization granted under subsection 21.04(1), and includes an authorization renewed under subsection 21.12(1). (autorisation)

General Council means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994. (Conseil général)

General Council Decision means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson's statement of that date. (décision du Conseil général)

patented product means a product the making, constructing, using or selling of which in Canada would infringe a patent in the absence of the consent of the patentee. (produit breveté)

pharmaceutical product means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product. (produit pharmaceutique)

TRIPS Agreement means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994. (Accord sur les ADPIC)

TRIPS Council means the council referred to in the TRIPS Agreement. (Conseil des ADPIC)

WTO means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994. (OMC)

Amending Schedules

21.03 (1) The Governor in Council may, by order,

(a) on the recommendation of the Minister and the Minister of Health, amend Schedule 1
(i) by adding the name of any patented product that may be used to address public health problems

afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration, and

(ii) by removing any entry listed in it;

(b) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country that has,

(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the

country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, and

(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through

diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;

(c) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision; and

(d) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend Schedule 4 by adding the name of **(i)** any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice

in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, or

(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance

and that has provided the Government of Canada with a notice in writing through diplomatic channels

(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,

(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency, **(C)** stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and

(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.

Restriction - Schedule 3

(2) The Governor in Council may not add to Schedule 3 the name of any WTO Member that has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency.

Removal from Schedules 2 to 4

(3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend any of Schedules 2 to 4 to remove the name of any country or WTO Member if

(a) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a leastdeveloped country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;

(b) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;

(c) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as

defined in paragraph 1(a) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;

- (d) in the case of a country listed in Schedule 4 that is not a WTO Member,
- (i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance,
- (ii) the country no longer faces a national emergency or other circumstances of extreme urgency,
- (iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or
- (iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;
- (e) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least developed country; and
- (f) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision.

Timeliness of orders

(4) An order under this section shall be made in a timely manner.

Authorization

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

Contents of application

(2) The application must be in the prescribed form and set out

- (a) the name of the pharmaceutical product to be manufactured and sold for export under the authorization;
- (b) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;
- (c) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;
- (d) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention;
- (e) the name of the country or WTO Member to which the pharmaceutical product is to be exported;
- (f) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and
- (g) any other information that may be prescribed.

Conditions for granting of authorization

(3) The Commissioner shall authorize the use of the patented invention only if

- (a) the applicant has complied with the prescribed requirements, if any;
- (b) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the Food and Drugs Act and its regulations, including the requirements under those regulations relating to the marking,

embossing, labelling and packaging that identify that version of the product as having been manufactured

(i) in Canada as permitted by the General Council Decision, and

(ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be;

(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,

(i) sought from the patentee or, if there is more than one, from each of the patentees, by certified or

registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and

(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(a) to (g); and

(d) the applicant also provides the Commissioner with

(i) if the application relates to a WTO Member listed in Schedule 2, a certified copy of the notice in

writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that WTO Member, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(ii) if the application relates to a country listed in Schedule 2 that is not a WTO Member, a certified

copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that country, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iii) if the application relates to a WTO Member listed in Schedule 3, a certified copy of the notice in

writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iv) if the application relates to a WTO Member listed in Schedule 4, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member is faced with a national emergency or other circumstances of extreme urgency and that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product, or

(v) if the application relates to a country listed in Schedule 4 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and stating that it is faced with a national emergency or other circumstances of extreme urgency, that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, that it agrees that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that country, or

(B) a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product.

Form and content of authorization

21.05 (1) The authorization must be in the prescribed form and, subject to subsection (2), contain the prescribed information.

Quantity

(2) The quantity of the product authorized to be manufactured by an authorization may not be more than the lesser of

- (a)** the maximum quantity set out in the application for the authorization, and
- (b)** the quantity set out in the notice referred to in any of subparagraphs 21.04(3)(d)(i) to (v), whichever is applicable. Disclosure of information on website

21.06 (1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the country or WTO Member to which it is to be exported, the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, as required by regulations made under the Food and Drugs Act, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported.

Obligation to maintain

(2) The holder must maintain the website during the entire period during which the authorization is valid.

Links to other websites

(3) The Commissioner shall post and maintain on the website of the Canadian Intellectual Property Office a link to each website required to be maintained by the holder of an authorization under subsection (1).

Posting on the website

(4) The Commissioner shall, within seven days of receipt, post on the website of the Canadian Intellectual Property Office each application for authorization filed under subsection 21.04(1).

Export notice

21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported:

- (a) the patentee or each of the patentees, as the case may be;
- (b) the country or WTO Member named in the authorization; and
- (c) the person or entity that purchased the product to which the authorization relates.

Royalty

21.08 (1) Subject to subsections (3) and (4), on the occurrence of a prescribed event, the holder of an authorization is required to pay to the patentee or each patentee, as the case may be, a royalty determined in the prescribed manner.

Factors to consider when making regulations

(2) In making regulations for the purposes of subsection (1), the Governor in Council must consider the humanitarian and non-commercial reasons underlying the issuance of authorizations under subsection 21.04(1).

Time for payment

(3) The royalties payable under this section must be paid within the prescribed time.

Federal Court may determine royalty

(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the royalty that would otherwise be required to be paid under subsection (1).

Application and notice

(5) An order may be made only on the application of the patentee, or one of the patentees, as the case may be, and on notice of the application being given by the applicant to the holder of the authorization.

Contents of order

(6) An order may provide for a royalty of a fixed amount or for a royalty to be determined as specified in the order, and the order may be subject to any terms that the Federal Court considers appropriate.

Conditions for making of order

(7) The Federal Court may make an order only if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration for the use of the invention or inventions to which the authorization relates, taking into account

- (a) the humanitarian and non-commercial reasons underlying the issuance of the authorization; and
- (b) the economic value of the use of the invention or inventions to the country or WTO Member.

Duration

21.09 An authorization granted under subsection 21.04(1) is valid for a period of two years beginning on the day on which the authorization is granted.

Use is non-exclusive

21.1 The use of a patented invention under an authorization is non-exclusive.

Authorization is non-transferable

21.11 An authorization is non-transferable, other than where the authorization is an asset of a corporation or enterprise and the part of the corporation or enterprise that enjoys the use of the authorization is sold, assigned or otherwise transferred.

Renewal

21.12 (1) The Commissioner shall, on the application of the person to whom an authorization was granted and on the payment of the prescribed fee, renew the authorization if the person certifies under oath in the renewal application that the quantities of the pharmaceutical product authorized to be exported were not exported before the authorization ceases to be valid and that the person has complied with the terms of the authorization and the requirements of sections 21.06 to 21.08.

One renewal

(2) An authorization may be renewed only once.

When application must be made

(3) The application for renewal must be made within the 30 days immediately before the authorization ceases to be valid.

Duration

(4) An authorization that is renewed is valid for a period of two years beginning on the day immediately following the day of the expiry of the period referred to in section 21.09 in respect of the authorization.

Prescribed form

(5) Applications for renewal and renewed authorizations issued under subsection (1) must be in the prescribed form.

Termination

21.13 Subject to section 21.14, an authorization ceases to be valid on the earliest of

- (a) the expiry of the period referred to in section 21.09 in respect of the authorization, or the expiry of the period referred to in subsection 21.12(4) if the authorization has been renewed, as the case may be,
- (b) the day on which the Commissioner sends, by registered mail, to the holder of the authorization a copy of a notice sent by the Minister of Health notifying the Commissioner that the Minister of Health is of the opinion that the pharmaceutical product referred to in paragraph 21.04(3)(b) has ceased to meet the requirements of the Food and Drugs Act and its regulations,

- (c) the day on which the last of the pharmaceutical product authorized by the authorization to be exported is actually exported,
- (d) thirty days after the day on which
- (i) the name of the pharmaceutical product authorized to be exported by the authorization is removed from Schedule 1, or
- (ii) the name of the country or WTO Member to which the pharmaceutical product was, or is to be, exported is removed from Schedule 2, 3 or 4, as the case may be, and not added to any other of those Schedules, and
- (e) on any other day that is prescribed.

Termination by Federal Court

21.14 On the application of a patentee, and on notice given by the patentee to the person to whom an authorization was granted, the Federal Court may make an order, on any terms that it considers appropriate, terminating the authorization if the patentee establishes that

- (a) the application for the authorization or any of the documents provided to the Commissioner in relation to the application contained any material information that is inaccurate;
- (b) the holder of the authorization has failed to establish a website as required by section 21.06, has failed to disclose on that website the information required to be disclosed by that section or has failed to maintain the website as required by that section;
- (c) the holder of the authorization has failed to provide a notice required to be given under section 21.07;
- (d) the holder of the authorization has failed to pay, within the required time, any royalty required to be paid as a result of the authorization;
- (e) the holder of the authorization has failed to comply with subsection 21.16(2);
- (f) the product exported to the country or WTO Member, as the case may be, under the authorization has been, with the knowledge of the holder of the authorization, re-exported in a manner that is contrary to the General Council Decision;
- (g) the product was exported, other than in the normal course of transit, to a country or WTO Member other than the country or WTO Member named in the authorization;
- (h) the product was exported in a quantity greater than the quantity authorized to be manufactured; or
- (i) if the product was exported to a country that is not a WTO Member, the country has permitted the product to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision.

Notice to patentee

21.15 The Commissioner shall, without delay, notify the patentee, or each of the patentees, as the case may be, in writing of any authorization granted in respect of the patentee's invention.

Obligation to provide copy of agreement

21.16 (1) Within fifteen days after the later of the day on which the authorization was granted and the day on which the agreement for the sale of the product to which the authorization relates was entered into, the holder of an authorization must provide by certified or registered mail, the Commissioner and the patentee, or each patentee, as the case may be, with

- (a) a copy of the agreement it has reached with the person or entity referred to in paragraph 21.04(2)(f) for the supply of the product authorized to be manufactured and sold, which agreement must incorporate information that is in all material respects identical to the information referred to in paragraphs 21.04(2)(a), (b), (e) and (f); and
- (b) a solemn or statutory declaration in the prescribed form setting out
- (i) the total monetary value of the agreement as it relates to the product authorized to be manufactured and sold, expressed in Canadian currency, and
- (ii) the number of units of the product to be sold under the terms of the agreement.

Prohibition

(2) The holder of an authorization may not export any product to which the authorization relates until after the holder has complied with subsection (1).

Application when agreement is commercial in nature

21.17 (1) If the average price of the product to be manufactured under an authorization is equal to or greater than 25 per cent of the average price in Canada of the equivalent product sold by or with the consent of the patentee, the patentee may, on notice given by the patentee to the person to whom an authorization was granted, apply to the Federal Court for an order under subsection (3) on the grounds that the essence of the agreement under which the product is to be sold is commercial in nature.

Factors for determining whether agreement is commercial in nature

(2) In determining whether the agreement is commercial in nature, the Federal Court must take into account

- (a) the need for the holder of the authorization to make a reasonable return sufficient to sustain a continued participation in humanitarian initiatives;
- (b) the ordinary levels of profitability, in Canada, of commercial agreements involving pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision; and
- (c) international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes.

Order

(3) If the Federal Court determines that the agreement is commercial in nature, it may make an order, on any terms that it considers appropriate,

- (a) terminating the authorization; or
- (b) requiring the holder to pay, in addition to the royalty otherwise required to be paid, an amount that the Federal Court considers adequate to compensate the patentee for the commercial use of the patent.

Additional order

(4) If the Federal Court makes an order terminating the authorization, the Federal Court may also, if it considers it appropriate to do so, make an order, on any terms that it considers appropriate,

- (a) requiring the holder to deliver to the patentee any of the product to which the authorization relates remaining in the holder's possession as though the holder had been determined to have been infringing a patent; or
- (b) with the consent of the patentee, requiring the holder to export any of the product to which the authorization relates remaining in the holder's possession to the country or WTO Member named in the authorization.

Restriction

(5) The Federal Court may not make an order under subsection (3) if, under the protection of a confidentiality order made by the Court, the holder of the authorization submits to a Court-supervised audit and that audit establishes that the average price of the product manufactured under the authorization does not exceed an amount equal to the direct supply cost of the product plus 15 per cent of that direct supply cost.

Definitions

(6) The following definitions apply in this section.

average price means

(a) in relation to a product to be manufactured under an authorization, the total monetary value of the agreement under which the product is to be sold, expressed in Canadian currency, divided by the number of units of the product to be sold under the terms of the agreement; and

(b) in relation to an equivalent product sold by or with the consent of the patentee, the average of the prices in Canada of that product as those prices are reported in prescribed publications on the day on which the application for the authorization was filed. (prix moyen)

direct supply cost, in relation to a product to be manufactured under an authorization, means the cost of the materials and of the labour, and any other manufacturing costs, directly related to the production of the quantity of the product that is to be manufactured under the authorization. (coût direct de fourniture)

unit, in relation to any product, means a single tablet, capsule or other individual dosage form of the product, and if applicable, in a particular strength. (unité)

Advisory committee

21.18 (1) The Minister and the Minister of Health shall establish, within three years after the day this section comes into force, an advisory committee to advise them on the recommendations that they may make to the Governor in Council respecting the amendment of Schedule 1.

Standing committee

(2) The standing committee of each House of Parliament that normally considers matters related to industry shall assess all candidates for appointment to the advisory committee and make recommendations to the Minister and the Minister of Health on the eligibility and qualifications of those candidates.

Website for notices to Canada

21.19 The person designated by the Governor in Council for the purpose of this section must maintain a website on which is set out a copy of every notice referred to in subparagraphs 21.04(3)(d)(ii) and (v) that is provided to the Government of Canada through diplomatic channels by a country that is not a WTO Member. The copy must be added to the website as soon as possible after the notice has been provided to the Government of Canada.

Review

21.2 (1) A review of sections 21.01 to 21.19 and their application must be completed by the Minister two years after this section comes into force.

Tabling of report

(2) The Minister must cause a report of the results of the review to be laid before each House of Parliament on any of the first fifteen days on which that House is sitting after the report has been completed.

Abuse of rights under patents:

65. (1) The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.

What amounts to abuse

(2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

(a) and (b) [Repealed, 1993, c. 44, s. 196]

(c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;

(d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;

(e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or

(f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

(3) and (4) [Repealed, 1993, c. 44, s. 196]

[...]

Definition of “patented article”:

(5) For the purposes of this section, the expression “patented article” includes articles made by a patented process.

CHILE

Law No. 19.039 on Industrial Property (Consolidated Text of February 6, 2012, approved by Decree-Law No. 3)

Article 51

Artículo 51.- Procederá pronunciarse respecto de una solicitud de licencia no voluntaria en los siguientes casos:

1) Cuando el titular de la patente haya incurrido en conductas o prácticas declaradas contrarias a la libre competencia, en relación directa con la utilización o explotación de la patente de que se trate, según decisión firme o ejecutoriada del Tribunal de Defensa de la Libre Competencia.

2) Cuando por razones de salud pública, seguridad nacional, uso público no comercial, o de emergencia nacional u otras de extrema urgencia, declaradas por la autoridad competente, se justifique el otorgamiento de dichas licencias.

3) Cuando la licencia no voluntaria tenga por objeto la explotación de una patente posterior que no pudiera ser explotada sin infringir una patente anterior. La concesión de licencias no voluntarias por patentes dependientes quedará sometida a las siguientes normas:

a) La invención reivindicada en la patente posterior debe comprender un avance técnico de significación económica considerable respecto a la invención reivindicada en la primera patente.

b) La licencia no voluntaria para explotar la patente anterior sólo podrá transferirse con la patente posterior.

c) El titular de la patente anterior podrá, en las mismas circunstancias, obtener una licencia no voluntaria en condiciones razonables para explotar la invención reivindicada en la patente posterior.

Tratándose de tecnología de semiconductores, la licencia sólo se podrá otorgar para fines públicos no comerciales o para rectificar la práctica declarada contraria a la competencia.

CHINA

Patent Law of the People's Republic of China (as amended up to the Decision of December 27, 2008, regarding the Revision of the Patent Law of the People's Republic of China)

Articles 48-54

Chapter VI Compulsory License for Exploitation of a Patent

Article 48 Under any of the following circumstances, the patent administration department under the State Council may, upon application made by any unit or individual that possesses the conditions for exploitation, grant a compulsory license for exploitation of an invention patent or utility model patent:

- (1) When it has been three years since the date the patent right is granted and four years since the date the patent application is submitted, the patentee, without legitimate reasons, fails to have the patent exploited or fully exploited; or
- (2) The patentee's exercise of the patent right is in accordance with law, confirmed as monopoly and its negative impact on competition needs to be eliminated or reduced.

Article 49 Where a national emergency or any extraordinary state of affairs occurs, or public interests so require, the patent administration department under the State Council may grant a compulsory license for exploitation of an invention patent or utility model patent.

Article 50 For the benefit of public health, the patent administration department under the State Council may grant a compulsory license for manufacture of the drug, for which a patent right has been obtained, and for its export to the countries or regions that conform to the provisions of the relevant international treaties to which the People's Republic of China has acceded.

Article 51 If an invention or utility model, for which the patent right has been obtained, represents a major technological advancement of remarkable economic significance, compared with an earlier invention or utility model for which the patent right has already been obtained, and exploitation of the former relies on exploitation of the latter, the patent administration department under the State Council may, upon application made by the latter, grant it a compulsory license to exploit the earlier invention or utility model.

Under the circumstance where a compulsory license for exploitation is granted in accordance with the provisions of the preceding paragraph, the patent administration department under the State Council may, upon application made by the earlier patentee, grant it a compulsory license to exploit the later invention or utility model.

Article 52 If an invention involved in a compulsory license is a semi-conductor technology, the exploitation thereof shall be limited to the purpose of public interests and to the circumstances as provided for in Subparagraph (2) of Article 48 of this Law.

Article 53 Except for the compulsory license granted in accordance with the provisions of Subparagraph (2) of Article 48 or Article 50 of this Law, compulsory license shall mainly be exercised for the supply to the domestic market.

Article 54 A unit or individual that applies for a compulsory license in accordance with the provisions of Subparagraph (1) of Article 48 or Article 51 of this Law shall provide evidence to show that it or he has, under reasonable terms, requests the patentee's permission for exploitation of the patent, but fails to obtain such permission within a reasonable period of time.

Article 55 The decision made by the patent administration department under the State Council on granting of a compulsory license for exploitation shall be notified to the patentee in a timely manner and shall be registered and announced. In a decision on granting of the compulsory license for exploitation shall, according to the reasons justifying the compulsory license, be specified the scope and duration for exploitation. When such reasons cease to exist and are unlikely to recur, the patent administration department under the State Council shall, upon request by the patentee, make a decision to terminate the compulsory license after examination.

Article 56 Any unit or individual that is granted a compulsory license for exploitation shall not have an exclusive right to exploitation and shall not have the right to allow exploitation by others.

Article 57 The unit or individual that is granted a compulsory license for exploitation shall pay reasonable royalties to the patentee, or handle the issue of royalties in accordance with the provisions of the relevant international treaties to which the People's Republic of China has acceded.

The amount of royalties to be paid shall be subject to consultation between the two parties. In the event of failure to reach an agreement between the two parties, the patent administration department under the State Council shall make a ruling.

Article 58 If a patentee is dissatisfied with the decision made by the patent administration department under the State Council -on granting of the compulsory license for exploitation, or if the patentee, or the unit or individual that has obtained the compulsory license for exploitation is dissatisfied with the ruling made by the patent administration department under the State Council regarding the royalties for the compulsorily licensed exploitation, it or he may take legal action before the people's court within three months from the date of receipt of the notification of the ruling.

HONG KONG, CHINA

Patents Ordinance (Chapter 514)

Sections 64 - 72

Part: VIII - COMPULSORY LICENCES FOR STANDARD PATENTS

Section: 64 Compulsory licences for standard patents

(1) At any time after the expiration of 3 years from the date of grant of a standard patent any person may apply to the court on one or more of the grounds specified in subsection (2)-

(a) for a licence under the patent;

(b) where the applicant is the Government, for the grant of a licence under the patent to any person specified in the application.

(2) The grounds referred to in subsection (1) are-

(a) where the patented invention is capable of being commercially worked in Hong Kong, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;

(b) where the patented invention is a product, that a demand for the product in Hong Kong is not being met on reasonable terms;

(c) where the patented invention is capable of being commercially worked in Hong Kong by manufacture, that it is being prevented or hindered from being so worked-

(i) in the case of a product, by the importation of the product; or

(ii) in the case of a process, by the importation of a product obtained directly by means of the process or to which the process has been applied;

(d) that by reason of the refusal by the proprietor of the patent to grant a licence or licences on reasonable terms-

(i) the working or efficient working in Hong Kong of any other patented invention which involves an important technical advance of considerable economic significance in relation to the patent is prevented or hindered; or

(ii) the establishment or development of commercial or industrial activities in Hong Kong is unfairly prejudiced; or

(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent or the establishment or development of commercial or industrial activities in Hong Kong, is unfairly prejudiced.

(3) The court may, if it is satisfied that any of those grounds are established, and subject to subsections (4) and (5), order the grant of a licence on such terms as it thinks fit-

(a) to the applicant, where the application is made under subsection (1)(a); or

(b) to the person specified in the application, where the application is made under subsection (1)(b).

(4) Where the application is made on the ground that the patented invention is not being commercially worked in Hong Kong or is not being so worked to the fullest extent that is reasonably practicable, and it appears to the court that the time which has elapsed since the grant of the patent was advertised in the official journal has for any reason been insufficient to enable the invention to be so worked, the court may adjourn the hearing for such period as will in the opinion of the court give sufficient time for the invention to be so worked. (Amended 2 of 2001 s. 14)

(5) No order shall be made under this section unless the court is satisfied that the applicant has made reasonable efforts to obtain authorization from the proprietor on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

(6) No order shall be made under this section in respect of a patent ("patent A") on the ground mentioned in subsection (2)(d)(i) unless the court is satisfied that the proprietor of the patent for the other invention ("patent B") is able and willing to grant to the proprietor of patent A and his licensees a licence under patent B on reasonable terms.

(7) An order granting a licence under this section shall provide-

(a) that the licence shall be non-exclusive; and

(b) that such licence shall be non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence, and in the case of a licence granted under subsection (6) the licence in respect of patent A shall only be assignable with the assignment of patent B, (Amended 2 of 2001 s. 7) and shall specify the scope and duration of such licence.

(8) An application may be made under this section in respect of a patent notwithstanding that the applicant is already the holder of a licence under the patent; and no person shall be stopped from relying on any of the matters specified in subsection (2) because of any admission made by him, whether in such licence or otherwise or by reason of his having accepted such licence.
[cf. 1977 c. 37 s. 48 U.K.]

Section: 65 Provisions about licences under section 64

(1) Where the court is satisfied, on an application made under section 64 in respect of a patent, that the manufacture, use or disposal of materials not protected by the patent is unfairly prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or the use of the patented process, the court may (subject to the provisions of that section) order the grant of licences under the patent to such customers of the applicant as it thinks fit as well as to the applicant.

(2) Where an application under section 64 is made in respect of a patent by a person who holds a licence under the patent, the court may-

- (a) if it orders the grant of a licence to the applicant, order the existing licence to be cancelled; or
- (b) instead of ordering the grant of a licence to the applicant, order the existing licence to be amended. [cf. 1977 c. 37 s. 49 U.K.]

Section: 66 Exercise of powers on applications under section 64

(1) The powers of the court on an application under section 64 in respect of a patent shall be exercised with a view to securing the following purposes-

- (a) that inventions which can be worked on a commercial scale in Hong Kong and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;
- (b) that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention;
- (c) that the interests of any person for the time being working or developing an invention in Hong Kong under the protection of a patent shall not be unfairly prejudiced.

(2) Subject to subsection (1), the court shall, in determining whether to make an order in pursuance of such an application, take account of the following matters-

- (a) the nature of the invention, the time which has elapsed since the grant of the patent was advertised in the official journal and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention; (Amended 2 of 2001 s. 14)
- (b) the ability of any person to whom a licence would be granted by the court to work the invention to the public advantage;
- (c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted, but the court shall not be required to take account of any such matter occurring subsequent to the making of the application.

(3) Any person aggrieved by an order made under section 64 or 65 may apply to the court for an order for the variation or cancellation of the licence if the court in all the circumstances should think fit.

[cf. 1977 c. 37 s. 50 U.K.]

Section: 67 Opposition to application under sections 64 to 66

The proprietor of the patent concerned or any other person wishing to oppose an application under sections 64 to 66 may, in accordance with rules of court, give to the court notice of opposition; and the court shall consider the opposition in deciding whether to grant the application.

[cf. 1977 c. 37 s. 52 U.K.]

Part: IX GOVERNMENT USE OF PATENTED INVENTIONS

Section: 68 Declaration of extreme urgency

The Chief Executive in Council may, for the purposes of applying sections 69 to 71, by regulation declare a period of extreme urgency whenever Chief Executive in Council considers it to be necessary or expedient in the public interest for the maintenance of supplies and services essential to the life of the community or for securing sufficient supplies and services essential to the life of the community.

Section: 69 Government use of patents during a period of extreme urgency

(1) During a period of declared extreme urgency a public officer authorized in writing by the Chief Executive or any person authorized in writing by such public officer may in relation to- (Amended 22 of 1999 s. 3)

(a) a patented invention, without the consent of the proprietor of the patent; or
(b) an invention in respect of which an application for a patent has been filed, without the consent of the applicant, do any act in Hong Kong in relation to the invention as appears to the public officer or person authorized to be necessary or expedient in connection with the urgency giving rise to the declaration under section 68.

(2) Any act done in relation to an invention by virtue of this section is in the following provisions of this section referred to as use, or Government use, of the invention; and “use” (徵用), in relation to an invention, in section 70 to 72 shall be construed accordingly.

(3) Government use may include any act which would, apart from this section, amount to an infringement of the patent concerned or, as the case may be, give rise to a right under section 88 to bring proceedings in respect of the application for a standard patent.

(4) Any Government use of the invention made at any time either-

(a) after the publication of an application for a standard patent or the grant of a short-term patent for the invention; or

(b) without prejudice to paragraph (a), in consequence of a relevant communication made otherwise than in confidence-

(i) after the deemed date of filing of the application for the standard patent for the invention or the date of filing of the application of the short-term patent for the invention, as the case may be; or

(ii) where priority was claimed, after the date of priority, shall be made on such terms as may be agreed, either before or after the use, by the Government and the proprietor of the patent or as may in default of agreement be determined by the court on a reference under section 72.

(5) Where an invention is used by virtue of this section at any time after publication of an application for a standard patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) include terms as to payment for the use, then (notwithstanding anything in those terms) any such payment shall be recoverable only-

(a) after such a patent is granted; and

(b) if (apart from this section) the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application as published.

(6) The authority of a public officer in respect of an invention may be given under this section either before or after the patent is granted, and may be given to any person whether or not he is authorized directly or indirectly by the proprietor of the patent to do anything in relation to the invention.

(7) Where any Government use of an invention is made by or with the authority of a public officer under this section, then the public officer shall notify the proprietor of the patent as soon as practicable, and furnish him with such information as to the extent of the use as he may from time to time require.

(8) A person acquiring anything disposed of in the exercise of powers conferred by this section, and any person claiming through him, may deal with it in the same manner as if the patent were held on behalf of the Government.

(9) Any reference in this section to a patented invention, in relation to any time, is a reference to an invention to which a patent has before that time been, or is subsequently, granted.

(10) In this section “relevant communication” (有關通訊), in relation to an invention, means a communication of the invention directly or indirectly by the proprietor of the patent or any person from whom he derives title.

(11) Subsection (4) is without prejudice to any rule of law relating to the confidentiality of information. [cf. 1977 c. 37 ss. 55 & 56 U.K.]

Section: 70 Rights of third parties in respect of Government use

(1) The provisions of any licence, assignment or agreement specified in subsection (3) are of no effect in relation to-

(a) any Government use of an invention by a public officer, or a person authorized by a public officer, by virtue of section 69; or

(b) anything done for Government use to the order of a public officer by the proprietor of a patent in respect of a patented invention or by the proprietor of an application in respect of an invention for which an application for a patent has been filed and is still pending, so far as those provisions-

(i) restrict or regulate the working of the invention, or the use of any model, document or information

relating to it; or

(ii) provide for the making of payments in respect of, or calculated by reference to, such working or use.

(2) The reproduction or publication of any model or document in connection with a working or use referred to in subsection (1) shall not be deemed to be an infringement of any copyright or protected layout-design (topography) subsisting in the model or document.

(3) The licence, assignment or agreement referred to in subsection (1) is any licence, assignment or agreement which is made, whether before or after the date of commencement of this Ordinance, between any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title (on the one hand), and any person whatever other than the Government (on the other hand).

(4) Where an exclusive licence granted otherwise than for royalties or other benefits determined by reference to the working of the invention is in force under the patent or application concerned, then-

(a) section 69(4) applies in relation to anything done in respect of the invention which, but for this section and section 69(1), would be an infringement of the rights of the licensee, with the substitution in those provisions of reference to the proprietor of the patent with reference to the licensee; and

(b) section 69(4) does not apply in relation to anything done in respect of the invention by the licensee by virtue of an authority given under section 69(1).

(5) Subject to subsection (4), where the patent, or the right to the grant of the patent, has been assigned to the proprietor of the patent or application in consideration of royalties or other benefits determined by reference to the working of the invention, then-

(a) section 69(4) applies in relation to any Government use of the invention as if reference to the proprietor of the patent included a reference to the assignor, and any sum payable for Government use under that subsection shall be divided between those persons in such proportion as may be agreed on by them or as may in default of agreement be determined by the court on a reference under section 72; and

(b) section 69(4) applies in relation to any act done in respect of the invention for Government use by the proprietor of the patent or application to the order of a public officer, as if that act were use made by virtue of an authority given under that section.

(6) Where section 69(4) applies to any use of an invention and a person holds an exclusive licence under the patent or application concerned (other than such a licence as is mentioned in subsection (4)) authorizing him to work the invention, then subsections (8) and (9) shall apply.

(7) In subsections (8) and (9) "the section 69(4) payment" (第 69(4)條付款) means such payment (if any) as the proprietor of the patent or application and the Government agree under section 69, or the court determines under section 72, should be made by the public officer concerned to the proprietor in respect of the use of the invention.

(8) The licensee shall be entitled to recover from the proprietor of the patent or application such part (if any) of the section 69(4) payment as may be agreed on by them or as may in default of agreement be determined by the court under section 72 to be just having regard to any expenditure incurred by the licensee-

(a) in developing the invention; or

(b) in making payments to the proprietor in consideration of the licence, other than royalties or other payments determined by reference to the use of the invention.

(9) Any agreement by the proprietor of the patent or application and the Government under section 69(4) as to the amount of the section 69(4) payment shall be of no effect unless the licensee consents to the agreement; and any determination by the court under section 69(4) as to the amount of that payment shall be of no effect unless the licensee has been informed of the reference to the court and is given an opportunity to be heard.

(10) In this section "the public officer concerned" (有關公職人員), in relation to any Government use of an invention, means the public officer by whom or on whose authority the use was made. [cf. 1977 c. 37 s. 57 U.K.]

Section: 71 **Compensation for loss of profit**

(1) Where Government use is made of an invention, the Government shall pay-

(a) to the proprietor of the patent; or

(b) if there is an exclusive licence in force in respect of the patent, to the exclusive licensee, compensation for any loss resulting from his not being awarded a contract to supply the patented product or, as the case may be, to perform the patented process or supply a thing made by means of the patented process.

(2) Compensation is payable only to the extent that such a contract could have been fulfilled from the existing manufacturing or other capacity of the proprietor or licensee; but is payable notwithstanding the existence of circumstances rendering him ineligible for the award of such a contract.

(3) In determining the loss, regard shall be had to the profit which would have been made on such a contract and to the extent to which any manufacturing or other capacity was under-used.

(4) No compensation is payable in respect of any failure to secure contracts to supply the patented product or, as the case may be, to perform the patented process or supply a thing made by means of the patented process, otherwise than for Government use.

(5) The amount payable shall, if not agreed between the proprietor or licensee and the Government, be determined by the court on a reference under section 72, and is in addition to any amount payable under section 69 or 70.

[cf. 1977 c. 37 s. 57A U.K.]

Section: 72 References of disputes as to Government use

(1) Any dispute as to-

(a) the exercise by a public officer, or a person authorized by a public officer, of the powers conferred by section 69;

(b) terms for Government use of an invention under section 69;

(c) the right of any person to receive any part of a payment made in pursuance of section 69(4); or

(d) the right of any person to receive a payment under section 71, may be referred to the court by either party to the dispute after a patent has been granted for the invention.

(2) In determining under this section any dispute between the Government and any person as to the terms for the Government use of an invention, the court shall have regard-

(a) to any benefit or compensation which that person or any person from whom he derives title may have received or may be entitled to receive directly or indirectly from any public officer in respect of the invention in question;

(b) to whether that person or any person from whom he derives title has in the court's opinion without reasonable cause failed to comply with a request of the public officer concerned for Government use of the invention on reasonable terms.

(3) On a reference under this section the court may refuse to grant relief by way of compensation in respect of Government use of an invention-

(a) during any further period specified under section 33(4), but before payment of the maintenance fee and any additional fee prescribed for the purposes of that section; or

(b) during any further period specified under section 39(4) or 126(5) (as the case may be), but before the payment of the renewal fee and any additional fee prescribed for the purposes of that section.

(4) Where an amendment of the specification of a patent has been allowed under this Ordinance or has been recorded under section 43(2), the court shall not grant relief by way of compensation under this section in respect of any such use before the decision to allow the amendment or the recording of the amendment unless the court is satisfied that the specification of the patent as published was framed in good faith and with reasonable skill and knowledge.

(5) If the validity of a patent is put in issue in proceedings under this section and it is found that the patent is only partially valid, the court may, subject to subsection (6), grant relief to the proprietor of the patent in respect of that part of the patent which is found to be valid and to have been used in Government use.

(6) Where in any such proceedings it is found that a patent is only partially valid, the court shall not grant relief by way of compensation, costs or expenses except where the proprietor of the patent proves that the specification of the patent was framed in good faith and with reasonable skill and knowledge, and in that event the court may grant relief in respect of that part of the patent which is valid and has been so used, subject to the discretion of the court as to costs and expenses and as to the date from which compensation should be awarded.

(7) As a condition of any such relief the court may direct that the specification of the patent shall be amended to its satisfaction upon an application made for that purpose under section 102, and an application may be so made accordingly, whether or not all other issues in the proceedings have been determined.

(8) In considering the amount of any compensation for Government use of an invention after publication of an application for a standard patent for the invention and before such a patent is granted, the court shall consider whether or not it would have been reasonable to expect, from a consideration of the application as published that a patent would be granted conferring on the proprietor of the patent protection for an act of the same description as that found to constitute that use, and if the court finds that it would not have been reasonable, it shall reduce the compensation to such amount as it thinks just.

(9) Where a person becomes the proprietor or one of the proprietors or an exclusive licensee of a patent (the new proprietor or licensee) by virtue of a transaction, instrument or event to which section 52 applies, then unless-

- (a) an application for registration of the prescribed particulars of the transaction, instrument or event is made before the end of the period of 6 months beginning with its date; or
- (b) the court is satisfied that it was not practicable for such an application to be made before the end of that period and that an application was made as soon as practicable thereafter, the new proprietor or licensee shall not be entitled to any compensation under section 69(4) (as it stands or as modified by section 70(4)) or to any compensation under section 71 in respect of any use of the patented invention by a public officer or a person authorized by a public officer under section 69 after the date of the transaction, instrument or event and before the prescribed particulars of the transaction, instrument or event are registered.

(10) One of 2 or more joint proprietors of a patent or application for a patent may without the concurrence of the others refer a dispute to the court under this section, but shall not do so unless the others are made parties to the proceedings; but any of the others made a defendant shall not be liable for any costs or expenses unless he enters an appearance and takes part in the proceedings.

[cf. 1977 c. 37 s. 58 U.K.]

Part: IXA IMPORT COMPULSORY LICENCES FOR PATENTED PHARMACEUTICAL PRODUCTS
Section: 72A Interpretation of Part IXA

In this Part, unless the context otherwise requires— “Director” (署長) means the Director of Health; “import compulsory licence” (進口強制性特許) means a compulsory licence granted under section 72C; “import compulsory licensee” (進口強制性特許持有人) means the holder of an import compulsory licence; “proprietor” (所有人), in relation to a patent, means the proprietor of the patent that is granted in Hong Kong.

(Part IXA added 21 of 2007 s. 5)

Section: 72B Declaration of extreme urgency for public health problem

(1) The Chief Executive in Council may, for the purposes of applying sections 72C to 72J, by notice published in the Gazette declare a period of extreme urgency whenever the Chief Executive in Council considers it to be necessary or expedient in the public interest to do so to address any public health problem or threatened public health problem in Hong Kong.

(2) Where a period of extreme urgency has been declared under subsection (1), the Chief Executive in Council shall review from time to time, or cause to be reviewed from time to time, the public health problem or the threatened public health problem leading to the declaration.

(3) The period of extreme urgency declared under subsection (1) continues to run until such a date as may be specified by the Chief Executive in Council by notice published in the Gazette terminating the period of extreme urgency.

(4) A notice published under subsection (1) or (3) is subsidiary legislation. (Part IXA added 21 of 2007 s. 5)

Section: 72C Grant of import compulsory licences for patented pharmaceutical products

During a period of extreme urgency declared under section 72B(1), where the Director considers that the pharmaceutical industry in Hong Kong has no or insufficient capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong, the Director may grant an import compulsory licence under the patent concerned, subject to such terms and conditions as he may impose, to a public officer or any other person to do in Hong Kong in relation to the product all or any of the following which appears to the Director to be necessary or expedient in connection with the extreme urgency giving rise to the declaration—

- (a) importing, putting on the market, stocking or using the product;
- (b) any other act which would, apart from this section, amount to an infringement of the patent concerned.

(Part IXA added 21 of 2007 s. 5)

Section: 72D Terms, conditions and nature of import compulsory licences

(1) The terms and conditions subject to which an import compulsory licence is granted under section 72C shall include—

(a) terms and conditions in respect of—

(i) the acts authorized to be done in relation to the patented pharmaceutical product under the licence;

(ii) the amount of the patented pharmaceutical product covered by the licence; and

(iii) the duration of the licence;

(b) terms and conditions providing that—

(i) the patented pharmaceutical product which is imported to Hong Kong under the licence shall not

be exported out of Hong Kong;

(ii) the patented pharmaceutical product shall be—

(A) clearly identified as being imported under the licence through specific labelling or marking; and

(B) distinguished from the same product made by or under authorization of the proprietor of the patent concerned through special packaging, colouring or shaping; and

(iii) the licence is non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence; and

(c) any other terms or conditions as the Director thinks fit having regard to the public health needs in Hong Kong in the period of extreme urgency declared under section 72B(1).

(2) An import compulsory licence is non-exclusive. (Part IXA added 21 of 2007 s. 5)

Section: 72E Payment of remuneration to proprietors of patents

(1) If remuneration has been paid to the proprietor of a patent granted in an exporting member for production and export of a patented pharmaceutical product to Hong Kong in accordance with the relevant instrument or legislation, no remuneration shall be paid to the proprietor of the patent concerned granted in Hong Kong for the import compulsory licence in relation to the product.

(2) If the proprietor of the patent concerned granted in Hong Kong establishes to the satisfaction of the Director that remuneration has not been paid to the proprietor of the patent granted in the exporting member for the production and export of the patented pharmaceutical product to Hong Kong in accordance with the relevant instrument or legislation and all legal remedies to recover payment of the remuneration in the exporting member have been exhausted, the Government shall pay to the proprietor of the patent concerned granted in Hong Kong such amount of remuneration—

(a) as may be agreed between the Director and the proprietor of the patent concerned granted in Hong Kong subject to any order made by the court on an application under section 72J(2); or
(b) as may be determined by the court on an application under section 72J(1) or (2), for the import compulsory licence in relation to the product.

(3) Before reaching any agreement as to the amount of remuneration, the Director shall take into account any advice given by the Director of Intellectual Property as regards the remuneration.

(4) The total amount of remuneration agreed under subsection (2)(a) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) shall not exceed 4% of the total purchase price for the product payable by the import compulsory licensee to the seller of the product in the exporting member.

(5) Where there is more than one patent in relation to the patented pharmaceutical product, the total amount of remuneration agreed under subsection (2)(a) shall be apportioned on an equal share basis among all the proprietors of the patents concerned.

(6) The Secretary for Commerce and Economic Development may by notice published in the Gazette vary the percentage specified in subsection (4).
(Part IXA added 21 of 2007 s. 5)

Section: 72F Notification of grant of import compulsory licences and remuneration agreed, etc.

(1) The Director shall as soon as practicable after the grant of an import compulsory licence under section 72C —

(a) give notice in writing to the proprietor of the patent concerned of the grant of the licence and its terms and conditions; and
(b) advertise in the official journal notice of the grant of the licence and its terms and conditions.

(2) The Director shall—

(a) as soon as practicable after any amount of remuneration has been agreed under section 72E(2)(a) between him and the proprietor of the patent concerned, advertise in the official journal a notice stating —

(i) the amount of remuneration so agreed with the proprietor of the patent concerned named in the notice and, where applicable, the apportionment of the amount of remuneration under section 72E(5); and

- (ii) that any other person who is entitled to claim remuneration payable under section 72E(2) may make an application to the court under section 72J(2); or
- (b) as soon as practicable after he is satisfied that he and the proprietor of the patent concerned have failed to agree on the amount of remuneration payable under section 72E(2), advertise in the official journal a notice stating—
 - (i) the fact of the failure to agree on the amount of remuneration with the proprietor of the patent concerned named in the notice; and
 - (ii) that any other person who is entitled to claim remuneration payable under that section may make an application to the court under section 72J(2). (Part IXA added 21 of 2007 s. 5)

Section: 72G Termination of import compulsory licences

(1) The Director may terminate an import compulsory licence by giving notice in writing to the import compulsory licensee if he is satisfied that any term or condition of the licence imposed under section 72C has been contravened.

(2) The Director shall as soon as practicable after the termination of an import compulsory licence under subsection (1)—

- (a) give notice in writing to the proprietor of the patent concerned of the termination; and
- (b) advertise in the official journal notice of the termination.

(Part IXA added 21 of 2007 s. 5)

Section: 72H Disposal of patented pharmaceutical products after period of extreme urgency etc.

(1) On the termination of the period of extreme urgency by a notice under section 72B(3), the import compulsory licensee shall take reasonable steps to recall or cause to recall any patented pharmaceutical product which is imported under the import compulsory licence from any person (other than a person who is in possession of the product privately for non-commercial purposes) who is in possession of the product disposed of in accordance with the licence.

(2) An import compulsory licensee shall—

- (a) surrender to the Director any patented pharmaceutical product which is in his possession or recalled under subsection (1); or
- (b) dispose of the product in such a way as may be agreed with the proprietor of the patent concerned granted in Hong Kong.

(3) Where a patented pharmaceutical product is surrendered to the Director under subsection

(2)(a)—

(a) the Government shall pay to the import compulsory licensee a sum equivalent to the purchase price for the product paid by the licensee to the seller of the product in the exporting member; and

(b) the Director shall—

- (i) dispose of the product in such a way as may be agreed with the proprietor of the patent concerned granted in Hong Kong; or
- (ii) in default of agreement, destroy the product as soon as practicable.

(4) For the avoidance of doubt, stocking of any patented pharmaceutical product which is imported under an import compulsory licence does not amount to an infringement of the patent concerned on the part of the import compulsory licensee or the Director from the termination of the period of extreme urgency by a notice under section 72B(3) until—

(a) the import compulsory licensee surrenders the product to the Director under subsection (2)(a) or disposes of the product under subsection (2)(b); or

(b) the Director disposes of the product under subsection (3)(b)(i) or destroys the product under subsection (3)(b)(ii), as the case may be. (Part IXA added 21 of 2007 s. 5)

Section: 72I No infringement of patents by persons to whom patented pharmaceutical products are disposed of in accordance with import compulsory licences

(1) A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence may, without consent of the proprietor of the patent concerned, put on the market, stock or use the product, in Hong Kong, for the purposes in connection with the extreme urgency giving rise to the declaration under section 72B(1) as if he had been authorized by the licence to do so.

(2) A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence shall not export or cause to export the product out of Hong Kong.
(Part IXA added 21 of 2007 s. 5)

Section: 72J References of disputes as to import compulsory licences

(1) If the Director and the proprietor of the patent concerned fail to agree on the amount of remuneration payable under section 72E(2), either party may, subject to subsection (5), apply to the court for an order to determine the amount of remuneration payable under that section.

(2) A person who is not a party to any agreement reached on the amount of remuneration under section 72E(2)(a) but is entitled to claim remuneration payable under section 72E(2) may, subject to subsection (5), apply to the court for an order for payment of remuneration under that section.

(3) In determining the appropriate amount of remuneration payable to the proprietor of the patent concerned, the court shall take into account all factors relevant to the circumstances, including—

- (a) the economic value to Hong Kong of the use of the patented pharmaceutical product imported under the relevant import compulsory licence; and
- (b) humanitarian or non-commercial factors relevant to the grant of the licence.

(4) The total amount of remuneration determined by the court under subsection (3) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) may exceed the maximum amount of remuneration that may be agreed under section 72E(2)(a).

(5) No application may be made under subsection (1) or (2) after the expiry of the period of 28 days from the date of the advertisement of the notice under section 72F(2), unless the court determines otherwise.

(6) Any person aggrieved by—

- (a) the grant of an import compulsory licence;
 - (b) any term or condition of an import compulsory licence imposed under section 72C;
 - (c) the apportionment of the amount of remuneration under section 72E(5); or
 - (d) the termination of an import compulsory licence under section 72G(1),
- may, within 28 days after the date of the advertisement of the notice under section 72F(1)(b) or (2)(a)(i) or the date of the termination of the licence (as the case may be) or such further period as may be allowed by the court, apply to the court for a review of the grant of the licence, the terms or conditions of the licence, the apportionment of the amount of remuneration or the termination of the licence (as the case may be).

(7) In a review the court may—

- (a) confirm, vary or cancel the import compulsory licence;
- (b) confirm, vary or cancel a term or condition of the import compulsory licence imposed under section 72C;

- (c) confirm or vary the apportionment of the amount of remuneration under section 72E(5);
- (d) confirm or reverse the termination of the import compulsory licence under section 72G(1);
- or
- (e) make any other order as the court thinks fit in the circumstances.

(8) The proprietor of the patent concerned may apply to the court for an order to terminate an import compulsory licence on the ground that any term or condition of the licence imposed under section 72C has been contravened.

(9) The court may, on an application under subsection (8)—

- (a) make an order to terminate the import compulsory licence if the court is satisfied that any term or condition of the licence imposed under section 72C has been contravened; and
- (b) make any other order as the court thinks fit in the circumstances.

(Part IXA added 21 of 2007 s. 5)

Part: IXB Export Compulsory Licences for Patented Pharmaceutical Products

Section: 72K Interpretation of Part IXB

In this Part, unless the context otherwise requires— “Director” (署長) means the Director of Health; “export compulsory licence” (出口強制性特許) means a compulsory licence granted under section 72M; “export compulsory licensee” (出口強制性特許持有人) means the holder of an export compulsory licence; “Hong Kong patent number” (香港專利編號), in relation to a patent, means—

- (a) a number assigned by the Registrar to a certificate issued in respect of the patent under section 27(1)(b);
- (b) a number assigned by the Registrar to a certificate of grant issued in respect of the patent under section 118(2)(b); or
- (c) a number assigned by the Registrar to a certificate of registration issued in respect of the patent under the Registration of Patents Ordinance (Cap 42) which has been repealed under section 154(1); “proprietor” (所有人), in relation to a patent, means the proprietor of the patent that is granted in Hong Kong. (Part IXB added 21 of 2007 s. 5)

Section: 72L Application for export compulsory licences for patented pharmaceutical products

(1) At any time after the grant of a standard patent or a short-term patent in respect of a patented pharmaceutical product, any person may apply to the Director for the grant of an export compulsory licence under the patent concerned in relation to the product under section 72M.

(2) The application shall be made in writing and—

(a) shall specify the following information—

- (i) the name and address of the applicant and of any agent or representative authorized by the applicant for the purpose of the application;
- (ii) the name of the patented pharmaceutical product to be made and sold for export under an export compulsory licence the subject of the application;
- (iii) the amount of the patented pharmaceutical product to be made and sold for export under the export compulsory licence;
- (iv) the name of the eligible importing member to which the patented pharmaceutical product is to be exported under the export compulsory licence;
- (v) the duration of the export compulsory licence applied for by the applicant;
- (vi) the Hong Kong patent number or Hong Kong patent numbers in relation to the patented pharmaceutical product;
- (vii) the proposed labelling, marking, packaging, colouring or shaping for the patented pharmaceutical product required by section 72N(1)(b)(ii);

- (viii) the address of a website on which the applicant is required to post the information referred to in section 72N(1)(b)(iii);
 - (ix) any information obtained pursuant to subsection (3);
 - (x) any other information as the Director may reasonably require for the purposes of granting the export compulsory licence; and
- (b) shall be accompanied by—
- (i) a copy of the written request from the eligible importing member, any representative, non-governmental organization or international health organization authorized by the eligible importing member to the applicant for the patented pharmaceutical product and the amount of the product requested;
 - (ii) a copy of the notification made by the eligible importing member to the TRIPS Council stating—
 - (A) the name and the amount of the patented pharmaceutical product requested by the eligible importing member;
 - (B) where the eligible importing member is not a least-developed country recognized by the United Nations, that the eligible importing member has no or insufficient capacity to manufacture the patented pharmaceutical product; and
 - (C) where the pharmaceutical product is patented in the eligible importing member, that the eligible importing member has granted or intends to grant a compulsory licence to import the product in accordance with the relevant instrument or legislation;
 - (iii) where applicable, a copy of notice of the intended application given to the proprietor of the patent concerned under subsection (4)(b)(i) or (5)(a)(i);
 - (iv) where applicable, a declaration made by the applicant under the Oaths and Declarations Ordinance (Cap 11) declaring that he has made reasonable efforts in accordance with subsection (4)(a) to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions but the efforts have not been successful within 28 days after they had been made; and
 - (v) if the pharmaceutical product is patented in the eligible importing member, documentary evidence of any compulsory licence granted by the eligible importing member for importation of the product.

(3) A person who intends to make an application under subsection (1) shall, before he makes the application, take reasonable steps to obtain from the eligible importing member information on the amount of the patented pharmaceutical product to be made and exported to the eligible importing member by any exporting member other than Hong Kong under any compulsory licence granted elsewhere.

(4) Where a person intends to make an application under subsection (1) and the eligible importing member has not notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person shall—

(a) not later than 28 days before the date of the application, make reasonable efforts to obtain authorization from the proprietor of the patent concerned on reasonable commercial terms and conditions to make and sell for export the patented pharmaceutical product of such amount as requested by the eligible importing member; and

(b) not later than 14 days before the date of the application—

(i) give the proprietor of the patent concerned notice of the intended application containing the information required under subsection (2)(a) (except subparagraphs (viii) and (x) of that subsection); and

(ii) attach to the notice all the documents and documentary evidence required under subsection (2)(b) (except subparagraphs (iii) and (iv) of that subsection).

(5) Where a person intends to make an application under subsection (1) and the eligible importing member has notified the TRIPS Council that it is faced with a national emergency or other circumstances of extreme urgency, the person shall—

- (a) (i) at any time before the application is made, give the proprietor of the patent concerned notice of the intended application containing the information required under subsection (2)(a) (except subparagraphs (viii) and (x) of that subsection); or
 - (ii) as soon as practicable after the application is made, give the proprietor of the patent concerned notice of the application containing the information required under subsection (2)(a);
 - (b) attach to the notice all the documents and documentary evidence required under subsection (2)(b) (except subparagraphs (iii) and (iv) of that subsection); and
 - (c) as soon as practicable after notice is given under paragraph (a), submit a copy of the notice to the Director.
- (Part IXB added 21 of 2007 s. 5)

Section: 72M Grant of export compulsory licences for patented pharmaceutical products

The Director may grant an export compulsory licence under the patent concerned, subject to such terms and conditions as he may impose, to an applicant to make a patented pharmaceutical product and sell the product for export to an eligible importing member if he is satisfied that—

- (a) all the requirements of section 72L have been met; (b) the amount of the product applied for by the applicant to be made and sold for export under the licence does not exceed the amount stated in the notification referred to in section 72L(2)(b)(ii)(A), after taking into account any information obtained pursuant to section 72L(3); and
- (c) the application is made in response to the request from the eligible importing member referred to in section 72L(2)(b)(i).

(Part IXB added 21 of 2007 s. 5)

Section: 72N Terms, conditions and nature of export compulsory licences

- (1) The terms and conditions subject to which an export compulsory licence is granted under section 72M shall include—
- (a) terms and conditions in respect of—
 - (i) the acts authorized to be done in relation to the patented pharmaceutical product under the licence; (ii) the amount of the patented pharmaceutical product authorized to be made and sold for export under the licence;
 - (iii) the eligible importing member to which the patented pharmaceutical product is to be exported under the licence; and
 - (iv) the duration of the licence;
 - (b) terms and conditions providing that—
 - (i) the licence is non-assignable except with that part of the enterprise or goodwill which enjoys the use of the patent under the licence;
 - (ii) the patented pharmaceutical product shall be—
 - (A) clearly identified as being made under the licence through specific labelling or marking; and
 - (B) distinguished from the same product made by or under authorization of the proprietor of the patent concerned through special packaging, colouring or shaping;
 - (iii) the export compulsory licensee shall, before shipment of the patented pharmaceutical product to the eligible importing member under the licence, post on the website maintained by or on behalf of the licensee or on the WTO website information in relation to—
 - (A) the amount of the patented pharmaceutical product that will be exported to the eligible importing member under the shipment; and
 - (B) the labelling, marking, packaging, colouring or shaping for the patented pharmaceutical product required by subparagraph (ii);
 - (iv) the export compulsory licensee shall pay to the proprietor of the patent concerned such amount of remuneration as determined by the Director under section 72P(1) for the export compulsory licence in relation to the product;
 - (v) where there is more than one patent in relation to the patented pharmaceutical product, the export compulsory licensee shall apportion on an equal share basis among all the proprietors of

the patents concerned the total amount of remuneration determined by the Director under section 72P(1);

(vi) subject to subparagraph (vii), the patented pharmaceutical product made under the licence shall be exported only to the eligible importing member specified in the licence; and

(vii) if the patented pharmaceutical product is also patented in the eligible importing member, the product shall be exported to the eligible importing member after it has granted a compulsory licence for importation of the product; and

(c) any other terms or conditions as the Director thinks fit.

(2) An export compulsory licence is non-exclusive.

(Part IXB added 21 of 2007 s. 5)

Section: 72O Notification of grant of export compulsory licences

The Director shall as soon as practicable after the grant of an export compulsory licence under section 72M—

(a) give notice in writing to the proprietor of the patent concerned, as identified pursuant to the information specified in the application in accordance with section 72L(2)(a)(vi), of the grant of the licence and its terms and conditions; and

(b) advertise in the official journal notice of the grant of the licence and its terms and conditions.
(Part IXB added 21 of 2007 s. 5)

Section: 72P Determination of remuneration payable to proprietors of patents

(1) The Director shall determine the amount of remuneration payable to the proprietor of the patent concerned under section 72N(1)(b)(iv).

(2) In determining the amount of remuneration, the Director shall take into account any advice given by the Director of Intellectual Property as regards the remuneration.

(3) The total amount of remuneration determined by the Director under subsection (1) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) shall not exceed 4% of the total purchase price for the product payable by the eligible importing member to the export compulsory licensee.

(4) The Secretary for Commerce and Economic Development may by notice published in the Gazette vary the percentage specified in subsection (3).

(Part IXB added 21 of 2007 s. 5)

Section: 72Q Termination of export compulsory licences L.N. 234 of 2007 22/02/2008

(1) The Director may terminate an export compulsory licence by giving notice in writing to the export compulsory licensee if he is satisfied that—

(a) any term or condition of the licence imposed under section 72M has been contravened; or

(b) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72L(2) is false, incorrect or incomplete in any material particular.

(2) The Director shall as soon as practicable after the termination of an export compulsory licence under subsection (1)— (a) give notice in writing to the proprietor of the patent concerned, as identified pursuant to the information specified in the application in accordance with section 72L(2)(a)(vi), of the termination; and

(b) advertise in the official journal notice of the termination. (Part IXB added 21 of 2007 s. 5)

Section: 72R References of disputes as to export compulsory licences

(1) Any person aggrieved by—

(a) the grant of an export compulsory licence;

(b) any term or condition of an export compulsory licence imposed under section 72M; or

(c) the termination of an export compulsory licence under section 72Q(1), may, within 28 days after the date of the advertisement of the notice under section 72O(b) or the date of the

termination of the licence (as the case may be) or such further period as may be allowed by the court, apply to the court for a review of the grant of the licence, the terms or conditions of the licence or the termination of the licence (as the case may be).

(2) In a review the court may—

- (a) confirm, vary or cancel the export compulsory licence;
- (b) confirm, vary or cancel a term or condition of the export compulsory licence imposed under section 72M;
- (c) confirm or vary the determination of the amount of remuneration under section 72P(1);
- (d) confirm or reverse the termination of the export compulsory licence under section 72Q(1);
or
- (e) make any other order as the court thinks fit in the circumstances.

(3) In determining the appropriate amount of remuneration payable to the proprietor of the patent concerned, the court shall take into account all factors relevant to the circumstances, including—

- (a) the economic value to the eligible importing member of the use of the patented pharmaceutical product exported to it under the relevant export compulsory licence; and
- (b) humanitarian or non-commercial factors relevant to the grant of the licence.

(4) The total amount of remuneration determined by the court under subsection (3) to be payable in respect of the patent or all the patents (if there is more than one patent in relation to the patented pharmaceutical product) may exceed the maximum amount of remuneration that may be determined by the Director under section 72P(1).

(5) The proprietor of the patent concerned may apply to the court for an order to terminate an export compulsory licence on the ground that—

- (a) any term or condition of the licence imposed under section 72M has been contravened; or
- (b) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72L(2) is false, incorrect or incomplete in any material particular.

(6) The court may, on an application under subsection (5)—

- (a) make an order to terminate the export compulsory licence if the court is satisfied that—
 - (i) any term or condition of the licence imposed under section 72M has been contravened; or
 - (ii) any information, document or documentary evidence specified in or accompanying the application in accordance with section 72L(2) is false, incorrect or incomplete in any material particular; and
- (b) make any other order as the court thinks fit in the circumstances. (Part IXB added 21 of 2007 s. 5)

Section: 72S **Signature of documents by partnerships, companies and associations**

For the purposes of this Part—

- (a) a document signed for or on behalf of a firm shall be signed by all of its partners, by any partner stating that he signs on behalf of the firm or by any other person who satisfies the Director that he is authorized by the firm to sign the document;
- (b) a document signed for or on behalf of a body corporate shall be signed by a director or the secretary or other principal officer of the body corporate or by any other person who satisfies the Director that he is authorized by the body corporate to sign the document; and
- (c) a document signed for or on behalf of an unincorporated body or association of persons other than a firm shall be signed by any person who satisfies the Director that he is authorized by the unincorporated body or association of persons (as the case may be) to sign the document. (Part IXB added 21 of 2007 s. 5)

COLOMBIA

Decision No. 486 of 14/09/ 2000 of the Commission of the Andean Community - Common Industrial Property Regime (Cartagena Agreement)

(Refer to ANDEAN Community below.)

Decreto N° 4302 de 2008 (13 de noviembre) - Por el cual se fija el procedimiento para la declaratoria de existencia de razones de interés público de acuerdo con lo dispuesto en el artículo 65 de la Decisión 486 de la Comisión de la Comunidad Andina.

Articles 1-9

Artículo 1°. *Objeto.* El presente decreto tiene por objeto establecer la competencia y el procedimiento para el trámite de declaratoria de la existencia de razones de interés público, a que refiere el artículo 65 de la Decisión 486 de la Comisión de la Comunidad Andina.

Artículo 2°. *Definiciones.* Para efectos del presente decreto se establecen las siguientes definiciones:

- **Autoridad competente:** Es el Ministerio o el Departamento Administrativo encargado de la formulación y adopción de las políticas y proyectos del sector que dirigen, en los términos del artículo 58 de la Ley 489 de 1998 y, que según la materia de que se trate, debe declarar mediante resolución motivada la existencia de razones de interés público para el otorgamiento de licencias obligatorias.

- **Declaratoria de existencia de razones de interés público:** Acto administrativo mediante el cual la autoridad competente declara la existencia de razones de interés público que soportan la necesidad de someter a licencia obligatoria las patentes de invención.

Artículo 3°. *Solicitud.* Las personas naturales o jurídicas interesadas en que se declare la existencia de razones de interés público con el propósito de que se otorgue una licencia obligatoria sobre productos objeto de patente o por el uso integral del procedimiento patentado, podrán solicitar dicha declaratoria ante la autoridad competente correspondiente, la cual procederá conforme al procedimiento previsto en el presente decreto.

Artículo 4°. *Procedimiento para la declaratoria de existencia de razones de interés público.* Para efectos de la declaratoria de la existencia de razones de interés público, se tendrá en cuenta lo siguiente:

1. La solicitud de declaratoria de las razones de interés público para someter a una patente a licencia obligatoria se debe presentar por el interesado ante la respectiva autoridad competente, la cual contendrá como mínimo las razones que fundamentan la petición, así como la relación de la(s) patente(s) que en criterio de los solicitantes deben ser sometidas a licencia obligatoria.
2. La autoridad competente, mediante acto motivado, dispondrá adelantar o no la respectiva actuación administrativa y comunicará dicha providencia al interesado.
3. Cuando la autoridad competente considere que terceros determinados o indeterminados pueden estar directamente interesados o resultar afectados con la decisión, procederá conforme a lo dispuesto por los artículos 14 y 15 del Código Contencioso Administrativo.
4. La autoridad competente para definir la solicitud de declaratoria de razones de interés público contará con un término de tres (3) meses para adoptar la decisión que corresponda, la cual será comunicada al solicitante y a los terceros interesados, en caso de haberlos.
5. La autoridad competente que expida la resolución de declaratoria de razones de interés público, la publicará en el **Diario Oficial**.

Parágrafo 1°. El trámite que se surta ante la autoridad competente, en los aspectos procedimentales no previstos en el presente decreto se regirá por lo dispuesto en el Código Contencioso Administrativo.

Parágrafo 2°. El procedimiento previsto en el presente decreto podrá ser también iniciado de oficio por la autoridad competente.

Artículo 5°. Contenido del Acto Administrativo de declaratoria. La resolución expedida por el correspondiente Ministerio o Departamento Administrativo en la que se declare que existen razones de interés público que ameriten la expedición de licencia(s) obligatoria(s) deberá identificar la situación que afecta el interés general; establecer las circunstancias que llevaron a la declaratoria y los motivos por las cuales se debe licenciar la patente; además, indicará las medidas o mecanismos necesarios que se deban adoptar para conjurar dicha afectación. Los aspectos relacionados con el alcance específico de la(s) licencia(s) obligatoria(s) que se concederán serán concretados por la Superintendencia de Industria y Comercio con base en lo previsto en la referida resolución, dentro del trámite a que se refiere el artículo 7° del presente decreto.

Parágrafo. Sin perjuicio de lo aquí dispuesto, el Ministerio o Departamento Administrativo que declare la existencia de razones de interés público, en el marco de sus competencias, podrá establecer medidas diferentes a la concesión de licencia(s) obligatoria(s).

Artículo 6°. Comité Técnico. Para efectos de la declaratoria de razones de interés público de que trata el artículo 4° del presente decreto, el respectivo Ministerio o Departamento Administrativo dispondrá de un Comité Técnico creado mediante resolución expedida por estas entidades, que deberá:

- a) Examinar y evaluar los documentos que se presenten;
- b) Solicitar la información que deba ser presentada por el interesado, así como la adicional o complementaria a la misma;
- c) Solicitar conceptos o apoyo técnico de otras entidades;
- d) Recomendar al Ministro o Director de Departamento Administrativo la decisión de declarar o no la existencia de razones de interés público y, la consecuente expedición del acto administrativo a que se refiere el artículo 4° del presente decreto.

Parágrafo 1°. El Comité podrá convocar a sus reuniones a funcionarios de cualquier entidad cuyo acompañamiento resulte pertinente o necesario (de conformidad con el mercado a que se refiere la solicitud), a efectos de analizar los asuntos que se le sometan a su consideración. Igualmente podrá invitar al peticionario para que amplíe los detalles de su solicitud, así como a los terceros interesados que se hagan parte en la actuación.

Parágrafo 2°. El término previsto en el artículo 4° del presente decreto se suspenderá mientras el peticionario allegue la información adicional solicitada por el Comité o se aportan los conceptos solicitados a otras entidades.

Artículo 7°. Trámite ante la Superintendencia de Industria y Comercio. La Superintendencia de Industria y Comercio, una vez se publique en el Diario Oficial y se comunique el acto administrativo a que se refiere el artículo 4° del presente decreto, adelantará el trámite correspondiente para el otorgamiento de la(s) licencia(s) obligatoria(s) que se le soliciten, de acuerdo con el procedimiento que para el efecto se establezca.

La autoridad competente prestará el apoyo que la Superintendencia de Industria y Comercio requiera durante dicho trámite, particularmente en lo relacionado con la determinación del

periodo por el cual se concederá la licencia y el monto y las condiciones de la compensación económica.

Artículo 8°. Del Régimen Transitorio. Las solicitudes presentadas para la declaratoria de existencia de razones de interés público antes de la entrada en vigencia del presente decreto, se tramitarán por el procedimiento aquí previsto.

Artículo 9°. Vigencia y derogatoria. El presente decreto rige a partir de la fecha de su publicación y deroga las disposiciones que le sean contrarias.

COSTA RICA

Law No. 6867 of April 25, 1983, on Patents, Industrial Designs and Utility Models (as amended up to Law No. 8686 of November 21, 2008)

Articles 18-20

Article 18.- Failure to work or insufficient industrial working

1. Grant of a patent shall imply an obligation to work it in Costa Rica in a permanent and stable fashion, so that the market is appropriately and reasonably supplied within the period of three years, beginning from the date of grant of the patent, or four years, beginning from the application for the patent, whichever is longest.

Nor may the working be interrupted for more than one year **(paragraph amended by Law No. 7979 of January 6, 2000, Article 2(e)).**

2. Repealed by LAW No. 8632 of March 25, 2008

3. For the purposes of the first paragraph of this Article, the local production and legitimate import of products shall be considered, inter alia, forms of working **(paragraph amended by LAW No. 7979 of January 6, 2000, Article 2 (e))**

4. Repealed by LAW No. 8632 of March 25, 2008

5. Upon the expiry of the periods referred to in paragraph 1 of this Article, any party may apply during the following year for the grant of a compulsory license due to failure to work. In the event that the grant of the compulsory license does not suffice to correct the failure to use the patent, the patent shall be declared to have lapsed. No proceedings for the lapsing or revocation of a patent may be brought before the expiry of the period of two years, beginning from the grant of the first compulsory license **(as amended by LAW No. 8632 of March 25, 2008)**

6. Authorization for compulsory licenses shall be considered on a case-by-case basis and shall extend to patents relating to components and processes which enable their working. Such uses shall be authorized primarily to supply the domestic market, in accordance with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property. Before a compulsory license is granted, the applicant shall prove that he has sufficient capacity to work the patented invention and that he has endeavored to obtain the authorization of the right holder on reasonable commercial terms and conditions, and that such attempts have not succeeded within the period set in the first paragraph of this Article **(as amended by LAW No. 8632 of March 25, 2008)**

7. The Industrial Property Registry shall decide, within a period of 90 calendar days, whether or not to grant a compulsory license, after hearing the parties. When granting such a license, it shall stipulate the conditions under which it is granted, limiting the scope and duration for the purposes authorized and the economic remuneration which the right holder receives. To do so, it shall take into consideration the particular circumstances of each case and the economic value of the authorization, and shall bear in mind the average royalties for the sector in question, in commercial licensing contracts between independent parties. Semiconductor technology may only be used for public non-commercial purposes or to correct a practice declared anti-competitive following judicial or administrative proceedings **(paragraph amended by LAW No. 7979 of January 6, 2000, Article 2(e))**

8. Appeals lodged against decisions to grant compulsory licenses shall not prevent licensees from working a license or interrupt the periods which are underway. Nor shall it prevent patent owners from receiving the royalties fixed by the Industrial Property Registry, for the part that is not subject to a complaint **(paragraph amended by LAW No. 7979 of January 6, 2000, Article 2(e))**

9. The grant and conditions of compulsory licenses may be amended at any time by agreement of the parties, at the request of one of them, or ex officio by the Industrial Property Registry where new facts so warrant and, in particular, where a patent owner has granted a license to third parties on conditions more favorable than those established. Similarly, authorization for compulsory licenses may be canceled without prejudice to the legitimate interests of those who have been granted authorization, if the circumstances which led to such authorization have ceased to exist and are unlikely to recur. The Industrial Property Registry shall examine, upon motivated request, whether such circumstances continue to exist; in addition, it shall be authorized to refuse to revoke an authorization if it is likely that the conditions which gave rise to such authorization will recur.
(paragraph amended by LAW No. 7979 January 6, 2000, Article 2(e))

10. Compulsory licenses shall not be exclusive and may not be transmitted, even in the form of the grant of a sublicense, except with the part of the company or business establishment which works the license. Licensees shall be obliged to work their patent within the period of one year, starting from the date on which it was granted, and may not suspend working for a longer period or the license granted will be automatically revoked **(paragraph amended by LAW No. 7979 of January 6, 2000, Article 2(e))**

11. Repealed by LAW No. 8632 of March 25, 2008

Article 19.- Compulsory licenses for dependent patents and compulsory licenses for anti-competitive practices

A.- Compulsory licenses in the case of dependent patents

1. If the invention claimed in a patent cannot be worked industrially in the country without infringing a prior patent, the Industrial Property Registry, at the request of the owner of the second patent, his licensee or the beneficiary of a compulsory license for the later patent, shall grant a compulsory license where necessary to avoid infringement of the prior patent, subject to the relevant provisions of Article 18 of this Law and to the following conditions:

- (a) the invention claimed in this second patent must offer a relevant technical advance, of considerable economic importance in respect of the invention claimed in the first patent;
- (b) the owner of the first patent shall be entitled to a cross-license on reasonable conditions, to work the invention claimed in the second patent;
- (c) the use authorized in the first patent may not be transferred without transferring the second patent.

2. The Industrial Property Registry may grant, in the same circumstances, a compulsory license in respect of the later patent, if asked to do so by the owner of the prior patent, his licensee or the beneficiary of a compulsory license for this patent.

B.– Compulsory licenses for anti-competitive practices

1. Compulsory licenses shall be granted where the Antitrust Commission has established that the patent owner has engaged in anti-competitive practices. In such cases, without prejudice to the appeals and hearings which shall be the responsibility of the patent owner, such grant shall not require the following conditions:

(a) the potential licensee has endeavored to obtain the owner's authorization as per paragraph 6 of Article 18 of this Law;

(b) it is to supply the domestic market

2. Notwithstanding the provisions in subparagraph (a) of paragraph 1 of this Article, the owner of the patent which forms the subject matter of the license shall be notified where reasonably possible.

3. For the purposes of this Law, anti-competitive practices shall be deemed to constitute *inter alia* the following:

(a) setting excessive or discriminatory prices for the patented goods;

(b) failing to supply the market on reasonable commercial terms;

(c) hindering business or productive activities

(Article amended by LAW No. 7979 of January 6, 2000, Article 2(f))

Article 20.– Licenses in the public interest

1. Where qualified reasons of extreme urgency, public interest, national emergency or security exist, the Executive may, by decree, subject the patent or the patent application to a compulsory license at any time, even without the owner's agreement, for the invention to be worked by a State body or by third parties authorized by the Government. The owner of the patent which forms the subject matter of the license shall be notified as soon as is reasonably possible. The grant of such licenses shall comply with the provisions contained in Article 18 of this Law, as appropriate.

2. The State shall compensate patent owners for licenses in the public interest. Owners may appeal to the administrative courts for the competent court to fix the respective financial remuneration. To do so, the judicial authorities shall consider the circumstances of each case and the economic value of the authorization, taking into account the rate of average royalties for the sector in question for commercial licensing contracts between independent parties.

3. Where the Government has granted a public interest license to a third party, that party shall reimburse the State, in full or in part, for the compensation due to the owner **(Article amended by Law No. 7979 of January 6, 2000, Article 2(f))**

CROATIA

Patent Act and Acts on Amendments to the Patent Act (OG Nos. 173/2003, 87/2005, 76/2007, 30/2009, 128/2010, 49/2011, 76/2013 and 46/2018)

Articles 67a-69d

VII Compulsory Licence

1. Common Provisions

Competence and Procedure for the Grant of a Compulsory Licence

Article 67a

(1) The Commercial Court in Zagreb shall be competent to grant compulsory licences.

- (2) The procedure for the grant of a compulsory licence shall be instituted by a legal action against the owner of a patent or a holder of a Supplementary Protection Certificate, containing an application for the grant of a compulsory licence. In the notice of legal action, the plaintiff shall indicate all the facts and present all the evidence, on which the application is based. The court shall decide on the grant of a compulsory licence by a judgment.
- (3) The decisions of the court issued in the procedures for the grant of a compulsory licence may be appealed in accordance with the rules laid down in the Act on Civil Proceedings.
- (4) In the absence of proof to the contrary, it shall be considered that, in the procedure for the grant of a compulsory licence, the owner of a patent or the holder of a Supplementary Protection Certificate is the person who is entered as such in the Register of Patents.
- (5) The Act on Civil Proceedings shall apply to particular matters relating to the procedure for the grant of a compulsory licence, not regulated by this Act.

2. Compulsory licences in the cases of insufficient exploitation of a patent, national emergencies, the need for protection from unfair market competition, exploitation of another patent or protected plant variety, and cross-licensing.

Grant of a Compulsory Licence

Article 68

- (1) The competent court in the Republic of Croatia may grant a compulsory license for lack or insufficiency of exploitation of a patent to any person filing a request for the grant of a compulsory license, or to the Government of the Republic of Croatia, if the patent owner has not exploited the invention protected by a patent in the territory of the Republic of Croatia on reasonable terms or has not made effective and serious preparations for its exploitation.
- (2) A request for the grant of a compulsory license based on paragraph (1) of this Article can be filed after the expiration of a period of four years as of the filing date of a patent application, or after the expiration of three years as of the date on which the patent was granted.
- (3) A compulsory license cannot be granted if the patent owner provides legitimate reasons to justify non-exploitation or insufficiency of exploitation of the protected invention.
- (4) On a reasoned request, the court may grant a compulsory license in respect of a first patent to the owner of a patent or to the owner of a plant variety right who cannot use his patent (second patent) or his plant variety right without infringing the first patent, provided that the invention claimed in the second patent or a protected plant variety involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The competent court may take any measure it regards as useful to verify the existence of such a situation.
- (5) In the case of a compulsory license as provided in paragraph 4 of this Article, the owner of the first patent shall be entitled to a cross license on reasonable terms to use the invention protected by the second patent or protected plant variety.
- (6) The court may grant a compulsory license if the exploitation of the patented invention is necessary in situations of extreme urgency (national security, public interest protection in the field of health, food supplying, environmental protection and improvement, specific commercial interest) or when it is necessary to remedy a practice determined after judicial or administrative process to be anticompetitive.
- (7) In the case of semi-conductor technology, a compulsory license may be granted only in the cases set out in paragraph 6 of this Article.
- (8) A compulsory license may be granted only if a person filing a request has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and if such efforts have not been successful within a reasonable period of time. The court may derogate from these conditions in the situations set out in paragraph (6) of this Article. The right holder shall be informed of the granting of a compulsory license as soon as reasonably possible.

Conditions Applicable to the Grant of a Compulsory License

Article 69

- (1) A compulsory license shall be non-exclusive, and its scope and duration shall be exclusively limited to the purpose for which it was authorized.
- (2) A compulsory license shall be transferred only with the production plant or the part thereof respectively, in which the invention it is granted for has been exploited.
- (3) A compulsory license shall be granted predominantly for the purposes of supplying the domestic market unless it is necessary to correct a practice determined after judicial or administrative process to be anti-competitive.
- (4) The competent authority shall, on a reasoned request of an interested person, cancel a compulsory license, subject to adequate protection of the legitimate interests of the persons so authorized, if and when the circumstances, which led to its authorization, cease to exist and are unlikely to recur.
- (5) The patent owner has the right to remuneration, taking into account the economic value of the authorization and need to correct anti-competitive practice.
- (6) A compulsory license according to Article 68 paragraph (4) of this Act shall be non-transferable except with a transfer of the second patent or the protected plant variety.

3. Compulsory licences for patents relating to the manufacture of pharmaceutical products intended for export to countries having public health problems

Granting of a Compulsory License

Article 69a

- (1) The court referred to in Article 67a paragraph 1 of this Act may grant, to any person instituting a legal action claiming the grant of a compulsory license in accordance with the provisions of the Regulation (EC) No. 816/2006, a compulsory license for a patent or a Supplementary Protection Certificate, required for the manufacture and sale of a pharmaceutical product, where such a product is intended for export to importing countries with public health problems.
- (2) In relation to compulsory licenses relating to the manufacture of pharmaceutical products for export to countries with public health problems, the terms within the meaning of this Act shall have the same meaning as those used in the Regulation (EC) No. 816/2006.
- (3) With an application for the grant of a compulsory license referred to in paragraph (1) of this Article, the applicant shall communicate the number of the granted patent or the Supplementary Protection Certificate for the invention which is the subject matter of the compulsory license, and the website address referred to in Article 10.6 of the Regulation (EC) No. 816/2006.
- (4) The provisions of this Act relating to compulsory licenses and the provisions of the Act on Civil Proceedings shall apply mutatis mutandis to particular matters relating to the procedure for the grant of a compulsory license, not regulated by the Regulation (EC) No. 816/2006.

Adoption of an Application for the Grant of a Compulsory License

Article 69b

- (1) If in the examination procedure concerning an application for the grant of a compulsory license it has been established that the application complies with all the requirements prescribed by the Regulation (EC) No. 816/2006, and the requirements prescribed by this Act and the Act on Civil Proceedings, the court shall issue a decision on the adoption of the application.
- (2) In its decision, the court shall indicate in detail specific conditions set out in Article 10 paragraphs 2 to 9 of the Regulation (EC) No. 818/2006, to be fulfilled by the licensee.
- (3) Indication of the grant of a compulsory license shall be entered in the Register of Patents or the Register of Supplementary Protection Certificates and published in the official gazette of the Office.
- (4) The court shall notify the Council for TRIPS through the intermediary of the Office of its final decisions relating to the grant of a compulsory license, the conditions under which it was granted, as well as of its termination and review, indicating the data prescribed by Article 12 of

the Regulation (EC) No. 816/2006. A copy of this notification shall be communicated by the Office to customs authorities and to the authority competent for medicines and medicinal products in the Republic of Croatia.

Refusal of an Application for the Grant of a Compulsory Licence

Article 69c

The court referred to in Article 67a paragraph (1) of this Act shall refuse an application for the grant of a compulsory license by a decision, if it fails to comply with the requirements set out in the Regulation (EC) No. 816/2006, and the requirements prescribed by this Act.

Termination or Modification of a Compulsory Licence

Article 69d

(1) The right holder or the licensee may institute a legal action claiming from the court to terminate a compulsory licence, if it has established that the counter party has failed to respect a decision on the grant of a compulsory license. In its decision to terminate the compulsory license, the court shall specify the time period within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to the countries in need referred to in Article 69a of this Act, or otherwise disposed of, in consultation with the right holder.

(2) When notified by the importing country that the amount of pharmaceutical product has become insufficient to meet its needs, the licensee may institute a legal action, claiming the modification of the licence conditions, for the purpose of permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned. In such cases the court shall apply expeditious proceedings. If the additional quantity of the product requested does not exceed 25%, the provisions of Article 69a paragraph (8) of this Act shall not apply.

CUBA

Decreto-Ley N^o 290 de 20 de noviembre de 2011 sobre las Invenciones y Dibujos y Modelos Industriales

Section 53-57 and 71

SECCION SEPTIMA

Otros usos sin la autorizacion del titular de la patente

ARTICULO 53.I.-La Oficina, a solicitud de un tercero y oido el parecer del órgano u organismo de la Administración Central del Estado que corresponda, sin la autorización del titular de los derechos, concede mediante una Resolución del Director General, licencia obligatoria por interes publico justificado en la explotación de la invención en el territorio nacional y para prevenir los abusos que resulten del ejercicio del derecho exclusivo conferido, en particular, en los casos siguientes:

- a) falta o insuficiencia de explotación del objeto de la patente, que genera efectos negativos en el mercado;
- b) la fijación de precios altos o discriminatorios, cuando existan ofertas de abastecimiento del mercado a precios significativamente inferiores a los ofrecidos por el titular de la patente, para el mismo producto;
- c) cuando la explotación por el titular haya sido interrumpida durante mas de un año;
- d) cuando los preparativos para explotar la invención no han sido serios y efectivos;
- e) si la patente se refiere a vacunas u otros productos farmaceuticos, cuando estos hayan sido puestos a disposición del publico mediante venta u oferta en cantidades nulas o insuficientes;

f) cuando una patente posterior no pueda ser explotada sin infringir los derechos de una patente anterior, siempre que no haya podido pactarse una licencia atendiendo a las condiciones siguientes:

I) la invención reivindicada en la patente posterior suponga un avance técnico significativo de una

importancia económica considerable con respecto a la invención reivindicada en la patente anterior;

II) el titular de la patente anterior tiene derecho a una licencia cruzada en condiciones razonables para

explotar la invención de la patente posterior; y

III) no puede cederse el uso autorizado de la patente anterior sin la cesión de la segunda patente.

g) para todo acto que constituya ejercicio abusivo de los derechos conferidos y para toda práctica que, a resultas de un proceso judicial o administrativo, se haya determinado que es anticompetitiva; o

h) cuando el titular de la patente se niegue a negociar una licencia voluntaria.

2. La Oficina, en los casos previstos en el apartado I de este artículo y sin perjuicio de lo establecido en el artículo 54, concede una licencia obligatoria cuando el potencial usuario haya intentado obtener una licencia del titular de los derechos, en términos y condiciones comerciales razonables, y estos intentos

no hayan surtido efecto en un plazo prudencial que no exceda los noventa días. El plazo se cuenta desde la fecha en que el potencial usuario comunicó al titular del derecho, mediante documento, la pretendida solicitud de licencia.

3. En los casos previstos en los incisos a) y d) del apartado 1 de este artículo, el potencial usuario no puede solicitar la licencia obligatoria antes de un plazo de cuatro años, contado a partir de la presentación de la solicitud de patente o de tres años a partir de la concesión de la patente, aplicándose el plazo que expire último.

4. Sin perjuicio de lo establecido, una solicitud de licencia obligatoria es rechazada si el titular de la patente no ha obtenido la autorización de los órganos reguladores nacionales correspondientes, por causas ajenas a su voluntad, debidamente comprobadas.

ARTICULO 54.I.-Para otorgar licencias obligatorias en situaciones excepcionales y en casos de uso público no comercial de la invención patentada, no se requiere haber intentado obtener una licencia del titular de los derechos.

2. En situaciones excepcionales, el Consejo de Defensa Nacional decide que se expida una licencia obligatoria, identifica la entidad productora y encarga a la entidad correspondiente para que, sobre la base de los fundamentos, condiciones y términos convenidos, oído el parecer de la institución pertinente, dicte la Resolución de concesión de licencia obligatoria.

3. Cuando el uso público no comercial de la invención patentada no este comprendido en una situación excepcional, le corresponde al Consejo de Ministros ejercer las facultades descritas en el apartado anterior y encargar a la Oficina para que dicte la Resolución de concesión de licencia obligatoria.

