

## **Committee on Development and Intellectual Property (CDIP)**

### **Fifth Session**

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### **PATENT RELATED FLEXIBILITIES IN THE MULTILATERAL LEGAL FRAMEWORK AND THEIR LEGISLATIVE IMPLEMENTATION AT THE NATIONAL AND REGIONAL LEVELS**

*Document prepared by the Secretariat*

1. In the context of the discussions on Development Agenda recommendation 14, at the fifth session of the Committee on Development and Intellectual Property (CDIP) held from April 26 to 30, 2010, in Geneva, some delegations made comments on the document prepared by the International Bureau of the World Intellectual Property Organization (WIPO) on "Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels".
2. The said comments are incorporated in the present revised version of document CDIP/5/4.
3. *The CDIP is invited to take note of the contents of this document and its Annexes.*

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### ANNEX I: PROVISIONS OF LAW

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- (1) Compulsory Licenses
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## EXECUTIVE SUMMARY

4. The Committee on Development and Intellectual Property (CDIP), at its fourth session held from November 16 to 20, 2009, in Geneva, requested the Secretariat to prepare a document on flexibilities in the area of patents, in the framework of actions for implementation of recommendation 14 under the WIPO Development Agenda. According to this recommendation, WIPO shall make available advice to developing countries, especially LDCs, on the implementation, understanding and use of flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).
5. Particular attention has been paid by Member States to the implementation and use of flexibilities in the field of patents, presumably because policy makers and experts have been confronted with the need for flexibilities in sensitive sectors, such as the health sector, where flexibilities have played an important role in policies promoting access to medicines.
6. Following the request of the CDIP, the Secretariat has prepared this preliminary study on the issue of patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional level. In view of the complexity of the topic, the approach chosen consists in presenting a non-exhaustive number of flexibilities in the patent area, accompanied by a conceptual development for each, as well as annexes and tables reflecting corresponding legal provisions and practices in a substantial number of countries. If this approach is acceptable to Member States, work on further flexibilities adopting the same approach would be submitted in the near future.
7. In addition to background information, this document is divided into four distinct parts, namely:

Part II is focused on the multilateral legal framework on patents; consideration is given to the effects that, at the international level, the change from the Paris Convention System of *asymmetries* to an increased level of harmonization after the TRIPS Agreement, when the concept of *flexibilities* became meaningful;

Part III gives attention to the implementation of multilateral treaties on patents, with special attention to the different situations among regions and among countries in the legislative implementation of the TRIPS Agreement;

Part IV delimits the concept of flexibilities, taking into account several proposals from experts and a brief attempt at an academic classification; and

Part V provides a non-exhaustive list of flexibilities in use, namely, compulsory licenses and government use; exhaustion of rights; research exemption; regulatory review exception; and utility models.
8. Annexes I and II follow this document. Annex I contains relevant provisions of the national and regional laws which are categorized in the tables of Annex II. Annex II categorizes some specific elements of the above-mentioned flexibilities which have been considered as the starting point for this work. Although the identified laws represent the current situation worldwide, not all laws could be included. Future work may allow the Secretariat to include such information.
9. The purpose of this preliminary study is to show that flexibilities are legal tools that countries can use as they see fit in their national developmental plans and within the

framework of the mandatory standards of international obligations. As can easily be recognized from the different legal provisions, policy makers and law makers have many options for the legal implementation of those flexibilities; therefore, careful attention to the variety of those provisions would be an important exercise for countries where the implementation of the TRIPS Agreement is still in progress.

10. If Member States consider it appropriate, discussions at the regional level might be a useful tool for examining how flexibilities work in practice. The interchange of experiences about the difficulties and advantages that countries encounter in the use of flexibilities could inform a later version of this document, and could also assist countries to consider those practical experiences when facing their own policy choices.

## I. BACKGROUND

11. At the fourth session of the Committee on Development and Intellectual Property (CDIP) held from November 16 to 20, 2009, in Geneva, Member States requested the Secretariat to prepare a document on flexibilities, taking into account the interest expressed in previous sessions by several delegations.
12. The subject of flexibilities is referred to mainly in recommendation 14 of the Development Agenda, stating that WIPO shall make available advice to developing countries, and especially LDCs, on the understanding and use of flexibilities contained in the TRIPS Agreement. This advice has been provided by WIPO through legislative assistance and policy advice in intellectual property matters.
13. The subject of flexibilities is a cross-cutting issue, not just among the different domains of intellectual property, but among intellectual property policies and other related policies. Nevertheless, particular attention has been given by Member States to the implementation and use of flexibilities in the field of patents, presumably because policy makers and experts have been confronted with the need for flexibilities in sensitive sectors, such as the health sector, where flexibilities have played an important role in policies promoting access to medicines. Therefore, it is appropriate to initiate this work in that domain.
14. The present document is submitted as a preliminary study on the issue of patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels. The document is divided into four distinct parts, namely: the multilateral legal framework on patents; the implementation of multilateral treaties on patents; the definition of flexibilities and attempted academic classification; and the identification of a group of flexibilities in use. Annex I shows provisions contained in several national and regional laws and Annex II includes a categorization of various provisions.

## II. THE MULTILATERAL LEGAL FRAMEWORK OF PATENTS

15. By the second half of the 19<sup>th</sup> century, many countries had recognized the value of the patent system as a tool for technological and economic development; consequently, several systems for the protection of inventions were established. In this initial period of the patent system, national laws were adopted based on standards determined by each government, keeping in mind mainly industrial policy and related concerns. Since no international convention in the field of industrial property existed at that time, it was rather difficult to obtain patents in foreign countries; for example, different treatments between foreign applicants and national applicants were often applied. Moreover, patent applications had to be filed roughly at the same time in all countries so that publication in one country would not destroy the novelty of the invention in the other countries. This inadequate protection for foreign inventors resulted in the adoption of the Paris Convention for the Protection of Industrial Property (Paris Convention) in 1883.<sup>1</sup>

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<sup>1</sup> The Paris Convention lays down a number of principles for the protection of industrial property abroad; three of them are most relevant here. Firstly, the principle of national treatment obliges each Member State to extend to the nationals of any other member States (including those persons and enterprises domiciled or having a commercial or industrial establishment in any other member States) the same treatment in respect of industrial property as it applies to its own nationals. Secondly, the

16. Since then, the Paris Convention has been subjected to several revisions (Brussels 1900, Washington 1911, The Hague 1925, London 1934, Lisbon 1958 and Stockholm 1967); each new Act incorporated new developments in the field and updated the Convention to new realities.<sup>2</sup> Also, important international treaties have been concluded as Special Agreements within the framework of the Paris Convention (Article 19) for the protections of industrial property. In the field of patents, the following Special Agreements have been implemented: the Patent Cooperation Treaty (PCT),<sup>3</sup> the Strasbourg Agreement Concerning the International Patent Classification (Strasbourg Agreement),<sup>4</sup> the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty)<sup>5</sup> and the Patent Law Treaty (PLT).<sup>6</sup> All those treaties are administered by WIPO and share among them some characteristics that are relevant to the objective of this study:

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right of priority facilitates the filing of patent applications in foreign countries. Any person who files, in a Contracting State, an application for a patent or utility model enjoys a right of priority for the subsequent filing in any other member State within a defined priority period (twelve months), provided that he meets the formalities prescribed in the Convention. Consequently, any subsequent application in another country before the expiration of the priority period will not be invalidated by reason of any acts accomplished in the interval. And thirdly, a patent cannot be refused, invalidated or otherwise terminated in any Contracting State on the ground that a patent for the same invention has been refused, invalidated, or terminated in any other Contracting State.

<sup>2</sup> This trend of constant revision was discontinued in 1981 when a diplomatic conference convened for a new revision focusing on patent-related matters was unable to reach a consensus.

<sup>3</sup> Under the PCT system, an applicant may file a single "international patent application" that has the same effect as a national application in each Contracting Party to the PCT. It also provides a streamlined procedure in those countries by establishing a single international procedure for certain operations to process patent applications (international phase). Consequently, the applicant can file and process his application under a single procedure with a single set of formality requirements during the international phase in accordance with the PCT and its Regulations.

<sup>4</sup> This Treaty provides for a common classification for inventions, including published patent applications, utility models and utility certificates. The International Patent Classification (IPC) is a hierarchical classification system in which the whole range of technology is divided into a number of sections, classes, subclasses and groups, in total approximately 70,000 subdivisions. This classification is indispensable for the retrieval of patent documents in the search for "prior art." Such retrieval is needed by patent-issuing authorities, potential inventors, research and development units, and others concerned with the application or development of technology, for considering the novelty of an invention or for determining the state of the art in a particular area of technology.

<sup>5</sup> The Treaty is intended to facilitate the disclosure of inventions that involve a microorganism or the use of a microorganism, when this disclosure is impossible or difficult to accomplish in writing; in such a case the disclosure requirement can be fulfilled through the deposit with a specialized institution of a sample of the microorganism. In order to eliminate the need to deposit in each country in which patent protection is sought, the Budapest Treaty provides that the deposit of a microorganism with any "international depositary authority" suffices for the purposes of patent procedure before the national patent offices of all Contracting States and before regional patent offices that have declared that they recognize the effects of the Treaty (the European Patent Office (EPO), the Eurasian Patent Organization (EAPO) and the African Regional Intellectual Property Organization (ARIPO) have made such declarations).

<sup>6</sup> The aim of the Patent Law Treaty (PLT) is to harmonize and streamline formal procedures in respect of national and regional patent applications and patents. With the significant exception of the filing date requirements, the PLT provides a maximum set of requirements which the Office of a Contracting Party may apply. This means that a Contracting Party is free to provide for requirements which are more generous, but not more restrictive, from the viewpoint of applicants and owners.