4. Sin perjuicio de lo anteriormente dispuesto, en situaciones excepcionales y en casos de uso público no comercial de la invención patentada, el titular de los derechos es notificado en cuanto sea razonablemente posible.

5. En los casos de graves problemas de salud pública u otras circunstancias de extrema urgencia, en la República de Cuba o en otro país, y cuando la capacidad de producción en el sector farmacéutico sea nula o insuficiente, pueden concederse licencias obligatorias, de conformidad con los compromisos internacionales contraídos por la República de Cuba y la legislación complementaria vigente, para:

a) la importación de productos farmacéuticos, cuando se determine por la autoridad competente que la capacidad de fabricación en el territorio nacional es insuficiente o inexistente; y

b) la exportación de productos farmacéuticos con fines de satisfacer necesidades de demanda en países con insuficiente o inexistente capacidad en ese sector.

ARTICULO 55.1.-El alcance y la duración de los usos autorizados por una licencia obligatoria se limitan al fin para el que hayan sido previstos y si se trata de tecnología de semiconductores, solo puede hacerse de ella un uso publico no comercial o utilizarse para rectificar una practica declarada contraria a la competencia tras un procedimiento administrativo o judicial.

2. Las licencias obligatorias que se concedan estan dirigidas, principalmente, a abastecer el mercado intemo.

3. Las licencias obligatorias se conceden con caracter no exclusivo y no pueden ser objeto de cesión, salvo con aquella parte de la entidad o de su activo intangible relacionada con la explotación de la invención.

ARTICULO 56.1.-El titular de la patente tiene el derecho a recibir una remuneración adecuada, segun las circunstancias propias de cada caso y el valor económico de la autorización.

2. La concesión de licencia obligatoria y la remuneración que se establezca pueden ser revisadas en la via judicial ante el tribunal cubano que corresponda, por el titular de la patente, sin que ello interrumpa los efectos de la licencia concedida.

ARTICULO 57.1.-La concesión de la licencia obligatoria puede revocarse por la Oficina, a reserva de la protección adecuada de los intereses legitimos de las personas que han recibido tales licencias, si las circunstancias que dieron origen a ella han desaparecido y no resulta probable que vuelvan a surgir.

2. Sin perjuicio de lo anterior, la Oficina esta facultada para dejar sin efecto la revocación de una licencia obligatoria, si resulta probable que las condiciones que dieron lugar a esa autorización se repitan.

SECCION CUARTA

Cancelacion

ARTiCULO 71.-Procede la cancelación de la patente cuando transcurridos al menos dos afios a partir de la concesión de una licencia obligatoria, esta no hubiera podido reducir los efectos de los abusos resultantes del ejercicio del derecho exclusivo

CYPRUS

The Patents Law of 1998

Articles 49-56

Non-Voluntary Licenses

Article 49.-(1) At any time after the expiration of four years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the Registrar on one or more of the grounds specified in paragraph (2) below

(a) for a non-voluntary license under the patent,

(b) where the applicant is a government department, for the grant to any person specified in the application of a license under the patent.

(2) The grounds for the submission for non-voluntary license are:

(a) where the patented invention is capable of being commercially worked in Cyprus but it is not being so worked or is not being so worked to the fullest extent that is reasonable practicable;

(b) where the patented invention is a product for which demand in Cyprus

(a) is not being met or

(b) is not being met on reasonable terms or

(c) that by reason of the refusal of the proprietor of the patent to grant a license or licenses on reasonable terms:

(i) a market for the export of any patented product made in Cyprus is not being supplied or
(ii) the working or efficient working in Cyprus of any other patented invention which makes a substantial contribution to the art is prevented or hindered or
(iii) the establishment or development of commercial or industrial activities in Cyprus is unfairly prejudiced;
(d) that by reason of conditions imposed by the proprietor of the patent on the grant of licenses under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in Cyprus is unfairly prejudiced.

(3) Subject to the provisions of paragraphs (4) and (6) below, if the Registrar is satisfied that any of the therein mentioned grounds are established, he may-

(a) where the application is under paragraph (1)(a) above, order the grant of a license to the applicant on such terms as the Registrar thinks fit;
(b) where the application is under paragraph (1)(b) above, order the grant of a license to the person specified in the application on such terms as the Registrar thinks fit.

(4) Where the application is made on the ground that the patented invention is not being commercially worked in Cyprus or is not being so worked to the fullest extent that is reasonably practicable, and it appears to the Registrar that the time which has elapsed since the publication in the Official Gazette of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, the Registrar may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.

(5) No entry shall be made in the register under this Article on the ground mentioned in paragraph (2)(c)(i) above, and any license granted under this Article on that ground shall contain such provisions as appear to the Registrar to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

(6) No order or entry shall be made under this Article in respect of a patent (the patent concerned) on the ground mentioned in paragraph (2)(c)(ii) above unless the Registrar is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a license under the patent for the other invention on reasonable terms.

(7) An application may be made under this Article in respect of a patent notwithstanding that the applicant is already the holder of a license under the patent; and no person shall be stopped or barred from alleging any of the matters specified in paragraph (2) above by reason of any admission made by him, whether in such a license or otherwise, or by reason of his having accepted such a license.

Provisions about Licenses under Article 49

Article 50.-(1) Where the Registrar is satisfied, on an application made under Article 49 above in respect of a patent, that the manufacture, use or disposal of materials not protected by the patent is unfairly prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licenses under the patent, or on the disposal or use of the patented product or the use of the patented process, he may (subject to the provisions of that Article) order the grant of licenses under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

(2) Where an application under Article 49 above is made in respect of a patent by a person who holds a license under the patent, the Registrar-

- (a) may, if he orders the grant of a license to the applicant, order the existing license to be canceled or
- (b) may, instead of ordering the grant of a license to the applicant, order the existing license to be amended.

(3) Where, on an application under Article 49 above in respect of a patent, the Registrar orders the grant of a license, he may direct that the license shall operate-

- (a) to deprive the proprietor of the patent of any right he has to work the invention concerned or grant licenses under the patent;
- (b) to revoke all existing licenses granted under the patent.

Exercise of Powers on Applications under Article 49

Article 51.-(1) The powers of the Registrar on an application under Article 49 above in respect of a patent shall be exercised with a view to securing the following general purposes:

- (a) that inventions which can be worked on a commercial scale in Cyprus and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;
- (b) that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention;
- (c) that the interests of any person for the time being working or developing an invention in Cyprus under the protection of a patent shall not be unfairly prejudiced.

(2) Subject to paragraph (1) above, the Registrar shall, in determining whether to make an order or entry in pursuance of such an application, take account of the following matters, that is to say-

- (a) the nature of the invention, the time which has elapsed since the publication in the Official Gazette of the Republic of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;
- (b) the ability of any person to whom a license would be granted under the order concerned to work the invention to the public advantage; and
- (c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted, but shall not be required to take account of matters subsequent to the making of the application.

Opposition and Arbitration

Article 52.-(1) The proprietor of the patent concerned or any other person wishing to oppose an application under Articles 49 to 51 above may, in accordance with the rules, give to the Registrar notice of opposition and the Registrar shall consider the opposition in deciding whether to grant the application.

(2) Where an application under Articles 49 to 51 above is opposed under paragraph (1) above and either-

- (a) the parties consent or
- (b) the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot in the opinion of the Registrar conveniently be made before him, the Registrar may at any time order the whole proceedings, or any question or issue of fact arising in them, to be referred to an arbitrator or mediator agreed upon by the parties, or in default of agreement, appointed by the Registrar.

(3) Where a question or issue of fact is so referred, the arbitrator or arbiter shall report his findings to the Registrar and the Registrar shall proceed to issue a decision.

Supplementary Provisions

Article 53. In any proceedings on an application made in relation to a patent under Articles 49 to 51 above, any statement with respect to any activity in relation to the patented invention, or with respect to the grant or refusal of licenses under the patent, contained in a report of the Commission for Protection against Unfair Competition shall be prima facie evidence of the matters stated.

Special Provisions where Patented Invention Is Being Worked Abroad

Article 54. The import into Cyprus of any product protected by a patent granted by any country member of the World Trade Organization shall be considered as use in Cyprus.

Exploitation by Government or by Third Parties Authorized by Government

Article 55. Where the national security or public safety so requires, the Council of Ministers may authorize, even without the agreement of the proprietor of the patent or the patent application, by notice published in the Official Gazette, a government agency or a person designated in such notice to make, use or sell an invention to which a patent or an application for a patent relates, subject to payment of equitable remuneration to the proprietor of the patent or the application for the patent. The decision of the Council of Ministers with regard to remuneration may be the subject of a recourse to the Court.

Provisions for Non-Voluntary License

Article 56. Where according to Articles 50, 51 and 55 of the present Law a license is given for use of the subject-matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement is waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The Registrar shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to review by the Court.

CZECH REPUBLIC

Act No. 527/1990 of November 27, 1990, on Inventions and Rationalization Proposals (as amended by No. Act No. 378/2007 Coll.)

Section 20

§ 20

Compulsory licence

(1) If the proprietor of the patent unreasonably does not exploit the invention at all or exploits it insufficiently and he did not accept a due offer for a licence agreement in a reasonable term, the Office, upon the justified request, may grant a non-exclusive right to use the invention (compulsory licence); the compulsory licence may not be granted before the expiry of the period of 4 years as from the filing date of the invention application or 3 years as from the grant of the patent; whichever period expires last.

(2) The compulsory licence may be also granted, where an important public interest is endangered.

(3) The Office shall establish conditions, the scope and duration of the compulsory licence in its decision concerning the granting of the compulsory licence, taking into account circumstances of the case. The compulsory licence may be granted mainly for the supply of the home market.

(4) The compulsory licence may only be assigned within the transfer of the enterprise or its part, where the entrepreneur uses the invention based on the compulsory licence (thereinafter "compulsory licence holder").

(5) The compulsory licence holder may waive the right to use the invention during the term of duration of the compulsory licence by notification made to the Office; on the day of delivery of the notification, the effect of decision on the grant of compulsory licence lapses.

(6) The Office shall revoke a compulsory licence or change conditions, scope or duration of the compulsory licence on the request of the proprietor of the patent in which he shall prove that conditions for the grant of compulsory licence have been changed and are unlikely to recur or the holder does not exploit the compulsory licence during one year or does not implement conditions established by the grant of the compulsory licence.

(7) The grant of a compulsory licence shall not affect the right of the proprietor of the patent for the compensation of the value of the licence. If the value of the licence is not agreed by concerned parties it shall be determined, upon request, by the court, taking into account the importance of the invention and the value of the licence contracts in the relevant technical field.

(8) The compulsory licence shall be recorded in the Patent Register (Section 69).

DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA

Law on Inventions of the Democratic People's Republic of Korea (as amended by Decree No. 597 of March 11, 1999, of the Presidium of the Supreme People's Assembly)

Article 31

Article 31 (Transfer of patent to state)

Where the patented science and technology is needed for the public interest, the state may take over the patent or the right to use the science and technology. In this case, the state shall reimburse the patent owner.

DENMARK

The Consolidate Patents Act (Consolidate Act No. 90 of January 29, 2019)

Sections 45-49

45.-(1) If a patent invention is not worked to a reasonable extent in this country when 3 years have elapsed from the grant of the patent and 4 years have elapsed from the filing of the patent application, any person wishing to work the invention in this country may obtain a compulsory license to do so, unless there are legitimate reasons for failure to work the invention.

(2) The Minister for Trade and Industry may direct that for the purposes of subsection 1 hereof working of the invention in another country shall be equivalent to working in this country. Such a provision may be made subject to reciprocity.

46.-(1) The proprietor of a patent for an invention, the use of which is dependent on a patent or a registered utility model which belongs to another person may obtain compulsory license for use of the protected invention of the latter patent or the protected model on utility model registration if the former invention makes up an essential technical progress of substantial economic importance.

(2) The proprietor of the patent of the invention or of the registered utility model for which use compulsory license has been granted pursuant to the provision in (1) shall on reasonable terms be able to obtain compulsory license for use of the other invention.

46a.-(1) An owner of a variety who cannot acquire or exploit a plant variety right without infringing a prior patent may apply for a compulsory license for use of the invention, if the compulsory license is necessary for the exploitation of the plant variety to be protected, against payment of an appropriate royalty. Compulsory license will only be granted provided that the owner of the variety proves that the variety constitutes essential technical progress of substantial economic importance in relation to the invention.

(2) Where, under the Danish Plant Variety Protection Act, a proprietor of a patent has obtained a compulsory license to exploit a protected plant variety, the owner of the plant variety has the right, on reasonable terms, to obtain cross-license for use of the invention.

47. When required by important public interests, any person who wishes to exploit an invention commercially for which another person holds a patent may obtain a compulsory license to do so.

48.-(1) Any person who, in this country, at the time when a patent application was made available to the public, was commercially exploiting the invention for which a patent is applied for, may, if the application results in a patent, obtain a compulsory license to exploit the invention, if very special circumstances make it desirable, and he had no knowledge and could not reasonably have obtained any knowledge of the application. Such a right shall also, under similar conditions, be enjoyed by any person who had made substantial preparations for commercial exploitation of the invention in this country.

(2) Such a compulsory license may include the time preceding the grant of the patent.

(3) The Minister for Business and Industry may direct that for the purposes of subsection 1 hereof exploitation of the invention in another country shall be equivalent to exploitation in this country. Such a provision may be made subject to reciprocity.

49.-(1) Compulsory license shall only be granted to persons who by agreement have not been able to obtain license on reasonable terms and who may be regarded as being able to make use of the invention in a reasonable and proper manner and in compliance with the license.

(2) A compulsory license shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licenses to others.

(3) Compulsory license can only be transferred to others together with the establishment in which it is used or in which the utilisation was intended. For compulsory license filed in accordance with Section 46(1) it shall moreover be applicable that transfer of compulsory license shall take place together with the patent the use of which is dependent on a patent or a registered utility model which belongs to another person.

(4) Compulsory license concerning semiconductor technology can only be filed for public, non-commercial use or for terminating an anti-competitive practice, which has been established by decree or administrative decision.

DJIBOUTI

Law No. 50/AN/09/6th L of July 19, 2009, on the Protection of Industrial Property

Articles 60-69

Subsection II Compulsory licenses

Article 60

Any person or entity under public or private law may, three years after the patent is granted or four years after the date on which the patent is applied for, obtain from the court a compulsory license for such patent, on the conditions provided for in Articles 61 and 62 below, if at the time of the request, and failing legitimate reasons, neither the owner of the patent or his successor in title: (TRANSLATOR,S NOTE – TEXT MISSING FROM ORIGINAL)

Article 61

Applications for compulsory licenses shall be lodged with the court. They must be accompanied by proof that the applicant has not been able to obtain from the patent owner a license to work by mutual agreement, in particular on reasonable commercial conditions and arrangements.

This proof shall not be required in the cases provided for in the following paragraph.

At any time, the court may, even without the approval of the owner of the patent, authorize a government agency or a third person designated by the court to work the invention if:

(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires,

(ii) it is determined that the manner of working of the invention or other use of the patent, by the owner of the patent or his licensee, shall be anti-competitive or constitute an abuse of the exclusive rights granted under the patent.

In the cases provided for in the previous paragraph, as well as in any case of public use for non-commercial purposes or in situations of national emergency, the patent owner shall nonetheless be informed of the decision as soon as is reasonably possible.

Article 62

Compulsory licenses may only be non-exclusive.

Compulsory licenses shall be non-exclusive and non-transferable, except with that part of the enterprise or goodwill that enjoys such use.

Any compulsory license shall be granted primarily to supply the Djiboutian market, except in the event of application of Article 31bis of the TRIPS Agreement.

They shall be granted on conditions set by the court, in particular with regard to their duration and scope, which shall be limited to the purposes for which the licenses have been granted, and shall be subject to payment of an appropriate royalty to the patent owner. Such royalties shall be fixed, taking into consideration the economic value of the working of the patent, as determined in the court's decision or given the need to correct anti-competitive or abusive practices.

These conditions may be amended by the court at the request of the patent owner or licensee.

These conditions for the granting of this compulsory license may be amended by the court at the request of the patent owner or licensee.

Article 63

Where the circumstances which led to the granting of the compulsory license no longer remain and will in all likelihood not recur, the license to work may be withdrawn on the condition that licensees' legitimate interests are adequately protected. The court may review, upon the substantiated request of any party having an interest therein, whether these circumstances still exist.

Article 64

Court decisions which have become final and have been taken pursuant to the provisions of this Subsection II must be immediately notified to the Djibouti Office of Industrial and Commercial Property, which shall enter them in the National Register of Patents.

Article 65

The beneficiary of a compulsory license may obtain from the court, on the conditions provided for in Articles 60 to 62 above, failing a mutual agreement, a compulsory license for a certificate of addition deriving from the patent itself even if such certificate has been granted prior to the expiry of the time periods stipulated in Article 60 above.

Article 66

Where an invention protected by a patent cannot be used without infringing the rights deriving from an earlier patent whose owner refuses to grant a license for use on reasonable commercial terms and arrangements, the owner of the subsequent patent may obtain a compulsory license from the court on the same conditions as those provided for in Articles 60 to 62 above, provided that: any application for a non-compulsory license shall be subject to the payment of a set fee.

Article 67

Where public health interests so dictate, patents granted for drugs, for processes to obtain drugs, for goods needed to obtain these drugs or for processes for manufacture of such products, may, where the drugs are made available to the public in quantity or quality that are inadequate or at abnormally high prices, be worked ex officio.

In situations of national emergency or to protect public health, the Government shall import in sufficient quantity and at an affordable cost medicines worked ex officio if it is unable to produce generic medicines itself.

Ex officio working shall be enacted by presidential decree, based on a proposal by the Minister of Health.

Article 68

The decree referred to in Article 67 above shall be notified to the patent owner, to the licensees, where applicable, and to the Djibouti Office of Industrial and Commercial Property, which shall enter it as of right in the National Register of Patents.

Article 69

On the day on which the Decree enacting the ex officio working of a patent is published, any qualified person may request the granting of a so-called "ex officio license" to work.

Such a license shall be requested and granted in the forms fixed by regulation. An ex officio license shall be granted on specific conditions, in particular with regard to its term and scope.

The royalties to which it gives rise shall be left to the discretion of the parties to determine.

Failing an agreement between them, such royalties shall be fixed by the court.

The ex officio license shall come into force on the date of notification of the act granting it to the parties. This act shall be entered as of right in the National Register of Patents. This license shall

be non-exclusive and non-transferable, except with that part of the enterprise or goodwill that enjoys such use.

If an ex officio license has been granted for an invention relating to a pharmaceutical product by an exporter country in the framework of the system described in Article 31bis of the TRIPS Agreement and the annex thereto, and if appropriate payment under the terms of Article 31(h) of that Agreement has been made in that country, the obligation to make another payment for the same product imported into Djibouti shall not apply.

DOMINICA

Patents Act, 1999 (Act 8 of 1999)

Sections 35, 38 and 39

35. (1) Where:

(a) the public interest, in particular national security, nutrition, health, or the development of other vital sectors of the national economy so requires; or

(b) the Minister has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and he is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practise,

The Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Minister's authorisation, as determined in the said decision, and, where a decision has been taken under subsection 1 (b), the need to correct anti-competitive practises.

(3) The Minister shall make his decision after hearing the owner of the patent and any interested person.

(4) A request for the Minister's authorisation to exploit a patented invention shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorisation, a request for contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions within a reasonable time.

(5) Subsection (4) shall not apply in cases of:

(a) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable;

(b) public non-commercial use, and

(c) anti-competitive practices determined as such by the Minister in accordance with subsection (1) (b).

(6) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorised for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive, and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.

(7) The authorisation shall not exclude –

- (i) the conclusion of license contracts by the owner of the patent; or
- (ii) the continued exercise, by the owner of the patent, of his rights under section 33(2); or
- (iii) the grant of a non-voluntary license under section 38.

(8) Where a third person has been designated by the Minister, the authorisation may only be transferred with the enterprise or business of that person or with the part of enterprise or business within which the patented invention is being exploited.

(9) The exploitation of the patented invention by the Government agency or third person designated by the Minister shall be predominantly for the supply of the market of Dominica.

(10) Upon the request of the owner of the patent, of the Government agency or of the third person authorised to exploit the patented invention, the Minister may, after hearing the parties, vary the terms of the decision authorising the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(11) Upon the request of the owner of the patent, the Minister shall terminate the authorisation if he is satisfied, after hearing the parties, that the circumstances which led to his decision have ceased to exist and are unlikely to recur, or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(12) Notwithstanding subsection (11), the Minister shall not terminate the authorisation if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.

38. (1) (a) At any time after the expiration of four years from the date of filing of a patent application or three years from the date of grant of the patent, whichever happens later, any interested person may apply to the Court for the grant of a non-voluntary licence under the patent on the grounds that the patented invention is not being exploited or is being insufficiently exploited by working the invention in Dominica, or by importation into Dominica.

(b) Notwithstanding paragraph (a), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Court that circumstances exist which justify the exploitation or insufficient exploitation of the patented invention in Dominica.

(2) The Court shall, where it grants a non-voluntary licence, fix –

- (a) the scope and function of the licence;
- (b) the time limit within which the licensee must begin to exploit the patented invention; and
- (c) the amount of the remuneration to be paid to the owner of the patent, and the conditions of the payment thereof.

The beneficiary of the non-voluntary licence shall:

- (a) have the right to exploit the patented invention in Dominica in accordance with the Court's order;

39. The powers of the Court on an application under section 38 shall be exercised with a view to ensuring that the inventor or other person beneficially entitled to a patent receives adequate remuneration having regard to the economic value of the licence.

DOMINICAN REPUBLIC

Law No. 20-00 of May 8, 2000, on Industrial Property

Articles 39-48

Article 39.- Exploitation of the Patent

For the effects of Article 41 of this law, exploitation of a patent is understood as follows:

- a) When the patent has been granted for a product or for a procedure for the obtaining of a product, supply to the internal market in reasonable quantity, quality and price, through production in this country and importation.
- b) When the patent has been granted for a procedure not included in subparagraph a), the use of the procedure on a commercial scale in this country.

Article 40.- Compulsory licenses

When a potential user has attempted to obtain the granting of a license from the patent holder under reasonable commercial terms and conditions and such attempts have not been effective after a period of two hundred and ten (210) days, counted from the date on which the respective license was applied for, the General Agency for Industrial Property, after prior hearing of the holder, shall be able to issue compulsory licenses relating to that patent. In all cases that merit it, the National Agency for Industrial Property shall concede compulsory licenses when the interested party demonstrates:

- a) That he/she possesses the technical and economic capacity to confront the exploitation in question. Technical capacity shall be evaluated by the competent authority, in compliance with the specific regulations in the country that exist in each field of activity. Economic capacity shall be understood as the possibility to fulfill the obligation that derive from the exploitation that is to be undertaken.
 - b) When the patent refers to raw material from which a final product is to be developed, that the applicant is able to develop the final product independently or through third parties in the country, save cases in which production is impossible in national territory.
- 2) To determine what is understood by reasonable commercial terms and conditions, the particular circumstances of each case and the economic value of the authorization must be taken into account, keeping in mind the average rate of royalties for the sector in question in contracts for commercial licenses between independent parties.

Article 41.- Compulsory License for Lack of Exploitation

- 1) After three (3) years from the granting of the patent, or four (4) years from the filing of the application, applying whichever term expires later, if the invention has not been exploited or when the exploitation of the same has been interrupted for more than one (1) year without justifiable cause, any person with the ability to exploit the invention may apply to the General Agency for Industrial Property to grant him or her an compulsory license for the patent in question.
- 2) A compulsory license shall not be granted when it is demonstrated that the lack or insufficiency of exploitation is due to fortuitous circumstances or *force majeure*, or to circumstances beyond the will or control of the patent holder and which justify the lack or insufficiency of exploitation. The lack of economic resources and the lack of economic viability of the exploitation are not considered justifying circumstances.

Article 42.- Compulsory Licenses for Anti-competitive Practices

Compulsory licenses shall be granted when the General Agency for Industrial Property has determined that the patent holder has indulged in anti-competitive practices. In such cases, without prejudice to the appeals available to the patent holder, the concession shall be carried out without the need to apply the procedure set forth in numeral 2 of Article 43.

For the purposes of this law, the following practices, among others, are considered to be anti-competitive:

- a) Setting excessive or discriminatory prices for the patented products. In particular, when there are offers of supply to the market at prices significantly lower than those offered by the patent holder for the same product.
- b) Failure to supply the market under reasonable commercial conditions.
- c) Hindrance of commercial or productive activities
- d) The other actions set forth as such by this code and every other action which national legislation typifies as anti-competitive, limiting or restrictive to competition.

Article 43.- Application for and Granting of Compulsory Licenses

1) Any person interested in obtaining a compulsory license must apply for it to the General Agency for Industrial Property. The application must indicate the conditions under which he or she intends to obtain the compulsory license.

2) The person applying for a compulsory license must confirm that he or she has previously requested a contractual license from the patent holder, and has not been able to obtain it under the conditions and within the time limits set forth in Article 40.

It shall not be necessary to fulfill this requirement in cases of national emergency or extreme urgency, or cases of a commercial use of the invention by a public agency. In such cases the patent holder shall be informed without delay of the granting of the license. Nor shall it be necessary to fulfill that requirement when the purpose of the license is to remedy an anti-competitive practice.

3) Without prejudice to that which is set forth in numeral 2, the General Agency for Industrial Property shall notify the patent holder of an application for compulsory license within a period of thirty (30) days, counted as of day of the filing of the application.

4) The patent holder must present his statements and arguments within a time limit no more than sixty (60) days, counted from the date of notification of the application for a compulsory license. If this time limit passes without the holder having expressed himself, the conditions presented by the applicant shall be considered as accepted.

5) In case the holder responds, the General Agency for Industrial Property, after first hearing the parties and if they should not come to agreement, shall set a reasonable remuneration which the patent holder shall receive, which shall be established according to Article 40.

6) The decisions with reference to the granting of these uses must be adopted within one hundred twenty (120) days from the filing of the application and the same shall be appealable. The substantiation of the appeal shall not have the effect of suspension.

Article 44.- Conditions for the Granting of Compulsory Licenses

1) To grant compulsory licenses, the following provisions must be observed:

a) The granting of same must be by the General Agency for Industrial Property.

b) The circumstances of each case shall be considered.

c) The compulsory licenses shall be extended to patents relating to the components and processes permitting their exploitation

d) The granting of these licenses shall not be exclusive.

e) They may not be assigned, except for that part of the company or of its intangible asset that forms part of it.

f) They shall be granted principally to supply the internal market, except in the cases established in Articles 41 and 46.

g) The patent holder shall receive a reasonable remuneration according to the circumstances of each case, taking into account the economic value of the authorization. In determining the amount of the remuneration in cases in which the compulsory licenses have been granted to remedy anti-competitive practices, the necessity of correcting such practices shall be taken into account and the revocation of the grant may be denied if it is considered probable that the conditions that caused that granting have been repeated.

- 2) The person to whom the compulsory license is granted must begin its exploitation within two years of the granting of the license to him.
- 3) When the patent protects any semiconductor technology, compulsory licenses shall be granted only for non-commercial public use, or to rectify a practice declared to be contrary to competition.
- 4) A compulsory license may be completely or partially revoked by the court created by this Code, upon request by the holder, if the circumstances that gave rise to the license have ceased to exist and it is improbable that they will again arise, so long as such revocation does not affect the legitimate interests of the licensee.
- 5) A compulsory license can be modified by the court created by this Code, upon application by an interested party, when so justified by new facts or circumstances.

Article 45.- Compulsory License in the Case of Dependent Patents

- 1) When an invention claimed in a subsequent patent cannot be exploited in this country without infringing an earlier patent, the General Agency for Industrial Property, upon the request of the holder of the first mentioned patent or of his licensee, or of the beneficiary of a compulsory license for that patent, may grant a compulsory license with regard to the earlier patent insofar as may be necessary to avoid the infringement.
- 2) The compulsory license shall be granted only when the invention claimed in the subsequent patent implies an important technical advance of considerable economic significance with regard to the invention claimed in the earlier patent.
- 3) When a compulsory license is granted in conformity with numeral 1, a compulsory license may be granted in the same circumstances with regard to the later patent, if the holder of the earlier patent, his licensee or the beneficiary of a compulsory license for said earlier patent applies for it.
- 4) A compulsory license of those set forth in this article cannot be granted as exclusive. This compulsory license can only be the object of transfer simultaneously with the dependent patent the industrial exploitation of which requires the license. The transfer of the compulsory license shall be subject to the provisions of Article 32, numeral 2, insofar as is appropriate.
- 5) The provisions of Articles 43 and 44, insofar as they are appropriate, are applicable to the licenses set forth in this article.

Article 46.- Public Interest licenses

For reasons of public interest, and in particular for reasons of emergency or national security declared by the Executive Power, the General Agency for Industrial Property, at the request of any interested person or competent authority, or on its own initiative, shall at any time order the following:

- a) that an invention which is the object of a patent or patent application being processed be exploited by a government agency or by one or more public or private persons designated for the purpose.
- b) that an invention that is the object of a patent or of a patent application being processed be open for the granting of licenses in the public interest, in which case the General Agency for Industrial Property shall grant a license for exploitation to any person who applies for it and has the ability to carry out such exploitation in this country.

Article 47.- Conditions for Public Interest Licenses

- 1) Every public interest license implies the corresponding payment to the patent holder. After prior hearing of the parties, and in the absence of an agreement, the amount and method of payment shall be set by the General Agency for Industrial Property, according to Articles 44, literal g).
- 2) A public interest license can refer to the execution of any of the actions referred to in Article 29, numeral 1.
- 3) The provisions of Articles 43 and 44, insofar as appropriate, are applicable to the granting of public interest licenses.

4) The granting of a compulsory license by reason of public interest shall not diminish the right of the patent holder to continue exploiting it.

Article 48.- Revocation of the Patent in Case of Abuse

1) At the request of any interested person or of any competent authority, the General Agency for Industrial Property can revoke a patent when the rights conferred by the patent are abused with regard to anti-competitive practices or abuse of a dominant market position in such a way that the national economy is unduly affected.

2) The request for revocation may not be presented until two years have passed counting from the date of granting of the first compulsory license.

ECUADOR

Decision No. 486 of 14/09/ 2000 of the Commission of the Andean Community - Common Industrial Property Regime (Cartagena Agreement)

(Refer to ANDEAN Community below.)

Ley de Medicamentos Genericos de Uso Humano (modificada al 13 de octubre de 2011)

Articles 1-28

Art. 1.-El Estado promoverá la producción, importación, comercialización y expendio de medicamentos genéricos de uso humano.

Art. 2.- Para efecto de esta Ley, debe entenderse como medicamentos genéricos aquellos que se registran y comercializan con la Denominación Común Internacional (DCI) del principio activo, propuesta por la Organización Mundial de la Salud (OMS) o en su ausencia con una denominación genérica convencional reconocida internacionalmente cuya patente de invención haya expirado. Esos medicamentos deberán mantener los niveles de calidad, seguridad y eficacia requeridos para los de marca.

Capítulo II Del Control de Precios

Art. 3.- Los precios de los medicamentos al consumidor serán establecidos por el Consejo Nacional de Fijación y Revisión de Precios de Medicamentos de Uso Humano. Para el efecto, créase el Consejo Nacional de Fijación y Revisión de Precios de Medicamentos de Uso Humano, adscrito al Ministerio de Salud Pública, con sede en la ciudad de Quito, y jurisdicción en todo el territorio nacional, que estará integrado por los siguientes miembros:

- a. El Ministro de Salud Pública, quien lo presidirá o su delegado permanente;
- b. El Ministro de Comercio Exterior, Industrialización, Pesca y Competitividad, o su delegado permanente; y,
- c. Un delegado de la Federación de Químicos Farmacéuticos y Bioquímicos Farmacéuticos del Ecuador.

Participarán con voz pero sin voto un delegado por cada uno de los siguientes organismos y entidades: ASOPROFAR, ALAFAR, ALFE, Junta de Beneficencia de Guayaquil, Sociedad de Lucha Contra el Cáncer, Federación Nacional de Propietarios de Farmacias del Ecuador y, Federación

Art. 4.-Nota: Artículo derogado por Ley No. 0, publicada en Registro Oficial Suplemento 555 de 13 de Octubre del 2011 .

Art. 5.-El Ministerio de Salud Pública controlará a través del Director General de Salud y las direcciones provinciales de salud, que los precios de venta al público no excedan a los establecidos por el Consejo Nacional de Fijación y Revisión de Precios de Medicamentos de Uso Humano.

Capítulo III De la Adquisición de los Medicamentos Genéricos

Art. 6.- Las entidades del sector público que tengan a su cargo prestaciones y programas de salud, están obligadas a adquirir exclusivamente medicamentos genéricos, de acuerdo al Cuadro Nacional de Medicamentos Básicos que será elaborado por el Consejo Nacional de Salud con las siguientes características para sus beneficiarios con las siguientes excepciones:

- a. Casos de medicamentos especiales que no consten en el Cuadro Nacional de Medicamentos Básicos;
- b. Cuando el medicamento de marca de similar calidad, se ofrezca a menor precio que el medicamento genérico; y,
- c. En caso de emergencia sanitaria debidamente declarada por el Ministro de Salud Pública, y/o las razones de fuerza mayor que no permitan conseguir el respectivo medicamento genérico. Salvo los casos de emergencia médica en que las entidades podrán adquirir sin limitación alguna, las excepciones para adquirir medicamentos de marca en cantidades importantes por parte de las entidades del sector público deberán ser previamente autorizadas por la autoridad de salud inmediata superior.

Art. 7.-Nota: Artículo derogado por numeral 10. de Derogatorias de Ley No. 1, publicada en Registro Oficial Suplemento 395 de 4 de Agosto del 2008 .

Art. 8.-Nota: Artículo derogado por Ley No. 67, publicada en Registro Oficial Suplemento 423 de 22 de Diciembre del 2006 .

Art. 9.-Nota: Artículo derogado por Ley No. 67, publicada en Registro Oficial Suplemento 423 de 22 de Diciembre del 2006 .

Art. 10.-Nota: Artículo derogado por Ley No. 67, publicada en Registro Oficial Suplemento 423 de 22 de Diciembre del 2006 .

Capítulo V Del Control de Calidad

Art. 11.-Nota: Artículo derogado por Ley No. 67, publicada en Registro Oficial Suplemento 423 de 22 de Diciembre del 2006 .

Capítulo VI De la Promoción

Art. 12.- El Consejo Nacional de Salud elaborará y publicará periódicamente el Registro Terapéutico Nacional que deberá ser actualizado permanentemente y contendrá la descripción de todos los medicamentos genéricos, tanto nacionales como importados, cuyo consumo esté autorizado en el país, con la descripción de sus propiedades, su denominación genérica y sus equivalentes de marca.

Art. 13.- El Ministerio de Salud Pública difundirá permanentemente el Registro Terapéutico Nacional entre los profesionales de la medicina y el personal que labore en establecimientos farmacéuticos. Con la colaboración de los medios de comunicación colectiva realizará campañas de difusión sobre las ventajas que esta Ley implica para los consumidores.

Art. 14.- En el desempeño de sus labores, en hospitales, clínicas, dispensarios, consultorios públicos y privados, los profesionales de la salud, tienen la obligación de prescribir en sus recetas el nombre del medicamento de marca y el genérico respectivo. Se exceptúan los casos de emergencia médica.

Art. 15.- Los establecimientos autorizados para la comercialización y venta al público de medicamentos de uso humano, están obligados a ofrecer en venta el equivalente genérico del fármaco de marca solicitado por el usuario.

Art. 16.- Los laboratorios farmacéuticos nacionales, deberán producir al menos el veinte por ciento de medicamentos genéricos de acuerdo a su especialidad.

Art. 17.- Se prohíbe cualquier forma de propaganda negativa directa o indirecta sobre medicamentos genéricos.

Art. 18.- Concédase acción popular para denunciar el incumplimiento de las disposiciones contenidas en esta Ley. Su control corresponderá a la Dirección General de Salud Pública, a través de los organismos seccionales correspondientes. Los valores recaudados por concepto de multas, serán destinados a promocionar el uso de medicamentos genéricos.

Capítulo VII Infracciones y Sanciones

Art. 19.- Las personas naturales o representantes de personas jurídicas que produzcan medicamentos genéricos o de marca que no cumplan con las normas de calidad, cantidad y eficacia terapéutica, serán sancionados con la pena de seis (6) meses a un (1) año y con multa de quince mil (15.000) dólares de los Estados Unidos, según corresponda la gravedad de la infracción. En caso de reincidir se dispondrá la suspensión del permiso de funcionamiento del laboratorio o establecimiento por el lapso de un (1) año, sin perjuicio de las acciones penales a que hubiere lugar.

Art. 20.- El proveedor que dolosamente importe medicinas que no reúnan las normas de calidad, cantidad, eficacia y seguridad, serán reprimidos con prisión de seis (6) meses a un (1) año y con multa de quince mil (15.000) dólares de los Estados Unidos, y no podrá volver a intervenir en la celebración de contratos de suministro de medicina de uso humano con entidades pertenecientes al sector público y privado.

Art. 21.- Serán sancionados con prisión de un (1) mes a un (1) año y multa de quince mil (15.000) dólares de los Estados Unidos, quienes vendan, adquieran o reciban a nombre de entidades del sector público, medicinas cuya fecha de expiración sea menor a un (1) año contado a partir de su recepción, excepto productos que por su naturaleza se degradan.

Art. 22.- El Ministro de Salud Pública, sancionará al Director del Instituto Nacional de Higiene y Medicina Tropical Leopoldo Izquieta Pérez, o a quien hiciera sus veces, con un (1) mes sin remuneración, en caso de que no dicte la resolución a la que se refiere el artículo 10 de esta Ley, dentro del plazo previsto. En caso de reincidencia, la sanción será de dos (2) meses sin remuneración. Si la reiteración fuere por tercera ocasión, la sanción será la destitución del cargo.

Art. 23.- Los profesionales de la salud que incumplan con lo dispuesto en el artículo 14 de esta ley, serán sancionados con multa de veinticinco (25) a cincuenta (50) dólares de los Estados Unidos. En caso de reincidencia, la multa será el doble de la impuesta la primera vez. Si el incumplimiento de tal obligación fuere por tercera ocasión, la sanción será la suspensión del ejercicio de la profesión por el lapso de treinta (30) a noventa (90) días, sanciones que serán impuestas por el Ministerio de Salud Pública previo informe del Tribunal de Honor de los respectivos colegios médicos.

Art. 24.- Serán sancionados con multa de cincuenta (50) a quinientos (500) dólares de los Estados Unidos, los propietarios de establecimientos farmacéuticos, representantes de personas jurídicas que se dediquen a la comercialización de fármacos que no mantengan en existencia el equivalente genérico de los medicamentos de marca que soliciten los usuarios, salvo aquellos que no se comercialice en el país, o no consten en el Cuadro Nacional de Medicamentos Básicos.

En caso de reincidencia, la multa será el doble de la impuesta la primera vez. Si incurriere por tercera ocasión en la misma infracción, la sanción será la suspensión del permiso de funcionamiento del local por seis (6) meses.

Art. 25.- Serán sancionados con prisión de seis (6) meses a dos (2) años y multa de dos mil (2.000) a diez mil (10.000) dólares de los Estados Unidos, los representantes o administradores de establecimientos farmacéuticos, laboratorios nacionales y extranjeros, proveedores de medicinas, tanto de marca como genéricos; que elevaren el precio de venta sobre los precios oficialmente fijados y el margen de utilidad establecido por el Consejo Nacional de Fijación y Revisión de Precios de Medicamentos de Uso Humano. El Director General de Salud exigirá el cumplimiento de los precios oficiales de venta al público y hará pública su resolución, a costa de los infractores. En caso de reincidencia, la multa será el doble de la que le hubiere sido impuesta la primera vez y la clausura definitiva del establecimiento que hubieren motivado el alza o la suspensión del permiso de importación en su caso.

Art. 26.- Serán sancionados con multa de dos mil (2.000) a diez mil (10.000) dólares de los Estados Unidos, quienes incumplieren lo dispuesto en los artículos 15 y 17 de esta ley. En caso de reincidencia la multa será el doble de la que le hubiere sido impuesta la primera vez y si es por tercera vez, la clausura del local farmacéutico.

Art. 27.- Será sancionado con prisión de seis (6) meses a dos (2) años todo acuerdo fraudulento entre productores y/o importadores, y/o distribuidores y/o vendedores de medicinas de uso humano, tendiente a perjudicar al consumidor y producir un incremento injustificado de precio.

Art. 28.- La facultad resolutive y sancionadora contemplada en esta Ley, en materia administrativa la tendrá el Ministro de Salud Pública y el Director General de Salud, quienes podrán delegarla a los directores provinciales de salud.

EGYPT

Law No. 82 of 2002 on the Protection of Intellectual Property Rights

Articles 23-25

Article 23

The Patent Office may, subject to the approval of a ministerial committee to be established by a decision of the Prime Minister, grant non-voluntary licenses for the exploitation of an invention. The committee decides the financial rights of the patent owner when such licenses are issued, in any of the following cases:

(1) Where the competent Minister finds — under the circumstances — that the exploitation of the patent will benefit the following:

(a) Public non-commercial interest. This includes the preservation of national security, health, environment and food safety.

(b) Cases of emergency or circumstances of extreme urgency.

A non-voluntary license to counter the conditions mentioned in items 1 and 2 is granted without prior negotiations with the patent owner or after a certain period of negotiations with the patent owner or offering reasonable conditions to acquire his agreement to the exploitation.

(c) Support of national efforts in vital sectors for economic, social and technological development, without unreasonable prejudice to the rights of the patent owner and taking into consideration the legitimate interests of third parties.

In cases stated in items 1 and 3, the owner of the patent shall be notified promptly of the decision of non-voluntary exploitation, and as soon as reasonably practicable in cases stated in item 2 .

(2) Upon the request of the Minister of Health, when the quantity of patented medicines made available fail to adequately meet the national needs, due to their poor quality or if they are offered at a prohibitive price, or if the patent is related to medicines addressing critical cases, incurable or endemic diseases or products used in the prevention of these diseases, or where the invention is related to the medicines, their manufacturing process, the raw materials necessary for their preparation or the process of manufacturing of those materials.

In all these cases, the decision of granting non-voluntary license shall be notified promptly to the owner of the patent.

(3) Where the patent owner refuses to grant license to a third party seeking the exploitation of the invention, whatever the purpose of the exploitation, and despite the offer of suitable terms and the lapse of reasonable negotiation time.

In this case, the party requesting the non-voluntary license shall provide evidence that he has made serious efforts to obtain a voluntary license from the patent owner.

(4) If the owner of the patent fails to exploit the invention in Egypt, himself or through his consent; or if the patent was not sufficiently exploited after the lapse of four years since the date of the application or three years since the grant of the patent, whichever comes later; or if the patent owner suspended, without a valid reason, the exploitation of the patent for more than one year.

The exploitation of a patent shall be through the manufacturing of the patented product or the use of the patented process in Egypt.

Nevertheless, where the Patent Office finds that, despite the expiration of either of the above mentioned time limits, failure to exploit the invention was due to legal, technical or economic reasons beyond the power of the owner of the patent, it may decide to allow him a sufficient period of grace for the exploitation of the invention.

(5) If it is determined that the patent owner has abused of or exercised the rights conferred by the patent in a manner that is contrary to fair competition, such as:

- (a) Fixing exorbitant prices for the patented products or preferential treatment of agents with regards to prices and sales conditions.
- (b) Failure to supply the local market with the patented product, or supplying it under prohibitive terms.
- (c) Stopping the production of the patented item or its production in a disproportionate manner, given the production capacity and the market needs.
- (d) Undertaking acts or practices which have adverse effect on the free competition, according to the prescribed legal norms.
- (e) Exercising of the rights conferred by the this Law in a manner that adversely affects the transfer of technology.

In all above cases, the non-voluntary license is granted without recourse to negotiation or the expiry of a time limit thereto, even if the non-voluntary license is not intended to satisfy the needs of the domestic market.

The Patent Office may refuse to terminate the non-voluntary license, where the conditions that called for it are likely to remain or to reoccur.

The compensation due to the owner of the patent shall take into account the prejudice caused by his arbitrary or unfair competition practices.

The Patent Office may revoke the patent if, two years after the grant of a non-voluntary license, it became clear that the grant of that license was not adequate to remedy the adverse effects caused to the national economy by the r the patent owner's abuse of his rights or his unfair competition practices.

Any concerned party may challenge the revocation of a patent before the Committee provided for in Article 36, and in accordance with the conditions and procedures prescribed in the Regulations.

(6) Where the exploitation of an invention by the legitimate patent holder requires inevitably the use of another invention, underlying concrete technical advance as well as technical and economical significance compared to the other, he shall be entitled to obtain a non-voluntary license for the exploitation of the other invention, in which case the other patent holder shall equally have the same right.

The licensed exploitation of one patent may not be assigned without the corresponding assignment of the other.

(7) The grant of a non-voluntary license in the field of semi-conductor technology shall be authorized for public non-commercial purposes only, or to remedy the consequences of any unfair competition practices.

The grant of non-voluntary licenses in the cases provided for in this Article, shall be in accordance with the rules and procedures prescribed in the Regulations.

Article 24

Where a non-voluntary license is to be issued, the following elements shall be taken into account:

(1) A request for the grant of the non-voluntary license shall be considered on the merits of each case. The license shall mainly seek to satisfy the needs of the domestic market.

(2) The requesting party shall prove that he has made serious attempts during a reasonable period of time to obtain a voluntary license from the patent holder against fair compensation, and that he failed.

(3) The patent owner may, within one month from his notification of the grant of the license, appeal to the Committee provided for in Article 36 and in accordance with the conditions and procedures stipulated by the Regulations, against the decision to grant the non-voluntary license to a third party.

(4) The party requesting the grant of a non-voluntary license, or the party to whom a non-voluntary license is granted, must have the capacity to efficiently exploit the invention in Egypt.

(5) The licensee must abide by the scope, terms and period prescribed by the decision granting the such a license. The Patent Office may extend the duration of the license if it expires without achieving its purpose.

(6) The use of the non-voluntary license shall be limited to the applicant; the Patent Office may however grant it to a third party.

(7) The beneficiary shall not assign the rights of a non-voluntary license to a third party except with the enterprise or the part related to the exploitation of the patent.

(8) The patent owner shall be entitled to a fair compensation for the exploitation of his invention. The amount of the compensation shall be fixed on the basis of the economic value of the invention. He shall have the right to appeal against the compensation assessment, within 30 days of being notified the decision, before the Committee provided for in Article 36, in accordance with the rules and procedures prescribed by the Regulations.

(9) The non-voluntary license shall lapse on the expiry of its duration. Nonetheless, the Patent Office may decide to terminate the non-voluntary license if the reasons which led to its grant cease to exist and are unlikely to reoccur; in which case, the procedure prescribed by the Regulations shall apply.

(10) The patent owner may request the termination of the non-voluntary license before its expiry, if the reasons which led to its grant cease to exist and are unlikely to reoccur.

(11) Where a non-voluntary license is terminated before its term, the legitimate interests of the licensee shall be taken into account.

(12) The non-voluntary license may be terminated or its terms amended by the Patent Office, or upon a request from any interested party, if within two years after the grant of the non-voluntary license, the licensee fails to exploit the subject matter of the license or to meet his obligations as prescribed by the license.

Article 25

Patents may be expropriated by decision of the competent Minister - subject to the approval of the ministerial committee referred to in Article 23 - on grounds relating to national defence and in cases of emergency which the grant of a non-voluntary license is insufficient to counter.

The expropriation may be limited to the right of exploitation only to satisfy the needs of the State.

In all cases, the expropriation shall be against a fair compensation, to be assessed by the committee provided for in Article 36 and on the basis of the economic value of the patent at the time the expropriation decision is made.

The expropriation decision shall be published in the Patent Gazette. The decision of the expropriation and that of the compensation assessment committee may be appealed before the Administrative Court, within 60 days from the date of notification of the decision to the interested party, by means of a registered letter with acknowledgement of receipt. The Court shall decide on such an appeal expeditiously.

EL SALVADOR

Law on Intellectual Property 1993 (as amended up to Legislative Decree No. 611 of February 15, 2017)

Articles 133-135

Art. 133. When reasons of emergency or national security have been declared and for as long as they persist, compulsory licenses may be granted for the exploitation of patents, provided that such grant is necessary to satisfy the basic needs of the population.

Licenses granted under the foregoing paragraph shall be neither transferable nor exclusive.

Art. 134. Compulsory licensing to be granted by the competent court, in accordance least the following:

- a) the scope of the license, its validity and acts for which granted, to be limited to the purposes of the rise;
- b) the amount and payment of remuneration due to patent holder;
- c) the necessary steps to fulfill its purpose license conditions; y
- d) compulsory license to supply the domestic market is granted.

where the patent protects any semiconductor technology, compulsory licenses granted only for public non-commercial use or for grinding a practical declared contrary to competition in the procedure. (1)

Art. 134-a.- a request of the holder of the patent, the competent court may revoke the compulsory license if the circumstances that led to its granting have disappeared, for which take the necessary precautions to protect the legitimate interests licensors. to this effect, besides the evidence submitted by the holder of the patent, it collects the information deemed necessary to verify those facts. (one)

Art. 135.- the holder of the patent or certificate may be granted by agreement, licenses for exploitation, which must be registered in the, for it to take effect against third parties. (one).

ESTONIA

Patents Act (consolidated text of January 1, 2015)

Section 47

§ 47. Compulsory licence

(1) A person who is interested in using a patented invention and is capable of doing so in the Republic of Estonia, may, upon refusal of the proprietor of the patent to grant a licence, file an action with a court for acquiring a compulsory licence if:

- 1) the proprietor of the patent has not used the invention in the Republic of Estonia within three years from the publication of the notice concerning the grant of the patent or within four years from the filing of the patent application, and in such case the term which will expire later shall apply;
- 2) the proprietor of the patent does not use the invention to an extent corresponding to the needs of the domestic market of the Republic of Estonia;
- 3) the patent hinders the use of another, technically advanced invention significant for the economy of the Republic of Estonia;

4) national defence, environmental protection, public health and other significant national interests of the Republic of Estonia require the use of the invention, including the need to use the invention in connection with a natural disaster or other emergency.

5) the patent hinders the grant of plant variety rights pursuant to the Plant Propagation and Plant Variety Rights Act or the use of the protected variety.

[RT I 2005, 70, 540 – entry into force 01.01.2006]

(1¹) A compulsory licence shall not be granted if the proprietor of a patent imports the product protected by the patent from any member state of the World Trade Organisation to an extent corresponding to the needs of the domestic market of the Republic of Estonia.

(2) In the case provided for in clause (1) 3) of this section, the proprietor of a patent has the right to acquire a compulsory licence for another invention, unless the exchange of licences is agreed on (cross-licence).

(3) Upon the grant of a compulsory licence, a court shall determine the terms and conditions of the compulsory licence, including the extent and duration of the use of the invention and the amount and procedure for payment of the licence fee. The extent and duration of the use of the invention shall be determined on the basis of the needs of the domestic market of the Republic of Estonia.

(4) The right to use an invention on the basis of a compulsory licence may transfer to another person only together with the enterprise in which the compulsory licence is used or was intended to be used pursuant to the terms of the compulsory licence.

(5) The grant of a compulsory licence does not hinder the proprietor of a patent from using the invention or granting licences to other persons.

(6) A compulsory licence is valid as of the date of making an entry in the register. A request for the making of a register entry together with a copy of the court judgment and information on payment of the state fee shall be filed with the Patent Office within one month after entry into force of the court judgment.

(7) If circumstances change, both the licensor and the licensee may file an action with a court for amendment of the terms of the compulsory licence.

(8) Regulation (EC) No 816/2006 of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 09.06.2006, pp. 1-7) applies to filing an action for acquiring a compulsory licence for the manufacture of pharmaceutical products protected by a patent for import or export.

[RT I 2009, 4, 24 – entry into force 01.03.2009]

§ 47¹. National non-commercial use

(1) A patented invention may be used by the Government of the Republic or a third person authorised by the Government of the Republic without the permission of the proprietor of the patent in the event of an epidemic within the meaning of the Communicable Diseases Prevention and Control Act and in an emergency situation within the meaning of the Emergency Situation Act (hereinafter national non-commercial use).

(2) National non-commercial use may include the activities specified in § 15 of this Act.

(3) The conditions for making decisions concerning national non-commercial use and for grant of compensation to the proprietor of a patent are provided by law.

[RT I 2009, 4, 24 – entry into force 01.03.2009]

ESWATINI

Patents, Utility Models and Industrial Designs Act No. 6 of 1997

Section 12

Rights conferred by patent, ARIPO Protocol patents, exploitation by Government or person thereby authorised.

12. (1) The exploitation of the patented invention in Swaziland by persons other than the owner of the patent shall require the latter's agreement.

(2) For the purposes of this Act, "exploitation" of a patented invention means any of the following acts -

(a) when the patent has been granted in respect of a product -

(i) making, importing, offering for sale, selling and using the product;

(ii) stocking such products for the purposes of offering for sale, selling or using;

(b) when the patent has been granted in respect of a process -

(i) using the process;

(ii) doing any of the acts referred to in paragraph (a) in respect of a product obtained directly by means of the process.

(3) The owner of the patent shall, in addition to any other rights, remedies or actions available to him, have the right, subject to subsection (4) and (6) and section 14 t to institute court-proceedings against any person who infringes the patent by performing, without his agreement, any of the acts referred to in subsection (2) or who performs acts which make it likely that infringement will occur.

(4) The rights under the patent shall not extend to:

(a) acts in respect of articles which have been put on the market in Swaziland by the owner of the patent or with his consent;

(b) the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Swaziland; or

(c) acts done for experimental purposes relating to a patented invention;

(d) acts performed by any person who in good faith, before the filing of, where priority is claimed, the priority date of application on which the patent is granted and In Swaziland, was using the invention or making effective and serious preparations for such use. to the extent such acts do not differ in nature or purpose from the: actual or envisaged prior use and provided that the right of prior user referred to 'herein may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business in which the use or preparations for use or have been made.

(5) A patent in respect of which Swaziland is a designated State, granted by ARIPO by virtue of the ARIPO Protocol, shall have the same effect in Swaziland as a patent under this Act unless the Registrar of Patents has communicated to ARIPO. in respect of the application therefor: a decision in accordance with the provisions of the Protocol, that if a patent is granted by AR1PO that patent shall have no effect in Swaziland.

(6) (a) Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires, the Minister may decide that even without the agreement of the owner of the patent, a government agency or a third person designated by the Minister may exploit the invention, subject to the payment of an equitable remuneration to the said owner therefor.

(b) The decision of the Minister may be appealable before the court within three (3) months from the date it was made.

ETHIOPIA

Inventions, Minor Inventions and Industrial Designs Proclamation No. 123/1995

Sections 29-33

29. Application for a Compulsory License

1. The patentee whose invention cannot be worked effectively without the invention patented earlier may apply for a compulsory license to use the earlier invention.
2. The earlier patentee whose invention cannot be worked effectively without the later invention may apply for a compulsory license to use the later invention.
3. Any person who is capable of working a patented invention may apply for a compulsory license, where the patentee fails, without legitimate reason to justify his inaction, to work his invention in Ethiopia, after the expiration of a period of three years from the date of grant of the patent or four years from the date of filing of the patent application which ever expires last.

30. Grant of Compulsory License

1. Where the Commission finds the request to be satisfactory, it shall grant a compulsory license.
2. The grant of a compulsory license shall not exclude the exploitation of the invention, the conclusion of license contracts by the owner of the patent or the grant of other compulsory licenses.
3. The decision made by the compulsory license shall be in the official gazette.
Commission to grant a registered and announced

31. Proof Required of the Applicant

The person requesting for a compulsory license to exploit an invention shall furnish proof that he has not been able to conclude a license contract with the patentee for the exploitation of the invention on reasonable terms.

32. Limitation of Rights of Licensee

1. Any person who is granted compulsory license for the exploitation of a patented invention shall not have an exclusive right of over the invention and shall not have a right to authorize exploitation by any other person.
2. The licensee shall have the right to exploit the patented invention in Ethiopia according to the terms set out in the decision- granting the license, and shall commence the working of the patented invention within the time limit fixed in the said decision.

33. Exploitation Fee

1. Any person who is granted a compulsory license shall pay the patentee a reasonable exploitation fee, the amount of which shall be fixed by both parties.
2. Where the parties disagree on the amount of fee, it shall be fixed by the Commission.

FINLAND

Patenttilaki 15.12.1967/550 (muutettu lailla 5.08.2016/717)

Sections 45-50

Section 45 - Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may

obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown. (22.12.1995/1695)

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

Section 46 - The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons.

The proprietor of a patent in respect of which a compulsory licence is granted under subsection (1) of this Section may obtain a compulsory licence to exploit the other invention unless there are special reasons to the contrary.

Section 46 a (30.6.2000/650) - Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

Applicants for the licence referred to in subsection 1 above must demonstrate that they have applied unsuccessfully to the holder of the patent to obtain a contractual licence and that the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.

Provisions concerning the right of a patent holder to obtain a compulsory licence for the exploitation of a plant variety protected by plant breeder's right are laid down by the Act on Plant Breeders' Rights (No. 789/1992).

Section 47 - In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so.

Section 48 - Any person who was commercially exploiting in this country an invention which is the subject of a patent application, at the time the application documents were made available under Section 22, shall, if the application results in a patent, be entitled to a compulsory licence for such exploitation, provided there are special reasons for this and also provided that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such a right shall also be enjoyed, under corresponding conditions, by any person who has made substantial preparations for commercial exploitation of the invention in this country.

Compulsory licences may also relate to the period of time preceding the grant of the patent.

Section 49 (22.12.1995/1695) - A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited.

Section 50 - Compulsory licences shall be granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid and any other conditions under the licence. In the event of a substantial change in the circumstances, the court may, on request, revoke the licence or lay down new conditions.

FRANCE

Code de la propriété intellectuelle (version consolidée au 25 mars 2019)

Articles L613-11–L613-20

Article L613-11

Toute personne de droit public ou privé peut, à l'expiration d'un délai de trois ans après la délivrance d'un brevet, ou de quatre ans à compter de la date du dépôt de la demande, obtenir une licence obligatoire de ce brevet, dans les conditions prévues aux articles suivants, si au moment de la requête, et sauf excuses légitimes le propriétaire du brevet ou son ayant cause :

- a) N'a pas commencé à exploiter ou fait des préparatifs effectifs et sérieux pour exploiter l'invention objet du brevet sur le territoire d'un Etat membre de la Communauté économique européenne ou d'un autre Etat partie à l'accord sur l'Espace économique européen ;
- b) N'a pas commercialisé le produit objet du brevet en quantité suffisante pour satisfaire aux besoins du marché français. Il en est de même lorsque l'exploitation prévue au a ci-dessus ou la commercialisation prévue au b ci-dessus a été abandonnée depuis plus de trois ans. Pour l'application du présent article, l'importation de produits objets de brevets fabriqués dans un Etat partie à l'accord instituant l'Organisation mondiale du commerce est considérée comme une exploitation de ce brevet.

Article L613-12 La demande de licence obligatoire est formée auprès du tribunal de grande instance : elle doit être accompagnée de la justification que le demandeur n'a pu obtenir du propriétaire du brevet une licence d'exploitation et qu'il est en état d'exploiter l'invention de manière sérieuse et effective. La licence obligatoire est accordée à des conditions déterminées, notamment quant à sa durée, son champ d'application et le montant des redevances auxquelles elle donne lieu. Ces conditions peuvent être modifiées par décision du tribunal, à la requête du propriétaire ou du licencié.

Article L613-13

Les licences obligatoires et les licences d'office sont non exclusives. Les droits attachés à ces licences ne peuvent être transmis qu'avec le fonds de commerce, l'entreprise ou la partie de l'entreprise auquel ils sont attachés.

Article L613-14

Si le titulaire d'une licence obligatoire ne satisfait pas aux conditions auxquelles cette licence a été accordée, le propriétaire du brevet et, le cas échéant, les autres licenciés peuvent obtenir du tribunal le retrait de cette licence.

Article L613-15

Le titulaire d'un brevet portant atteinte à un brevet antérieur ne peut exploiter son brevet sans l'autorisation du titulaire du brevet antérieur ; ledit titulaire ne peut exploiter le brevet postérieur sans l'autorisation du titulaire du brevet postérieur. Lorsque le titulaire d'un brevet ne peut l'exploiter sans porter atteinte à un brevet antérieur dont un tiers est titulaire, le tribunal de grande instance peut lui accorder une licence d'exploitation du brevet antérieur dans la mesure nécessaire à l'exploitation du brevet dont il est titulaire et pour autant que cette invention constitue à l'égard du brevet antérieur un progrès technique important et présente un intérêt économique considérable. La licence accordée au titulaire du brevet postérieur ne peut être transmise qu'avec ledit brevet. Le titulaire du brevet antérieur obtient, sur demande présentée au tribunal, la concession d'une licence réciproque sur le brevet postérieur. Les dispositions des articles L. 613-12 à L. 613-14 sont applicables.

Article L613-15-1

Lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, il peut demander la concession d'une licence de ce brevet dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger et pour autant que la variété constitue à l'égard de l'invention revendiquée dans ce brevet un progrès technique important et présente un intérêt économique considérable. Lorsqu'une telle licence est accordée, le titulaire du brevet obtient à des conditions équitables, sur demande présentée au tribunal, la concession d'une licence réciproque pour utiliser la variété protégée. Les dispositions des articles L. 613-12 à L. 613-14 sont applicables.

Article L613-16

Si l'intérêt de la santé publique l'exige et à défaut d'accord amiable avec le titulaire du brevet, le ministre chargé de la propriété industrielle peut, sur la demande du ministre chargé de la santé publique, soumettre par arrêté au régime de la licence d'office, dans les conditions prévues à l'article L. 613-17, tout brevet délivré pour :

- a) Un médicament, un dispositif médical, un dispositif médical de diagnostic in vitro, un produit thérapeutique annexe ;
- b) Leur procédé d'obtention, un produit nécessaire à leur obtention ou un procédé de fabrication d'un tel produit ;
- c) Une méthode de diagnostic ex vivo. Les brevets de ces produits, procédés ou méthodes de diagnostic ne peuvent être soumis au régime de la licence d'office dans l'intérêt de la santé publique que lorsque ces produits, ou des produits issus de ces procédés, ou ces méthodes sont mis à la disposition du public en quantité ou qualité insuffisantes ou à des prix anormalement élevés, ou lorsque le brevet est exploité dans des conditions contraires à l'intérêt de la santé publique ou constitutives de pratiques déclarées anticoncurrentielles à la suite d'une décision administrative ou juridictionnelle devenue définitive. Lorsque la licence a pour but de remédier à une pratique déclarée anticoncurrentielle ou en cas d'urgence, le ministre chargé de la propriété industrielle n'est pas tenu de rechercher un accord amiable.

Article L613-17

Du jour de la publication de l'arrêté qui soumet le brevet au régime de la licence d'office, toute personne qualifiée peut demander au ministre chargé de la propriété industrielle l'octroi d'une licence d'exploitation. Cette licence est accordée par arrêté dudit ministre à des conditions déterminées, notamment quant à sa durée et son champ d'application, mais à l'exclusion des redevances auxquelles elle donne lieu. Elle prend effet à la date de la notification de l'arrêté aux parties. A défaut d'accord amiable approuvé par le ministre chargé de la propriété industrielle et le ministre chargé de la santé publique, le montant des redevances est fixé par le tribunal de grande instance. Article L613-17-1 La demande d'une licence obligatoire, présentée en application du règlement (CE) n° 816/2006 du Parlement européen et du Conseil, du 17 mai 2006, concernant l'octroi de licences obligatoires pour des brevets visant la fabrication de produits pharmaceutiques destinés à l'exportation vers des pays connaissant des problèmes de santé publique, est adressée à l'autorité administrative. La licence est délivrée conformément aux conditions déterminées par l'article 10 de ce règlement. L'arrêté d'octroi de la licence fixe le montant des redevances dues La licence prend effet à la date la plus tardive à laquelle l'arrêté est notifié au demandeur et au titulaire du droit.

Article L613-17-2

Toute violation de l'interdiction prévue à l'article 13 du règlement (CE) n° 816/2006 du Parlement européen et du Conseil, du 17 mai 2006, précité et à l'article 2 du règlement (CE) n° 953/2003 du Conseil, du 26 mai 2003, visant à éviter le détournement vers des pays de l'Union européenne de certains médicaments essentiels constitue une contrefaçon punie des peines prévues à l'article L. 615-14 du présent code.

Article L613-18

Le ministre chargé de la propriété industrielle peut mettre en demeure les propriétaires de brevets d'invention autres que ceux visés à l'article L. 613-16 d'en entreprendre l'exploitation de manière à satisfaire aux besoins de l'économie nationale. Si la mise en demeure n'a pas été suivie d'effet dans le délai d'un an et si l'absence d'exploitation ou l'insuffisance en qualité ou en quantité de l'exploitation entreprise porte gravement préjudice au développement économique et à l'intérêt public, les brevets, objets de la mise en demeure, peuvent être soumis au régime de licence d'office par décret en Conseil d'Etat. Le ministre chargé de la propriété industrielle peut prolonger le délai d'un an prévu ci-dessus lorsque le titulaire du brevet justifie d'excuses légitimes et compatibles avec les exigences de l'économie nationale. Du jour de la publication du décret qui soumet le brevet au régime de la licence d'office, toute personne qualifiée peut demander au ministre chargé de la propriété industrielle l'octroi d'une licence d'exploitation. Cette licence est accordée par arrêté dudit ministre à des conditions déterminées quant à sa durée et son champ d'application, mais à l'exclusion des redevances auxquelles elle donne lieu. Elle prend effet à la date de notification de l'arrêté aux parties. A défaut d'accord amiable, le montant des redevances est fixé par le tribunal de grande instance.

Article L613-19

L'Etat peut obtenir d'office, à tout moment, pour les besoins de la défense nationale, une licence pour l'exploitation d'une invention, objet d'une demande de brevet ou d'un brevet, que cette exploitation soit faite par lui-même ou pour son compte. La licence d'office est accordée à la demande du ministre chargé de la défense par arrêté du ministre chargé de la propriété industrielle. Cet arrêté fixe les conditions de la licence à l'exclusion de celles relatives aux redevances auxquelles elle donne lieu. La licence prend effet à la date de la demande de licence d'office. A défaut d'accord amiable, le montant des redevances est fixé par le tribunal de grande instance. A tous les degrés de juridiction, les débats ont lieu en chambre du conseil.

Article L623-22

L'Etat peut, à tout moment, par décret, exproprier en tout ou en partie pour les besoins de la défense nationale les obtentions végétales, objet de demandes de certificat ou de certificats. A défaut d'accord amiable, l'indemnité d'expropriation est fixée par le tribunal de grande instance.

Article L623-22-1

Lorsque le titulaire d'un brevet portant sur une invention biotechnologique ne peut exploiter celle-ci sans porter atteinte à un droit d'obtention végétale antérieur, il peut demander la concession d'une licence pour l'exploitation de la variété protégée par le droit d'obtention, pour autant que cette invention constitue à l'égard de la variété végétale un progrès technique important et présente un intérêt économique considérable. Le demandeur doit justifier qu'il n'a pu obtenir du titulaire du droit d'obtention une licence d'exploitation et qu'il est en état d'exploiter la variété de manière effective et sérieuse.

Article L623-22-2

La demande de licence prévue à l'article L. 623-22-1 est formée auprès du tribunal de grande instance. La licence est non exclusive. Le tribunal détermine notamment sa durée, son champ d'application et le montant des redevances auxquelles elle donne lieu. Ces conditions peuvent être modifiées par décision du tribunal, à la demande du titulaire du droit ou de la licence. Les droits attachés à cette licence ne peuvent être transmis qu'avec l'entreprise ou la partie de l'entreprise ou le fonds de commerce auquel ils sont attachés. Lorsqu'une telle licence est accordée, le titulaire du droit d'obtention obtient à des conditions équitables, sur demande présentée au tribunal, la concession d'une licence réciproque pour utiliser l'invention protégée. Si le titulaire d'une licence ne satisfait pas aux conditions auxquelles cette licence a été accordée, le titulaire du certificat d'obtention végétale et, le cas échéant, les autres licenciés peuvent obtenir du tribunal le retrait de cette licence.

Article L623-22-3

Toute personne de droit public ou de droit privé peut obtenir une licence obligatoire dans les conditions prévues au présent article et à l'article L. 623-22-4. La demande de licence obligatoire est formée auprès du tribunal de grande instance du lieu de situation du titulaire du droit. Elle doit être accompagnée de la justification que :

1° Le demandeur n'a pu obtenir une licence dans un délai d'un an à dater de sa demande auprès du titulaire du certificat ;

2° Qu'il est en état d'exploiter la variété de manière sérieuse et effective ;

3° Que la licence est d'intérêt public eu égard, notamment, à l'insuffisance notoire d'approvisionnement du marché agricole concerné par cette variété. La demande de licence obligatoire peut être présentée, dans les conditions fixées aux deuxième à cinquième alinéas du présent article, par le titulaire du certificat délivré pour une variété essentiellement dérivée d'une variété protégée qui n'a pas pu obtenir du titulaire du certificat de la variété initiale les autorisations nécessaires à l'exploitation de sa propre variété. Le titulaire du certificat protégeant la variété initiale peut obtenir, dans les mêmes conditions, une licence du certificat protégeant la variété essentiellement dérivée. La licence obligatoire est non exclusive. Le tribunal détermine notamment sa durée, son champ d'application et le montant des redevances auxquelles elle donne lieu. Ces conditions peuvent être modifiées par le tribunal à la requête du titulaire ou du licencié. Si le titulaire d'une licence obligatoire ne satisfait pas aux conditions auxquelles cette licence a été accordée, le titulaire du certificat d'obtention et, le cas échéant, les autres licenciés peuvent obtenir du tribunal le retrait de cette licence.

Article L623-22-4

Les droits attachés à une licence obligatoire ne peuvent être ni cédés, ni transmis, si ce n'est avec l'entreprise ou la partie de l'entreprise à laquelle ils sont rattachés. Cette cession ou transmission est, à peine de nullité, soumise à l'autorisation du tribunal.

GAMBIA

Industrial Property Act (Cap. 95:03)

Sections 3 and 14

Section 3 Patents.

[...]

(11) A patent granted by the Office shall, in each designated State, be subject to provisions of the applicable national law on compulsory licenses, forfeiture or the use of patented inventions in the public interest.

Section 14 Non-voluntary licence.

14. (1) On the request of any person who proves his ability to work a patented invention in The Gambia, made to the Registrar General after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Registrar General may with the 'approval of the Minister, grant a non-voluntary licence if the patented invention is not worked or is insufficiently worked in The Gambia.

(2) Notwithstanding the provisions of subsection (1) of this section, a non-voluntary licence shall not be granted if the owner of the patent satisfies the Registrar General that circumstances

exist (other than importation) which justify the non-working or insufficient working of the patented invention in The Gambia.

(3) The beneficiary of the non-voluntary licence shall have the right to exploit (other than to import) the patented invention in The Gambia according to the terms set down in the decision granting the licence shall commence the working of the patented invention in The Gambia within the time limit fixed in the said decision and thereafter, shall work the patented invention sufficiently in The Gambia, subject to the payment of an equitable remuneration therefor as determined in the said decision.

(4) The grant of the non-voluntary licence shall not exclude-

(a) the conclusion of licence contracts by the owner of the patent or the grant of other non-voluntary licences; or

(b) the exploitation of the patented invention under subsection (6) of section 12 of this Act.

GEORGIA

Law of Georgia No. 1791 of February 5, 1999, on Patents (as amended up to Law No. 3235 of August 13, 2018)

Article 521

მუხლი 521. სავალდებულო ლიცენზია

1. პატენტის მფლობელის ნებართვის გარეშე შესაძლებელია გაიცეს პატენტით დაცული გამოგონების ან/და სასარგებლო მოდელის საქართველოს ტერიტორიის ფარგლებში გამოყენებისათვის სავალდებულო ლიცენზია (შემდგომ – სავალდებულო ლიცენზია).

2. სავალდებულო ლიცენზიის გაცემასთან დაკავშირებით გადაწყვეტილებას იღებს საქართველოს ეკონომიკისა და მდგრადი განვითარების სამინისტროსთან არსებული სავალდებულო ლიცენზიის გაცემასთან დაკავშირებით გადაწყვეტილების მიმღები მუდმივმოქმედი საბჭო (შემდგომ – მუდმივმოქმედი საბჭო). მისი შემადგენლობა განისაზღვრება საქართველოს მთავრობის დადგენილებით.

3. სავალდებულო ლიცენზიის გაცემის წესი და პირობები განისაზღვრება საქართველოს მთავრობის დადგენილებით დამტკიცებული „პატენტით დაცული გამოგონების და სასარგებლო მოდელის გამოყენებისათვის სავალდებულო ლიცენზიების გაცემის წესის“ შესაბამისად.

4. სავალდებულო ლიცენზიის გაცემის თაობაზე განცხადებას დაინტერესებული პირი წარუდგენს მუდმივმოქმედი საბჭოს.

5. დაუშვებელია სავალდებულო ლიცენზიის ექსკლუზიურად მხოლოდ 1 პირზე გაცემა.

6. დაუშვებელია სავალდებულო ლიცენზიის სხვა პირისათვის გადაცემა.

7. სავალდებულო ლიცენზია შესაძლებელია გაიცეს იმ შემთხვევაში, თუ:

ა) აუცილებელია პატენტის გამოყენება სტიქიური უბედურების, კატასტროფის, ეპიდემიის, თავდაცვის, საზოგადოებრივი ჯანმრთელობის დაცვის დროს;

ბ) პატენტით დაცული გამოგონების ან/და სასარგებლო მოდელის გამოყენება შეუძლებელია სხვა, უფრო ადრინდელ პატენტზე პატენტის მფლობელის ან მისი უფლებამონაცვლის განსაკუთრებული უფლებების დაურღვევლად.

8. ამ მუხლის მე-7 პუნქტის „ა“ ქვეპუნქტით გათვალისწინებულ შემთხვევაში სავალდებულო ლიცენზიის გაცემა შეიძლება მოითხოვოს სახელმწიფო ორგანომ, თუ დაასაბუთებს შესაბამისი საფუძვლის არსებობას.

9. ამ მუხლის მე-7 პუნქტის „ბ“ ქვეპუნქტით გათვალისწინებულ შემთხვევაში სავალდებულო ლიცენზიის გაცემის თაობაზე განცხადება უნდა შეიცავდეს იმის დასაბუთებას, რომ გამოგონება ან სასარგებლო მოდელი არის მნიშვნელოვანი ტექნიკური

გადაწყვეტა, რომელიც არსებითად დამოკიდებულია ადრინდელი პატენტით დაცულ გამოგონებაზე ან სასარგებლო მოდელზე და რომელსაც აქვს საზოგადოებისათვის არსებითი ეკონომიკური უპირატესობები ადრინდელი პატენტით დაცულ გამოგონებასთან ან სასარგებლო მოდელთან შედარებით.

10. ამ მუხლის მე-7 პუნქტის „ბ“ ქვეპუნქტის საფუძველზე სავალდებულო ლიცენზიის მიმღები შესაბამისი გამოგონების ან სასარგებლო მოდელის პატენტით დაცვის შემთხვევაში ვალდებულია გასცეს კერძო ლიცენზია იმ პატენტის მფლობელზე, რომლის პატენტის გამოსაყენებლადაც გაიცა სავალდებულო ლიცენზია.

11. სავალდებულო ლიცენზიის გაცემა შეიძლება მხოლოდ იმ შემთხვევაში, თუ სავალდებულო ლიცენზიის სავარაუდო მიმღები წარუმატებლად ეცადა, გონივრულ ვადაში, მისაღები კომერციული პირობებით მიეღო ლიცენზია პატენტის მფლობელისაგან ან მისი უფლებამონაცვლისაგან.

12. ამ მუხლის მე-11 პუნქტით განსაზღვრული პირობა შესაძლებელია არ იქნეს გათვალისწინებული გადაუდებელი აუცილებლობის შემთხვევაში, რის შესახებაც პატენტის მფლობელს დაუყოვნებლივ უნდა ეცნობოს.

13. სავალდებულო ლიცენზიის ობიექტის გამოყენების ფარგლები, სავალდებულო ლიცენზიის მოქმედების ვადა, შესაბამისი კომპენსაციის ოდენობა განისაზღვრება იმ მიზნის მიხედვით, რომლისთვისაც იქნა ნებადართული შესაბამისი გამოგონების ან/და სასარგებლო მოდელის გამოყენება. ასეთი გამოყენება ნებადართულია, უპირველეს ყოვლისა, საქართველოს ბაზრის მოთხოვნილებების დასაკმაყოფილებლად.

14. სავალდებულო ლიცენზიის გაცემის შემთხვევაში პატენტის მფლობელს ეძლევა შესაბამისი კომპენსაცია მისაღები კომერციული პირობებით.

15. სავალდებულო ლიცენზიის გაცემის თაობაზე გადაწყვეტილება პერიოდულად გადაიხედება და უქმდება, თუ აღარ არსებობს სავალდებულო ლიცენზიის გაცემის აუცილებლობის გამომწვევი გარემოება.

16. სავალდებულო ლიცენზიის გაცემის შემთხვევაში საქპატენტს რეესტრში შეაქვს შესაბამისი ჩანაწერი და სათანადო მონაცემებს აქვეყნებს ბიულეტენში სავალდებულო ლიცენზიის გაცემიდან 1 თვის ვადაში.

17. სავალდებულო ლიცენზიის გაცემის თაობაზე გადაწყვეტილება და შესაბამისი კომპენსაციის გაცემის შესახებ გადაწყვეტილება შესაძლებელია გასაჩივრდეს სასამართლოში.

18. სავალდებულო ლიცენზია არ არის „ლიცენზიებისა და ნებართვების შესახებ“ საქართველოს კანონით გათვალისწინებული ლიცენზია.

საქართველოს 2017 წლის 23 დეკემბრის კანონი №1918 - ვებგვერდი, 11.01.2018წ.

GERMANY

Patentgesetz (zuletzt geändert durch Gesetz vom 8. Oktober 2017)

Sections 13 and 24

Section 13

(1) A patent shall have no effect should the Federal Government order that the invention is to be used in the interest of public welfare. Nor shall the effect of a patent extend to any use of the invention ordered in the interests of the security of the Federal Republic by the competent highest federal authority or, on the latter's instructions, by a subordinate agency.

(2) Should an order under subsection (1) be challenged, the Federal Administrative Court [Bundesverwaltungsgericht] shall have jurisdiction if said order was issued by the Federal Government or the competent highest federal authority.

(3) In those cases referred to in subsection (1), the patentee shall have a claim against the Federal Republic for reasonable compensation. In the event of dispute as to the amount, legal action may be brought before the ordinary civil courts. Any order by the Federal Government under the first sentence of subsection (1) shall be communicated to the person recorded as patentee in the Register (Section 30(1)) before the invention is used. If the highest federal authority that has issued an order or an instruction under the second sentence of subsection (1) becomes aware that a claim for compensation has arisen under the first sentence, said highest federal authority shall communicate this to the person recorded in the Register as patentee.

Section 24 [Compulsory licence; withdrawal of the patent]

(1) The non-exclusive authorisation to commercially use an invention shall be granted by the Federal

Patent Court in an individual case in accordance with the following provisions (compulsory licence)

where:

1. a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and

2. the public interest calls for the grant of a compulsory licence.

(2) Where a licence seeker cannot exploit an invention for which he holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date, he shall be entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory licence from the proprietor of the patent if

1. the condition under subsection (1) no. 1 is fulfilled, and

2. his own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date.

The proprietor of the patent can require the licence seeker to grant him a cross-licence on reasonable

terms and conditions for the use of the patented invention with the later filing or priority date.

(3) Subsection (2) shall apply mutatis mutandis where a plant breeder cannot obtain or exploit a plant

variety right without infringing an earlier patent.

(4) A compulsory licence under subsection (1) may be granted for a patented invention in the field of

semi-conductor technology only where this is necessary to eliminate those anti-competitive practices

pursued by the proprietor of the patent which have been established in court or administrative proceedings.

(5) Where the proprietor of the patent does not apply the patented invention in Germany or does not do so predominantly, compulsory licences in accordance with subsection (1) may be granted to ensure an adequate supply of the patented product on the German market. Import shall thus be equivalent to the use of the patent in Germany.

(6) The grant of a compulsory licence in respect of a patent shall be admissible only after the patent has been granted. The compulsory licence may be granted subject to limitations and made dependent on conditions. The extent and the duration of use shall be limited to the purpose for which the compulsory licence was granted. The proprietor of the patent shall be entitled to remuneration from the proprietor of the compulsory licence, such remuneration being equitable in the circumstances of the case and taking into account the economic value of the compulsory licence. Where, in relation to recurrent remuneration payments due in the future, there is a substantial change in the circumstances which governed the fixing of the amount of remuneration, each party shall be entitled to require a corresponding adjustment. Where the circumstances upon which the grant of a compulsory licence was based no longer apply and if their recurrence is improbable, the proprietor of the patent can require withdrawal of the compulsory licence.

(7) A compulsory licence in respect of a patent may be transferred only together with the business which is involved in exploiting the invention. A compulsory licence in respect of an invention which is the subject-matter of a patent with an earlier filing or priority date may be transferred only together with the patent with a later filing or priority date.

GHANA

Patent Act, 2003 (Act 657)

Sections 13 and 14

Section 13—Exploitation by Government or Authorized Person.

(1) Where

(a) public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires, or

(b) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or the owner's licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy that practice the Minister may decide that, even without the consent of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the owner of an adequate remuneration, taking into account the economic value of the Minister's decision as determined in the decision, and where a decision has been taken under subsection (1) (b), the need to correct anti-competitive practices.

(3) The Minister shall take a decision after hearing the owner of the patent and any interested person if that person wishes to be heard.

(4) Upon a request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify the variation.

(5) Upon the request of the owner of the patent, the Minister shall terminate the authorization if the Minister is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to the Minister's decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by the Minister has failed to comply with the terms of the decision.

(6) Notwithstanding subsection (5), the Minister shall not terminate the authorization if the Minister is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by the Minister justifies the maintenance of the decision.

(7) Where a third person has been designated by the Minister, the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(8) The authorization shall not exclude

(a) the conclusion of licence contracts by the owner of the patent; or

(b) the continued exercise, by the owner of the patent, of the owner's rights under section 11 (2).

(9) A request for the Minister's authorization shall be accompanied with evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual licence, but that, that person has been unable to obtain the licence on reasonable commercial terms and conditions and within a reasonable time.

(10) Subsection (9) does not apply in cases of national emergency or other circumstances of extreme urgency but in such cases, the Registrar shall notify the owner of the patent of the Minister's decision as soon as reasonably practicable.

(11) The exploitation of the invention by the Government agency or third person designated by the Minister shall be predominantly for the supply of the market in the country.

(12) The exploitation of an invention in the field of semi-conductor technology shall only be authorized for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or the owner's licensee, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary licence would remedy the practice.

(13) A person aggrieved by the Minister's decision under this section may appeal to the court.

Section 14—Non-Voluntary Licences.

(1) On a request, made to the court after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the court may issue a non-voluntary licence if the court is satisfied that the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by importation, in the country.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in the country.

(3) The decision for issuing the non-voluntary licence shall specify

(a) the scope and function of the licence,

(b) the time limit within which the licensee shall begin to exploit the patented invention, and

(c) the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

(4) The beneficiary of the non-voluntary licence may

(a) exploit the patented invention in the country according to the terms specified in the decision issuing the licence, or

(b) commence the exploitation of the patented invention within the time limit specified in the decision, and

(c) exploit the patented invention sufficiently.

(5) Where

(a) the invention claimed in a patent cannot be exploited in the country without infringing a patent granted on the basis of an application benefiting from an earlier filing or where appropriate, priority date, and

(b) where the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the court, upon the request of the owner of the later patent, may issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is issued under subsection (5), the court, upon the request of the owner of the earlier patent, shall issue a non-voluntary licence in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary licence under subsections (5) and (6), subsection (3) shall apply with such modifications as are necessary with the proviso that no time limit needs to be specified.