- (i) the motivation for those treaties related only to IP and not to trade issues;
- (ii) there is a great degree of flexibility in the implementation of those treaties, even in the case of treaties dealing with substantive standards of IP protection, such as the Paris Convention, where the *room to manoeuvre* left to members of the Union is wide. This policy space that the Treaty gave to members is called by academics and experts the *asymmetries* of the Paris Convention, instead of using the more recent expression of *flexibilities*, which is mainly used to refer to the policy space left by the TRIPS Agreement; and
- (iii) any difference concerning the interpretation or the implementation of those treaties that cannot be resolved by negotiations may be brought before the international Court of Justice.<sup>7</sup> Compared to the treaties adopted under the auspices of WIPO, one of the main provisions of the TRIPS Agreement is the dispute settlement system established under the WTO Agreement.<sup>8</sup>

**(a) The Asymmetries of the Paris Convention**

17. As mentioned before, the policy space left by the Paris Convention to countries members of the Union was referred to as *asymmetries*. The implementation of the Paris Convention that members enjoy was derived from the application of the principle of national treatment, as established in Article 2(1) of the Convention, which reads:

“Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention...”

18. This means that, where the Paris Convention does not establish minimum mandatory standards, members of the Union are free to set those standards in their law. In the case of patents, there is no such standard of protection indicated in the Paris Convention;<sup>9</sup> there is no indication, for example, of the requirements of patentability, nor what should constitute eligible subject matter, among other things. Therefore, under the Paris Convention, to have a patent system in place is not a choice,<sup>10</sup> but important points for policy consideration in the patent field remain open for governments to decide.

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<sup>7</sup> Article 28 of the Paris Convention and Article 59 of the PCT.

<sup>8</sup> Articles XXII and XXIII of GATT 1994 (except subparagraph 1(b) and 1(c) of Article XXIII), as elaborated and applied by the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes, apply to consultations and the settlement of disputes under the TRIPS Agreement. This means that benefits enjoyed in another trade area may be withdrawn in retaliation for the violation of the TRIPS Agreement (so-called cross-retaliation).

<sup>9</sup> The Paris Convention provides for a number of minimum standards of protection for marks (e.g., Article 6*bis*, 6*quinquies*, 6*septies* and Article 7).

<sup>10</sup> The Paris Convention provides certain common rules that are either required or permitted to be implemented under national legislation. In the field of patents, they include the right of the inventor to be mentioned in the patents (Article 4*ter*), questions as to importation of articles covered by patents, failure to work the patented invention and compulsory licenses (Article 5A), grace period for the payment of maintenance fees (Article 5*bis*), limitation of patent rights where the patented invention is on a means of transportation entering the territory temporarily (Article 5*ter*), process patent protection where a product manufactured by such process was imported (Article 5*quater*), and temporary protection in respect of goods exhibited at international exhibitions (Article 11). Many of those

19. Therefore, countries are free to set their own standards of patent protection in their national laws which will also apply to other members of the Union. However, in case no protection is available to their own nationals - for instance because the invention is excluded from patentability - the same standard would apply for nationals of other countries. Thus, if pharmaceutical products are excluded in a given country, neither a national of that country nor of any other country, would be able to secure protection for their inventions on this type of product, without any challenge to the Paris Convention.<sup>11</sup>

**(b) Flexibilities in the TRIPS Agreement**

20. A different approach is taken in the TRIPS Agreement, which lays down the minimum substantive standards of protection that must be provided by WTO Members. There is a common understanding among experts that those standards were set broadly at the current level of developed countries at the time of the negotiations of the Uruguay Round;<sup>12</sup> therefore a reduction of *the room for manoeuvre* was the consequence of the inclusion of new minimum substantive standards.
21. Developing countries, aware of the implications of this change to a new “post TRIPS era” where policy space has been reduced, are looking for a better understanding of this set of rules, to be able to implement the Agreement in a consistent manner as well as to take advantage of the options available, which might be used in the implementation of the Agreement according to their national policy choices.<sup>13</sup> These options are defined by the concept of *flexibilities*.
22. Thus, flexibilities are derived from the normal exercise of treaty implementation. All treaties provide options for countries’ decisions and choices when implementation is undertaken.

**III. THE IMPLEMENTATION OF MULTILATERAL TREATIES ON PATENTS**

23. International treaties have to be implemented in the national legal system in order to be recognized as *source de droit*. In certain countries, treaties are directly implemented, and in other cases it is necessary to adopt a national law or equivalent legal measure. It

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provisions leave a number of issues open to national legislators. For instance, Article 11 requires Member States to provide temporary protection in respect of goods exhibited at international exhibitions, leaving Member States to choose the means for implementing such protection by their domestic legislation.