(8) In the case of a non-voluntary licence issued under subsection (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary licence is subject to payment of the prescribed fee.

(10) Section 13(4) to (13) shall apply with such modifications as are necessary.

GREECE

Law No. 1733/1987 on Technology Transfer, Inventions and Technological Innovation

Articles 13 and 14

Article 13

Non-contractual licence

1. The competent court mentioned in paragraph 10 of the present article may grant to a third party, without prior consent of the patentee, a licence for exploitation of the patent in case that the following prerequisites concur accumulatively:

- A period of three years has elapsed since the grant of the patent or a period of four years has elapsed since the filing date of the patent application;
- The relevant invention has not been exploited in Greece or, in case it has, the production of the products thereof is insufficient to cover local demand;
- The third party is in a position to exploit productively the invention covered by the patent;
- The third party notified the patentee, one month prior to the initiation of the judicial proceedings, regarding his intention to request a non-contractual licence.

2. The non-contractual licence shall not be granted in case the patentee justifies lack of exploitation or insufficient exploitation in the country. The importation of the product does not constitute an excuse for the invocation and application of this paragraph.

The regulation of item 1 above shall not apply to products imported from Member States of the European Union and the Member States of the World Trade Organization(1).

3. The grant of a non-contractual licence may not exclude other contractual or non-contractual licences. The non-contractual licence may be assigned only along with the part of the enterprise which exploits the invention.

4. The owner of the patent may request from the competent court mentioned in paragraph 10 the grant of a non-contractual licence on an earlier patent, provided that his invention relates to the invention of the earlier patent, the productive exploitation of said invention is not possible without offending the rights of the owners of the earlier patent and his invention constitutes a significant progress in comparison with the invention of the prior patent. When the aforementioned non-contractual licence has been granted, the owner of the earlier patent may request the granting of a non-contractual licence for the subsequent invention.

5. The non-contractual licence shall be granted following petition of the interested party before the competent court mentioned in paragraph 10.

The petition is accompanied by the opinion of the Industrial Property Organisation regarding the existence of the prerequisites for granting the non-contractual licence in accordance with the preceding paragraphs, the amount, the terms of the compensation to be given to the owner of the patent, and the exclusive or non exclusive character of the exploitation of the invention. The Industrial Property Organisation states its opinion following petition of the party interested in exploiting the patent. The opinion of O.B.I. is granted within one month from the date the relevant petition is filed and is not binding for the competent court. Copy of the application for granting a non-contractual licence along with the relevant opinion of O.B.I. and the note fixing the day of the trial shall be notified to the owner of the patent and to the beneficiaries of other contractual or non-contractual licences.

6. In case the petition is approved, the competent court grants a non-contractual licence. The licence pertains to the extent of the exploitation rights of the invention, the duration of its validity, the date of commencement of the productive exploitation of the invention in Greece and the amount and terms of compensation to be paid to the patentee by the beneficiary of the licence. The amount and the terms of the compensation are determined in accordance with the extent of the industrial exploitation of the protected invention.

7. The decision of the court in accordance with paragraph 6 shall be recorded to the Patents Register of O.B.I., published in the Industrial Property Bulletin and notified to the persons mentioned in paragraph 5.

8. Following petition of the owner of the patent or the beneficiary of the non-contractual licence, the competent court mentioned in paragraph 10 may amend the terms of granting of the licence if new data justify the amendment or revoke the non contractual licence if its beneficiary does not respect the terms of the licence or if the prerequisites for its granting have ceased existing. If the immediate revocation brings about a significant damage to the beneficiary of the non-contractual licence, the court may allow the continuation of the exploitation for a reasonable period of time.

9. The non-contractual licence does not grant the right for importation of the products covered by the invention.

10. The competent court for the grant, assignment, amendment or revocation of a non-contractual licence is the three member court of first instance at the place of residence of the petitioner, which judges in accordance with the proceeding of article 741 to 781 of the Code of Civil Procedure Law.

Article 14

Licence to the Public Sector

1. For imperative reason of serving public health and national defence after justified decision of the Minister of Industry, Energy, and Technology and, according to the case, any competent Ministers, a licence for exploitation of an invention can be granted to bodies of the public sector which may exploit the invention in Greece, provided that the relevant invention has not been productively exploited in Greece or the production of the products thereof is insufficient to cover local needs.

2. Prior to the issue of the relevant decision, the patentee and anyone who is in position to give useful advice, are called upon to express their views.

3. By the same decision, following the opinion of O.B.I., the amount and the terms of the compensation to the owner or the patent are determined. The amount of the compensation is determined in accordance with the extent of the industrial exploitation of the invention. In case of disagreement of the patentee as regards the amount of the compensation, the compensation is determined by the relevant one-member court of first instance of the jurisdiction, in the injunction proceedings.

GRENADA

Industrial Property Bill of 2002

Sections 14 and 14A

Exploitation by Government or authorised persons

14. (1) If –

(a) the public interest (in particular, national security, nutrition, person health or the development of other vital sectors of the national economy) so requires; or

the [Minister of Finance] has determined that the manner of exploitation by the owner of the patent or a licensee is anticompetitive, and the Minister [for Legal Affairs] is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice,

the Minister [for Legal Affairs] may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the invention under this section is limited to the purpose for which it was authorized and is subject to the payment to the owner of adequate remuneration, taking into account the economic value of the Minister's decision, as determined in the said decision, and, where a decision has been taken under paragraph (b) of subsection (1), the need to correct anti-competitive practices.

(3) The Minister [of Finance] and the Minister [of Legal Affairs] must take a decision under subsection (1) only after hearing the owner of the patent and any interested person who wishes to be heard.

(4) Upon the request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister [of Legal Affairs] may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(5) (a) Upon the request of the owner of the patent, the Minister [of Legal Affairs] must terminate the authorization if the Minister is satisfied, after hearing the parties, (if either or both wish to be heard) that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister must not terminate the authorization if he or she is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated justifies the maintenance of the decision.

(6) If a third person has been designated by the Minister under subsection (1), the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(7) The authorization must not exclude –

(a) the conclusion of licence contracts by the owner of the patent;

(b) the continued exercise, by the owner of the patent, of the rights under section [12](2); or

(c) the issue of a non-voluntary licence under subsections (1) and (2) of section [14 A.]

(8) (a) A request for the Minister's authorization must be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual licence, but that that person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(b) Paragraph (a) of this subsection does not apply in cases of national emergency or other circumstances of extreme urgency, but in such cases the owner of the patent must be notified of the Minister's decision as soon as reasonably practicable.

(9) The exploitation of the invention by the Government agency or third person designated by the Minister must be predominantly for the supply of the market in Grenada.

(10) The exploitation of an invention in the field of semi-conductor technology can only be authorized for public non-commercial use or if a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or the owner's licensee, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary licence would remedy such practice.

(11) Decisions of a Minister under any of subsections (1) to (10) may be the subject of an appeal to the High Court.

Non-voluntary licences

[14A. (1) If the invention claimed in a patent ("later patent") cannot be exploited in Grenada without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date ("earlier patent"), and if the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the [Registrar] [Court], upon the request of the owner of the later patent, may issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(2) If a non-voluntary licence is issued under subsection (1), the [Registrar] [Court], upon the request of the owner of the earlier patent, must issue a non-voluntary licence in respect of the later patent.

(3) If a non-voluntary licence is issued under subsection (1) or (2), the issuing authority must fix the scope and function of the licence, the amount of the remuneration to be paid to the owner of the patent and the conditions of payment.

(4) In the case of a non-voluntary licence issued under subsection (1), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (2), only with the earlier patent.

(5) The issue of a non-voluntary licence is subject to payment of the prescribed fee.

(6) If a non-voluntary licence is issued under subsection (1) or (2), subsections (2) to (8) and (10) of section [14] apply with necessary modifications.]

GUATEMALA

Industrial Property Law, Decree No. 57 of 18/09/2000

Sections 134-137

Licencia Obligatorias

134. Por razón de interés público y en particular por razones de emergencia nacional, salud pública, seguridad nacional o uso público no comercial, o bien, para remediar alguna práctica anticompetitiva, previa audiencia al interesado, el Registro podrá, a petición de la autoridad o de una persona interesada, disponer en cualquier tiempo:

- a) Que la invención objeto de una patente o de una solicitud de patente en trámite sea usada o explotada industrial o comercialmente por una entidad estatal o por una o más personas de derecho público o privado designadas al efecto; o
- b) Que la invención objeto de una patente o de una solicitud de patente en trámite quede abierta a la concesión de una o más licencias obligatorias, en cuyo caso la autoridad nacional competente podrá conceder tal licencia a quien la solicite, con sujeción a las condiciones establecidas.

Cuando la patente protegiera alguna tecnología de semiconductores, sólo se otorgará licencias obligatorias para un uso público no comercial, o para rectificar una práctica declarada contraria a la competencia en el procedimiento aplicable.

Solicitud de Licencia Obligatoria

135. La persona que solicite una licencia obligatoria deberá acreditar haber pedido previamente al titular de la patente una licencia contractual, que no ha podido obtenerla en términos y condiciones comerciales razonables y que esos intentos no surtieron efecto en un plazo que no podrá ser menor de los noventa días siguientes al primer requerimiento. No será necesario cumplir este requisito tratándose de una licencia obligatoria en casos de emergencia nacional, de extrema urgencia o de un uso no comercial de la invención por una entidad pública. En ambos casos el titular de la patente será informado sin demora de la concesión de la licencia.

La solicitud de licencia obligatoria deberá indicar las condiciones bajo las cuales se pretende obtener la licencia y, junto con la misma, deberá acompañarse la documentación que justifique el otorgamiento de la licencia y la capacidad técnica y económica del solicitante para explotar adecuadamente la patente. Esta prueba no será necesaria en los casos y situaciones señalados en la segunda parte del párrafo que antecede.

De la solicitud se dará audiencia al titular de la patente por el plazo de un mes y, con su contestación o sin ella, el Registro resolverá sobre la procedencia o no de conceder la licencia.

La resolución del Registro que otorgue una licencia obligatoria contendrá:

- a) El alcance de la licencia, incluyendo su vigencia y los actos para los cuales se concede, que se limitarán a los fines que la motivaron;
- b) El monto y la forma de pago de la remuneración debida al titular de la patente; y
- c) Las condiciones necesarias para que la licencia cumpla su propósito.

Condiciones Relativas a la Licencia Obligatoria

Condiciones Relativas a la Licencia Obligatoria

136. Son condiciones necesarias relativas al otorgamiento de la licencia obligatoria, entre otras, las siguientes:

- a) La licencia obligatoria se concederá principalmente para abastecer el mercado interno;
- b) El titular de la patente objeto de una licencia obligatoria recibirá una remuneración adecuada, según las circunstancias del caso y el valor económico de la licencia. A falta de acuerdo entre las partes, el Registro fijará el monto y la forma de pago de la remuneración, para lo cual podrá

tomar en cuenta además información que recabe sobre el promedio de regalías que en el mismo sector se haya establecido en contratos de licencia celebrados entre terceras partes; y
c) Una licencia obligatoria no podrá concederse con carácter exclusivo, no podrá ser objeto de cesión, ni de sub licencia y sólo podrá transferirse con la empresa o el establecimiento, o con aquella parte del mismo, que explota la licencia.

A solicitud del titular de la patente, el Registro podrá cancelar la licencia obligatoria si las circunstancias que dieron lugar a su otorgamiento han desaparecido y no es probable que vuelvan a ocurrir, para lo cual tomará las previsiones necesarias para proteger los intereses legítimos de los licenciarios. Para tal efecto, además de las pruebas aportadas por el titular de la patente, el Registro recabará la información que estime necesaria para verificar esos hechos. Contra las resoluciones que dicte el Registro relativas al otorgamiento o revocación de una licencia obligatoria y las condiciones de la misma, incluyendo la remuneración que deba pagarse al titular de la patente y cualquier modificación de tales condiciones, se podrán interponer los recursos a que se refiere el artículo 13 de esta Ley, los que deben tramitarse y resolverse con absoluta prioridad.

Si la licencia obligatoria se otorga para remediar o eliminar prácticas que a resultas de un proceso judicial o administrativo se ha determinado que son anticompetitivas, no serán aplicables las normas contenidas en el párrafo uno del artículo 134 de esta ley. En este caso, para determinar la remuneración del titular de la patente se tendrá en cuenta que el objeto de la licencia es poner fin a prácticas anticompetitivas. Asimismo, podrá denegarse la revocación de la licencia si resulta probable que las condiciones que dieron lugar al otorgamiento de la misma se repitan.

Licencia Obligatoria por Dependencia de Patentes

137. Cuando una licencia obligatoria fuera solicitada para permitir la explotación de una patente posterior ("segunda patente"), que no pudiera ser explotada sin infringir otra patente anterior ("primera patente"), se observarán las siguientes condiciones adicionales:

- a) La invención reivindicada en la segunda patente debe suponer un avance técnico relevante de una importancia económica considerable, con respecto a la invención reivindicada en la primera patente;
- b) La licencia obligatoria para explotar la primera patente sólo podrá transferirse con la segunda patente; y
- c) El titular de la primera patente tendrá derecho a una licencia sobre la segunda patente, en condiciones razonables para explotar la invención objeto de la segunda patente.

HONDURAS

Ley de Propiedad Industrial (aprobada por Decreto N° 12-99-E)

Articles 65-70

Artículo 65. - A los efectos de la presente Ley, se entenderá por explotación de una patente lo siguiente:

- 1) Cuando la patente se haya concedido para un producto, el abastecimiento de mercado interno conforme a la demanda del producto, sea mediante producción local, importación, o ambos;
- 2) Cuando la patente se haya concedido para un procedimiento no comprendido en e numeral 3) del presente Artículo, el empleo de ese procedimiento en escala comercial en Honduras; y,
- 3) Cuando la patente se haya concedido para un procedimiento obtención de un producto, el abastecimiento del mercado interno conforme a la demanda del producto obtenido por ese sistema, mediante el empleo del procedimiento en el país o en el extranjero.

Artículo 66. - A solicitud de cualquier persona que acredite su capacidad para explotar la invención patentada, presentada después de cuatro (4) años contados desde la fecha de presentación de la solicitud de patente o de tres (3) años contados desde la fecha de concesión de la patente, aplicándose el plazo que expire más tarde, el Registro de la Propiedad Industrial podrá previa audiencia del titular de la patente, conceder una licencia obligatoria para la explotación conforme al Artículo 65 de esta Ley.

No se concederá una licencia obligatoria cuando se demuestra que la falta o insuficiencia de explotación se debe a un caso fortuito o de fuerza mayor, o a circunstancias que escapan a la voluntad o al control del titular de la patente y que justifican la falta o insuficiencia de explotación Industrial de la invención patentada. No serán consideradas circunstancias justificativas la falta de recursos económicos ni la falta de viabilidad económica de la explotación.

Antes de conceder una licencia obligatoria, la Oficina de Registro dará oportunidad al titular de la patente para que dentro del plazo de dos (2) años contados a partir de la notificación que se haga a éste proceda a su explotación.

Artículo 67. - La persona que solicite una licencia obligatoria de conformidad con el artículo 62 de esta Ley, deberá acreditar fehacientemente haber pedido previamente al titular de la patente, una licencia contractual y que no ha podido obtenerla en condiciones y plazos razonables. La Solicitud de licencia obligatoria indicará las condiciones bajo las cuales pretende obtenerse la licencia.

Cuando la licencia obligatoria se solicitara para una patente en la cual se reivindicara alguna tecnología de semiconductores, la licencia sólo se concederá para un uso público no comercial a favor de una autoridad pública o de otra persona que actúe por cuenta de ella o para rectificar una práctica declarada contraria a la competencia mediante el procedimiento administrativo o judicial correspondiente.

La resolución de concesión de la licencia obligatoria establecerá:

El alcance o extensión de la licencia, especificando en particular el período y los actos, que será principalmente para abastecer el mercado interno del país;

La cuantía y la forma del pago que deberá efectuar el licenciatario, debiendo determinarse dicho pago sobre la base de la amplitud de la explotación de la invención objeto de la licencia, y el valor económico de la licencia; y,

Otras condiciones que el Registro de la Propiedad Industrial estime necesarios o convenientes para la mejor explotación de la patente.

Artículo 68. - Una licencia obligatoria concedida de conformidad con el Artículo 66 de esta Ley, podrá ser revocada por el Registro de la Propiedad Industrial, a solicitud de la persona interesada, si el beneficiario de la licencia incumpliese las obligaciones que le incumben, o si las circunstancias que dieron origen a la licencia hubiesen desaparecido y no fuese probable que vuelvan a surgir. La licencia obligatoria podrá ser modificada por el Registro, a solicitud de alguna de las partes, cuando nuevos hechos o circunstancias lo justifiquen, en particular cuando el titular de la patente hubiese otorgado licencias contractuales en condiciones más favorables que las acordadas al beneficiario de la licencia obligatoria.

La licencia obligatoria prevista en el Artículo 66 de la presente Ley no podrá concederse con carácter de exclusiva. Tal licencia no podrá ser objeto de cesión ni de sub-licencia y solo podrá transferirse con el establecimiento, o con aquella parte de la empresa o del establecimiento, en que se explota industrialmente la invención. La transferencia se sujetará a las disposiciones del Artículo 20, párrafo segundo de la misma, en cuanto corresponda.

Artículo 69. - Cuando una invención reivindicada en una patente no pudiera explotarse industrialmente en el país sin que ello infrinja una patente anterior, el Registro de la Propiedad Industrial, a petición del titular de aquella patente o de su licenciataria, o del beneficiario de una licencia obligatoria sobre esa patente, podrá conceder una licencia obligatoria respecto de la patente anterior, en la medida que fuese necesario para evitar la infracción de esa patente anterior.

Tal licencia solo se concederá cuando la invención reivindicada en la patente posterior suponga un avance técnico de una importancia económica considerable con respecto a la invención que es objeto de la patente anterior.

Cuando se concediere una licencia obligatoria de acuerdo con el párrafo anterior, el Registro de la Propiedad Industrial podrá en las mismas circunstancias conceder una licencia obligatoria con respecto a la patente posterior, si lo solicitare el titular de la patente anterior, su licenciataria, o el beneficiario de una licencia obligatoria sobre dicha patente anterior.

Una licencia obligatoria de las previstas en este Artículo no podrá concederse con carácter de exclusiva. Esta licencia obligatoria sólo podrá ser objeto de cesión, transferencia o sublicencia cuando simultáneamente fuese objeto de cesión, transferencia o licencia la patente dependiente cuya explotación industrial requiere de la licencia. La cesión, transferencia o sublicencia de la licencia obligatoria se sujetará a las disposiciones del párrafo segundo de la presente Ley, en cuanto corresponda.

Serán aplicables a las licencias previstas en el presente Artículo, las disposiciones de los artículos 67 y 68 de esta Ley, en cuanto corresponda.

Artículo 70. - Por razones de interés público, y en particular en casos de emergencia o por razones de seguridad nacional, nutrición o salud pública, la Secretaría de Estado en los Despachos de Industria y Comercio podrá, a petición de cualquier persona natural o jurídica, entidad del Estado, o de oficio, disponer en cualquier tiempo lo siguiente:

- 1) Que una invención objeto de una patente o de solicitud de patente en trámite sea explotada por una entidad estatal o por una o más personas de derecho público o privado designada al efecto; y,
- 2) Que una invención objeto de una patente o de una solicitud de patente en trámite quede abierta a la concesión de licencias de interés público, en cuyo caso el Registro de la Propiedad Industrial otorgará una licencia de explotación a cualquier persona que lo solicite y tuviera capacidad para efectuar tal explotación en el país.

HUNGARY

Act No. XXXIII of 1995 on the Protection of Inventions by Patents (consolidated text of June 17, 2017)

Articles 31-33/A

Compulsory licenses for lack of exploitation

Article 31

If within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires last, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a license for such purpose, a compulsory license shall be granted to the applicant for the license, unless the patentee justifies the lack of exploitation.

Compulsory licenses in respect of dependent patents

Article 32

(1) If the patented invention cannot be exploited without infringing another patent (hereinafter referred to as “the dominant patent”), a compulsory license shall be granted, on request and to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the dominant patent.

(2) Where a compulsory license has been granted under paragraph (1) with respect to a dominant patent, the holder of such a patent shall be entitled on reasonable terms to a license to exploit the invention claimed in the dependent patent according to the common provisions on compulsory licenses.

(3) The provisions of Article 33(1) and (2) shall also apply *mutatis mutandis* if the subject matter of a plant variety protection provided for in Chapter XIII cannot be exploited without infringing a patent.

Compulsory licenses to address public health problems

Article 33/A

(1) The Hungarian Patent Office shall grant a compulsory license for the exploitation of an invention in the cases and on the terms laid down in Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2007 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (hereinafter referred to as “Regulation 816/2006/EC”).

(2) The licensee may not grant a license of exploitation on the basis of the compulsory license under paragraph (1).

(3) The licensee may relinquish his compulsory license under paragraph (1) at any time.

Unless relinquished or cancelled, a compulsory license under paragraph (1) shall have effect until expiration of the term of validity fixed by the Hungarian Patent Office or until the lapse of patent protection.

ICELAND

Patents Act No. 17/1991 (as amended up to Act No. 126/2011)

Articles 45-49

Article 45

If a patented invention is not worked to a reasonable extent in this country when three years have elapsed from the grant of the patent and four years have elapsed from the filing of the patent application, any person wishing to work the invention in this country may obtain a compulsory license to do so unless there are shown legitimate reasons for the failure to work the invention.

Subject to reciprocity [the Minister]¹⁾ may direct that, for the purposes of Paragraph 1, working of the invention in another country shall be equivalent to working in this country.

1) Act No. 98/2009, Art. 12 (Valid from October 1, 2009)

Article 46

[The proprietor of a patent for an invention, the exploitation of which is dependent on a patent held by another person, may obtain a compulsory license to exploit the invention protected by the latter patent if the former invention is considered to represent an important technical advance, which has considerable economic significance.

In the event of a compulsory license being granted to exploit a patented invention in pursuance of Paragraph 1, the proprietor of that invention shall be entitled to obtain, upon reasonable terms, a compulsory license to exploit the other invention.] ¹⁾

1) Act No. 36/1996, Art. 17 (Valid from June 1 1996)

[Article 46 a)

A holder of a plant variety who can neither acquire nor exploit a plant variety right without infringing a prior patent may request a compulsory licence for a reasonable payment to exploit the invention if the licence is necessary to exploit the variety to be protected. A compulsory licence shall be granted only if the plant variety holder demonstrates that the variety involves technically important progress and leads to considerable financial benefit in comparison to the invention in the patent.

If a patent holder has obtained a compulsory licence on the basis of the Act on Plant Variety Rights, No. 58/2000, to exploit a protected plant variety, the holder of the plant variety is entitled to a compulsory cross-licence on reasonable terms to exploit the invention.] ¹⁾

1) Act No. 22/2004, Art. 6 (Valid from May 11 2004)

Article 47

When required by important public interests, any person who wishes to exploit an invention commercially for which another person holds a patent may obtain a compulsory license to do so.

Article 48

Any person who, in this country, at the time when a patent application was made available to the public, was commercially exploiting the invention for which a patent is applied for, may, if the application results in a patent, obtain a compulsory license to exploit the invention if very special circumstances make it desirable and he had no knowledge and could not reasonably have obtained any knowledge of the application. Such a right shall also, under similar conditions, be enjoyed by any person who had made substantial preparations for commercial exploitation of the invention in this country.

A compulsory license in accordance with Paragraph 1 may include the time preceding the grant of the patent.

Article 49

[A compulsory license may only be granted to a person who has not been able to reach agreement to obtain a license on reasonable terms and may be presumed to be capable of exploiting the invention in a reasonable and acceptable way and in accordance with the terms of the license. [In the event of a national emergency or other circumstances of extreme urgency, it is permissible to waive the requirement for prior negotiations, though the patent holder shall in such cases be notified of this use as soon as reasonably practicable. Further provisions may be made through regulations.]¹⁾

A compulsory license shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licenses to others.

A compulsory license may only be transferred to others together with the business in which it is exploited or in which the exploitation was intended. Furthermore, where a compulsory license has been granted as provided for in Paragraph 1 of Article 46, transfer of a compulsory license may only occur concurrent with transfer of the patent which was dependent upon a patent held by another party.

A compulsory license concerning semi-conductor technology may only be granted for public exploitation which is not of a commercial nature, or to prevent behaviour which a court or government authority has regarded as anti-competitive.]²⁾

[A compulsory licence may be granted for exporting medicines to developing countries and countries which are struggling with a severe public health problem, in accordance with the decision of the World Trade Organisation's General Council of 30 August 2003 on the TRIPS agreement and public health. The party requesting a compulsory license must show that they have, for a period of thirty days, made unsuccessful efforts to obtain authorisation for manufacture from the patent holder. However, the above-mentioned requirement for negotiations does not apply in the event of an emergency or other circumstances of extreme urgency. Compulsory licenses, under the terms of this paragraph, will only be granted upon the fulfilment of conditions further specified in regulations ³⁾ that are in compliance with the aforementioned decision of the World Trade Organisation's General Council, for instance regarding quantities and drug labelling.]¹⁾

1) Act No. 127/2005, Art. 1 (Valid from December 30 2005)

2) Act No. 36/1996, Art. 18 (Valid from June 1 1996)

3) Regulation No. 1011/2006.

INDIA

Patents Act, 1970 (as amended up to Patents (Amendment) Act, 2005)

Sections 82-94, 99-102, and 146

82. Definition of "patented articles" and "patentee".—In this Chapter, unless the context otherwise requires,-

- (a) "patented article" includes any article made by a patented process; and
- (b) "patentee" includes an exclusive licensee.

83. General principles applicable to working of patented inventions.—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,-

- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economical welfare, and to a balance of rights and obligations;
- (d) that patents granted do not impede protection of public health and nutrition and should act as instruments to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
- (e) that patents granted do not in any way prohibit central Government in taking measures to protect public health;
- (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

84. Compulsory licences.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant on compulsory license on patent on any of the following grounds, namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonable price, or

(c) that the patented invention is not worked in the territory of India.

(2) Any application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be stopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application filed under this section, the controller shall take into account,-

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of application.

Explanation.- For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months".

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,-

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use

or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, preventions to challenges to the validity of patent or coercive package licensing, or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by-

(i) the patentee or person claiming under him, or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceeding for infringement.

85. Revocation of patents by the Controller for non-working.— (1) Where, in respect of a patent, a compulsory licence has been granted, the Central Government or person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.

(2) Every application under sub-section (1) shall contain such particulars as may be prescribed, the facts upon which the application is based, and, in the case of an application other than by the central Government, shall also set out the nature of the applicant's interest.

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.

(4) Every application under sub-section (1) shall ordinarily be decided within one year of its being presented to the Controller.

86. Power of Controller to adjourn applications for compulsory licences, etc., in certain cases.—(1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.

(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

87. Procedure for dealing with applications under sections 84 and 85.— (1) Where the Controller is satisfied, upon consideration of an application under section 84, Or section 85, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal.

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.

88. Powers of Controller in granting compulsory licences.— (1) Where the Controller is satisfied on application made under section 84 that the manufacture, use or sale of materials not protected by the patent is prejudiced by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, he may, subject to the provisions of that section, order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

(2) Where an application under section 84 is made by a person being the holder of a licence under the patent, the Controller may, if he makes an order for the grant of a licence to the applicant, order the existing licence to be cancelled, or may, if he thinks fit, instead of making an order for the grant of a licence to the applicant, order the existing licence to be amended.

(3) Where two or more patents are held by the same patentee and an applicant for a compulsory licence establishes that the reasonable requirements of the public have not been satisfied with respect to some only of the said patents, then, if the Controller is satisfied that the applicant cannot efficiently or satisfactorily work the licence granted to him under those patents without infringing the other patents held by the patentee and if those patents involve important technical advancement of considerable economic significance in relation to the other patents, he may, by order, direct the grant of a licence in respect of the other patents also to enable the licensee to work the patent or patents in regard to which a licence is granted under section 84.

(4) Where the terms and conditions of a licence have been settled by the Controller, the licensee may, at any time after he has worked the invention on a commercial scale for a period of not less than twelve months, make an application to the Controller for the revision of the terms and conditions on the ground that the terms and conditions settled have proved to be more onerous than originally expected and that in consequence thereof the licensee is unable to work the invention except at a loss: Provided that no such application shall be entertained a second time.

89. General purposes for granting compulsory licences.—The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,-

(a) that patented inventions are worked on a commercial scale in India without undue delay and to the fullest extent that is reasonably practicable;

(b) that the interests of any person for the time being working or developing an invention in India under the protection of a patent are not unfairly prejudiced.

90. Terms and conditions of compulsory licences.— (1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure-

- (i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;
- (ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;
- (iii) that the patented articles are made available to the public at reasonably affordable prices.
- (iv) that the licence granted is a non-exclusive licence;
- (v) that the right of the licensee is non-assignable;
- (vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest;
- (vii) that the licence is granted with a predominant purpose of supplying in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of subsection (7) of section 84;
- (viii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use;
- (ix) that in the case the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, licensee shall be permitted to export the patented product, if need be.”

(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do, in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the royalty and other remuneration, if any, payable to the patentee, the quantum of import, the sale price of the imported article, and the period of importation), and thereupon the Controller shall give effect to the directions.

91. (1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply to the Controller for the grant of a licence of the first mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently, or to the best advantage possible.

(2) No order under sub-section (1) shall be made unless the Controller is satisfied-

- (i) that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a licence in respect of the other invention on reasonable terms; and
- (ii) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in India.

(3) When the Controller is satisfied that the conditions mentioned in sub-section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a licence under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent or his licensee: Provided that the licence granted by the controller shall be non-assignable except with the assignment of the respective patents.

(4) The provisions of sections 87, 88 and 89 shall apply to licences granted under this section as they apply to licences granted under section 84.

92. Special provision for compulsory licences on notifications by Central Government. (1)

If the Central Government is satisfied in respect of any patent or class of patents in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary or expedient in the public interest that compulsory licences should be granted at any time after the sealing thereof to work the invention or inventions, it may make a declaration to that effect in the Official Gazette, and thereupon the following provisions shall have effect, that is to say-

(i) the Controller shall, on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms as he thinks fit;

(ii) in settling the terms of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that is necessary in-

- (i) a circumstance of national emergency; or
- (ii) a circumstance of extreme urgency; or
- (iii) a cause of public non-commercial use,

Which may arise or is required, as the case may be, including public health crises, related to Acquired Immune deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section: Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

92A. (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) The controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned product to such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

Explanation:- for the purposes of this section, "pharmaceutical products" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use".

93. Order for licence to operate as a deed between parties concerned.—Any order for the grant of a licence under this Chapter shall operate as if it were a deed granting a licence executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.

94. Termination of compulsory licence.— (1) On an application made by the patentee or any other person deriving title or interest in the patent, a compulsory licence granted under section 84 may be terminated by the Controller, if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur. Provided that the holder of the compulsory licence shall have the right to object to such termination.

(2) While considering an application under sub-section (1), the controller shall take into account that the interest of the person who had previously been granted the licence is not unduly prejudiced.

99. Meaning of use of invention for purposes of Government.—(1) For the purposes of this Chapter, an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking.

(2) [Omitted by the Patents (Amendment) Act, 2002]

(3) Nothing contained in this Chapter shall apply in respect of any such importation, making or using of any machine, apparatus or other article or of any such using of any process, or of any such importation, using or distribution of any medicine or drug, as may be made by virtue of one or more of the conditions specified in section 47.

100. Power of Central Government to use inventions for purposes of Government.—(1)

Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may use the invention for the purposes of Government in accordance with the provisions of this Chapter.

(2) Where an invention has, before the priority date of the relevant claim of the complete specification, been duly recorded in a document, or tested or tried, by or on behalf of the Government or a Government undertaking, otherwise than in consequence of the communication of the invention directly or indirectly by the patentee or by a person from whom he derives title, any use of the invention by the Central Government or any person authorised in writing by it for the purposes of Government may be made free of any royalty or other remuneration to the patentee.

(3) If and so far as the invention has not been so recorded or tried or tested as aforesaid, any use of the invention made by the Central Government or any person authorised by it under sub-section (1), at any time after grant of the patent or in consequence of any such communication as aforesaid, shall be made upon terms as may be agreed upon either before or after the use, between the Central Government or any person authorised under sub-section (1) and the patentee, or, as may in default of agreement be determined by the High Court on a reference under section 103: Provided that in case of any such use of any patent, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent.

(4) The authorisation by the Central Government in respect of an invention may be given under this section, either before or after the patent is granted and either before or after the acts in respect of which such authorisation is given are done, and may be given to any person, whether or not he is authorised directly or indirectly by the applicant or the patentee to make, use, exercise or vend the invention or import the machine, apparatus or other article or medicine or drug covered by such patent.

(5) Where an invention has been used by or with the authority of the Central Government for the purposes of Government under this section, then, except in case of national emergency or other circumstances of extreme urgency or for non-commercial use, the Government shall notify the patentee as soon as practicable of the fact and furnish him with such information as to the extent of the use of the invention as he may, from time to time, reasonably require; and where the invention has been used for the purposes of a Government undertaking, the Central Government may call for such information as may be necessary for this purpose from such undertaking.

(6) The right to make, use, exercise and vend an invention for the purposes of Government under sub-section (1) shall include the right to sell, on non-commercial basis, the goods which have been made in exercise of that right, and a purchaser of goods so sold, and a person claiming through him, shall have the power to deal with the goods as if the Central Government or the person authorised under sub-section (1) were the patentee of the invention.

(7) Where in respect of a patent which has been the subject of an authorisation under this section, there is an exclusive licensee as is referred to in sub-section (3) of section 101, or where such patent has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention (including payments by way of minimum royalty), the notice directed to be given under sub-section (5) shall also be given to such exclusive licensee or assignor, as the case may be, and the reference to the patentee in sub-section (3) shall be deemed to include a reference to such assignor or exclusive licensee.

101. Rights of third parties in respect of use of invention for purposes of Government.—

(1) In relation to any use of a patented invention, or an invention in respect of which an application for a patent is pending, made for the purposes of Government-

(a) by the Central Government or any person authorised by the Central Government under section 100; or

(b) by the patentee or applicant for the patent to the order made by the Central Government, the provisions of any licence, assignment or agreement granted or made between the patentee or applicant for the patent (or any person who derives title from him or from whom he derives title) and any person other than the Central Government shall be of no effect so far as those provisions-

(i) restrict or regulate the use for the purposes of Government of the invention, or of any model, document or information relating thereto, or

(ii) provide for the making of payments in respect of any use of the invention or of the model, document or information relating thereto for the purposes of Government, and the reproduction or publication of any model or document in connection with the said use for the purposes of Government shall not be deemed to be an infringement of any copyright subsisting in the model or document.

(2) Where the patent, or the right to apply for or obtain the patent, has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention, then, in relation to any use of the invention made for the purposes of Government by the patentee to the order of the Central Government, sub-section (3) of section 100 shall have effect as if that use were made by virtue of an authority given under that section; and any use of the invention for the purposes of Government by virtue of sub-section (3) of that section shall have effect as if the reference to the patentee included a reference to the assignor of the patent, and any sum payable by virtue of that sub-section shall be divided between the patentee and the assignor in such proportion as may be agreed upon between them or as may in default of agreement be determined by the High Court on a reference under section 103.

(3) Where by virtue of sub-section (3) of section 100, payments are required to be made by the Central Government or persons authorised under sub-section (1) of that section in respect of the use of an invention for the purposes of Government and where in respect of such patent there is an exclusive licensee authorised under his licence to use the invention for the purposes of Government, such sum shall be shared by the patentee and such licensee in such proportions, if any, as may be agreed upon between them or as may in default of agreement be determined by the High Court on a reference under section 103 to be just, having regard to any expenditure incurred by the licensee-

(a) in developing the said invention; or

(b) in making payments to the patentees other than royalties or other benefits determined by reference to the use of the invention.

102. Acquisition of inventions and patents by the Central Government. — (1) The Central Government may, if satisfied that it is necessary that an invention which is the subject of an application for a patent or a patent should be acquired from the applicant or the patentee for a public purpose, publish a notification to that effect in the Official Gazette, and thereupon the invention or patent and all rights in respect of the invention or patent shall, by force of this section, stand transferred to and be vested in the Central Government.

(2) Notice of the acquisition shall be given to the applicant, and, where a patent has been granted, to the patentee and other persons, if any, appearing in the register as having an interest in the patent.

(3) The Central Government shall pay to the applicant, or, as the case may be, the patentee and other persons appearing on the register as having an interest in the patent such compensation as may be agreed upon between the Central Government and the applicant, or the patentee and other persons; or, as may, in default of agreement, be determined by the High Court on a reference under section 103 to be just having regard to the expenditure incurred in connection with the invention and, in the case of a patent, the term thereof, the period during which and the manner in which it has already been worked (including the profits made during such period by the patentee or by his licensee whether exclusive or otherwise) and other relevant factors.

146. Power of Controller to call for information from patentees.—(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under subsection (1) or subsection (2) in such manner as may be prescribed.

INDONESIA

Articles 81-107 of Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents

Articles 1-29 of Peraturan Menteri Hukum dan Hak Asasi Manusia Republik Indonesia Nomor 39 Tahun 2018 Tentang Tata Cara Pemberian Lisensi-Wajib Paten¹

Part Three Compulsory Licenses

Section 1

Article 81

A compulsory License is non-exclusive.

Article 82

(1) A compulsory License is a License to implement a Patent that is granted based on a Decision of the Minister upon request on the following grounds:

- a. Patent Holder has not fulfilled his/her obligation to make products or use the process in Indonesia as referred to in Article 20 section (1) within a period of 36 (thirty six) months after the granting of a Patent;
- b. Patent has been implemented by the Patent Holder or the Licensee in any forms and by any manners that harm the public interest; or
- c. a Patent as the result of development from a Patent that has been granted earlier cannot be exploited without infringing other protected Patent.

(2) A request for compulsory License as referred to in section (1) is subject to fees.

¹ Available at: <http://peraturan.go.id/peraturan/view.html?id=11e92047c961d070a15a303932303330> (Accessed May 3, 2019)

Paragraph 2

Request for a Compulsory Licensing

Article 83

(1) A request for a compulsory License on the ground as referred to in Article 82 section (1) point a may be filed after the period of 36 (thirty six) months as from the date of granting of a Patent.

(2) A request for a compulsory License on the ground as referred to in Article 82 section (1) point b and point c may be submitted at any time after a Patent is granted.

(3) The request for a compulsory License as referred to in Article 82 section (1) point c may only be granted if the Patent to be implemented contains novelty that is more advanced than existing Patent.

Article 84

(1) A compulsory License as referred to in Article 82 section (1) may only be granted by the Minister provided that:

a. the applicant or his/her Proxy can show evidence that he/she has the capability to personally and fully implement the relevant Patent and has facilities to readily implement the relevant Patent;

b. the applicant or his/her Proxy has made efforts in a period for not later than 12 (twelve) months to acquire a License from the Patent Holder on the basis of normal terms and conditions but did not succeed; and

c. the Minister has the opinion that the relevant Patent may be implemented in Indonesia on a feasible economic scale and can be benefit to the public.

(2) The evidence as referred to in section (1) point a must be completed with a statement from competent institution upon request from the applicant or his/her Proxy.

Article 85

In the event that a compulsory License is filed on the grounds as referred to in Article 82 section (1) point c, thus:

a. the Patent Holder is entitled to mutual Licensing to use the other parties' Patent under reasonable terms; and

b. the implementation of Patent by Licensee cannot be transferred unless it is transferred together with assignment of the other Patent.

Article 86

(1) Examination on a request for a compulsory License is conducted by an ad-hoc expert team appointed by the Minister in accordance with the relevant Patent field.

(2) In conducting the examination as referred to in section (1), the expert team invites the Patent Holder to have his/her opinion heard.

(3) The Patent Holder is required to express his/her opinion not later than 30 (thirty) Days as from the date of notification.

(4) If the Patent Holder does not express his/her opinion in period of time as referred to in section (3), the Patent Holder is deemed to approve the granting of a compulsory License.

Paragraph 3

Issuance, Suspension, or Refusal of Request for Compulsory License

Article 87

(1) The Minister notifies the decision to grant, suspend, or refuse a request for compulsory License to:

a. the applicant or his/her Proxy; and

b. the Patent Holder or his/her Proxy.

(2) The notification as referred to in section (1) is communicated not later than 7 (seven) Days as from the date of the decision to grant, suspend, or refuse a request for compulsory License.

Article 88

(1) In the event that the Minister grants a request for a compulsory License as referred to in Article 87, the Minister stipulates a Ministerial Decision on granting a compulsory License to the applicant or his/her Proxy, including the amount of Remuneration and method of payment.

(2) The stipulation of decision on granting a compulsory License as referred to in section (1) is carried out not later than 90 (ninety) Days as from the requesting date for compulsory License.

(3) A period of time as referred to in section (2) excludes the period of suspension to not later than 12 (twelve) months as from the date of notification of suspension by the Minister.

(4) Decision on granting a compulsory License as referred to in section (1) mentions:

- a. that the compulsory License is non-exclusive;
- b. the reasons for granting the compulsory License;
- c. evidence, including statement or explanations, which form the basis for granting the compulsory License;
- d. the period of compulsory License;
- e. the amount of Remuneration payable by the compulsory Licensee to the Patent Holder and the method of payment;
- f. the conditions for termination of compulsory License and matters which may cancel the compulsory License;
- g. scope of compulsory License for entire or partial Patent requested for a compulsory License; and
- h. other matters necessary to protect the interests of concerned parties in a fair manner.

(5) Further provisions on the format of decision of granting a compulsory License as referred to in section (1) are regulated by a Ministerial Regulation.

Article 89

Decision of the Minister on the granting of a compulsory License as referred to in Article 88 section (1) may be a subject of a lawsuit to the Commercial Court.

Article 90

(1) The Minister may suspend or refuse the granting of compulsory License on the grounds provided by a recommendation from expert team and declaration from Patent Holder, the prevailing Patent requires time longer than 36 (thirty six) months to be commercially implemented in Indonesia.

(2) Pertinent declaration of Patent Holder as referred to in section (1) must be supplemented with evidence that a period of 36 (thirty six) months is not sufficient to implement the Patent commercially in Indonesia.

Article 91

(1) The suspension of granting a compulsory License as referred to in Article 90 section (1) is provided for a period of 12 (months) as from the date of notification to suspend granting of Compulsory License by the Minister.

(2) The Minister stipulates a decision to grant or refuse a request for compulsory License within a period of 14 (fourteen) Days as from the end of date of suspension period.

Article 92

(1) Compulsory Licensee must provide Remuneration to the Patent Holder.

(2) Provisions regarding the amount of Remuneration and method of payment as referred to in section (1) are regulated by a Ministerial Regulation.

Article 93

(1) The Minister may grant a compulsory License to make pharmaceutical products patented in Indonesia to serve a purpose of medication of human diseases.

(2) The Minister may grant a compulsory License to import supply of pharmaceutical products patented in Indonesia yet has not been feasible to be made in Indonesia to serve a purpose of medication of human diseases.

(3) The Minister may grant a compulsory License to export pharmaceutical products patented and made in Indonesia to serve a purpose of medication of human diseases upon request from developing or least developed countries.

Paragraph 4

Recording of Compulsory License

Article 94

(1) The Minister is obligated to record the granting of compulsory License in the Patent database and publish it in electronic media and/or non-electronic media.

(2) Recording and publishing granting of compulsory License as referred to in section (1) are carried out not later than 30 (thirty) Days as from the date of stipulation of granting of compulsory License by the Minister.

Article 95

(1) The Minister sends the copy of decision on granting compulsory License to:

- a. applicant of compulsory License or his/her Proxy;
- b. Patent Holder or his/her Proxy.

(2) The sending of decision as referred to in section (1) is carried out not later than 30 (thirty) Days as from the date of the decision of granting a compulsory License as referred to in Article 88 section (1).

Article 96

(1) Every Person may file a request for an excerpt of decision to grant a compulsory License.

(2) A request for an excerpt of decision to grant a compulsory License as referred to in section (1) must be submitted in writing either electronically or non-electronically to the Directorate General of Intellectual Property subject to fees.

Paragraph 5

Implementation of Compulsory License

Article 97

Compulsory License is granted to a Licensee for a period of time without exceeding the Patent protection period requested by the Compulsory License.

Article 98

Implementation of Compulsory License by the Licensee is deemed as implementation of a Patent requested on said Compulsory License.

Article 99

The granting of a compulsory License does not release a Patent Holder from the obligation to pay annual fee in accordance with the prevailing legislation.

Article 100

In the event that a compulsory License is related to technology of semi-conductor, the holder of compulsory License may only uses compulsory License for:

- a. non-commercial public interest; or
- b. action based on court order or decision of relevant agency stating that the implementation of said Patent constitutes a monopoly or unfair competition.

Article 101

In the event of implementing compulsory License, the holder of compulsory License may cooperate with other parties both nationally and internationally.

Paragraph 6

Transfer of Compulsory License

Article 102

(1) A compulsory License is not transferrable, except due to inheritance.

(2) In the event that a compulsory License is transferred by inheritance, the Ministerial Decision on granting Compulsory License remains in effect to the beneficiary.

(3) A compulsory License which is transferred from inheritance as referred to in section (1) must be reported to the Minister to be recorded in the patent database and published in an electronic media and/or non-electronic media.

(1) A compulsory license which is transferred from inheritance as referred to in section (1) remains bound to the requirements and conditions particularly on the period as set out in the decision of granting compulsory license as referred to in Article 86 section (4).

(4) A compulsory License which is transferred from inheritance as referred to in section (1) remains bound to the requirements and conditions particularly on the period as regulated in the decision of granting compulsory License as referred to in Article 88 section (4).

(5) If the beneficiary does not report the transfer of compulsory License as referred to in section (3) to the Minister, the Ministerial Decision on granting a compulsory License is invalid.

Paragraph 7

Termination of Compulsory License

Article 103

(1) A compulsory License is terminated because of the expiry of period set forth on the decision to grant a compulsory License by the Minister or due to a decision of the Commercial Court with a permanent legal power to nullify the Ministerial Decision regarding the granting of a compulsory License.

(2) Other than the expiry of period of time of a compulsory License and a decision of the Commercial Court to nullify the decision to grant a compulsory License as referred to in section (1), a compulsory License may also be terminated because of nullification based on the Ministerial Decision upon request of Patent Holder provided that:

- a. the grounds that formed the basis for granting a compulsory License is no longer exist;
- b. the compulsory Licensee has evidently not implemented the compulsory License or has not made

appropriate preparations for immediate implementation; or

- c. the compulsory Licensee is no longer complying with other terms and conditions.

(3) A request for nullification of compulsory License on the grounds as referred to in section (2) point b may be carried out after compulsory Licensee does not implement compulsory License Patent within 24 (twenty-four) months since the date of decision of granting a compulsory License.

(4) Other terms and conditions which must be complied by the compulsory Licensee as referred to in section (2) point c may be:

- a. payment of Remuneration; or
- b. compliance to the scope of License, set forth in the decision to grant a Compulsory License.

Article 104

(1) The Minister is required to notify the decision on nullification of a compulsory License as referred to in Article 103 section (2) to:

- a. Patent Holder or his/her Proxy; and
- b. Compulsory Licensee or his/her Proxy.

(2) Notification of the Ministerial Decision on nullification of compulsory License as referred to in section (1) is communicated not later than 14 (fourteen) Days as from the issuance date of the Ministerial Decision on nullification of compulsory License.

Article 105

(1) The Minister is required to record the termination of compulsory License as referred to in Article 103 section (1) and section (2) in the Patent database and publish it on electronic media and/or non-electronic media.

(2) The record of the termination of compulsory License as referred to in section (1) is done not later than 14 (fourteen) Days as from the date of terminated compulsory License.

Article 106

Termination of a compulsory License results in the restoration of the right of Patent Holder to the relevant Patent as from the date of recording as referred to in Article 105 section (1).

Article 107

Further provisions regarding terms and procedures on granting a compulsory License are regulated by a Ministerial Regulation.

IRAN

Patents, Industrial Designs and Trademarks Registration Act Of the Islamic Republic of Iran (2008)

Article 17

Article 17 - The Government, or the person authorized by the Government, subject to following arrangements, may use the patent,

a) Where, in view of the respective Minister or the highest authority of the competent organization the public interest, including national security, nutrition, health or the development of other vital sectors of the national economy requires that the Government, or any person exploit the invention, and or the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive and the concerned authority is satisfied that the exploitation of the invention would remedy such problem, the matter will be discussed in a Committee comprising of Head of the State Organization for Registration of Deeds and Properties, one of the Judges of the Supreme Court as nominated by the Head of the Judiciary, the Prosecutor General, representative of the President of I.R. of Iran and the Minister or the highest authority of the concerned organization. If approved a government agency or a third party, designated by the said Committee, may exploit the invention without the consent of the owner.

b) The exploitation of a patent shall be limited to the purpose for which it was authorized and shall be subject to payment to the said owner of an adequate remuneration thereof, taking into account the economic value of the decision. If the owner or any other interested party wishes to be heard, the Commission shall render its decision after having heard their statements and taking into consideration the exploitation in anti-competitive practices. The Commission may, upon request of the owner of the patent, or the Government agency or the third party authorized to exploit the patented invention, after hearing both or either of the parties as appropriate and necessary, proceed to make a fresh decision.

c) If the holder of the patent claims that, the circumstances that led to making the decision have ceased to exist and are unlikely to recur or if he claims that the Government agency or third party designated by Committee has failed to comply with the terms of the decision, the matter shall be discussed and examined by the Committee and after hearing the patent owner, the

Minister or the highest authority of the concerned organization and the exploiter, the exploitation permit shall be terminated and, as the case may be, the authorization shall be issued for the owner or another exploiter. However, the authorization shall not be terminated if, subject to the provisions of the present paragraph, the Committee is satisfied that the need for adequate protection of the legitimate interests of the persons who have obtained the authorization justifies the maintenance of the decision.

In cases where a third person has been designated by the Commission, the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

d) The authorization provided for in the present Article shall not impede the following acts:

1. The conclusion of a License Contract by the owner of the patent, subject to provisions of the present Article;
2. The continued exercise, by the owner of the patent, of his rights under Article 15(a);
3. The issuance of a non-voluntary license under subsections h (1) and (2) of the present Article.

e) The request for the Commission's authorization shall be accompanied by the evidence that the Government agency or the authorized person has submitted a request to the owner of the patent for a license, but that the said person or agency has been unable to obtain such a license on reasonable terms and conditions and within a reasonable time.

Provisions of this subsection shall not apply in cases of emergency arising from national interests or cases of *Force Majeure*, at the total discretion of the Committee, provided that in such cases the owner of the patent shall be notified of the Commission's decision as soon as possible.

f) The exploitation of the invention by the Government agency or a third person designated by the Committee shall be predominantly for the supply of in the Iranian market.

g) The authorization issued by the Commission for exploitation of a patent in the field of semi-conductor technology shall be authorized only for public non-commercial use or where the Minister or the highest ranking authority of the concerned organization has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive.

h) The non-voluntary exploitation authorization may be issued in the following cases under the following conditions:

1. If it is claimed in a Letters Patent that the patent cannot be exploited without using an earlier patent and that the later patent, compared to the earlier patent, involves an important technical advance and is of considerable economic importance, the Industrial Property Office, upon the request of the owner of the later patent, may issue an authorization for using the earlier patent to the extent necessary, without consent of its owner.

2. Where a non-voluntary license is issued under subsection (1) above without consent of the owner, the Industrial Property Office, upon the request of the owner of the earlier patent, shall issue a non-voluntary license in respect of the later patent as well.

3. In the case of a request for the issuance of a non-voluntary license under subsections (1) and (2) hereof, the decision issuing the non-voluntary license shall fix the scope and function of the authorization and the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

4. In the case of a non-voluntary license issued under subsection (1) above, its transfer shall be authorized only with the later patent, or, in the case of a non-voluntary license under subsection (2) above, only with the earlier patent.

5. The request for the issuance of a non-voluntary license shall be subject to the payment of the prescribed fee.
6. In the case of a non-voluntary license issued under subsections (1) and (2) hereof, subsections (b) to (f) and (i) of the present Article shall apply *mutatis mutandis*.
- i) Appeals may be lodged with the Public Courts of Tehran against resolutions of the Commission made within the scope of the subsections of the present Article.

IRAQ

Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law No. 65 of 1970 as last amended by Coalition Provisional Authority Order Number 81

Articles 2 and 28-30b

Article 2 - "The Registrar may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively:

- A) If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible.
- B) 1. If the patentee does not exploit it or exploits it insufficiently before the elapse of four years as of the application date or three years as of the granting date, the period to be applied is the one that elapses later. However, the Registrar may grant the patentee an additional grace period if it is deemed that reasons beyond the control of the patentee have prevented exploitation.
2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the relevant International Conventions, the importation of the subject goods of the patent to Iraq shall be deemed utilization of the patent.
- C. If rights are exercised by the patentee in such a way as to prevent others from competing fairly."

Article 28 - "The following shall be taken into consideration when compulsory licenses are granted:

- A) Each application for a license shall be decided separately for its specific conditions and circumstances.
- B) The applicant shall have tried to obtain a license from the patentee under reasonable remuneration and conditions but did not reach an agreement during a reasonable period of time in the case provided for in paragraph (B) of Article 27 of this Law.
- C) The scope and duration of the license shall be limited to the purpose for which it is granted. If the license application relates to semiconductor technology, then it shall only be granted for noncommercial public good or to rectify practices deemed by the competent judicial or administrative authority to be anticompetitive.
- D) The license to exploit shall not be exclusive.
- E) The license shall not be assignable to third parties.
- F) The license shall only be granted for meeting the demand in the local market except in cases where practices have been deemed by the competent judicial or administrative authority to be anticompetitive.
- G) The patentee shall receive an equitable remuneration which takes into account the economic value of the patent."

Article 29 - "The Registrar may cancel the compulsory license sua sponte or on the strength of an application from the patentee if the reasons for its grant lapsed. This license cancellation shall, however, preserve the rights of those involved in the compulsory license."

Article 30 - "The provisions and procedures related to licensing of patent utilization shall be prescribed pursuant to regulations to be issued to this aim."

Article 30b - "The Registrar's compulsory license decision shall be appealable to the Minister within 60 days of its notification."

IRELAND

Patents Act 1992

Sections 70-78

Compulsory licences.

70.— (1) At any time after the expiration of the period of three years, or such other period as may be prescribed, beginning on the date of the publication of notice of grant of a patent any person may apply to the Controller for a licence under the patent, or for an entry in the register to the effect that licences under the patent are to be available as of right, on any or all of the following grounds:

(a) that

(i) a demand in the State for the subject matter of the patent is not being met or is not being met on reasonable terms, or

(ii) a demand in the State for a product which is protected by the patent is being met by importation other than from a member of the World Trade Organisation;

(b) that the establishment or development of commercial or industrial activities in the State is unfairly prejudiced.

(2) If an invention protected by a patent (in this section referred to as 'the second patent') cannot be exploited in the State without infringing rights deriving from another patent (in this section referred to as 'the first patent') the proprietor of the second patent may apply to the Controller for a licence under the first patent to the extent necessary for the exploitation of the invention concerned, provided that such invention involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.

(3) Where an application is made under this section, if the Controller is satisfied:

(a) that any of the grounds specified in subsection (1) are established, or

(b) that an invention protected by a patent cannot be exploited without infringing rights deriving from the first patent as referred to in subsection (2), the Controller may make an order in accordance with the application and, where the order is for the grant of a licence, the order may require the licence to be granted upon such terms as the Controller thinks fit, provided that:

(i) any licence granted shall be non-exclusive;

(ii) any licence granted shall be predominantly for the supply of the market in the State;

(iii) any licence granted may only be assigned with the prior authorisation of the Controller and with that part of the enterprise or goodwill which uses the patented invention and, in the case of a licence granted on an application under subsection (2) in respect of the first patent, the licence may only be assigned by the proprietor of the second patent in conjunction with the assignment of the second patent;

(iv) a licence shall only be granted subject to the payment to the proprietor of the patent of adequate remuneration in the circumstances of the case, taking into account the economic value of the licence;

(v) the scope and duration of the licence shall be limited to the purpose for which it is granted;

(vi) any licence granted on an application under subsection (1) in respect of a patent which relates to semi-conductor technology shall only be for public non-commercial use;

(vii) no order shall be made on an application under subsection (2) unless the proprietor of the second patent is able and willing to grant the proprietor of the first patent and the licensee of that proprietor a cross-licence, on reasonable terms, to use the invention claimed in the second patent.

(4) The Controller shall, in determining whether to make an order pursuant to an application under this section, take account of the following matters, namely—

(a) the nature of the relevant invention, the time which has elapsed since the grant of the patent and the measures already taken by the proprietor or any licensee to make full use of the invention,

(b) the ability of any person to whom a licence would be granted under the order to exploit the patent to the public advantage, and

(c) the risks to be undertaken by that person in providing capital and exploiting the patent if the application is granted.

(5) Section 68(3) shall apply to a licence granted pursuant to an order under this section as it applies to a licence granted by virtue of section 68.”.

Provisions as to compulsory licences.

71.— (1) Where an order for the grant of a licence or for an entry in the register has been made pursuant to an application under section 70, any person may apply to the Controller to amend or cancel the order on the grounds that the circumstances which led to the order have changed or have ceased to exist and are unlikely to recur.

(2) Where the Controller is satisfied that the circumstances referred to in subsection (1) have changed or have ceased to exist and are unlikely to recur, the Controller may order the amendment or cancellation of the existing order upon such terms as the Controller thinks fit, including, in particular, terms which provide for the protection of the interests of the licensee concerned.

(3) Section 73 shall, in so far as it is applicable, apply in relation to an application under subsection (1).

(4) Where, following an application under subsection (1), an order is amended, subsections (1), (2) and (3) shall, in so far as they are applicable, apply in relation to the order so amended.

Licences, etc. on application of Minister of Government.

72.- (1) At any time after the expiration of the period of three years beginning on the date of the publication of notice of grant of a patent, or such other period as may be prescribed under section 70(1), any Minister of the Government may apply to the Controller upon any one or more of the grounds specified in section 70 for an entry in the register to the effect that licences under the patent are to be available as of right, or for the grant to any person specified in the application of a licence under the patent, and the Controller may, if satisfied that any of those grounds are established, make an order in accordance with the application.

(2) Sections 70(3) and 71 shall, so far as applicable, apply in relation to an application and an order made under this section as they apply in relation to an application and an order under section 70.

Procedure on applications under sections 70 and 72.

73.- (1) Every application under section 70 or 72 shall specify the nature of the order sought by the applicant and shall contain a statement (to be verified in such manner as may be prescribed) setting out the nature of the applicant's interest (if any) and the facts upon which the application is based and shall be accompanied by evidence indicating that the applicant sought to obtain a

licence from the proprietor of the patent but has been unable to obtain such a licence on reasonable terms and within a reasonable time.

(1A) The Controller may, when so requested by the applicant, dispense with the evidence referred to in subsection (1)—

- (a) where there exists a national emergency or other circumstances of extreme urgency, or
- (b) in the case of an application for a licence for public non-commercial use:

Provided that the proprietor of the relevant patent has been informed as soon as reasonably practicable of the intention of the applicant to apply to the Controller for a licence under the patent.

(2) Where the Controller is satisfied, upon consideration of any application referred to in subsection (1), that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the proprietor of the relevant patent and any other persons appearing from the register to be interested in the patent in respect of which the application is made, and shall advertise the application in the Journal.

(3) The proprietor of the relevant patent or any other person desiring to oppose an application referred to in subsection (1) may, within such time as may be prescribed, give to the Controller notice of opposition.

(4) A notice of opposition given under this section shall contain a statement (to be verified in such manner as may be prescribed) setting out the grounds on which the relevant application is opposed.

(5) Where a notice of opposition is duly given under this section, the Controller shall notify the applicant and shall, subject to the provisions of section 74 with respect to arbitration, determine the question.

Appeals and references to arbitrator.

74.- (1) On any appeal from any order made by the Controller in pursuance of an application under section 70, 71 or 72 the Attorney General shall be entitled to appear and be represented.

(2) Where an application is opposed and either:

- (a) the parties consent; or
- (b) the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot, in the opinion of the Controller, conveniently be made before him,

the Controller may at any time order the whole proceedings, or any question or issue of fact arising therein, to be referred to an arbitrator agreed on by the parties, or, in default of agreement, appointed by the Controller.

(3) Where the whole proceedings are referred under this section, section 35 of the Arbitration Act, 1954 (which relates to the statement of cases by arbitrators for the decision of the Court), shall not apply to the arbitration; but unless the parties otherwise agree before the award of the arbitrator is made, an appeal to the Court shall lie from the award.

(4) Where a question or issue of fact is referred under this section, the arbitrator shall report his findings to the Controller.

Supplementary provisions as to licences.

75.- (1) Any order under this Act for the grant of a licence shall, without prejudice to any other method of enforcement, have effect as if it were a deed, executed by the proprietor of the patent and all other necessary parties, granting a licence in accordance with the order.

(2) An order may be made on an application under section 70, 71 or 72 for an entry in the register to the effect that licences under the relevant patent are to be available as of right notwithstanding any contract which would have precluded the making of such an entry in respect of the patent on the application of the proprietor of the patent under section 68, and any such order shall for all purposes have the same effect as an entry made in pursuance of an application under section 68.

(3) No order shall be made in pursuance of any application under section 70, 71 or 72 which would be at variance with the Treaty establishing the European Economic Community or with the TRIPs Agreement.

PART V

USE OF INVENTIONS FOR THE SERVICE OF THE STATE

76.- Assignment of invention, application, or patent to Minister of Government.

(1) Any inventor, or any applicant for or proprietor of a patent, may (either for or without valuable consideration) make to a Minister of the Government, and such Minister may take on behalf of the State, an assignment of the whole of or any share or interest in the benefit of an invention, of a patent application therefor, or of any patent obtained or to be obtained therefor, and where a Minister of the Government takes any such assignment, such Minister may do, or, as may be appropriate, join in doing, on behalf of the State, all or any of the following things, that is to say-

(a) develop and perfect such invention,

(b) form or promote an incorporated company or an unincorporated association of persons to develop and perfect such invention,

(c) sell or lease any such patent application or patent or grant licences under any such application or patent on such terms as he shall, with the agreement of the Minister for Finance, think proper,

(d) form or promote an incorporated company or an unincorporated association of persons to work commercially any such invention,

(e) do all such things as may be necessary for the maintenance or preservation of any such application or patent or be otherwise incidental to the ownership thereof.

(2) Every Minister of the Government shall, before the 1st day of April in every year, lay before each House of the Oireachtas a report of every (if any) exercise by him during the year ending on the previous 31st day of December of the several powers conferred on him by paragraph (c) or (d) of subsection (1) and also, if and so far as he considers it to be in the public interest, of any or all of the powers conferred by paragraph (a), (b) or (e) of subsection (1).

(3) All expenses incurred by a Minister of the Government under this section shall, to such extent as may be sanctioned by the Minister for Finance, be paid out of moneys provided by the Oireachtas.

Right to use inventions for service of State.

77.- (1) A patent and a patent application shall have to all intents the like effect as against the State as it has against an individual; provided that any Minister of the Government may, by himself or by such of his officers, servants or agents as may be authorized in writing by him or by any other person acting on his behalf at any time after the making of an application for a patent, do for the service of the State any of the following acts in the State in relation to an

invention which is the subject of the application or patent, without the consent of the applicant for or the proprietor of the patent, that is to say-

- (a) where the invention is a product, make, use, import or stock the product or dispose of or sell or offer to dispose of or sell it to any person;
- (b) where the invention is a process, use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a);
- (c) supply or offer to supply to any person any of the means, relating to an essential element of that invention, for putting the invention into effect.

(2) Anything done by virtue of subsection (1) in relation to an invention which is the subject of an application or a patent, is subsequently in this section and in section 78 referred to as "use of the invention" and the doing of any such thing shall not amount to an infringement of the application or patent concerned.

(3) Use of an invention under this section shall be subject to such terms as may, either before or after the use thereof, be agreed on, with the approval of the Minister for Finance, by any Minister of the Government and the applicant for or the proprietor of the patent relating to the invention, or, in default of agreement, as may be settled in the manner hereinafter provided, and the terms of any agreement or licence concluded between such applicant or proprietor and any person other than a Minister of the Government shall not operate to prevent or regulate the use of the invention for the service of the State.

(4) Where an invention which is the subject of any patent or application for a patent has, before the date of filing, or, where priority is claimed, the priority date of the application, been duly recorded in a document by, or been tried by or on behalf of any Minister of the Government (such invention not having been communicated directly or indirectly by the applicant for or the proprietor of the relevant patent), any Minister of the Government or such of his officers, servants or agents as may be authorized in writing by him, may use the invention so recorded or tried for the service of the State free of any royalty or other payment to the applicant for or the proprietor of the patent, notwithstanding the existence of the application or patent, and, if in the opinion of such Minister the disclosure to the applicant or the proprietor, as the case may be, of the document recording the invention or the evidence of the trial thereof would be detrimental to the public interest, such disclosure may be made confidentially to counsel on behalf of such applicant or proprietor or to any independent expert mutually agreed upon.

(5) Where any use of an invention is made by or with the authority of a Minister of the Government under this section, then, unless it appears to such Minister that it would be contrary to the public interest so to do, the Minister shall notify the applicant for or the proprietor of a patent (if any) relating to the invention as soon as practicable after the use is begun and furnish him with such information as to the extent of the use as he may from time to time reasonably require.

(6) In the case of any dispute as to or in connection with the use of an invention under this section or the terms therefor, or as to the existence or scope of any record or trial referred to in subsection (4), the matter shall be referred to the Court for decision, and the Court shall have the power to refer the whole matter or any question or issue of fact arising thereon to be heard by an arbitrator upon such conditions as it may direct; the Court or arbitrator in settling the dispute shall be entitled to take into consideration any benefit or compensation which the applicant for or proprietor of a patent (if any) relating to the invention or any other person interested in such application or in such patent may have received directly or indirectly from the State in respect of such application or patent.

(7) In any proceedings under this section the Minister of the Government who is a party to the proceedings may-

- (a) put in issue the validity of the relevant patent without applying for its revocation;
- (b) if the proprietor of a patent is a party to the proceedings, apply for revocation of the patent upon any ground upon which a patent may be revoked under section 58.

(8) The right to use an invention for the service of the State under the provisions of this section shall include a power to dispose of or sell, or offer to dispose of or sell, any products made in pursuance of such right which are no longer required for the service of the State.

(9) Any person who acquires products disposed of or sold in the exercise of powers conferred by this section and any person claiming through him shall have power to deal with the products in the same manner as if they had been made pursuant to a patent held on behalf of the State.

(10) In this section "service of the State" means a service financed out of moneys charged on or advanced out of the Central Fund or moneys provided by the Oireachtas or by a local authority for the purposes of the Local Government Act, 1941.

Use of inventions pursuant to section 77; supplementary provisions.

78.- (1) During any period when an order under subsection (2)(a) is in force the power exercisable in relation to an invention by a Minister of the Government, or a person authorized by a Minister of the Government under section 77, shall include power to use the invention for any purpose which appears to such Minister to be necessary or expedient-

- (a) for the maintenance of supplies and services essential to the life of the community;
- (b) for securing a sufficiency of supplies and services essential to the well-being of the community;
- (c) for promoting the productivity of commerce and industry, including agriculture;
- (d) generally for ensuring that the whole resources of the community are available for use and are used, in a manner best calculated to serve the interests of the community;
- (e) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory other than the State that is in grave distress; or
- (f) for ensuring the public safety and the preservation of the State.

- (2) (a) Where the Government are of opinion that, owing to the existence of exceptional circumstances, it is desirable in the interests of the community that a power conferred by subsection (1) shall be available, they may by order declare that the power shall be available.
- (b) Where an order under paragraph (a) of this subsection is for the time being in force and the Government are of the opinion that the exceptional circumstances referred to in that paragraph no longer exist, they shall by order revoke the first-mentioned order.

ISRAEL

Patent Law, 5727-1967 as consolidated 2014

Sections 104-119, 121-130

Article Three: Use of Inventions in the Interest of the State

Right of State to exploit invention

104. The Minister may permit the exploitation of an invention by Government departments or by an enterprise or agency of the State, whether a patent for it has or has not already been granted or has or has not already been applied for, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services.

Right of State to permit exploitation of invention

Right of State to permit exploitation of invention

105. The Minister may, if he finds that that is necessary for the purposes enumerated in section 104, grant a permit under that section to a person who operates under contract with the State, in order to ensure or facilitate the implementation of that contract and for the requirements of the State only.

Notice of Grant of exploitation permit

106. When a permit has been granted under this Article, the Minister shall notify the owner of the invention or the patent holder and the holder of the exclusive license that the permit was granted and the scope of the permitted use, unless National security requires otherwise.

Article Four: Obligation of the State to Pay Compensation and Royalties

Compensation for restriction of activities

107. If an order was made under section 94 or 99 or if a permit was not granted under section 98 or 103, then the Treasury shall pay to the owner of the invention compensation at the rate set by agreement between the parties or – in the absence of agreement – by the compensation and royalties committee established under section 109.

Royalties for use of patents by the State

108. If a permit was granted under sections 104 or 105, then the State Treasury shall pay to the owner of the invention, to the patent holder or to the holder of an exclusive license, as the case may be, royalties set by agreement between the parties or – in the absence of agreement – set by the compensation and royalties committee.

Compensation and royalties committee

109. The Minister of Justice shall appoint a committee on compensation and royalties, which shall decide on claims for compensation and royalties under this Article; the members of the committee shall be a Justice of the Supreme Court, the Registrar and an additional member from among the teachers at an institution of higher education, within its meaning in the Council for Higher Education Law 5718-1958.

Guidelines for determination of royalties

110. When it is about to determine royalties, the committee shall also consider the scope and character of the permitted exploitation, and it may take into account royalties stipulated in licenses, the conditions of which are similar to those of the permit.

Exclusive jurisdiction of committee

111. No Court or tribunal shall consider any matter within the jurisdiction of the compensation and royalties committee, and every decision by the committee shall be final.

Article Five: General Provisions

Definition 112. In this Chapter, “Minister” – the Minister designated by the Government.

Rules of procedure of committees

113. A contestations committee, as said in sections 96 or 101 and the compensation and royalties committee (hereafter in this Article: “committees”) shall each prescribe its own rules of procedure, as far as those were not prescribed by or under this Law.

Proceedings not public

Proceedings not public

114. Proceedings before the committees shall not be open to the public unless the committee so ordered for a particular matter, and no person shall publish anything about proceedings in camera, except with the committee’s permission.

Powers of committees

115. (a) The committee shall have power –

- (1) to obtain any written or oral evidence which they deem necessary;
 - (2) to summon any person to appear before them to give evidence or to produce any document in his possession, to interrogate him and to demand from him any document in his possession;
 - (3) to compel the attendance of any person who did not comply with a summons and did not justify that to their satisfaction, order him to pay all costs caused by his non-compliance or by compelling his attendance, and fine him an amount of money of not more than IL 75;
 - (4) to obligate any witness to give evidence on oath or affirmation in the manner customary in Court;
 - (5) to fine an amount of money of not more than IL 75 any person who was called to give evidence on oath or affirmation or to produce a document and who refused to do so without reasonable justification, on condition that no person shall be required to answer a question, if by answering it he might incriminate himself, and he shall not be fined for refusing to answer it;
 - (6) to admit any written or oral evidence, even if it would not be admissible in a civil or criminal trial;
 - (7) to award to a person summoned to attend a session of the committee an amount of money which, in the opinion of the committee, he spent in consequence of his attendance.
- (b) The compensation and royalties committee may order that the amount of compensation or royalties not in dispute be paid, wholly or in part, before it makes its final decision.

CHAPTER SEVEN: RESTRICTION OR CANCELLATION OF PATENT HOLDER'S RIGHTS IN THE PUBLIC INTEREST

Article One: Compulsory Licenses

Definitions

116. In this Article – “patented product” – a product for which, or for the production process of which a patent was granted; “patent holder” – includes the holder of an exclusive license under the patent.

Power to grant compulsory license

117. (a) If the Registrar is satisfied that a patent holder abuses his monopoly, then he may grant a license to exploit the invention that is the subject of the patent to a person who applied therefor in the prescribed manner and paid the prescribed fee.
- (b) The Registrar shall not entertain an application under this section, unless it was submitted later than three years after the date on which the patent was granted or four years after the date on which the patent application was submitted, whichever is later.

Power to require notification concerning exploitation of patent (amendment no. 4) 1999

118. (a) At the end of the time said in section 117, the Registrar may demand that a patent holder notify him in writing, within sixty days of the date of the demand, whether he exploits the patented invention in Israel by way of production or of importation, and if so, what is the extent of the production or of the importation and the location of the production area.
- (b) The Registrar shall demand the notification under this section if he was requested to do so by use of the prescribed form and if the prescribed fee was paid.
- (c) If the patent holder does not respond to the demand within 60 days after the date of the demand or within an additional period prescribed by the Registrar, then that shall be deemed an admission on the part of the patent holder that he abuses the monopoly conferred on him by the patent for the invention, in respect of which the notice was sent.

Abuse of monopoly defined

119. The exercise of a monopoly conferred by a patent shall be deemed abusive, if one of the following circumstances exists in respect of the invention, the product or the process which is the subject of the patent, and if the patent holder did not provide a reasonable justification for its existence:

(1) all the demand for the product is not satisfied in Israel on reasonable terms;
(2) the conditions attached by the patent holder to the supply of the product or to the grant of a license for its production or use are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent;

(amendment no. 4) 1999

(3) Repealed.

(amendment no. 4) 1999

(4) Repealed.

(amendment no. 4) 1999

(5) Repealed.

(amendment no. 4) 1999

120. Repealed.

Compulsory license to exploit earlier patent on which the fate of a later patent depends

(amendment no. 4) 1999

121. (a) If a patented invention (hereafter: later invention) cannot be exploited without infringing an invention, for which the patent application date was earlier (hereafter: earlier invention), then the Registrar may, if so requested by the patent holder of the later invention, grant him a license to exploit the earlier invention to the extent necessary for the exploitation of the later invention, on condition that the later invention incorporates an important technological innovation over the earlier invention, which is of great economic importance.

(amendment no. 4) 1999

(b) If the earlier and the later invention serve the same purpose, then a license under subsection (a) shall be granted on condition that the owner of the later invention grant a similar license to the owner of the earlier invention if he so requests.

(amendment no. 2) 1995

(c) In the case of a patent application for which priority was claimed under section 10(a), the date of the previous application, within the meaning of section 10(a), shall be deemed the patent application date for purposes of this section.

(amendment no. 4) 1999

(d) A license given to the owner of a later invention under the provisions of subsection (a) is not transferable, unless the rights to the later invention are transferred together with the license.

Factors to be taken into account in granting compulsory license (amendment no. 4) 1999

122. In dealing with an application for a license under section 117, the Registrar shall also take the following factors into account:

(amendment no. 4) 1999

(1) the applicant's ability to remedy the fault, because of which the license was applied for;

(amendment no. 4) 1999

(2) the public interest, which generally requires that inventions that can be exploited in Israel by way of production or by way of import should be so exploited to the greatest extent possible under existing circumstances and without delay;

(3) the right to reasonable remuneration, taking the nature of the invention into account, for exploitation of the patented invention;

(amendment no. 4) 1999

(4) protection of the rights of any person who exploits in Israel, by way of production or by way of import, the invention to which the application for the license relates and of persons engaged in developing that invention;

(amendment no. 4) 1999

(5) the nature of the invention, the time elapsed since the patent was granted, and the steps taken by the patent holder or by his representative for the exploitation of the invention in Israel by way of production or by way of import.

Restriction of scope of compulsory license (amendment no. 4) 1999

123. A license under this Chapter shall be granted mainly for the requirements of the local market.

(amendment no. 8) 2011

124. (a) As soon as possible after an application for a license under this Chapter was submitted, the Registrar shall – at the applicant's expense – publish a notice in Internet that the application was submitted, and in it he shall invite all persons with an interest in the application or likely to be adversely affected by the grant of the license to join the proceedings.

(b) If a person wishes to join the proceeding, then he shall give notice thereof in the prescribed manner and at the prescribed time, and he shall pay the prescribed fee, and when he has done so he shall be deemed an applicant or a respondent in the proceeding, as the case may be.

(c) This section shall add to and not derogate from the provision of section 159.

Effect of compulsory license

125. A compulsory license under this Chapter shall go into effect thirty days after the day of the Registrar's decision or on a later date prescribed by the Registrar; if an appeal was submitted against the decision, then the Court may delay its going into effect or it may attach conditions to its going into effect or to its delay.

Conditions of license (amendment no. 4) 1999

126. A license under this Chapter shall be a non-exclusive license, and the Registrar shall prescribe its conditions when he grants it, including the royalties or other consideration which the licensee shall pay to the patent holder, all as is reasonable and appropriate in the circumstances of the case and having taken the patent holder's legitimate interests into account, and the Registrar shall also prescribe –

(1) circumstances under which the license shall be deemed void or shall be cancelled or its conditions shall be changed;

(amendment no. 4) 1999

(2) having taken into account, inter alia, the economic value of the license and the patent, the ways of determining the amount of the royalties or of the other consideration, when and how they shall be paid;

(3) the ways of marking the product produced under the license.

Forced transfer of license (amendment no. 4) 1999

126A. A license granted under this Chapter is not transferable, unless the part of the business or of the good will connected to the use of the patent is transferred together with the license.

Review

127. The owner of a patent for which a license was granted under this Chapter may apply to the Registrar in the prescribed form and manner for a review of the license granted, because the circumstances which existed when the license was granted have changed or because the licensee violated one of its conditions, and the Registrar may cancel the license or change its conditions, if he is satisfied that it is right so to do.

Compulsory license to be treated like a license by agreement

128. A license under this Chapter and its conditions shall be treated like a license granted under an agreement between the patent holder and any other person who may be a party to the agreement, and the licensee.

Article Two: Cancellation of Patents in the Public Interest

Power of Registrar to cancel patents

129. (a) The Registrar may cancel a patent for which a license was granted under this Chapter, if he is satisfied that granting the license did not suffice to prevent the abuse of the monopoly which was the ground for granting the license.

(b) The Registrar shall not entertain an application under this section, unless it was submitted by a person qualified to receive the license and unless two years have passed since the day on which a license under this Chapter was first granted in respect of that patent.

Effect of cancellation order

130. Cancellation of a patent under section 129 shall go into effect 60 days after the date of the Registrar's decision, or on a later date prescribed by the Registrar; if an appeal was submitted against the cancellation, then the Court may delay its going into effect or it may attach conditions to its going into effect or to its delay.

ITALY

Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Legislative Decree No. 63 of May 11, 2018)

Articles 70-73

Art. 70

Licenza obbligatoria per mancata attuazione

1. Trascorsi tre anni dalla data di rilascio del brevetto o quattro anni dalla data di deposito della domanda se questo termine scade successivamente al precedente, qualora il titolare del brevetto o il suo avente causa, direttamente o a mezzo di uno o più licenziatari, non abbia attuato l'invenzione brevettata, producendo nel territorio dello Stato o importando oggetti prodotti in uno Stato membro della Unione europea o dello Spazio economico europeo ovvero in uno Stato membro dell'Organizzazione mondiale del commercio, ovvero l'abbia attuata in misura tale da risultare in grave sproporzione con i bisogni del Paese, può essere concessa licenza obbligatoria per l'uso non esclusivo dell'invenzione medesima, a favore di ogni interessato che ne faccia richiesta.

2. La licenza obbligatoria di cui al comma 1 può ugualmente venire concessa, qualora l'attuazione dell'invenzione sia stata, per oltre tre anni, sospesa o ridotta in misura tale da risultare in grave sproporzione con i bisogni del Paese.

3. La licenza obbligatoria non viene concessa se la mancata o insufficiente attuazione è dovuta a cause indipendenti dalla volontà del titolare del brevetto o del suo avente causa. Non sono comprese fra tali cause la mancanza di mezzi finanziari e, qualora il prodotto stesso sia diffuso all'estero, la mancanza di richiesta nel mercato interno del prodotto brevettato od ottenuto con il procedimento brevettato.

4. La concessione della licenza obbligatoria non esonera il titolare del brevetto o il suo avente causa dall'onere di attuare l'invenzione. Il brevetto decade, qualora l'invenzione non sia stata attuata entro due anni dalla data di concessione della prima licenza obbligatoria o lo sia stata in misura tale da risultare in grave sproporzione con i bisogni del Paese.

Art. 71

Brevetto dipendente

1. Può essere concessa licenza obbligatoria se l'invenzione protetta dal brevetto non possa essere utilizzata senza pregiudizio dei diritti relativi ad un brevetto concesso in base a domanda precedente. In tale caso, la licenza può essere concessa al titolare del brevetto posteriore nella misura necessaria a sfruttare l'invenzione, purché questa rappresenti, rispetto all'oggetto del precedente brevetto, un importante progresso tecnico di considerevole rilevanza economica.
2. La licenza così ottenuta non è cedibile se non unitamente al brevetto sull'invenzione dipendente. Il titolare del brevetto sull'invenzione principale ha diritto, a sua volta, alla concessione di una licenza obbligatoria a condizioni ragionevoli sul brevetto dell'invenzione dipendente.

Art. 72

Disposizioni comuni

1. Chiunque domandi la concessione di una licenza obbligatoria ai sensi degli articoli 70 e 71, deve provare di essersi preventivamente rivolto al titolare del brevetto e di non avere potuto ottenere da questi una licenza contrattuale ad eque condizioni.
2. La licenza obbligatoria può essere concessa soltanto contro corresponsione, da parte del licenziatario ed a favore del titolare del brevetto o dei suoi aventi causa, di un equo compenso e purché il richiedente la licenza fornisca le necessarie garanzie in ordine ad una soddisfacente attuazione dell'invenzione a norma delle condizioni fissate nella licenza medesima.
3. La licenza obbligatoria non può essere concessa quando risulti che il richiedente abbia contraffatto il brevetto, a meno che non dimostri la sua buona fede.
4. La licenza obbligatoria può essere concessa per uno sfruttamento dell'invenzione diretto prevalentemente all'approvvigionamento del mercato interno.
5. La licenza obbligatoria è concessa per durata non superiore alla rimanente durata del brevetto e, salvo che vi sia il consenso del titolare del brevetto o del suo avente causa, può essere trasferita soltanto con l'azienda del licenziatario o con il ramo particolare di questa nel quale la licenza stessa viene utilizzata.
6. La concessione della licenza obbligatoria non pregiudica l'esercizio, anche da parte del licenziatario, dell'azione giudiziaria circa la validità del brevetto o l'estensione dei diritti che ne derivano.
7. Nel decreto di concessione della licenza vengono determinati l'ambito la durata, le modalità per l'attuazione, le garanzie e le altre condizioni alle quali è subordinata la concessione in relazione allo scopo della stessa, la misura e le modalità di pagamento del compenso. In caso di opposizione, la misura e le modalità di pagamento del compenso sono determinate a norma dell'articolo 80.
8. Le condizioni della licenza possono, con decreto del Ministero delle attività produttive, essere variate su richiesta di ognuna delle parti interessate, qualora sussistano validi motivi al riguardo.
9. Per la modificazione del compenso si applica l'articolo 80.
10. Nel caso in cui il titolare del brevetto per il quale sia stata concessa licenza obbligatoria o il suo avente causa conceda a terzi l'uso del brevetto medesimo a condizioni più vantaggiose di quelle stabilite per la licenza obbligatoria, le condizioni stesse sono estese alla licenza obbligatoria, su istanza del licenziatario.

Art. 73.