<sup>11</sup> Under the TRIPS Agreement, specific provisions mandate patent protection for pharmaceutical and agricultural chemical products (Articles 27, 65.4 and 70.8) as well as provide for transitional periods for the implementation of this obligation. These transitional periods have lapsed, with the exception of LDCs which enjoy an extension until 2016.

<sup>12</sup> See Paul Vandoren, ‘The implementation of the TRIPS Agreement’, *Journal of World IP* (1999) Vol 2, Page 27.

<sup>13</sup> See Ng-Loy Wee Loon ‘Exploring Flexibilities within the Global IP Standards’, *I.P.Q.* (2009) 2, 162-164. Also, Nuno Pires de Carvalho, ‘Seminar for Certain Asian Countries on Flexible Implementation of TRIPS Provisions’, Singapore, July 2008: “the TRIPS Agreement, even if it is an instrument of harmonization, where it is not a straightjacket, because it still leaves open in many areas and instances the possibility of WTO Members to conform national standards of intellectual property protection in order to pursue national public policies”.

would be beyond the scope of this document to examine in depth the two major theories, monist and dualist, on the nature of the relationship of international and municipal laws.<sup>14</sup> It is more helpful to focus on the conditions that a given country may apply directly and easily, without the assistance of any other instrument, such as an international rule of law that is precise and detailed, for example Article 6*bis* of the Paris Convention, which has been the direct source of well-known trademark protection in many countries. However, in other cases the rules contained in international treaties establish only general principles, leaving the parties to the treaty a *room for manoeuvre* when implementing it. In those cases, members would be free to adopt in their national laws the choices that fit better with their national policies.<sup>15</sup> This kind of rule is called non-self-executing international law.

24. In general terms, there are two kinds of non-self-executing international rules:<sup>16</sup> those not creating obligations for the State but merely allowing for discretionary power; and those which, although they create obligations, cannot be implemented because the necessary organs or mechanisms have not yet been developed. An example of a non-self-executing rule is one that is vague or indeterminate, especially when it contains declarations of principles rather than specific rules. Multilateral treaties similar to national constitutions contain mainly global goals, are wide sources of inspiration for the solution of concrete problems not foreseen in the text, and allow for necessary evolution in changing circumstances. Some academics have indicated as examples of non-self-executing international law certain provisions of the TRIPS Agreement.<sup>17</sup>
25. In the specific case of the TRIPS Agreement, it is unclear whether Members of the WTO are able to apply it directly or have to incorporate it into national law through legislation. Members may determine certain administrative matters, such as the designation of competent authorities for granting or enforcing rights, or what is the most convenient process for the prosecution of those rights, among many other things. Members also have a wide range of options regarding matters not covered in the Treaty.<sup>18</sup>
26. The legislative implementation process and, particularly, how policy options have been incorporated in the national legislation of Members, vary from one region to the next, and within one region from one country to another. To some scholars, the response to commitments for implementation was not enthusiastic, to some extent justified by the

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<sup>14</sup> According to the monist doctrine, the law is a single unit composed of binding legal rules that form two legal sub-systems, related in hierarchic order. In that sense, an international agreement signed by a specific country does not need to be implemented expressly within the national legal system, because it is already part of the system. On the other hand, the dualist doctrine holds that the international system and the national system are two different entities; in that sense an international treaty, in order to be applied in a specific country, needs a national implementation law.

<sup>15</sup> At the regional level the EU, in order to harmonize the national legal systems of its Member States, issues Directives containing general principles and objectives that are adopted by the EC legislative bodies. Then Member States would be free to implement them in their national system, taking into account the principles and objectives of the EC Directive.

<sup>16</sup> See Benedetto Conforti, *International Law and the Role of Domestic Legal Systems* (1993) Kluwer Academic Publisher.

<sup>17</sup> About the definition of TRIPS as “non-self-executing” international law, see Andrés Moncayo von Hase, ‘The application and interpretation of the TRIPS in Intellectual Property and International Trade’, *Kluwer Law International* (1998) edited by Carlos M. Correa and Abdulqawi A. Yusuf.

<sup>18</sup> For example, Members may choose their own standards of patentability and rules defining ownership of inventions.

perception of some Members that TRIPS' higher standards of protection would be a net negative in terms of welfare cost.<sup>19</sup> Nevertheless, implementation of the TRIPS Agreement in an important number of developing and least-developed countries (LDCs) started before the Treaty entered into force; for the TRIPS Agreement 2000 dateline, 28 developing country Members completed in advance their implementation process, 22 developing country Members showed outstanding legislative reforms, and 13 LDCs implemented legislative reforms in advance of their general mid-2013 deadline. Some developing countries had TRIPS-compatible legislation in place well in advance of the 2000 deadline, such as Chile, Mexico and South Korea. In the case of LDCs, the situation varies markedly: while some who have the right to use the transition period have not yet adopted implementing legislation, there are others that passed implementing legislation in advance of the initial 2006 transition period (for example, 12 francophone country members of OAPI, which are bound by the revised Bangui Agreement (2002)). Notably, Cambodia and Nepal committed themselves to apply the TRIPS Agreement before the 2013 deadline.