Revoca della licenza obbligatoria

1. La licenza obbligatoria e' revocata con decreto del Ministero delle attivita' produttive, qualora non risultino adempiute le condizioni stabilite per l'attuazione dell'invenzione oppure qualora il titolare della licenza non abbia provveduto al pagamento del compenso nella misura e con le modalita' prescritte.

2. La licenza obbligatoria e' altresì revocata con decreto del Ministero delle attivita' produttive se e quando le circostanze che hanno determinato la concessione cessino di esistere ed e' improbabile che tornino a verificarsi oppure su istanza concorde delle parti.

3. La revoca puo' essere richiesta dal titolare del brevetto con istanza presentata all'Ufficio italiano brevetti e marchi, che ne da' pronta notizia mediante lettera raccomandata con avviso di ricevimento al titolare della licenza obbligatoria, il quale, entro sessanta giorni dalla data di ricevimento della raccomandata, puo' opporsi motivatamente alla revoca, con istanza presentata all'Ufficio italiano brevetti e marchi. Si applicano le disposizioni dell'articolo 199, commi 3, 4, 5, 6 e 7.

4. In caso di revoca, colui che aveva ottenuto la licenza puo' attuare l'invenzione alle stesse condizioni, nei limiti del preuso o in quelli che risultano da preparativi seri ed effettivi.

JAPAN

Patent Act (Act No. 121 of April 13, 1959, as amended up to December 30, 2018)

Articles 83 and 92-97

Article 83 (Award granting non-exclusive license where invention is not worked)

(1) Where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed.

(2) Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Commissioner of the Patent Office for an award.

Article 92 (Award granting non-exclusive license to work own patented invention)

(1) Where a patented invention falls under any of the cases as provided in Article 72, the patentee or exclusive licensee may request the other person under the said Article to hold consultations to discuss granting a non-exclusive license to work the patented invention or a non-exclusive license on the utility model right or the design right.

(2) The other person under Article 72 who is requested to hold consultations under the preceding paragraph may request the patentee or exclusive licensee requesting such consultations to hold consultations to discuss granting a non-exclusive license to the extent of the patented invention that the said patentee or exclusive licensee intend to work with a non-exclusive license on the patent right, on the utility model right or on the design right granted through consultations.

(3) Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (1), the patentee or the exclusive licensee may request the Commissioner of the Patent Office for an award.

(4) Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (2) and where a request for an award is filed under the preceding paragraph, the other person under Article 72 may request the Commissioner of the Patent Office for an award only within the time limit for the submission of a written answer by the said other person designated by the Commissioner of the Patent Office under Article 84 as applied mutatis mutandis under paragraph (7).

(5) In the case of paragraph (3) or (4), the Commissioner of the Patent Office shall not render an award to the effect that a non-exclusive license is to be granted where the granting of the non-exclusive license will be unreasonably prejudicial to interest of the other person under Article 72, the patentee or the exclusive licensee.

(6) In the case of paragraph (4), in addition to the case provided for in the preceding paragraph, the Commissioner of the Patent Office shall not render an award ordering a non-exclusive license to be granted if an award ordering a non-exclusive license to be granted is not rendered with respect to the request for an award under paragraph (3).

(7) Articles 84, 85(1) and 86 through 91-2 shall apply mutatis mutandis to the award under paragraph (3) or (4).

Article 93 (Award granting non-exclusive license for public interest)

(1) Where the working of a patented invention is particularly necessary for the public interest, a person(s) intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license.

(2) Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Minister of Economy, Trade and Industry for an award.

(3) Articles 84, 85 (1) and 86 through 91-2 shall apply mutatis mutandis to the award under the preceding paragraph.

Article 94 (Transfer, etc. of non-exclusive license)

(1) Except for a non-exclusive license granted by an award under Article 83(2), 92(3), 92(4) or 93(2) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, a non-exclusive license may be transferred only where the business involving the working of the relevant invention is also transferred, where the consent of the patentee (or, in the case of non-exclusive license on the exclusive license, the patentee and the exclusive licensee) is obtained and where the transfer occurs as a result of general succession including inheritance.

(2) Except for a non-exclusive license granted by an award under Article 83(2), 92 (3), 92(4) or 93(2) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, a non-exclusive licensee may establish a right of pledge on the non-exclusive right only where the consent of the patentee (or, in the case of non-exclusive license on the exclusive license, the patentee and the exclusive licensee) is obtained.

(3) A non-exclusive license granted by an award under Article 83(2) or 93(2) may be transferred only where the business involving the working of the relevant invention is also transferred.

(4) Where a non-exclusive license is granted by an award under Article 92(3) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, the said non-exclusive license shall be transferred together with the patent right, utility model right or design right of the non-exclusive licensee on which the non-exclusive license is granted and the business involving the working of the relevant invention in the case where each right is transferred together with the said business, and shall be extinguished in the case where each right of the said non-exclusive licensee is extinguished or transferred independently of the said business.

(5) A non-exclusive license granted by an award under Article 92(4) shall be transferred together with the patent right, utility model right or design right of the non-exclusive licensee on which the non-exclusive license is granted, and shall be extinguished in the case where the said patent right, utility model right or design right is extinguished.

(6) Article 73(1) shall apply mutatis mutandis to non-exclusive licenses.

Article 95 (Right of pledge)

Unless otherwise agreed upon by contract, where a right of pledge is established on a patent right, exclusive license or non-exclusive license, the pledgee may not work the patented invention.

Article 96

A right of pledge on a patent right, exclusive license or non-exclusive license may be exercised against any consideration to be paid for the patent right, exclusive license or non-exclusive license or any money or goods to be received by the patentee or the exclusive licensee for the working of the patented invention; provided, however, that the pledgee have to attach the consideration, money or goods prior to the payment of money or delivery of goods.

Article 97 (Waiver of patent right, etc.)

(1) Where there is an exclusive licensee, pledgee or non-exclusive licensee as provided in Article 35(1), 77(4) or 78(1), a patentee may waive the patent right, only where the consent of the said exclusive licensee, pledgee or non-exclusive licensee is obtained.

(2) Where there is a pledgee or non-exclusive licensee as provided in Article 77(4), an exclusive licensee may waive the exclusive license, only where the consent of the said pledgee or non-exclusive licensee is obtained.

(3) Where there is a pledgee, a non-exclusive licensee may waive the non-exclusive license, only where the consent of the said pledgee is obtained.

JORDAN

Temporary Law No. 71 of 2001 Amending the Patent Law

Articles 22-26

Article 22

The Minister may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively:

A) If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for non-commercial public good provided that the patentee is notified as soon as it becomes possible.

B) 1. If the patentee doesn't exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation.

2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods of the patent to the kingdom shall be deemed utilization of the patent.

C) If the patentee exercises his rights in such a way as to prevent others from competing fairly.

D) If the exporting will be done to countries which suffer from pandemics or epidemic illnesses in compliance with the Kingdom's obligations under the World Trade Organization agreements and the decisions issued pursuant thereto.

Article 23

The following shall be taken into consideration when compulsory licenses are granted:

A) Each application for a license shall be decided separately for its specific conditions and circumstances.

B) The applicant shall have tried to obtain a license from the patentee under reasonable remuneration and conditions but did not reach an agreement during a reasonable period of time in the case provided for in paragraph (B) of Article 22 of this law.

C) The scope and duration of the license shall be limited to the purpose for which it is granted. If the license application relates to semiconductor technology, then it shall only be granted for non-commercial public good or to rectify practices deemed by the competent judicial or administrative authority to be anticompetitive.

D) The license to exploit shall not be exclusive.

E) The license shall not be assignable to third parties.

F) The license shall be granted for meeting the demands in the local market with the exception of the circumstances stipulated in paragraphs (c) and (d) of Article (22) of this law.

G) The applicant shall receive an equitable remuneration which takes into account the economic value of the invention. For such a valuation the case stipulated in paragraph (d) of Article (22) of this law shall take into consideration the conditions and proceedings which are present in the international agreements and decisions which the Kingdom is subject to pursuant to joining the World Trade Organization.

Article 24

The Minister may cancel the compulsory license by himself or on the strength of an application from the patentee if the reasons for its grant disappeared. This license cancellation shall however preserve the rights of those involved in the compulsory license.

Article 25

The provisions and procedures related to licensing of patent utilization shall be prescribed pursuant to regulations to be issued to this aim.

Article 26

The Minister's compulsory-licence decision shall be appealable to the High Court of Justice within 60 days of its notification.

KAZAKHSTAN

Patent Law No. 427 of 16/07/1999 (as amended up to Law of the Republic of Kazakhstan № 378-V of 31 October 2015)

Articles 11(4) and 14(6)

Article 11

[...]

4. When the patentee does not use the industrial property object and refuses to conclude a licensing agreement on acceptable commercial terms within 90 calendar days from the day of request, any person shall have the right to apply to a court with a claim on being granted a compulsory non-exclusive licence when the object of industrial property was not continuously used after the first publication of information on the issue of the protection document on the industrial property object during any three years preceding the date of submission of such claim. If the patentee does not prove that the non-use is stipulated by good reasons, the court shall grant the indicated licence with determination of limits of use, deadlines, amount and procedure for payments. The amount of payments shall be established not lower than the market price of the licence as defined in accordance with the established practice.

Compulsory license shall also be issued in the following cases:

- 1) need to ensure national security or protection of public health;
- 2) abuse by a patent holder of his exclusive rights, contribution or non-objection to abuse of such exclusive rights by another person with his consent.

Provision in accordance with present paragraph of compulsory license in respect of an invention in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial body has determined that the existing practice is violation of anti-competitive legislation of the Republic of Kazakhstan and that the grant of compulsory license would remedy such practice.

Any compulsory license shall be issued in the first instance for providing for demands of the domestic market of the Republic of Kazakhstan, except when the compulsory license concerns a patent claiming a pharmaceutical product or a process to obtain a pharmaceutical product, and the purpose of the license is to export the patented product or the product manufactured by the patented process to a territory with no or insufficient manufacturing capacity, in accordance with international agreements, ratified by the Republic of Kazakhstan.

The right to use the indicated industrial property object may be assigned by the person to whom the compulsory licence was granted to other person only together with the relevant production in which this item is used.

The compulsory licence shall be subject to revocation by the court in the case of termination of the circumstances which were the reason for its issue.

Article 14

[...]

6. In emergency situations in the country the Government of the Republic of Kazakhstan shall have the right to allow to use the object of industrial property without the consent of the patentee, but with immediate notification of him and payment of commensurate compensation. The disputes on the amount of compensation shall be resolved by the court.

KENYA

Industrial Property Act, 2001 (Act No. 3 of 2001, as amended up to Act No. 11 of 2017)

Sections 72-78 and 80

Compulsory Licences for Non-Working and Similar Reasons

72.—(1) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the Tribunal for a licence to exploit the patented invention on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the owner of the patent satisfies the Tribunal that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Kenya.

Compulsory Licences Based Upon Interdependence of Patents

73.—(1) Where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the latter patent may request the Tribunal at any time for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent.

(2) The owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent.

(3) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(4) In this section, “earlier patent” or “first patent” means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and “latter patent” or “second patent” shall be construed accordingly.

Preconditions for Grant of Compulsory Licences

74.—(1) A compulsory licence shall not be granted unless the person requesting the licence—
(a) satisfies the Tribunal that he has asked the owner of the patent for a contractual licence but has been unable to obtain the licence on reasonable commercial terms and within a reasonable time; and

(b) offers guarantees satisfactory to the Tribunal to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to his request.

(2) The requirement under subsection (1)(a) shall be waived in the case of a national emergency or other circumstances of extreme urgency, provided the owner of the patent shall be so notified as soon as is reasonably practicable.

Grant and Terms of Compulsory Licences

75.—(1) In considering a request for a compulsory licence, the Tribunal shall decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant taking into account any terms agreed by the parties, proceed to fix the terms which shall be deemed to constitute a valid contract between the parties and shall be governed by the provisions of contractual licences.

(2) In fixing the terms under subsection (1), the Tribunal shall ensure that the compulsory licence—

- (a) is limited, in scope and duration, to the purpose for which it was authorized, and in the case of semi-conductor technology, shall only be for public non-commercial use or to remedy a practice determined after a judicial or administrative process to be anti-competitive;
- (b) is limited predominantly for the supply of the domestic market;
- (c) does not entitle the licensee to grant further licences, without the consent of the owner of the patent;
- (d) is non-exclusive; and
- (e) provides for the payment to the owner of the patent of remuneration which is equitable with due regard to all the circumstances of the case, including the economic value of the licence.

(3) A representative of the Institute and of the Government shall have the right to appear and be heard at the hearing of an application for a compulsory licence, before the Tribunal.

76. Transfer of compulsory licence

A compulsory licence may be transferred only with that part of the industrial undertaking or its goodwill, in which the relevant invention is used and no such transfer shall be valid until the consent of the Tribunal has been obtained.

77. Cancellation of compulsory licences

(1) On the application of any interested party, the Tribunal may cancel a compulsory licence if—

- (a) the licensee fails to comply with the terms of the licence; or
- (b) the conditions which justified the grant of the licence have ceased to exist and are unlikely to recur; provided that the legitimate interests of the licensee are adequately protected.

(2) On the application of the Minister, or on the application of the owner of the patent, the Tribunal may, cancel the compulsory licence if, within two years from the grant of the licence, the licensee has not taken the necessary steps to work the relevant invention sufficiently so as to remedy the deficiencies or to satisfy the requirements which gave rise to his application for the said licence.

(3) On the application of the owner of the patent or the licensee, the Tribunal may vary the terms of a compulsory licence if new facts justify the variation and in particular if the patentee has granted contractual licence on more favourable terms.

78. Registration of grants, cancellation or variation

Where the Tribunal grants, cancels or varies the terms of a compulsory licence, the Tribunal shall instruct the Managing Director, to record the grant, cancellation or variation in the register without payment of any fee.

80. Exploitation of the Patented Inventions by the Government or by Third Persons Authorised by the Government

(1) Subject to this section, where—

- (a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of other vital sector of the national economy so requires; or
- (b) the Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive, the Minister may, upon application to him in the prescribed form and after consultation with the Institute and the owner of the patent,

order that the protected invention shall be exploited by a Government Ministry, Department, agency or other person as the Minister may designate in the order subject to the payment of adequate compensation to the owner of the patent in accordance with this section.

(1A) Upon exercising the powers conferred upon him under subsection (1), the Minister may, notwithstanding any of the measures set out in this section, authorize by written order the importation, manufacture or supply, or authorize the utilization of any molecule or substance whatsoever by any individual, corporation or society as named or described by any individual, corporation or society as named or described in the order without notice to the patent holder or any other notifiable party, and such order shall remain in force until revoked by the Minister in writing, after giving six months' prior notice of his intention of such revocation to the party named or described in the order.

(1B) An order made under the subsection (1A) shall not require the payment of compensation to the owner of the patent or licence holder or any other party so interested.

(1C) The Minister shall, notwithstanding any of the measures set out in this section, authorise the utilisation of any process for the manufacture, sale or supply of any molecule or substance whatsoever by any individual, corporation or society as named or described in the order, and such order shall remain in force until revoked by the Minister in writing, giving six months prior notice of intention of such revocation to the party named or described in the order.

(2) No application shall be made under subsection (1) unless the applicant has unsuccessfully sought a contractual licence from the owner of the patent:

Provided that the provisions of this subsection shall not apply in cases of national emergency or other extreme urgency in which case the Minister shall cause the contents of the order to be communicated to the owner of the patent as soon as reasonably practicable.

(3) An order under this section shall be subject to such conditions as the Minister may deem necessary.

(4) Where an order under this section is made, the Managing Director shall fix the amount of the compensation to be paid to the owner of the patent, such compensation being equitable with due regard to all the circumstances of the case and in particular, the economic value of the patent.

(5) An order under this section shall not preclude the owner of the patent from concluding a licence contract or from exercising the powers conferred by section 54 of this Act.

(6) The Minister may, upon the request of the owner of the patent or the Government Ministry, Department, agency or other person designated by the Minister for the purposes of any order under this section and after hearing all interested parties, vary the terms of the order to the extent that changed circumstances justify such variation.

(7) The Minister may, upon the request of the owner of a patent and after hearing all interested parties, revoke an order under this section—

(a) if satisfied that the circumstances necessitating the order have ceased and are unlikely to recur; or

(b) where the Government Ministry, Department, agency or other person designated for the purposes of the order is in breach of any condition imposed under subsection (3).

(8) The authorization of any person in an order under this subsection shall not be transferable except to a business or enterprise owned or operated by that person.

(9) The exploitation of the invention pursuant to an order under this section shall be primarily for the supply of the market in Kenya.

(10) An order relating to the exploitation of an invention in the field of semi-conductor technology shall only be made where the Tribunal has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is not competitive and the Minister is satisfied that the issuance of such order would remedy such practice.

(11) Any person aggrieved by any decision of the Minister under this section may appeal to the Tribunal.

KYRGYZ REPUBLIC

Law of the Kyrgyz Republic No. 8 of January 14, 1998, on Patents (as amended up to Law No. 76 of April 10, 2015)

Article 12

Article 12. Obligations of the Patent Owner and Compulsory Licenses

If the object of industrial property is not used or insufficiently used by the patent owner or persons to whom the rights for it has been transferred, within three years as of the date of granting a patent, that leads to insufficient supply of the appropriate goods or services at the market of goods and services, any person wishing and ready to use patent of an industrial property, in the event of refusal of the patent owner to conclude licensing agreement with this person on the conditions pursuant to the common practice, has the right to apply to court with an action to provide him a compulsory license for the use of this object.

If the patent owner fails to prove that the non-use or insufficient use of an object of industrial property is conditioned by excusable reasons, the court shall grant the indicated license specifying the scope of use, the amount, time limits and procedures of payment. The amount of payment must not be lower than the price of the license, which is determined in compliance with the established practice.

The patent owner that cannot use an invention without infringing the rights of the other owner of a patent for an invention or for a utility model, who has refused to conclude a licensing agreement based on the conditions that are in compliance with the common practice, has the right to apply to court with an appeal to grant him a compulsory license for the exploitation of an invention or utility model under condition that his invention presents an important technological achievement of the significant economic value with respect to the invention or utility model patent for which belongs to the other person.

If the indicated license is provided, the court must establish the limits for the use of an invention or utility model, patent for which belongs to the other person, in the scope necessary to exploit an invention patented by the person requiring to provide him a compulsory license, as well as the amount, terms and payment order. The amount of payment must be established not less than the price for a license, which is determined in compliance with the common practice.

In the emergency situations (disasters, catastrophes, big accidents), as well as in the interests of the national security, the Government of the Kyrgyz Republic shall have the right to grant a compulsory license coupled to payment of an applicable compensation to a patent owner, in this case the volume and time of exploitation of the patented object of industrial property shall be

restricted by the purposes for which it was allowed. Disputes arising due to such exploitation shall be decided by court.

The compulsory license shall always be non-exclusive license, it cannot be reassigned to another person.

LAO PEOPLE'S DEMOCRATIC REPUBLIC

Law No. 38/NA of November 15, 2017, on Intellectual Property

Sections 53 and 54

Section 53: Compulsory license of Patent or Petty Patent

In case of necessity in protection of the country, protection of peace, food supply, safety concerning health of the people of Lao, without the purpose of trade, the Government may permit a person and other organization to exploit the patent or petty patent without the consent of the owner of said patent or petty patent. However, the exploitation must be based on the scope of permission of the government. The owner of the patent or petty patent must be informed and be paid a suitable royalty. The owner of the patent or petty patent can submit an argument on the unsuitable order or royalty within 60 days from the date of having been informed of such order.

In case the country is in emergency status due to natural causes or war, the Prime Minister can order a person or organization to exploit the patent or petty patent and to proceed as stated earlier.

Section 54: Exploitation of Patent or Petty Patent

In case of the invention or device which has been granted a patent or petty patent has not been exploited or not fully exploited 3 years after grant of the patent or petty patent, the government shall inform the owner of the rights to submit an explanation in writing within 90 days. If there is no response or the response is not satisfactory, the government shall allow others who apply for exploitation to exploit same.

LATVIA

Patentu likums (Ar grozījumiem: 01.01.2016.)

Section 54

Section 54. Compulsory Licence

(1) If within four years after filing date of application or within three years after the date when the notification regarding the grant of a patent was published, the patented invention has not been used or has been used in an insufficient amount in the Republic of Latvia, any person may submit to the administrative court an application with a request to provide a permit (compulsory licence) to it to use the patented invention in conformity with this Law and court judgement. This provision shall not be applied if the proprietor of the patent proves to the court that there have been substantiated reasons for the failure to use or insufficient use of the invention.

(2) If the proprietor of the patent of a biotechnological invention is not able to use it without violating the prior rights to the plant variety, he or she may apply for a compulsory licence for the use of such plant variety, which is protected by the referred rights, and pay a compensation to the proprietor, determined by the court. In the case of a grant of such licence,

the proprietor of the plant variety is entitled to qualify for a cross-licence with substantiated requirements for the use of the protected invention.

(3) The compulsory licence of the patented invention may be obtained in conformity with Paragraphs one and two of this Section, if:

- 1) the patented subject or the product acquired with a patented method is of vital importance for ensuring of the welfare, protection or economic interests of Latvian citizens; or
- 2) an invention which is of a significant economic importance may not be used without the use of another earlier patented invention.

(4) The compulsory licence shall be granted by the court if the submitter of the claim within a reasonable time period has made an effort to acquire, but has not acquired the licence from the proprietor of the patent with acceptable commercial terms.

(5) If an emergency situation has been declared in the State, a compulsory licence may be granted by the Cabinet.

(6) The court, in the case provided for in Paragraph three, Clause 1 of this Section, reviewing the facts of the case regarding the grant of a compulsory licence, in addition shall observe the following requirements:

- 1) the amount of and the time period for use of the patent may be restricted, depending on the purpose for which the compulsory licence has been granted;
- 2) the compulsory licence shall be regarded as equal to a non-exclusive licence;
- 3) a compulsory licence may not be transferred to another person, except for the case when it is transferred together with an undertaking, which is directly related to the use of the relevant patent or a part of such undertaking; and
- 4) the compulsory licence shall be granted for use in the internal market of Latvia.

(7) The court, in the case provided for in Paragraph three, Clause 2 of this Section, upon reviewing the facts of the case regarding the grant of a compulsory licence shall, in addition, observe the following requirements:

- 1) the proprietor of the patent granted earlier (first) may request a cross-licence with reasonable terms for the use of an invention from the proprietor of later granted patent; and
- 2) the licence to the first patent shall not be transferred further unless it is transferred together with the rights to the later patent.

(8) The court may decide regarding the termination of the time period for a compulsory licence, if the facts referred to in Paragraph one or Paragraph three, Clause 1 of this Section no longer exist and a repeated commencement thereof is hardly credible.

(9) The holder of a compulsory licence shall pay to the proprietor of the patent a compensation, the amount of which shall be determined by the court, observing the economic value of the licence, the extent of use of an invention and other circumstances.

LEBANON

Law No. 240/2000 of 2000 on Patents

Articles 32-39

Article 32

In compliance with Article 5 of the Paris Union Convention of 1883 (as amended), every person, subject to public or private laws, is entitled after three years from the date of the patent grant, to present an official request for a compulsory license to exploit the invention in Lebanon, according to the conditions hereinafter stated, if the patent owner or his successors did not exploit the patent or actually and practically prepare to exploit the invention being the subject of the patent in the Lebanese Territory.

Compulsory license may also be requested if the patent owner or his successors started the exploitation, then seized to do so for a period not less than three years for no legitimate reason.

Article 33

The request for a compulsory license is presented by serving the patent owner before the First Instance Civil Court of Beirut and evidence that the plaintiff:

1. Has exerted efforts to acquire the patent owner's approval to exploit such, according to appropriate commercial conditions, and that such efforts were unsuccessful within a proper period of time. In case of national emergencies or force majeure or public utilization for non-commercial purposes provided that the patent owner is notified urgently.
2. Should have the needed qualifications and capacities in order to seriously and effectively exploit the invention.

Each request for a compulsory license shall be considered separately according to stipulations defined by the judicial decision so as the scope and period of such license be restricted to the purpose of the utilization so as to fulfill the needs of the local market in the majority of cases and so as the compensations due to the patent owner be equivalent to the economic value of the invention.

Compulsory licensing may not be exclusive.

The patent owner or the licensees may refer to the Court to amend conditions of the license or terminate such, provided that new circumstances impose such action.

The Court may insure the presence and validity of circumstances that justified principally granting the license such an action shall be based upon the request of a beneficiary.

Article 34

The compulsory license may not be transferred to third parties without the Court permission, otherwise it shall be void and null. The exception from the Court permission is the case where the investing enterprise transfers it or is joined, merged or split.

Article 35

If the compulsory license owner does not comply to the conditions as stipulated in the Court decision, then the patent owner or any of the other licensees may resort to the court to issue a decision to repeal such compulsory license.

Article 36

Upon the request of the Minister in charge and for purposes of protecting the public health, food safety and safeguarding the public interest in areas of vital importance in the economic, social and technological development the Cabinet of Ministers may subject the invention patents granted in Lebanon to Compulsory Administrative licensing if the products produced as a result of such patents are offered to the public in quantities or qualities that does not fulfill the market requirements or are offered at exaggerated prices.

Once the decision is published in the public gazette, any person qualified to work the patent invention in a serious and practical manner is entitled to request a non-exclusive license to the patent in Lebanon from the Minister of Economy and Trade.

Such license is granted by issuing a conditioned decision by the Minister of Economy and Trade, such conditions shall include its period and scope of application in Lebanon. Exceptionally the annual compensation is to be agreed upon between the patent owner and the licensee, otherwise the civil court of Appeal of Beirut shall determine such compensation the economic value of the license.

The Compulsory Administrative License shall come into effect from the date serving such decision to the patent owner, Intellectual Property Protection Authority and the right owners of the patent whose titles are registered in the patents register at the Authority hereinbefore mentioned.

Article 37

The State, for National Security reasons may acquire a license to an invention patent based on a decision issued by the Minister of Economy and Trade upon the request of the Minister of National Defense.

Such Compulsory Administrative License is granted by a decision issued by the Minister of Economy and Trade stipulating the conditions but excluding the related compensation.

If the annual compensation is not amicably agreed upon, it shall be determined by Beirut Civil Court of Appeal.

Such license shall come into effect from the date of the request of the Minister of National Defense and shall be notified to the patent owner, the Intellectual Property Protection Authority and the patent rights owners whose titles are registered in the patents register at the Authority hereinbefore mentioned.

Article 38

The State may, for National Security reasons own in part or in whole any invention patent by issuing a decree that also states a fair compensation for such proprietary and to be served to the patent owner, the Intellectual Property Protection Authority and to patent rights owners whose titles are registered in the patents register at the Authority hereinbefore mentioned.

Article 39

3. The administrative decisions hereby mentioned may be appealed before Beirut Civil Court of Appeal within thirty days of the decisions being served.

4. The stipulations mentioned do not prevent resorting to arbitration in matters where conciliation is possible.

LIBYA

Law No. 8 of 1959 on Patents and Industrial Designs and Models

Articles 23 and 28-30

Article No. 23

If the Office of Industrial & Commercial Property Protection noticed that the invention is related to defense affairs or it has an actual military value, it shall brief the Ministry of Defense immediately on the patent application and on the attached documents.

The Minister of Defense has the right to challenge granting the patent to the applicant within three months as of patent application date, in return for purchasing the invention from him or making a deal with him to exploit it.

Article No. 28

If the invention has not been utilized in Libya or in the country of origin within three years as of granting date of the patent, it becomes cancelled.

Article No. 29

If the Office of Industrial & Commercial Protection found, despite of expiry of stated deadlines mentioned in the previous article, that non exploitation of the invention was due to compelling circumstances, he may be granted an extended period of not more than two years in order to utilize it perfectly.

Article No. 30

Competent government departments may be granted a compulsory license through a decision issued by the Minister of National Economy to utilize the invention due to reasons related to pro bono publico or national defense.

In such circumstances, the owner of the patent has the right to get a fair compensation, which shall be estimated with the knowledge of the stated committee in article No.20, and grievances against its decisions are made before the Supreme Federal Court within sixty days as of committee's date of declaration of decision to the grievant.

LIECHTENSTEIN

Federal Act of June 25, 1954, on Patents for Inventions (status as of April 1, 2019)

(Refer to Swiss Law below.)

LITHUANIA

Law No. I-372 of January 18, 1994, on Patents (as amended by Law No. X-1119 of May 10, 2007)

Articles 38 and 39

Article 38. Compulsory Cross-licensing when an Invention is Related to the Protected Plant Variety

Where a breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the patent owner will be entitled to a cross-licence on reasonable terms to use the protected variety.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

Applicants for the licences referred to in paragraphs 1 and 2 of this Article must demonstrate that:

1) they have applied unsuccessfully to the owner of the patent of a biological invention or the holder of the plant variety right to obtain a contractual licence;

2) the plant variety or the biological invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

The court shall make a decision regarding the granting of licences referred to in paragraphs 1 and 2 of this Article, the amount of royalty and other conditions and extent of a compulsory licence. If the conditions of granting of a compulsory licence change or disappear, at the request of the owner of the patent of a biological invention or the holder of the plant variety right, the court may revoke a compulsory licence or change its conditions.

Offices keeping a list of protectable plant varieties and the Patent Register of the Republic of Lithuania shall be responsible for the registration, in the manner prescribed by legal acts, of the licences referred to paragraphs 1 and 2 of this Article.

Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights shall apply.

Article 38¹. Compulsory Licence for Pharmaceutical Products

A competent institution authorised by the Government shall grant mandatory licences in compliance with Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Article 39. Exploitation of an Invention with the Authorisation of the Government of the Republic of Lithuania

The Government of the Republic of Lithuania may adopt a resolution to permit a State or municipal institution, natural or legal persons to market, without the consent of the owner of a patent, a patented invention within the territory of the Republic of Lithuania, if:

- 1) an invention protected by a patent is related to public needs, national security and public health protection, development of economically important sectors;
- 2) the court determines that a method of the exploitation of an invention employed by the owner of a patent or licensee is anti-competitive.

An invention may be exploited only for the purpose in respect of which the resolution has been adopted. The owner of a patent must, for the exploitation of the invention, be remunerated fairly, taking into consideration economic value of the invention.

If the owner of a patent or a person who has authorisation to use an invention, requests, the Government of the Republic of Lithuania may, taking into consideration their reasons, change the conditions of the use of a patented invention, and time limits of the validity of permission. When authorisation to use a patented invention is issued to the owner of a patent which improves a previously patented invention (second invention) and that may infringe the exclusive rights of the owner of the first patent, the Government of the Republic of Lithuania shall, before the adoption of this resolution, take into consideration the following additional conditions:

- 1) the claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- 2) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.
- 3) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.

The Government of the Republic of Lithuania may declare the resolution null and void, if the circumstances which led to the authorisation to use a patented invention cease to exist, or if a

State or municipal institution, natural or legal persons use a patented invention for the purpose other than that in respect of which the resolution has been adopted.

Authorisation to exploit an invention must be non-exclusive, i.e. the owner of a patent shall not lose the right to use a patented invention himself, and it shall not prohibit the owner of a patent to conclude license agreements related to the use of a patented invention as well as to further exploit a patented invention or to implement his rights in other ways.

Authorisation to use a patented invention may not be transferred, except when the enterprise (or a part thereof) in which a patented invention is used, is transferred in a manner prescribed by law.

Attached to a request to permit the exploitation of a patented invention must be evidences confirming that the person seeking authorisation has requested, but has not received authorisation of the owner of a patent to use the patented invention. This provision shall not apply in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use of a patented invention. The owner of a patent must be informed in writing about a resolution, which is being drawn up, concerning the authorisation to use a patented invention, and about an intention to use a patented invention for the purposes provided for in subparagraph 1 of paragraph 1 of this Article.

Resolutions of the Government of the Republic of Lithuania concerning the authorisation to use a patented invention without the consent of the owner of a patent may be appealed against in court in a manner prescribed by law.

Upon the receipt of the resolution of the Government of the Republic of Lithuania concerning the authorisation to exploit an invention, the State Patent Bureau shall publish information on the authorisation in the next issue of its Official Bulletin.

LUXEMBOURG

Law of July 20, 1992, on the Changes in the System for Patents for Invention (as amended by the Law of May 24, 1998)

Articles 59-66

TITLE VII COMPULSORY LICENSES AND EX OFFICIO LICENSES

Compulsory Licenses

Art. 59.-1. On expiry of a period of three years from the grant of a patent or four years from the filing date of the patent application, whereby the period of time that expires the latest shall be taken into consideration, and subject to the conditions laid down in the following Articles, any public or private legal person may be granted a compulsory license under the patent provided that, at the time of the application for such license and failing legitimate reasons, neither the owner of the patent nor his successor in title:

(a) has begun to work or has made real and effective preparations for working the invention that is the subject matter of the patent on the territory of the Grand Duchy or of any other State Member of the Agreement Establishing the WTO;

(b) has worked the invention that is the subject matter of the patent in a manner sufficient to satisfy the needs of the Luxembourg market.

2. The same shall apply where working in the Grand Duchy or another State Member of the Agreement Establishing the WTO has been discontinued for more than three years.

Procedure for Obtaining and Conditions of a Compulsory License

Art. 60.-1. The request for a compulsory license shall be made to the Court; it shall be accompanied by proof that the requester has not been able to obtain a license from the owner of the patent and that he is in a position to work the invention in an effective and serious manner.

2. The license may only be non-exclusive; it shall be granted on fixed terms, particularly in respect of its duration, its field of application and the amount of the royalties to be paid in consideration thereof. Those terms may be amended by court decision on a request by the owner or the licensee.

3. A license shall be granted mainly for the supply of the Luxembourg market. When setting the amount of the royalties, the Court shall take into account the economic value of the license.

4. Judgments given in accordance with the above provisions shall be subject to appeal whatever the value in dispute.

Withdrawal of Compulsory License

Art. 61.-1. If the holder of a compulsory license fails to comply with the terms under which the license was granted, the owner of the patent and, as appropriate, the other licensees may obtain withdrawal of the license by the Court.

2. Withdrawal of a compulsory license may also be obtained where the circumstances that had led to its granting cease to exist and will not reoccur in all probability.

Dependent Patents

Art. 62.-1. The owner of a patent concerning an improvement of an invention already patented on behalf of another person may not work his invention without the consent of the owner of the earlier patent; the latter owner may not work the patented improvement without the consent of the owner of the patent of improvement.

2. After hearing the public prosecutor, and in the public interest, the Court may grant to the owner of the patent of improvement, at his request which shall not be made before expiry of the period specified in Article 59, a non-exclusive license to the extent necessary for working the invention that is the subject of the patent of improvement and to the extent that the invention that is the subject of the patent of improvement constitutes a substantial technical advance and significant economic value in relation to the earlier patent. On a request submitted to the Court, the owner of the earlier patent shall be granted a license under the patent of improvement.

3. The provisions of Articles 59, 60, 61 and 65 shall apply.

Ex Officio Licenses

Art. 63.-1. A patent shall be subject to ex officio licensing if a Grand Ducal Order, following the compulsory opinion of the Council of State, has declared the implementation of the invention to be of public interest. Save in cases of emergency, such order may not be issued unless it is established that the owner of the patent is not willing to voluntarily grant licenses under reasonable commercial conditions and terms.

2. As from the date of publication of the order subjecting the patent to ex officio licensing, any qualified person may apply to the Minister for the grant of a license to work the patent. Such license may only be non-exclusive and shall be granted by an order of the Minister on fixed conditions, in particular with regard to its duration and field of application, but excluding the amount of royalties to be paid in consideration thereof. The license shall be granted mainly for the supplying of the Market of Luxembourg. The license shall take effect from the date of notification of the order to the parties.

3. Failing amicable agreement between the parties concerned, the amount of the royalties shall be laid down by the Court. In setting the amount of the royalties, the Court shall take into account the economic value of the license.

4. An ex officio license may be withdrawn by a reasoned order of the Minister on expiry of a period of time to be laid down in the order granting the license if the patented invention is not worked in a serious manner or if the working does not comply with the conditions that have been imposed or agreed. It may also be withdrawn if the circumstances that have led to its being granted cease to exist and will not reoccur in all probability.

Compulsory or Ex Officio Licenses in the Field of Semiconductors

Art. 63bis. If the subject matter of a patent is an invention in the field of semiconductor technology, a compulsory or ex officio license may be granted only for a use that is intended to remedy a practice that has been declared contrary to competition law following judicial or administrative proceedings.

Obligations of the Owner of a Patent that is the Subject Matter of a Compulsory License or an Ex Officio License

Art. 64. The owner of a patent that is the subject matter of a compulsory license or an ex officio license shall be required to supply to the licensee, at the time of the grant of the license, any technical information that is in his possession at that time and is essential for the implementation of the patented invention.

Transfer of a Compulsory License or an Ex Officio License

Art. 65.-1. The rights deriving from a compulsory license or an ex officio license may only be assigned together with the business, undertaking or part of the undertaking to which they belong.

2. A license as referred to in Article 62.2, first sentence, may furthermore only be assigned together with the patent of improvement.

Entry of Decisions Relating to Compulsory License and Ex Officio Licenses

Art. 66.-1. Compulsory licenses, ex officio licenses and decisions relating to them shall be entered in the Register at the request of the beneficiary on submission of a certified copy of the record of the Court or administrative decision that has granted them or, where appropriate, has modified them and proof of payment of the entry fee.

2. The exercise of rights deriving from a compulsory license or an ex officio license by the licensee shall be subject to fulfillment of the entry formalities.

MADAGASCAR

Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property in Madagascar (of July 31, 1989)

Articles 36 and 37

36.—(1) Any interested natural or legal person may request, on the expiry of a period of four years as from the filing date of the patent application or three years as from the date of grant of the patent, the period of time that expires last being applied, from the competent court the grant of a compulsory license, against fair and equitable remuneration, on one or more of the following grounds:

(i) the patented invention has not been worked or has been insufficiently worked within the country;

(ii) the patentee refuses to grant licenses under reasonable conditions;

(iii) working of the patented invention within the country does not satisfy, under reasonable conditions, demand for the product.

(2) When applying paragraph (1), a compulsory license shall be granted only if the patentee is unable to give legitimate grounds for the lack of working or insufficient working within the country.

(3) The compulsory license shall be non-exclusive and may only be transferred, even in the form of the granting of a sublicense, together with the establishment of the beneficiary of the license or with that part of the establishment within which the patented invention is being worked.

(4) A compulsory license may only be withdrawn as the result of a court decision.

37.—(1) Any owner of a patent who is not prevented by the conditions of an earlier license may request the Agency to enter in the special register, with respect to his patent, the notice “license of right.” Such notice shall afford to any interested person the right to obtain a license to work that patent under conditions which, failing agreement between the parties, shall be laid down by the competent court.

(2) The State may obtain *ex officio*, at any time for reasons of public interest, a license to work an invention that is covered by a patent application or a patent whether such exploitation be carried out by the State itself or on its behalf. The royalties due under an *ex officio* license shall be determined by agreement between the State and the applicant or owner of the patent or the successor in title of the applicant or owner. Failing amicable agreement, the royalties shall be laid down by the competent court within the meaning of Article 135.

MALAYSIA

Patents Act No. 291 of 1983 as last amended on 2006

Sections 49-54 and 84

Section 49. Application for compulsory licences.

(1) At any time after the expiration of three years from the grant of a patent, or four years from the filing date of the patent application, whichever is the later, any person may apply to the Registrar for a compulsory licence under any of the following circumstances:

(a) where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason;

(b) where there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet public demand without any legitimate reason.

(2) A compulsory licence shall not be applied for unless the person making the application has made efforts to obtain authorization from the owner of the patent on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

(3) The application for a compulsory licence shall be in compliance with such regulations as may be prescribed by the Minister.

Section 49A. Application for compulsory licence based on interdependence of patents.

(1) If the invention claimed in a patent (“later patent”) cannot be worked in Malaysia without infringing a patent granted on the basis of an application benefiting from an earlier priority date (“earlier patent”), and if the invention claimed in the later patent constitutes, in the opinion of the Corporation, an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent, the Corporation, upon the request of the

owner of the later patent, the licensee of a licence contract under the later patent or the beneficiary of a compulsory licence under the later patent, may grant a compulsory licence to the extent necessary to avoid infringement of the earlier patent.

(2) If a compulsory licence is granted under subsection (1), the Corporation, upon the request of the owner of the earlier patent, the licensee of a licence contract under the earlier patent or the beneficiary of a compulsory licence under the earlier patent, may grant a compulsory licence under the later patent.

Section 50. Request for grant of compulsory licence.

(1) In an application for a compulsory licence under section 49 or section 49A, the applicant shall set forth the amount of royalty, the conditions of the exploitation of the patent and the restrictions of the rights of the licensor or the licensee, as the case may be, and a request for the said licence.

(2) Where an application for a compulsory licence is filed pursuant to section 49 or section 49A, and this section, the Registrar shall notify the applicant, the licensor or the licensee, as the case may be, of the date the application shall be considered by the Corporation.

(3) The licensor or the licensee, as the case may be, shall be furnished with a copy of the application as mentioned in subsection (1).

Section 51. Decision by the Corporation.

(1) In considering the application for a compulsory licence under section 49 or section 49A, the Corporation may require the applicant, the licensor or the licensee, as the case may be, to appear before the Corporation to give a statement or to hand to the Corporation any document or any other item.

(2) When the application has been considered by the Corporation and a decision has been made, the applicant, the licensor or the licensee, as the case may be, shall be notified of the decision.

Section 52. Scope of compulsory licence.

Upon the granting of the compulsory licence to the applicant the Corporation shall fix -

- (a) the scope of the licence specifying in particular the period for which the licence is granted;
- (b) the time limit within which the beneficiary of the compulsory licence shall begin to work the patented invention in Malaysia; and
- (c) the amount and conditions of the royalty due from the beneficiary of the compulsory licence to the owner of the patent.

Section 53. Limitation of compulsory licence.

(1) A compulsory licence granted by the Corporation -

- (a) shall not be assigned otherwise than in connection with the goodwill or business or that part of the goodwill or business in which the patented invention is used;
- (b) shall be limited to the supply of the patented invention predominantly in Malaysia.

(2) The beneficiary of the compulsory licence shall not conclude licence contracts with third persons under the patent in respect of which the compulsory licence was granted.

Section 54. Amendment, cancellation and surrender of compulsory licence.

(1) Upon the request of the owner of the patent or of the beneficiary of the compulsory licence, the corporation may amend the decision granting the compulsory licence to the extent that new facts justify such amendment.

(2) Upon the request of the owner of the patent, the Corporation shall cancel the compulsory licence -

- (a) if the ground for the grant of the compulsory licence no longer exists;
- (b) if the beneficiary of the compulsory licence has, within the time limit fixed in the decision granting the licence, neither begun the working of the patented invention in Malaysia nor made serious preparations towards such working;

- (c) if the beneficiary of the compulsory licence does not respect the scope of the licence as fixed in the decision granting the licence;
- (d) if the beneficiary of the compulsory licence is in arrears of the payment due, according to the decision granting the licence.
- (3) The beneficiary of the compulsory licence may surrender the licence by a written declaration submitted to the Registrar who shall record the surrender in the Register, publish it, and notify the owner of the patent.
- (4) The surrender shall take effect from the date the Patent Registration Office receives the declaration of the surrender.

Section 84. Rights of Government.

- (1) Notwithstanding anything contained in this Act-
 - (a) where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or
 - (b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit a patented invention.
- (2) The owner of the patent shall be notified of the decision of the Minister as soon as is reasonably practicable.
- (3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the owner of the patent of an adequate remuneration for such exploitation, taking into account-
 - (a) the economic value of the Minister's authorization as determined in the decision; and
 - (b) where a decision has been taken under paragraph (1)(b), the need to correct anti-competitive practices.
- (4) The Minister shall make his decision under subsection (3) after hearing the owner of the patent and any other interested person if they wished to be heard.
- (5) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized either-
 - (a) for public non-commercial use; or
 - (b) where a judicial or relevant authority has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Minister is satisfied that the authorization would remedy such anti-competitive practice.
- (6) The authorization shall not exclude-
 - (a) the continued exercise by the owner of the patent of his rights under subsection 36(1); or
 - (b) the issuance of compulsory licences under Part X.
- (7) Where a third person has been designated by the Minister, the authorization may only be transferred with the goodwill or business of that person or with that part of the goodwill or business in which the patented invention is being exploited.
- (8) The exploitation of the invention by the Government agency or the third person designated by the Minister shall be predominantly for the supply of the market in Malaysia.
- (9) Upon the request of-
 - (a) the owner of the patent; or (b) the Government agency or the third person authorized to exploit the patented invention,the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.
- (10) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances mentioned in subsection (1) which led to his decision have ceased to exist and are

unlikely to recur or that the Government agency or the third person designated by him has failed to comply with the terms of the decision.

(11) Notwithstanding subsection (10), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or the third person designated by him justifies the maintenance of the decision.

(12) The owner of a patent, a Government agency or the third person authorized to exploit a patented invention may appeal to the Court against the decision of the Minister under this section.

(13) In this section "Government agency" means the Federal Government or the Government of a State and includes a Ministry or Department of that Government.

MALTA

Patents and Designs Act (Chapter 417)

Articles 39 and 40

Non-voluntary licences.

39. (1) The Civil Court, First Hall, may, on a writ of summons filed by any person who proves his ability to work the patented invention in Malta, made after the expiration of a period of four years from the date of filing the application for the patent or three years from the grant of the patent, whichever is later, direct the Controller to grant a non-exclusive, non-voluntary licence if the patented invention is not worked or is insufficiently worked in Malta.

(2) The grant of the non-voluntary licence shall be subject to the payment of such equitable remuneration to the proprietor of the patent as may be determined by the Civil Court, First Hall, and may be permitted if, prior to the institution of such proceedings, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and if such efforts have not been successful within a reasonable period of time.

(3) Notwithstanding sub article (1), a non-voluntary licence shall not be granted if the Court is convinced that circumstances exist which justify the non-working or insufficient working of the patented invention in Malta.

(4) In deciding whether to grant a non-voluntary licence, the Court shall give both the proprietor of the patent and the person requesting the non-voluntary licence an adequate opportunity to present arguments according to the provisions of the Code of Organization and Civil Procedure.

(5) Any non-voluntary licence shall be revoked when the circumstances which led to its granting cease to exist, taking into account the legitimate interests of the proprietor of the patent and of the licensee. The continued existence of these circumstances shall be reviewed upon the request of the proprietor of the patent by writ of summons before the Civil Court, First Hall.

(6) Article 27(3)(a) of this Act shall be interpreted in the sense that if the patented product is put on the market by a licensee pursuant to a non-voluntary licence, it will not be deemed to have been put on the market with the express consent of the proprietor of the patent.

(7) The scope and duration of a non-voluntary licence shall be limited to the purpose for which it was authorised and shall be:

(a) non-exclusive,

(b) non-assignable, except with that part of the enterprise or goodwill which enjoys such authorisation,

- (c) terminated if and when the circumstances which led to it cease to exist, and
- (d) predominantly for the supply of the domestic market.

(8) The Civil Court, First Hall, may on a writ of summons filed by the owner of a patent (the second patent) which cannot be exploited without infringing an earlier patent (the first patent), direct the Comptroller to grant a non-exclusive, non-voluntary licence provided that:

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to sue the invention claimed in the second patent; and
- (iii) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(9) Where a breeder cannot acquire plant variety protection or exploit a plant variety without infringing a prior patent, he may apply to the Civil Court, First Hall, for a compulsory licence for non-exclusive use of the invention protected by the patent in so far as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.

Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety:

Provided that an applicant for a licence referred to in above shall demonstrate that:

- (a) he had applied unsuccessfully to the holder of the prior patent to obtain a contractual licence;
- (b) the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the prior patent.

(10) Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention:

Provided that an applicant for a licence referred to in above shall demonstrate that:

- (a) he had applied unsuccessfully to the holder of the prior plant variety right to obtain a contractual licence;
- (b) the invention constitutes significant technical progress of considerable economic interest compared with the plant variety protected by the prior plant variety right.

(11) With regard to plant variety protection sub articles (9) and (10) shall only come into force when the relevant form of plant variety protection comes into force as provided in article 4(5)(e).

Exploitation by Government or by third parties authorised by Government.

40. (1) Where the national security or public safety so requires, the Minister may authorise, even without the agreement of the proprietor of the patent or the patent application, by notice published in the prescribed form, a Government agency or a person designated in the said notice to make, use or sell an invention to which a patent or an application for a patent relates, subject to payment of equitable remuneration to the proprietor of the patent or the application for the patent.

(2) The conditions set out in article 39(7) and (8) shall also apply in respect of an authorisation issued by the Minister under this article.

(3) Any decision taken by the Minister under this article may be the subject of an appeal in an action by writ of summons before the Civil Court, First Hall.

MAURITIUS

Patents, Industrial Designs and Trademarks Act 2002

Sections 23 and 24

Exploitation by Government or Person Thereby Authorized

23.—(1) Where the competent authority—

(a) is satisfied that the public interest including, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or

(b) has, on the application of any party, determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive and that it is necessary to remedy such anti-competitive practice;

it may, upon a request being made, authorise, even without the agreement of the owner of the patent, authorise a Government agency or a third person to exploit the patented invention.

(2) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment, to the owner, of an adequate compensation.

(3) For the purposes of a decision under subsection (1) the competent authority shall take—

(a) into account the economic value of the authorization, as determined in the said decision, and where a decision has been taken under subsection (1)(b), the need to correct anti-competitive practices; and

(b) his decision after hearing the owner of the patent and any interested person, whenever necessary.

(4) A request for the authorization under subsection (1) shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual licence, but that the latter has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(5) Subsection (4) shall not apply in cases of—

(a) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the competent authority's decision as soon as reasonably practicable;

(b) public non-commercial use; and

(c) anti-competitive practices determined as such by the competent authority in accordance with subsection (1)(b).

(6) The exploitation of a patented invention in the field of semi-conductor technology by a person other than the owner, shall only be authorized—

(a) where the competent authority has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and is satisfied that the issuance of the non-voluntary licence would remedy such practice; or

(b) for public non-commercial use.

(7) The authorization shall not exclude—

(a) the conclusion of licence contracts by the owner of the patent; or

(b) the continued exercise, by the owner of the patent, of his rights under section 21; or

(c) the issuance of a non-voluntary licence under section 24.

(8) Where a third person has been authorised by the competent authority, the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(9) Upon a request of the owner of the patent, or the Government agency or of the third person authorized to exploit the patented invention, the competent authority may, after hearing the parties, whenever necessary, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that any change in circumstances justifies such variation.

(10) Upon the request of the owner of the patent, the competent authority shall terminate the authorization if he is satisfied, after hearing the parties, whenever necessary, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person authorised has failed to comply with the terms of the decision.

(11) Notwithstanding subsection (10), the competent authority shall not terminate the authorization where he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person authorised, justifies the maintenance of the decision.

(12) The decision of the competent authority under this section shall be subject to review by the Supreme Court.

Non-Voluntary Licences

24.—(1) Upon request made to the Controller after the expiration of a period of 4 years from the date of filing of the patent application or 3 years from the date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary licence if he is satisfied that the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by importation, in Mauritius.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Mauritius.

(3) The decision issuing the non-voluntary licence shall fix—

- (a) the scope and the function of the licence;
- (b) the time limit within which the licensee must begin to exploit the patented invention; and
- (c) the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

(4) The holder of the non-voluntary licence shall—

- (a) have the right to exploit the patented invention in Mauritius according to the terms set out in the decision issuing the licence;
- (b) commence the exploitation of the patented invention within the time limit fixed in the said decision; and
- (c) thereafter, exploit the patented invention sufficiently.

(5) Where—

- (a) the invention claimed in a patent (later patent) cannot be exploited in the country without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date (earlier patent); and
- (b) the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent;

the Controller, upon the request of the owner of the later patent, may issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is issued under subsection (5), the Controller, upon the request of the owner of the earlier patent, shall issue a non-voluntary licence in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary licence under subsections (5) and (6), subsection (3) shall apply mutatis mutandis with the proviso that no time limit needs to be fixed.

(8) In the case of a non-voluntary licence issued under subsection (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary licence shall be subject to payment of a prescribed fee.

(10) Sections 23(2) to 23(12) shall apply mutatis mutandis to a non-voluntary licence issued under this section.

MEXICO

Law on Industrial Property (consolidated text published in the Official Journal of the Federation on May 18, 2018)

Articles 70, 73 and 77

Article 70. In the case of inventions, after three years from the date of grant of the patent, or four years from the filing of the application, whichever period elapses later, any person may apply to the Institute for the grant of a compulsory license to use said invention, where it has not been used, unless there are duly justified reasons for such non-use.

A compulsory license shall not be granted when the patent owner or the holder of a contractual license has been importing the patented product or a product obtained using the patented process.

Article 73. On expiration of the period of two years following the date of grant of the first compulsory license, the Institute may for administrative purposes declare the patent lapsed if the grant of the compulsory license has not remedied the non-working thereof, or if the patent owner has not proved the working thereof or the existence of reasons that are justified in the opinion of the Institute.

The payment of royalties under a compulsory license shall end when the patent lapses or is invalidated, or for any other reason provided for in this Law.

Article 77. For reasons of national emergency or security, and for as long as those reasons obtain, including the outbreak of serious diseases declared as requiring priority attention by the General Health Council, the Institute shall, in a declaration published in the **Official Journal**, determine that use may be made of certain patents by means of the grant of licenses of public utility in cases where, if such use were not made, the production, supply or distribution to the public of staple goods and services or medicines would be prevented, hindered or made more expensive.

In cases of serious disease causing an emergency situation or threatening national security, the General Health Council shall issue the declaration of priority attention either on its own initiative or in response to a written request by the national institutions specialized in disease which are accredited by the General Health Council, in which it justifies the need for priority attention.

Once the Council's declaration has been published in the Official Journal, pharmaceutical firms may request that the Institute grant a license of public utility, and the Institute shall grant said license after hearing the parties, for as short a period as justified by the case in accordance with the opinion of the Council, within 90 days, starting from the date on which the request is submitted to the Institute.

The Ministry of Health shall determine the conditions of production and quality, duration and scope of application of said license, as well as the classification of the applicant's technical ability. After listening to both parties, the Institute shall establish a reasonable total in royalties for the owner of the patent.

The grant may cover one or all of the prerogatives referred to in subparagraphs I or II of Article 25 of this Law.

With the exception of the grant of licenses of public utility as referred to in paragraphs two and three of this Article, other licenses shall be granted in accordance with the terms contained in paragraph two of Article 72. None of the licenses referred to in this Article may be exclusive or transferable.

MONACO

Law No. 606 of June 20, 1955, on Patents

Articles 33 - 43

Titre - V DES LICENCES OBLIGATOIRES

Article 33 .- Tout brevet d'invention délivré depuis plus de trois ans dont, sans excuse valable, le titulaire n'a pas entrepris l'exploitation sérieuse et effective, personnellement ou par l'intermédiaire d'un licencié, peut faire l'objet d'une demande de licence dite "licence obligatoire"; il en est de même du brevet dont l'exploitation aura été abandonnée depuis plus de trois ans.

Le titulaire d'un brevet pour lequel une licence obligatoire aura été accordée est obligé de laisser le bénéficiaire de cette licence exploiter son brevet sans y mettre ni obstacle, ni opposition, sous peine de dommages et intérêts à l'égard du titulaire de la licence obligatoire.

Article 34 .- Toute personne qui demande une licence obligatoire doit apporter la justification qu'elle s'est préalablement adressée au titulaire du brevet et n'a pu obtenir de lui amiablement licence d'exploiter.

Article 35 .- La demande qui doit faire état de la justification prévue à l'article précédent est formée auprès du tribunal de première instance, seul compétent.

L'assignation, signifiée au titulaire du brevet et aux autres intéressés, s'il y en a, est dénoncée le jour même, par le demandeur, à peine de nullité, au service de la propriété industrielle, pris en la personne de son représentant qualifié, qui peut intervenir aux débats, s'il le juge opportun, ou faire connaître son avis au tribunal.

Les règles posées par le livre II de la première partie du Code de procédure civile sont applicables à l'instance, mais il y sera fait obligatoirement application des dispositions du titre XVe de ce livre, concernant l'interrogatoire des parties, sans préjudice de toute autre mesure d'instruction, s'il y a lieu.

Le Ministère public sera entendu dans ses conclusions.

Article 36 .- Dans sa décision, le tribunal constate, s'il y a lieu, que le brevet d'invention n'a pas fait l'objet d'une exploitation effective et sérieuse ; il se prononce sur la valeur des excuses invoquées et, le cas échéant, sur l'existence d'un abus de monopole justifiant l'octroi d'une licence obligatoire.

Pour apprécier l'existence de l'abus, il tient compte de toutes les circonstances, et, en particulier, des conditions et de l'intérêt d'une exploitation éventuelle du brevet.

Sa décision fixe les conditions auxquelles la licence obligatoire est accordée, notamment en ce qui concerne sa durée, et le montant des redevances dues. Ces conditions, ultérieurement, soit à la demande du titulaire du brevet, soit à la demande du licencié, feront l'objet d'une révision par le tribunal, après instruction publique et contradictoire, dans les formes et conditions prévues à l'article précédent.

Article 37 .- La licence obligatoire ne peut être que non exclusive.

Toutefois, le breveté ne peut consentir à d'autres licenciés des conditions plus avantageuses que celles de la licence obligatoire.

Article 38 .- La décision du tribunal accordant une licence obligatoire est notifiée par le greffe général à chacune des parties en cause. Cette décision du tribunal est susceptible d'appel. La cour instruit l'affaire et statue dans les formes et conditions prescrites à l'article 29. Toutes les décisions prises par les juridictions compétentes en matière de licences obligatoires doivent être immédiatement notifiées par le greffe général au service de la propriété industrielle et mentionnées au registre spécial des brevets.

Article 39 .- Le titulaire d'une licence obligatoire ne jouit pas de plein droit des certificats d'addition rattachés au brevet ; il peut, cependant, à défaut d'entente amiable, demander, dans les mêmes formes que ci-dessus, que lui soit accordée la licence d'exploitation d'un certificat d'addition, même si ce certificat a été délivré depuis moins de trois ans, ou si ce certificat a été cédé par le titulaire du brevet ou si celui-ci l'exploite directement ou en a autorisé l'exploitation par un tiers.

Article 40 .- Le titulaire d'une licence obligatoire peut exercer l'action en contrefaçon, à moins que le titulaire du brevet ou les autres bénéficiaires de la licence ne s'y opposent. Cette opposition doit être formulée dans le délai d'un mois après que le licencié ait fait connaître au titulaire du brevet son intention d'exercer l'action par lettre recommandée avec accusé de réception.

Article 41 .- Toute cession volontaire, à titre onéreux ou gratuit, totale ou partielle des droits résultant d'une licence obligatoire, est, à peine de nullité, soumise par le cédant à l'autorisation du tribunal qui a accordé cette licence, dans les formes et conditions prévues à l'article 35 ci-dessus, l'article 38 étant applicable en cas d'appel.

Le retrait de la licence obligatoire peut être prononcé à la demande du breveté et sans préjudice de tous dommages et intérêts, par le tribunal correctionnel au cas où il fait application des dispositions de l'article 44 ci-après et où les faits réprimés sont consécutifs à une cession de la licence obligatoire consentie en méconnaissance des dispositions du présent article.

Article 42 .- Si le titulaire d'une licence obligatoire ne satisfait pas aux conditions auxquelles cette licence lui a été octroyée, le service de la propriété industrielle, le titulaire du brevet, les autres licenciés ou tout autre demandeur en licence, peuvent saisir le tribunal qui a accordé la licence obligatoire, d'une demande tendant, soit au retrait de cette licence, soit à la modification des conditions dont elle est assortie.

Les articles 35 et 38 ci-dessus sont applicables.

Article 43 .- Toute action en nullité du brevet doit être exercée contre le breveté. Si une décision de justice devenue définitive constate la nullité du brevet, le titulaire de la licence obligatoire est libéré de toutes les obligations résultant de la décision lui accordant la licence obligatoire.

MONGOLIA

Patent Law of 25/06/1993 (as amended up to 1 September 2016)

Article 20

Article 20. Compulsory licences

1. In the following cases, on the request of any interested person, a compulsory licence in respect of a patented invention may be granted by the [Intellectual Property Office]:

- 1) if the invention must be used for a purpose associated with the public interest and in particular with national security, food supply or health
- 2) if the invention has not been used or has been insufficiently used for a period of four years from the filing date of the patent application or three years from the date of the grant of the patent (whichever period expires last) and the patent owner does not satisfy the [Intellectual Property Office] that circumstances exist which justify the lack of use of the invention in Mongolia;
- 3) if the patent owner sets unacceptable terms for the exploitation of the invention.

2. If the patent owner disagrees with a decision of the [Intellectual Property Office] to grant a compulsory licence he or she may appeal to the Court.

MONTENEGRO

Law on Patents (Official Gazette of Montenegro, No. 42/2015)

Articles 57-72

Compulsory Licences

Article 57

(1) If the holder of a patent refuses to license the right of commercial use of a protected invention to other persons or sets unreasonable conditions for such licensing, the state administrative authority competent for the field in which the invention shall be employed may, after considering the merits of each individual case, grant a compulsory licence upon a request of the interested person if:

1) patent holder himself or a person authorised by him does not use the protected invention or uses it insufficiently in Montenegro;

2) the commercial use of an invention that has been subsequently protected in the name of another person is not possible, without the use of the protected invention in whole or in part.

(2) The interested person shall be required to prove that he has made reasonable efforts, before filing the request referred to in paragraph 1 of this Article, to obtain authorisation from the right holder to use the protected invention on reasonable commercial terms and conditions and that he has not received such authorisation within a reasonable period of time.

(3) The interested person, referred to in paragraph 1, item 1 of this Article, may only be a person who proves that he has the appropriate technological capacity and production facilities for the commercial use of the protected invention.

(4) In the case referred to in paragraph 1, item 2 of this Article, an interested person may only be the

holder of the patent for subsequently protected invention, provided that:

1) the subsequently protected invention involves a technical advancement of special economic significance in relation to the invention protected by the first patent; and that
2) the holder of the first patent is entitled, on reasonable terms, to a cross-licence to use the subsequent invention.

(5) Authorisation for the use of the invention protected by the first patent shall be non-transferable

except in the case of simultaneous transfer of the subsequent patent.

Remuneration

Article 58

(1) The holder of a compulsory licence shall be required to pay the patent holder a mutually agreed remuneration.

(2) In the absence of an agreement on the amount and method of payment of such remuneration, the competent court shall decide, taking into account the merits of each individual case and the economic value of the compulsory licence.

Approval and Revocation of Compulsory License

Article 59

(1) The scope and duration of a compulsory licence shall be limited to the purpose for which it has been granted.

(2) A compulsory licence shall not be exclusive.

(3) A compulsory licence may be assigned only with the company or a part thereof, where it is used.

(4) A compulsory licence shall predominantly be granted for the supply of the domestic market.

(5) A compulsory licence may be terminated, subject to adequate protection of the legitimate interest of the persons so authorized, if and when circumstances that have led to its grant cease to exist and are unlikely to recur.

(6) Upon substantiated request, the state administrative authority referred to Article 57 paragraph 1 of this Law shall re-examine the further existence of circumstances under paragraph 5 above.

(7) A request for the grant of a compulsory licence cannot be filed before the expiry of a period of four years from the filing date of the patent application or three years from the date of the grant of a patent, whichever of the two time limits expires later.

(8) A compulsory licence shall not be granted if the patent holder provides valid reasons for non-use or for insufficient use of a protected invention.

Compulsory Licence in the Public Interest

Article 60

(1) The compulsory licence under Article 57 of this Law may also be granted prior to the expiry of the time limit specified in Article 59, paragraph 7, if the exploitation of the protected invention is necessary for the fulfilment of public interest (the protection of public health and providing food, and the protection of public interests in the fields of vital significance for socio-economic and technological development) or if the protected invention is used in a manner considered to be contrary to the principles of free competition.

(2) In the event of public interest, the provisions of Article 57, paragraph 2 of this Law shall not apply. Nevertheless, the right-holder shall be notified of the compulsory licence grant proceedings as soon as possible.

(3) The decision on the request of an interested person for the grant of a compulsory licence in the public interest shall be taken by the Government, after it reviews the merits of each individual case.

(4) A compulsory licence in public interest may be terminated if the circumstances that have led to its grant cease to exist and are unlikely to recur.

(5) Upon substantiated request, the Government shall re-examine the further existence of circumstances under Article 4 above.

(6) If it is likely that the circumstances that led to distortion of the competition in the market reoccur, the Government may reject the termination of a compulsory licence in the public interest.

Remuneration for the Compulsory License in the Public Interest

Article 61

(1) The holder of a compulsory licence in the public interest shall be required to pay the patent holder remuneration referred to in Article 58 of the Law.

(2) If a compulsory license in public interest has been granted in order to rectify anti-competitive practice, when determining the total amount of remuneration, the need to remedy such practice shall be taken into account.

(3) The compulsory licence in the public interest shall be subject to the provisions of Article 59, paragraphs 1, 2, 3, and 5 and Article 60, paragraphs 4 and 5 of this Law.

(4) Notwithstanding the provisions of paragraph 3 of this Article, the provisions of Article 59, paragraph 3 of this Law shall not apply to the compulsory license in the public interest, if the license was issued for reasons to eliminate the circumstances that led to a distortion of the competition in the market.

Issuing Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products

for Export to Countries with Public Health Problems

Article 62

(1) The Government may issue a compulsory license for a patent and/or supplementary protection certificate necessary for the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems to any person who submits the request for the issuance of a compulsory license in accordance with the provisions of this Law.

(2) The request for a compulsory license under paragraph 1 of this Article may be filed if there is a patent or supplementary protection certificate in Montenegro covering the manufacture and sale for export to eligible importing countries with public health problems.

(3) When deciding on the issuance of a compulsory license what shall specifically be taken into consideration is the need to implement the Decision of the General Council of WTO of 30 June 2003 on the implementation of point 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 (hereinafter the Decision).

(4) The pharmaceutical product referred to in paragraph 1 of this Article is each product of the pharmaceutical industry, including drugs for human use, which implies any substance or combination of substances intended for the treatment or prevention of disease in humans, as well as any substance or combination of substances which can be applied to human beings for the purpose of restoring, correcting or modifying physiological functions by inducing pharmacological, immunological or metabolic action, or to making a medical diagnosis, including active ingredients and diagnostic kits *ex vivo*.

(5) The importing country referred to in paragraph 1 of this Article is each country in which is exporting pharmaceutical product, which can be:

- 1) any least-developed country appearing as such in the United Nations list;
- 2) WTO member, other than the least developed member states under item 1 of this paragraph, that has made a notification to the Council for TRIPS of its intention to use the system as an importing country, whether it will use it as a whole or in a limited way;
- 3) a country that is not a member of the WTO, but the Committee for the Development Assistance of the Organization for Economic Cooperation and Development (hereinafter OECD) listed it on the list of low-income countries whose gross national product per capita of less than 745 dollars, and that has sent a notice to government of its intention to use the system as an importing country, whether it is used as a whole or in a limited way.

(6) Any WTO member state that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing country that meets the requirements of paragraph 5 of this Article.

Extension to Least Developed Countries and the Developing Countries which are not Members of the WTO

Article 63

(1) The importing country which is not a member of the WTO, which is the least-developed country i.e. developing country, and which meets the requirements of Article 62, paragraph 5 of this Law, must meet additional requirements, namely to:

1) in accordance with the Decision send due notice of intention to use the system as an importing country directly to the Government;

2) indicate in the notice referred to in item 1 of this paragraph that the system of the importing country shall be used to solve the problem of public health, not as a means to achieve the goals of industrial and trade policies, and to adopt the measures referred to in paragraph 4 of the Decision.

(2) The Government may, at the request of the right holder or upon its own initiative, terminate the compulsory license if the importing country fails to respect its obligations under paragraph 1, item 2 of this article.

An Application for the Issuance of a Compulsory License

Article 64

An application for the issuance of a compulsory license under Article 62, paragraph 1 of this law contains:

1) information on the requirements for the issuance of compulsory licenses in other countries for the same product with information on the quantities and the respective importing country;

2) information on request for the issuance of a compulsory license and his representative, if any;

3) non-proprietary name of the pharmaceutical product which the applicant intends to manufacture and sell under the compulsory license;

4) the quantity of the pharmaceutical product which the applicant intends to manufacture under a compulsory license;

5) the importing country or countries ;

6) evidence of prior negotiations with the right-holder, in accordance with the provisions of Article 66 of this Law;

7) evidence of a special request which specifies the amount of the required product, sent by the authorized representative of the importing country or non-governmental organization acting with the formal authorization of one or more importing countries or UN bodies and other international health organizations that work with formal authority of one or more of the importing countries.

Verification

Article 65

(1) In deciding on the request for the issuance of a compulsory license under Article 62, paragraph 1 of this Law, the Government is obliged to verify in particular:

1) whether each of the importing countries cited in the request, which is a member of the WTO, has made a notification to the WTO in accordance with the Decision, or whether each importing country cited in the request, which is not a member of the WTO, has sent a notice to the Government in accordance with the provisions of this Law in respect of each of the products of the request, without prejudice to the possibility that the least developed countries have under the Decision of the Council for TRIPS of 27 June 2002;

2) that the quantity of the product specified in the request does not exceed the quantity of which the importing country which is a member of the WTO informed the WTO or the quantity of which the importing country which is not a member of the WTO informed the Government;

3) that, taking into account other compulsory licenses issued in another country, the total quantity of the product authorized to be produced in relation to any importing country does not significantly exceed the quantity of which the importing country which is a member of the WTO informed the WTO, i.e. the Government if the importing country is not a member of the WTO.

(2) An applicant for a compulsory license shall specify in the request, or include the information referred to in paragraph 1 of this Article in the request.

Prior Negotiations

Article 66

(1) A compulsory license under Article 62, paragraph 1 of this Law may be issued only if the applicant proves that he has put reasonable effort, for a period of 30 days before applying for a compulsory license, to get approval of the right-holder for use of the invention on reasonable market terms and conditions.

(2) The provisions of paragraph 1 of this Article shall not apply in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31 item b of the TRIPS Agreement.

The Conditions under Which Compulsory License is Issued

Article 67

(1) A compulsory license under Article 62, paragraph 1 of this Law shall be issued as a non-exclusive, and its scope and duration, which must be stated in the decision on the issuance of compulsory license, are related solely to the reasons for which the license was issued.

(2) The quantity of product that, based on the license referred to in paragraph 1 of this Article, may be manufactured shall not exceed the quantity necessary to satisfy the needs of the importing country or importing countries cited in the request, taking into account the quantity of products manufactured under compulsory licenses issued in another country.

(3) The license conditions do not affect the method of distribution in the importing country.

(4) A compulsory license under paragraph 1 of this Article may be transferred only together with the manufacturing plant in which the invention for which it was issued is exploited.

(5) The decision referred to in paragraph 1 of this Article shall specify the actions the applicant is entitled to and which are necessary for the manufacture for export and distribution in the country or countries that are listed in the request.

(6) No product produced or imported under a compulsory license may be offered for sale or put on the market in any country which is not specified in the request, unless the importing country avails itself of point 6 sub-item (i) of the decision to export in co-party of regional trade agreement with which it shares a health problem for which the license was issued.

Additional Terms

Article 68

(1) The decision referred to in Article 67, paragraph 1 of this law shall order that products manufactured under a compulsory license shall be clearly identified through special labels and markings as products manufactured under a compulsory license.

(2) The products referred to in paragraph 1 of this Article shall be distinguished from products produced by the right-holder through special packaging and/or special colours or shapes, if possible, and if there is no significant impact on price.

(3) Packages or documents relating to the product must contain a note that the product was manufactured under a compulsory license, the name of the authority that issued the compulsory license and license number, and a clear note that the product is intended solely for export and distribution in the importing country or importing countries.

(4) Detailed information on the characteristics of the products referred to in paragraph 1 of this Article shall be made available to the administrative authority in charge of customs (hereinafter referred to as the Customs Authority) in Montenegro.

(5) Detailed information about the characteristics of the product referred to in paragraph 1 of this Article shall be made available to the customs authorities of the Member States of the European Union.

(6) The decision referred to in paragraph 1 of this Article orders the licensee, that prior to shipment to the importing country, post on its website, the address of which shall be communicated to the Government, the following information:

1) the quantities of the product and the importing countries to which the products are delivered under the compulsory license;

2) the distinguishing features in product labelling in accordance with paragraph 2 of this Article.

(7) If the product for which a compulsory license is issued in Montenegro is patented in the importing country cited in the request, this product can be exported only if the importing country has issued a compulsory license for the importation, sale and/or distribution of the product concerned.

Payment of Remuneration to the Rights-holder

Article 69

The decision referred to in Article 67, paragraph 1 of this Law shall order the applicant to pay remuneration to the rights-holder, as determined as follows:

1) in the cases of emergency or other circumstances of extreme urgency or in cases of public non-commercial use, in accordance with Article 31 (b) of the TRIPS Agreement, the remuneration shall be a maximum of 4% of the total price to be paid by the importing country or to be paid on its behalf;

2) In all other cases, the remuneration shall be determined taking into account the economic value of the authorization by the country of import or the importing country under the license, as well as humanitarian and non-commercial circumstances in connection with the issuance of the license.

Inspection of the Books and Documents of the Licensee

Article 70

(1) Upon the finality of the decision referred to in Article 67, paragraph 1 above, at the request of the right-holder for the preservation of evidence, the competent court may inspect the books and other business records of the licensee, for the sole purpose of verifying the fulfilment of all obligations of the decision determining the issuing of a compulsory license, in particular test data on the final destination of the product.

(2) In the business records and other documentation, the licensee is required to record the data on the export of products in the form of export declarations certified by the Customs, as well as the evidence of import.

Refusal of the request for the Issuance of a Compulsory License

Article 71

The Government shall refuse a request to issue a compulsory license under Article 62, paragraph 1 of this Law, which does not contain the elements necessary for a decision under Articles 64 and 65 of this Law, or if the conditions for issuing a compulsory license under this Law have not been met.

Termination or Modification of a Compulsory License

Article 72

(1) The right holder or licensee may submit a request to the Government to terminate the compulsory license if it finds that the other party fails to comply with a decision on issuing a compulsory license.

(2) Through the decision on the termination of the compulsory license, the Government shall determine the period within which the licensee shall, at his own expense, redirect all of the products that are in his ownership, care, control or authority to the importing countries with public health problems or otherwise remove them in consultation with rights-holder.

(3) If the importing country provides notice to the licensee that the amount of pharmaceutical products has become insufficient to meet its needs, the licensee may require modification of the license for the production and export of additional quantities of the product to the extent necessary to meet the needs of the importing country.

(4) The procedure according the requirement referred to in paragraph 3 of this Article is urgent.

(5) In deciding on application under paragraph 3 of this Article, the provisions of Article 65, paragraph 1 above shall not apply, if the additional quantity of the product requested does not exceed 25% of the originally approved amount.

MOROCCO

Law No. 17-97 on the Protection of Industrial Property (as amended by Laws No. 31-05 and No. 23-13)

Articles 25, 31, 38-39, 60, 62, 66, 67 and 75

Chapitre III : Des licences d'office

Section 1: Des licences d'office octroyées dans l'intérêt de la santé publique

Article 25 : Pour l'application des dispositions du 2^e alinéa de l'article 67 de la loi n°17-97 précitée, l'autorité gouvernementale chargée de la santé transmet la demande d'exploitation d'office d'un brevet d'invention dans l'intérêt de la santé publique a l'autorité gouvernementale chargée de l'industrie et du commerce.

L'autorité gouvernementale chargée de l'industrie et du commerce notifie la demande d'exploitation d'office visée au 1^{er} alinéa ci-dessus, par lettre recommandée avec accusé de réception, au(x) titulaire(s) du brevet d'invention concerne, et, le cas échéant, au(x) titulaire(s) de licence sur ce brevet inscrite au registre national des brevets, ou à leur mandataire, aux fins de présenter par écrit, par lettre recommandée avec accusé de réception, leurs observations dans un délai de 15 jours à compter de la réception de ladite notification.

A l'expiration du délai de 15 jours prévu au 2^e alinéa ci-dessus, l'autorité gouvernementale chargée de l'industrie et du commerce soumet, pour avis, la demande d'exploitation d'office visée au 1^{er} alinéa ci-dessus, accompagnée, le cas échéant, des observations susmentionnées, à une commission technique dont la composition et les modalités de fonctionnement sont fixées par arrêté conjoint de l'autorité gouvernementale chargée de l'industrie et du commerce et de l'autorité gouvernementale chargée de la santé.

Cette commission technique doit donner son avis dans un délai de deux mois à compter de la date de sa saisine.

Article 31: Pour l'application des dispositions de l'article 71 de la loi n°17-97 précitée, la mise en demeure des propriétaires des brevets d'invention, d'en entreprendre l'exploitation de manière à satisfaire aux besoins de l'économie nationale, est faite par décision motivée de l'autorité gouvernementale chargée de l'industrie et du commerce a la demande de l'autorité gouvernementale directement concernée par l'objet du brevet d'invention.

Cette décision précise les besoins de l'économie nationale qui n'ont pas été satisfaits.

Cette décision est notifiée par l'autorité gouvernementale chargée de l'industrie et du commerce, par lettre recommandée avec accusé de réception, au(x) propriétaire(s) du brevet d'invention et, le cas échéant, au(x) titulaire(s) de licence sur ce brevet inscrite au registre national des brevets, ou à leur mandataire, ainsi qu'à l'Office.

Article 38: Pour l'application des dispositions du 2^e alinéa de l'article 75 de la loi n°17-97 précitée, la licence d'office pour les besoins de la défense nationale est accordée par décret sur proposition de l'autorité gouvernementale chargée de l'industrie et du commerce à la demande de l'autorité chargée de la défense nationale.

Ce décret est publié au Bulletin Officiel.

Il est immédiatement notifié à l'autorité chargée de la défense nationale, au(x) propriétaire(s) de la demande de brevet d'invention ou du brevet d'invention et, le cas échéant, au(x) titulaire(s) de licence sur ladite demande ou ledit brevet inscrite au registre national des brevets, ainsi qu'à l'Office qui inscrit ce décret d'office audit registre.

Article 39: Les dispositions du présent chapitre III sont applicables aux certificats d'addition et aux certificats de schémas de configuration (topographies) de circuits intégrés, en application respectivement des dispositions des articles 29 et 93 de la loi n°17-97 précitée.

Article 60 : Toute personne de droit public ou privé peut, trois ans après la délivrance du brevet ou quatre ans après la date de dépôt de la demande de brevet, obtenir du tribunal une licence obligatoire de ce brevet, dans les conditions prévues aux articles 61 et 62 ci-dessous, si au moment de la requête, et sauf excuses légitimes, le propriétaire du brevet ou son ayant cause :

- a) n'a pas commencé à exploiter ou fait des préparatifs effectifs et sérieux pour exploiter l'invention objet du brevet sur le territoire du Royaume du Maroc;
- b) n'a pas commercialisé le produit objet du brevet en quantité suffisante pour satisfaire aux besoins du marché marocain; ou
- c) lorsque l'exploitation ou la commercialisation du brevet au Maroc a été abandonnée depuis plus de trois ans.

Article 62. La licence obligatoire ne peut être que non exclusive.

Toute licence obligatoire doit être octroyée principalement pour l'approvisionnement du marché marocain.

Elle est accordée à des conditions déterminées par le tribunal, notamment quant à sa durée et à son champ d'application, qui seront limités aux fins auxquelles la licence est accordée, ainsi que le montant des redevances auxquelles elle donne lieu. Ces redevances sont fixées selon le cas d'espèce, compte tenu de la valeur économique de la licence.

Ces conditions peuvent être modifiées par le tribunal à la requête du propriétaire ou du licencié.

Article 66. Lorsqu'une invention protégée par un brevet ne peut être exploitée sans qu'il soit porté atteinte aux droits attachés à un brevet antérieur dont le propriétaire refuse la licence d'exploitation à des conditions et modalités commerciales raisonnables, le propriétaire du brevet ultérieur peut obtenir du tribunal une licence obligatoire, dans les mêmes conditions que celles prévues aux articles 60 à 62 ci-dessus, sous réserve :

- a) que l'invention revendiquée dans le brevet ultérieur suppose un progrès technique important, d'un intérêt économique considérable par rapport à l'invention revendiquée dans le brevet antérieur;
- b) que le titulaire du brevet antérieur ait droit à une licence réciproque à des conditions raisonnables pour utiliser l'invention revendiquée dans le brevet ultérieur; et
- c) que la licence en rapport avec le brevet antérieur soit incessible sauf si le brevet ultérieur est également cédé.

Article 67. Si l'intérêt de la santé publique l'exige, les brevets délivrés pour des médicaments, pour des procédés d'obtention de médicaments, pour des produits nécessaires à l'obtention de ces médicaments ou pour des procédés de fabrication de tels produits, peuvent, au cas où ces médicaments ne sont mis à la disposition du public qu'en quantité ou qualité insuffisante ou à des prix anormalement élevés, être exploités d'office.

L'exploitation d'office est édictée par un acte administratif à la demande de l'administration chargée de la santé publique.

Article 75. L'État peut obtenir d'office, à tout moment, pour les besoins de la défense nationale, une licence pour l'exploitation d'une invention, objet d'une demande de brevet ou d'un brevet, que cette exploitation soit faite par lui-même ou pour son compte.

La licence d'office est accordée à la demande de l'administration chargée de la défense nationale par un acte administratif.

Cet acte fixe les conditions de la licence à l'exclusion de celles relatives aux redevances auxquelles elle donne lieu. La licence prend effet à la date de la demande de licence d'office. À défaut d'accord amiable entre le propriétaire du brevet et l'administration intéressée, le montant des redevances est fixé par le tribunal administratif de Rabat.

MOZAMBIQUE

Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015)

Articles 92-95

ARTICLE 92

Compulsory licence

1. The invention may be exploited by authorization of the relevant Minister without the consent of the patent holder, for reasons of public interest.
2. For the purposes of this article an invention is in the public interest if it is of fundamental importance to public health, national defence and economic and technological development.
3. The application for a compulsory licence shall be addressed to the IPI, accompanied by proof that the applicant sought a contractual licence from the patent holder and did not obtain it on reasonable commercial terms and within a reasonable time.
4. The provisions of the above paragraph shall not apply to cases of national emergency or other circumstances of extreme urgency.
5. The IPI shall, in all cases mentioned in this article, immediately notify the owner of the patent of the grounds for granting the compulsory licence.
6. The patent holder shall receive adequate remuneration from the beneficiary, adjusted to each particular case and taking into account the commercial value of the patent.
7. The extent and duration of such use is limited to the purposes for which the patent exploitation was authorized.
8. Although the use provided for in terms of this article is not exclusive, it may not be disposed of unless it is transferred or ceded with the enterprise that exploits the patented invention.
9. The exploitation of the invention by a third party designated by the competent authorities in accordance with this article, shall be predominantly aimed at supplying the domestic market.

ARTICLE 93

Opposition to non-exploitation

The patent holder may at any time oppose an application for a compulsory licence by a third party, substantiated by facts that show that the failure to comply with the law was not attributable to him.

ARTICLE 94

Proof of exploitation

1. Proof of exploitation shall be done by an official certificate that must be issued by the competent body in the respective area of exploitation.
2. The above document shall certify that the invention is being exploited in manufacturing processes in industrial plants where it claims it is worked or that the subject matter of the invention is actually being marketed.

ARTICLE 95

Dependent patents

1. A patent is said to be dependent when its purpose constitutes a substantial technical progress in relation to the earlier patent.
2. A product patent may be considered dependent upon the respective process patent, and likewise, a process patent may be considered dependent upon a product patent.
3. When any of the above circumstances occur, there shall be no right to cross-licence.

NAMIBIA

Industrial Property Act 2012 (Act No 1 of 2012)

Sections 55-62

PART 9 Compulsory Licences

Compulsory licence for non-working or insufficient-working

55. (1) Any person may, after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, in the prescribed form and manner make an application to the Tribunal to exploit a patented invention in Namibia.

(2) On receipt of an application made under subsection (1), the Tribunal may grant such person a compulsory licence to exploit the patent on such terms and conditions as determined by the Tribunal, if the patented invention was not adequately exploited in Namibia by the owner of the patent or his or her licensee by working the invention locally.

(3) Despite subsection (2), a compulsory licence may not be granted if the owner of the patent satisfies the Tribunal that circumstances exist which justify the lack of adequate exploitation of the invention.

(4) On request made to the Tribunal of any person who proves that the rights in a patent are being abused, the Tribunal may grant such a person a compulsory licence to exploit the patent on such terms and conditions as determined by the Tribunal.

(5) The person to whom a compulsory licence is granted under subsection (2) or (4) has the right to exploit the patented invention in Namibia, otherwise than by importing the patented invention, according to the terms and conditions set out in the determination by the Tribunal, and must commence the exploitation of the patented invention within the time limit fixed in that determination and, thereafter, must exploit the patented invention to an adequate extent.

(6) A compulsory licence granted under this section is non-exclusive and in particular does not exclude

- (a) the exploitation by the owner of the patent of his or her rights under section 41
- (b) the granting of voluntary licences to third parties by the owner of the patent under section 51; or
- (c) the granting of other compulsory licences under this section or section 56 or 57.

(7) The decision by the Tribunal granting the compulsory licence must

- (a) the scope and function of the licence;
- (b) the time limit within which the licensee must begin to exploit the patented invention; and
- (c) the amount of the adequate compensation to be paid to the owner of the patent and the conditions of payment.

(8) When making a decision under subsection (7) the Tribunal must take

- (a) that the scope of the exploitation of the patented invention by the licensee must be limited to the purpose for which the licence was authorised;
- (b) that, after hearing both parties, the terms and conditions of the licence may be varied to the extent that changed circumstances justify such variation; and
- (c) that the compensation to be paid to the owner of the patent must be reasonable in the circumstances, taking into account the economic value of the licence.

(9) A party who is aggrieved by the decision of the Tribunal made under this section, may appeal against the decision to the court.

Compulsory licence based on interdependence of patents

56. (1) If the invention claimed in a patent (herein referred to as the “later patent”) cannot be exploited in Namibia without infringing a patent granted on the basis of an application having an earlier filing date or, where appropriate, priority date (herein referred to as the “earlier patent”), and provided that the invention claimed in the later patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent, the Tribunal may, on application made in the prescribed manner by the owner of the later patent, grant to the owner of the later patent a compulsory licence under the earlier patent to the extent necessary to avoid infringement of the earlier patent.

(2) Where a compulsory licence is issued under subsection (1), the Tribunal must, on application in the prescribed manner by the owner of the earlier patent, grant to the owner of the earlier patent a compulsory licence on reasonable terms in respect of the later patent.

(3) In the case of an application for the issuance of a compulsory licence under subsections (1) and (2), the provisions of sections 55(6), (7) and (8) relating to the conditions for the grant of a compulsory licence do, with the necessary changes, apply, except that no time limit needs to be determined for the exploitation to commence.

(4) In the case of a compulsory licence issued under subsection (1), any transfer of the licence may be made only with the transfer of the later patent, or, in the case of a compulsory licence issued under subsection (2), only with the transfer of the earlier patent.

(5) A party who is aggrieved by the decision of the Tribunal made under this section, may appeal against the decision to the court.

Compulsory licence in public interest

57. (1) Where

- (a) the public interest, in particular national security, nutrition, health or the development of other vital sectors of the national economy, so requires;
- (b) a national emergency or circumstances of extreme urgency have arisen, including a public health crisis, which requires the use of the patented invention;
- (c) the Namibian Competition Commission (hereafter “the Commission”) established in terms of the Competition Act, 2003 (Act No. 2 of 2003) (hereafter “the Competition Act”) has determined that the manner of exploitation, of the patent by the owner of the patent or his or her licensee, constitutes a restrictive business practice prohibited under Part I or Part II of Chapter 3 of the

Competition Act, and the Minister is satisfied that the exploitation of the invention in accordance with this section would remedy such practice;

(d) an interested party has unsuccessfully endeavoured at least for a period of six months to obtain the patent owner's licence for the use of the patented invention on reasonable terms and conditions, and the refusal of the patent owner to grant a licence has the effect that the trade or industry or agriculture of Namibia, or the trade of a class of persons in Namibia, or the establishment of any new trade or industry in Namibia is being prejudiced and it is in the public interest that a licence should be granted; or

(e) a patented product relates to a pharmaceutical product in respect of which Namibia has insufficient or no manufacturing capacity as contemplated in the Decision of the General Council of the WTO of August 30, 2003 or in Article 31bis of TRIPS, and a licence for the importation of the patented product is required as contemplated in the said decision or article, the Minister may, on submission to him or her of an application as contemplated in subsection (3), decide that, even without the consent of the owner of the patent, a third person designated by the Minister may be authorised by way of a compulsory licence to exploit a patented invention, including by the importation of the patented invention, on such terms and conditions as determined by the Minister.

(2) The exploitation of the patented invention under a licence granted under this section is limited to the purpose for which it was authorised and is subject to the payment to the owner of the patent of an adequate compensation therefor, taking into account the economic value of the Minister's authorisation, as determined in the said decision, and, where a decision has been taken under subsection (1)(c), the need to correct the restrictive business practices.

(3) An application may be submitted by any interested party for the Minister's authorisation under subsection (1), which application must be accompanied by evidence that the owner of the patent has received, from the person seeking the authorisation, a written request for a voluntary licence, but that that person has been unable to obtain such a licence on reasonable terms and conditions and, in the case of an application under subsection (1)(d), within a period of six months from the written request.

(4) Where importation takes place pursuant to the Decision of the General Council of the WTO of August 30, 2003 or Article 31 bis of TRIPS whichever is applicable as contemplated in subsection (1)(e), and the exporting country issues a compulsory licence for the same patented invention, no compensation is payable to the owner of the patent as contemplated in subsection (2).

(5) The provisions of subsection (3) with regard to a prior request for a voluntary licence do not apply in cases of

(a) national emergency or other circumstances of extreme urgency as contemplated in subsection (1)(b);

(b) public non-commercial use; and

(c) restrictive business practices determined as such by the Commission in accordance with subsection (1)(c), except that, in such cases the owner of the patent must be notified of the Minister's decision as soon as is reasonably practicable.

(6) The exploitation of a patented invention in the field of semi-conductor technology may only be authorised under this section either for public non-commercial use or where the Commission has determined that the manner of exploitation of the patented invention, by the owner of the patent or his or her licensee, is a restrictive business practice prohibited under the Competition Act and if the Minister is satisfied that the issuance of the non-voluntary licence would remedy such practice.

(7) Any authorisation under this section is non-exclusive and in particular does not exclude –
(a) the exploitation by the owner of the patent of his or her rights under section 41; or
(b) the granting of voluntary licence contracts to third parties by the owner of the patent under section 51; or
(c) the grant of a compulsory licence under section 55 or 56.

(8) Where a third person has been designated and authorised by the another party together with the enterprise or business of that third person or with the part of the enterprise or business within which the patented invention is being exploited.

(9) Except where the compulsory license is issued under subsection 1(c), the compulsory license will be predominantly for the supply of the domestic market.

(10) On written application made to him or her by the owner of the patent, or by the third person authorised to exploit the patented invention, the Minister may, after hearing the parties, vary the terms and conditions of the decision authorising the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(11) On written application made to him or her by the owner of the patent, the Minister must terminate the authorisation if he or she is satisfied, after hearing the parties, that the circumstances which led to the decision have ceased to exist and are unlikely to recur, or that the third person designated by the Minister has failed to comply with the terms and conditions of the decision.

(12) Despite subsection (11), the Minister may not terminate the authorisation if he or she satisfied that the need for adequate protection of the legitimate interests of the third person designated by the Minister justifies the maintenance of the decision.

(13) A party who is aggrieved by the decision of the Minister which is made under this section, may appeal against the decision to the Tribunal.

(14) An appeal against the grant of a compulsory licence does not stay or suspend the use of the patented invention during the appeal process and the patent holder's sole remedy is limited to an action for the recovery of adequate compensation.

Procedure for grant of compulsory licences

58. (1) An application for a compulsory licence under sections 55, 56 or 57 may be submitted by any interested party in the manner prescribed.

(2) An application must be accompanied by

- (a) where required, evidence that the owner of the patent has received, from the person seeking the compulsory licence, a written request for a voluntary contractual licence, but that that person has been unable to obtain such a licence on reasonable commercial terms and conditions within the prescribed period, except in cases mentioned in section 57(6); and
- (b) evidence of the payment of the prescribed fee.

(3) The patent owner or any other person appearing from the register to be interested in the patent may in the prescribed manner oppose the application.

(4) The Tribunal, or the Minister, as the case may be, must consider the application on its merits and may

- (a) order the grant to the applicant of a licence on such conditions as it, he or she may deem fit, including a condition in the circumstances contemplated in section 55(5) precluding the licensee from importing into Namibia any product made from or out of the patented invention; or

(b) if it or he or she considers that the grant of the licence is not justified, refuse the application and give reasons for such refusal to the person who made the request.

Grant and terms of compulsory licences

59. (1) Any compulsory licence granted under section 55 or 56 is nonexclusive and is not transferable except to a person to whom the business or the part of the business in connection with which the rights under the licence were exercised has been transferred.

(2) The Tribunal or the Minister may order that a licence granted in terms of section 55 or 56 or 57, as the case may be, be deemed to have been granted on the date on which the application for a licence has been received.

(3) A licence granted under section 55 or 56 must include a provision that, subject to adequate protection of the legitimate interests of the licensee, the licence must, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the Tribunal are unlikely to recur.

(4) Any licence granted under section 55 or 56 or 57 may be amended or revoked by the Tribunal or the Minister as the case may be.

Rights and obligations of licensee under a compulsory licence

60. Subject to the conditions that may be attached to a compulsory licence, a licensee under this Part has the same rights and obligations as any other licensee under a patent.

Recordal of compulsory licences

61. (1) A compulsory licence granted under section 55 or 56 or 57 must be submitted to and retained by the Registrar who must keep its contents confidential but must record the grant thereof in the appropriate register and must publish a reference to such grant in the bulletin.

(2) A compulsory licence has no effect against third parties until the recordal under subsection (1) has been effected.

(3) The recordal of the grant of a compulsory licence effected under subsection (1) may be cancelled on request to the Registrar in the prescribed manner, accompanied by proof that such licence has expired or has been terminated.

Licences of right

62. (1) At any time after the date of the grant and sealing of a patent, the owner of a patent may apply to the Registrar for the patent to be endorsed with the words "licences of right" and where such an application is made the Registrar must, if satisfied that the patent owner is not precluded by contract from granting licences under the patent, cause the patent to be endorsed accordingly.

(2) Where a patent has been endorsed under this section

(a) any person is at any time thereafter entitled as of right to a licence under the patent upon such conditions as may, in the absence of agreement, be decided by the Tribunal on the application of the patent owner or the person requiring the licence;

(b) the Tribunal may, on the application of the holder of any licence granted under the patent before the endorsement, order such licence to be replaced by a licence to be granted by virtue of the endorsement on conditions to be decided by the Tribunal;

(c) no interdict may, in proceedings for infringement of the patent (other than by the importation of goods), be granted against the defendant if he or she undertakes to take a licence upon conditions to be decided by the Tribunal, and the amount, if any, recoverable from the defendant by way of damages must in such case not exceed double the amount which would

have been payable by him or her as licensee if such a licence had been granted before the earliest infringement; and

(d) the renewal fee payable in respect of the patent after the date of the endorsement is one half of the renewal fee which would have been payable if the patent had not been so endorsed.

(3) The licensee under a licence granted by virtue of the endorsement of a patent in terms of this section may, (unless in the case of a licence where the conditions are determined by agreement, the licence otherwise expressly provides), call on the patent owner to institute proceedings in respect of any infringement of the patent, and if the patent owner fails to do so within two months after being so called upon, the licensee may institute proceedings for the infringement in his or her own name as if he or she were the owner of the patent, joining the patent owner as a defendant.

(4) A patent owner so joined as a defendant under subsection (3) is not liable for any costs unless he or she enters an appearance and takes part in the proceedings.

(5) An application for the endorsement of a patent in terms of this section must contain a statement, to be verified in such manner as may be prescribed, that the patent owner is not precluded by contract from granting licences under the patent, and the Registrar may require from the applicant such further evidence as he or she may think necessary.

(6) An application under this section for the endorsement of a patent of addition must be dealt with as an application for the endorsement of the patent for the main invention also, and an application made under this section for the endorsement of a patent in respect of which a patent of addition is in force, must be dealt with as an application for the endorsement of the patent of addition also, and where a patent of addition is granted in respect of a patent already endorsed under this section, the patent of addition must also be so endorsed.

(7) Every endorsement of a patent in terms of this section must be recorded in the register and must be advertised in the bulletin and in such other manner as the Registrar may direct, to bring the endorsement to the notice of interested persons.

PART 10 Exploitation by Government

Exploitation of patented invention by Government or person authorised by Government

63. (1) For purposes of this section “public interest” includes, but is not limited to, public health, nutrition, agriculture, national emergency, relief, social service, socio-economic development and national security purposes.

(2) Despite anything to the contrary in this Act, where a vital public interest requires that one or more acts of exploitation, including stocking, be performed with respect to a patented invention, the Minister may decide that the patented invention be, even in the absence of the consent of the owner of the patent, exploited by a government ministry, office or agency as defined in the Public Service Act, 1995 (Act No. of 1995) (hereafter “government entity”) or by a third person, including a contractor, subcontractor, or any other person, firm or corporation undertaking any activity for a non-commercial purpose for or on behalf of a government entity, designated by the Minister.

(3) Authorisation in relation to the use of an invention under this section may be given either before or after the use of the invention.

(4) Where the Minister knows, without conducting a patent search, that it is using or will use or has used or will have used a valid patent, the Minister must promptly notify the patent holder.

(5) Any government entity or third person authorised to use an invention pursuant to subsection (2) must pay adequate compensation, as determined by the Minister, to the owner of the patent for the use of the invention.

(6) Where exploitation of a patented invention pursuant to subsection (2) involves importation of a product and such importation takes place pursuant to the Decision of the General Council of the WTO of August 30, 2003 or Article 31 bis of TRIPS whichever is applicable, and the exporting country issues a compulsory licence for the same patented invention, no compensation is payable to the owner of the patent as contemplated in subsection (5).

(7) The owner of the patent may appeal to the Tribunal against any decision of the Minister made in terms of subsection (2) or of the Minister made in terms of subsection (5).

(8) An appeal against the decision of the Minister does not stay or suspend the use of the patented invention during the appeal process, the patent holder's sole remedy being limited to a claim against the government entity or the third person authorised to use the invention for the recovery of adequate compensation.

NETHERLANDS

Articles 57-59 of Patent Act of 15/12/1994, (Text as it applies on 03/06/2009) and Policy Rules on issuing compulsory licenses pursuant to WTO decision WT/L/540 on the implementation of paragraph 6 of the Doha declaration on the TRIPS Agreement and public health, under section 57 of the Act on Patent of 1995, of 23/12/2004

Article 2 of the Policy Rules on issuing compulsory licenses pursuant to WTO decision WT/L/540

Article 57

1. If Our Minister considers it in the public interest he may grant a licence under a patent to a party that he designates, provided that he precisely indicates the relevant content. Before rendering his decision, unless it is incompatible with the urgency of the matter Our Minister shall ascertain whether the patent holder is willing to grant the licence voluntarily and on reasonable terms. To this end, he shall give the patent holder an opportunity to express his opinions on the matter in writing and, at his request, also orally. The patent holder and the licensee shall be notified of the decision. In his decision Our Minister may impose upon the licensee the obligation to provide security within a certain term. The lodging of an objection and an appeal shall have a suspensive effect, unless the decision of Our Minister provides otherwise in view of the urgency of the matter.

2. If, after three years have elapsed since the grant of the patent, neither the patent holder nor any other party who has been granted a licence operates an industrial establishment in the Kingdom or in another State to be designated by general order in council for the Kingdom in which the product concerned is being made or where the process concerned is being applied in good faith and on a sufficient scale, the patent holder shall be obliged to grant the licence needed for operating such an establishment unless valid reasons are shown to exist for the absence of such an establishment. This obligation shall apply in respect of the holder of a European patent if, after three years have elapsed since the date on which the notification of the grant of the European patent was published in accordance with Article 97(4) of the European Patent Convention, an industrial establishment as referred to above is not in operation in the

Netherlands or in the Netherlands Antilles or in another State to be designated by general order in council for the Kingdom.

3. Paragraph (2) shall not apply if the patent holder or any other party who has been granted a licence has an industrial establishment in operation in that part of the continental shelf contiguous to the Netherlands or Netherlands Antilles in which the Kingdom has sovereign rights, in which those acts referred to in that paragraph are performed in good faith and on a sufficient scale, provided that such acts are associated with and performed during the exploration for or recovery of natural resources.

4. The patent holder is obliged at all times to grant a licence required for the use of a patent granted in respect of an application that has the same or a later date of filing or, if a right of priority exists in respect of the application, the same or later date of priority, insofar as the patent for which the licence is requested represents a considerable technical advance involving a considerable economic value; however the patent holder will be obliged to grant a licence required for the use of a European patent only after the term for filing an opposition to the European patent has expired or after opposition proceedings thus instituted have ended. The scope of such a licence shall not extend further than is necessary for the use of the licensee's patent. The latter will be obliged to grant a reciprocal licence under his patent to the holder of the other patent.

5. The patent holder shall grant a plant breeder a licence in exchange for a reasonable fee if the plant breeder cannot obtain or exploit a plant breeder's right in respect of the plant variety without infringing the patent that was granted earlier and the licence is necessary for the exploitation of the plant variety to be protected, which represents a significant technical advance involving a considerable economic value in respect of the invention protected by the patent.

6. If a patent holder is granted a licence on the ground of Article 42(2) of the Dutch Seeds and Planting Materials Act (Zaaizaad- en Plantgoedwet), the patent holder shall grant the holder of the plant breeder's right a reciprocal licence, at the latter's request, to use the protected invention subject to reasonable conditions.

Article 57a

Notwithstanding the provisions contained in Article 57, a compulsory patent licence in the field of semiconductor technology may be granted only for non-commercial use by the government or in order to combat an act that has been determined to be restrictive of competition after judicial or administrative proceedings.

Article 58

1. If the licence referred to in Article 57(2), (4), (5) or (6) is unjustifiably withheld, the licence shall be granted by the court on the basis of a claim brought by the interested party. At the claimant's request the Office shall enter the writ of summons in the patent register.

2. If a patent is granted on the basis of this Kingdom Act, the claimant's claim shall be inadmissible if he does not attach to his writ of summons the results of a report by the Office or the European Patent Office as referred to in the European Patent Convention concerning the state of the art with regard to the subject matter of the patent for which the licence is being claimed.

3. The grant of a licence claimed pursuant to the first sentence of Article 57(4) may be suspended, subject to a term or subject to no term, if a claim to have the patent for which the licence is being claimed invalidated has been submitted within two months after service of the writ of summons in which the licence is claimed.

4. In the description of the licence granted the court may derogate from the licensee's claims and may also require that the licensee furnish security within a certain term. A licence granted pursuant to the first sentence of Article 57(4) may be transferred only together with the licence holder's patent. A licence granted pursuant to the first or third sentence of Article 57(4) shall not expire because the patent on which the licence is granted has lapsed upon the expiry of the period referred to in Article 36(6) or has been successfully claimed, but such a licence shall expire insofar as the patent is invalidated in whole or in part as a result of the claim referred to in paragraph (3).

5. A decision within the meaning of Article 57(1) or a court decision that has become final and has acquired the force of *res judicata* shall be entered in the patent register by the Office. If an obligation to furnish security has been imposed, the entry shall not be made before that obligation has been met. A fee, the amount of which shall be fixed by general order in council for the Kingdom, shall be due for the entry. The licence shall enter into effect only after the entry, but shall subsequently also have effect with regard to parties who became entitled to the patent after the entry in the register of the writ of summons referred to in paragraph (1). However, a registered licence granted on the ground of Article 57(4) shall have retroactive effect to the date on which the writ of summons was entered.

6. On the ground of a claim brought by the initiating party, in the absence of agreement the court shall fix the fee that the licensee must pay to the patent holder. In that context the court may also require that the licensee furnish security within a certain term or confirm or change the security stipulated by virtue of Article 57(1) or paragraph (5) of this Article.

Article 58a

1. A licence granted on the ground of Article 57 is not exclusive.

2. A licence granted on the ground of Article 57 may be transferred only together with the part of the business or the goodwill of the part of the business in which the licence is exercised.

3. A licence granted on the ground of Article 57 may be revoked if, taking into consideration a reasonable protection of the licensee's justified interests, the circumstances that led to the licence being granted have ceased to exist and it is unlikely that they will be revived. On the ground of a substantiated request the authority that granted the licence shall investigate whether the aforementioned circumstances continue to apply.

Article 59

1. In the interest of the defence of the Kingdom, and on a joint recommendation by Our Minister and Our Minister who is directly concerned, it may be provided by Royal Decree that the State shall be authorised to perform or cause others to perform acts, to be described precisely in that Decree, that the patent holder to be specified in that Decree has the exclusive right to perform pursuant to Articles 53 and 53a. The authorisation shall apply as long as the patent is in effect, unless a shorter term has been specified in the Decree.

2. Upon the entry into force of a Decree as referred to in paragraph (1), Our Minister who is directly concerned shall determine, by agreement with the patent holder, the fee to be paid to the patent holder by the State. If Our Minister who is directly concerned has not reached an agreement with the patent holder within six months from the date of the entry into force of that

Decree, Article 58(6) shall apply mutatis mutandis, with the exception of the provisions concerning the furnishing of security.

Article 2 of the Policy Rules on issuing compulsory licenses pursuant to WTO decision WT/L/540

1. In the interests of solving public health problems in an importing state or group of states, the Minister shall, upon receiving an application that satisfies the requirements of articles 3 and 4 of these policy rules, issue a compulsory licence as referred to in section 57, subsection 1 of the Patents Act 1995 for the pharmaceutical product that is needed to address the public health problems in question.

2. The compulsory licence shall at a minimum state the type and amount of the pharmaceutical product to which the compulsory licence issued for the purposes of the order applies.

3. The compulsory licence shall relate only to pharmaceutical products intended for the national market or markets of the importing state or group of states.

NEW ZEALAND

Patents Act 2013 (Reprint December 2018)

Sections 169-188

Subpart 5—Compulsory licences
Compulsory licences for supply of patented inventions
predominantly in New Zealand

169 Application for compulsory licence where market is not being supplied, or is not being supplied on reasonable terms, in New Zealand

(1) Any person may apply to the court for the grant of a licence under a patent on either of the grounds specified in subsection (2) at any time after the later of—

- (a) the expiry of 3 years from the date that the patent is granted; or
- (b) the expiry of 4 years from the patent date.

(2) The grounds are that a market for the patented invention—

- (a) is not being supplied in New Zealand; or
- (b) is not being supplied on reasonable terms in New Zealand.

170 Court may order grant of licence

(1) The court may make an order for the grant of a licence in accordance with an application under Section 69 on any terms that the court thinks fit if the court is satisfied that either of the grounds referred to in section 169(2) is established.

(2) However,—

- (a) a licence must not be granted under this section for a patent relating to an integrated circuit;
- (b) no order may be made under subsection (1) that would be contrary to any treaty, convention, arrangement, or engagement applying to New Zealand and any convention country.

(3) A licence granted under this section—

- (a) is not exclusive; and
- (b) must not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and
- (c) is limited to the supply of the patented invention predominantly in New Zealand; and
- (d) must be recorded in the patents register by the Commissioner as soon as is reasonably practicable after the Commissioner receives a copy of the order made under subsection (1).

(4) Any licence granted under this section may, on the application of an interested person, be terminated by the court if the court is satisfied that the grounds on which the licence was granted have ceased to exist.

Compulsory licences for export of pharmaceutical products

171 Court may order grant of licence for export of pharmaceutical products to certain countries

- (1) The court may, on an application made by any person, make an order for the grant of a licence under a patent if the court is satisfied that—
- (a) the patented invention is—
 - (i) a pharmaceutical product; or
 - (ii) a process for making a pharmaceutical product; and
 - (b) the pharmaceutical product is needed to address a serious public health problem in 1 or more overseas countries specified in the application (for example, an epidemic, whether actual or imminent, of HIV/AIDS, tuberculosis, malaria, or other disease); and
 - (c) each of those overseas countries is either—
 - (i) an eligible importing Member that has made a notification in respect of the product under either paragraph 2(a) of the relevant decision or paragraph 2(a) of the Annex to the TRIPS agreement; or
 - (ii) a country that is currently specified in respect of the product in a notice under Section 172; and
 - (d) all of the pharmaceutical products made under the licence will be exported to those overseas countries.
- (2) A licence granted under this section—
- (a) is not exclusive; and
 - (b) must not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and
 - (c) must be recorded in the patents register by the Commissioner as soon as is reasonably practicable after the Commissioner receives a copy of the order made under subsection (1).
- (3) Any licence granted under this section may, on the application of an interested person, be terminated by the court if the court is satisfied that the grounds on which the licence was granted have ceased to exist.
- (4) For the purposes of this section and sections 172 to 174,—
- eligible importing Member means,—
- (a) if the amendment to the TRIPS agreement to insert Article 31bis has not yet taken effect, an eligible importing Member within the meaning of paragraph 1 of the relevant decision;
 - (b) if the amendment to the TRIPS agreement to insert Article 31bis has taken effect, an eligible importing Member within the meaning of that Article pharmaceutical product includes a medicine or vaccine, an active ingredient of a medicine or vaccine that is necessary for its manufacture, or a diagnostic kit needed for the use of a medicine or vaccine relevant decision means the decision of the General Council of the World Trade Organization of 30 August 2003 relating to the implementation of paragraph 6 of the Doha Declaration on the TRIPS agreement and public health.

172 Secretary of Foreign Affairs and Trade may publish notices that specify eligible countries

- (1) This section applies if—
- (a) the government of a country that is not a member of the World Trade Organization has sent to the Government of New Zealand a request for the country to be specified under this section for the purposes of section 171 (1) (c) (ii) in respect of a particular pharmaceutical product; and
 - (b) the request sets out information relating to why the government of that country considers that either—
 - (i) the country has no manufacturing capacity in its pharmaceutical sector for the pharmaceutical product; or
 - (ii) the country's manufacturing capacity in its pharmaceutical sector for the pharmaceutical product (excluding any capacity owned or controlled by the patentee) is currently insufficient for the purposes of meeting its need for the product; and

(c) the request specifies the expected quantity of the pharmaceutical product that is needed by the country.

(2) The Secretary of Foreign Affairs and Trade (the Secretary) may, after a request from a country has been received under subsection (1), by notice in the *Gazette*, specify the country for the purposes of section 171 (1) (c) (ii) in respect of the relevant pharmaceutical product if he or she is satisfied that either—

(a) the country has no manufacturing capacity in its pharmaceutical sector for the product; or
(b) the country's manufacturing capacity in its pharmaceutical sector for the product (excluding any capacity owned or controlled by the patentee) is currently insufficient for the purposes of meeting its need for the product.

(3) The notice under subsection (2) must—

(a) specify the country and pharmaceutical product; and
(b) specify the expected quantity of the pharmaceutical product that is needed by the country (as notified to the Government of New Zealand under subsection (1)); and
(c) state that the Secretary is satisfied of the matters specified in subsection (2) and his or her reasons for being so satisfied.

(4) The Secretary may, by notice in the *Gazette*,—

(a) amend or revoke a notice under subsection (2);
(b) revoke a notice under subsection (2) and replace it with another.

(5) The Secretary must publish a copy of a notice under subsection (2) on an Internet site maintained by, or on behalf of, the Ministry of Foreign Affairs and Trade.

(6) To avoid doubt, a notice under subsection (2) is neither a legislative instrument nor a disallowable instrument for the purposes of the Legislation Act 2012 and does not have to be presented to the House of Representatives under section 41 of that Act.

173 Terms of licence

(1) An order under section 171 must specify terms of the licence relating to the following matters:

(a) the name and address of the licensee;
(b) the name of the patented invention for which the licence has been granted;
(c) the name of the country or countries to which the pharmaceutical products made under the licence must be exported;
(d) the maximum quantity of pharmaceutical products that may be exported to each of those countries (which must be no more than the court considers is necessary to meet the needs of the country);
(e) the duration of the licence;
(f) the address of the licensee's Internet site for the purposes of subsection (2) (e).

(2) A licence granted under section 171 is subject to the following terms:

(a) all pharmaceutical products made under the licence must be clearly identified, through specific labelling or marking, as having been made under a compulsory licensing scheme for the export of the product;

(b) all pharmaceutical products made under the licence must have particular distinguishing features (for example, special packaging or special colouring or shaping of the products) if including those features is feasible and does not have a significant impact on price;

(c) all pharmaceutical products made under the licence must be exported to the country or countries specified under subsection (1) (c);

(d) the licensee must, before exporting the pharmaceutical products to a country specified under subsection (1)(c), supply to the Council for Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization a statement containing the following information for the purpose of the information being published on the WTO Internet site:

(i) the quantities of the pharmaceutical product to be exported to the country;

(ii) the specific labelling or marking referred to in paragraph (a) and any distinguishing features of the pharmaceutical products referred to in paragraph (b):

(e) the licensee must, before exporting the pharmaceutical products to a country specified under subsection (1)(c), publish the information specified in paragraph (d) on the licensee's Internet site.

(3) A licence granted under section 171 may be subject to any other terms that the court thinks fit.

(4) For the purposes of this section,—

licensee's Internet site means an Internet site maintained by, or on behalf of, the licensee

WTO Internet site means an Internet site maintained by, or on behalf of, the World Trade Organization.

174 Copy of order must be sent to Commissioner and Secretary of Foreign Affairs and Trade

(1) The Registrar of the court must, as soon as is reasonably practicable after an order is made under section 171, send a copy of the order to the Commissioner and the Secretary.

(2) The Secretary must, as soon as is reasonably practicable after receiving a copy of the order, publish a copy of the order on an Internet site maintained by, or on behalf of, the Ministry of Foreign Affairs and Trade.

175 Remuneration payable to patentee

If a licence is granted under this subpart to a person, that person must pay to the patentee the remuneration—

(a) that is agreed between that person and the patentee; or

(b) that is determined by a method agreed between that person and the patentee; or

(c) that is determined by the court on the application of that person or the patentee in default of agreement

176 Person applying for licence must have made efforts to obtain licence from patentee on reasonable commercial terms and conditions

A licence must not be granted under this subpart unless the person applying for the licence, having made efforts to obtain a licence from the patentee on reasonable commercial terms and conditions, has been unable to obtain a licence, or to obtain a licence on reasonable commercial terms and conditions, from the patentee within a reasonable period of time.

177 Exercise of powers on applications under section 169, 171, or 175

(1) The powers of the court on an application under section 169, 171 or 175 must be exercised with a view to ensuring that the inventor or other person beneficially entitled to a patent receives adequate remuneration having regard to the nature of the invention.

(2) For the purposes of subsection (1), the court must, in the case of a licence under section 171, have regard to the economic value of the products made under the licence to the country to which the products will be exported under the licence.

178 Order for grant of licence has effect as deed

(1) Any order under this subpart for the grant of a licence has effect as if it were a deed, executed by the patentee and all other necessary parties, granting a licence in accordance with the order.

(2) Subsection (1) does not limit any other method of enforcement.

Subpart 6—Crown use of inventions

179 Crown use of inventions

(1) Any government department, and any person authorised in writing by a government department, may exploit any invention for the services of the Crown at any time after the complete specification relating to an application for a patent for the invention has become open to public inspection.

(2) The exploitation of an invention under subsection (1) is not an infringement,—

(a) if the application for a patent is pending, of the nominated person's rights in the invention; or

(b) if a patent has been granted for the invention, of the patent.

(3) Subsection (1)—

- (a) is subject to sections 186 to 188; but
- (b) applies despite any other provision of this Act.

(4) For the purposes of this subpart,—

(a) any use of an invention for the supply to the government of any country outside New Zealand of products required for the defence of that country must be treated as exploitation of the invention for the services of the Crown if that supply is made in accordance with any agreement or arrangement between the Government of New Zealand and the government of that country:

(b) the power of a government department or a person authorised by a government department under this section to exploit an invention includes the power to sell to any person any products made in the exercise of the powers conferred by this section that are no longer required for the purpose for which they were made:

(c) the power of a government department or a person authorised by a government department under this section to sell an invention does not, in the case of an application for a patent or a patent relating to an integrated circuit, extend to the sale of the invention to the public.

180 Order in Council may declare use to be Crown use

Any use of an invention must, for the purposes of this subpart, be treated as a use for the services of the Crown if the Governor-General, by Order in Council, declares that the use of the invention by a person, or by any class of persons, engaged in a particular industry is necessary or desirable to enable full benefit to be derived by the members of the public in New Zealand of any enterprise or undertaking in which the Crown or any government department has a complete or an almost complete monopoly.

181 Protection of buyers

The buyer of any products sold in the exercise of powers conferred by section 179, and any person claiming through the buyer, has the power to deal with them in the same manner as if the patent were held on behalf of the Crown.

182 Rights of third parties in respect of Crown use

(1) This section applies in relation to any use of a patented invention, or of an invention for which a patent application is pending, made for the services of the Crown—

(a) by a government department or a person authorised by a government department under section 179; or

(b) by the patentee, nominated person, or applicant for the patent to the order of a government department.

(2) The provisions of any licence, assignment, or agreement made between the patentee, nominated person, or applicant for the patent, or any person who derives title from that person or from whom that person derives title, and any person other than a government department is of no effect to the extent that those provisions—

(a) restrict or regulate the use of the invention referred to in subsection (1); or

(b) restrict or regulate the use of any model, document, or information relating to the invention in relation to the use of the invention referred to in subsection (1); or

(c) provide for the making of payments for any of those uses or calculated by reference to any of those uses.

(3) The reproduction or publication of any model or document in connection with a use referred to in subsection (1) is not an infringement of any copyright subsisting in the model or document.

(4) Subsection (2)—

(a) applies whether the licence, assignment, or agreement is made before or after the commencement of this section; and

(b) is subject to sections 186 and 188.

183 Reference of disputes concerning Crown use

(1) The following disputes may be referred to the court by either party to the dispute in the manner that is prescribed by rules of the court:

(a) any dispute concerning the exercise by a government department or a person authorised by a government department of the powers conferred by section 179:

(b) any dispute concerning the terms for the use of an invention for the services of the Crown under that section.

(2) In any proceeding under this section, the government department may,—

(a) if the patentee is a party to the proceeding, apply for the revocation of the patent on any ground on which a patent may be revoked under subpart 11 of Part 3; and

(b) in any case, put in issue the validity of the patent without applying for its revocation.

(3) In determining any dispute referred to the court under this section, the court must have regard to—

(a) any benefit or compensation that the nominated person or patentee may have received, or may be entitled to receive, directly or indirectly from any government department or person authorised by a government department in respect of the invention; and

(b) the need to ensure that the nominated person or patentee receives adequate remuneration having regard to the nature of the invention.

184 Court may refer matter to special or official referee or arbitrator

(1) In any proceeding under section 183, the court may order the whole proceeding or any question or issue of fact arising in the proceeding to be referred to a special or official referee or an arbitrator on any terms that the court thinks fit.

(2) References to the court in section 183 must be construed as including a reference to the special or official referee or arbitrator.

185 Special provisions as to Crown use during emergency

(1) The powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 179 include the power to exploit the invention for any purpose that appears to the government department necessary or desirable—

(a) to avoid prejudice to the security or defence of New Zealand; or

(b) to assist in the exercise of powers and the implementation of civil defence emergency management during a state of emergency declared under the Civil Defence Emergency Management Act 2002.

(2) This section is subject to section 186 to 188.

186 Nature and scope of rights under section 179

(1) The right to use an invention under section 179—

(a) is not exclusive; and

(b) must not be assigned otherwise than in connection with the goodwill of the business in which the invention is used; and

(c) is, despite section 179 (4) (a), limited to the supply of the invention predominantly in New Zealand by a government department or a person authorised by a government department under that section.

(2) The right to use an invention under section 179 may, on the application of any interested person, be terminated by the court if the court is satisfied that the circumstances that gave rise to the right to use the invention have ceased to exist and are unlikely to recur.

(3) The right to use an invention under section 179 is, except in a case to which section 185 applies, subject to the government department or person authorised by a government department under section 179 having first made efforts to obtain the consent of the nominated person or the patentee for the use of the invention on reasonable commercial terms and conditions, and having failed to obtain that consent, or to obtain that consent on reasonable commercial terms and conditions, within a reasonable period of time.

187 Duty to inform nominated person or patentee

(1) If any use of an invention is made by or with the authority of a government department under section 179, the government department must, as soon as practicable after the use of the invention has begun, notify and provide the nominated person or patentee with any information concerning the extent of the use as the nominated person or patentee may from time to time require.

(2) Subsection (1) does not require the government department to notify or disclose information to the nominated person or patentee if to do so would, or might reasonably be expected to, prejudice the security or defence of New Zealand.

188 Nominated person or patentee entitled to remuneration

The Crown must, if an act is done under section 179, pay to the nominated person or patentee the remuneration—

- (a) that is agreed between the nominated person or patentee and the Crown; or
- (b) that is determined by a method agreed between the nominated person or patentee and the Crown; or
- (c) that is determined by the court under section 183 in default of agreement.

NICARAGUA

Law on Patents, Utility Models and Industrial Designs (No. 354 of 2000)

Sections 51-56

Compulsory Licenses

51. At the request of an interested party or competent authority, the Intellectual Property Registry may, after having heard the owner of the patent, grant compulsory licenses for reasons of public interest or national emergency, or to control any anti-competitive practice. The Intellectual Property Registry shall order that:

- (a) the invention for which a patent has been granted or for which a patent application is pending be used or exploited industrially or commercially by a State body or by one or more persons under public or private law designated for the purpose;
- (b) the invention for which a patent has been granted or a patent application is pending remain open for the grant of one or more compulsory licenses, in which case the Registry may grant such a license to whoever may apply for one, subject to established conditions.

Those acts that unduly affect free competition or constitute an abuse of a dominant market position are included among those that are not consistent with the proper exercise of patent rights.

Where the patent protects any kind of semiconductor technology, the compulsory license shall be granted only for non-commercial public use, or to control a practice declared anti-competitive in an appropriate procedure.

Request for a Compulsory License

52. A person who requests a compulsory license shall prove that he has already applied to the owner of the patent for a contractual license and has been unable to obtain one with a reasonable term and on reasonable commercial conditions. It shall not be necessary to meet this requirement in the case of a compulsory license for reasons of national emergency, extreme urgency or non-commercial use of the invention by a public body. It shall likewise be unnecessary to meet this requirement where the compulsory license is intended to control an anti-competitive practice. In both cases the owner of the patent shall be informed without delay of the grant of the license.

The request for a compulsory license shall specify the conditions on which the requester wishes to obtain the license.

The owner of the patent shall be notified of the request and shall be party to the proceedings.

Conditions Governing Compulsory Licenses

53. The compulsory license shall be granted mainly to supply the domestic market, and its owner shall receive adequate remuneration according to the circumstances of the case and the economic value of the license. In the absence of agreement the Intellectual Property Registry shall set the amount of the remuneration and the manner of its payment.

The compulsory license may not be granted with exclusive rights, or be the subject of assignment or sublicensing, and it may only be transferred together with the business or establishment or part thereof that exploits the license.

Compulsory License in the Case of Patent Dependency

54. Where a compulsory license is requested to permit the working of a later patent that cannot be worked without infringing an earlier patent, the following additional conditions shall be observed:

- (a) the invention claimed in the later patent must represent a substantial technical advance of considerable economic importance in relation to the invention claimed in the earlier patent;
- (b) the compulsory license for working the earlier patent may only be assigned together with the later patent;
- (c) the owner of the earlier patent may under the same circumstances obtain a compulsory license on reasonable terms for the exploitation of the invention claimed in the later patent.

Grant of the Compulsory License

55. The resolution granting a compulsory license shall specify:

- (a) the scope of the license, including its duration and the acts for which it is granted, which shall be limited to the purposes that gave rise to it;
- (b) the amount and manner of payment of the remuneration payable to the owner of the patent;
- (c) the conditions necessary for the license to achieve its purpose.

Revocation and Amendment of the Compulsory License

56. A compulsory license may be wholly or partly revoked by the Intellectual Property Registry at the request of any interested party if the licensee fails to comply with the obligations incumbent on him, or if the circumstances that gave rise to the license have ceased to exist and are unlikely to recur. In the latter case the Intellectual Property Registry may make the necessary arrangements for the adequate protection of the legitimate interests of the licensee affected by the revocation.

A compulsory license may be amended by the Intellectual Property Registry at the request of the interested party where new facts or circumstances dictate, especially where the owner of the patent has granted contractual licenses on terms more favorable than those accorded to the beneficiary of the compulsory license.

NIGERIA

Patents and Designs Act of 1971 (Chapter 344) (Version 1990)

Paragraphs 1-23

First Schedule

Compulsory Licences and use of patents for service of government agencies

Part I Compulsory Licences

1. Subject to this Part, at any time after the expiration of a period of four years after the filing of a patent application or three years after the grant of a patent, whichever period last expires, a person may apply to the Court for the grant of a compulsory licence on one or more of the following grounds-

- (a) that the patented invention, being capable of being worked in Nigeria, has not been so worked;
- (b) that the existing degree of working, of the patented invention in Nigeria does not meet on reasonable terms the demand for the product;
- (c) that the working of the patented invention in Nigeria is being hindered or prevented by the importation of the patented article; and
- (d) that, by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced.

2. If an invention protected by a patent in Nigeria cannot be worked without infringing rights derived from a patent granted on an earlier application or benefiting from an earlier foreign priority, a compulsory licence may be granted to the patentee of the later patent to the extent necessary for the working of his invention if the invention-

- (a) Serves industrial purposes different from those served by the it, invention which is the subject of the earlier patent; or
- (b) constitutes substantial technical progress in relation to that last mentioned invention.

3. If the two inventions mentioned in paragraph 2 of this Schedule serve the same industrial purposes, a compulsory licence may be granted under that paragraph only on condition that a compulsory licence shall also be granted in respect of the later patent to the patentee of the earlier patent, if he so requests.

4. A compulsory licence shall not be granted in respect of a patent if the patentee satisfies the court that his actions in relation to the patented invention are justifiable in the circumstances, but he shall not be held to have so satisfied the court if he merely shows that the patented article is freely available for importation.

5. A compulsory licence shall not be granted unless the applicant-

- (a) satisfies the court that he has asked the patentee for a contractual licence but has been unable to obtain such a license on reasonable terms and within a reasonable time; and
- (b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies (or to satisfy the requirements) which gave rise to his application.

6. A compulsory license-

- (a) entitles the licensee to do any act mentioned in section 6 of this Act except importation;
- (b) does not entitle the licensee to grant further licences;
- (c) Shall be non-exclusive, and
- (d) may contain additional obligations and restrictions as regards both the licensee and the patentee.

7. A compulsory licence may be transferred only with the industrial undertaking in which the relevant invention is used, and no such transfer shall be valid until the consent of the court has been obtained.

8. On hearing an application for a compulsory licence, the court shall first decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant and the parties cannot agree on the terms, proceed to fix the terms (including adequate royalties having regard extent to which the relevant invention is to be worked which shall be deemed to constitute a valid contract between the parties.

9. On the application of the patentee, the court may cancel a compulsory licence if-

- (a) the licensee fails to comply with the terms of the licence; or
- (b) the conditions which justified the grant of the licence have ceased to exist, so however that in the latter case a reasonable time shall be given to the licensee to cease working the relevant invention if an immediate cessation would cause him to suffer substantial damage.

10. On the application of the patentee or licensee, the court may vary the terms of a compulsory licence if new facts justify the variation, and in particular (without prejudice to the generality of the foregoing) if the patentee has granted contractual licences on more favourable terms.

11. Where the court grants, cancels or varies the terms of a compulsory licence-

- (a) the proper officer of the court shall inform the Registrar, who shall register the grant, cancellation or variation without fee; and
- (b) the grant, cancellation or variation shall have no effect as against third parties until it has been registered.

12. A representative of the Minister shall have the right to appear and be heard at the hearing of an application for a compulsory licence.

13. The Minister by order in the Federal Gazette may provide that, for certain patented products and processes (or for certain categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or for public health, compulsory licences may be granted before the expiration of the period mentioned in paragraph 1 above and may permit importation.

14. For the purposes of this Part, references to the working of a patented invention are to be construed as references to-

- (a) the manufacture of a patented article; or
- (b) the application of a patented process; or
- (c) the use in manufacture of a patented machine, by an effective and serious establishment existing in Nigeria on a scale which is adequate and reasonable in the circumstances.

Part II Use of Patents for service of government agencies

15. Notwithstanding anything in this Act, where a Minister is satisfied that it is in the public interest to do so, he may authorise any person to purchase, make, exercise or vend any patented article or invention for the service of a government agency in the Federal Republic.

16. The authority of a Minister under paragraph 15 of this Schedule may be given-

- (a) before or after the relevant patent has been granted;
- (b) before or after the doing of the acts in respect of which the authority is given; and
- (c) to any person whether or not he is authorised directly or indirectly by the patentee to make, use, exercise or vend the relevant article or invention.

17. Paragraphs 15 and 16 of this Schedule shall have effect so as to exempt-

- (a) the Government;
- (b) any person authorised under those paragraphs;
- (c) any supplier of the Government or of any such person; and
- (d) any agent of any such supplier, from liability for the infringement of any patent relating to the relevant article or invention and from liability to make any payment to the patentee by way of royalty or otherwise.

18. Where any act is done in respect of an article on the authority of a Minister under paragraph 15 of this Schedule, then, unless it appears to the Minister that it would be contrary to the public interest to do so, the Ministry concerned with the act shall furnish the patentee with such information, as to the extent of the act as the patentee may from time to time require.

19. The revisions of any licence, assignment or agreement made before or after the commencement of this Act between a patentee and any person, other than the Government, or a Ministry shall be of no effect in so far as those provisions restrict or regulate the use of a patented article or invention or provide for the making of payment in respect of any such use, or are calculated by reference thereto.

20. During any period of emergency the powers exercisable in relation to a patented article or invention on the authority of a Minister under paragraph 15 of this Schedule shall include power to purchase make, use, exercise and vend the article or invention for any purpose which appears to the Minister necessary or expedient-

(a) for the efficient prosecution of any war in which the Federal Republic may be engaged; or (b) for the maintenance of supplies and services essential to the life of the community; or

(c) for securing a sufficiency of supplies and services essential to the well-being of the community; or

(d) for promoting the productivity of industry, commerce and agriculture; or

(e) for fostering and directing exports and reducing imports (or any class or classes of imports) from all or any countries and for redressing the balance of trade; or

(f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community.

21. Where a patented article is purchased, made, used, exercised or vended by or on behalf of a government agency, the benefit of this Part shall extend to the agency and to persons acting in any capacity on its behalf.

22. This Part shall apply to a patented article forfeited under any law relating to customs and excise; and, on any such forfeiture, the Government may use or sell the article as if it had been imported for the use of a government agency in Nigeria.

23. In this Part, unless the context otherwise requires- "articles" includes-

(a) any drugs or pharmaceutical preparations, substances or materials; and

(b) any plant, machinery or apparatus, whether fixed to the land or not after importation, patented under the law of a country other than Nigeria;

"export" means export from Nigeria;

"Federal Republic" means the Federal Republic of Nigeria, and includes any State of the Federation; "Government" means the Federal Government, and includes the Governor of any State of the Federation;

"Government agency" means any Federal or State Ministry or Department of Government, and includes-

(a) a voluntary agency hospital, that is to say, an hospital in Nigeria (not being a hospital operated by the government) which is wholly or partly maintained by the Federation or a State by way of grant in aid or otherwise;

(b) a local authority, that is to say, any administration, council or other authority exercising limited governmental powers in a defined area within a State;

(c) a statutory corporation, that is to say, a body corporate directly established by law to which in the performance of its functions the Government or a Minister is empowered by law to give directions; and

(d) Any company which is owned or controlled by the Government;

"Ministry" means a Federal or State Ministry or Department of Government;

"Minister" means a Minister of the Federation and a State Commissioner;

“Period of emergency” means any period of emergency however declared or notified by or on behalf of the Government or any successor Government;
“Person” includes the Government or a Ministry;
“War” includes civil war.

NORTH MACEDONIA

Law on Industrial Property No. 07-1006/1 of 12/02/2009

Articles 97, 98, 100, 102, 104, 105, 107 and 108

Compulsory license

Article 97

(1) If the patent holder does not use the invention protected by a patent or uses it in a scope which is insufficient to the needs of the national market, and rejects to enter into a license agreement or sets unmarketable conditions for entering into that contract, the right to use the invention, by a compulsory license, may be assigned to another person, with the obligation to pay the fee to the patent holder.

(2) Compulsory license may also be issued if the utilisation of the invention protected by a patent is necessary due to emergency situations in the country, protection of public interest in the area of health, food, protection and promotion of the environment or if it is of particular interest to a certain industrial field or if it is necessary for implementing the judicial and administrative procedure related to protection of competition.

(3) The exemptions in granting compulsory license as referred to in paragraph (1) of this Article shall be possible in the situations referred to in paragraph (2) of this Article, for which the patent holder shall be notified as soon as possible.

(4) Request for a compulsory licence referred to in paragraph (1) of this Article may not be submitted prior to the expiry of a period of four years from the date of filing the patent application i.e. prior to the expiry of a period of three years from the date of the patent granting, in case this period expires later.

(5) A compulsory licence shall not be issued if the patent holder proves that there are legal constraints which justify the fact that invention protected by a patent has not been used or has been insufficiently used.

(6) In the cases referred to in paragraph (2) of this Article, the compulsory license may be issued even prior to the expiry of the period laid down in paragraph (4) of this Article.

Particularities of the compulsory license

Article 98

(1) A compulsory license may not be exclusive.

(2) The compulsory licence shall be valid as long as there is reason for which it has been issued.

(3) On the elaborated request of the interested person, the compulsory license shall be cancelled if there are no longer the reasons for which the license has been issued, and there is no possibility for those reasons to occur again, provided that the legitimate rights to the assignee of the compulsory licence are protected.

(4) The compulsory license may not be transferred, unless the transfer is done together with the production capacity i.e. with part of it that uses the invention for which the license has been issued.

(5) Compulsory license shall be issued for the needs of the national market, unless it is proved in the legal proceedings that this is contrary to the protection of competition on the market.

Compulsory licence for dependent patent

Article 100

(1) A compulsory licence may also be issued if the invention protected by a patent cannot be used as a whole or partially without using another invention protected by a former patent, whereby the later invention, representing a more significant technical improvement, is of particular importance to the economy or to fulfilling the general needs.

(2) If a compulsory license is issued in accordance with paragraph (1) of this Article, the holder of the previous patent may request a compulsory license to use the invention of the latter patent for a relevant fee.

Compulsory license for the needs of public health

Article 102

(1) Any person that has filed an application in compliance with the provisions of this Law may be issued, by the court, a compulsory patent license i.e. a supplementary protection certificate for the needs of production and sale of pharmaceutical products, where such a product is intended to be exported in the importing countries with problems in public health.

(2) When deciding upon issuing compulsory license, the court shall take into consideration the WTO General Council Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health of 14 November 2001, (hereinafter referred to as: "Decision").

(3) The pharmaceutical product referred to in paragraph (1) of this Article shall be any product in the pharmaceutical industry, including the medications for human use, which include any substance or mixture of substances designed for treatment or prevention of human diseases including any substance or mixture of substances which may be applied to people in terms of renewal, improvement, or adjustment to their physiological functions by causing pharmaceutical, immunological, or metabolic effects or by giving the medical diagnosis, including active components and accessories to diagnose outside the alive human body.

Lawsuit to issue compulsory license for the needs of public health

Article 104

(1) The lawsuit that includes an application for issuing a compulsory license for the needs of the public health shall be submitted to the court in compliance with Article 101 of this Law if there is a patent or a supplementary protection certificate in the territory of the Republic of Macedonia that covers the works for production and sale for the purpose of exporting.

(2) The one submitting the lawsuit for compulsory license shall be bound to attach the following to the lawsuit:

- 1) applications for compulsory licenses in other countries for the same product, with data on the quantities and the importing countries;
- 2) the applicant for compulsory license, and in case there is an agent, data about the agent;
- 3) name of the pharmaceutical product i.e. not subject to protection, which the applicant plans to produce on the basis of compulsory license;
- 4) quantity of the pharmaceutical product that the applicant plans to produce on the basis of compulsory license;
- 5) data on the importing country;
- 6) evidence about the previous negotiations with the right holder in compliance with paragraph (5) of this Article; and
- 7) evidence about the application of the authorised agent of the importing country or the non-governmental organisation which operates with an authorisation from one or more importing countries or UN bodies or another international health organisation, which operates with an authorisation of one or more importing countries indicating the quantity of the required product.

Preconditions for compulsory license

Article 105

(1) Compulsory license may be issued only if within a period of 30 days prior to submitting the lawsuit, the applicant has unsuccessfully tried to get a consent from the right holder to utilise the protected invention under reasonable conditions and terms.

(2) The provision of paragraph (1) of this Article shall not apply in case of necessity or other circumstance of final necessity in the country or in case of non-commercial use, in compliance with Article 31, item b) of the TRIPS Agreement.

Properties of the issuing compulsory license for the needs of public health

Article 107

(1) The compulsory license may not be exclusive.

(2) The duration and the scope of the compulsory license stated in the court decision regarding the license shall depend only from the duration of the reason due to which it had been issued.

(3) The quantity of products that may be produced on the basis of the compulsory license must not exceed the quantity which is necessary to respond to the needs of the importing countries i.e. the importing countries stated in the lawsuit, taking into consideration the quantity of products produced in other countries on the basis of the compulsory license.

(4) The compulsory license may be transferred only together with the production capacity i.e. with the part of it, in which the invention for which the compulsory license has been issued is used.

Requirements for issuing compulsory license for the needs of public health

Article 108

(1) The product which is produced or imported on the basis of a compulsory licence may not be offered for sale or placed on the market of a country i.e. not indicated in the application, except when the importing country, in compliance with item 6, subitem (i) of the Decision, imports in a country that has also signed the regional trade agreement and has the same problem in the field of health.

(2) The packing or any relevant text must contain a clear indication that the product is a subject to a compulsory license, the name of the court granting the license and the number of the subject, a clear indication that the product is intended exclusively for export and distribution in the importing country or the importing countries and detailed data regarding the product provided for customs authorities in the Republic of Macedonia.

(3) Compulsory license shall be issued for the needs of the local market, unless proved in the judicial procedure of issuing that this is contrary to the protection of competition on the market.

(4) If the product for which in the Republic of Macedonia a compulsory license has been issued, is patent granted in the import country indicated in the application, the product may be exported only if that country has issued a compulsory license for export, sale, and/or distribution of that product.

(5) The conditions under which the license is issued shall not affect the method of distribution in the importing country.

NORWAY

Sections 45-50a of the Patent Act No. 9 of 15/12/1967 (as last amended by Act No.80 of 29/06/2007)

Sections 96-100 Regulations to the Norwegian Patents Act

Section 45. Where three years have elapsed from the grant of the patent and four years from the filing of the patent application without the invention being worked in this country to a

reasonable extent, anyone who wishes to work the invention in this country may obtain a compulsory licence for that purpose, provided there is no legitimate reason for the failure to work the invention.

For the purpose of the first paragraph, utilization of the invention shall, in contracting states in the WTO treaty or the EEA, be given equal status as utilization within this country, provided that the patent rights do not prevent national imports. The same applies for utilization in other states, to the extent it complies with a reciprocal duty following an international treaty.

Section 46. The holder of a patent for an invention, the use of which is dependent on a patent owned by someone else, may obtain a compulsory licence to use the invention protected by the latter patent provided that the former invention involves an important technical advance of considerable economic significance in relation to the latter invention.

The holder of the patent for the invention to which the compulsory licence applies shall be entitled to obtain a compulsory licence on reasonable terms to use the other invention.

Section 46 a. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may, subject to payment of an appropriate royalty, apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for exploitation of the plant variety to be protected. A compulsory licence will only be granted where the applicant can demonstrate that the plant variety constitutes significant technical progress of considerable financial interest in relation to the invention.

If a patent holder has been granted a compulsory licence for the exploitation of a protected plant variety according to Act No 32, March 12, 1993 about Plant variety protection Section 28 second paragraph, the holder of the plant variety right is entitled to a compulsory licences of the patented invention on reasonable terms.

Section 47. Any person who wants to exploit an invention commercially, which has been patented by someone else, may be given a compulsory licence

- when required by important public interests.
- when the patent rights are exploited in a way that significantly limits competition.

Section 48. Anyone who, at the time a patent application was made available to the public, was commercially exploiting the invention for which a patent is applied for in this country, may, if the application results in a patent, obtain a compulsory licence for the exploitation of the invention, provided that special circumstances make it desirable, and that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such right shall also, on similar conditions, be enjoyed by anyone who has made substantial preparations for commercial exploitation of the invention in this country. The compulsory licence may also comprise the time preceding the grant of the patent.

Section 49. A compulsory licence may only be granted to someone who has made efforts to obtain a licence on reasonable business terms by agreement, without achieving it in reasonable time, and may be presumed able to exploit the invention in a manner which is acceptable and which is in compliance with the terms of the licence.

A compulsory licence shall not prevent the patent holder from exploiting the invention himself or from granting licences.

A compulsory licence shall only be assignable in conjunction with the enterprise where it is exploited or in which the exploitation was intended. Furthermore, a compulsory licence

obtained according to the first paragraph of section 46 may only be assigned in conjunction with the dependent patent.

In the case of semi-conductor technology, compulsory licences shall only be granted for public non-commercial use or to remedy practice determined after judicial or administrative process to be anti-competitive or based on section 47 nr.2.

A compulsory licence shall mainly be given with the aim of supplying the domestic market. The King may, by regulation, determine provisions which depart from this.
Section 50. The court shall grant a compulsory licence in accordance with this section, and the Norwegian Competition Authority in accordance with section 50 a.

In a decision considering a compulsory licence, the court shall also determine to what extent the invention may be exploited and stipulate the compensation and the other terms of the licence. The compensation shall be appropriate, taking into account the circumstances in each case. The value of the licence shall be taken in consideration when assessing the compensation. If circumstances should change considerably, the court may, at the request of either party, cancel the licence or stipulate new terms.

In a decision granting or extending a compulsory licence, the court may find that the owner of the compulsory licence shall have the right to exploit the invention in accordance with the decision during the period prior to the decision becoming legally binding. Motion for preliminary enforcement has to be put forward prior to the judge's final deliberations on the merits of the case. If the compulsory licence is cancelled because the decision is opposed before becoming legally binding, the owner of the compulsory licence shall be obliged to pay compensation for the loss caused by the exploitation, to an extent considered reasonable. The third sentence shall apply correspondingly if restrictions are imposed on the compulsory licence. In a decision under the first sentence, the court may instruct the licensee to furnish security for liability under the third and fourth sentences. If a decision granting or extending a compulsory licence is opposed before becoming legally binding, the court to which the decision is brought, may make or reverse a decision under the first and fourth sentences. The decision is made by a ruling or by the final decision in the matter, cf. the second sentence. A ruling under the sixth sentence may only be opposed in connection with an appeal of the final decision in the matter.

Section 50 a. A request for a compulsory licence made to the Norwegian Competition Authority, shall state the grounds for the request and provide details of the circumstances referred to in section 49 first paragraph. The claim shall set out the scope of the licence and compensation and any further conditions the party considers reasonable. A prescribed fee shall be paid. If the application does not fulfil these requirements, The Norwegian Competition Authority shall grant a reasonable period of time for rectification. The demand shall be rejected if the deficiency in the request is not rectified within the time limit, unless the Norwegian Competition Authority finds reasons to grant a new period of time for rectification.

The Norwegian Industrial Property Office, Board of Plant Varieties, or any other public agency shall, upon request from the Norwegian Competition Authority or the Board of Appeals, provide an opinion on the case within 6 weeks from the date of the request.

Anyone can provide the Norwegian Competition Authority or the Board of Appeals with the information these authorities require in connection with cases concerning compulsory licences. The Norwegian Competition Authority may summon the parties to an oral hearing if necessary. The King may, by regulation, determine specific rules for the procedures.

The regulation in section 50 third paragraph apply correspondingly for cases under this section, nevertheless the Norwegian Competition Authority or the Board of Appeals do not have the authority to cancel or amend a licence which has been granted or tried by a court of law.

For implementation of an administrative decision, the Public Administration Act section 42 applies. If the compulsory licence is cancelled or limited following a challenge or a lawsuit filed within two months of the Norwegian Competition Authority's or the Board of Appeals' decision, the licensee is obliged to pay reasonable compensation for the economic loss the exploitation has caused. The Norwegian Competition Authority or the Board of Appeals may in the decision concerning the compulsory licence require as a condition that the licence holder provide security for the liability, in accordance with this paragraph's second sentence.

In a lawsuit the court has full judicial power to review all aspects of the Norwegian Competition Authority's or the Board of Appeals' decision in accordance with this paragraph. A lawsuit may not be filed on the grounds that the decision on a compulsory licence has been dismissed summarily or rejected. A lawsuit, filed by the patent holder in accordance with this paragraph, must be brought against the holder of the compulsory licence.

Chapter 16. Compulsory Licence and Exhaustion

Section 96. Request for a Compulsory Licence

Anyone who submits a request for a compulsory licence to the Norwegian Competition Authority in accordance with section 50 a of the Patents Act shall, on demand, pay a fee of NOK 10,000 to the Norwegian Competition Authority. If the fee is not paid within the time limit set by the Norwegian Competition Authority, the request for a compulsory licence shall be rejected.

Section 97. Compulsory Licence to Manufacture and Export Products

If the requirements in section 98 have been complied with, a producer of pharmaceutical products in Norway shall, on request, be granted a compulsory licence in accordance with section 47 of the Patents Act to manufacture and export pharmaceutical products to an eligible importing state that has requested the producer to supply the products. An eligible importing state shall be a state or a customs territory that meets the following requirements:

- 1.the state or territory is among the least developed states or territories according to the UN's classification at the time in question or has insufficient manufacturing capacity in accordance with the Annex to the WTO's General Council Decision of August 30, 2003 (the WTO Medicines Decision)
- 2.the state or territory has notified the WTO's TRIPS Council in accordance with the WTO Medicines Decision, paragraphs 1 (b) and 2 (a).

If the state is not a party to the WTO Agreement, the notification in accordance with the first paragraph, no. 2, shall be given to the Norwegian Ministry of Foreign Affairs.

Section 98. Requirements for Compulsory Licence to Manufacture and Export Products

A compulsory licence in accordance with section 97 will only be granted if the following requirements have been complied with:

- 1.efforts have been made to obtain a licence on reasonable business terms by agreement in Norway, in so far as this is required in accordance with section 49, first paragraph, of the Patents Act
- 2.the product is covered by the WTO Medicines Decision, paragraph 1 (a)
- 3.the product will exclusively be manufactured for export to the eligible importing state in order to cover said state's current need for the product for health purposes, as described in the notification stipulated in section 97 of these Regulations

4. the invention is not protected by a patent in the eligible importing state or the eligible importing state has granted or has undertaken proceedings to obtain a compulsory licence in accordance with Article 31 of the Agreement on Trade-related Aspects of Intellectual Property Rights of April 15, 1994 (the TRIPS Agreement) and the WTO Medicines Decision.

When assessing of what constitutes reasonable business terms in accordance with section 49, first paragraph, of the Patents Act and when determining the prescribed fee payable in accordance with section 50, second paragraph, of the Patents Act, the economic value to the importing state of the exploitation of the invention shall be taken into account.

More detailed terms and requirements for granting a compulsory licence may be imposed in the decision to grant the licence, cf. section 50, second paragraph, of the Patents Act. This shall include terms and requirements stipulating:

1. that the packaging and container shall be clearly distinguishable from those of products being offered for sale in Norway or in another state by the patent holder himself or with the patent holder's consent
2. that the products shall be labelled so that it is clearly shown that the medicinal product has been manufactured on the basis of a compulsory licence in Norway for export to a specified importing state in accordance with the WTO Medicines Decision that the manufacture and export shall cease if the compulsory licensee learns
3. that the products are being used to an appreciable degree for purposes that are not in accordance with the terms and requirements for granting the compulsory licence, cf. the first paragraph, no. 3.

Section 99. Notification of Grant of Compulsory Licence to Manufacture and Export Products
The competent court or the Norwegian Competition Authority shall notify the TRIPS Council about the compulsory licence in accordance with the WTO Medicines Decision, paragraph 2 (c). If the state is not a party to the WTO Agreement, the notification shall be given to the Norwegian Ministry of Foreign Affairs.

The compulsory licensee shall post information on his website in accordance with the specifications in the WTO Medicines Decision, paragraph 2 (b) (iii).

Section 100. Limited Exhaustion for Medicinal Products Marketed in Individual EEA Member States

A patent holder may refuse exploitation in Norway of patented medicinal products that have been brought on the market in Bulgaria, Estonia, Croatia, Latvia, Lithuania, Poland, Rumania, Slovakia, Slovenia, the Czech Republic or Hungary by the patent holder himself or with the patent holder's consent if patent protection or a supplementary protection certificate cannot be obtained for the medicinal product in the country in question at the time at which the application for such protection was filed in Norway, cf. section 3, third paragraph, no. 2, of the Patents Act.

Anyone who wishes to import into Norway a patented medicinal product in accordance with the first paragraph shall notify the patent holder or his successor in title hereof not later than one month before the application for a marketing licence is filed, cf. section 4-8 b of Regulations No. 1559 of December 22, 1999 relating to medicinal products.

OMAN

Law on Industrial Property Rights Royal Decree 67/2008: Promulgating the Law on Industrial Property Rights

Article 13

Article (13):

1 - A) Compulsory licenses are granted where:

- 1) If the public interest implied that;
- 2) If a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention would remedy such practice. Before issuing granting decision, he may listen to the patent owner or anyone of interest;
- 3) If the owner of the patent is abusively exercising his exclusive rights and/or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights;
- 4) If the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Oman, either through manufacture in Oman or through importation;
- 5) If there were another patent application (the "second patent") claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in the first patent without infringing which the second patent cannot be exploited.

B) The Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was licensed, provided that an adequate remuneration be paid to the patent owner in the circumstances of each case, taking into account the economic value of the Minister's decision, and the provisions of the WTO General Council, when applicable with regard to the determined remuneration on granting a compulsory license of a patent claiming a pharmaceutical product or a process of making such a pharmaceutical product.

2 - A compulsory license may not be applied for on the ground of insufficient availability of the patented product or of the product manufactured with the patented process, as established in subsection (1)(a)(4), of this article before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever periods expires last; it shall be refused if the patentee justifies his inaction or insufficient action by legitimate reasons.

3 - Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing both parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

4 - A) Upon the request of the owner of the patent, the Minister shall terminate the compulsory license if he is satisfied, after hearing both parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the compulsory licensed person has failed to comply with the terms of the decision.

B) - The Minister may decide not to terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the compulsory-licensed justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(2) of this article, if and when the conditions which led to such compulsory license are likely to recur.

5 - The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

6 - The compulsory license shall always be non-exclusive. Therefore, it shall not exclude: a) the exploitation of the invention by the patent owner himself, either through manufacture in Oman or through importation or both; and b) the conclusion of license contracts by the owner of the patent; and c) the continued exercise, by the owner of the patent, of his rights under the provisions of this law.

7 - A) A request for the compulsory license shall be addressed to the Minister. It shall be accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time not exceeding six months from the date of filing the voluntary license application to the patent owner, unless the particular circumstances of the case show otherwise.

B) Evidence concerning a previous attempt of obtaining a voluntary license, under previous paragraph, shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

8 - The exploitation of the invention for which a compulsory license has been issued shall be predominantly for the export of a pharmaceutical product or a process to make such a protected pharmaceutical product for supply of the market in Oman or for a foreign territory or country with no or with insufficient manufacturing capacity of this pharmaceutical product or the process to make it, in accordance with the terms and conditions of the Decision of the General Council of the WTO.

9 - Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.

10 - Where a compulsory license is granted under subsection (1)(A)(5): a) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and b) the license of the first patent shall be non-assignable except with the assignment of the second patent.

11 - The provisions of this article shall apply, where appropriate and mutatis mutandis, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.

PAKISTAN

Patents Ordinance, 2000 (As amended by Patents (Amendment) Ordinance of 2002)

Sections 58 and 59

58. Exploitation by a Government agency or third person.-

(1) Subject to sub-section (2), where -

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- (ii) the Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or
- (iii) the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or
- (iv) where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology, the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.

(2) The Federal Government shall, before taking any decision under sub-section (2), give the owner of the patent and any interested person an opportunity of being heard if he wishes to be heard.

(3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Federal Government authorization, as determined in the said decision, and where a decision has been taken under sub-section (1), the need to correct anti-competitive practices.

(4) A request for the Federal Government authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time:

Provided that this sub-section shall not apply in cases of -

- (i) national emergency or other circumstantial urgency provided that in such cases the owner of the patent shall be informed of the decision of the Federal Government as soon as reasonably practicable;
- (ii) public non-commercial use; and
- (iii) anti-competitive practices determined as such by a judicial or administrative body in accordance with clause (ii) of sub-section (1).

(5) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized either for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Federal Government is satisfied that the issuance of the non-voluntary license would remedy such practices.

(6) The authorization shall be considered on its individual merits and shall not prohibit-

- (i) the conclusion of license contracts by the owner of the patent;
- (ii) the continued exercise, by the owner of the patent, of his rights under section 30; or
- (iii) the issuance of a non-voluntary license under section 59.

(7) Where a third person has been designated by the Federal Government, the authorization may only be transferred with the enterprise or business of the person or with the part of the enterprise or business within which the patented invention is being exploited.

(8) Where the exploitation of the invention by the Government agency or third person designated by the Federal Government is authorized under clause (i) of sub-section (1), it shall be predominantly for the supply of the market in Pakistan.

(9) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Federal Government may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(10) Upon the request of the owner of the patent, the Federal Government shall, subject to adequate protection of the legitimate interest of the persons so authorized, terminate an authorization if it is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by it has failed to comply with the terms of the decision.

(11) Notwithstanding the provisions of sub-section (10), the Federal Government shall not terminate an authorization if it is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by it justified the maintenance of the decision.

(12) An appeal shall lie to the High Court against the decisions of the Federal Government under sub-sections (1) to (9).

59. Powers of Controller in granting compulsory licenses.-

(1) On request, made in the prescribed manner to the Controller after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary license to prevent the abuses which might result from the exercise of the rights conferred by the patent, for example, failure to work.

(2) Notwithstanding the provisions of sub-section (1), a non-voluntary license shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Pakistan.

(3) The decision issuing the non-voluntary license shall fix-

- (i) the scope and function of the license;
- (ii) the time limit within which the licensee must begin to exploit the patented invention; and
- (iii) the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

(4) The beneficiary of the non-voluntary license shall have the right to exploit the patented invention in Pakistan according to the terms set out in the decision issuing the license, shall commence the exploitation of the patented invention within the time limit fixed in the said decision and, thereafter, shall exploit the patented invention sufficiently.

(5) If the invention claimed in a patent, hereinafter referred to as "later patent", cannot be exploited in Pakistan without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date, hereinafter referred to as "earlier patent", and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Controller, upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary license is issued under sub-section (5), the Controller upon the request of the owner of the earlier patent shall issue a non-voluntary license in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary license under sub-sections (5) and (6), sub-section (3) shall apply mutatis mutandis with the provision that no time limit needs to be fixed.

(8) In the case of a non-voluntary license issued under sub-section (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary license issued under sub-section (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary license shall be subject to payment of the prescribed fee.

(10) The provisions of sub-sections (2) to (10) of section 58 shall apply mutatis mutandis for issuance of a non-voluntary license under this section.

PAPUA NEW GUINEA

Patents and Industrial Design Act 2000

Sections 32-35

32. EXPLOITATION BY GOVERNMENT OR PERSON AUTHORISED BY GOVERNMENT. (1)

Where -

(a) the public interest, in particular, national security, nutrition, health or the development of other sectors of the national economy so requires; or

(b) the Minister has determined that the manner of exploitation of a patented invention by the owner or his licensee is anti-competitive, and he is satisfied that the exploitation of a patented invention in accordance with this Division would remedy such practice, the Minister may at the request of a Government agency or other person authorise, by notice in the National Gazette, the exploitation of the patented invention by the requesting agency or person predominantly for the supply of the market in Papua New Guinea, even without the agreement of the owner of the patent.

(2) The Minister may impose such terms and conditions on an authorisation under section* (1) as he thinks fit.

(3) Subject to Subsection (5), prior to granting an authorisation under Subsection (1), the Minister must be satisfied that the owner of the patent has received from the Government agency or person requesting the authorisation, a request for a contractual licence, but that that Government agency or person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(4) Subject to Subsection (5), the Minister shall not authorise the exploitation of the patented invention under Subsection (1) until he has given the owner of the patent and any other person known to the Minister to be an interested person, an opportunity to be heard, and where they wish to be heard, has heard them.

(5) Subsections (3) and (4) do not apply in cases of national emergency under Part X of the **Constitution** or in other circumstances of extreme emergency, but in such cases the owner of the patent shall be notified of the decision of the Minister as soon as is reasonably practicable.

(6) The exploitation of a patented invention which is authorised by the Minister under Subsection (1) shall -

(a) be limited to the purpose for which the Minister authorised its use; and

(b) be subject to payment to the owner of the patent of adequate remuneration as determined by the Minister; and

(c) shall not exclude -

(i) the conclusion of licensing contracts by the owner of the patent; and

(ii) the continued exercise, by the owner of the patent, of his rights under Section 29 (1).

(7) In determining the amount of compensation referred to in Subsection (6) (b), the Minister shall take into account -

(a) the economic value of his decision under Subsection (1); and

(b) where the decision has been taken under Subsection (1) (b), the need to remedy the anti-competitive practices.

33. VARIATION OF TERMS OF DECISION AUTHORISING EXPLOITATION OF A PATENTED INVENTION.

(1) The Minister may, on the written request of -

(a) the owner of the patent; or

(b) the authorised Government agency or person; or

(c) any other interested person,

(iii) in relation to a patented invention which is the subject of a decision by the Minister under Section 32 (1), vary any terms or conditions of the decision authorising the exploitation.

(2) Before varying any terms or conditions of an authorisation the Minister shall hear such of the parties referred to in Subsection (1) as wish to be heard.

34. TERMINATION OF AUTHORISATION.

(1) Subject to this section, the Minister may, on the written request of the owner of the patent or any other interested party, where he is satisfied that -

(a) the circumstances which led to his authorisation under Section 32 (1) have ceased to exist and are unlikely to recur; or

(b) that the Government agency or person authorised by him has failed to comply with the terms of his authorisation under Section 32 (1), terminate his authorisation.

(2) The Minister shall not terminate an authorisation where he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or person authorised by him under Section 32 (1) justify the maintenance of his authorisation.

(3) Before terminating an authorisation the Minister shall hear such of the parties referred to in Section 32 (1) as wish to be heard.

35. TRANSFER OF AUTHORISATION.

In the case of a person authorised by the Minister under Section 32 (1), the authorisation may only be transferred with the enterprise or business of that person, or with that part of the enterprise or business of that person within which the patented invention is being exploited.

PARAGUAY

Patents Law No. 1630 of 29/11/2000

Articles 42-46

Article 42. Other uses without authorization of the holder. In the event that a potential user shall have attempted to obtain the concession of a license from the holder of a patent under reasonable terms and commercial conditions and such attempts shall not have produced results, the Industrial Property Department, after a term of ninety days from the date of application for the relevant license, may permit other uses of the said patent without authorization of the holder, pursuant to the provisions of the present law.

When the application refers to technology sectors that do not enjoy protection in the country on the effective date of the present law and the patent applied for comprises the raw material from which the end product is to be developed, the licensee shall be obliged to purchase the said raw material, molecule or principle, from the holder of the patent or from whoever he shall indicate. The price to be paid shall be the price that at which the same are offered in the international market. In the event that a preferential price exists in favor of the holder's affiliates, the said holder shall offer that price to the licensee. The holder shall sell the same to the licensee promptly and in due course.

In the event that another supplier offers the relevant raw material to the licensee at a price 15% (fifteen percent) lower than that offered by the license holder, the licensee may purchase the same duly justifying that the purchased raw material has been legally placed in the national or international market by the patent holder, by a third party with consent thereof, or is legally permitted.

Article 43. Compulsory licenses or other uses due to lack of exploitation. Any interested party may apply to the Industrial Property Department for a compulsory license after three years from the concession of the patent or four years after presentation of the application, the later of which shall be applicable if the invention has not been exploited, or effective and serious preparations to do so have not been made or when exploitation thereof has been suspended for a period of more than one year, whenever the situation is not attributable to circumstances of force majeure.

The objective difficulties or of a legal technical character that are beyond the will of the holder of the patent, and which prevent the exploitation of the invention shall be considered causes of force majeure, besides those so recognized by the law.

The lack of technical or economic resources, or the economic unfeasibility of the exploitation shall be beyond the will of the patent holder, shall also be recognized as justification.

Article 44. Compulsory licenses or other uses without authorization of the patent holder for public interest reasons. The Executive Branch may grant compulsory licenses or other uses not authorized by the patent holder for reasons of sanitary emergency, national defense or security, socio-economic and technological development of certain strategic sectors, as well as when exceptional situations may affect the national interest, scope and duration of which shall be defined in the relevant decree.

Article 45. Compulsory licenses due to anticompetitive practices. By express resolution, the Industrial Property Department may grant compulsory licenses of an invention patent when the competent authority, through a procedure that grants rights of defense and other guarantees to the holder, shall determine that the latter has incurred in anticompetitive practices, abuse of rights conferred by the patent or abuse of a dominant position in the market.

To the effects of the present law, anticompetitive practices shall be deemed to be, among others, the following:

- a) price fixing of the patented product at comparatively excessive levels in comparison with the average international prices;
- b) the existence of offers to supply the market at prices significantly lower than those offered by the patent holder;
- c) the refusal to supply the local market adequately and regularly with the raw materials or patented product under commercially reasonable conditions;
- d) when the efficient exploitation in the country of the patented invention contributing to technological development is prevented or impeded by the patent holder; and,
- e) the sundry other cases considered in special laws.

Article 46. Licenses for dependent patents. A compulsory license shall be granted to allow exploitation of a new patent –second patent- when the same cannot be exploited without infringing another patent –first patent- in the event that the following conditions are fulfilled:

- a) that the invention claimed in the second patent shall contemplate an important technical advance in regard to the invention claimed in the first patent;
- b) that the holder of the first patent shall have the right to obtain a crossed license under reasonable conditions to exploit the invention claimed in the second patent; and,
- c) that the use authorized under the first patent cannot be assigned without assignment of the second patent;

PERU

Decision No. 486 of 14/09/ 2000 of the Commission of the Andean Community - Common Industrial Property Regime (Cartagena Agreement)

(Refer to ANDEAN Community below.)

Legislative Decree No. 1075 on Approval of the Supplementary Provisions of Decision No. 486 of the Andean Community Commission Establishing the Common Regime on Industrial Property (as amended up to Legislative Decree No. 1397)

Artículo 40.- Licencias obligatorias

Previa declaratoria, mediante decreto supremo, de la existencia de razones de interés público, de emergencia o de seguridad nacional; esto es, emergencia nacional u otras circunstancias de extrema urgencia o en casos de uso público no comercial; y solo mientras estas razones permanezcan, en

cualquier momento se podrá someter la patente a licencia obligatoria. En tal caso, se otorgarán las licencias que se soliciten. El titular de la patente objeto de la licencia será notificado cuando sea razonablemente posible.

La dirección nacional competente establecerá el alcance o extensión de la licencia obligatoria, especificando en particular, el período por el cual se concede, el objeto de la licencia, el monto y las condiciones de la compensación económica.

La concesión de una licencia obligatoria no menoscaba el derecho del titular de la patente a seguir explotándola. Cualquier decisión relativa a dicha licencia estará sujeta a revisión judicial.

PHILIPPINES

Intellectual Property Code of the Philippines (Republic Act No. 8293) (2015 Edition)

Sections 74, 93-97, 100 and 101

SEC. 74. Use of Invention by Government. –

74.1 A Government Agency of third person authorized by the Government may exploit the invention even without the agreement of the patent owner where:

- (a) The public interest, in particular national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or
- (b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive; or
- (c) In the case of drugs and medicines, there is a national emergency or other circumstance of extreme urgency requiring the use of the invention; or
- (d) In the case of drugs and medicines, there is non-commercial use of the patent by the patentee, without satisfactory reason; or
- (e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health.
- (f) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; and
- (g) The existence of a national emergency or other circumstances of extreme urgency, referred to under Section 74.1 (c), shall be subject to the determination of the President of the Philippines for the purpose of determining the need for such use or other exploitation, which shall be immediately executory.

SEC. 93. Grounds for Compulsory Licensing. - The Director General of the Intellectual property Office may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances:

- 93.1. National emergency or other circumstances of extreme urgency;
- 93.2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or
- 93.3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or
- 93.4. In case of public non-commercial use of the patent by the patentee, without satisfactory reason;

93.5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: *Provided*, That the importation of the patented article shall constitute working or using the patent; (Secs. 34, 34-A, 34-B, R.A. No. 165a) and

93.6. Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the secretary of the Department of Health.

SEC. 93 A. Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement. –

93-A.1. The Director General of the Intellectual property Office, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: *Provided*, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the product imported under this provision.

The grant of a special compulsory license under this provision shall be an exception to Section 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory.

No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

93 A.2. A compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: *Provided*, that, a compulsory license has been granted by such country or such country has , by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement.

93 A.3. The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippines laws, particularly Section 72.1 and section 74 of the Intellectual property Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws.

SEC. 94. Period for Filing a Petition for a Compulsory License. –

94.—1. A compulsory license may not be applied for on the grounds stated in Subsection 93.5 before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last.

2. A compulsory license which is applied for on any of the grounds stated in Subsections 93.2, 93.3, 93.4 and 93.6 and Section 97 may be applied for at any time after the grant of the patent. (Sec. 34(1), R.A. No. 165)

SEC. 95. Requirement to Obtain a License on Reasonable Commercial Terms. - 95.1. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

95.2. The requirement under Subsection 95.1 shall not apply in the following cases:

- (a) Where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (b) In situations of national emergency or other circumstances of extreme urgency;

(c) In cases of public non-commercial use.

(d) In cases where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the department of Health

95.3. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable.

95.4. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. (n)

95.5. Where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the secretary of the department of Health, the right holder shall be informed promptly.

SEC. 96. *Compulsory Licensing of Patents Involving Semi-Conductor Technology.* - In the case of compulsory licensing of patents involving semi-conductor technology, the license may only be granted in case of public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. (n)

SEC. 97. *Compulsory License Based on Interdependence of Patents.*- If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

97.1. The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

97.2. The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;

97.3. The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and

97.4. The terms and conditions of Sections 95, 96, and 98 to 100 of this Act. (Sec. 34-C, R.A. No. 165a)

SEC. 100. *Terms and Conditions of Compulsory License.* The basic terms and conditions including the rate of royalties of a compulsory license shall be fixed by the Director of Legal Affairs subject to the following conditions:

100.1. The scope and duration of such license shall be limited to the purpose for which it was authorized;

100.2. The license shall be non-exclusive;

100.3. The license shall be non-assignable, except with that part of the enterprise or business with which the invention is being exploited;

100.4. Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: Provided, That this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive;

100.5. The license may be terminated upon proper showing that circumstances which led to its grant have ceased to exist and are unlikely to recur: Provided, That adequate protection shall be afforded to the legitimate interest of the licensee; and

100.6. The patentee shall be paid adequate remuneration taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice which was determined after judicial or administrative process, to be anti-competitive,

the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration. (Sec. 35-B, R.A. No. 165a)

SEC. 101. Amendment, Cancellation, Surrender of Compulsory

License. - 101.1. Upon the request of the patentee or the licensee, the Director of Legal Affairs may amend the decision granting the compulsory license, upon proper showing of new facts or circumstances justifying such amendment.