27. For the sake of clarity, it is worth mentioning that to have an implementing legislation does not mean that policy choices based on the available flexibilities in the TRIPS Agreement are reflected in the law; nevertheless, experience has been gained by developing countries in this process. For example, in a study conducted by WHO,<sup>20</sup> findings show the use by an important number of countries of flexibilities such as compulsory licenses,<sup>21</sup> parallel importation,<sup>22</sup> regulatory review exception<sup>23</sup> and transition periods.<sup>24</sup> Notwithstanding these findings, WHO called attention to those countries which are not making full use of available flexibilities.<sup>25</sup>
28. WIPO has been actively assisting countries on the implementation of their intellectual property legal system. During the period from October 2006 to September 2009, legal advice, comments and draft laws were provided in response to requests from the authorities of 49 countries.<sup>26</sup> In the same period, advisory missions and outreach

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<sup>19</sup> Daniel Gervais, '(Re)implementing the TRIPS Agreement on Trade-Related Aspects of Intellectual Property to Foster Innovation', *Journal of World Intellectual Property* (2009), Vol 12, no 5, pp 349.

<sup>20</sup> 'Has the implementation of TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favors public health?', *Bulletin of the World Health Organization*, (Nov. 2004) Vol. 82 No. 11 Geneva.

<sup>21</sup> The findings in the WHO study show that all countries examined, with the exception of Panama, included compulsory licenses in their legislation. All 10 countries that included compulsory licenses permitted their use in the case of national emergencies, 9 in case of public interest, 8 to remedy an anticompetitive practice, and 9 in the case of dependent patents.

<sup>22</sup> According to the WHO Study, Argentina, Andean Countries, Dominican Republic and Panama allow parallel importation.

<sup>23</sup> The WHO study mentions that express provisions are included in the legislation of Brazil and the Dominican Republic.

<sup>24</sup> Argentina, Egypt and India used the 2005 transition period for the granting of product patent protection for pharmaceuticals.

<sup>25</sup> The WHO study highlighted that countries involved in the study "have not been incorporating into their legislation all of the advantages that the TRIPS Agreement can provide. This means that these countries are not making full use of the mechanism that may enable them to ensure better health for the public, particularly in regard to gaining access to medicines".

<sup>26</sup> Afghanistan, Andorra, Angola, Argentina, Bangladesh, Bhutan, Bosnia & Herzegovina, Botswana, Brunei, Cambodia, CARICOM, Central African Republic, China, Colombia, Costa Rica, Djibouti, Dominican Republic, Ecuador, El Salvador, Equatorial Guinea, Grenada, Honduras, Indonesia, Lebanon, Maldives, Marshall Islands, Montenegro, Nepal, Nicaragua, OAPI, The Pacific Forum

missions on IP laws were undertaken in 15 countries,<sup>27</sup> mainly to discuss with the government authorities new or revised legislation, or to consult on specific topics of IP law. WIPO has organized a number of national, regional and international seminars and workshops regarding flexibilities and public policies in the patent field,<sup>28</sup> occasionally in association with other international organizations such as WTO. Therefore, technical assistance provided by WIPO and other international organizations and NGOs, as well as bilateral technical assistance, have proven useful to address the challenges that developing countries face in the implementation of multilateral treaties on IP, and particularly the TRIPS Agreement.<sup>29</sup>

#### IV. CLASSIFICATION AND MEANING OF FLEXIBILITIES

29. Member States of WIPO-administered treaties enjoy an important degree of *room for manoeuvre* in the implementation of their obligations, and experience has been gained through the implementation of all those treaties. Some experts believe that the foundation of the available flexibilities are to be found in the negotiation process of the TRIPS Agreement, where policy autonomy for implementation was agreed by Members, as trade negotiators favored an agreement with a great degree of built-in flexibility.<sup>30</sup> Moreover, the term “flexibility” is contained in certain provisions such as paragraph 6 of the Preamble of the TRIPS Agreement:

“[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”.

30. The meaning of the word “flexibility” as used in the Preamble is explained by Article 66.1, which reads:

“In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of...”

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Islands, Pakistan, Panama, Paraguay, Peru, Rwanda, the S.A.D.C. Countries, Senegal, Seychelles, South Africa, St. Lucia, Thailand, Trinidad and Tobago, Turkmenistan, Ukraine, United Arab Emirates, Uruguay, Viet Nam and Zanzibar.

<sup>27</sup> Afghanistan, Botswana, Colombia, Costa Rica, Dominican Republic, India, Maldives, Pakistan, Panama, Peru, Rwanda, Spain, Syria, Uruguay and Trinidad & Tobago.

<sup>28</sup> From October 2008 to October 2009, 8 national and 3 regional seminars were organized on the issue of flexibilities, as well as the Conference on Intellectual Property and Public Policy Issues, held in July 2009, in Geneva.

<sup>29</sup> Technical assistance may also be needed on the implementation of FTAs that incorporate IP matters, which may pose the same challenges to developing countries as multilateral treaties, see Pedro Roffe and David Vivas with Gina Vea, ‘Maintaining Policy Space for Development’, ICTSD, Issue Paper No. 19.

<sup>30</sup> Sisule F. Musungu and Cecilia Oh, Study commissioned by the CIPIH (August 2005), ‘The use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?’.

31. Nevertheless, in the experts' view, it was during the negotiation process<sup>31</sup> leading to the Doha Declaration on TRIPS and Public Health that the expression "flexibilities" gained widespread use, particularly by trade negotiators, and after the Declaration, this concept became part of the glossary of the IP community.
32. Much has been said and written about flexibilities, and many different opinions have been expressed, for example, it has been highlighted by experts and policy makers that flexibilities shouldn't be an excuse to avoid compliance with TRIPS obligations, while, on the other hand, attention has been drawn to the fact that flexibilities are not always the solution for problems in the field of intellectual property due, among others, to different economic development levels. This wide range of opinion reflects an essentially political aspect of the concept of flexibilities.

**(a) Definition**

33. One author<sup>32</sup> has defined flexibilities as a range of rights, safeguards and options that WTO Members can exploit in their implementation of the TRIPS Agreement; others construct the concept upon the idea of vagueness of some clauses of the treaty.<sup>33</sup> Another author<sup>34</sup> describes TRIPS patent-related flexibilities, limited to health matters, as follows:

"WTO Members countries were giving some *room to manoeuvre* and customize their patent laws in accordance with their unique legal systems, public-health situations and development needs. In particular, Members were given the ability to adopt certain measures that neutralize the impact of exclusive rights, promote competition and facilitate access to medicines. There were several flexibilities inherent in the TRIPS Agreement. All of those measures, consistent with the TRIPS Agreement, reduce prices and increase the affordability of medicines, without negatively affecting future R&D".

34. The term "flexibilities" means that there are different options through which TRIPS obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with. This definition would effectively delimit the scope of the concept through the following elements:
- (i) it highlights the idea of various options for means of implementation;
  - (ii) it refers to the legislative process of implementation, reflecting that the first step to get advantage of a given flexibility consists in incorporating it into the national law;
  - (iii) it refers to the reason for flexibilities, which is to accommodate national interest; and

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<sup>31</sup> Document IP/C/W/296, 29 June 2001, Paragraph 5: "Some provisions of the TRIPS Agreement may elicit different interpretations. This 'room to manoeuvre' served the purpose of accommodating different positions held by Members at the time of negotiations of the Agreement. We strongly believe that nothing in the TRIPS Agreement reduces the range of options available to Governments to promote and protect public health, as well as other overarching public policy objectives. The TRIPS Council must confirm this understanding as early as possible".

<sup>32</sup> Carolyn Deere, *The Implementation Game*, Oxford University Press (2009), p.68.

<sup>33</sup> In general, applying the concept of international law, one way to introduce flexibility into an international treaty is to formulate it vaguely, but to introduce a system of dispute settlement with binding effects for its interpretation, to fill gaps and to facilitate further developments.

<sup>34</sup> Elena Ghanotakis, 'Access to Medicines for Developing Countries', *Journal of World IP* (2004), vol 7, issue 14.

- (iv) it reflects that a given flexibility needs to be compatible with the provisions and principles of the treaty.

**(b) Classification**

35. Flexibilities could be classified in just two categories: those regarding transition periods, and “substantive” flexibilities in the TRIPS Agreement.<sup>35</sup> A more detailed classification could distinguish among: (i) subject matter which qualifies for protection; (ii) scope of the protection; (iii) modes of IP enforcement; and (iv) matters of administration.<sup>36</sup>
36. Perhaps the most useful way of grouping flexibilities takes into account the point in time at which Members may resort to them:<sup>37</sup> (i) in the process of the acquisition of the right; (ii) defining the scope of the right; and (iii) when enforcing the right.

**(i) Flexibilities in the process of acquisition of the right**

37. The first modality of flexibilities seeks to ensure that the titles of industrial property rights are adequate and proper, in order to create legal certainty. In the area of patents, flexibilities apply to both formal and substantive requirements of patentability: for instance, flexibilities on the application of the mandatory requirement of disclosure allow a given country to adopt a more stringent requirement than the minimum established by Article 29.1 of the TRIPS Agreement. Similarly, using the flexibility available to define the meaning of “sufficient disclosure”, a given country could require the description of the process for making the claimed product or parts of the product; or it could demand that the disclosure be adapted to the technological level of the receiving country, in order to promote effective technological dissemination; or it could require disclosure of access to genetic resources, in order to ensure compliance with access and benefit sharing requirements; or it might demand disclosure of sources of public funding. In the same group of flexibilities, we find those related to substantive requirements, such as the definition of invention (inventions vs. discoveries, such as genes or gene sequences; inventions vs. small, incremental improvements such as new salts, esters and polymorphs).<sup>38</sup>

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<sup>35</sup> Sisule F. Musungu and Cecilia Oh ‘The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?’, (2006) South Center.