101.2. Upon the request of the patentee, the said Director may cancel the compulsory license:

(a) If the ground for the grant of the compulsory license no longer exists and is unlikely to recur;

(b) if the licensee has neither begun to supply the domestic market nor made serious preparation therefor;

(c) if the licensee has not complied with the prescribed terms of the license;

101.3. The licensee may surrender the license by a written declaration submitted to the Office.

101.4. The said Director shall cause the amendment, surrender, or cancellation in the Register, notify the patentee, and/or the licensee, and cause notice thereof to be published in the IPO Gazette. (Sec. 35-D, R.A. No. 165a)

POLAND

Industrial Property Law of 30/06/2000 (as amended up to Act of 24 July 2015)

Articles 82-88

Article 82

1. The Patent Office may grant authorisation to exploit a patented invention of another person (a compulsory license), where:

(i) it is necessary to prevent or eliminate a state of national emergency, in particular in the field of defence, public order, the protection of human life and health, as well as the protection of natural environment, or

(ii) it has been established that the patent has been abused within the meaning of Article 68, or

(iii) it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand that an authorisation be given to him for the exploitation of the invention that is the subject matter of the dependent patent (cross-license).

2. The grant of a compulsory license for the exploitation of an invention in the case referred to in paragraph (1)(iii) shall be conditional upon ascertainment that the exploitation of the invention that is the subject matter of the dependent patent, where the both inventions concern the same subject matter, involves an important technical advance of considerable economic significance. In case of an invention concerning semi-conductor technology, a compulsory license may only be granted to counteract unreasonable anti-competitive practices.

3. Where the Patent Office finds that the patent is abused within the meaning of Article 68, it may decide that a compulsory license may be applied for and shall announce this in "Wiadomości Urzędu Patentowego".

4. A compulsory license may be granted, if the applying party is able to prove that it has earlier made, in good faith, efforts to obtain a license. This requirement may be waived in the case of a compulsory license to be granted for the purpose of preventing or eliminating a state of national emergency or where it is announced that a compulsory license may be applied for.

5. Where it is announced that a compulsory license may be applied for, waiver of the requirement referred to in paragraph (4) shall not be applicable in respect of applications for the grant of a license submitted after the expiration of a period of one year counted from the date of that announcement.

6. The provision of paragraph (1)(iii) shall apply accordingly, where a plant breeder is not able to exercise his right to the protected plant variety or demands a cross-license to be granted to him by the patent holder.

Article 83

The compulsory license shall be non-exclusive.

Article 84

1. The person exploiting the invention under a compulsory license shall be obliged to pay a royalty to the patent holder.
2. Patent Office shall determine the scope and duration of a compulsory license, the detailed terms and conditions of its exercise, as well as the amount, in proportion to the market value of the license, of the royalty and the manner and time limits of payment.

Article 85

A compulsory license may only be transferred together with the enterprise or with that of its part, in which it is worked. A compulsory license relating to the earlier patent may only be transferred to a third party together with the dependent patent.

Article 86

When reasonable in specific circumstances, the decision on the grant of a compulsory license may, at the request of the interested party, be changed, in part relating to the scope and duration of the license or to the amount of the royalty, two years after it was taken.

Article 87

Compulsory licenses and cross-licenses shall, at the request of the interested party, be entered in the Patent Register.

Article 88

The provisions on the grant of a compulsory license in the case referred to in Article 82(1)(iii) shall apply accordingly to a utility model, whose exploitation would encroach upon the earlier patent.

PORTUGAL

Industrial Property Code (approved by Decree-Law No. 110/2018 of December 10, 2018)

Article 106-113

Artigo 106.º

Perda e expropriação da patente

1 — Pode ser privado da patente, nos termos da lei, quem tiver que responder por obrigações contraídas para com outrem ou que dela seja expropriado por utilidade.

2 — Qualquer patente pode ser expropriada por utilidade pública mediante o pagamento de justa indemnização, se a necessidade de vulgarização da invenção, ou da sua utilização pelas entidades públicas, o exigir.

3 — É aplicável, com as devidas adaptações, o preceituado no Código das Expropriações.

Artigo 107.º

Obrigatoriedade de exploração

1 — O titular da patente é obrigado a explorar a invenção patenteada, diretamente ou por intermédio de pessoa por ele autorizada, e a comercializar os resultados obtidos por forma a satisfazer as necessidades do mercado nacional.

2 — A exploração deve ter início no prazo de quatro anos a contar da data do pedido de patente, ou no prazo de três anos a contar da data da concessão, aplicando -se o prazo mais longo.

3 — É possível gozar de direitos de patente sem discriminação quanto ao local da invenção, ao domínio tecnológico e ao facto de os produtos serem importados de qualquer país membro da União Europeia, ou da OMC, ou produzidos localmente.

Artigo 108.º

Licenças obrigatórias

1 — Podem ser concedidas licenças obrigatórias sobre uma determinada patente, quando ocorrer algum dos seguintes casos:

- a) Falta ou insuficiência de exploração da invenção patenteada;
- b) Dependência entre patentes;
- c) Existência de motivos de interesse público.

2 — As licenças obrigatórias serão não exclusivas e só podem ser transmitidas com a parte da empresa ou do estabelecimento que as explore.

3 — As licenças obrigatórias só podem ser concedidas quando o potencial licenciado tiver desenvolvido esforços no sentido de obter do titular da patente uma licença contratual em condições comerciais aceitáveis e tais esforços não tenham êxito dentro de um prazo razoável.

4 — A licença obrigatória pode ser revogada, sem prejuízo de proteção adequada dos legítimos interesses dos licenciados, se e quando as circunstâncias que lhe deram origem deixarem de existir e não sejam suscetíveis de se repetir, podendo a autoridade competente reexaminar, mediante pedido fundamentado, a continuação das referidas circunstâncias.

5 — Quando uma patente tiver por objeto tecnologia de semicondutores, apenas podem ser concedidas licenças obrigatórias com finalidade pública não comercial.

6 — O titular da patente receberá uma remuneração adequada a cada caso concreto, tendo em conta o valor económico da licença.

7 — A decisão que conceda ou denegue a remuneração é suscetível de recurso judicial ou arbitral, nos termos dos artigos 47.º a 49.º

Artigo 109.º

Licença por falta de exploração da invenção

1 — Expirados os prazos que se referem no n.º 2 do artigo 107.º, o titular que, sem justo motivo ou base legal, não explorar a invenção, diretamente ou por licença, ou não o fizer de modo a ocorrer às necessidades nacionais, pode ser obrigado a conceder licença de exploração da mesma.

2 — Pode, também, ser obrigado a conceder licença de exploração da invenção o titular que, durante três anos consecutivos e sem justo motivo ou base legal, deixar de fazer a sua exploração.

3 — São considerados justos motivos as dificuldades objetivas de natureza técnica ou jurídica, independentes da vontade e da situação do titular da patente, que tornem impossível ou insuficiente a exploração da invenção, mas não as dificuldades económicas ou financeiras.

4 — Enquanto uma licença obrigatória se mantiver em vigor, o titular da patente não pode ser obrigado a conceder outra antes daquela ter sido cancelada.

5 — A licença obrigatória pode ser cancelada se o licenciado não explorar a invenção por forma a ocorrer às necessidades nacionais.

Artigo 110.º

Licenças dependentes

1 — Quando não seja possível a exploração de uma invenção, protegida por uma patente, sem prejuízo dos direitos conferidos por uma patente anterior e ambas as invenções sirvam para fins industriais distintos, a licença só pode ser concedida se se verificar o carácter indispensável da primeira invenção para a exploração da segunda e, apenas, na parte necessária à realização desta, tendo o titular da primeira patente direito a justa indemnização.

2 — Quando as invenções, protegidas por patentes dependentes, servirem para os mesmos fins industriais e tiver lugar a concessão de uma licença obrigatória, o titular da patente anterior também pode exigir a concessão de licença obrigatória sobre a patente posterior.

3 — Quando uma invenção tiver por objeto um processo de preparação de um produto químico, farmacêutico ou alimentar protegido por uma patente em vigor, e sempre que essa patente de processo representar um progresso técnico notável em relação à patente anterior, tanto o titular da patente de processo como o titular da patente de produto têm o direito de exigir uma licença obrigatória sobre a patente do outro titular.

4 — Quando um obtentor de uma variedade vegetal não puder obter ou explorar um direito de obtenção vegetal sem infringir uma patente anterior, pode requerer uma licença obrigatória para a exploração não exclusiva da invenção protegida pela patente, na medida em que essa licença seja necessária para explorar a mesma variedade vegetal, contra o pagamento de remuneração adequada.

5 — Sempre que seja concedida uma licença do tipo previsto no número anterior, o titular da patente tem direito a uma licença recíproca, em condições razoáveis, para utilizar essa variedade protegida.

6 — Quando o titular de uma patente, relativa a uma invenção biotecnológica, não puder explorá-la sem infringir um direito de obtenção vegetal anterior sobre uma variedade, pode requerer uma licença obrigatória para a exploração não exclusiva da variedade protegida por esse direito de obtenção, contra o pagamento de remuneração adequada.

7 — Sempre que seja concedida uma licença do tipo previsto no número anterior, o titular do direito de obtenção tem direito a uma licença recíproca, em condições razoáveis, para utilizar a invenção protegida.

8 — Os requerentes das licenças referidas nos n.os 4 e 6 devem provar que:

a) Se dirigiram, em vão, ao titular da patente ou de direito de obtenção vegetal para obter uma licença contratual;

b) A variedade vegetal, ou invenção, representa um progresso técnico importante, de interesse económico considerável, relativamente à invenção reivindicada na patente ou à variedade vegetal a proteger.

9 — O disposto no presente artigo aplica -se, igualmente, sempre que uma das invenções esteja protegida por patente e a outra por modelo de utilidade.

Artigo 111.º

Interesse público

1 — O titular de uma patente pode ser obrigado a conceder licença para a exploração da respetiva invenção por motivo de interesse público.

2 — Considera -se que existem motivos de interesse público quando o início, o aumento ou a generalização da exploração da invenção, ou a melhoria das condições em que tal exploração se realizar, sejam de primordial importância para a saúde pública ou para a defesa nacional.

3 — Considera -se, igualmente, que existem motivos de interesse público quando a falta de exploração ou a insuficiência em qualidade ou em quantidade da exploração realizada implicar grave prejuízo para o desenvolvimento económico ou tecnológico do País.

4 — A licença por motivo de interesse público é conferida por despacho do membro do Governo competente em razão da matéria.

Artigo 112.º

Pedidos de licenças obrigatórias

- 1 — As licenças obrigatórias devem ser requeridas junto do INPI, I. P., apresentando o requerente os elementos de prova que possam fundamentar o seu pedido.
- 2 — Os pedidos de licenças obrigatórias são examinados pela ordem em que forem requeridos junto do INPI, I. P.
- 3 — Recebido o pedido de licença obrigatória, o INPI, I. P., notifica o titular da patente para, no prazo de dois meses, dizer o que tiver por conveniente, apresentando as provas respetivas.
- 4 — O INPI, I. P., aprecia as alegações das partes e as garantias da exploração da invenção oferecidas pelo requerente da licença obrigatória, decidindo, no prazo de dois meses, se esta deve ou não ser concedida.
- 5 — Em caso afirmativo, notifica ambas as partes para, no prazo de um mês, nomearem um perito que, juntamente com o perito nomeado pelo INPI, I. P., acorda, no prazo de dois meses, as condições da licença obrigatória e a indemnização a pagar ao titular da patente.

Artigo 113.º

Notificação e recurso da concessão ou recusa da licença

- 1 — A concessão ou recusa da licença e respetivas condições de exploração é notificada a ambas as partes pelo INPI, I. P.
- 2 — Da decisão do INPI, I. P., que concedeu ou recusou a licença, ou apenas das condições em que a mesma tenha sido concedida, cabe recurso para o tribunal competente, nos termos dos artigos 38.º e seguintes, no prazo de três meses a contar da data da notificação a que se refere o número anterior.
- 3 — A decisão favorável à concessão só produz efeitos depois de transitada em julgado e averbada no INPI, I. P., onde são pagas as respetivas taxas, como se de uma licença ordinária se tratasse.
- 4 — Um extrato do registo referido no número anterior é publicado no Boletim da Propriedade Industrial.

QATAR

Decree Law No, (30) for the Year 2006 To Issue Patents' Law

Articles 15-20

Article 15

Whoever it may concern shall be allowed, after the expiration of three years of patent granting date, to apply for a mandatory license for exploiting the invention under any of the following causes:

- a) No serious or effective exploitation of the patent throughout a period of three years of granting;
- b) Cessation of exploitation of the invention protected by the patent by the patent holder for two successive years without giving any acceptable reasons to the office;
- c) Refusal by the patent owner to give contractual licensing for exploiting the invention thus impeding the establishment or development of industrial and commercial activities in the State.

In all cases, mandatory license shall not be issued if the patent owner provides legitimate reasons. However, importing the product shall not serve as legitimate reason. Mandatory license shall be issued by the Minister, and the patent owner shall be entitled to complain against the decision to the committee stipulated in Article 7 of the law hereby in accordance with the terms and conditions indicated in the executive bylaws of the law hereby.

Article 16

Mandatory license to exploit the invention shall not be granted unless the applicant presents the evidence that the patent owner has been notified by the registered mail of the reasons behind applying for a license, and that no agreement has not been reached with him/her within the period prescribed by the executive bylaws of the law hereby.

Article 17

The mandatory license shall entitle the licensee to undertake any or all the business entitled to the patent owner under the license, except for importing the product. The license owner shall be entitled to use the civil or penal rights of the patent owner to protect and exploit the invention in case of any default by the patent owner in spite of being notified.

Article 18

Mandatory license shall not be granted to whoever fails to provide the warranties necessary for exploiting the invention in overcoming the deficiencies or meeting the needs that require applying for such a mandatory license.

A person granted a mandatory license shall not be entitled to grant others a license to exploit or dispose of the patent. The Minister shall cancel any license if the licensee violates its conditions or if the reasons that has justified granting such license cease to exist. The licensee shall be entitled to complain against that decision to the committee stipulated in Article 7 of the law hereby in accordance with the terms and conditions indicated in the executive bylaws of the law hereby.

Mandatory license shall not be transferred except with the other parts of the licensee enterprise or that part which exploits the invention. Such transfer shall be subject to the Minister's approval; otherwise, it shall be deemed invalid.

Article 19

Mandatory licenses and their relevant decisions, verdicts or applications shall be registered in a special book at the office in accordance with the terms and conditions indicated in the executive bylaws of the law hereby.

Article 20

Whoever it may concern shall be allowed shall be allowed to apply to the competent court for revoking the patent or the mandatory license, if such patent or license have been issued in the following cases:

- a) Non compliance with the conditions of the law or its executive bylaws;
- b) Non observance of the priority of the previous applications.

The patent owner, licensee or any relevant person shall be summoned to the court session devoted for hearing the case. In case a revocation verdict is issued, reference on such issue shall be made in the special register. The executive bylaws shall decide the manner of publishing.

REPUBLIC OF KOREA

Patent Act (Act No. 950 of December 31, 1961, as amended up to Act No. 14112 of March 29, 2016)

Article 106 and 107

Article 106 (Expropriation of Patents) (1) The Government may expropriate patents if deemed necessary for national defense at the time of a war, incident, or similar emergency.

(2) If a patent is expropriated, all rights to the invention, except the patent, shall be extinguished.

(3) When the Government expropriates a patent under paragraph (1), it shall pay reasonable compensation to the patentee, exclusive licensee, or non-exclusive licensee.

(4) Matters necessary for expropriating patents and paying compensation therefor shall be prescribed by Presidential Decree.

Article 106-2 (Execution of Patented Inventions by Government, etc.) (1) If the Government deems it necessary to non-commercially execute a patented invention due to a national or dire emergency, or for the public interests, it may directly execute the patented invention or authorize any person other than the Government to execute it on its behalf.

(2) When the Government or any person other than the Government referred to in paragraph (1) knew or becomes aware that any other person's patent exists, the Government or the person other than the Government shall immediately notify the patentee, exclusive licensee, or non-exclusive licensee of the execution under paragraph (1).

(3) When the Government or any person other than the Government referred to in paragraph (1) executes a patented invention under paragraph (1), the Government or the person other than the Government shall pay reasonable compensation to the patentee, exclusive licensee, or non-exclusive licensee.

(4) Matters necessary for executing a patented invention and paying compensation therefor shall be prescribed by Presidential Decree.

Article 107 - Adjudication for the Grant of a Nonexclusive License

(1) Where a patented invention falls under any of the following subparagraphs, a person who intends to work the patented invention may request the Commissioner of the Korean Intellectual Property Office to make an adjudication (referred to as "an adjudication") for the establishment of a nonexclusive license, provided no agreement is reached despite having a consultation (referred to as "a consultation" in this Article) under reasonable conditions with the patentee or exclusive licensee on the grant of a nonexclusive license for the patented invention or a consultation is impossible to arrange; however, the person may request an adjudication even in the absence of a consultation if the patented invention is to be worked non commercially for the public interest or in any case that falls under subparagraph (iv):

(i) where the patented invention has not been worked for more than three consecutive years in the Republic of Korea, except for natural disasters, unavoidable circumstances or other justifiable reasons prescribed by Presidential Decree;

(ii) where the patented invention has not continuously been worked commercially or industrially in the Republic of Korea on a substantial scale during a period of three years or more without justification, or where the domestic demand for the patented invention has not been satisfied to an appropriate extent and under reasonable conditions;

(iii) where working the patented invention noncommercially is necessary for the interests of the public; or

(iv) where working the patented invention is necessary to remedy a practice determined to be unfair after the judicial or administrative process;

(v) where working the patented invention is necessary for the export of medicine to a country (referred to as "an importing country") that intends to import the medicine (including effective ingredients that are necessary for the production of the medicine and diagnostic kits necessary for the use of the medicine) in order to treat *diseases that threaten the health of the majority of its citizens*.

(2) Paragraph (1)(i) and (ii) of this Article shall not apply unless a period of four years has elapsed after the filing date of the application for the patented invention.

(3) In adjudicating the authorization of a nonexclusive license, the Commissioner of the Korean Intellectual Property Office shall consider the necessity of each request.

(4) When the Commissioner of the Korean Intellectual Property Office makes an adjudication under subparagraphs (i) to (iii) or (v) of paragraph (1), the following conditions apply to the person for whom the adjudication was made:

(i) where the adjudication is made under subparagraphs (i) to (iii) of paragraph (1), the nonexclusive license must be implemented for the primary purpose of meeting domestic demand; and

(ii) where the adjudication is made under subparagraph (v) of paragraph (1), all the medicine produced under the terms of the adjudication must be exported to importing countries.

(5) The Commissioner of the Korean Intellectual Property Office shall ensure that reasonable consideration is given to every adjudication. When making an adjudication under subparagraph (iv) or (v) of paragraph (1), the Commissioner of the Korean Intellectual Property Office may consider the factors in each of the following subparagraphs:

(i) where an adjudication is made under subparagraph (iv) of paragraph (1), the need to rectify unfair transactions; and

(ii) where an adjudication is made under subparagraph (v) of paragraph (1), the economic value generated in importing countries by the working of the patented invention.

(6) For semiconductor technology, a request for adjudication may be made only in the cases set forth in subparagraph (1)(iii) (where the noncommercial working of the patented invention is permitted in a limited way for the interests of the public) and (1)(iv).

(7) An importing country is limited to a country which is either a World Trade Organization (WTO) member country that has notified the WTO of the following particulars or a non-WTO member country listed in a Presidential decree, and which has notified the Republic of Korea of the following particulars:

(i) the name of the medicine and the quantity required by an importing country;

(ii) where the importing country is not one of the least developed countries listed in a resolution of the General Assembly of the United Nations, confirmation by the importing country that it has insufficient or no manufacturing capability to produce the medicine concerned; and

(iii) where the medicine concerned is patented in the importing country, confirmation by the importing country that it has granted or intends to grant a compulsory license.

(8) The term medicine in paragraph (1)(v) of this Article refers to any of the definitions in the following subparagraphs:

(i) patented medicine;

(ii) medicine manufactured by means of a patented process;

(iii) patented effective ingredients necessary for the production of the medicine; or

(iv) patented diagnostic kits necessary for the production of the medicine.

(9) The documents for submission and other necessary matters concerning a request for adjudication are prescribed by Presidential Decree.

REPUBLIC OF MOLDOVA

Law No. 50-XVI of March 7, 2008, on the Protection of Inventions (as amended up to Law No. 101 of May 26, 2016)

Articles 28 and 29

Article 28 - Compulsory License

(1) If after the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later, the patent owner has not exploited the patent in the territory of the Republic of Moldova or if he has not undertaken serious and effective preparations for such purpose, the courts may grant a compulsory license, on request, to any interested person, unless the patent owner justifies the lack or insufficiency of exploitation. No distinction shall be made between the domestic products or imported products for the purposes of establishing the fact of the lack of exploitation or insufficient exploitation of the patent.

(2) A compulsory license shall be granted solely where the proposed user has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This

requirement may be waived in the cases referred to in paragraph (3) below. In such cases, the patent owner shall be notified as soon as reasonable practicable.

(3) A compulsory license may be granted in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

(4) In the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.

(5) A compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.

(6) The respective methods and procedures for the implementation of principles contained in this article are laid down in the Regulations.

Article 29 - Conditions Applicable to Compulsory Licenses

(1) At the time of grant of a compulsory license to exploit the patent under Article 28 above, the court shall specify the types of use covered by such license and the terms and conditions to be observed. The following conditions shall apply:

- a) the scope and duration of such use shall be limited to the purpose for which it was authorized;
- b) such use shall be non-exclusive;
- c) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- d) any such use shall be authorized predominantly for the supply of the domestic market, except where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive;
- e) a court may authorize, upon motivated request, that authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The judicial authority shall have the authority to refuse termination of authorization if and where the circumstances which led to such authorization are likely to recur;
- f) the license holder shall pay the patent owner an adequate remuneration, taking into account the economic value of the authorization and, eventually, the need to remedy an anti-competitive practice;
- g) in case of a compulsory license for a dependent patent or a plant variety patent, the use authorized in respect of the first patent shall be non-assignable, except with the assignment of the second patent.

(2) The legal validity of any decision relating to the authorization of use referred to in paragraph (1) and any other decision relating to the remuneration provided for in respect of such use shall be subject to judicial review or other independent review by a higher authority.

(3) The holder of the license shall notify the AGEPI the decision of the judicial authority to grant or, where appropriate, to terminate a compulsory license. The Agency shall enter the court decision in the National Register of Patents and publish it in BOPI.

(4) If the holder of a compulsory license has not undertaken any effective and serious preparation for exploiting the invention within one year following grant of the license, the compulsory license may be cancelled by the decision of the court. In any event, a compulsory license shall terminate if its holder has not begun exploitation of the invention within 2 years following the date on which the license was granted to him.

ROMANIA

Law No. 64/1991 on Patents (as amended up to Law No. 83/2014)

Articles 43-47

Art. 43 - Upon request by any interested person, the Court of Bucharest may grant a compulsory license after 4 years have elapsed from the patent application filing date or after 3 years have elapsed from the grant of the patent, whichever period expires later.

(2) The provisions of paragraph 1 shall only apply where the invention has not been exploited or has been insufficiently exploited on the territory of Romania, and the patent owner cannot justify his inaction and where no agreement has been reached with him regarding the conditions and commercial methods for applying the invention.

(3) The Court of Bucharest shall authorize the compulsory license, provided that it considers, based on given circumstances, that, in spite of all efforts made by the interested person, no agreement could be reached within a reasonable time period.

(4) Besides the cases referred to in paragraph 2, a compulsory license may be authorized by the Court of Bucharest:

- a) in national emergency cases;
- b) in other cases of extreme emergency;
- c) in cases of public use for non-commercial purposes.

(5) The grant of the compulsory license, for one of the reasons provided under paragraph 4, shall not require the fulfillment of the conditions mentioned under paragraph 2. Nevertheless, the licensee shall inform the applicant or patent owner about the authorization given by the Court, within the shortest delay.

(6) In cases of public use for non-commercial purposes, the Government or third parties authorized by the Government, if they know or have demonstrable reasons to know that a valid patent is or will be used by the Government or the third parties, shall inform the patent owner accordingly, within a reasonable time.

(7) In cases where a patent cannot be exploited without infringing the rights conferred by other patent granted for an application having a prior regular national filing date, a compulsory license for exploiting the second patent may only be authorized if the following additional conditions are cumulatively fulfilled:

- a) the invention claimed in the second patent involves an important technical advance of considerable economic significance as compared with the invention in the first patent;
- b) the owner of the first patent is entitled to a cross-license on reasonable terms for using the invention claimed in the second patent;
- c) the use authorized in respect of the first patent shall be non-transferable, except for the transfer of the second patent.

Art. 44 - (1) Compulsory licenses shall be non-exclusive and shall be granted by the Court of Bucharest, under specific conditions regarding their extent and duration, as well as the amount of royalties to which the right holder is entitled, established in accordance with the commercial value of the licenses granted.

(2) Beneficiaries of the compulsory license can also be the Government or third parties authorized by the Government.

(3) Compulsory licenses shall be authorized mainly for supplying the market.

(4) The extent and duration of compulsory licenses shall be limited to the purposes for which they have been authorized. In case of the inventions in the semiconductor technology field, the license shall be granted only for public non-commercial purposes or to remedy a practice declared as anti-competitive, as a result of a judiciary or administrative procedure.

(5) When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory license for the invention protected by said patent.

(6) When the owner of a patent relating to a biotechnological invention cannot exploit the patent without infringing a prior plant variety patent, he may request a compulsory license for the exploitation of the plant variety protected by said patent.

(7) Where a compulsory license is authorized for remedying an anti-competitive practice, the provisions of Art. 43, paragraphs (3) and (4) and Art. 44, paragraph (3) shall not be applicable.

Art. 45 - The compulsory license shall not be transferred otherwise than with the part of the enterprise or the stock of goods benefitting by said use.

Art. 46 - (1) Upon the justified request presented by the interested person, the Court of Bucharest may withdraw the compulsory license, when the circumstances leading to the grant of the license ceased to exist, provided that the legitimate interests of the licensee should be protected adequately. The license shall not be withdrawn if the circumstances which determined the grant of the license are likely to occur again.

(2) The decisions of the Court of Bucharest concerning the authorization for using a compulsory license, as well as those concerning the remuneration prescribed as against the use of the license, may be appealed against only with the Court of Appeal of Bucharest.

Art. 47 - The final and irrevocable Court decisions concerning the grant or the withdrawal of the compulsory license, as the case may be, shall be communicated by the interested person to OSIM, which shall enter said decisions in the National Register of Patent Applications or in the National Register of Patents, as the case may be, and shall publish the mention of such decisions in the Official Industrial Property Bulletin within one month from communication.

RUSSIAN FEDERATION

Civil Code of the Russian Federation (Parts One to Four) The consolidated Part One of the Civil Code takes into account amendments up to Federal Law No. 459-FZ of December 29, 2017, which entered into force on January 9, 2018 (see Section I, Chapter 3, Article 37 of this consolidated Part One for detailed amendments).

Articles 1239, 1360 and 1362

Article 1239. Compulsory License

In cases provided for by the present Code, a court may, at the request of an interested person, take a decision to provide this person, on conditions determined in the judicial decision, with rights to use a result of intellectual activity, the exclusive right to which belongs to another person (a compulsory license).

Article 1360. Use of an Invention, Utility Model, or Industrial Design in the Interests of National Security

In the interests of national security the Government of the Russian Federation shall have the right to permit the use of an invention, utility model, or industrial design without the consent of the patent holder provided that he is notified as soon as possible and payment to him a reasonable remuneration.

Article 1362. Compulsory License to an Invention, Utility Model, or Industrial Design

1. If an invention or industrial design fails to be used or is insufficiently used by the patent holder during the four years from date of the issuance of a patent, or a utility model – during three years from the date of granting the patent, which leads to insufficient offer of respective goods, works or services on the market, any person willing and ready to use such invention, utility model, or industrial design, given the refusal of the patent holder to conclude with such a

person a license contract on terms corresponding to common practice shall have the right to initiate a legal action against the patent holder for the granting of a compulsory simple (non-exclusive) license for the use within the territory of the Russian Federation of an invention, utility model, or industrial design. In the writ, this person shall indicate the proposed terms of the granting to him of such a license, including the scope of use of the invention, utility model, or industrial design, the amount, procedure, and terms of payments. If the patent holder does not prove that nonuse or insufficient use by him of the invention, utility model, or industrial design is based on valid excuses, the court shall rule the granting of the license indicated in the first subparagraph of the present Paragraph and the terms of its granting. A total amount of payments for such a license shall be determined in the decision of the court on the level not lower than the cost of a license determined in similar cases.

The effect of a compulsory simple (nonexclusive) license may be terminated by judicial procedure on a suit initiated by the patent holder if the circumstances that resulted in granting of such a license cease to exist and their reappearance is unlikely. In such a case the court shall fix the time and procedure for termination of the compulsory simple (nonexclusive) license and of the rights that arose under this license.

Granting in accordance with the rules of the present Paragraph of a compulsory simple (nonexclusive) license for the use of an invention related to the semiconductor technology, shall be allowed exclusively for its non-commercial use in state, social or other public interests or for the purpose of changing the situation 61 which in due course is considered to be violating the requirements of the antimonopoly legislation of the Russian Federation.

2. If the patent holder cannot use the invention to which he has the exclusive right without infringing thereby the rights of the holder of another patent (the first patent) to an invention or utility model who has refused to conclude a license contract on terms corresponding to common practice, the patent holder shall have the right to initiate court action against the holder of the patent (the second patent) for the granting of a compulsory simple (nonexclusive) license for the use within the territory of the Russian Federation of the invention or utility model of the holder of the first patent. The terms of granting such a license proposed by the holder of the second patent, including the scope of use of the invention or utility model, the amount, procedure, and schedule of payments shall be indicated in the lawsuit. If this patent holder having the exclusive right to such a dependent invention proves that it is an important technical achievement and has a significant economic advantage over the invention or utility model of the holder of the first patent, the court shall rule the granting compulsory simple (nonexclusive) license. A right obtained under this license to use the invention protected by the first patent may not be transferred to other persons except in case of alienation of the second patent. A total amount of payments for such a compulsory simple (nonexclusive) license shall must be determined in the decision court on the level not lower than the cost of a license determined in similar cases.

In the case of granting under the present Paragraph of a compulsory simple (nonexclusive) license, the holder of the patent for the invention or utility model, the right to use of which is granted on the basis of the aforesaid license shall also have the right to obtain a simple (nonexclusive) license for use of the dependent invention in connection with which the compulsory simple (nonexclusive) license was granted on terms corresponding to the common practice.

3. On the basis of the court ruling provided for by Paragraphs 1 and 2 of the present Article, the federal executive authority for intellectual property shall effect official registration of the compulsory simple (nonexclusive) license.

SAINT LUCIA

Patents Act, 2001.

Sections 51-54, 57-59 and 61

Compulsory licences

51.— (1) At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the Registrar —

- (a) for a licence under the patent;
 - (b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or
 - (c) where the applicant is a Government department, for the grant to any person specified in the application of a licence under the patent;
- if it appears at the time such application is filed, one or more of the grounds specified in subsection (2) are met.

(2) The grounds referred to in subsection (1) are —

- (a) that there is no production of the patented product or application of the patented process in Saint Lucia without any legitimate reason;
- (b) that there is no product produced in Saint Lucia under the patent for sale in Saint Lucia or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason;
- (c) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms —
 - (i) a market for the export of any patented product made in Saint Lucia is not being supplied;
 - (ii) the working or efficient working in Saint Lucia of any other patented invention which makes a substantial contribution to the art is prevented or hindered; or
 - (iii) the establishment or development of commercial or industrial activities in Saint Lucia is unfairly prejudiced; and
- (d) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in Saint Lucia, is unfairly prejudiced.

(3) Subject to subsections (4) to (6), if the Registrar is satisfied that any of those grounds under subsection (2) are established, the Registrar may —

- (a) where the application is made pursuant to subsection (1) (a), order the grant of a licence to the applicant on such terms, including the transfer of know-how associated with the patented invention, as the Registrar thinks fit;

(4) Where —

- (a) an application is made on the ground that there is no production of the patented product or application of the patented process in Saint Lucia; or
- (b) there is insufficient or no product produced under the patent for sale in Saint Lucia; and it appears to the Registrar that the time which has elapsed since the publication in the Gazette of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, the Registrar may by order adjourn the application for such period as will in the Registrar's opinion give sufficient time for the invention to be so worked.

(5) No entry shall be made in the register under this section on the ground mentioned in subsection (2) (c) (i), and any licence granted under this section on that ground shall contain

such provisions as appear to the Registrar to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

(6) No order or entry shall be made under this section in respect of a patent on the ground mentioned in subsection (2) (c) (ii) unless the Registrar is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent and his or her licensees a licence under the patent for the other invention on reasonable terms.

(7) An application may be made under this section in respect of a patent notwithstanding that the applicant is already the holder of a licence under the patent, and no person shall be stopped or barred from alleging any of the matters specified in subsection (2) by reason of any admission made by him or her, whether in such a licence or otherwise, or by reason of his or her having accepted such a licence.

Inventions relating to food or medicine or surgical or curative device

52.— (1) At any time after the date of the grant of a patent in respect of —

(a) a substance capable of being used as food or medicine or in the production of food or medicine;
(b) a process for producing any substance mentioned in paragraph (a); or
(c) any invention capable of being used as or as part of a surgical or curative device;
the Registrar may, on application made to him or her by any person, order the grant to the applicant of a licence under the patent on such terms as the Registrar thinks fit, unless it appears to the Registrar that there are good reasons for refusing the application.

(2) A licence granted under this section shall entitle the licensee to make, use or dispose of the invention as a food or medicine, or for the purpose of the production of food or medicine or as part of a surgical or curative device.

(3) An application under this section may be made notwithstanding that the applicant is already the holder of a licence under the patent.

(4) A licence granted under this section and section 51 may permit the licensee to import the patented product.

Provisions as to licences under section 51 or 52

53.— (1) Where the Registrar is satisfied, on an application made under section 51 or 52 in respect of a patent, that the manufacture, use or disposal of materials not protected by the patent is unfairly prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or the use of the patented process, the Registrar may, subject to those sections, order the grant of licences under the patent to such customers of the applicant as the Registrar thinks fit as well as to the applicant.

(2) Where an application under section 51 or 52 is made in respect of a patent by a person who holds a licence under the patent, the Registrar may —

(a) if he or she orders the grant of a licence to the applicant, order the existing licence to be cancelled; or
(b) instead of ordering the grant of a licence to the applicant, order the existing licence to be amended.

(3) Section 49 (5) and (6) apply to a licence granted pursuant to an order under section 51 or 52 and to a licence granted by virtue of an entry under section 51 as it applies to a licence granted by virtue of an entry under section 49.

Exercise of powers on application under section 51

54.— (1) The powers of the Registrar on an application under section 51 in respect of a patent shall be exercised with a view to securing the following general purposes —

- (a) that inventions which can be worked on a commercial scale in Saint Lucia and which should in the public interest be so worked shall be worked without undue delay such that they are available in Saint Lucia to an adequate extent and supplied on reasonable terms;
- (b) that the interests of any person for the time being working or developing an invention in Saint Lucia under the protection of a patent shall not be unfairly prejudiced;
- (c) that the royalty and other remuneration, if any, reserved to the inventor or other person beneficially entitled to a patent is reasonable having regard to the nature of the invention.

(2) Subject to subsection (1), the Registrar shall, in determining whether to make an order or entry pursuant to such an application, take account of the following matters —

- (a) the nature of the invention, the time which has elapsed since the publication in the journal of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;
- (b) the ability of any person to whom a licence would be granted under the order to work the invention to the public advantage; and
- (c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted; but shall not be required to take account of matters subsequent to the making of the application.

Use of patented inventions for services of Government

57.— (1) Notwithstanding anything in this Act, any Government department and any person authorised in writing by a Government department may, for the services of the Government and in accordance with this section, do any of the following acts in Saint Lucia in relation to a patented invention without the consent of the proprietor of the patent —

- (a) where the invention is a product, may —
 - (i) make, use, import, obtain or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing, obtaining or keeping it; or
 - (ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of any drug and medicine, or dispose or offer to dispose of it for any purpose whatever;
 - (b) where the invention is a process, may use it or, in relation to any product obtained directly by means of the process, do anything mentioned in paragraph (a);
 - (c) without prejudice to paragraphs (a) and (b), where the invention or any product obtained directly by means of the invention is a drug or medicine, may sell or offer to sell the drug or medicine;
 - (d) may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;
 - (e) may dispose or offer to dispose of anything which was made, used, imported, obtained or kept in the exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported, obtained or kept, as the case may be;
- and anything done by virtue of this subsection shall not amount to an infringement of the patent.

(2) Any act done in relation to an invention by virtue of this section is in this section referred to as use of the invention; and “use”, in relation to an invention, in sections 58 to 60 shall be construed accordingly.

(3) So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a Government department otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

(4) So far as the invention has not been so recorded or tried, any use of it made by virtue of this section at any time either —

(a) after the publication of the application for the patent for the invention; or
(b) without prejudice to paragraph (a), in consequence of a relevant communication made after the priority date of the invention otherwise than in confidence; shall be made on such terms as may be agreed either before or after the use by the Government department and the proprietor of the patent or as may in default of agreement be referred to an arbitrator agreed on by the parties or, in default of agreement, appointed by the Registrar.

(5) The arbitrator to whom any reference is made under subsection (4) shall report his or her findings to the Registrar.

(6) The expenses of and incidental to an arbitrator under subsection (4) shall, in default of agreement between the parties, be borne equally by the parties to the reference.

(7) Where an invention is used by virtue of this section at any time after publication of an application for a patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) include terms as to payment for the use, then, notwithstanding anything in those terms, any such payment shall be recoverable only —

(a) after such a patent is granted; and

(b) if, apart from this section, the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims, as interpreted by the description or claims, in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Registry.

(8) The authority of a Government department in respect of an invention may be given under this section either before or after the patent is granted and either before or after the use in respect of which the authority is given is made, and may be given to any person whether or not he or she is authorised, directly or indirectly, by the proprietor of the patent to do anything in relation to the invention.

(9) Where any use of an invention is made by or with the authority of a Government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, the department shall notify the proprietor of the patent as soon as practicable after the second of the following events, that is to say, the use is begun and the patent is granted, and furnish him or her with such information as to the extent of the use as he or she may from time to time require.

(10) A person acquiring anything disposed of in the exercise of the powers conferred by this section, and any person claiming through him or her, may deal with it in the same manner as if the patent were held on behalf of the Government.

(11) In determining under this section any dispute between a Government department and any person as to the terms for the use of an invention for the services of the Government, the arbitrator shall have regard —

(a) to any benefit or compensation which that person or any person from whom he or she derives title may have received or may be entitled to receive, directly or indirectly, from any Government department in respect of the invention; and

(b) to whether that person or any person from whom he or she derives title has in the arbitrator's opinion without reasonable cause failed to comply with a request of the department to use the invention for the services of the Government on reasonable terms.

(12) On a reference under this section, the arbitrator may refuse to grant relief by way of compensation in respect of the use of an invention for the services of the Government during any further period specified under section 32(3), but before the payment of the renewal fee and any additional fee prescribed for the purposes of that section.

(13) Where an amendment of the specification of a patent has been allowed under any of the provisions of this Act, the arbitrator shall not grant relief by way of compensation under this section in respect of any such use before the decision to allow the amendment unless the Registrar is satisfied that the specification of the patent as published was framed in good faith and with reasonable skill and knowledge.

(14) In considering the amount of any compensation for the use of an invention for the services of the Government after publication of an application for a patent for the invention and before such a patent is granted, the arbitrator shall consider whether or not it would have been reasonable to expect, from a consideration of the application as published under section 23, that a patent would be granted conferring on the proprietor of the patent protection for an act of the same description as that found to constitute that use, and if the arbitrator finds that it would not have been reasonable, he or she shall reduce the compensation to such amount as he or she thinks just.

(15) Where, by virtue of a transaction, instrument or event to which section 39 applies, a person becomes the proprietor or one of the proprietors or an exclusive licensee of a patent, the new proprietor or licensee, and a Government department or a person authorised by a Government department subsequently makes use of the patented invention under this section, the new proprietor or licensee shall not be entitled to any compensation under subsection (4), as it stands or as modified by section 59 (3), in respect of a subsequent use of the invention before the transaction, instrument or event is registered unless —

- (a) the transaction, instrument or event is registered within the period of six months beginning with its date; or
- (b) the Registrar is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.

(16) In this section, “relevant communication”, in relation to an invention, means a communication of the invention, directly or indirectly, by the proprietor of the patent or any person from whom he or she derives title.

(17) Subsection (4) is without prejudice to any rule of law relating to the confidentiality of information.

Interpretation, etc., of provisions about Government use

58.— (1) Any reference in section 57 to a patented invention, in relation to any time, is a reference to an invention for which a patent has before that time been, or is subsequently, granted.

(2) In this Part, unless the context otherwise requires, “the services of the Government” includes —

- (a) the supply of anything for foreign defence purposes;
 - (b) the production or supply of drugs and medicines required for the provision of pharmaceutical, medical or dental services in any prescribed dispensary, hospital or other medical institution maintained by or on behalf of the Government and in any dispensary, hospital or medical institution which the Minister may specify by notification in the Gazette; and
 - (c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Minister thinks necessary or expedient;
- and “use for the services of the Government” shall be construed accordingly.

(3) In subsection (2) (a) and section 57 (1) (a), references to a sale or supply of anything for foreign defence purposes are references to a sale or supply of the thing —

(a) to the government of any country outside Saint Lucia pursuant to an agreement or arrangement between the Government and the government of that country, where the thing is required for the defence of that country, where the thing is required for the defence of that country or of any other country whose government is party to any agreement or arrangement with the Government in respect of defence matters; or

(b) to the United Nations, or to the government of any country belonging to that organisation, pursuant to an agreement or arrangement between the Government and that organisation or government of the country belonging to that organisation, where the thing is required for any armed forces operating pursuant to a resolution of that organisation or any organ of that organisation.

Rights of third parties in respect of Government use

59.— (1) In relation to —

(a) any use made for the services of the Government of an invention by a Government department, or a person authorised by a Government department, by virtue of section 57; or
(c) anything done for the services of the Government to the order of a Government department by the proprietor of a patent in respect of a patented invention or by the proprietor of an application in respect of an invention for which an application for a patent has been filed and is still pending;

the provisions of any licence, assignment or agreement to which this subsection applies shall be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use, and the reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(2) Subsection (1) shall apply to any licence, assignment or agreement which is made, whether before or after the commencement date, between, on the one hand, any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and, on the other hand, any person other than a Government department.

(3) Where an exclusive licence granted otherwise than for royalties or other benefits determined by reference to the working of the invention is in force under the patent or application, then —

(a) in relation to anything done in respect of the invention which, but for this section and section 57, would constitute an infringement of the rights of the licensee, section 57 (4) shall have effect as if for the reference to the proprietor of the patent there were substituted a reference to the licensee; and

(b) in relation to anything done in respect of the invention by the licensee by virtue of an authority given under section 57, that section shall have effect as if section 57(4) were omitted.

(4) Subject to subsection (3), where a patent, or the right to the grant of a patent, has been assigned to the proprietor of the patent or application in consideration of royalties or other benefits determined by reference to the working of the invention, then —

(a) in relation to any use of the invention by virtue of section 57, subsection (4) of that section shall have effect as if the reference to the proprietor of the patent included a reference to the assignor, and any sum payable by virtue of that subsection shall be divided between the proprietor of the patent or application and the assignor in such proportion as may be agreed on by them or as may in default of agreement be determined by the court on a reference under section 57; and

(b) in relation to any act done in respect of the invention for the services of the Government by the proprietor of the patent or application to the order of a Government department, section 57 (4) shall have effect as if the act was use made by virtue of an authority given under that section.

(5) Where section 57 (4) applies to any use of an invention and a person holds an exclusive licence under the patent or application, other than such a licence as is mentioned in subsection (3) authorising him or her to work the invention, then subsections (7) and (8) shall apply.

(6) In subsections (7) and (8), “the section 57 (4) payment” means such payment, if any, as the proprietor of the patent or application and the Government department agree under section 57, or the arbitrator determines under that section, should be made by the department to the proprietor in respect of the use of the invention.

(7) The licensee shall be entitled to recover from the proprietor of the patent or application such part, if any, of the section 57 (4) payment as may be agreed on by them or as may, in default of agreement, be determined by the court under section 57 to be just having regard to any expenditure incurred by the licensee —

(a) in developing the invention; or

(b) in making payments to the proprietor in consideration of the licence, other than royalties or other payments determined by reference to the use of the invention.

(8) Any agreement by the proprietor of the patent or application and the Government department under section 57 (4) as to the amount of the section 57 (4) payment shall be of no effect unless the licensee consents to the agreement; and any determination by the arbitrator under section 57 (4) as to the amount of that payment shall be of no effect unless the licensee has been informed of the reference to the arbitrator and is given an opportunity to be heard.

(9) Where any model, document or information relating to an invention is used in connection with —

(a) any use of the invention which falls within subsection (1) (a); or

(b) with anything done in respect of the invention which falls within subsection (1) (b); section 57 (4) shall, whether or not it applies to any such use of the invention, apply to the use of the model, document or information as if for the reference in it to the proprietor of the a patent there was substituted a reference to the person entitled to the benefit of any provision of an agreement which is rendered in operative by this section in relation to that use, and in section 57 the references to terms for the use of an invention shall be construed accordingly.

(10) Nothing in this section shall be construed as authorising the disclosure to a Government department or any other person of any model, document or information to the use of which this section applies in contravention of any such licence, assignment or agreement as is mentioned in this section.

Special provisions as to Government use during emergency

61.— (1) During any period of emergency within the meaning of this section, the powers exercisable in relation to an invention by a Government department or a person authorised by a Government department under section 57 shall include power to use the invention for any purpose which appears to the department necessary or expedient —

(a) for the efficient prosecution of any war in which Saint Lucia may be engaged;

(b) for the maintenance of supplies and services essential to the life of the community;

(c) for securing a sufficiency of supplies and services essential to the well-being of the community;

(d) for promoting the productivity of industry, commerce and agriculture;

(e) for fostering and directing exports and reducing imports, or imports of any class, from all or any countries and for redressing the balance of trade;

(f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or
(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside Saint Lucia which is in grave distress as a result of a war;
and any reference in this Act to the services of the Government shall, in respect of any period of emergency, include a reference to those purposes.

(2) In this section, “the use of an invention” includes, in addition to any act constituting such use by virtue of section 57, any act which would, apart from that section and this section, amount to an infringement of the patent or, as the case may be, give rise to a right under section 72 to bring proceedings in respect of the application, and any reference in this Act to “use for the services of the Government” shall, as respects any period of emergency, be construed accordingly.

(3) In this section, “period of emergency” means any period beginning with such date as may be declared by the Minister by order published in the Gazette to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.

SAO TOME AND PRINCIPE

Intellectual Property Code (approved by Decree-Law No. 23/2016)

Articles 111 - 116

ARTICLE 111

COMPULSORY LICENSING

1. Compulsory licenses may be granted for a certain patent, in any of the following cases:
 - a) Lack or insufficient exploitation of the patented invention;
 - b) Dependent patents;
 - c) For reasons of public interest.
2. The compulsory licenses are not exclusive and can only be transferred with the part of the company or establishment that use them.
3. Compulsory licenses may only be granted when the potential licensee has made efforts to obtain from the patentee a contractual licence on commercially acceptable terms and such efforts were not successful within a reasonable period of time.
4. The compulsory license may be revoked, without prejudice to the adequate protection of the legitimate interests of the licensees, if and when the circumstances which gave rise to it cease to exist and are unlikely to recur; the competent authority may on a substantiated request, re-examine the continuation of such circumstances.
5. When a patent has as its object semiconductor technology, only compulsory licences with a non-commercial public purpose may be granted.
6. The patentee shall receive remuneration which is adjusted to each particular case, taking into account the economic value of the patent.
7. The decision to grant or deny the remuneration is subject to judicial appeal or arbitration, pursuant to Articles 50 to 59.

ARTICLE 112

LICENCE DUE TO FAILURE TO EXPLOIT AN INVENTION

1. On expiry of the time periods referred to in paragraph 2 of Article 110, the owner who, without just cause or legal basis, does not exploit the invention, directly or through a licence, or does not do so to meet national needs, may be obliged to grant to another a licence to exploit the invention.

2. The owner of a licence of exploitation of the invention may also be obliged to grant it to another if he does not exploit it for three consecutive years without just cause or legitimate reasons.

ARTICLE 113

DEPENDENT LICENCES

1. If it is not possible to exploit a patented invention, without prejudice to the rights of a previous patent, and the two inventions are used for different industrial purposes, a licence may only be granted if the first invention is essential to the exploitation of the second, and only in the part necessary for said exploitation, and the owner of the first patent is entitled to fair compensation.

2. If the inventions that protected by dependent patents serve the same industrial purpose and a compulsory licence are to be granted, the previous patentee may also demand a compulsory licence for the subsequent patent.

3. When an invention concerns a preparation process of a chemical, pharmaceutical or food product protected by a patent in force, and whenever this process patent represents a remarkable technical progress in relation to the prior patent, both the owner of the process patent and the owner of the product patent are entitled to demand a compulsory licence for the other owner's patent.

4. If a plant breeder cannot obtain or exploit a plant securing right without infringing a prior patent, he may request for a compulsory licence for the non-exclusive use of the invention protected by the patent inasmuch as this licence is necessary to exploit the same plant variety, subject to payment of an appropriate sum.

5. Whenever a licence of the type provided for in the previous paragraph is granted, the patentee is entitled to a reciprocal licence, on reasonable terms, to use the protected variety.

6. If the owner of a patent concerning a biotechnological invention is unable to exploit it without infringing a prior plant variety securing right, he may request a compulsory licence for the non-exclusive use of the plant variety protected by that securing right, subject to payment of an appropriate sum.

7. Whenever a licence of the type provided for in the previous paragraph is granted, the plant variety rights' holder is entitled to a reciprocal licence, on reasonable terms, to use the protected invention.

8. Applicants for the licences referred to in paragraphs 4 and 6 must prove that: a) They have unsuccessfully applied to the patentee or the plant securing rights holder to obtain a contractual licence; b) The plant variety or the invention constitutes significant technical progress of considerable economic interest in relation to the invention claimed in the patent or to the plant variety being protected.

9. The provisions of this Article shall also apply whenever one of the inventions is protected by a patent and the other by a utility model.

ARTICLE 114
PUBLIC INTEREST

1. A patentee may, in the public interest, be obliged to grant a license for the exploitation of his invention.

2. It is considered that there are reasons of public interest when the beginning, the increase or the generalization of the exploitation of the invention, or the improvement of the conditions under which such exploitation takes place, are of vital importance to public health or national defense.

3. It shall also be considered to be reasons of public interest if the failure to exploit or insufficient quality or quantity of exploitation is highly detrimental to the country's economic or technological development.

4. The Government shall be responsible for granting a licence in the public interest.

ARTICLE 115
APPLICATIONS FOR COMPULSORY LICENCES

1. Compulsory licenses shall be requested from the SENAPIQ-STP, and applicants shall submit evidence to substantiate their request.

2. Applications for compulsory licenses are examined in the order in which they are submitted to the SENAPIQ-STP.

3. On receiving the application for a compulsory licence, the SENAPIQ-STP shall give the patentee a period of two months to respond as he deems fit together with the respective evidence.

4. The SENAPIQ-STP shall consider the parties' submissions and the guarantees offered by the applicant of the compulsory licence for the exploitation of the invention and shall decide, within two months, whether the licence should be granted.

5. If the SENAPIQ-STP decides to grant the licence, it shall notify both parties to within one month appoint an expert who, together with the expert appointed by the SENAPIQ-STP shall agree, within two months, on the conditions of the compulsory licence and the compensation payable to the patentee.

ARTICLE 116
NOTICE OF AND APPEAL AGAINST THE GRANTING OR REFUSAL OF A LICENCE

1. SENAPIQ-STP shall inform both parties of the grant or refusal of a licence and its exploitation conditions.

2. An appeal may be lodged against the decision of SENAPIQ-STP granting or refusing the licence or only against the conditions, under which it was granted, may be appealed to the competent court, in terms of Articles 50 et seq., within three months from the date of the notification referred to in the previous paragraph.

3. A decision to grant the licence shall only take effect after its confirmation and annotation at the SENAPIQ-STP, where the appropriate fees shall be paid as for an ordinary licence.

4. An extract of the registration referred to in the paragraph above shall be published in the Intellectual Property Bulletin.

SAUDI ARABIA

Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs of 2004

Articles 24-28

Article Twenty Four:

(a) The City may grant a compulsory license to a third party to exploit an invention covered by the patent or a layout design of an integrated circuit covered by a certificate of design upon an application submitted to it, according to the following:

(1) The application shall be submitted after the elapse of four years from the date of filing the patent application or three years from the date of granting the patent, whichever expires later, without the owner of the protection document exploiting his invention or having exploited it in an inadequate fashion, unless he justifies that with a legitimate excuse.

(2) The applicant for the compulsory license must prove that he has exerted -over a reasonable period of time- efforts in order to obtain a contractual license on the basis of reasonable commercial conditions, and for a reasonable financial compensation. However, this provision and the provision of the preceding paragraph do not apply where the applicant is a government body or a person authorized by it, and the aim was to meet public interest - especially security, health, nutrition or the development other vital sectors of the national economy- or to meet a state of emergency or other very compelling circumstances, or where the aim thereof was public non-commercial purposes. In the latter case, and upon knowledge of the existence of a patent or a certificate of design, their holder shall be promptly informed.

(3) The compulsory license is basically granted to make the invention or design available in the local markets. But this provision does not apply where the aim of the license is to prevent or restrict practices against which a decision or judgment is issued declaring them to be acts of unlawful competition.

(4) The decision granting the license shall specify the scope and term of the license, according to the purpose for which it was granted. The license shall be subject to termination if the conditions for which it was granted cease to exist and their recurrence is not likely, with due regards to the lawful interests of the licensee.

(5) The license shall not be exclusive.

(6) Each application shall be independently decided.

(7) The owner of the protection document or the holder of a certificate of a design shall be awarded a fair compensation. The Committee shall determine the amount of the compensation, and the licensee undertakes to pay it.

(b) If the compulsory license is related to a patent of semiconductor technology , the purpose of the license shall be for public non-commercial purposes only or to control acts concerning which a decision or judgment is issued declaring them to be acts of unlawful competition.

(c) If the patent involves a significant technological advance with a considerable economic value, which requires the exploitation of another patent, the City may grant that owner of the protection document a compulsory license to exploit the other patent. In such a case the compulsory license shall not be assigned unless the other patent is assigned. The owner of the other patent shall be entitled to a counter license from the compulsory licensee, in accordance with reasonable conditions.

Article Twenty Five:

(a) The City may grant a compulsory license to a third party to exploit a plant variety patented by a plant patent, upon an application submitted to it in accordance with the following:

(1) The compulsory license is necessary to protect public interest.

(2) The applicant for the compulsory license being able financially and technically.

(3) Failure of the applicant to obtain a license from the owner of the plant patent at reasonable terms.

(4) The elapse of three years between the date of granting the plant patent and the date of applying for the compulsory license.

(5) The compulsory license shall not be restricted to performing all or some of the acts referred to in Article 56 of this Law to meet the needs of the local market.

(6) The owner of the patent shall be awarded a fair compensation. The Committee shall determine the amount of compensation, and the licensee shall undertake to pay it.

(b) The City may instruct the owner of the plant patent to provide the holder of a compulsory license with the required quantity of propagation material for the use of the compulsory license in a reasonable fashion.

(c) In other than exceptional circumstances, the compulsory license shall not be granted for a period less than two years or more than four years. The City may extend the term for additional periods, upon verifying that the grounds for granting the compulsory license still exist.

Article Twenty Six:

If a compulsory license is granted for a patented subject matter the beneficiary of the compulsory license may not assign it to others, unless the assignment includes all or part of the firm benefiting from the license or its goodwill. The City's approval of the assignment is required; otherwise, it shall be null and void. If the City approves such assignment, the assignee becomes liable for the obligations assumed by the first beneficiary prior to the approval of the assignment.

Article Twenty Seven:

The City may amend the decision to grant the compulsory license if need arises. The owner of the protection document or the beneficiary of the compulsory license may request the City to make this amendment if its pre-requisites are fulfilled. The reasons for the decision of the City to amend the license or to reject the request must be stated.

Article Twenty Eight:

The City shall cancel the compulsory license in the following cases:

(a) If the beneficiary of the license fails to exploit it in a way that satisfies the Kingdom's needs, within two years from the grant of the license, renewable for an equal period, if it is proved that there

is a legitimate cause.

(b) If the beneficiary of the compulsory license fails to pay the due fees within ninety days from the due date, including the compensations to which the owner of the protection document is entitled, as

stipulated in the decision granting the license.

(c) If the beneficiary of the compulsory license fails to observe any condition necessary for granting of the license.

SERBIA

The Law on Patents of 4 January 2012 (Official Gazette of the Republic of Serbia № 99/2011)

Articles 26-28 and 30-38

Compulsory License

Article 26

If the right holder refuses to license the right of commercial use of a protected invention to other persons or sets unreasonable conditions for such licensing, the government authority competent in the field in which the invention shall be employed may, at the request of an interested party after considering the merits of each individual case, grant a compulsory license, in the following cases:

- 1) if the right holder himself or a person authorized by him does not use the protected invention or uses it insufficiently in the Republic of Serbia;
- 2) if the commercial use of an invention that has been subsequently protected in the name of another person is not possible, without the use of the protected invention in whole or in part;
- 3) when it is necessary to remedy a practice determined after judicial or administrative process to be anticompetitive

The request for the grant of a compulsory license cannot be filed before the expiration of a period of four years from the date of filing of the patent application or before the expiration of a period of three years from the grant of the patent or petty patent, whichever period expires last.

Before making a request under the paragraph 1 of this Article the interested person shall be required to prove that he has made efforts to obtain authorization for the use of the protected invention from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

The interested person, referred to in paragraph 1, item 1) of this Article, may only be a person who proves that he has the appropriate technological capacity and production facilities for the commercial use of the protected invention.

The interested person referred to in paragraph 1, item 2) of this Article may only be the right holder of the second invention, under the following conditions:

- 1) that the second invention involves a technical advancement of special economic significance in relation to the first protected invention and that
- 2) the owner of the first invention is entitled, on reasonable terms, to a cross-license to use the second invention.

Authorization for the use of the earlier protected invention shall be non-assignable except with the assignment of the second patent.

A compulsory license cannot be granted if the patent owner provides legitimate reasons to justify non-exploitation or insufficiency of exploitation of the protected invention.

Provisions of paragraphs 2. and 3. of this Article shall not apply to compulsory license granted when the public emergency endangers the survival of the state or its citizens or in cases of public non-commercial use.

Holder of patent shall be promptly informed on the procedure on granting compulsory license referred to in paragraph 8. of this Article.

In the case of semi-conductor technology, a compulsory license may be granted only in cases of public non-commercial use or when it is necessary to remedy a practice determined after judicial or administrative process to be anti-competitive.

Remuneration to the Right Holder

Article 27

The holder of a compulsory license shall be required to pay the right holder a mutually agreed remuneration. In the absence of an agreement on the amount and method of payment of such remuneration, the competent court shall decide, taking into account the merits of each individual case and the economic value of the compulsory license.

Scope and Duration of Compulsory License

Article 28

The scope and duration of a compulsory license shall be limited to the purpose for which it has been granted.

A compulsory license shall not be exclusive.

A compulsory license may be assigned only with the manufacturing plant that exploits the invention for which the license has been granted.

A compulsory license shall predominantly be granted for the supply of the domestic market.

A compulsory license may be terminated if and when circumstances that have led to its grant cease to exist and are unlikely to recur.

On reasoned request, the government authority competent in the field in which the invention shall be employed shall re-examine the further existence of circumstances referred to in paragraph 5 of this Article.

Compulsory Licenses of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems

Article 30

Government authority responsible for the Health, may grant a compulsory license in relation to patents and Supplementary Protection Certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to importing countries having public health problems to any person who submits a request in accordance with the provisions of this Law. In deciding to grant compulsory license the Government authority responsible for the Health will take particular into account the need for execution of decisions of the WTO Council on 30 August 2003 on the implementation of item (6) of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health on 14 November 2001 (hereinafter: the Decision).

Pharmaceutical product specified in paragraph 1 of this Article means any product of the pharmaceutical industry including medicinal products for human use, by which is meant any substance or combination of substances presented as having properties for treating or preventing disease in human beings and any substance or combination of substances which may be used to human beings, for the purpose of restoring, correcting or adjustment physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis, including active ingredients and diagnostic kits *ex vivo*.

Importing country referred to in paragraph 1 of this Article is any country to which the pharmaceutical product is to be exported. The following are eligible importing countries:

- 1) any least-developed country appearing as such in the United Nations list;
- 2) any member of the WTO, other than the least-developed country members referred to in to item (1) of this paragraph, that has made a notification to the Council for TRIPS of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way;
- 3) any country that is not a member of the WTO, but is listed in the OECD Development Assistance Committee's list (hereinafter the OECD) of low-income countries with a gross national product per capita of less than amount established by the OECD Development Assistance Committee, and has made a notification to the Government of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

Any WTO member that has made a declaration that it will not use the system as the importing WTO member is not an eligible importing country.

Importing countries that are not WTO members, and that are the least developed countries and developing countries and that meet the requirements referred to in paragraph 3 of this Article must fulfil following additional conditions:

- 1) the importing country is obliged to make the notification pursuant to the Decision directly to the Government;
- 2) the importing country is obliged, to state in the notification that it will use the system to address public health problems and not as an instrument to pursue industrial or commercial policy objectives and that it will adopt the measures referred to in paragraph 4 of the Decision; Government authority responsible for the Health, may at the request of the right holder, or on its own initiative, terminate a compulsory license if the importing country has failed to honour its obligations referred to in paragraph 5 item 2) of this Article.

The request referred to in paragraph 1 of this Article must include:

- 1) information about the requirements for the grant of compulsory licenses in other states for the same product with details of the quantities and importing countries concerned;
- 2) data on the requester and of any representative whom he has appointed to act for him;
- 3) the non-proprietary name of the pharmaceutical product or products which the person who has filed the request for the grant of compulsory license intends to manufacture and sell for export under the compulsory license;
- 4) the amount of pharmaceutical product which the requester intends to produce under the compulsory license;
- 5) the importing country or countries;
- 6) evidence of prior negotiation with the right holder pursuant to paragraph 11 of this Article;
- 7) evidence of a specific request from authorized representatives of the importing country or countries or a non-governmental organization acting with the formal authorization of one or more importing countries or UN bodies or other international health organizations, indicating the quantity of product required.

Government authority responsible for the Health, shall notify the right holder without delay of the requirement for a compulsory license and before the grant of the compulsory license shall give the right holder an opportunity to comment on the request and to provide the competent authority with relevant information regarding the request.

When deciding on the request for the grant of compulsory license government authority responsible for the Health, shall verify that:

- 1) each importing country cited in the request which is a WTO member has made a notification to the WTO pursuant to the Decision, or each importing country cited in the request which is not a WTO member has made a notification to the Government pursuant to this Article in respect of each of the products covered by the request. The foregoing does is without prejudice to the flexibility that least developed countries have under the Decision of the Council for TRIPS of 27 June 2002;
- 2) the quantity of product cited in the request does not exceed that notified to the WTO by an importing country which is a WTO member, or to the Government by an importing country which is not a WTO member;
- 3) taking into account other compulsory licenses granted elsewhere, the total amount of product authorized to be produced for any importing country does not significantly exceed the amount notified by that country to the WTO, in the case of importing countries which are WTO members, or to the Government, in the case of importing countries which are not WTO members.

The person who has filed the request for the grant of compulsory license is obliged to specify the data prescribed in paragraph 9 of this Article in the request for the grant of compulsory license.

A compulsory license may only be granted if the requester provides the evidence that he has made efforts to obtain authorization from the right holder and that such efforts have not been successful within a period of thirty days before submitting the request.

The provision referred to in paragraph 11. of this Article shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

Compulsory License Conditions for Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems

Article 31A compulsory license may only be granted as a non-exclusive, its scope and duration must be indicated in the decision and they are related solely to the purpose for which a compulsory license was granted. The amount of products manufactured under the license shall not exceed what is necessary to meet the needs of the importing country or countries cited in the request, taking into account the amount of products manufactured under other compulsory licenses granted elsewhere.

A compulsory license may be assigned only with the manufacturing plant that exploits the invention for which the license has been granted.

The decision on the grant of a compulsory license shall contain the actions to which the person who has filed the request for the grant of compulsory license is entitled and which are necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the request. No product made or imported under the compulsory license shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under item 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question.

The decision on the grant of a compulsory license shall require:

- 1) that the products made under the compulsory license must be clearly identified, through specific labelling or marking, as being produced under compulsory license, must be distinguished from those made by the rights holder through special packaging and/or special colouring or shaping, provided that such distinction is feasible and does not have a significant impact on price,
- 2) the packaging and any associated literature must bear an indication that the product is subject to a compulsory license, giving the name of the authority that has granted the compulsory license and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned,
- 3) details of the product characteristics shall be made available to the customs authorities of the Republic of Serbia.

The decision on the grant of a compulsory license shall require that the licensee shall before shipment to the importing country post on a website, about which the licensee shall notify the Government authority responsible for the Health, the following information:

- 1) the quantities being supplied under the compulsory license and the importing countries to which they are supplied;
- 2) the distinguishing features of the product or products concerned.

If the product covered by the compulsory license granted in the Republic of Serbia is protected by patent of petty patent in the importing countries cited in the request, the product shall only be exported if those countries have issued a compulsory license for the import, sale and/or distribution of the products.

The decision on the grant of a compulsory license shall require that licensee shall pay the remuneration to the right holder as determined as follows:

- 1) in the cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country or on its behalf;

2) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorized under the license to the importing country or countries concerned, as well as humanitarian and non-commercial circumstances relating to the issue of the license.

After the decision to grant a compulsory license becomes final, the authority which the Government authority responsible for the Health delegates competence may, on the proposal for the preservation of evidence, submitted by the right holder, access to books and records kept by the licensee, for the sole purpose of checking whether all obligations cited in the decision to grant compulsory license, and in particular those relating to the final destination of the products, have been met. The books and records shall include proof of exportation of the product, through a declaration of exportation certified by the customs authority, as well as evidence of import.

The license conditions are without prejudice to the method of distribution in the importing country.

Refusal of the Request to Grant a Compulsory License

Article 32

The Government authority responsible for the Health shall refuse the request to grant a compulsory license if the request does not contain the elements necessary for taking the decision referred to in Article 30. of this Law or if the conditions to grant the license prescribed by Article 31. of this Law are not met.

Notification

Article 33

The Government authority responsible for the Health shall notify the Council for TRIPS of its final decisions to grant compulsory license for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, of the specific conditions attached to it, as well as on its modification and termination.

The information provided shall include the following details of the license:

- 1) the name and address of the licensee;
- 2) the product concerned;
- 3) the quantity to be supplied;
- 4) the importing country;
- 5) the duration of the license;
- 6) the website referred to in Article 31 paragraph 5 of this Law.

Prohibition of Importation

Article 34

The import of products manufactured under a compulsory license granted under the paragraph 30 of this Law for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse shall be prohibited into the Republic of Serbia.

Paragraph 1 of this Article shall not apply in the case of re-export to the importing country cited in the request and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing country.

Action by Customs Authorities

Article 35

If there are sufficient grounds for suspecting that products manufactured under a compulsory license granted pursuant to this Law are being imported into the Republic of Serbia contrary to Article 34 paragraph 1 of this Law, customs authorities shall suspend the release of, or detain the products concerned for the time necessary to obtain a decision of the Government authority responsible for the Health on the character of the imported products, not exceeding ten working

days. If special circumstances apply, the custom authority may extend the period of the detention by a maximum of ten working days.

The right holder and the manufacturer or exporter of the products concerned shall be informed without delay of the detention of the products referred to in paragraph 1 of this Article and shall be given ample opportunity to supply the custom authority with information and evidence on the relevant products.

If it is confirmed in the period of the detention, violation of the compulsory license contrary to the prohibition of the Article 34 paragraph 1 of this Law, custom authority shall ensure that the products are seized and disposed of in accordance with customs regulations.

The procedure of detention or seizure of the goods shall be carried out at the expense of the importer in accordance with customs regulations and for the costs for the procedure of detention or seizure jointly with the importer is liable any other person who attempted illicit importation.

If the products detained by customs authorities are subsequently found not to violate the prohibition referred to in Article 34 paragraph 1 of this Law and if the customs regulations has been complied with, the custom authority shall release the products in the territory of the Republic of Serbia.

The custom authority shall inform the Government authority responsible for the Health of any decisions on seizure or destruction in accordance with this Article.

Exceptions to the Prohibition of Importation

Article 36

Articles 34 and 35 of this Law, shall not apply to import of small quantities of goods contained in travellers' personal luggage for personal and non-commercial use within the limits laid down in respect of relief from customs duty.

Termination or Modification of the Compulsory License

Article 37

Right holder or licensee may request from the Government authority responsible for the Health to terminate the compulsory license if it finds that the opposing party does not comply with license conditions. In a decision on the termination of a compulsory license, the Government authority responsible for the Health shall, in consultation with the right holder, set a period in which the licensee shall at its expense, redirect all the products that are in his ownership in the country with the need as referred to in Article 30 paragraph 9 of this Law or otherwise disposed.

If the importing country submits a notification that the quantity of pharmaceutical products has become insufficient to meet its needs, the licensee may require modification of conditions of the license permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned.

Procedure on request referred to in paragraph 2 of this Article is urgent.

If additional quantity of products does not exceed 25%, originally approved amount of pharmaceutical products in deciding on the request referred to in paragraph 2 of this Article the provisions of Article 30 paragraph 9 of this Law shall not apply.

Legal Protection

Article 38

The Government authority referred to in Articles 26, 29 and 30 of this Law shall take the decision on the grant of a compulsory license, refusal of the request to grant a compulsory license, modification and termination of the compulsory license.

Decisions of the Government authority referred to in paragraph 1 of this Article on the grant of a compulsory license, refusal of the request to grant a compulsory license, modification and termination of the compulsory license may be appealed with the Government within 15 days of receipt of the decision.

Administrative dispute proceedings may be instituted against the decision on the appeal rendered by the Government within 30 days from the date of the receipt of the Government's decision.

SINGAPORE

Patents Act (Chapter 221) (Revised Edition 2005, as amended up to the Patents (Amendments) Act 2017)

Sections 55-57 and 60-62

Compulsory licences

55.—(1) Any interested person may apply to the court for the grant of a licence under a patent on the ground that the grant of the licence is necessary to remedy an anti-competitive practice.

(2) Without prejudice to the generality of subsection (1), the court may determine that the grant of a licence is necessary to remedy an anti-competitive practice if —

(a) there is a market for the patented invention in Singapore;

(b) that market —

(i) is not being supplied; or

(ii) is not being supplied on reasonable terms; and

(c) the court is of the view that the proprietor of the patent has no valid reason for failing to supply that market with the patented invention, whether directly or through a licensee, on reasonable terms.

(3) Subject to this section, if the court is satisfied that the ground referred to in subsection (1) is established, the court may make an order for the grant of a licence in accordance with the application upon such terms as the court thinks fit.

(4) A licence granted under this section —

(a) is not exclusive; and

(b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used.

(5) Any licence granted under this section may, on the application of any interested party, be terminated by the court where the court is satisfied that the ground upon which the licence was granted has ceased to exist and is unlikely to recur.

(6) Where a licence is granted under this section to any person, the person shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed between the person and the patentee or, in default of agreement, as is determined by the court on the application of the person or the patentee.

(7) The powers of the court on an application under this section shall be exercised with a view to securing that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the economic value of the licence.

(8) No order shall be made in pursuance of any application under this section which would be at variance with any treaty or international convention relating to patents to which Singapore is a party.

Use of patented inventions by Government and authorised parties

56.—(1) Subject to sections 60, 61 and 62, but notwithstanding any other section of this Act, the Government and any party authorised in writing by the Government may do anything in relation to a patented invention —

- (a) for a public non-commercial purpose; or
- (b) for or during a national emergency or other circumstances of extreme urgency, and anything done by virtue of this section shall not amount to an infringement of the patent.

(1A) Without prejudice to the generality of subsection (1), subject to sections 60, 61 and 62, but notwithstanding any other section of this Act, the Government and any party authorised in writing by the Government may import any relevant health product, and do anything in relation to any relevant health product so imported, for or during a national emergency or other circumstances of extreme urgency, if the Government has given the Council for TRIPS a relevant notification in relation to the relevant health product.

(2) For the purposes of this section and section 57 —

- (a) any use of an invention for the supply to the government of any country outside Singapore, in pursuance of any agreement or arrangement between the Government of Singapore and the government of that country, of articles required for the defence of that country shall be deemed to be a use of the invention for a public non-commercial purpose; and
- (b) the power of the Government or any party authorised by the Government to do anything in accordance with this section shall not, in the case of a patent relating to an integrated circuit, extend to sale of the invention to the public.

(3) The purchaser of any article sold in the exercise of the powers conferred by this section, and any person claiming through the purchaser, shall have power to deal with it in the same manner as if the patent were held on behalf of the Government.

(4) In this section —

“integrated circuit” means a product, in its final or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in and on, or in or on, a piece of material and which is intended to perform an electronic function;

“relevant notification” means a notification that satisfies the requirements of —

- (a) paragraph 2(a) of the Doha Declaration Implementation Decision; or
- (b) paragraph 2(a) of the Annex to the TRIPS Agreement.

Rights of third parties in respect of Government use

57.—(1) In relation to —

- (a) anything done in accordance with section 56 by the Government or any party authorised in writing by the Government; or
- (b) anything done to the order of the Government —
 - (i) for a public non-commercial purpose; or
 - (ii) for or during a national emergency or other circumstances of extreme urgency, by the proprietor of a patent in respect of the patented invention or by the proprietor of an application for a patent in respect of the invention for which the application has been filed and is still pending, the provisions of any licence, assignment or agreement to which this subsection applies shall, subject to sections 60, 61 and 62, be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use.

(2) The reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(3) Subsection (1) shall apply to any licence, assignment or agreement which is made, whether before or after 23rd February 1995, between (on the one hand) any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and (on the other hand) any person other than the Government.

Nature and scope of rights under section 56

60.—(1) The right to use a patented invention under section 56 —

(a) is not exclusive;

(b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and

(c) is, notwithstanding subsection (2) (a) of section 56, limited to the supply of the patented invention predominantly in Singapore by the Government or a party authorised by the Government under that section.

(1A) The right under section 56 to use a relevant health product which is imported under section 56(1A) does not include a right to export the relevant health product.

(2) The right to use a patented invention under section 56 may, on the application of any interested party, be terminated by the court, where the court is satisfied that the circumstances that gave rise to the right to use the patented invention have ceased to exist and are unlikely to recur.

(3) Where the court has terminated the right under section 56 to use a patented invention, the court may make such consequential orders as it thinks necessary.

Duty to inform patentee

61.—(1) Where anything set out in section 66(1) is done in relation to a patented invention by the Government or a party authorised in writing by the Government for a public non-commercial purpose, the Government department that did or authorised the doing of the thing shall inform the patentee promptly of the doing of the thing.

(2) Where anything set out in section 66(1) is done in relation to a patented invention by the Government or a party authorised in writing by the Government for or during a national emergency or other circumstances of extreme urgency, the Government department that did or authorised the doing of the thing shall, as soon as reasonably practicable, inform the patentee of the doing of the thing.

Patentee entitled to remuneration

62.—(1) Subject to subsection (2), where an act is done under section 56, the Government shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed, between the Government and the patentee having regard to the economic value of the patented invention or as may, in default of agreement, be determined by the court under section 58.

(2) No remuneration shall be payable under subsection (1) in respect of the import or subsequent use under section 56(1A) of any relevant health product, if the patentee has received or will receive any other remuneration in respect of that relevant health product.

SLOVAK REPUBLIC

Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and Amendment of Some Acts [Patent Act (as amended up to Act No. 242/2017 Coll.)]

Articles 27 and 28

Compulsory licence

Article 27

(1) On request the court shall be entitled to grant a compulsory licence to any person who can prove the capability to exploit an invention, which is a subject-matter of a granted patent, within the territory of the Slovak Republic, provided that

- a) 4 years have expired since filing of an application or 3 years have expired from granting a patent, where the time limit, which expires later, shall apply,
- b) person requesting granting of a compulsory licence has offered before filing a request to a patent owner a proper conclusion of a licence agreement, whilst this offer was not accepted by a patent owner within three months from its filing, and
- c) invention has not been exploited within the territory of the Slovak Republic without an appropriate reason by a patent owner, or it has been exploited insufficiently, while a subject-matter of a patented invention as a product has not been supplied to the market of the Slovak Republic in a sufficient quantity. Non-existence of an appropriate reason shall be presupposed, unless proved otherwise.

(2) Compulsory licence may be granted only as a non-exclusive licence, whilst its duration and scope shall be limited to purpose for which it has been granted provided that domestic market needs shall be satisfied preferentially.

(3) If a subject-matter of a patent is a technology of semiconductor products, compulsory licence may be granted only for public non-commercial exploitation or to prevent a patent owner from further action, which pursuant to a decision of a competent body can be considered as an action abusing or restricting economic competition, or in case of serious public interest menace.

(4) Notwithstanding paragraph 1(a) and (b) compulsory licence may be granted in case of serious public interest menace.

(5) Notwithstanding presuppositions pursuant to paragraph 1 and conditions pursuant to paragraph 2, a court shall be entitled to grant a compulsory non-exclusive licence for utilisation of a biotechnological invention on request, if a cultivator shall not be able to exploit or acquire right to a plant variety without infringing earlier right to a patent, if the plaintiff proves that

- a) before filing a request he has offered to a patent owner a proper conclusion of a licence agreement, whilst this offer was not been accepted by a patent owner within three months from its filing, and
- b) plant variety represents an important technical progress of a considerable economic importance comparable with an invention which is a subject-matter of a request for granting a compulsory licence.

(6) In case of granting a compulsory licence pursuant to paragraph 5, a patent owner shall have right for granting a cross compulsory licence for utilisation of a plant variety pursuant to a special regulation.2)

(7) If a patent owner has granted a compulsory licence for utilisation of a plant variety pursuant to a special regulation, 13b) an owner of a cultivator certificate shall have right for granting a cross compulsory licence for utilisation of a biotechnological invention.

(8) Assignment or transfer of right of a compulsory licence holder shall be possible exclusively as a part of an assignment or transfer of a company or of its part, within which an invention is being used on a basis of a compulsory licence.

(9) A holder of a compulsory licence shall be entitled to waive rights from a compulsory licence by a written notice delivered to the Office. Waiver of right shall come into effect from the day of delivery of a notice to the Office or on a later day which is stated in a notice as a day from which a compulsory licence rights holder waives his rights.

Article 28

(1) By granting a compulsory licence, the right of the patent holder to adequate remuneration shall remain unaffected; Article 26(3) shall apply *mutatis mutandis* for the purposes of determining remuneration for exploitation of an invention, which is subject-matter of a compulsory licence.

(2) In case of substantial change of circumstances, which led to granting of a compulsory licence, the court, on the request of one of the parties to the licence, shall be entitled to cancel a decision on granting a compulsory licence, provided that re-occurrence of reasons for granting a compulsory licence is improbable or compulsory licence rights have not been used during one year.

(3) The Industrial Property Office of the Slovak Republic shall enter valid decision on granting and cancelling of compulsory licence into the Patent Register.

SLOVENIA

Industrial Property Act of 23/05/2001 (as amended up to 6 December 2013)

Articles 125 and 126

Article 125

Compulsory licences

(1) The court may decide that a third party or the Government of the Republic of Slovenia exploit the invention without the authorisation of the owner of the patent:

(a) where the public interest concerning, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires, or

(b) where the court has determined that the owner of the patent or his licensee abuses the patent rights, in particular where the manner of exploitation, contrary to the adopted regulations, restrains competition.

(2) The court shall grant compulsory licences under paragraph (1) with regard to given circumstances and after hearing the owner of the patent.

(3) Compulsory licences under paragraph (1) shall be granted provided that the person filing the request proves that he has made efforts to conclude a licence contract with the owner of the patent on reasonable commercial terms and that such efforts failed to succeed within a reasonable period of time.

(4) Paragraph (3) shall not apply if a state of war or similar state of emergency has been declared. Nevertheless, the owner of the patent shall be notified of the decision of the court as soon as reasonably practicable.

Article 126

Conditions for granting compulsory licences

(1) Compulsory licences under Article 125 shall be granted under the following conditions:

- (a) scope and duration shall be limited with regard to their purpose;
- (b) they shall be non-exclusive;
- (c) they shall be non-transferable, with the exception of the part of the enterprise or business of the licence owner to which the licence refers;
- (d) they shall be granted primarily for the supply of the market of the Republic of Slovenia.

(2) Where a patent, hereinafter referred to as “the second patent”, cannot be exploited without infringing another patent, hereinafter referred to as “the first patent”, the following conditions, in addition to those of Article 125 and paragraph (1) above, for the grant of compulsory licence in respect of the first patent shall be met:

- (a) the invention claimed in the second patent shall involve a technical advance of considerable economic significance compared to the invention claimed in the first patent;
- (b) the owner of the first patent shall under reasonable conditions be entitled to a crosslicence to use the invention claimed in the second patent;
- (c) the use authorised in respect of the first patent shall not be transferable except with the simultaneous transfer of the second patent.

(3) The court shall decide that a compulsory licence expire if the circumstances which led to it being granted have ceased to exist and are unlikely to recur.

SOUTH AFRICA

Patents Act No. 57 of 1978 as last amended by Act, No. 58 of 2002

Sections 55 and 56

55. Compulsory licences in respect of dependent patents.

Where the working of a patent (hereinafter referred to as a dependent patent) without infringement of a prior patent is dependent upon the obtaining of a licence under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the commissioner for a licence under the prior patent, and the commissioner may grant such a licence on such conditions as he may impose, but including a condition that such licence shall be used only for the purpose of permitting the dependent patent to be worked and for no other purpose: Provided that the commissioner shall not grant such a licence unless—

- (a) the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the prior patent;
- (b) the proprietor of the dependent patent granted the proprietor of the prior patent on reasonable terms a cross-licence to use the invention claimed in the dependent patent; and
- (c) the use authorised in respect of the prior patent is not assignable except with the assignment of the dependent patent.

[S. 55 amended by s. 44 of Act No. 38 of 1997.]

56. Compulsory licence in case of abuse of patent rights.

(1) Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.

(2) The rights in a patent shall be deemed to be abused if—

(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;

(b) [Para. (b) deleted by s. 45 (b) of Act No. 38 of 1997.]

(c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

(d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or

(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.

(3) The patentee or any other person appearing from the register to be interested in the patent may in the prescribed manner oppose the application.

(4) (a) The commissioner shall consider the application on its merits and may order the grant to the applicant of a licence on such conditions as he or she may deem fit, including a condition precluding the licensee from importing into the Republic any patented articles.

[Para. (a) substituted by s. 45 (c) of Act No. 38 of 1997.]

(b) If the commissioner is of the opinion that an order directing the grant of a licence is not justified, he may refuse the application.