<sup>36</sup> See Ng-Loy Wee Loon, ‘Exploring Flexibilities within the Global IP Standards’, *I.P.Q.* (2009), 2, 162-164.

<sup>37</sup> Nuno Pires de Carvalho, ‘Seminar for Certain Asian Countries on Flexible Implementation of TRIPS Provisions’, Singapore, July 2008.

<sup>38</sup> The Report of the Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy* (2002), London, recommends to developing countries the use of TRIPS flexibilities to exclude from patents the following: diagnostic, therapeutic and surgical methods for the treatment of humans and animals; plants and animals, with a restrictive definition of microorganisms; new uses of known products; plant varieties and where possible, genetic material. It also suggests that developing countries apply strict standards of novelty, inventive step and industrial application or utility, and make use of strict patentability and disclosure requirements to prevent unduly broad claims in patent applications. For developed countries, it recommends that they apply an absolute standard of novelty such that any disclosure anywhere in the world can be considered prior art; take greater account of traditional knowledge when examining patent applications; and require disclosure of information in the patent application of the geographical source of biological materials from which the invention is derived.

**(ii) Flexibilities related to the scope of the patent right**

38. The second category consists of measures to ensure that the right is adequately framed and dimensioned having in mind the objectives of its protection: to achieve social and economic welfare and to guarantee a balance of rights and obligations (Article 7). This group of flexibilities includes the possibility of using patented inventions for experimental purposes or for obtaining data necessary for anticipating marketing approval. They also include the grant of compulsory licenses on grounds of public interest (in all its modalities, such as lack of exploitation, and abusive and anti-competitive practices). The exhaustion of patent exclusivity is within this group of flexibilities.

**(iii) Flexibilities related to the use and enforcement of patent right**

39. Right holders, in order to benefit from the full enjoyment of their rights, should be able to rely on the enforcement measures that each Member state has put in place. As an example, civil judicial procedures must be available, and judicial authorities must have the power to order an infringer to desist from an infringement and to pay adequate damages to compensate for the injury. Therefore, the third category consists of the group of flexibilities related to the enforcement of IP rights. In this regard, Member States are entitled to take necessary steps to prevent abusive and anti-competitive practices in the enforcement of IP rights (including the preventive control of such practices in contractual licenses). Another example of flexibility available in the field of enforcement that could be mentioned is the one related to damages, according to which a given country may /limit the owners' entitlement to damages, to those cases in which the infringer "knowingly, or with reasonable grounds to know, engaged in infringing activity".
40. The examples mentioned illustrate the broad range of options for Member States to set out rules that meet TRIPS obligations, while still paying attention to national needs. Striking the right balance in each discipline is a precondition for the IP system, and particularly for patents, to support countries' economic development.<sup>39</sup>

**V. FIVE SPECIFIC FLEXIBILITIES**

41. The TRIPS Agreement is a minimum standards agreement,<sup>40</sup> which allows Members to provide more extensive protection of intellectual property if they wish. Therefore, while some countries may wish to provide more protection than what is required by the Agreement, other countries might favor the idea of providing only minimum standards of

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<sup>39</sup> Keith E. Maskus, 'Intellectual Property Rights in the Global Economy', *Institute for International Economics* (2000), p.176.

<sup>40</sup> The TRIPS Agreement established standards concerning the availability, scope and use of patent rights. They include: (i) basic standards for patentability and a limited list of exceptions to patentable subject matter (Article 27); (ii) regarding availability of patents and the enjoyment of rights, no discrimination as to the field of technology, the place of invention and whether products are imported or locally produced (Article 27.1); (iii) rights conferred by a patent (Article 28) and exceptions to the rights (Article 30); (iv) conditions concerning the disclosure of the invention in a patent application (Article 29); (v) compulsory licenses (Article 31); (vi) availability of judicial review process for any decision to revoke or forfeit a patent (Article 32); (vii) the term of protection (Article 33) and (viii) the burden of proof in deciding whether a product was obtained by a patented process (Article 34).

protection. We will focus on those flexibilities which appear to be of primary concern to developing countries and LDCs.