(c) A licence granted under this section shall include a provision that, subject to adequate protection of the legitimate interests of the licensee, the licence shall, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the commissioner, are unlikely to recur.

[Para. (c) added by s. 45 (d) of Act No. 38 of 1997.]

(5) Any licence granted under this section shall be non-exclusive and shall not be transferable except to a person to whom the business or part of the business in connection with which the rights under the licence were exercised has been transferred.

[Sub-s. (5) substituted by s. 45 (e) of Act No. 38 of 1997.]

(6) [Sub-s. (6) deleted by s. 45 (f) of Act No. 38 of 1997.]

(7) In determining the conditions on which any licence is granted the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.

(7A) The commissioner may order that a licence granted in terms of this section shall be deemed to have been granted on the date on which the application has been received by the registrar.

[Sub-s. (7A) inserted by s. 2 (b) of Act No. 76 of 1988.]

(8) Any order of the commissioner under this section shall be made with a view to avoiding the abuse found by the commissioner to have been established.

(9) The commissioner may amend or revoke any licence granted under this section.

(10) Subject to the conditions that may be attached to the licence, a licensee under this section shall have the same rights and obligations as any other licensee under a patent.
[Sub-s. (10) substituted by s. 45 (g) of Act No. 38 of 1997.]

(11) [Sub-s. (11) deleted by s. 45 (h) of Act No. 38 of 1997.]

(12) [Sub-s. (12) deleted by s. 45 (h) of Act No. 38 of 1997.]

(13) (a) The commissioner may, when ordering the grant of a licence under subsection (4) (a), award costs against the applicant or patentee concerned or any person opposing the relevant application.

(b) In so awarding costs, the commissioner shall inter alia have regard to—

- (i) the nature and extent of the abuse found by him to have been established; and
- (ii) whether the application for a licence under this section might have been avoided by the grant, by the patentee concerned to the applicant, of a voluntary licence on reasonable terms.

(14) For the purposes of this section the expression “patented article” includes any composition of matter or any product of a patented process or method or any product produced by a patented machine.

SPAIN

Law No. 24/2015 of July 24, 2015, on Patents (as amended by Law No. 6/2018 of July 3, 2018)

Artículo 90 – 101

CAPÍTULO I

Obligación de explotar la invención y requisitos para la concesión de licencias obligatorias

Artículo 90. Obligación de explotar.

1. El titular de la patente está obligado a explotar la invención patentada bien por sí o por persona autorizada por él mediante su ejecución en España o en el territorio de un Estado miembro de la Organización Mundial del Comercio, de forma que dicha explotación resulte suficiente para abastecer la demanda en el mercado español.
2. La explotación deberá realizarse dentro del plazo de cuatro años desde la fecha de presentación de la solicitud de patente, o de tres años desde la fecha en que se publique su concesión en el “Boletín Oficial de la Propiedad Industrial”, aplicándose automáticamente el plazo que expire más tarde.
3. La prueba de que la invención está siendo explotada de conformidad con lo dispuesto en el apartado 1 incumbe al titular de la patente.

Artículo 91. Supuestos de concesión de licencias obligatorias.

Procederá la concesión de licencias obligatorias sobre una determinada patente cuando concurra alguno de los supuestos siguientes:

- a) Falta o insuficiencia de explotación de la invención patentada.
- b) Dependencia entre las patentes, o entre patentes y derechos de obtención vegetal.
- c) Necesidad de poner término a prácticas que una decisión administrativa o jurisdiccional firme haya declarado contrarias a la legislación nacional o comunitaria de defensa de la competencia.
- d) Existencia de motivos de interés público para la concesión.

e) Fabricación de productos farmacéuticos destinados a la exportación en aplicación del Reglamento (CE) n.º 816/2006 del Parlamento Europeo y del Consejo, de 17 de mayo de 2006, sobre la concesión de licencias obligatorias sobre patentes relativas a la fabricación de productos farmacéuticos destinados a la exportación a países con problemas de salud pública.

Artículo 92. Licencias obligatorias por falta o insuficiencia de explotación.

1. Una vez finalizado el plazo previsto en el artículo 90 para iniciar la explotación de la invención patentada, cualquier persona podrá solicitar la concesión de una licencia obligatoria si en el momento de la solicitud, y salvo excusas legítimas, no se ha iniciado la explotación de la patente o cuando tal explotación, una vez transcurrido dicho plazo, haya sido interrumpida durante más de un año.
2. Se considerarán como excusas legítimas las dificultades objetivas de carácter técnico legal, ajenas a la voluntad y a las circunstancias del titular de la patente, que hagan imposible la explotación del invento o que impidan que esa explotación sea mayor de lo que es.

Artículo 93. Licencias obligatorias por dependencia.

1. Cuando no sea posible explotar el invento protegido por una patente sin menoscabo de los derechos conferidos por una patente o por un derecho de obtención vegetal anterior, el titular de la patente posterior podrá solicitar una licencia obligatoria, para la explotación del objeto de la patente o de la variedad objeto del derecho de obtención vegetal anterior, mediante el pago de un canon adecuado.
2. Cuando no sea posible explotar un derecho de obtención vegetal sin menoscabo de los derechos conferidos por una patente anterior, el obtentor podrá solicitar una licencia obligatoria, para la explotación del invento protegido por la patente, mediante el pago de un canon adecuado.
3. Si una patente tuviera por objeto un procedimiento para la obtención de una sustancia química o farmacéutica protegida por una patente en vigor, tanto el titular de la patente de procedimiento como el de la patente de producto, tendrán derecho a la obtención de una licencia obligatoria sobre la patente del otro titular.
4. Los solicitantes de las licencias a que se refieren los apartados anteriores deberán demostrar:
 - a) Que la invención o la variedad representa un progreso técnico significativo de considerable importancia económica con relación a la invención reivindicada en la patente anterior o a la variedad protegida por el derecho de obtención vegetal anterior.
 - b) Que han intentado, sin conseguirlo en un plazo prudencial, obtener del titular de la patente o del derecho de obtención vegetal anterior, una licencia contractual en los términos previstos en el artículo 97.1.
5. Cuando proceda la concesión de una licencia obligatoria por dependencia, también el titular de la patente o del derecho de obtención vegetal anterior podrá solicitar el otorgamiento, en condiciones razonables, de una licencia para utilizar la invención o la variedad protegida por la patente o por el derecho de obtención vegetal posterior.
6. Las licencias obligatorias por dependencia se otorgarán solamente con el contenido necesario para permitir la explotación de la invención protegida por la patente, o de la variedad protegida por el derecho de obtención vegetal de que se trate, y quedarán sin efecto al declararse la nulidad o la caducidad de alguno de los títulos entre los cuales se dé la dependencia.
7. La tramitación y la resolución de las solicitudes de licencias obligatorias por dependencia para el uso no exclusivo de una invención patentada, se regirá por lo dispuesto en la presente Ley. La tramitación y la resolución de las solicitudes de licencias obligatorias por dependencia para el uso de la variedad protegida por un derecho de obtentor se regirán por su legislación específica.

Artículo 94. Licencias obligatorias para poner remedio a prácticas anticompetitivas.

1. La resolución administrativa o jurisdiccional firme que haya declarado la violación del derecho de la competencia por parte del titular de la patente se comunicará a la Oficina Española de Patentes y Marcas por la Comisión Nacional de los Mercados y la Competencia o por el Juez o Tribunal que la haya emitido.

2. Cuando la resolución decreta directamente la sujeción de la patente al régimen de licencias obligatorias, la Oficina Española de Patentes y Marcas la publicará en el «Boletín Oficial de la Propiedad Industrial» y procederá de acuerdo con lo previsto en los artículos 98 y 99 de esta Ley.
3. No será precisa en este caso la justificación de la negociación previa entre el titular de la patente y el potencial usuario, solicitante de la licencia obligatoria. La necesidad de corregir las prácticas anticompetitivas se podrá tener en cuenta al determinar el canon de la licencia.
4. Sin perjuicio de lo previsto en los apartados precedentes, cuando el Gobierno considere que existen razones de interés público para poner término a prácticas anticompetitivas, la sujeción de la patente al régimen de licencias obligatorias podrá acordarse por real decreto de acuerdo con lo previsto en el artículo siguiente.

Artículo 95. Licencias obligatorias por motivos de interés público.

1. Por motivo de interés público, el Gobierno podrá someter, en cualquier momento, una solicitud de patente o una patente ya otorgada, al régimen de licencias obligatorias, disponiéndolo así por real decreto.
2. Se considerará en todo caso que existen motivos de interés público cuando:
 - a) La iniciación, el incremento o la generalización de la explotación del invento, o la mejora de las condiciones en que tal explotación se realiza, sean de primordial importancia para la salud pública o para la defensa nacional.
 - b) La falta de explotación o la insuficiencia en calidad o en cantidad de la explotación realizada implique grave perjuicio para el desarrollo económico o tecnológico del país.
 - c) Las necesidades de abastecimiento nacional así lo exijan.
3. El real decreto al que se hace referencia en el apartado 1 deberá ser acordado a propuesta del Ministerio de Industria, Energía y Turismo. En los casos en que la importancia de la explotación del invento se relacione con la salud pública o con la defensa nacional, la propuesta deberá formularse conjuntamente con el Ministro competente en materia de sanidad o de defensa, respectivamente.
4. El real decreto que disponga la sujeción de la patente al régimen de licencias obligatorias podrá establecer directamente, en todo o en parte, el alcance, condiciones y canon de licencia en los supuestos previstos en el artículo 97.2, o remitir la fijación de tales condiciones al oportuno procedimiento ante la Oficina Española de Patentes y Marcas previsto en el capítulo siguiente para su concreción en la resolución que conceda la licencia.
5. Cuando la sujeción al régimen de licencias obligatorias por motivos de interés público se deba a su importancia para la defensa nacional, podrá reservarse la posibilidad de solicitar tales licencias a una o varias empresas determinadas.

Artículo 96. Licencias obligatorias para la fabricación de medicamentos destinados a países con problemas de salud pública.

1. Las solicitudes de licencias obligatorias presentadas en aplicación del Reglamento (CE) n.º 816/2006 del Parlamento Europeo y del Consejo, de 17 de mayo de 2006, sobre la concesión de licencias obligatorias sobre patentes relativas a la fabricación de productos farmacéuticos destinados a la exportación a países con problemas de salud pública, se dirigirán a la Oficina Española de Patentes y Marcas, en los modelos normalizados que se establezcan al efecto. Las licencias se tramitarán conforme a lo dispuesto en el citado Reglamento (CE) n.º 816/2006 y se registrarán por lo dispuesto en el mismo.
2. La licencia surtirá efecto a partir de la fecha en la que la resolución que la conceda se notifique al solicitante y al titular del derecho, aplicándose la que sea posterior. La resolución que acuerde la licencia establecerá el canon de la misma. La licencia podrá ser revocada por la Oficina Española de Patentes y Marcas si el licenciataria no cumple las condiciones bajo las que fue otorgada de acuerdo con lo previsto en el artículo 16 del citado Reglamento (CE) n.º 816/2006.

3. Sin perjuicio de cualquier otra consecuencia legalmente prevista toda infracción de la prohibición prevista en el artículo 13 del Reglamento (CE) n.º 816/2006 y en el artículo 2 del Reglamento (CE) n.º 953/2003 del Consejo, de 26 de mayo de 2003, destinado a evitar el desvío comercial hacia la Unión Europea de determinados medicamentos esenciales, se considerará una infracción de la patente sobre la que recae la licencia.

CAPÍTULO II

Procedimiento de concesión de las licencias obligatorias

Artículo 97. Justificación previa del solicitante de la licencia.

1. Previamente a la solicitud de una licencia obligatoria el interesado deberá probar que ha intentado, sin conseguirlo en un plazo prudencial, obtener del titular de la patente una licencia contractual en términos y condiciones comerciales razonables. Para las licencias previstas en el artículo 96, y salvo que se den las circunstancias previstas en el artículo 9.2 del Reglamento (CE) n.º 816/2006 al que se refiere el apartado 1 del artículo precedente, este plazo será en todo caso de treinta días, anteriores a la presentación de la solicitud.

2. Lo dispuesto en el apartado anterior no será aplicable:

- a) En los casos de emergencia nacional o en otras circunstancias de extrema urgencia.
- b) En los casos de uso público no comercial.
- c) En el supuesto previsto en la letra c) del artículo 91.

Artículo 98. Solicitud de la licencia.

1. La solicitud de licencia obligatoria, dirigida a la Oficina Española de Patentes y Marcas en el modelo normalizado que se establezca al efecto, deberá ir acompañada de la prueba que acredite el intento previo de licencia contractual, salvo en los casos previstos en el apartado 2 del artículo anterior. La solicitud estará sujeta al pago de la tasa correspondiente.

2. El solicitante, además de concretar su petición, deberá exponer las circunstancias que la justifiquen, aportar las pruebas de que disponga en apoyo de sus afirmaciones, y acreditar que cuenta con los medios y garantías suficientes para llevar a cabo una explotación real y efectiva de la invención patentada acorde con la finalidad de la licencia.

Artículo 99. Tramitación y resolución.

1. La Oficina Española de Patentes y Marcas dará traslado de una copia de la solicitud con los documentos que la acompañen al titular de la patente, a fin de que conteste en el plazo máximo de un mes. La contestación deberá ir acompañada de las pruebas que justifiquen las alegaciones realizadas. Si el titular de la patente no contestara dentro del plazo, dicha Oficina procederá a la concesión de la licencia.

2. Cuando, valoradas las alegaciones y pruebas presentadas, la Oficina Española de Patentes y Marcas considere que se dan las circunstancias que justifican la concesión de la licencia, invitará a las partes para que en el plazo de dos meses designen un mediador común o, en su defecto, nombre cada una un experto que, junto a un tercer experto nombrado por la mencionada Oficina, acuerden las condiciones de aquélla.

3. A falta de acuerdo sobre la designación de mediador o experto, o sobre las condiciones de la licencia en el plazo de dos meses adicionales, la Oficina Española de Patentes y Marcas decidirá sobre la concesión de la licencia y resolverá en consecuencia.

4. La resolución que otorgue la licencia deberá determinar el contenido de ésta. En particular habrá de fijar el ámbito de la licencia, el canon, la duración, las garantías que deba prestar el licenciatario, y cualesquiera otras cláusulas que aseguren el cumplimiento por su parte de las condiciones que justifican la concesión de la licencia.

5. Durante la tramitación del expediente, la Oficina Española de Patentes y Marcas podrá realizar de oficio las actuaciones que sean pertinentes y puedan ser de utilidad para resolver sobre la concesión de la licencia. Dicha Oficina podrá suspender por una sola vez la tramitación a petición justificada de ambas partes, en las circunstancias previstas en el Reglamento de ejecución de esta Ley.

6. La resolución determinará los gastos que hayan de ser sufragados por cada parte, que serán los causados a instancia suya. Los gastos comunes serán pagados por mitad. Podrá imponerse el pago de todos los gastos a una de las partes cuando se declare que ha actuado con temeridad o mala fe.

7. La interposición de un recurso administrativo o jurisdiccional contra la resolución que ponga término al expediente no suspenderá la ejecución del acto impugnado, pero la Oficina Española de Patentes y Marcas podrá autorizar al licenciataria previa petición fundada de éste, a demorar el comienzo de la explotación hasta que sea firme la concesión de la licencia.

CAPÍTULO III

Régimen de las licencias obligatorias

Artículo 100. Características de las licencias obligatorias.

1. Las licencias obligatorias no serán exclusivas.
2. La licencia llevará aparejada una remuneración adecuada según las circunstancias propias de cada caso, habida cuenta de la importancia económica de la invención.
3. Si la patente recae sobre tecnología de semiconductores las licencias obligatorias solo podrán tener por objeto un uso público no comercial o utilizarse para rectificar una práctica declarada anticompetitiva tras un procedimiento judicial o administrativo.
4. Las relaciones que mantengan el titular de la patente y el licenciataria con motivo de la concesión de una licencia obligatoria deberán atenerse a la buena fe. Para el titular de la patente, la aplicación de este principio incluirá la obligación de poner a disposición del licenciataria los conocimientos técnicos que posea y resulten necesarios para poder proceder a una adecuada explotación comercial del invento.

En caso de violación de este principio, declarada por sentencia judicial, por parte del titular de la patente, el licenciataria podrá pedir a la Oficina Española de Patentes y Marcas que reduzca el canon fijado para la licencia, en proporción a la importancia que tenga para la explotación del invento la obligación incumplida. Si en las mismas condiciones se declarase la actuación del licenciataria contraria a la buena fe contractual, el licenciante podrá instar de la mencionada Oficina la extinción de la licencia obligatoria.

5. La licencia obligatoria comprenderá los certificados complementarios de protección que al concederse la licencia o posteriormente, recaigan sobre el objeto de la patente de base incluido en el ámbito de la licencia obligatoria.
6. En cuanto no se opongan a lo dispuesto en este Título o en la normativa comunitaria, serán de aplicación a las licencias obligatorias las normas establecidas para las licencias contractuales previstas en el Título VIII, Capítulo II, de esta Ley.

Artículo 101. Cesión, modificación y cancelación de las licencias obligatorias.

1. Para que la cesión de una licencia obligatoria sea válida, será preciso que la licencia se transmita junto con la empresa o parte de la empresa que la explote y que la cesión sea expresamente anotada por la Oficina Española de Patentes y Marcas. Tratándose de licencias por dependencia de patentes será preciso, además, que la licencia se transmita junto con la patente dependiente.
2. Será nula, en todo caso, la concesión de sublicencias por parte del titular de una licencia obligatoria.
3. Tanto el licenciataria como el titular de la patente podrán solicitar de la Oficina Española de Patentes y Marcas la modificación del canon u otras condiciones de la licencia obligatoria cuando existan nuevos hechos que justifiquen el cambio y, en especial, cuando el titular de la patente otorgue, con posterioridad a la licencia obligatoria, licencias contractuales en condiciones injustificadamente más favorables a las de aquella.
4. Si el licenciataria incumpliera grave o reiteradamente algunas de las obligaciones que le corresponden en virtud de la licencia obligatoria, la Oficina Española de Patentes y Marcas, previa audiencia de la parte afectada, de oficio o a instancia de parte interesada, podrá cancelar la licencia.

SRI LANKA

Intellectual Property Act No. 36 of 2003

Section 86

Limitation of owner's rights.

86. (1) The provisions of section 84 shall—

- (i) extend only to acts done for industrial or commercial purposes and in particular shall not extend to acts done only for the purpose of scientific research ;
- (ii) not preclude a person having the rights referred to in section 87 or a licensee, from exploiting the patented invention ;
- (iii) not extend to the presence or use of products on foreign vessels, aircraft, spacecraft, or land vehicles which temporarily or accidentally enter the waters, airspace or territory of Sri Lanka ;
- (iv) not extend to acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under licence.

(2) (a) Any person, body of persons, a government department or a statutory body may make an application to the Director General for the purpose of obtaining a licence to exploit a patent in the manner hereafter provided.

(b) Upon the receipt of such application, the Director General may issue a license for exploitation if he is satisfied that the applicant has made efforts to obtain approval from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

(c) Director-General may waive the requirements set out in paragraph (b) where he has satisfied himself of the existence of a national emergency or any other circumstances of extreme urgency or in case of public non-commercial use for the purposes such as national security, nutrition, health or for the development of others vital section of the national economy.

(d) The exploitation of the patent shall be limited in scope and duration to the purpose as is specified in the licence. Such exploitation shall be predominantly for the purpose of supply to the domestic market.

(e) The Director-General shall consider each application on its individual merits before granting a licence to exploit a patent.

(f) The issuance of a licence shall be non-exclusive and subject to the payment of adequate remuneration to the owner of the patent taking into consideration the economic value as determined by the Director-General, and where applicable, the need to correct anti-competitive practices.

(g) Where such application is for the exploitation of the patent (the second patent) which cannot be exploited without infringing another patent (the first patent), the following conditions shall apply :

- (i) the invention claimed in the second patent shall involve and important technical advance of considerable economic significance in relation to the invention claimed in the first patent ;
- (ii) the owner of the first patent shall be entitled to a cross licence on reasonable terms to exploit the invention claimed in the second patent ; and
- (iii) the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(h) The decision of the Director-General, shall be notified in writing to the owner of the patent as soon as practicable.

(i) The Director-General, shall upon, the request of the owner or of the beneficiary of the licence, after hearing the parties, vary his decision by amending the terms subject to which licence for the exploitation of the patent is issued to the extent only that the changed circumstances justify such variation.

(j) The Director-General shall upon the request of the owner, terminate the non-voluntary license if he is satisfied that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the license has failed to comply with terms of such licence.

(k) Notwithstanding anything contained in paragraph, (j) the Director-General shall not terminate a licence, if he is satisfied that adequate protection of the legitimate interest of the beneficiary of the licence justifies the continuity of such licence.

(l) The licence to exploit a patent may be transferred only with the enterprise or the business of the licensee of such patent or with the part of such enterprise or business, in relation to which the licence to exploit has been granted.

(m) Where a judicial or administrative body has determined that the manner of exploitation of a patent by its owner or its licensee is anti-competitive, and the Director-General is satisfied that the exploitation of a patent in accordance with this section would remedy such practice, the Director-General may authorize any person, body of persons, government departments or statutory body to exploit the patent without a licence of the owner of the patent. The provisions of the above paragraphs except those of paragraphs (b), (c) and (g) shall be applicable to such licence.

(3) Any person aggrieved by any decision of the Director-General under subsection (2), may tender an appeal therefrom. The provisions of section 173 shall, mutatis mutandis, apply in respect of such appeal.

SUDAN

Patent Law no. 58 of 1971

Sections 34-44

Chapter Nine: Compulsory Licenses

34. Compulsory License for Non-Working and Similar Reasons:

(1) At any time after the expiration of a period of four years from the date of the filing of an application for a patent, or three years from the date of the grant of a patent, whichever period expires last, any person interested may, in accordance with the conditions specified in Section 44, apply for the grant of a compulsory license upon one or more of the following grounds:

(a) that the patented invention, capable of being worked within the Democratic Republic of the Sudan, has not been so worked within the terms of subsection (3);

(b) that the working of the patented invention within the Democratic Republic of the Sudan does not meet on reasonable terms the demand for the product;

(c) that the working of the patented invention within the Democratic Republic of the Sudan is being prevented or hindered by the importation of the patented article;

(d) that, by reason of the refusal of the registered owner of the patent to grant licenses on reasonable terms, the establishment or development of industrial or commercial activities in the Democratic Republic of the Sudan is unfairly and substantially prejudiced.

(2) In all the above cases, a compulsory license shall not be granted if the owner of the patent proves that his actions in respect of the patented invention are legitimately justifiable in the circumstances. Importation shall not constitute a legitimate reason.

(3) The working of a patented invention under this Section means the manufacture of a patented article, the application of a patented process, or the use in manufacture of a patented machine, by an effective and serious establishment existing within the Democratic Republic of the Sudan, and on a scale which is adequate and reasonable in the circumstances.

(4) A compulsory license shall permit the Licensee to perform some or all the acts referred to in Section 21 with the exception of importation.

35. Compulsory License for Products and Processes Declared to be of Vital Importance for the Defense or Economy of the Country or for Public Health:

The Minister may, by order, provide that, for certain patented products or processes, or for certain categories of such products and processes, which are declared by that order of vital importance for the defense or the economy of the Democratic Republic of the Sudan or for public health, compulsory licenses may be granted, in the conditions provided for in Section 34, even before the expiration of the period mentioned in subsection (1) of that Section and even for importation into the Democratic Republic of the Sudan.

36. Compulsory Licenses Based Upon Inter-Dependence of Patents:

(1) If an invention protected by a patent within the Democratic Republic of the Sudan cannot be worked without infringing rights deriving from a patent granted on a prior application or benefiting from an earlier priority, a compulsory license may, upon application, be granted under the conditions specified in Section 44 to the registered owner of the later patent, to the extent necessary for the working of his invention, insofar as such invention serves industrial purposes different from those of the invention forming the subject of the earlier patent, or constitutes noteworthy technical progress in relation to it.

(2) If the two inventions serve the same industrial purpose, a compulsory license shall be granted only if a license is granted in respect of the later patent to the registered owner of the earlier patent, if he so requests.

37. Refusal of Contractual License:

Any person who applies for a compulsory license under Sections 34, 35 or 36 must furnish proof showing that he has previously approached the registered owner of the patent, by registered letter, requesting a contractual license, but has been unable to obtain such a license from him on reasonable terms and within a reasonable time.

38. Guarantee Required from Applicant for a Compulsory License:

In the cases provided for in Sections 34 and 35, a compulsory license shall be granted only to an applicant offering the necessary guarantees to work the invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to the application for the compulsory license.

39. Scope of Compulsory Licenses:

(1) Compulsory licenses shall be non-exclusive.

(2) The terms of a compulsory license, fixed in accordance with Section 44, may contain obligations and restrictions both for the licensee and for the registered owner of the patent.

40. Compensation: A compulsory license shall only be granted subject to the payment of adequate royalties commensurate with the extent to which the invention is worked.

41. Transfer of Compulsory License:

(1) A compulsory license may only be transferred with the undertaking of the licensee or with that portion of his undertaking which uses the patented invention. Any such transfer shall, on pain of invalidity, require the authorization of the authority which granted the compulsory license.

(2) Sections 42 and 44 shall be applicable to the transfer of a compulsory license.

(3) The grantee of a compulsory license shall not be entitled to grant sublicenses.

42. Registration of Compulsory License:

Every compulsory license shall, either at the request of the interested party or following notification to the Patent Office provided for in subsection 44(4), be registered at the Patent Office without fee. The license shall have no effect as against third parties until such registration.

43. Amendment and Cancellation of Compulsory License:

- (1) Upon the request of the registered owner of the patent or of the licensee of the compulsory license, the terms of the license may be amended by the authority which granted it when new facts so justify, in particular when the registered owner of the patent grants contractual licenses on terms more favorable to the contractual licensees.
- (2) At the request of the registered owner of the patent, the compulsory license may be cancelled if the licensee does not comply with the prescribed terms of the license or if the conditions which justified the grant of the compulsory license have ceased to exist; in the latter case, a reasonable time shall be given to the licensee to cease working the invention if an immediate stoppage would cause serious damage to him.
- (3) Sections 42 and 44 shall be applicable to the amendment and cancellation of compulsory licenses.

44. Procedure:

- (1) Any application for a compulsory license shall be made to the Court.
- (2) The Registrar of the Court shall invite, by registered letter, the applicant for the compulsory license and the registered owner of the patent to appear or to be represented before the Court within a reasonable time; the Court shall hear the party or parties or their representatives who have appeared. before granting a compulsory license, the Court shall seek the advice of the Minister, who may delegate a representative to intervene at the hearing and to make any pertinent observations.
- (3) The Court shall first decide whether a compulsory license may be granted. If it finds that it may be granted, it will give the parties reasonable time to agree on the terms. If there is no agreement between the parties when the time limit expires, the Court shall fix the terms, including the amount of royalties referred to in section 40. The terms of a compulsory license, including those relating to royalties, shall be considered to constitute a valid contract between the parties.
- (4) The decision of the Court granting a compulsory license shall be notified by the Registrar of the Court to each of the parties involved and to the Patent Office.

SWEDEN

Patents Act (1967:837) (as amended up to Act (2018:273))

Articles 44-50

Article 44. (Enters into force on the date determined by the Government). If a patent had been transferred to another party or a license has been granted, this fact shall, upon request, be recorded in the Register of Patents.

If it has been proved that a license recorded in the Register has ceased to be valid, the recording of the license shall, upon request, be cancelled.

The first and second Paragraphs apply also to any right referred to in Article 53, second Paragraph, and to any compulsory license, however not to a compulsory license to exploit an invention protected by a European patent referred to in Article 80, third Paragraph.

In cases or matters concerning a patent, the party that has last been recorded as patent holder in the Register of Patents be deemed to be the patent holder. (Act 2016:726).

Article 45. A compulsory license to exploit an invention in Sweden may be granted if
1. three years have passed from the point in time when the patent was granted and four years from the filing of the patent application,

2. the invention is not exploited to a reasonable extent in Sweden, and
3. any acceptable reason is lacking why the invention is not being exploited.

For the purposes of application of the first Paragraph, item 2, the import of the invention to Sweden from a State within the European Economic Area or a State or a Territory party to the Agreement on the Establishment of the World Trade Organization (WTO) shall be put on an equal footing with exploitation of an invention. (Act 2004:159)

Article 46. A holder of a patent for an invention the exploitation of which is depending on a patent belonging to someone else may be granted a compulsory license to exploit the invention protected by the other patent. Such a license may be granted only if the applicant proves that the first-mentioned invention constitutes an important technical progress of considerable economic interest compared with the other invention.

If a compulsory license is granted pursuant to the first Paragraph, the holder of the patent in which a compulsory license has been granted is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the other invention. (Act 2004:159).

Article 47. If a public interest of exceptional importance so requires, anyone who desires to commercially exploit an invention for which another party holds a patent may obtain a compulsory license to do so.

Article 48. Any party which in this country was commercially exploiting an invention which is the subject of a patent application at the time when the application documents were made available pursuant to Article 22, may, if the application results in a patent, obtain a compulsory license for the exploitation, if exceptionally strong reasons exist and it had no knowledge of the application and had not reasonably been able to obtain such knowledge. Under corresponding conditions such a right shall also be granted to anyone who has made substantial preparations for commercial exploitation of the invention in this country. A compulsory license may also apply for a time before the patent was granted.

Article 49. A compulsory license may only be granted to a party that can be assumed to exploit the invention in an acceptable manner and in conformity with the license. The applicant must also prove that he or she has unsuccessfully turned to the patent holder for obtaining a contractual license on reasonable conditions. A compulsory license does not prevent the patent holder from exploiting the invention himself or to grant licenses. A compulsory license may be assigned to someone else only together with a business where it is exploited or was intended to be exploited. In respect of compulsory licenses referred to in Article 46, first Paragraph, and Article 46 a, first Paragraph, it also applies that the license may be assigned only together with the patent or the plant variety right on which the license is based. (Act 2004:159).

Article 50. A compulsory license is granted by the Court, which also decides to what extent the invention may be exploited and establishes the remuneration and other terms for the license. When substantially changed circumstances call for it, the Court may, upon demand, revoke the license or establish new conditions for it.

SWITZERLAND

Federal Act of June 25, 1954, on Patents for Inventions (status as of April 1, 2019)

Articles 36-40e

Art. 36 Dependent inventions

1 If a patented invention cannot be used without infringing a prior patent, the proprietor of the later patent has the right to a nonexclusive licence to the extent required to use his invention, provided that the invention represents an important technical advance of considerable economic significance in relation to the invention that is the subject-matter of the prior patent.

2 A licence to use the invention that is the subject-matter of the prior patent may only be transferred jointly with the later patent.

3 The proprietor of the prior patent may make the grant of a licence conditional on the proprietor of the later patent granting him a licence to use his invention in return.

Art. 36a Dependent plant variety rights

1 When a plant variety right may not be claimed or used without infringing an earlier-granted patent, the plant breeder or the owner of the plant variety has the right to a non-exclusive licence to the extent

required to obtain and use his plant variety right, provided that the plant variety represents an important advance of considerable economic significance in comparison to the patent-protected invention. For varieties for agriculture and food, the criteria under the Seed Ordinance of 7 December 1998⁸⁵ serve as a reference point.

2 The proprietor of the patent may make the grant of a licence conditional on the owner of the plant variety granting him a licence to use his plant variety right in return.

Art. 37 Action for the grant of a licence

1 Three years from the date of the grant of the patent, or at the earliest four years after filing the patent application, any person with a legitimate interest may apply to the court for the grant of a non-exclusive licence to use the invention if the proprietor of the patent has not sufficiently exploited it in Switzerland by the time of the action and cannot justify such a failure. Importing is also considered domestic exploitation.

2 [...]

3 At the request of the plaintiff, the court may grant a licence immediately after the action has been filed without prejudice to the final judgment providing that, in addition to the conditions set out in paragraph 1, the plaintiff provides prima facie evidence that he has an interest in the immediate use of the invention and that he provides adequate security to the defendant; the defendant shall be given the opportunity to be heard beforehand.

Art. 38 Action for cancellation of the patent

1 If the grant of licences does not suffice to meet the demand of the domestic market, any person with a proven interest may bring an action for the cancellation of the patent after a period of two years

from the grant of the first licence under Article 37 paragraph 1.

2 If the legislation of the country of which the proprietor of the patent is a national or in which he is resident allows an action for cancellation of the patent for failure to exploit the invention in that country as early as three years after the grant of the patent, such an action shall be allowed instead of the action for the grant of a licence, subject to the conditions specified in Article 37 for the grant of licences.

Art. 39 Exceptions

The Federal Council may decree Articles 37 and 38 to be inapplicable with regard to nationals of countries granting reciprocity.

Art. 40 Licence in the interest of the public

1 Where public interest so dictates, the person to whom the proprietor of the patent has, without sufficient reason, refused to grant the licence requested, may apply to the court for the grant of a licence to use the invention.

Art. 40a Compulsory licences in the field of semi-conductor technology

For inventions in the field of semi-conductor technology, a nonexclusive licence may only be granted to remedy a practice held to be anti-competitive in court or administrative proceedings.

[...]

Art. 40c Compulsory licences for diagnostic tools

For inventions concerning a diagnostic product or procedure for humans, a non-exclusive licence shall be granted to remedy a practice held to be anti-competitive in court or administrative proceedings.

Art. 40d Compulsory licences for the export of pharmaceutical products

1 Any person may bring an action before the court to be granted a nonexclusive licence for the manufacture of patent-protected pharmaceutical products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics (beneficiary country).

2 Countries that have declared in the World Trade Organization (WTO) that they wholly or partly renounce their claim to a licence in accordance with paragraph 1 are excluded from being beneficiary

countries in accordance with the terms of their declaration. All other countries that fulfil the requirements of paragraph 1 may be beneficiary countries.

3 The licence in accordance with paragraph 1 is limited to the production of the pharmaceutical product in the quantity that meets the requirements of the beneficiary country; the total quantity must be exported to the beneficiary country.

4 The owner of the licence in accordance with paragraph 1, as well as any manufacturer that produces products under licence, must ensure that they are clearly identified as products that have been produced under a licence in accordance with paragraph 1, and that the products are distinguished by their packaging or by their special colouring or shape from patent-protected products, provided this does not have a significant impact on the price of the products in the beneficiary country.

5 The Federal Council shall regulate the requirements for the grant of licences in accordance with paragraph 1. In particular, it shall stipulate the information or notifications the responsible court must possess in order to be able to decide on the grant of the licence in accordance with paragraph 1, and shall regulate the measures in accordance with paragraph 4.

Art. 40e Common provisions for Articles 36-40d

1 The licences provided for in Articles 36–40d are granted only if efforts by the applicant to obtain a contractual licence on appropriate market terms within a reasonable period of time have been unsuccessful; in the case of a licence in accordance with Article 40d, a period of 30 working days is regarded as reasonable. Such efforts are not required in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

2 The scope and term of the licence are limited to the purpose for which it has been granted.

3 The licence may only be transferred with that part of the enterprise which uses the licence. This also applies to sub-licences.

4 The licence is primarily granted for supplying the domestic market. Article 40d remains reserved.

5 The proprietor of the patent has the right to appropriate remuneration. In assessing the remuneration, the circumstances of the individual case and the economic value of the licence are taken into account. In the case of a licence under Article 40d, the remuneration is determined by taking into account the economic value of the licence in the importing country, its level of development and the urgency in public health and humanitarian terms. The Federal Council shall specify the method of calculation.

6 The court shall decide on the grant and revocation of licences, on their scope and duration as well as on the remuneration payable. In particular, it shall revoke an entitled person's licence on request if the circumstances that led to its being granted no longer apply and it is not expected that they will arise again. Appropriate protection of the legal interests of the entitled person remains reserved. Where a licence is granted under Article 40d, legal remedies have no suspensive effect.

SYRIAN ARAB REPUBLIC

Law No. 18 of 2012
[non-official translation]²

Articles 39-41

Chapter Seven.

Compulsory licenses

Article 39-

The Directorate, after the approval of a ministerial committee that is formulated by a decision of the prime minister, shall grant obligatory licenses to employ the invention, and the Committee stipulates the financial rights to the patent owner when issuing these licenses, in the following conditions:

First: If the minister in charge, considering the situation at hand, finds that the employment of the invention achieves the following:

1- Purposes of non-commercial public interest, such as the preservation of national security, health, and safety of the environment, food and climate.

2- Facing emergency or requirements of extreme circumstances,

The obligatory license to handle the conditions mentioned in articles 1 and 2, shall be as follows:

a- By-passing the need of negotiation with the patent owner.

b- The elapse of lengthy time in negotiation with the owner without reaching agreement.

c- Offering reasonable terms to obtain the owner's approval of patent employment without reaching agreement.

3- Supporting the national efforts in sectors vital for development in economy, society, technology, environment, climate and food, without causing unreasonable breach of the rights of the patent owner, and with consideration of the legitimate rights of third party.

4- The patent owner must be notified of the compulsory license decision within 15 days in the cases mentioned in articles 1 and 3, and at the earliest time possible in the cases mentioned in article 2.

² Available at:
<http://www.agip.com/UploadFiles/Laws/En%20%20New%20patent%20law%20No%20%2018.doc>
(Accessed May 3, 2019)

Second: Upon request of the minister of health, in any of the events of insufficiency of the patently protected medicines to meet the country's needs, or of the extra ordinary rise in their prices, or if the patent is associated with severe cases, chronic ,incurable or dwelling diseases, or products used in the protection from those diseases ,whether the invention was associated with the medicines, their mode of production ,the basic raw material that enters in their production or the method of preparation of the necessary raw material for their production. And in all these conditions the patent owner must be notified of the decision that grants the obligatory license within 15 days.

Third: If the patent owner refused the licensing of third party to employ the invention, whatever is the purpose of the usage, in spite of offering him proper terms, and the elapse of reasonable time in negotiation, in accordance with the provisions stated in the Executive List. The applicant for obligatory license, in this event, has to prove that he has made serious attempts to obtain voluntary license from the patent owner.

Fourth: If the patent owner does not invest the patent in Syria ,or make it available in the markets for reasonable prices with or without his knowledge ,or if investing it was insufficient in spite of the elapse of four years since the patent application date ,or three years since the date of granting it, whichever was longer, and also if the patent owner halted the invention employment for no valid reason for a period that exceeds a year.

This employment shall be in the form of producing the protected product in Syria, or in the usage of the manufacture method protected by the patent to produce it.

And nevertheless, if the Directorate views that, in spite of the expiry of any of the two said terms, failure in employing the invention is attributed to legal, technical or economic reasons that are beyond the patent owner's intention, the Directorate may grant him a six month grace period to employ the invention.

Fifth: If the patent owner is proved to be exigent ,or practicing his patently acquired rights such as:

1-Exaggeration in the selling price of the patently protected products, or discrimination between clients with regards to the product's prices and conditions of selling.

2-Failure to maintain the availability of the patently protected product in the market, or providing it under transgressed terms.

3-Discontinuation of the patently protected product in the market ,or producing amounts that do not attain the balance between production capability and market requirements.

4-Carrying out actions or behaviours that negatively impact on free competition within the prevailing legal limits.

5- Practice of the rights that the law avails in a manner that impacts negatively on technology transfer.

In all the aforementioned cases, compulsory licensing shall be issued needless of negotiation, or expiry of time frame of carrying it, and it will be published in the Protection Gazette at the expense of the licensee.

The Directorate may refuse the termination of obligatory license, if the conditions that led to its issuance ,indicate its continuity or forecast its recurrence.

At the time of assessment of accrued compensation to patent owner, the damages caused by his transgressed or counter-competitive actions must be taken in consideration.

The Directorate may cancel the patent , after the elapse of two years from the issuance date of obligatory license, if it finds that the license was insufficient to alleviate the negative results that affected the national economy due to the exigencies of patent owner in practicing his rights or due to his non-competitive practices.

Everyone concerned may contest the patent cancellation in front of the ministerial committee in accordance with the situations and procedures set in the Executive List of this Law.

Sixth: If the employment of an invention, by the owner of the invention patent right, cannot be performed unless performed with the employment of another invention useful to it, and the first invention comprises tangible technical advancement, and economic and artful importance in comparison with the other, the right's owner is entitled to acquire an obligatory license facing the other, and the latter is entitled to the same right in this situation.

Seventh: In the cases of inventions related to semiconductors ,obligatory license shall not be granted except for non-commercial public welfare purposes ,or to remedy effects proven as non-competitive.

Granting obligatory licenses in the conditions stated in this article shall be carried out in accordance with the situations and procedures set in the Executive List of this Law.

Article 40-

The following must be taken in consideration at the issuance of obligatory licenses:

- 1- A request of obligatory license must be decided on in view of each case's circumstances separately, and the license must aim ,in principle, at the provision of local market's requirements.
- 2- The applicant for an obligatory license must prove that he made serious efforts to obtain a voluntary license from the patent's owner in exchange of an equitable compensation but he failed.
- 3- The patent owner must have the right of objection to the decision, that granted the obligatory license to a third party, in front of the ministerial committee mentioned in article39 of this Law, within thirty days from the date of his notification of this license, and the committee's decision shall be contestable in front of the competent court within thirty days from the date of notification, according to the procedures stated in the Executive List.
- 4- The applicant for a compulsory license or the person in whose favor the license is issued must be capable of employing the invention in a serious manner in the Syrian Arab Republic.
- 5- The licensee in an obligatory license must undertake to employ the invention within the boundaries, conditions and time frame stated in the decision of granting this compulsory license, and if the license's duration expires without the absence of the reasons for granting this license, the Directorate may renew the duration.
- 6- Employment of obligatory license is confined to its applicant. Nevertheless, the Directorate may grant it to a third party, after the approval of the ministerial committee stated in article39.
- 7- The patent owner is entitled to receive an equitable compensation in return for employment of his invention, and in assessing this compensation ,the economic value of the invention must be taken in consideration, and the patent owner has the right to complain from compensation assessment decision to the Ministerial committee stated in article 39 within thirty days from the date of his notification of the decision ,in accordance with the situations and procedures mentioned in the Executive List of this Law.
- 8- The obligatory license must terminate with the expiry of its term, but nevertheless the Directorate may decide, by its own will, or on the basis of a request by any concerned party, and after approval of the ministerial committee, stated in article 39 of this Law, to abrogate the obligatory license before its expiry, if the reasons for granting it discontinue,. With ruling out the possibility of their recurrence . To this end, the procedure stated in the Executive List must be followed.
- 9- The invention owner is entitled to request the termination of obligatory license before the expiry of its time limit if the reasons that led to acquiring it discontinue, with ruling out their recurrence.
- 10- The lawful interests of the licensee must be considered at the termination of compulsory license prior to its expiry.

11- The Directorate shall have the right to cancel the compulsory license or amend its conditions, in its own prerogative, or on the basis of a request by a relevant party ,after approval of the ministerial committee ,stated in article 39 of this Law ,if the licensee fails to employ the license ,or if he defaulted on his obligations ,stipulated in the compulsory licensing.

Article 41-

By a decision of the minister in charge ,after approval of the ministerial committee referred to in article 39 of this Law ,the patent ownership may be cancelled ,for reasons relating to national security and in the events of utmost necessity whereby compulsory licensing is insufficient to face the events.

And cancellation of ownership may be confined to cancelling the right of employment of the invention to meet the needs of the State. However ,cancelation of ownership shall be in exchange for an equitable compensation of which assessment is the task of the ministerial committee stated in article 39 of this Law, and corresponding to the prevalent economic value at the time of issuing the decision of ownership cancellation . The decision of ownership cancellation shall be published in the Ownership Protection Gazette at the expense of the Directorate .Contesting the ownership cancellation decision and the Committee's decision of assessment of compensation shall be in front of the competent court within sixty days from

The date of notification of the relevant party of the decision ,and the court decides in this contest in an urgent manner.

TAJIKISTAN

Law of the Republic of Tajikistan No. 17 of February 28, 2004, on Inventions (as amended in 20.08.2016)

Articles 18, 20, 26, and 28

Article 18. Use of invention, utility model and industrial design without consent of the patent owner

For the purposes to ensure national security interests, relevant executive authority holds right to give agreement to use the invention, utility model and industrial design without permission of the patent owner. In these cases appropriate compensation shall be paid to the patent owner. In case the patent owner disagrees with the amount of compensation, can appeal in an administrative order or to the court.

Article 20. Compulsory license and other cases of use without permission of the patent owner

1. Any legal entity or natural person can appeal to the court by the claim on assignment of the compulsory license for use of invention, utility model and industrial design in case the patent owner or his/her successor do not use the invention, utility model and industrial design from the date of grant of patent for 3 years without reasonable ground, do not take serious preparatory works for use, or terminate the use more than 3 years and refuse to grant license after expiry of this period. Compulsory license holds non-exclusive character.

If the licensee does not use the compulsory license for 2 years from the date grant of license, patent owner can take into the court for cancellation of the license by the order designated by the relevant executive authority.

From the date of granting compulsory license, relations between the patent owner and the person who get compulsory license shall deemed to be equal to the relations between the licensor and the licensee designated by this Law.

2. By following the conditions below, subject matter of the patent can be used in other cases by the state or the persons authorized by them without permission of the patent owner:

2.1. grant of permission for such a use shall be based on individual peculiarities of the subject matter of the patent;

2.2. permission for use can be granted, in case efforts of the user requested to the right owner before such kind of use to get consent, resulted in failure providing admissible commercial conditions.

This condition may be not followed in case of emergency or force-major, as well as in cases use of the right by the state for non-commercial purposes of the state. In this case patent right owner must be informed as soon as possible;

2.3. scope and term of such kind of use shall be restricted by the purpose of given consent; in the field of semiconductors technology it only shall be regarded for non-commercial purposes by the state or prevention of the practice defined as restricting the competition in the result of judicial or administrative procedures;

2.4. such kind of use does not carry exclusive character;

2.5. without being part of the enterprise or its intangible assets, which realizes such kind of use, cannot be assigned to the other persons;

2.6. main purpose for consent to any such use shall be firstly, meeting the demands of internal market;

2.7. providing ensure of legal interests of the persons received consent, right to use shall be terminated if the circumstances that led to this kind of use eliminates and probability of repetition of them are low.

Relevant executive authority holds discretion to reconsider the issue of granting permission for such use if a well-founded application containing the cases indicated in this article has been received;

2.8. relevant bonus (compensation) is paid to the right owner taking into consideration of features of every case and economic value of the agreement;

2.9. decision on the agreement for such kind of use and the bonus (compensation) paid to the right owner can be complained in judicial and administrative order;

2.10. conditions indicated in Paragraph 2.2 and 2.6 of this Article shall not be applied in case grant of agreement for use of the subject matter of the patent for the purposes of elimination of the practice defined as restricting the competition in the result of judicial or administrative procedures.

Amount of the bonus (compensation) may be taken into account while regarding the necessity of elimination of the practice restricting the competition. In case there is possibility of recurrence of the grounds for giving consent, relevant executive authority may refuse the revocation of the consent;

2.11. if the consent for such kind of use is given for impossibility of the use of patent (second patent) without infringement of the other patent (first patent) rights, the following additional conditions shall be applied:

a) invention must reflect in itself significant technical solution which has huge economic value in the claim document for obtaining the second patent in comparison with the invention which is the subject matter of the first patent;

b) must have the right to conclude a cross-license agreement based on reasonable terms for use of the invention claimed by the second patent of the owner of the first patent;

c) right to use the first consent granted to the first patent cannot be granted to the others excluding assignment of rights on the second patent.

3. The following terms must be reflected in the license agreement while granting compulsory license to the exported patented pharmaceutical products:

a) production under license can be produced only in the quantity needed for the purpose of meeting minimum demands of imported state;

b) product produced under license must be differentiated from the imported product by the relevant sign or mark. Such kind of distinction of the products produced under license can be realized by the special bendings and (or) directly colors of the products (forms) only on

conditions that this factors of distinction shall be capable and not influence the prices of the products;

c) Following information about the licensed products shall be placed on the Internet-site (web-site) of the World Trade Organization before the export of them:

quantity of the products exported to all directions;

distinctive features of the products .

Article 26. Rights of a patent owner

If a patent holder cannot use an invention to which he has an exclusive right, without infringing on the rights of the holder of another patent (first patent) which has refused to conclude a license contract on the terms complying with the prevailing practices, the holder of the patent shall have the right to file a claim with the court for the issuance of a compulsory license (Article 28 of this Law) for the use of that invention on the territory of the Republic of Tajikistan. In the claim the conditions for granting such license to the holder of the second patent shall be indicated, including the scope of use of the invention, the amount of, procedure and terms for payments.

If the holder of the second patent, having an exclusive right to such dependent invention, proves that it is an important technical achievement and that it has significant economic advantages over the invention of the holder of the first patent, the court shall take a decision on granting him a compulsory license.

The right obtained under such license of using the invention may not be assigned to other persons, except for the case of alienation of the second patent. When a compulsory license is granted in accordance with the present item, the holder of the first patent, on the terms complying with the prevailing practices, shall have the right to obtain a nonexclusive license for the use of the dependent invention.

Article 28. Compulsory license

The patent owner shall be obliged to use the invention. In the event that an invention remains unused or insufficiently used by the patent owner for five years after the date of publication of the grant of a title of protection, any person willing and ready to use the invention may, if the patent owner refuses to enter into a license contract with such party on such terms and conditions as are consistent with prevailing practice, go to court to demand the grant thereto of a compulsory license to use such invention.

If the owner of a title of protection fails to prove that he made no or insufficient use of the invention for a valid reason, the court shall make a decision on the grant of a compulsory license

Where a compulsory license is granted on the basis of a court finding, such license shall set limits on the use of the invention the title of protection for which is owned by the other person to the extent which may be necessary to use the invention owned by the person who demanded that grant of such compulsory license, and shall prescribe the amount of royalties, as well as time periods and procedures for their payment.

For national security reasons and in force majeure circumstances (natural disasters, catastrophes, major accidents) the Government of the Republic of Tajikistan shall have the right to authorize the use of an invention subject to payment of a commensurate compensation to the patent owner, whereby the scope and duration of use of the patented invention shall be limited to the purpose for which it was authorized. A compulsory license shall be non-exclusive; it may not be reassigned to another person. Disputes arising as a result of such use shall be settled by the court.

A compulsory license shall be subject to mandatory registration with the Patent Office, without which it shall be deemed invalid.

THAILAND

Patent Act B.E. 2522 of 11/03/1979 as amended by the Patent Act No.2 B.E 2535 and the Patent Act No.3 B.E. 2542

Sections 45-52

45. Any patentee may, in accordance with the rules and procedures as prescribed in the Ministerial Regulations, apply to the Director-General for an entry to be made in the register to the effect that any other person may obtain a license.

At any time after an entry has been made, the Director-General shall grant a license under the patent to any person who applies for such a license on such conditions, restrictions and royalty terms as agreed upon by the patentee and the applicant. If the patentee and the applicant cannot agree within the period as prescribed by the Director-General, the Director-General shall grant a license on such conditions, restrictions and royalty terms as he deems appropriate.

Any of the parties may appeal the decision of the Director-General made under the preceding paragraph to the Board within thirty days from the receipt of the decision.

The decision of the Board shall be final.

The application for and grant of a license under the second paragraph shall comply with the rules and procedures as described by the Ministerial Regulations.

Where an entry is made pursuant to the first paragraph, the annual fees in respect of the patent after the date of the entry shall be reduced as prescribed by a Ministerial Regulations, by at least one half of the annual fees which would be payable if the entry had not been made.

46. At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows:

(1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or

(2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

Whether it is an application under (1) or (2), the applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed in the Ministerial Regulations.

47. If the working of any claim in a patent is likely to constitute an infringement of a claim in a patent of any other person, the patentee, desiring to exploit his own patent, may apply to the Director-General for a license under the patent of the other person under the following criteria:

(1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;

(2) the patentee shall be entitled to a cross-license on reasonable terms;

(3) the applicant shall not assign his right in the license to other persons except with the assignment of his patent.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed by the Ministerial Regulations.

47bis. - If the working of any claim in the patent having obtained a license under Section 46 is likely to constitute an infringement of a claim in a patent of any other person, the applicant for a license under Section 46 may apply to the Director- General for a license under the patent of the other person under the following criteria:

(1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;

(2) the applicant shall not assign his right in the license to other persons.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having purposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedure prescribed by the Ministerial Regulations.

48. Where a compulsory license is granted under Section 46, 47 or 47bis , the patentee shall be entitled to remuneration. The licensee under Section 38 shall be entitled to remuneration where a compulsory license is granted under 46, 47 or 47bis, provided that he has the exclusive right to grant licenses to other persons. In such circumstances, the patentee shall not be entitled to such remuneration.

49. In an application for a license made under Section 46, 47 or 47bis, the applicant shall set forth the amount of remuneration, the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licensee under paragraph 2 of Section 48, and a request for a license. In the application for a license under Section 47, the applicant shall also offer a license under his patent to the other party.

50. Where it is decided by the Director-General that a license shall be granted to the applicant under Section 46, 46 bis or 47, the Director-General shall set forth the royalty and the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licensee under Section 48 paragraph 2 as agreed upon by the patentee and the applicant. If no agreement has been reached by the parties within the period prescribed by the Director-General, the Director-General shall fix the royalty and prescribed the conditions and restriction as he deems appropriate subject to the following requirements:

- (1) the scope and duration of the license shall not be more than necessary under the circumstances;
- (2) the patentee shall be entitled to further license others;
- (3) the license shall not be entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license;
- (4) the licensing shall be aimed predominantly for the supply of the domestic market;
- (5) the remuneration fixed shall be adequate for the circumstances of the case.

The decision of the Director-General made under the first paragraph of the Section is appealable to the Board within sixty days from the date on which such decision is received.

The issuance of a licensing certificate shall comply with the form, rules and procedures prescribed in the Ministerial Regulations.

50bis. A license issued under Section 46 may be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur provided that the termination does not affect the rights or interests of the licensee under the license.

The application for termination of a license under the first paragraph shall be in accordance with the forms, rules and procedures prescribed in the Ministerial Regulations, the provisions of Section 49 paragraphs two and three and Section 50 applying *mutatis mutandis*.

51. In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 46 bis and 47.

In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply *mutatis mutandis*.

52. - During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay.

The patentee may appeal the order or the amount of remuneration to the court within sixty days from the receipt of the order.

TONGA

Industrial Property Act No. 19 of 1994

Sections 13 and 15

13 - Rights conferred by patent; exploitation by Government or person thereby authorized.

(1) Exploitation in respect of a patented invention means any of the following acts —

(a) when the patent has been granted in respect of a product, the making, importing, exporting, offering for sale, setting and using the products or stocking such products for the purposes of offering for sale;

(b) when the patent has been granted in respect of a process, using the process or doing any of the acts referred to in sub-paragraph (a) in respect of a product obtained directly by means of the process.

(2) Subject to subsections (4) and (5) and section 15, the exploitation of the patented invention in Tonga by persons other than the owner of the patent shall require the patentee's permission.

(3) The patentee shall, in addition to any other rights, remedies or actions available to him, have the right, subject to subsections (4) and (5) and section 15, to institute court proceedings against any person who exploits the patent without his permission, or who performs acts which may likely infringe the patented invention.

(4) The rights under the patent shall not extend,

(a) to acts in respect of articles which have been put on the market in Tonga by the patentee or with his consent;

(b) to the use of articles on aircraft, land vehicles, or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Tonga;

(c) to acts done only for experimental purposes relating to a patented invention;

(d) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention in Tonga or was making effective and serious preparations in Tonga for such use, to the extent that such acts do not differ in nature or purpose from the actual or envisaged prior use; this right may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

(5) (a) Where the public interest, in particular, national security, nutrition, health or the development of other vital sector of the national economy so require, the Minister may decide that, even without the permission of the patentee, a government agency or a third person designated by the Minister may exploit the invention, subject to the payment of an equitable remuneration to the patentee.

(b) The decision of the Minister with regard to remuneration may be the subject of an appeal before the Court.

15 - Non-voluntary licences

(1) On the request of any person who proves his ability to work a patented invention in Tonga made to the Registrar after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Registrar may grant a non-voluntary licence if the patented invention is not worked or is insufficiently worked in Tonga.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the patentee satisfies the Registrar that circumstances exist which justify the non-working or insufficient working of the patented invention in Tonga. Importation shall not constitute such a circumstance.

(3) The beneficiary of the non-voluntary licence shall have the right to exploit, other than to import, the patented invention in Tonga according to the terms set down in the decision granting the licence and, shall commence the working of the patented invention in Tonga within the time limit fixed in the said decision and, thereafter, shall work the patented invention sufficiently in Tonga, subject to the payment of an equitable remuneration therefor as determined in the said decision.

(4) The grant of the non-voluntary licence shall not exclude, —

(a) the conclusion of a licence contract by the patentee or the grant of other non-voluntary licences; or

(b) the exploitation of the patented invention under section 13(5).

TRINIDAD AND TOBAGO

Patents Act No. 21 of 1996 as last amended by the Act No. 18 of 2000

Sections 46 and 48

Non-voluntary licences

46.-(1) At any time after the expiration of three years from the date of grant of a patent under this Act or four years from the date of the filing, whichever is later, any person interested may apply to the Court for the grant of a licence under the patent on any of the following grounds, namely that a market for the patented invention is not being supplied, or is not being supplied on reasonable terms in Trinidad and Tobago.

(2) Subject to subsections (4), (5), (6) and (7), if the Court is satisfied that either of the grounds referred to in subsection (1) is established, the Court may make an order for the grant of the licence in accordance with the application on such terms as the Court thinks fit.

(3) A licence granted under this section:

(a) is not exclusive;

(b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and

(c) is limited to the supply of the patented invention predominantly in Trinidad and Tobago.

(4) Where the Court is satisfied that the grounds on which any licence granted under this section have ceased to exist, it may, on the application of any interested party, terminate such licence.

(5) Any person to whom a licence is granted under this section shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed upon between that person and the patentee, or in default of agreement, as the Court may, taking into account the economic value of the licence, determine on the application of either party.

(6) Before a licence is granted under subsection (1), the Court must be satisfied that the person applying for the licence has made efforts to obtain a licence from the patentee on reasonable commercial terms and conditions within a reasonable time, but has failed to do so.

(7) A licence shall not be granted under this section in respect of a patent relating to semiconductor technology except for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.

Use of patented invention for services of the State

48.-(1) Where the public interest so requires, or where the Minister decides that the manner of exploitation by the owner of a patent or his licensee is anti-competitive, then subject to subsection (2) the Minister may authorize a State agency or any person in writing, to make use, exercise or vend the patented invention for the services of the State subject to the payment of adequate compensation to the owner thereof, taking into account the economic value of the exploitation, and anything done by virtue of this subsection shall not amount to an infringement of the patent.

(2) Before issuing his authorization under subsection (1), the Minister shall hear the owner of the patent and any other interested party who may wish to be heard.

(3) Subsection (2) does not apply in the case of a national emergency.

(4) The Minister may upon the request of any of the parties, vary the terms of the authorization.

(5) (a) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied that the circumstances which led to his decision have ceased to exist and are unlikely to recur, or that the State agency or person authorized by him has failed to comply with the terms of the authorization;

(b) Notwithstanding paragraph (a), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the State agency or the person authorized by him justifies maintaining the decision.

(6) An authorization granted to a person other than a State agency shall be subject to the conditions prescribed by subsection (3) of Section 46.

(7) (a) Before an authorization is granted under subsection (1), the Minister must be satisfied that the proposed user has made efforts to obtain a licence from the patentee on reasonable commercial terms and conditions within a reasonable time, but has failed to do so;

(b) Paragraph (a) shall not apply in cases of national emergency or other circumstances of extreme urgency, provided however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as is reasonably practicable.

(8) Any decision of the Minister under subsections (1), (4) or (5) may be subject to judicial review.

TUNISIA

Law No. 2000-84 of August 24, 2000, on Patents

Articles 69, 70, 78 and 80

69. Any interested party may, after the expiry of the period provided for in Article 51 of this Law, obtain a compulsory license at any time in any of the following cases:

— where the invention to which the patent relates has not started to be worked industrially in Tunisia, or where no real and effective preparations have been made for such working, within the period provided for in Article 51 of this Law;

— where the product which is the subject matter of the invention has not been marketed in sufficient quantities to meet the needs of the Tunisian market;
— where the industrial or commercial exploitation of the invention to which the patent relates has been abandoned for more than three years in Tunisia.

70. Any application for the grant of the compulsory license shall be filed with the competent court.

The applicant for a compulsory license shall provide proof that he has already sent the owner of the patent a registered letter with advice of receipt to request a contractual license, but has not been able to obtain such a license on reasonable terms and conditions or within a reasonable period. He shall also supply proof that he capable of exploiting the invention effectively and conscientiously.

In no event shall a compulsory license for non-working or insufficient working be granted if the owner of the patent provides evidence of a legitimate excuse.

The compulsory license shall be non-exclusive. The rights deriving from the license may only be transferred together with the business, the company or the part of the company to which they are attached.

78. The minister responsible for industry may formally call upon the owners of patents to undertake the working thereof in such a way as to meet the needs of the national economy or the need to safeguard the environment.

Where the formal notice has not been acceded to within a period of one year, and where the non-working or the qualitative or quantitative inadequacy of the working undertaken seriously prejudices economic development and the public interest, the patents to which the notice relates may be made subject to the ex officio license regime by order of the minister responsible for industry.

The minister responsible for industry may extend the period provided for in the second paragraph of this Article where the owner of the patent provides proof of legitimate reasons attributable to the demands of the national economy.

Where public health interests dictate, patents granted for drugs, for the products necessary for the production of such drugs or for processes for the manufacture of such products may, where the drugs are made available to the public at levels of quality or quantity that are inadequate or at abnormally high prices, be made subject, at the request of the minister responsible for public health, to the ex officio license regime by order of the minister responsible for industry.

The State may at any time, for the purposes of national defense or national security, obtain an ex officio license for the exploitation of an invention covered by a patent application or patent, whether that exploitation is engaged in by itself or through a third party.

The ex officio license shall be granted at the request of the minister concerned by order of the minister responsible for industry.

80. The ex officio license shall be non-exclusive. The rights deriving from that license may only be transferred together with the business or the company or part of the company to which they are attached.

TURKEY

*Law No. 6769 of December 22, 2016, on Industrial Property
[non-official translation]³*

Article 129-137

ARTICLE 129-(1) Compulsory license can be given in case that at least one of the conditions indicated below is fulfilled:

- a) In accordance with the Article 130 the invention subject to the patent is not used.
 - b) The dependency of the patent issues indicated in the Article 131 is present.
 - c) The public benefit indicated in the Article 132 is present.
 - ç) In the case that the terms indicated in the Protocol Modifying the Agreement on Trade Related Aspects of the Intellectual Property Rights to which we entered via the Law no. 6471 dated 30/4/2013 are met, the export of the pharmaceutical products due to the public health problems in other countries is present,
 - d) The breeder is not able to develop a new plant type without infringing the previous patent.
 - e) Patent own period even if he/she requested a contract based license under reasonable commercial terms from the patent owner are included in the request. The court sends one copy of the compulsory license request and one copy of each attached documents to the patent owner without delay. One month period is given to the patent owner starting from the date of notification for him/her to present opinions together with the proofs opposing these.
- (3) The court sends the opinions of the patent owner, if any, to the requester of the compulsory license and decisions for the rejection of the request or granting of the compulsory license within one month. This period cannot be extended. If the patent owner has not demurred to the compulsory license request, the court decides the compulsory license without delay.
- (4) In the decision in which the compulsory license is given, the scope, license fee, term of the license, the warranty given by the licensee, time of start of usage and the precautions providing the substantial and effective usage of the patent shall be indicated.
- (5) When legal actions are applied for against the court decision, if the proofs presented by the patent owner for stopping the compulsory license application are found sufficient, the usage of the invention is delayed until the finalization of the decision related to the license.
- (6) The situation of the patent owner being not able to use the patent right without infringing a breeder right belonging to a plant type can be subject to compulsory license. In this case the provisions of the Law no. 5042 are applied.
- (7) If a license is given in accordance with the Clause 1 Item (d), the parent owner for the usage of the protected plant type can request granting a mutual license in reasonable conditions to him/herself; if a license is given in accordance with the Clause 6, the owner of the breeder right for the new plant type for the usage of the protected invention can request it.
- (8) For the licenses indicated in the Clause 1 Item (d) and the Clause 6 the requester can request the court for granting a compulsory license to him/herself by proving that;
- a) He/she applied to the owner of the breeder right of a new plant type or to the patent owner to acquire a contract based license, but could not reach a solution,
 - b) When compared to the protected plant type or invention protected by patent, the next invention or plant type shows an important technical improvement providing a great deal of economic benefit.
- (9) The provision of the Clause 1 Item (ç) being reserved, the compulsory license is launched to the domestic market essentially.

³ https://www.jetro.go.jp/ext_images/world/middle_east/ip/law/tr_201707.pdf

Compulsory license in nonuse condition

ARTICLE 130- (1) Patent owner or the person whom he/she authorized is obligated to use the invention protected by patent. In the assessment of use the market conditions and the conditions out of patent owner's control and will are considered.

(2) Whichever is later, at the end of three years after the decision of granting patent is published in the Bulletin or at the end of four year period after the patent application, any related persons can request for granting of compulsory license with the justifications that the invention subject to patent has not started to be used or no substantial or actual preparations are made for usage or the usage is not at a level to meet the domestic market need. Without a justified reason, the said condition is also applied in cases that the use of the invention is an uninterruptedly stopped for consecutive three years.

Compulsory license in case of dependence of the patent subjects

ARTICLE 131- (1) In the case that the invention subject to patent cannot be used without infringing the rights provided by the previous patent, as there will be a dependence between the patent subjects, the owner of the later dated patent cannot use the invention subject to the former dated patent without the consent of its owner.

(2) In case that there is a dependence between the patent subjects, the owner of the later dated patent, for using the invention subject to the patent, can request a compulsory license to be granted, provided that the invention shows an important technical improvement providing a great deal of economic benefit compared to the invention subject to the former dated patent. If a compulsory license is given to the later dated patent owner, the former dated patent owner can request a compulsory license to be granted to him/her for the usage of the invention subject to the later dated patent.

(3) In case of invalidity or termination of one of the patents with dependence the compulsory license decision is also dismissed.

Compulsory license due to public benefit

ARTICLE 132- (1) In cases that starting to use, increasing the usage of, extension in general of, or improvement for a beneficial use of the invention subject to patent carries an importance with the public health or national security reasons, or the nonuse of or the insufficient use in quality or quantity of the invention subject to patent shall cause substantial damages regarding the economic or technological development of the country, the following can be decided by the Cabinet upon the request of the related ministry:

- a) Issue of compulsory license due to the reason that there is public benefit,
- b) Conditional issue compulsory license for the public benefit, if the usage of the invention sufficient enough to meet the public benefit can be realized by the patent owner.

(2) If the usage of the invention subject to patent application or patent is important regarding the public health or national security, an offer is made by the related ministry by taking statement of approval from the National Defense Ministry or the Ministry of Health.

(3) The compulsory licenses given with the justification of public benefit can be exclusive. The compulsory license decision given with the justification of being important regarding the national security can be limited with usage of the invention by one or a few companies.

The legal quality of the mandatory license and trust relationship

ARTICLE 133- (1) The compulsory license is not exclusive however the compulsory licenses given with the justification of public benefit can be exclusive. The compulsory license is given under certain conditions considering the period, the license fee and the usage field. The court considers the economic value of the patent while determining the license fee. In the compulsory licenses to be given in accordance with the Article 129 Clause 1 Item (ç), when determining the license fee, the non-commercial and humane purposes are taken into consideration and the economic value of such usage regarding the importing country are considered.

(2) In case that the compulsory license is granted, the licensee does not have the right to give sub-licenses and import the patent subject. However in the compulsory license given with the

justification of public benefit, the licensee can import the patent subject, if it is authorized explicitly for import due to public benefit. This import permit shall be given as limited and for a temporary period of time.

(3) Due to the compulsory license, if the trust relationship born between the patent owner and the licensee is breached by the patent owner, the licensee can request discount of the license fee to the patent owner, according to the effect of the breach in valuation of the invention.

Compulsory license scope in the additional patent

ARTICLE 134- (1) The compulsory license also covers the additions of the patents that are present at the acceptance date of the license. If new additional patents are given after the compulsory license is granted and these are serving the same purpose of usage with the patent subject to license, the licensee can request the court for the additional patents to be included in the scope of the compulsory license. If the parties cannot agree on the license fee or on the other terms of the extended license due to the additional patents these are determined by the court.

Transfer of the compulsory license

ARTICLE 135- (1) In order for the transfer of the compulsory license to be valid, it should be transferred together with the business or the part of the business in which the license is utilized. In the case that the compulsory license is given due to the justification of dependence of the patent subjects, the license is transferred together with the dependent patents.

Request for change in the conditions and cancelation of the compulsory license

ARTICLE 136-(1) After the compulsory license is granted, the licensee or the patent owner can request the court for modifications to be made in the license fee or terms of the compulsory license, depending on the events that incur later on such as having granted a contract-based license under better terms compared to the compulsory license or that justify the modification.,
(2) In case that the licensee infringes substantially its obligations due to the compulsory license or continuously fails to fulfill them, upon the request of the patent owner, the court can cancel the license, the compensation rights of the patent owner being reserved.
(3) If the conditions that cause that the issue of the compulsory license cease to exist and the possibility of relapse is unlikely, the court cancels the compulsory license upon request.

The applicability of the provisions of the contract based licenses

ARTICLE 137- (1) Not being contradictory to the provisions in the Articles 129 to 136, the provisions related to the contract based license indicated in the articles 125 and 126 are also applied to the compulsory licenses.

TURKMENISTAN

Patent Act No. 867-XII of 01/10/1993

Article 38

Article 38. License

1. Any natural person or entity who wishes to use patented invention, industrial pattern or registered trade mark should have patent from the holder for invention or industrial pattern and the license from the holder of evidence for trade mark. License agreement is concluded for certain period, subject to registration in Turkmenpatent and comes into force from the date of its registration. Without registration the license agreement is considered invalid.

2. The holder of patent (temporary patent) for invention may ask Turkmenpatent to publish application on giving to any natural person or entity the right to use invention (open license). In

this case duty for maintenance of patent (temporary patent) is decreased by 50% beginning from the year following the year of publication of such application.

Person who wishes to use indicated invention should conclude an agreement with patent holder on payments.

3. In the interests of defense of Turkmenistan and for maintenance of public order the Cabinet of Ministers of Turkmenistan has the right to permit to use the object of industrial property without agreement of patent holder with payment of money compensation, which are comparable with market price of the license.

4. When issuing the state order to the enterprise on manufacturing the products with using inventions the patent (temporary patent) on which belonging to other natural persons or entities in Turkmenistan and also to foreign citizens, the body issuing the state order provides the license acquisition.

UGANDA

The Industrial Property Act of 6 January 2014

Articles 58-66

58. Compulsory licences for non-working and similar reasons.

(1) After the expiration of four years from the filing date of an application or three years from the grant of a patent, whichever last expires, a person may apply to the Minister for a licence to exploit the patented invention on the grounds that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Uganda.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the owner of the patent satisfies the Minister that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Uganda.

59. Compulsory licences based upon interdependence of patents.

(1) Where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the later patent may request the Minister for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his or her invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent.

(2) The owner of the first patent is entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent.

(3) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(4) In this section, "earlier patent" or "first patent" means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and "later patent" or "second patent" shall be construed accordingly.

60. Preconditions for grant of compulsory licences.

(1) A compulsory licence shall not be granted unless the person requesting the licence—

(a) satisfies the Minister that he or she has requested the owner of the patent for a contract licence but has been unable to obtain the licence contract on reasonable commercial terms and within a reasonable time; and

(b) offers a guarantee satisfactory to the Minister to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to his or her request.

(2) The requirement under subsection (1)(a) shall be waived in the case of a national emergency or other circumstances of extreme urgency or where the application is based on anti-competitive practices; except that the registrar shall notify the owner of the patent as soon as reasonably possible of the waiver.

61. Grant and terms of compulsory licences.

(1) When considering a request for a compulsory licence, the Minister shall decide whether a compulsory licence may be granted and shall, if it decides in favour of the grant and after taking into account any terms agreed by the parties, proceed to fix the terms which shall be taken to constitute a valid contract between the parties and shall be governed by the provisions on contractual licences.

(2) When fixing the terms under subsection (1), the Minister shall ensure that the compulsory licence—

(a) is limited, in scope and duration, to the purpose for which it was authorized, and in the case of semi-conductor technology, shall only be for public non-commercial use or to remedy a practice determined after a judicial or administrative process to be anti-competitive;

(b) is limited predominantly for the supply of the regional market;

(c) does not entitle the licensee to grant further licences without the consent of the owner of the patent;

(d) is non-exclusive; and

(e) provides for the payment to the owner of the patent of remuneration which is equitable having regard to all the circumstances of the case, including the economic and social value of the licence.

(3) A representative of the registrar and the patent owner shall have the right to appear and be heard at the hearing before the Minister of an application for a compulsory licence.

62. Transfer of compulsory licence.

A compulsory licence may be transferred only with that part of the industrial undertaking or its goodwill, in which the relevant invention is used and the transfer shall not be valid until the consent of the Minister is obtained.

63. Cancellation of compulsory licence.

(1) On the application of an interested party, the Minister may cancel a compulsory licence if—

(a) the licensee fails to comply with the terms of the licence; or

(b) the conditions which justify the grant of the licence have ceased to exist and are unlikely to recur; but the legitimate interests of the licensee shall be adequately protected.

(2) On the application of the owner of the patent, the Minister may cancel the compulsory licence if, within two years from the grant of the licence, the licensee has not taken the necessary steps to work the relevant invention sufficiently so as to remedy the deficiencies or to satisfy the requirements which gave rise to his or her application for the licence.

(3) On the application of the owner of the patent or the licensee, the Minister may vary the terms of a compulsory licence if new facts on the owner's part justify the variation and in particular if the patent owner has granted a contractual licence on more favourable terms.

64. Registration of grant, cancellation or variation.

Where the Minister grants, cancels or varies the term of a compulsory licence, the Minister shall instruct the registrar to record the grant, cancellation or variation in the register without payment of any fee.

65. Licence as of right.

(1) The owner of the patent may request the registrar to make an entry in the register to the effect that a licence under the patent is to be available as of right.

(2) The request shall be notified by the registrar to the licensee under the patent.

(3) A licensee may, within the prescribed time limit, object to the entry requested under subsection (1) on the ground that the owner of the patent is, by the relevant licence contract, precluded from granting further licences.

(4) Where the registrar receives no objection under subsection (3) or considers all objections made to be unfounded, the registrar shall make the requested entry in the register and shall publish the entry.

(5) Where a patent is the subject of an entry under this section, a person may require the owner of the patent to grant him or her a non-exclusive licence under the patent on terms which, in the absence of an agreement between the parties, shall be fixed by the court.

(6) The amount of the annual fees with respect to a patent, which is the subject of an entry under this section, that falls due after the date of the entry, shall be reduced by half.

(7) The owner of the patent may at any time request the registrar to cancel an entry under this section and the registrar shall cancel the entry after payment by the owner of the balance of all annual fees which would have been payable if no entry had been made and the registrar shall publish the cancellation of any entry under this section.

(8) Section 63(3) shall apply, with the necessary modifications, where the terms of a licence granted under subsection (5) have been fixed by the court.

PART XI—EXPLOITATION OF PATENTED INVENTIONS BY THE GOVERNMENT OR BY THIRD PARTIES AUTHORISED BY THE GOVERNMENT

66. Exploitation of patented inventions by the Government or by third parties authorised by the Government.

(1) Subject to this section, where—

(a) the public interest, in particular, national security, nutrition, health, environmental conservation, national emergency or the development of other vital sectors of the national economy requires; or

(b) the registrar determines that the manner of exploitation of an invention by the owner of the patent or his or her licensee is not competitive, the Minister may, upon application to him or her in the prescribed form and after consultation with the registrar and the owner of the patent, order that the protected invention shall be exploited by a Government ministry, a department, an agency or other person as the Minister may designate in the order subject to the payment of adequate compensation to the owner of the patent in accordance with this section.

(2) An order under subsection (2) shall remain in force until it is revoked by the Minister in writing, after giving six months prior notice of his or her intention to revoke to the party named or described in the order.

(3) An order made under subsection (2) shall not require the payment of compensation to the owner of the patent or licence holder or any other party interested.

(4) The Minister may, notwithstanding any of the measures set out in this section, by written order authorise the utilisation of any process for the manufacture, sale or supply of any molecule or substance, by any individual, corporation, society or other enterprise named or described in the order without notice to the patent holder or any other noticeable party.

(5) An order under subsection (4) and that order shall remain in force until revoked by the Minister in writing, after giving six months prior notice of intention to revoke to the party named or described in the order.

(6) An application shall not be made under subsection (1) unless the applicant has unsuccessfully sought a licence contract from the owner of the patent.

(7) Subsection (1) shall not apply in a case of national emergency or other extreme urgency and in that case the Minister shall cause the contents of the order to be communicated to the owner of the patent as soon as practicable.

(8) An order under this section shall be subject to conditions that the Minister considers necessary.

(9) Where an order under this section is made, the Minister shall determine the amount of compensation to be paid to the owner of the patent, and the compensation shall be equitable

having regard to all the circumstances of the case and in particular, the economic and social value of the patent.

(10) An order under this section shall not preclude the owner of the patent from concluding a licence contract or from exercising the powers conferred by section 38.

(11) The Minister may, upon the request of the owner of the patent or the Government ministry, a department, an agency or other person designated by the Minister for the purpose of any order under this section and after hearing all interested parties, vary the terms of the order to the extent that changed circumstances justify the variation.

(12) The Minister may, upon the request of the owner of a patent and after hearing all interested parties, revoke an order under this section—

(a) if satisfied that the circumstances necessitating the order have ceased and are unlikely to recur; or

(b) where the Government Ministry, department, agency or other entity or person designated for the purposes of the order is in breach of any condition imposed under subsection (7).

(13) The authorisation of a person in an order under this section shall not be transferable except to a business or enterprise owned or operated by that person.

(14) The exploitation of the invention under an order made under this section shall be primarily for the supply of the regional market.

(15) An order which relates to the exploitation of an invention in the field of semi-conductor technology shall only be made where the court has determined that the manner of exploitation of the patented invention by the owner of the patent or his or her licensee is not competitive and the Minister is satisfied that the issue of the order would remedy that practice.

(16) A person who is aggrieved by a decision of the Minister under this section may appeal to the court.

UKRAINE

The Law of Ukraine № 3687-XII of 15 December 1993 on Protection of Rights to Inventions and Utility Models (as amended up to 5 December 2012)

Article 30

Article 30 - Expropriation of the Right to an Invention (Utility Model)

(1) If an invention (utility model), excluding a secret invention (utility model) is not used or is inadequately used in Ukraine within 3 years from the date of publishing the data on granting a patent or from the date when the use of an invention (utility model) has been terminated, any person who wishes and is ready to use an invention (utility model) may appeal to the court for granting the right to use an invention (utility model) provided that the owner of rights has rejected the conclusion of the license agreement.

If the patent owner does not prove that the fact of nonuse of an invention (utility model) is caused by important reasons, the court shall make a decision on granting the permission to an interested person to use an invention (utility model) and define the volume of its use, the term of the permission, the amount and procedure of remunerating the patent owner. In this case, the right of the patent owner to grant permissions to use an invention (utility model) shall not be restricted.

(2) The patent owner shall be obliged to grant the permission (license) to use an invention (utility model) to the owner of the patent that has been granted later provided that an invention (utility model) of the latter is intended for other purpose or has significant technical and economical advantages and may not be used without infringement of the rights of the owner the patent that has been granted earlier. The permission shall be granted in the volume that is necessary for the use of an invention (utility model) by the owner of the patent that has been

granted later. In this case, the owner of the patent that has been granted earlier shall have the right to obtain on acceptable conditions a license to use an invention (utility model) that is protected by the patent that has been granted later.

(3) With the purpose to protect the health of population, ecological safety and other public interests, the Cabinet of Ministers of Ukraine may permit the use of the patented invention (utility model) by a defined person without the consent of the patent (declarative patent) owner provided that this owner has groundlessly rejected granting a license for the use of an invention (utility model).

In this case:

1. the permission for such a use shall be granted with consideration of specific circumstances;
2. the volume and the duration of such a use shall be determined by purpose of the granted permission and, in the case of semiconductor technology this shall be purely non-commercial use by bodies of the state power or implementing an anticompetition practice by the decision of a relevant body of the state power;
3. the permission for such a use shall not deprive the patent owner of the right to grant permissions for the use of an invention (utility model);
4. the right to such a use shall not be transferred excluding the case when it is transferred together with the part of the enterprise or business practice in which this use is carried out;
5. the use shall be permitted mainly for providing the internal market needs;
6. the notification concerning the grant of the permission for the use of an invention (utility model) shall be sent to the patent owner at the first opportune moment;
7. the permission for the use shall be revoked in case of discontinuance of circumstances under which this permission has been granted;
8. an adequate compensation in accordance with an economic value of an invention (utility model) shall be paid to the patent owner.

The resolution of the Cabinet of Ministers of Ukraine concerning the grant of the permission for the use of an invention (utility model), the validity period and conditions of the grant, revocation of the permission for the use, amount and procedure of paying a remuneration to the patent owner may be appealed in court procedure.

(4) The owner of the patent (declarative patent) for a secret invention or a declarative patent for a secret utility model may grant a license for the use of his invention (utility model) only to a person that has a permission of the State Expert to access to this invention (utility model). If the said person cannot come to the agreement with the patent owner on the grant of the license, the Cabinet of Ministers of Ukraine shall have the right to permit the use of a secret invention (utility model) according to Paragraph 3 of this Article.

(5) The court shall resolve any disputes on the conditions of the grant of licenses, on the amounts and the procedure of obtaining money compensation.

UNITED ARAB EMIRATES

Federal Law No. 31 For The Year 2006 Pertaining To The Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs

Articles 24-32

Article (24)

1 - If the owner of the letters patent or the holder of the utility certificate have not used or made use of the letters patent or the utility certificate, then any interested party may according to article (30) of this law obtain a compulsory license under the following conditions:

- a- The period of at least 3 years since the issuance of the letters patent has passed.
- b- The proposed licensee should demonstrate the efforts made to obtain the license from the patentee for a reasonable price and under reasonable commercial conditions. The required procedures will be set in the implementing regulations in this regard.
- c- The license should not be issued in absolute terms. The license may include obligations and boundaries for both the licensor and the licensee.
- d- The license should be intended to satisfy the basic requirements of the local market. The proposed licensee must offer the necessary guarantees set in the implementing regulations of this law in order to sufficiently exploit the invention to remedy the deficiency or meet the needs that lead to requesting the compulsory license.
- e- The scope of the license should be in line with the objective for which it has been issued.
- f- The patentee should receive a fair compensation.
- g- The use of the patent should be restricted to the licensee. The license cannot be transferred to a third party except where the ownership of the establishment of the licensee or the part thereof utilizing the patent has been assigned. Such a transfer should be approved by the competent court and be bound to articles (28) and (32) of this law.
- h- In the case of semi-conductor technology, the license shall only be for public, non-commercial use, or to remedy a practice determined after judicial or administrative process to be anti-competitive.

2 - The compulsory license shall not be granted if the owner of the letters patent or utility certificate offers plausible justification. Importing the product is not considered as plausible justification.

Article (25)

1 - The compulsory license shall warrant the licensee the right to undertake some or all of the activities referred to in article (15) of this law under the licensing conditions, with the exception of the right of importing the product.

2 - The licensee shall be entitled to practice the civil and the penal rights against the owner of the letters patent or the holder of the utility certificate if they are unduly utilizing their invention or being aware of illegal practices related thereto.

Article (26)

The issuance of a compulsory license shall not preclude issuing of other compulsory licenses .

Article (27)

1 - Upon request made by the interested parties, the competent owner of the letters patent or the holder of the utility certificate from using the invention in personal terms, or granting others licenses for such a usage.

2 - The competent court may disregard the items (a) and (b) provided for in article (24) of this law if the application for the compulsory license has been dictated by a general emergency case or by a highly urgent public need , or has been intended for non- commercial purposes.

Article (28)

The application for the compulsory license shall be submitted to the competent court in the form of lawsuit being filed against the owner of the letters patent or the holder of the utility certificate. The department shall be notified of the lawsuit for the purpose of representation . The two parties shall then be given the grace period decided by the court for reaching an agreement. This period may be extended if so justified before the court. By the end of this period the court shall decide whether or not the compulsory license is to be issued. Should the compulsory license be issued, the court shall determine the conditions and the scope of the license , and the compensation due to the licensee or to the holder of the utility certificate as provided for in article (24) of this law. The decision shall be communicated to the second party and to the department for registration in the appropriate record , and shall be published in the industrial property circular after the prescribed fees have been paid. The decision shall come into force for other parties after the date of publication thereof.

Article (29)

- 1 - Upon a decree by the Minister, a compulsory license shall be issued for use of an invention protected by a letters patent or by a utility certificate if the said invention has a significant contribution to the public interest, as provided for in article (24) without prejudice to the provisions of article (24) (a) and (b).
- 2 - The minister's decree pertaining to the compulsory license may be appealed before the competent court within sixty days as of the date of publishing the said decree in the industrial property circular.

Article (30)

- 1 - If it is impossible to use an invention protected by a patent or a utility certificate in the United Arab Emirates without violating rights derived from a patent or a utility certificate granted by virtue of a previous application, then it is permissible to grant the owner of the letters patent or the utility certificate a compulsory license according to the conditions set forth in article (24) of such law to the degree necessary to use his invention if such invention serves industrial purposes different from such purposes related to the invention of the former patent or utility certificate or represents a marked technical advance in relation thereto.
- 2 - If the two inventions serve the same industrial purpose, the compulsory license shall be granted to the subsequent patent or utility certificate while keeping the right for the owner of the former patent or utility certificate to obtain a license for the subsequent patent or utility certificate, if he applies for such.
- 3 - The two parties may also agree in writing between them and notify the Administration of their agreement to record it in the related register.

Article (31)

- 1 - The authority which has given the compulsory license may amend the conditions thereof pursuant to the application of the patent or the utility certificate's owner or the licensee by a compulsory license, if such is justified by new facts and especially if the owner of the patent or the utility certificate is granted a contractual license with conditions better than the compulsory license .
- 2 - The authority which has given the compulsory license may decide on the cancellation thereof by virtue of the owner of the patent or the utility certificate's application , if the licensee doesn't follow the conditions of the license or if the causes which justified granting thereof were no longer valid and in such case the licensee shall be given a reasonable time limit to cease exploiting the invention if the immediate cessation harms him .
- 3 - The provisions of the two articles (35) and (36) of such law shall be effective on amending or canceling the compulsory licenses .

Article (32)

1 - Compulsory licenses must be registered in the appropriate record, and published in the industrial property circular after payment of the prescribed fees set forth in the implementing regulations of this law .

2 - Licenses issued according to article (29) shall be entitled for fees waiver if the invention is being used by the government.

UNITED KINGDOM

Patents Act of 1977

Sections 48-51, 55-57 and 59

48 Compulsory licences: general

(1) At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the comptroller on one or more of the relevant grounds -

(a) for a licence under the patent;

(b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or

(c) where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent.

(2) Subject to sections 48A and 48B below, if he is satisfied that any of the relevant grounds are established, the comptroller may -

(a) where the application is under subsection (1)(a) above, order the grant of a licence to the applicant on such terms as the comptroller thinks fit;

(b) where the application is under subsection (1)(b) above, make such an entry as is there mentioned;

(c) where the application is under subsection (1)(c) above, order the grant of a licence to the person specified in the application on such terms as the comptroller thinks fit.

(3) An application may be made under this section in respect of a patent even though the applicant is already the holder of a licence under the patent; and no person shall be estopped or barred from alleging any of the matters specified in the relevant grounds by reason of any admission made by him, whether in such a licence or otherwise, or by reason of his having accepted a licence.

(4) In this section "the relevant grounds" means -

(a) in the case of an application made in respect of a patent whose proprietor is a WTO proprietor, the grounds set out in section 48A(1) below;

(b) in any other case, the grounds set out in section 48B(1) below.

(5) A proprietor is a WTO proprietor for the purposes of this section and sections 48A, 48B, 50 and 52 below if -

(a) he is a national of, or is domiciled in, a country which is a member of the World Trade Organisation; or

(b) he has a real and effective industrial or commercial establishment in such a country.

(6) A rule prescribing any such other period under subsection (1) above shall not be made unless a draft of the rule has been laid before, and approved by resolution of, each House of Parliament.

48 A Compulsory licences: WTO proprietors

(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are -

(a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;

(b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms -

(i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or

(ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;

(c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

(2) No order or entry shall be made under section 48 above in respect of a patent whose proprietor is a WTO proprietor unless -

(a) the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions; and

(b) his efforts have not been successful within a reasonable period.

(3) No order or entry shall be so made if the patented invention is in the field of semi-conductor technology.

(4) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(b)(i) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

(5) A licence granted in pursuance of an order or entry so made shall not be assigned except to a person to whom the patent for the other invention is also assigned.

(6) A licence granted in pursuance of an order or entry made under section 48 above in respect of a patent whose proprietor is a WTO proprietor -

(a) shall not be exclusive;

(b) shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part;

(c) shall be predominantly for the supply of the market in the United Kingdom;

(d) shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence; and

(e) shall be limited in scope and in duration to the purpose for which the licence was granted.

48B Compulsory licences: other cases

(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are -

- (a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;
- (b) where the patented invention is a product, that a demand for the product in the United Kingdom -
 - (i) is not being met on reasonable terms, or
 - (ii) is being met to a substantial extent by importation from a country which is not a member State;
- (c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked -
 - (i) where the invention is a product, by the importation of the product from a country which is not a member State,
 - (ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;
- (d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms -
 - (i) a market for the export of any patented product made in the United Kingdom is not being supplied, or
 - (ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or
 - (iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
- (e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

(2) Where -

- (a) an application is made on the ground that the patented invention is not being commercially worked in the United Kingdom or is not being so worked to the fullest extent that is reasonably practicable; and
- (b) it appears to the comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, he may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.

(3) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(a) above if -

- (a) the patented invention is being commercially worked in a country which is a member State; and
- (b) demand in the United Kingdom is being met by importation from that country.

(4) No entry shall be made in the register under section 48 above on the ground mentioned in subsection (1)(d)(i) above, and any licence granted under section 48 above on that ground shall contain such provisions as appear to the comptroller to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

(5) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(d)(ii) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

50A Powers exercisable following merger and market investigations(1) Subsection (2) below applies where –

(a) section 41(2), 55(2), 66(6), 75(2), 83(2), 138(2), 147(2) or 160(2) of, or paragraph 5(2) or 10(2) of Schedule 7 to, the Enterprise Act 2002 (powers to take remedial action following merger or market investigations) applies;

(b) the Competition Commission or (as the case may be) the Secretary of State considers that it would be appropriate to make an application under this section for the purpose of remedying, mitigating or preventing a matter which cannot be dealt with under the enactment concerned; and

(c) the matter concerned involves –

(i) conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences; or

(ii) a refusal by the proprietor of a patent to grant licences on reasonable terms.

(2) The Competition Commission or (as the case may be) the Secretary of State may apply to the comptroller to take action under this section.

(3) Before making an application the Competition Commission or (as the case may be) the Secretary of State shall publish, in such manner as it or he thinks appropriate, a notice describing the nature of the proposed application and shall consider any representations which may be made within 30 days of such publication by persons whose interests appear to it or him to be affected.

(4) The comptroller may, if it appears to him on an application under this section that the application is made in accordance with this section, by order cancel or modify any condition concerned of the kind mentioned in subsection (1)(c)(i) above or may, instead or in addition, make an entry in the register to the effect that licences under the patent are to be available as of right.

(5) References in this section to the Competition Commission shall, in cases where section 75(2) of the Enterprise Act 2002 applies, be read as references to the Office of Fair Trading.

(6) References in section 35, 36, 47, 63, 134 or 141 of the Enterprise Act 2002 (questions to be decided by the Competition Commission in its reports) to taking action under section 41(2), 55, 66, 138 or 147 shall include references to taking action under subsection (2) above.

(7) Action taken by virtue of subsection (4) above in consequence of an application under subsection (2) above where an enactment mentioned in subsection (1)(a) above applies shall be treated, for the purposes of sections 91(3), 92(1)(a), 162(1) and 166(3) of the Enterprise Act 2002 (duties to register and keep under review enforcement orders etc.), as if it were the making of an enforcement order (within the meaning of the Part concerned) under the relevant power in Part 3 or (as the case may be) 4 of that Act.

51 Powers exercisable in consequence of report of Competition Commission

(1) Where a report of the Competition Commission has been laid before Parliament containing conclusions to the effect –

(a) [repealed]

(b) [repealed]

(c) on a competition reference, that a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest, or

(d) on a reference under section 11 of the Competition Act 1980 (reference of public bodies and certain other persons), that a person is pursuing a course of conduct which operates against the public interest, the appropriate Minister or Ministers may apply to the comptroller to take action under this section.

(2) Before making an application the appropriate Minister or Ministers shall publish, in such manner as he or they think appropriate, a notice describing the nature of the proposed application and shall consider any representations which may be made within 30 days of such publication by persons whose interests appear to him or them to be affected.

(3) If on an application under this section it appears to the comptroller that the matters specified in the Commission's report as being those which in the Commission's opinion operate, or operated or may be expected to operate, against the public interest include -

(a) conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences, or

(b) a refusal by the proprietor of a patent to grant licences on reasonable terms he may by order cancel or modify any such condition or may, instead or in addition, make an entry in the register to the effect that licences under the patent are to be available as of right.

(4) In this section "the appropriate Minister or Ministers" means the Minister or Ministers to whom the report of the Commission was made.

55 Use of patented inventions for services of the Crown

(1) Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say -

(a) where the invention is a product, may -

(i) make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or

(ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;

(b) where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above;

(c) without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;

(d) may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;

(e) may dispose or offer to dispose of anything which was made, used, imported or kept in the exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported or kept (as the case may be), and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.

(2) Any act done in relation to an invention by virtue of this section is in the following provisions of this section referred to as use of the invention; and "use", in relation to an invention, in sections 56 to 58 below shall be construed accordingly.

(3) So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a government department or the United Kingdom Atomic Energy Authority otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

(4) So far as the invention has not been so recorded or tried, any use of it made by virtue of this section at any time either -

(a) after the publication of the application for the patent for the invention; or

(b) without prejudice to paragraph (a) above, in consequence of a relevant communication made after the priority date of the invention otherwise than in confidence; shall be made on such terms as may be agreed either before or after the use by the government department and the proprietor of the patent with the approval of the Treasury or as may in default of agreement be determined by the court on a reference under section 58 below.

(5) Where an invention is used by virtue of this section at any time after publication of an application for a patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) above include terms as to payment for the use, then (notwithstanding anything in those terms) any such payment shall be recoverable only -

(a) after such a patent is granted; and

(b) if (apart from this section) the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.

(6) The authority of a government department in respect of an invention may be given under this section either before or after the patent is granted and either before or after the use in respect of which the authority is given is made, and may be given to any person whether or not he is authorised directly or indirectly by the proprietor of the patent to do anything in relation to the invention.

(7) Where any use of an invention is made by or with the authority of a government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, the department shall notify the proprietor of the patent as soon as practicable after the second of the following events, that is to say, the use is begun and the patent is granted, and furnish him with such information as to the extent of the use as he may from time to time require.

(8) A person acquiring anything disposed of in the exercise of powers conferred by this section, and any person claiming through him, may deal with it in the same manner as if the patent were held on behalf of the Crown.

(9) In this section "relevant communication", in relation to an invention, means a communication of the invention directly or indirectly by the proprietor of the patent or any person from whom he derives title.

(10) Subsection (4) above is without prejudice to any rule of law relating to the confidentiality of information.

(11) In the application of this section to Northern Ireland, the reference in subsection (4) above to the Treasury shall, where the government department referred to in that subsection is a department of the Government of Northern Ireland, be construed as a reference to the Department of Finance for Northern Ireland.

56 Interpretation, etc., of provisions about Crown use

(1) Any reference in section 55 above to a patented invention, in relation to any time, is a reference to an invention for which a patent has before that time been, or is subsequently, granted.

(2) In this Act, except so far as the context otherwise requires, "the services of the Crown" includes -

- (a) the supply of anything for foreign defence purposes;
- (b) the production or supply of specified drugs and medicines; and
- (c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient; and “use for the services of the Crown” shall be construed accordingly.

(3) In section 55(1)(a) above and subsection (2)(a) above, references to a sale or supply of anything for foreign defence purposes are references to a sale or supply of the thing - (a) to the government of any country outside the United Kingdom, in pursuance of an agreement or arrangement between Her Majesty’s Government in the United Kingdom and the government of that country, where the thing is required for the defence of that country or of any other country whose government is party to any agreement or arrangement with Her Majesty’s Government in respect of defence matters; or (b) to the United Nations, or to the government of any country belonging to that organisation, in pursuance of an agreement or arrangement between Her Majesty’s Government and that organisation or government, where the thing is required for any armed forces operating in pursuance of a resolution of that organisation or any organ of that organisation.

(4) For the purposes of section 55(1)(a) and (c) above and subsection (2)(b) above, specified drugs and medicines are drugs and medicines which are both -

(a) required for the provision of -

(ai) primary medical services under the National Health Service Act 2006, the National Health Service (Wales) Act 2006, part I of the National Health Service (Scotland) Act 1978 or any corresponding provisions of the law in force in Northern Ireland or the Isle of Man or primary dental services under the National Health Service Act 2006, the National Health Service (Wales) Act 2006, or any corresponding provisions of the law in force in Northern Ireland or the Isle of Man, or

(i) pharmaceutical services, general medical services or general dental services under Chapter 1 of Part 7 of the National Health Service Act 2006 or Chapter 1 of Part 7 of the National Health Service (Wales) Act 2006 (in the case of pharmaceutical services), Part II of the National Health Service (Scotland) Act 1978 (in the case of pharmaceutical services or general dental services), or the corresponding provisions of the law in force in Northern Ireland or the Isle of Man, or

(ii) personal medical services or personal dental services provided in accordance with arrangements made under section 17C of the 1978 Act (in the case of personal dental services), or the corresponding provisions of the law in force in Northern Ireland or the Isle of Man, or

(iii) local pharmaceutical services provided under a pilot scheme established under section 134 of the National Health Service Act 2006, or section 92 of the National Health Service (Wales) Act 2006, or an LPS scheme established under Schedule 12 to the National Health Service Act 2006, or Schedule 7 to the National Health Service (Wales) Act 2006, or under any corresponding provision of the law in force in the Isle of Man, and

(b) specified for the purposes of this subsection in regulations made by the Secretary of State.

57 Rights of third parties in respect of Crown use

(1) In relation to -

(a) any use made for the services of the Crown of an invention by a government department, or a person authorised by a government department, by virtue of section 55 above, or

(b) anything done for the services of the Crown to the order of a government department by the proprietor of a patent in respect of a patented invention or by the proprietor of an application in respect of an invention for which an application for a patent has been filed and is still pending, the provisions of any licence, assignment, assignation or agreement to which this subsection applies shall be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the

making of payments in respect of, or calculated by reference to, such working or use; and the reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(2) Subsection (1) above applies to a licence, assignment, assignation or agreement which is made, whether before or after the appointed day, between (on the one hand) any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and (on the other hand) any person whatever other than a government department.

(3) Where an exclusive licence granted otherwise than for royalties or other benefits determined by reference to the working of the invention is in force under the patent or application concerned, then -

(a) in relation to anything done in respect of the invention which, but for the provisions of this section and section 55 above, would constitute an infringement of the rights of the licensee, subsection (4) of that section shall have effect as if for the reference to the proprietor of the patent there were substituted a reference to the licensee; and

(b) in relation to anything done in respect of the invention by virtue of an authority given under that section, that section shall have effect as if the said subsection (4) were omitted.

(4) Subject to the provisions of subsection (3) above, where the patent, or the right to the grant of the patent, has been assigned to the proprietor of the patent or application in consideration of royalties or other benefits determined by reference to the working of the invention, then -

(a) in relation to any use of the invention by virtue of section 55 above, subsection (4) of that section shall have effect as if the reference to the proprietor of the patent included a reference to the assignor, and any sum payable by virtue of that subsection shall be divided between the proprietor of the patent or application and the assignor in such proportion as may be agreed on by them or as may in default of agreement be determined by the court on a reference under section 58 below; and

(b) in relation to any act done in respect of the invention for the services of the Crown by the proprietor of the patent or application to the order of a government department, section 55(4) above shall have effect as if that act were use made by virtue of an authority given under that section.

(5) Where section 55(4) above applies to any use of an invention and a person holds an exclusive licence under the patent or application concerned (other than such a licence as is mentioned in subsection (3) above) authorising him to work the invention, then subsections (7) and (8) below shall apply.

(6) In those subsections "the section 55(4)" payment means such payment (if any) as the proprietor of the patent or application and the department agree under section 55 above, or the court determines under section 58 below, should be made by the department to the proprietor in respect of the use of the invention.

(7) The licensee shall be entitled to recover from the proprietor of the patent or application such part (if any) of the section 55(4) payment as may be agreed on by them or as may in default of agreement be determined by the court under section 58 below to be just having regard to any expenditure incurred by the licensee -

(a) in developing the invention, or

(b) in making payments to the proprietor in consideration of the licence, other than royalties or other payments determined by reference to the use of the invention.

(8) Any agreement by the proprietor of the patent or application and the department under section 55(4) above as to the amount of the section 55(4) payment shall be of no effect unless the licensee consents to the agreement; and any determination by the court under section 55(4) above as to the amount of that payment shall be of no effect unless the licensee has been informed of the reference to the court and is given an opportunity to be heard.

(9) Where any models, documents or information relating to an invention are used in connection with any use of the invention which falls within subsection (1)(a) above, or with anything done in respect of the invention which falls within subsection (1)(b) above, subsection (4) of section 55 above shall (whether or not it applies to any such use of the invention) apply to the use of the models, documents or information as if for the reference in it to the proprietor of the patent there were substituted a reference to the person entitled to the benefit of any provision of an agreement which is rendered inoperative by this section in relation to that use; and in section 58 below the references to terms for the use of an invention shall be construed accordingly.

(10) Nothing in this section shall be construed as authorising the disclosure to a government department or any other person of any model, document or information to the use of which this section applies in contravention of any such licence, assignment, assignation or agreement as is mentioned in this section.

59 Special provisions as to Crown use during emergency

(1) During any period of emergency within the meaning of this section the powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 55 above shall include power to use the invention for any purpose which appears to the department necessary or expedient -

(a) for the efficient prosecution of any war in which Her Majesty may be engaged;

(b) for the maintenance of supplies and services essential to the life of the community;

(c) for securing a sufficiency of supplies and services essential to the well-being of the community;

(d) for promoting the productivity of industry, commerce and agriculture;

(e) for fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade;

(f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or

(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside the United Kingdom which is in grave distress as the result of war; and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes.

(2) In this section the use of an invention includes, in addition to any act constituting such use by virtue of section 55 above, any act which would, apart from that section and this section, amount to an infringement of the patent concerned or, as the case may be, give rise to a right under section 69 below to bring proceedings in respect of the application concerned, and any reference in this Act to "use for the services of the Crown" shall, as respects any period of emergency, be construed accordingly.

(3) In this section "period of emergency" means any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.

(4) A draft of an Order under this section shall not be submitted to Her Majesty unless it has been laid before, and approved by resolution of, each House of Parliament.

UNITED REPUBLIC OF TANZANIA

Sections 53-60 of The Patents (Registration) Act

Section 14 of The Zanzibar Industrial Property Act, 2008 (Act No. 4 of 2008)

53. Compulsory licence for non-working and similar reasons

(1) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may, in proceedings instituted by him against him by the said owner, request the court for the grant of a compulsory licence on any of the following grounds that is to say-

- (a) that the patented invention, being capable of being worked in the United Republic has not been so worked;
- (b) that the existing degree of working of the patented invention in the United Republic does not meet in reasonable terms the demand for the patented product on the domestic market or for the purposes of exportation;
- (c) that the working of the patented invention in the United Republic is being hindered or prevented by the importation of the patented product; and
- (d) that, by reason of the refusal of the owner of the patent to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in the United Republic, or the possibilities of exportation from the United Republic, are unfairly and substantially prejudiced.

(2) Where the patented invention is a process, the phrase "patented product" in subsection (1) means a product obtained directly by means of the process.

(3) A compulsory licence shall not be granted in respect of a patent if the owner of the patent satisfies the court that his actions in relation to the patented invention are justifiable in the circumstances.

54. Compulsory licences for interdependence of patents

(1) Where a patented invention cannot be worked without infringing rights derived from an earlier patent the owner of the later patent may, in proceedings instituted by him against the owner of the earlier patent or in proceedings instituted against him by the latter owner, request the court at any time for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention if the invention-

- (a) serves industrial purposes different from those served by the invention which is the subject of the earlier patent; or
- (b) constitutes substantial technical progress in relation to that last mentioned invention.

(2) If the two inventions mentioned in subsection (1) serve the same industrial purposes, a compulsory licence may be granted under that subsection only on condition that a compulsory licence shall also be granted in respect of the later patent to the owner of the earlier patent if he so requests.

(3) In this section, "earlier patent" means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and "later patent" shall be construed accordingly.

55. Compulsory licences for products and processes of vital importance

(1) The Minister may, by order published in the Gazette, direct that, for a patented invention concerning a certain kind of product, or a process for the manufacture of such a product,

declared in the order to be of vital importance for the defence or for the economy or for public health, a compulsory licence may be granted.

(2) A compulsory licence with respect to any product or process specified in the order referred to in subsection (1) may be requested at any time after the grant of the relevant patent, in court proceedings instituted against or by the owner of the said patent.

56. Preconditions to grant of compulsory licences

A compulsory licence shall not be granted unless the person requesting such licence—

- (a) satisfies the court that he has asked the owner of the patent for a contractual licence but has been unable to obtain such a licence on reasonable terms and within a reasonable time, and
- (b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements, which gave rise to his request.

57. Grant and terms of compulsory licences

(1) In considering a request for a compulsory licence, the court shall first decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant and taking into account any terms agreed by the parties, proceed to fix the terms, which shall be deemed to constitute a valid contract between the parties and shall be governed by the provisions of Part X.

(2) In fixing the terms under subsection (1), the court shall ensure that the compulsory licence—

- (a) entitles the licensee to do any act which is mentioned in section 36, except that this shall not apply to importation unless a request was made under section 55;
- (b) does not entitle the licensee to grant further licences, without the consent of the owner of the patent;
- (c) is non-exclusive; and
- (d) provides for the payment to the owner of the patent of remuneration which is equitable with due regard to all the circumstances of the case.

(3) A representative of the Registrar shall have the right to appear and be heard at the hearing of an application for a compulsory licence.

58. Transfer of compulsory licences

A compulsory licence may be transferred only with the industrial or commercial undertaking in which the relevant invention is used, and no such transfer shall be valid until the consent of the court has been obtained.

59. Cancellation of compulsory licences and variation of terms

(1) On the application of the owner of the patent, the court may cancel a compulsory licence if—

- (a) the licensee fails to comply with the terms of the licence;
- (b) the conditions which justified the grant of the licence have ceased to exist, so however that in the latter case a reasonable time shall be given to the licensee to cease working the relevant invention if an immediate cessation would cause him to suffer substantial damage.

(2) On the application of the Registrar, the court shall, and on the application of the owner of the patent, the court may, cancel the compulsory licence if, within two years from the grant of the licence, the licensee has not taken the necessary steps to work the relevant invention sufficiently so as to remedy the deficiencies or to satisfy the requirements which gave rise to the owner's request for the said licence.

(3) On the application of the owner of the patent or the licensee, the court may vary the terms of a compulsory licence if new facts justify the variation, and in particular and without prejudice to the generality of the foregoing if the patentee has granted contractual licences on more favourable terms.

60. Registration of grants, cancellation or variation

Where the court grants, cancels or varies the terms of a compulsory licence, the court shall inform the Registrar, who shall register without fee in the register the grant, cancellation or variation of the compulsory licence.

Compulsory licenses and Government use

14.(1)(a) Where

- (i) the public interest, in particular, national security, national emergency, nutrition, health, or the development of other vital sectors of the national economy so requires; or
- (ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice; or
- (iii) the owner of the patent is abusively exercising his exclusive rights or neglecting in taking measures to prevent his licensee(s) from abusively exercising the licensed exclusive rights; or
- (iv) the invention is not available in sufficient quantities or quality or at predetermined reasonable prices in Zanzibar, either through manufacture in Zanzibar or through importation; or
- (v) the patented invention which is capable of being worked in Zanzibar is not being worked or is not being so worked to the fullest extent that is reasonably practicable, after the expiry of 3 years from the grant of the patent or 4 years from the filing of patent application; or
- (vi) the applicant for the license has unsuccessfully endeavoured during a period of 90 days to obtain the patent holder's consent for the use of the patented invention under reasonable terms and conditions; or
- (vii) the second patent claiming an invention that involves an important technical advance of considerable economic significance in relation to an invention claimed in first patent without infringing which the second patent cannot be exploited.

the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or any other person, firm or corporation, undertaking any activity for or on behalf of the Government department or a third person either designated by the Minister or by application may exploit the invention, each request for a compulsory licence shall be considered by the Ministry on its individual merits, the exploitation of the invention shall be limited to the purpose for which it was licensed and shall be subject to the payment to the said owner of an adequate remuneration in the circumstances of each case, taking into account the economic value of the Minister's decision, as determined in the said decision, and, where a decision has been taken under paragraph (ii) of this paragraph, the need to correct anti-competitive practices.

(b) The remuneration of a compulsory license shall be determined as a percentage of net sales taking into account the value of the license in the relevant domestic market, but shall not exceed 4%, the

remuneration shall be reduced or excluded when the license is necessary to remedy anti-competitive practices where importation takes place pursuant to the Decision of the General Council of the World

Trade Organization of August 30, 2003 or Article 31 TRIPS whichever that is applicable, and the exporting country issues a compulsory license for the same patented invention, payment of remuneration is waived.

(2) Upon request of the owner of the patent, of the Government agency or any other person, firm, or corporation undertaking any activity for or on behalf of the Government department or of the third person licensed to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(3)(a) Upon the request of the owner of the patent, the Minister may terminate the compulsory license if he is satisfied, after hearing the parties, if either or both wish to be heard that the circumstances which led to his decision have ceased to exist and unlikely to recur.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the compulsory license if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or any other person, firm or corporation undertaking any activity for or on behalf of the Government department or third person designated by him justifies the maintenance of the decision or, if the compulsory license was granted to remedy an anti-competitive practice under subsection (1)(a)(ii) of this section and when the conditions which led to such compulsory license are likely to recur, if the compulsory license is terminated, the Minister shall ensure that the legitimate interests of the compulsory licensee are adequately protected, particularly when the compulsory licensee has made serious preparations or commenced to execute the invention.

(4) The compulsory license may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(5) The compulsory license shall always be non-exclusive, and not exclude:

(i) the exploitation of the invention by the patent owner himself, either through manufacture in Zanzibar or through importation or both; and

(ii) the conclusion of license contracts by the owner of the patent; and

(iii) the continued exercise, by the owner of the patent, of his rights under section 12(1)(2) and (3) of this Act.

(6)(a) A request for the compulsory license shall be addressed to the Minister and accompanied by evidence that the owner of the patent has received, from the person seeking the compulsory license, a request for a contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a period of forty five days of the request for a contractual license.

(b) Evidence concerning a previous attempt of obtaining a voluntary license, under paragraph (a), shall not be required in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or when the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable.

(7) The exploitation of the invention by the Government agency or any other person, firm or corporation undertaking any activity for or on behalf of the government department or third person licensed by the Minister shall be predominantly for the supply of the market in Zanzibar except if it is under section 14(1)(a)(ii) of this Act or where the purpose of the compulsory license is to export in accordance with the terms and conditions of the decision of the General Council of the World Trade Organization of August 30, 2003 or in accordance with Art. 31 of TRIPS when it enters into force.

(8) Compulsory licenses of inventions in the field of semi-conductor technology shall only be granted for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented inventions, by the owner of the patents or his licensees, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.

(9) Where a compulsory license is granted under subsection (1)(vii), of this section,

(a) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(b) the license of the first patent shall be non-assignable except with the assignment of the second patent.

(10) The provisions of this section shall apply, where appropriate and mutatis mutandis, to pending patent applications, except in the case of insufficient availability of the patented product or of the product manufactured with the patented process.

(11) Notwithstanding anything in this Act, any Government department or any person authorized by competent authority may, for the interest of the public, make, use, exercise, import, keep and vend any patented invention; and anything done by virtue of this subsection shall not amount to infringement of the patent concerned and any appeal against the determination of the Minister shall not stay or suspend the Government use.

UNITED STATES OF AMERICA

28 U.S.C. § 1498

42 U.S.C. § 2183

42 U.S.C. § 7608

40 C.F.R. § 95.2

28 U.S.C. § 1498. Patent and copyright cases

a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Notwithstanding [1] the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust. For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States prior to July 1, 1918.

A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which Government time, materials or facilities were used.

42 U.S.C. § 2183. Nonmilitary utilization

(a) Declaration of public interest

The Commission may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if (1) the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy; and (2) the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter.

(b) Action by Commission

Whenever any patent has been declared affected with the public interest, pursuant to subsection(a) of this section—

(1) the Commission is licensed to use the invention or discovery covered by such patent in performing any of its powers under this chapter; and

(2) any person may apply to the Commission for a nonexclusive patent license to use the invention or discovery covered by such patent, and the Commission shall grant such patent license to the extent that it finds that the use of the invention or discovery is of primary importance to the conduct of an activity by such person authorized under this chapter.

42 U.S.C. § 7608. Mandatory licensing

Whenever the Attorney General determines, upon application of the Administrator—

(1) that—

(A) in the implementation of the requirements of section 7411, 7412, or 7521 of this title, a right under any United States letters patent, which is being used or intended for public or commercial use and not otherwise reasonably available, is necessary to enable any person required to comply with such limitation to so comply, and

(B) there are no reasonable alternative methods to accomplish such purpose, and

(2) that the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country, the Attorney General may so certify to a district court of the United States, which may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine. Such certification may be made to the district court for the district in which the person owning the patent resides, does business, or is found.

40 C.F.R. § 95.2 Petition for mandatory license.

(a) Any party required to comply with sections 111, 112 or 202 of the Act (42 U.S.C. 7411, 7412 or 7521) may petition to the Administrator for a mandatory patent license pursuant to section 308 of the Act (42 U.S.C. 7608), under a patent that the petitioner maintains is necessary to enable the petitioner to comply with Sections 111, 112 or 202 of the Act.

(b)(1) Each petition shall be signed by the petitioner and shall state the petitioner's name and address. If the petitioner is a corporation, the petition shall be signed by an authorized officer of the corporation, and the petition shall indicate the state of incorporation. Where the petitioner elects to be represented by counsel, a signed notice to that effect shall be included with the petition at the time of filing.

(2) Each petition shall include a copy of the patent under which a mandatory patent license is sought. The petition shall identify all current owners of the patent and shall include a copy of all assignment documents relevant to the patent that are available from the United States Patent and Trademark Office.

(3) Each petition must identify any person whose interest the petitioner believes may be affected by the grant of the license to which the petition is directed.

(4) Each petition must contain a concise statement of all of the essential facts upon which it is based. No particular form of statement is required. Each petition shall be verified by the petitioner or by the person having the best knowledge of such facts. In the case of facts stated on information and belief, the source of such information and grounds of belief shall be given. The statement of facts shall include the following:

- (i) An identification of the provisions of the Act and/or regulations thereunder that the petitioner maintains petitioner will be able to comply with if the petitioner is granted the patent license that is the subject of the petition;
- (ii) An identification of the nature and purpose of the petitioner's intended use of the patent license;
- (iii) An explanation of the relationship between the patented technology and the activities to which petitioner proposes to apply the patented technology, including an estimate of the effect on such activities stemming from the grant or denial of the patent license;
- (iv) A summary of facts demonstrating that the patent under which a mandatory patent license is sought is being used or is intended for public or commercial use;
- (v) An explanation of why a mandatory patent license is necessary for the petitioner to comply with the requirements of sections 111, 112 or 202 of the Act, and why the patented technology is not otherwise available;
- (vi) An explanation of why there are no other reasonable alternatives for accomplishing compliance with sections 111, 112 or 202 of the Act;
- (vii) An explanation of why the unavailability of a mandatory patent license may result in a substantial lessening of competition or a tendency to create a monopoly in any line of commerce in any section of the United States;
- (viii) A summary of efforts made by the petitioner to obtain a patent license from the owner of the patent, including the terms and conditions of any patent license proposed by petitioner to the patent owner; and
- (ix) The terms, if any, on which the owner of the patent has proposed to grant the petitioner a patent license.

(5) Each petition shall include a proposed patent license that states all of the terms and conditions that the petitioner proposes for the patent license.

(6) Petitions shall be addressed to the Assistant Administrator for Air and Radiation, Mail Code 6101, U.S. Environmental Protection Agency, Washington, DC 20460.

(c) Petitions that do not include all of the information required in paragraph (b) of this section shall be returned to the petitioner. The petitioner may supplement the petition and resubmit the petition.

(d) If the Administrator, or the Administrator's designee, finds that the criteria in §95.3 are not met, or otherwise decides to deny the petition, a denial of the petition shall be sent to the petitioner, along with an explanation of the reasons for the denial.

(e) If the Administrator, or the Administrator's designee, finds that the criteria in §95.3 are met and decides to apply to the Attorney General for a patent license under section 308 of the Act, notice of such application shall be given to the petitioner, along with a copy of the application sent to the Attorney General.

URUGUAY

*Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs (1.827*R) (of September 2, 1999)*

Articles 54-70 and 73

Subsection I

Licences and Other Uses for Failure to Work

54. Any interested party may request a compulsory license after three years have elapsed since the grant of the patent or four years since the date of application, whichever expires last, if the invention has not been exploited or if serious and effective preparations have not been made for its exploitation or if exploitation has been suspended for more than one year, provided that there are no reasons of force majeure.

In addition to the reasons recognized in the legislation, insurmountable objective problems of a technical or legal nature such as delays in the granting of authorizations by government bodies, independent of the will of the owner of the patent, which make working the patent impossible, shall be considered reasons of force majeure.

The exploitation of a patent shall include its production, use, import or any other commercial activity undertaken and related to its subject matter.

In this respect, the working of the patent by a representative or licensee shall be considered carried out by the owner of the patent.

Subsection II

Compulsory Licences or Other Uses Without the Patent Owner's Consent for Reasons of Public Interest

55. In special situations that might affect the general interest, defense or national security, the economic, social and technological development of certain sectors strategic for Uruguay, as well as for urgent health reasons or other like reasons of public interest, the Executive may, by means of a special resolution, grant compulsory licenses or other uses without the patent owner's consent and their scope and term shall be adapted to the purpose for which they were granted.

56. The patent owner's rights may be restricted in accordance with the provisions of the preceding Article if commercial supplies essential to cover the domestic market's needs are lacking or insufficient.

57. Where a compulsory license or other uses without the patent owner's consent are granted, the application for a license or other use shall be notified to the owner and to the licensee of the patent within the prescribed period of 30 days, at the expiry of which it shall be considered approved if no specific objection has been lodged.

The regulations shall define the other procedures and the requirements to be met for the granting of licenses or other uses. The regulations shall ensure the equal participation of all those interested in working the patent, providing for the necessary conciliation and arbitration bodies.

Persons applying to work the subject matter of the patent shall specify the terms on which they seek to obtain it, their economic situation and the availability of an establishment approved by the competent authority to carry out the work.

58. Decisions granting compulsory licenses or other uses pursuant to the preceding Article shall determine the final or provisional scope thereof and other aspects relating to compulsory licenses.

59. Authorization for such uses may be withdrawn, subject to appropriate protection of the legitimate interests of the persons who had received authorization, if the circumstances which gave rise to the authorization no longer exist and it is unlikely that they will recur. The competent authorities shall be empowered to examine whether such circumstances still exist, subject to a substantiated request.

Subsection III

Compulsory Licenses and Other Uses Without the Patent Owner's Consent for Reasons of Anti-competitive Practices

60. By means of a special decision, the National Industrial Property Directorate may grant compulsory licenses for a patent if the competent authority, following administrative or judicial proceedings which give the owner the right of defense and other guarantees, has determined that the owner has been involved in anti-competitive practices, or has abused the rights conferred by the patent or a dominant market position.

61. The circumstances cited in the preceding Article shall include the following:

- (a) the fixing of prices that are excessive in comparison with the average international market price for the patented product;
- (b) offers to supply the market at prices significantly lower than those proposed by the owner of the patent;
- (c) refusal to furnish the local market with adequate and regular supplies of the raw materials or the product patented, on fair commercial terms;
- (d) obstructing or causing prejudice to commercial or production activities in Uruguay;
- (e) any acts which restrict trade to an unjustified degree or are detrimental to the transfer of technology.

62. After a period of two years as of the grant of the first compulsory license or other uses for reasons of anti-competitive practices or abuse of the rights conferred by a patent, if the owner continues the acts or practices that led to the compulsory license or other uses, the right to the patent may be cancelled, either automatically or at the request of an interested party, subject to notice within the prescribed period of 30 days.

63. The cancellation of a patent or license may not affect the acts committed or agreements reached while it was in force in relation to the working of the patent and may not prevent the marketing of the products concerned.

Subsection IV

Other Compulsory Licenses and Other Uses Without the Patent Owner's Consent

64. Any interested party may obtain a compulsory license or other uses without the patent owner's consent if he has requested the owner for a contractual license and has been unable to obtain it on commercially fair terms customary in Uruguay, within 90 days following the request.

In any event, the National Industrial Property Directorate shall grant a compulsory license or other uses without the owner's consent if the interested party proves that:

- (a) he has the technical and economic capacity to work the patent in question. Technical capacity shall be assessed by the competent authority in conformity with the special rules in force in Uruguay for each branch of activity. Economic capacity shall mean the capacity to meet the obligations arising from working the patent;
- (b) he has a business structure that helps to promote the local market for the product that is the subject matter of the license;
- (c) if the patent relates to a raw material from which the end product is to be developed, he is able to carry out such development himself or through third parties in Uruguay, unless it is impossible to produce the product in Uruguay.

In the case of technology sectors that were not protected at the time this Law entered into force and if the patent includes raw material from which an end product is to be developed, the

licensee shall be obliged to obtain the raw material, molecule or principle from the owner of the patent or a person designated by him at the price at which they supply international markets and the patent owner shall undertake to sell them in the proper form and in a timely manner. If the owner gives his subsidiaries a special price, he shall offer the licensee the same price.

The licensee may obtain the raw material from another supplier if it is offered at a price that is 15% (fifteen per cent) lower than the price offered by the patent owner in Uruguay. In such cases, the licensee shall prove that the raw material obtained in this way has been put on sale lawfully, in Uruguay or abroad, by the owner of the patent or by a third party with his consent or legally authorized by him.

65. The remuneration provided in the preceding Article shall be fixed in accordance with the provisions of Article 77(b) of this Law.

66. Compulsory licenses or other uses without the owner's consent may not extend beyond the acts of working or marketing the subject matter of the license in Uruguay throughout the term of the patent and in respect of any application.

67. After a compulsory license has been granted, the owner of the patent shall furnish all the information needed to work the subject matter of the license, for example, technical know-how, manufacturing protocols, testing or verification techniques, and shall authorize use of patents relating to components or manufacturing processes connected with the patent that is the subject matter of the license.

Unsubstantiated refusal by the owner to furnish the technical know-how and to transfer the technology needed to achieve the purpose or failure to sell the raw material in the proper form and in a timely manner if it was the subject matter of the patent shall immediately lead to loss of the owner's royalty rights.

68. Patents shall lapse if, two years after the grant of the first compulsory license or other uses without the owner's consent, the holder of the compulsory license is unable to exploit the subject matter of the license for reasons attributable to the owner of the patent or his contractual licensee.

Reasons attributable to the owner of the patent shall mean inter alia refusal to provide the information or the authorization mentioned in the preceding Article.

Subsection V
Dependent Patents

69. If a patented invention or utility model cannot be exploited in Uruguay without infringing an earlier patent, the owner or a licensee under any title of one of the patents may request the grant of a compulsory license covering the other dependent patent if it is needed to work the patent and avoid infringement.

Where the subject matter of one patent is a product and the subject matter of the other a process, it shall be considered that they are dependent patents for the purposes of their working.

70. Licenses or uses without the owner's consent for the purpose of working a dependent patent shall be granted subject to the following conditions:

- (a) the invention claimed in the second patent must represent a significant technical step of considerable economic importance in comparison with the invention claimed in the first patent;
- (b) the owner of the first patent shall have the right to obtain a cross license on fair terms in order to work the invention claimed in the second patent;
- (c) assignment of the authorized use of the first patent shall include use of the second patent.

[...]

73. A compulsory license or other uses without the owner's consent may not:
- (a) be exclusive;
 - (b) be the subject of a sublicense;
 - (c) be granted to a defrauder;
 - (d) be transferred without the firm or enterprise or the part thereof which exploits the subject matter of the license.

UZBEKISTAN

Law of the Republic of Uzbekistan № 1062-XII of 6 May 1994 on Inventions, Utility Models and Industrial Designs (as amended up to Law of the Republic of Uzbekistan № ZRU-446 of 14 September 2017)

Article 32

Article 32. Provision of the right to use industrial property subject matter

Any person who is not a patent owner shall be entitled to use industrial property subject matter protected by a patent only with the consent of the patent owner on the basis of a licensing agreement.

A patent owner may submit to the Patent Office a request to grant any person the right to use industrial property subject matter (open license). In this case, the patent fee for maintaining the patent in force shall be reduced by 50 per cent from the year following that of publication of information concerning such a request by the Patent Office.

A person who has expressed a desire to acquire an open license shall conclude with a patent owner an agreement to grant a non-exclusive license. Disputes relating to the conditions of an agreement shall be examined by the courts. A request by a patent owner for the grant of the right to an open license shall not be withdrawn.

In the cases provided for by legislation, the Cabinet of Ministers of the Republic of Uzbekistan may permit the use of industrial property subject matter without the consent of the patent owner but with the payment of appropriate compensation thereto.

If a patent owner is unable to use industrial property subject matter in connection with the fact that other protected subject matter, belonging to another natural or legal person, is used therein, he shall be entitled to demand from that person the grant of a license for the use of this subject matter on the conditions provided for by agreement.

VIET NAM

Law on Intellectual Property (No. 50/2005/QH11)

Articles 132, 133, 136, 137, 145 and 146

Article 132.- Elements limiting industrial property rights

Under this Law, industrial property rights may be limited by the following elements:

1. Right of prior users to inventions or industrial designs;
2. Obligations of owners, including:
 - a/ To pay remunerations to the authors of inventions, industrial designs or layout-designs;
 - b/ To use inventions or marks.
3. Licensing of inventions under decisions of state competent agencies.

Article 133.- Rights to use inventions on behalf of the State

1. Ministries and ministerial-level agencies shall have the right to, on behalf of the State, use or permit other organizations or individuals to use inventions in domains under their respective management for public and non-commercial purposes, national defense, security, disease prevention and treatment and nutrition for the people, and to meet other urgent social needs without having to obtain permission of invention owners or their licensees under exclusive contracts (hereinafter referred to as holders of exclusive right to use inventions) according to Articles 145 and 146 of this Law.

2. The use of inventions mentioned in Clause 1 of this Article shall be limited within the scope of and under the conditions for licensing provided for in Clause 1, Article 146 of this Law, except where such inventions are created by using material-technical facilities and funds from the state budget.

Article 136.- Obligation to use inventions and marks

1. Owners of inventions are obliged to manufacture protected products or apply protected processes to satisfy the requirements of national defense, security, disease prevention and treatment and nutrition for the people or to meet other social urgent needs. When there arise the needs mentioned in this Clause but invention owners fail to perform such obligation, the competent state agency may license such inventions to others without permission of invention owners according to the provisions of Articles 145 and 146 of this Law.

2. Owners of marks are obliged to use such marks continuously. Where a mark has not been used for 5 consecutive years or more, the ownership right to such mark shall be invalidated according to the provisions of Article 95 of this Law.

Article 137.- Obligations to authorize the use of principal inventions for the purpose of using dependent inventions

1. A dependent invention means an invention created based on another invention (hereinafter referred to as principal invention) and may only be used on the condition that the principal invention is also used.

2. Where the owner of a dependent invention can prove that his/her invention makes an important technical advance as compared with the principal invention and has a great economic significance, he/she may request the owner of the principal invention to license such principal invention with reasonably commercial price and conditions.

Where the owner of a principal invention fails to satisfy the request of the owner of a dependent invention without justifiable reasons, the concerned competent state agency may license such invention to the owner of the dependent invention without permission of the owner of the principal invention according to the provisions of Articles 145 and 146 of this Law.

Article 145.- Bases for compulsory licensing of inventions

1. In the following cases, the right to use an invention may be licensed to another organization or individual under a decision of the competent state agency defined in Clause 1, Article 147 of this Law without permission from the holder of exclusive right to use such invention:

a/ Where the use of such invention is for public and non-commercial purposes or in service of national defense, security, disease prevention and treatment and nutrition for people or other urgent needs of the society.

b/ Where the holder of exclusive right to use such invention fails to fulfill the obligations to use such invention provided for in Clause 1, Article 136 and Clause 5, Article 142 of this Law upon the expiration of a 4-year duration as from the date of filing the invention registration application and the expiration of a 3-year duration as from the date of granting the invention patent;

c/ Where a person who wishes to use the invention fails to reach an agreement with the holder of exclusive right to use such invention on the entry of an invention license contract in spite of his/her efforts made within a reasonable time for negotiation on satisfactory commercial price and conditions;

d/ Where the holder of exclusive right to use such invention is considered having performed anticompetition practices banned by competition law.

2. The holder of exclusive right to use an invention may request the termination of the use right when the bases for licensing provided for in Clause 1 of this Article no longer exist and are unlikely to recur, provided that such termination shall not be prejudicial to the invention licensee;

Article 146.- Conditions of limitation on the right to use inventions licensed under compulsory decisions

1. The right to use an invention licensed under a decision of a competent state agency must be compliant with the following conditions:

a/ Such licensed use right is non-exclusive;

b/ Such licensed use right is only limited to a scope and duration sufficient to achieve the licensing objectives, and largely for the domestic market, except for the cases specified at Point d, Clause 1, Article 145 of this Law. For an invention in semi-conductor technology, the licensing thereof shall be only for public and non-commercial purposes or for handling anti-competition practices according to the provisions of the competition law;

c/ The licensee must neither assign nor sub-license such right to others, except where the assignment is effected together with the transfer of his/her business establishment;

d/ The licensee shall have to pay the holder of exclusive right to use the invention a satisfactory compensation depending on the economic value of such use right in each specific case, and compliant with the compensation bracket set by the Government.

2. Apart from the conditions specified in Clause 1 of this Article, the right to use an invention licensed in any of the cases specified in Clause 2, Article 137 of this Law must also satisfy the following conditions:

a/ The holder of exclusive right to use the principal invention shall also be licensed to use the dependent invention on reasonable terms;

b/ The licensee of the right to use the principal invention must not assign such right, except where the assignment is effected together with all rights to the dependent invention.

ZAMBIA

The Patents Act 2016 (Act No 40 of 2016)

Sections 99-102 and 105-108

Compulsory licence

99. (1) A person may, after three years from the date of the grant of a patent, apply to the Minister for the grant of a compulsory licence on any of the following grounds:

(a) that without reasonable cause, the patentee does not work the patented process in Zambia;

(b) that the patented product or article is not available to the public in Zambia in sufficient quantity or at an affordable price;

(c) that the refusal by the patentee to grant a contract licence, on reasonable terms, is prejudicial to the country's establishment and development of industries or commercial activities;

(d) that the applicant for a contract licence has failed to obtain the patentee's consent for the use of the patented invention, under reasonable terms and conditions;

(e) that the interest of public health or nutrition demand the commercial working of the patented invention in Zambia;

(f) that there is a need to remedy the abuse of intellectual property rights or anti-competitive practices; or (g) that there is a national emergency which requires the use of the patented invention.

(2) The Minister shall, within three months of receiving an application for a compulsory licence, inform the patentee and give the patentee an opportunity to be heard.

(3) Where the Minister, in consultation with the Registrar, is satisfied with the submissions made by the patentee, disputing any ground referred to in subsection (1), the Minister shall reject the application made by an interested person for the grant of a compulsory licence in respect of a patented invention.

(4) Where the Minister, in consultation with the Registrar, is satisfied that any of the grounds, referred to in subsection (1), is established, the Minister shall direct the Registrar to issue a compulsory licence to the applicant on such terms and conditions as the Minister considers appropriate in the circumstances.

(5) A compulsory licence, granted by the Minister in accordance with subsection (4), shall not be an exclusive licence and shall not entitle the licensee to grant further licences to third parties without the written consent of the patentee.

(6) A person who is granted a compulsory licence, in accordance with subsection (4), shall be required to pay the patentee such remuneration as is considered equitable, with regard to all the circumstances, including the economic value of the licence.

(7) The Minister may, in consultation with the Registrar, on the request of a patentee or licensee or on the order of the High Court, vary the terms and conditions of a compulsory licence.

(8) Subsection (3) shall not apply where a compulsory licence is granted as a result of a national emergency.

(9) Where a compulsory licence has been granted, in accordance with this section, the use of the licence shall be for the supply of the domestic market.

Grant of compulsory licence for inter-dependent inventions

100. (1) Where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of a later patent may apply to the Registrar, in the prescribed manner, for the grant of a compulsory licence with respect to the earlier patent, to the extent necessary for the working of a later patent, if the invention constitutes an important technical advancement of economic value.

(2) Where the Registrar is satisfied with an application, referred to in subsection (1), the Registrar shall issue a compulsory licence to the applicant on such terms and conditions as the Registrar shall consider appropriate in the circumstances.

(3) The owner of an earlier patent shall be entitled to a crosslicence, on reasonable terms and conditions, to use the invention claimed in the second patent.

(4) The use, authorised by a compulsory licence, referred to in subsection (1), shall only be transferable to another person on the assignment of a second patent.

(5) In this section—

“earlier patent” means a patent granted for an earlier invention or a patent for an invention claiming an earlier priority date; and

“second patent” means a validly granted patent which cannot be worked without infringing another patent.

Compulsory licence granted under regulation

101. The Minister may, by statutory instrument, direct the Registrar to grant compulsory licences with respect to patented products declared by the Government, to be of vital importance to the defence, public health, the environment or the economy of the country.

Revocation of compulsory licence

102. The Minister may on the application of an interested person, or on the advice of the Registrar, revoke a compulsory licence on any of the following grounds:

- (a) that the licensee has failed to comply with the terms of the licence;
- (b) that the conditions which justified the grant of the licence have ceased to exist and are unlikely to recur;
- (c) that the interests of the licensee have been adequately protected;
- (d) that the licensee has failed, within twenty-four months from the grant of the licence, to take the necessary steps to work the invention to satisfy the reason for the grant of a compulsory licence; or
- (e) that the patentee has granted the licensee a licence contract on more favourable terms.

PART XIV

EXPLOITATION OF PATENTED INVENTION BY GOVERNMENT

Use of invention by Government

105. Where the Government requires, for purposes of public health, the environment or national emergency, that a patented invention be exploited, for non-commercial purposes, by the Government or an authorised person, the Minister may, with or without the consent of the patentee, authorise in a prescribed manner, the exploitation of the patented invention.

Notification of patentee by Government

106. (1) Where the Government or an authorised person knows, without conducting a patent search that it is using or will be using a patented invention for purposes referred to in section one hundred and five, the Minister shall, as soon as it is practicable, notify the patentee of the use or the intended use of the patented invention.

(2) A patentee who is aggrieved by the decision of the Minister made in accordance with this section may, within three months of the decision, appeal to the High Court.

Extent, duration and limitation of use of patented invention

107. (1) The extent and duration of the use of a patented invention, by the Government or an authorised person, shall be limited to the purposes referred to in section one hundred and five.

(2) The use of the patented invention, in accordance with section one hundred and five shall not be assignable or exclusive.

Compensation of patentee for use of patented invention

108. (1) Where a patented invention is used by the Government or an authorised person, the patentee shall be paid, within a prescribed period, by the Government or the authorised person, such remuneration as may be considered equitable compensation, with regard to all the circumstances, including the economic value of the patented invention.

(2) A patentee aggrieved with the amount of compensation paid in accordance with subsection (1) may, within three months of being paid the compensation, appeal to the High Court.

ZIMBABWE

Patents Act (Chapter 26:03, as amended up to Act No. 14/2002)

Sections 30A-32, 35 and 36

30A Compulsory licence in respect of dependent patents

Where the working of a patent (hereinafter referred to as a dependent patent) without infringement of a prior patent is dependent upon the obtaining of a licence under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the Registrar for a licence under the prior patent, and the Registrar may grant such a licence on such conditions as he may impose, including a condition that such licence shall be used only for the purpose of permitting the dependent patent to be worked and for no other purposes: Provided that the Registrar shall not grant such a licence unless—

- (a) the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed;
- (b) the proprietor of the dependent patent granted the proprietor of the prior patent on reasonable terms a cross-licence to use the invention claims in the dependent patent;
- (c) the use authorized in respect of the prior patent is not assignable except with the assignment of the dependent patent. [inserted by Act 9 of 2002, with effect from the 20th December, 2002.]

31 Compulsory licence in case of abuse or insufficient use of patent rights

(1) Subject to subsection (15), any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, within a period of six months from the initial request for a voluntary licence, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention in question have not been or will not be satisfied. [amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(2) An application under subsection (1) shall—

- (a) set out fully the nature of the applicant's interest, the facts on which he bases his case and the relief he seeks; and
- (b) be accompanied by an affidavit verifying the facts set out in the application.

(3) If, after consideration of an application under subsection (1), the Registrar is satisfied that the applicant has a bona fide interest and that a prima facie case for relief has been made out, he shall direct the applicant—

- (a) to serve copies of the application and of the relevant affidavit upon the patentee and upon any other person appearing from the Register to be interested in the patent; and
- (b) to advertise the application in the Journal.

(4) If the patentee or any other person wishes to oppose the grant of a licence under this section, he may, within the prescribed period or within such further period as the Registrar may on application allow, deliver to the Registrar a counter-statement, verified by affidavit, setting out fully the grounds on which the application is opposed, and shall at the same time serve upon the applicant copies of the counter-statement and of such affidavit.

(5) When, in relation to an application or an opposition thereto, the provisions of subsections (1) to (4) have been complied with to the extent therein required, the Registrar shall consider the application and may—

(a) order the grant of a licence to the applicant on such terms as the Registrar thinks fit, including a condition precluding the licensee from importing into Zimbabwe any patented articles.

(b) refuse to grant the licence. [amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(6) The reasonable requirements of the public referred to in subsection (1) shall be considered not to have been satisfied in any of the following circumstances—

(a) if the patented invention, being an invention capable of being worked in Zimbabwe, is not being worked therein on a commercial scale and there is no satisfactory reason for such non-working;

Provided that, if an application for a compulsory licence is made on this ground and the Tribunal is of the opinion that the time which has elapsed since the sealing of the patent has by reason of the nature of the invention or for any other reason been insufficient to enable the invention to be worked within Zimbabwe on a commercial scale, the Tribunal may make an order adjourning the hearing of the application for such period as will in its opinion be sufficient for that purpose;

(b) if the working of the invention within Zimbabwe on a commercial scale is being prevented or hindered by the importation of the patented article by—

(i) the patentee or persons claiming under him; or

(ii) persons directly or indirectly purchasing from the patentee; or

(iii) persons against whom the patentee is not taking or has not taken proceedings for infringement;

(c) if the demand for the patented article in Zimbabwe is not being met to an adequate extent and on reasonable terms;

(d) if, by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry of Zimbabwe or the trade of any person or class of persons trading in Zimbabwe or the establishment of any new trade or industry in Zimbabwe is being prejudiced, and it is in the public interest that a licence or licences should be granted;

(e) if any trade or industry in Zimbabwe or any person or class of persons engaged therein is being prejudiced by unfair conditions attached by the patentee, whether before or after the appointed day, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process;

(f) if any condition, which under section forty-four is null and void as being in restraint of trade and contrary to public policy, has been inserted in any contract made in relation to the sale or lease of or any licence to use or work any article or process protected by the patent:

Provided that, for the purpose of determining whether there has been any abuse of the monopoly rights under a patent, due regard shall be had to the fact that patents are granted not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Zimbabwe without undue delay.

(6a) In the event of a practice determined after judicial or administrative process to be anti-competitive, the requirements contained in subsection (1) that the interested person shows that he has been unable to obtain a licence shall not apply. [inserted by Act 9 of 2002, with effect from the 20th December, 2002.]

(7) The Tribunal may order the grant to the applicant of a licence on such terms as it may think expedient, including a term precluding the licensee from importing into Zimbabwe any goods the importation whereof, by persons other than the patentee or persons claiming under him, would be an infringement of the patent.

(8) The terms of a licence ordered to be granted under subsection (7) shall be so framed as—

(a) to authorise the making, use or vend of the invention primarily to satisfy the market in Zimbabwe, except in the case of a determination of anti-competitive practices, in which case no such restriction shall apply; and

(b) to secure to the patentee the reasonable royalty compatible with the successful working of the invention within Zimbabwe on a commercial scale and at a reasonable profit; and
(c) to be based on product-specific research and development costs, taking into account the domestic market share of the total world market: Provided that paragraph (b) shall not be construed as to exclude the need to correct anti-competitive practices which may be taken into account in determining the amount of remuneration in such cases. [amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(9) In addition to any other terms of a licence ordered to be granted under subsection (7), the licence shall be revocable at the discretion of the Tribunal if—

(a) the circumstances that led to its grant cease to exist and are unlikely to recur; or

(b) the licensee fails to—

(i) work the invention within the time specified in the order; or

(ii) expend the amount specified in the licence as being the amount which he is able and willing to provide for the purpose of working the invention on a commercial scale within Zimbabwe; or

(iii) pay the patentee the royalties payable in terms of the licence. [inserted by Act 9 of 2002, with effect from the 20th December, 2002.]

(10)

.....

[repealed by Act 9 of 2002, with effect from the 20th December, 2002.]

(11) In deciding to whom a licence is to be granted under section (7), the Tribunal shall, unless good reason is shown to the contrary, prefer an existing licensee to a person who, according to the Register, has no interest in the patent.

[amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(12)

.....

[repealed by Act 9 of 2002, with effect from the 20th December, 2002.]

(13) A licensee under this section shall be entitled to call upon the patentee concerned to institute any proceedings which may be necessary to prevent infringement of the patent in question and shall in all other respects have the same rights as any other licensee, and if the patentee fails, within two months after being called upon by the licensee or within such further period as the Tribunal may allow, to institute any such proceedings, the licensee may himself institute such proceedings as if he were the

patentee, making the patentee a defendant, but the patentee shall not be liable for any costs in connection with such proceedings unless he enters an appearance and takes part in those proceedings.

(14) The existence of a compulsory licence granted solely on the ground that an invention is not being worked in Zimbabwe on a commercial scale shall not preclude the grant of further licences, including compulsory licences, in respect of that invention, but the holder of any compulsory licence shall not be entitled to transfer that licence or grant a sub-licence thereunder except to a person to whom the business or the part of the business in connection with which the rights under the licence were exercised, has been transferred.

(15) No licence shall be granted in terms of this section or of section thirty-two while an entry in terms of section twenty-nine in respect of the relevant patent remains in the Register.

[amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(16) An appeal shall lie from any refusal of the Registrar to issue directions in terms of subsection (3).

(17) For the purposes of this section—
“patented article” includes any article made by a patented process.

32 Inventions relating to food or certain other commodities

(1) Subject to subsection (15) of section thirty-one and without prejudice to the other foregoing provisions of this Act, where a patent is in force in respect of—

(a) a substance capable of being used as food or medicine or in the production of food or medicine; or

(b) a process for producing a substance referred to in paragraph (a); or

(c) any invention capable of being used as or as part of a surgical or curative device or in protection of the environment; [amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(d) any invention capable of substantially improving the technological, social and economic development of the country. [substituted by Act 9 of 2002, with effect from the 20th December, 2002.] the Tribunal shall, on application made to it by any person interested, order the grant to the applicant of a licence under the patent on such terms as it thinks fit, unless it appears to the Tribunal that there are good reasons for refusing the application.

(1a) Subject to subsections (2) and (3), the terms of a licence under this section shall be so framed as—

(a) to authorise the working of the invention primarily to satisfy the market in Zimbabwe, except in the case of a determination of anti-competitive practices, in which case no such restriction shall apply; and

(b) to secure to the patentee the reasonable royalty compatible with the successful working of the invention within Zimbabwe on a commercial scale and at a reasonable profit. [inserted by Act 9 of 2002, with effect from the 20th December, 2002.]

(2) In settling the terms of a licence under this section the Tribunal shall endeavour to secure that food, medicine and surgical and curative devices and environment protection devices and any invention referred to in paragraph (d) of subsection (1) shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. [amended by the General Laws Amendment (No. 2) Act 14 of 2002 with effect from the 24th January, 2003.]

(3) A licence granted under this section shall entitle the licensee to make, use, exercise and vend the invention—

(a) as a food or medicine or for the purposes of the production of food or medicine; or

(b) as part of a surgical or curative or environment protection device or any invention referred to in paragraph (d) of subsection (1);

but for no other purposes. [amended by the General Laws Amendment (No. 2) Act 14 of 2002 with effect from the 24th January, 2003.]

(4) In addition to any other terms of a licence under this section, the licence shall be revocable at the discretion of the Tribunal if—

(a) the circumstances that led to its grant cease to exist and are unlikely to recur; or

(b) the licensee fails to—

(i) work the invention within the time specified in the order; or

(ii) expend the amount specified in the licence as being the amount which he is able and willing to provide for the purpose of working the invention on a commercial scale within Zimbabwe; or

(iii) pay the patentee the royalties payable in terms of the licence. [inserted by Act 9 of 2002, with effect from the 20th December, 2002.] 33 Supplementary provisions as to licences An order under this Act for the grant of a licence shall, without prejudice to any other method of

enforcement, have effect as if it were an agreement executed by the patentee and all other necessary parties granting a licence in accordance with the order. 34 Use of patented inventions for service of the State

(1) Notwithstanding anything in this Act, any department of the State or any person authorized in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section.

(2) Any use of an invention made by virtue of subsection (1) shall be made upon such terms and conditions as may be agreed upon between the Minister and the patentee with the approval of the Minister responsible for finance or, in default of such agreement, as may be determined by the Tribunal on a reference under subsection (1) of section thirty-six.

[amended by Act 9 of 2002, with effect from the 20th December, 2002.]

(3)

.....

[repealed by Act 9 of 2002, with effect from the 20th December, 2002.]

(4) The authority of the Minister in respect of an invention may be given under subsection (1)—

(a) either before or after the patent is granted and either before or after the acts in respect of which the authority is given are done; and

(b) to any person, whether or not he is authorized directly or indirectly by the patentee to make, use, exercise or vend the invention.

(5) Where any use of an invention is made by or with the authority of the Minister under subsection (1), then, unless it appears to him that it would be contrary to the public interest so to do, the Minister shall notify the patentee as soon as practicable after the use is begun, and furnish him with such information as to the extent of the use as he may from time to time require.

(6) For the purposes of this section and sections thirty-five and thirty-six, any use of an invention for the supply to the government of a country outside Zimbabwe, in pursuance of any agreement or arrangement between the Government of Zimbabwe and the government of that country, of articles required for the defence of that country shall be deemed to be a use of the invention for the service of the State, and the power of a department of the State or a person authorized by the Minister under this section to make, use and exercise an invention shall include power—

(a) to sell such articles to the government of any country in pursuance of any such agreement or arrangement as aforesaid; and

(b) to sell to any person any articles made in the exercise of the powers conferred by this section which are no longer required for the purpose for which they were made. Provided that any such use as provided for herein shall be permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. [proviso inserted by Act 9 of 2002, with effect from the 20th December, 2002.]

(7) The purchaser of any articles sold in the exercise of powers conferred by this section and any person claiming through him shall have power to deal with them in the same manner as if the patent were held on behalf of the President.

(8) Regulations in terms of section ninety-six may govern the rights of third parties in relation to any use of a patented invention, or an invention in respect of which an application for a patent is pending, made for the service of the State in terms of this section or section thirty-five.

35 Special provisions as to State use during emergency

(1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient—

(a) for the efficient prosecution of any war in which Zimbabwe may be engaged; or

(b) for the maintenance of supplies and services essential to the life of the community; or

(c) for securing a sufficiency of supplies and services essential to the well-being of the community; or

(d) for promoting the productivity of industry, commerce or agriculture;

or

(e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade; or

(f) generally, for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or

(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in grave distress as the result of war; and any reference in that section or in section thirty-six to the service of the State shall be construed as including a reference to the purposes referred to in paragraphs

(a) to (g).

(2) In subsection (1)— “period of emergency” means any period beginning on such date as may be declared by the Minister, by statutory instrument, to be the commencement and ending on such date as may be so declared to be the termination of a period of emergency.

36 Reference of disputes as to State use

(1) Any dispute as to—

(a) the exercise by a department of the State or a person authorized by the Minister of the powers conferred by section thirty-four; or

(b) the terms for the use of an invention for the service of the State thereunder; or

(c) the compensation payable upon a reference to the Tribunal under subsection (4) of section twenty; or

(d) the right of any person to receive any part of a payment determined in terms of paragraph (b) or (c); may be referred to the Tribunal by any party to the dispute in such manner as may be prescribed.

(2) In any proceedings under this section to which a department of the State is a party, the Minister may—

(a) if the patentee is a party to the proceedings, apply for revocation of the patent upon any ground upon which a patent may be revoked under section forty-five;

(b) in any case, put in issue the validity of the patent without applying for its revocation.

(3) If in any proceedings under this section any question arises whether an invention has been recorded or tried as mentioned in section thirty-four or has been used by or on behalf of or to the order of a department of the State under subsection (3) of section twenty, and the disclosure of any document recording the invention or of any evidence at the trial or use thereof would, in the opinion of the Minister, be prejudicial to the public interest, the disclosure may be made confidentially to the legal practitioner, if any, appearing for the other party or to an independent expert agreed upon by the parties.

(4) In determining under this section any dispute between a department of the State and any person as to terms for the use of an invention for the service of the State, the Tribunal shall have regard to any benefit or compensation which that person or any person from whom he derives

title may have received or may be entitled to receive, directly or indirectly, from any department of the State in respect of the invention in question. [amended by Act 9 of 2002, with effect from the 20th December, 2002.]

AFRICAN INTELLECTUAL PROPERTY ORGANIZATION (OAPI)

Agreement Revising the Bangui Agreement of 02/03/1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), 24/02/1999)

Annex I
Articles 46-56

Article 46 Non-Voluntary License for Non-Working

(1) At the request of any person made after the expiry of a period of four years from the filing date of the patent application or three years from the date of grant of the patent, whichever period expires last, a non-voluntary license may be granted where one or more of the following conditions are fulfilled:

(a) the patented invention is not being worked on the territory of a member State at the time the request is made;

(b) the working of the patented invention on such territory does not meet the demand for the protected product on reasonable terms;

(c) on account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced.

(2) Notwithstanding the provisions of paragraph (1) above, a non-voluntary license may not be granted if the owner of the patent provides legitimate reasons for the non-working of the invention.

Article 47 Non-Voluntary License for a Dependent Patent

Where a patented invention cannot be worked without infringing the rights under an earlier patent whose owner refuses to authorize its use on reasonable commercial terms and procedures, the owner of the later patent may obtain a non-voluntary license for such use from the court on the same terms as those that apply to the non-voluntary licenses granted under Article 46 and on the following additional conditions:

(a) the invention claimed in the later patent must represent substantial technical progress, of considerable economic interest, in relation to the invention claimed in the earlier patent;

(b) the owner of the earlier patent has the right to a reciprocal license on reasonable terms for the use of the invention claimed in the later patent;

(c) the use authorized in relation to the earlier patent shall be intransferable except where the later patent is also transferred.

Article 48 Request for the Grant of a Non-Voluntary License

(1) The request for the grant of a non-voluntary license shall be made to the civil court of the domicile of the patentee or, if the latter is domiciled abroad, to the civil court of either his elected domicile or the place in which he has named an agent for the purposes of filing. Only requests made by persons domiciled on the territory of a member State shall be considered. The owner of the patent or his agent shall be informed thereof without delay.

(2) The request shall contain

(a) the name and address of the requester;

(b) the title of the patented invention and the number of the patent in respect of which a non-voluntary license is requested;

(c) evidence that the working of the patented invention on the above-mentioned territory does not meet demand for the protected product on reasonable terms;

(d) in the case of a non-voluntary license requested under Article 45 above, a statement by the requester in which he undertakes to work the patented invention on the territory of one of the member States in such a way as to meet the needs of the market.

(3) The request shall be accompanied

(a) by proof that the requester has previously approached the owner of the patent, by registered letter, requesting a contractual license, but has been unable to obtain such a license from him subject to reasonable commercial terms and procedures and within a reasonable time;

(b) in the case of a non-voluntary license requested under Article 46 or 47, by proof that the requester is capable of working the patented invention.

Article 49 Grant of Non-Voluntary License

(1) The civil court shall examine whether the request for the grant of a non-voluntary license satisfies the requirements of Article 48 above. If the request does not satisfy the said specified requirements, the court shall reject it. Before rejecting the request, the court shall inform the requester of the deficiencies of his request and shall allow him to make the necessary corrections.

(2) Where the request for the grant of a non-voluntary license satisfies the requirements of Article 48 above, the civil court shall notify it to the owner of the patent concerned, and also to any licensee whose name appears in the Register of Patents, and shall invite them to submit their observations on the said request in writing within a period of three months. Such observations shall be communicated to the requester. The civil court shall likewise notify the request to any government authorities concerned. The civil court shall hold a hearing on the request and the observations received to which the requester, the owner of the patent, any licensee whose name appears in the Register of Patents and any government authorities concerned shall be invited.

(3) Once the procedure prescribed in paragraph (2) above has been completed, the civil court shall take a decision on the request, either granting or refusing the non-voluntary license.

(4) If the non-voluntary license is granted, the decision of the civil court shall specify

(a) the scope of the license, specifying in particular the acts referred to in Article 1(2) of this Annex to which it extends and the period for which it is granted, it being understood that a non-voluntary license granted under Article 46 or 47 above cannot extend to the act of importation;

(b) the amount of the remuneration to be paid by the licensee to the owner of the patent; in the absence of agreement between the parties, such remuneration shall be equitable, due regard being had to all the circumstances of the case.

The said amount shall be subject to judicial revision.

(5) The decision of the civil court shall be in writing and shall state the grounds on which it is based. The civil court shall convey the decision to the Organization, which shall register it. The civil court shall publish the decision and shall notify it to the requester and to the owner of the patent. The Organization shall notify the decision to any licensee whose name appears in the Special Register of Patents.

Article 50 Rights and Obligations of the Holder of a Non-Voluntary License

(1) After the expiry of the time limit for appeal specified in Article 52 of this Annex, or once an appeal decision has been handed down that wholly or partly upholds the decision by which the civil court granted the non-voluntary license, the grant of the latter shall authorize the licensee to exploit the patented invention according to the terms laid down in the decision of the civil court or in the appeal decision, and shall require him to pay the remuneration specified in the said decisions.

(2) The grant of a non-voluntary license shall not affect either license contracts in force or non-voluntary licenses in force and shall not preclude the conclusion of other license contracts or the grant of other non-voluntary licenses. The patentee may not however grant to other licensees more favorable terms than those of the non-voluntary license.

Article 51 Limitation of the Non-Voluntary License

(1) The beneficiary of the non-voluntary license may not, without the consent of the owner of the patent, grant any third party permission to perform any of the acts that he is authorized to perform under the non-voluntary license.

(2) Notwithstanding the provisions of paragraph (1) above, a non-voluntary license may be transferred together with the establishment of the beneficiary of the non-voluntary license or with the portion of his establishment that exploits the patented invention. No such transfer shall be valid without the authorization of the civil court. Before granting the authorization, the civil court shall give the owner of the patent a hearing. The civil court shall notify the authorization to the Organization, which shall register and publish it. Any transfer so authorized shall cause the new beneficiary of the non-voluntary license to accept the same obligations as those that were incumbent on the former beneficiary.

Article 52 Amendment and Withdrawal of the Non-Voluntary License

(1) At the request of the owner of the patent or the beneficiary of the non-voluntary license, the civil court may amend the decision on the grant of the non-voluntary license where new facts justify such amendment.

(2) At the request of the owner of the patent, the civil court shall withdraw the nonvoluntary license

(a) if the grounds for its grant have ceased to exist;

(b) if the beneficiary exceeds the scope of the license under Article 49(4)(a) above;

(c) if the beneficiary is in arrears with the payment of the remuneration referred to in Article 49(4)(b) above.

(3) Where the non-voluntary license is withdrawn under paragraph (2)(a) above, the beneficiary of the non-voluntary license shall be allowed a reasonable period within which to cease working the invention where immediate cessation would have serious adverse consequences for him.

(4) The provisions of Articles 48 and 49 of this Annex shall apply to the amendment or withdrawal of the non-voluntary license.

Article 53 Appeals

(1) The owner of the patent, the licensee whose name appears in the Special Register or any person who has requested the grant of a non-voluntary license may, within a period of one month from the publication specified in Articles 49(5), 51(2) or 52(4) above, appeal to the competent higher jurisdiction against a decision taken under Articles 49(3), 51(2) or 52 above.

(2) The appeal referred to in paragraph (1) above contesting the grant of a nonvoluntary license, the authorization to transfer a non-voluntary license or the amendment or withdrawal of a non-voluntary license shall have staying effect.

(3) The decision on appeal shall be notified to the Organization, which shall register and publish it.

Article 54 Defense of Rights Granted

(1) Any beneficiary of a contractual or non-voluntary license may, by registered letter, summon the owner of a patent to bring the necessary judicial actions for civil or criminal sanctions for any violation, mentioned by the said beneficiary, of the rights under the patent.

(2) If, within three months of the summons provided for in paragraph (1) above, the owner of the patent refuses or fails to institute the actions referred to in the said paragraph, the beneficiary of a license that has been registered may institute the actions in his own name, without prejudice to the owner's right to intervene in the actions.

Article 55 Cessation of the Obligations of the Beneficiary of the Non-Voluntary License

Any action seeking invalidation of the patent shall be directed against the patentee. If a final legal judgment declares the patent invalid, the beneficiary of the non-voluntary license shall be released from all obligations resulting from the decision granting him the nonvoluntary license.

Article 56 Ex-Officio Licenses

(1) Where certain patents are of vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously Compromises the satisfaction of the country's needs, they may be made subject, by an

administrative enactment of the competent Minister of the member State concerned, to the non-voluntary license regime. The said enactment shall specify the beneficiary administration or organization, the conditions, term and scope of the non-voluntary license and the amount of royalties payable.

(2) In the absence of amicable agreement between the owner of the patent and the administration concerned on the said conditions, they shall be set by the civil court.

(3) Ex-officio licenses shall be subject to the same conditions as the non-voluntary licenses granted under Article 46.

AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO)

Harare Protocol on Patents and Industrial Design

Section 3(12)

Section 3 Patents

[...]

(12) A patent granted by the Office shall in each designated State be subject to provisions of the applicable national law on compulsory licences, forfeiture or the use of patented inventions in the public interest.

ANDEAN COMMUNITY

Decision No. 486 of 14/09/ 2000 of the Commission of the Andean Community - Common Industrial Property Regime (Cartagena Agreement)

Articles 61-69

Chapter VII

Compulsory License Regime

61. On the expiry of a period of three years following the grant of the patent, or four years following the application for the patent, whichever is the longer, the competent national office may grant a compulsory license for the industrial manufacture of the product to which the patent relates, or for the full use of the patented process, at the request of any interested party, but only where, at the time of the request, the patent has not been worked as provided in Articles 59 and 60 in the member country in which the license is applied for, or where the working of the invention has been suspended for more than a year.

The compulsory license shall not be granted if the owner of the patent provides legitimate reasons for his failure to act, which may be reasons of force majeure, in accordance with the domestic provisions of each member country.

A compulsory license shall only be granted where the person who requests it has previously attempted to obtain a contractual license from the owner of the patent on reasonable commercial terms and conditions, and where that attempt has not had any effect within a reasonable time.

62. The grant of compulsory licenses referred to in the foregoing Article shall proceed subject to notification of the owner of the patent in such a way that, within the following 60 days, he may present his arguments if he sees fit.

The competent national office shall determine the scope or extent of the license, and in particular shall specify the period for which it is granted, its subject matter, the amount of the royalties and the conditions for the payment thereof. The said royalties shall be adequate, depending on the particular circumstances of each case, due regard being had especially to the economic value of the authorization.

A challenge to the compulsory license shall not prevent exploitation or have any effect on periods that have not expired. Its introduction shall not prevent the owner of the patent from charging, in the intervening period, the royalties specified by the competent national office in respect of the part not challenged.

63. At the request of the owner of the patent or the licensee, the licensing conditions may be altered by the competent national office where new circumstances dictate, and in particular where the owner of the patent grants another license on terms more favorable than those previously granted.

64. The licensee shall be bound to exploit the invention within a period of two years following the date of grant of the license, unless he justifies his inaction with a claim of unforeseen circumstances or force majeure. If he fails to do so, the competent national office shall revoke the compulsory license at the request of the owner of the patent.

65. On a declaration by a member country of the existence of public interest, emergency or national security considerations, and only for as long as those considerations obtain, the patent may be made subject to compulsory licensing. In that case the competent national office shall grant such licenses as may be applied for. The owner of the patent so licensed shall be notified where reasonably possible.

The competent national office shall specify the scope or extent of the compulsory license, and in particular the term for which it is granted, its subject matter and the amount of royalties and the conditions for the payment thereof.

The grant of a compulsory license for reasons of public interest shall not diminish the right of the owner of the patent to continue to work the said patent.

66. The competent national office shall, either ex officio or at the request of a party, and after having obtained the consent of the national authority on free competition, grant compulsory licenses where practices are noted that adversely affect free competition, especially an abuse by the owner of the patent of his dominant position on the market.

In such cases, when the amount of royalties is determined, due regard shall be given to the need to correct anti-competitive practices.

The competent national office shall refuse to revoke the compulsory license where it is probable that the circumstances that gave rise to it could recur.

67. The competent national office shall grant a license at any time where it is applied for by the owner of a patent the working of which requires the use of another, and where the said owner has been unable to secure a contractual license on reasonable terms. Such a license shall, without prejudice to the provisions of Article 68, be subject to the following:

(a) the invention claimed in the second patent must embody substantial technological progress in relation to that claimed in the first;

(b) the owner of the first patent shall have the right to a cross-license on reasonable terms for exploitation of the invention claimed in the patent; and

(c) the license under the first patent may not be assigned without assignment also of the second.

68. Compulsory licenses shall be subject to the following in addition to the foregoing provisions:
- (a) they shall not be exclusive, and no sublicense may be granted;
 - (b) they may only be transferred with the part of the enterprise or its intangible assets that enable them to be worked; the transfer shall be evidenced in writing and registered with the competent national office. Failing this they shall be devoid of legal effect;
 - (c) they may be revoked, subject to the adequate protection of the legitimate interests of persons who have been authorized under them, where the circumstances that gave rise to them no longer obtain and are unlikely to recur;
 - (d) their scope and duration shall be limited according to the purposes for which they have been granted;
 - (e) in the case of patents for invention that protect semiconductor technology, the compulsory license shall be granted only for public, non-commercial use or to remedy or rectify a practice declared contrary to free competition by the competent national authority under Articles 65 and 66;
 - (f) they shall provide for adequate remuneration according to the circumstances of each case, due regard being had to their economic value, without prejudice to the provisions of Article 66; and
 - (g) their use shall be mainly to supply the domestic market.

69. Compulsory licenses that do not conform to the provisions of this Chapter shall be devoid of legal effect.

COOPERATION COUNCIL FOR THE ARAB STATES OF THE GULF (GCC)

Patent Regulation of the Cooperation Council for the Arab States of the Gulf (as at 23704/2002)

Articles 19-22

Article 19

19/1 where the owner has never exploited the patented invention, or has insufficiently exploited it according to Article (13), the Board of Directors may grant a compulsory license, with observation of the following:

19/1/1 At least three years have elapsed after the grant of the patent.

19/1/2 the applicant proves that he exerted, over a reasonable period of time, efforts to obtain license from the patent owner for an adequate compensation, under fair terms.

19/1/3 that the license is not exclusive.

19/1/4 that the license is essentially granted to meet the demands of the local market.

19/1/5 that the license decision defines the scope and terms of the license, according to the purposes for which it was granted.

19/1/6 that the patent owner shall be paid an adequate compensation.

19/1/7 that the exploitation of the patent shall be limited to the licensee.

The license shall not be transferable to others except in case of change of ownership of the licensee's establishment, or the section, which exploits the patent, provided the Board of Directors, approves such transfer.

19/2 should the invention relate to "semi - Conductors" technologies, licensing shall only be permitted for public, general, and none commercial purposes, or to rectify practices that proved none competitive by judiciary or administrative decisions.

Article 20:

20/1 The decision granting the compulsory license shall not prevent granting of other compulsory licenses or deprive the patent owner from exploiting the same invention himself, or granting other exploitation licenses.

20/2 The Board of Directors may disregard clauses (19/1/1, and 19/1/2) of this Regulation if the request of compulsory license was due to a state of emergency, or due to a dire public necessity, or for non commercial use, in one or more council States.

20/3 if a government agency in a Council Member State requests a compulsory license to exploit a certain invention, based on the public interest, the Board of Directors may approve the grant of the license according to the terms of Article (19), with observation of clauses 20/1, 20/2.

Article 21:

Should the exploitation of an invention is of a significant technical advance and a considerable economic importance which require use of another invention, the Board of Directors may grant one or both parties a compulsory license to exploit the other invention unless they mutually agree on exploitation in an amicable manner. In such case, provisions of articles (19, and 20), shall be observed.

Article 22:

The Compulsory license shall be cancelled in the following cases:

22/1 If the beneficiary of this license fails to exploit it sufficiently in the Cooperation Council States within two years from the date of the grant of the license, renewable for another two years should the delay be found to be due to a legitimate reason.

22/2 if the beneficiary of the compulsory license fails to pay the due amounts and the amounts stipulated in the Bylaws within three months from the date of maturity.

22/3 if the beneficiary of the compulsory license fails to satisfy any other term that is stipulated in the decision granting the license.

22/4 if the circumstances due to which the license was granted end, and are unlikely to reoccur, if the legitimate rights of the licensee shall be observed.

EURASIAN PATENT ORGANIZATION (EAPO)

The Eurasian Patent Convention

Article 12

Article 12 Compulsory Licenses

(1) Compulsory licenses for the use of a Eurasian [patent by third parties may be granted in conformity with the Paris Convention for the Protection of Industrial Property by the competent authority of a Contracting State with effect in the territory of that State.

(2) A decision to grant a compulsory license may be contested in the courts or other competent authorities of the contracting State in the territory of which the compulsory license has been granted.

EUROPEAN UNION

Article 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Articles 1-20 of Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems⁴

Article 12 Compulsory cross-licensing

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.
2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.
3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
 - (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
 - (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.
4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

[End of Appendix and of document]

⁴ Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R0816> (Accessed May 7, 2019)