42. Various papers have been published with the aim to identify flexibilities available in the context of the TRIPS Agreement. For instance, in a South Center document<sup>41</sup> dealing with access to medicine, the following patent-related flexibilities were identified: compulsory licensing; parallel importation; provisions related to patentable subject matter; provisions relating to patent rights; and provisions relating to abuse of rights, competition and the control of anti-competitive practices. Along the same line, an article entitled "Access to Medicines for Developing Countries"<sup>42</sup> described the right to grant compulsory licenses, parallel imports, and exceptions to exclusive rights.
43. Indeed, academicians have shown great interest in the issue of flexibilities in intellectual property, and an extensive set of literature is available on this topic. For example, one author<sup>43</sup> has identified the following patent-related flexibilities: exhaustion of rights and parallel importation; scope of patentability and optional exclusion; exceptions to patents<sup>44</sup> rights and enforcement. The same author also suggested matters not covered by the Agreement through which national policies may be developed: utility models, disclosure of origin of genetic material and prior informed consent, and traditional knowledge (folklore and cultural heritage were also mentioned).
44. Several publications consulted indicate the following measures as available flexibilities in the TRIPS implementation: compulsory licenses; exhaustion of rights; research exemption and regulatory review exception.<sup>45</sup> Also, the utility model system has been mentioned as an important policy tool to promote indigenous innovation. This group of flexibilities is a good starting point for this preliminary study.
45. As to each of the five cases of flexibilities, we will begin with the basic notion and then mention some of the elements that allow different implementation approaches. Those different approaches are reflected in the laws included as annexes of this document, and which are categorized in the tables for a better identification.

**(a) Compulsory Licenses and Government Use**

46. A large number of countries have provisions in their national legislation that allow the government and/or third parties, under certain circumstances and conditions, to use a patented invention without the authorization of the right holder. Such provisions differ from other exceptions, since the right to remuneration is an important element of the balance between the right holder's interest and other, wider interests. In general, compulsory licenses are considered as an instrument to prevent abuses of the exclusivity

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<sup>41</sup> Sisule F. Musungu and Cecilia Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', (2006) South Center.

<sup>42</sup> Elena Ghanotakis, 'Access to Medicines for Developing Countries', *Journal of World IP* (2004), vol 7, issue 14.

<sup>43</sup> Carolyn Deere, *The Implementation Game* (2009), Oxford University Press, p.75.

<sup>44</sup> On this specific flexibility, there a number of studies, including Christopher Garrison, 'Exceptions to Patents Rights in Developing Countries', *UNCTAD-ICSTD*, issue paper No. 17 and WIPO document on 'Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (SCP/13/3)'.

<sup>45</sup> Two of the experts invited to the WIPO Colloquium on selected Patents Issues that took place in Geneva on February 2007 (Prof. Joseph Straus and Dr. Gopalakrishnan) also focused on the same list of flexibilities in their presentations.

inherent in the patent rights. Also, they are seen as safeguards for governments to ensure national security and to respond to national emergencies.

47. Some commentators consider that the existence of a statutory provision on compulsory licenses is an important tool to ensure a fair exercise of patent rights, such as encouraging the conclusion of voluntary licenses at reasonable conditions, or inducing competition.<sup>46</sup> Also, a study jointly commissioned by the World Bank and ARIPO, which analyzed the use of compulsory licenses as a tool to improve access to medicines in Africa, concluded that in four of the countries where local production was tried, only in one case was a compulsory license effectively granted (Zimbabwe);<sup>47</sup> in the other three cases, a voluntary license was agreed (Kenya,<sup>48</sup> South Africa,<sup>49</sup> and Ghana<sup>50</sup>). However, another author takes a more cautious approach in stating that it could be neither measured nor discounted to what extent the threat of applying a compulsory license enhances the bargaining position of would-be voluntary licensees.<sup>51</sup>
48. WTO Members have to comply with Article 31 of the TRIPS Agreement regarding the conditions to be met in the grant of compulsory licenses; this document further refers to some of the possible grounds for compulsory licenses, without exhausting all possibilities. As confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, each Member has the right to grant compulsory licenses<sup>52</sup> and the freedom to determine the grounds upon which such licenses are granted.
49. These grounds generally include one or more of the following: non-working or insufficient working of the patented invention; anti-competitive practices and unfair competition; public interest, including public health, national security, national emergencies and other circumstances of extreme urgency; failure to obtain a voluntary license under reasonable

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<sup>46</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (2001), p.328.

<sup>47</sup> Zimbabwe amended its Patent Act in 2002, incorporating several of the flexibilities available in the TRIPS Agreement, such as compulsory licenses (Section 34). The local production of ARV products was part of the Government's strategy to promote access to those medicines. In this connection, the Ministry of Justice in its letter of April 8, 2003, commissioned the local pharmaceutical company Varichem to produce antiretroviral or HIV-related drugs. In July 2003 Varichem launched its first generic ARV product, VARIVAR. According to the study, the company's main obstacles to successfully accomplish its plans were: absence of prequalification by the WHO; the cost of in vivo bioequivalence trials; and the cost of materials (APIs).

<sup>48</sup> COSMOS, one of 30 local generic manufacturers, applied for a compulsory license (Section 80 of the Industrial Property Act of 2001). The right holders (GSK and Boehringer) granted to COSMOS a voluntary licenses to manufacture and market Lamivudine, Nevirapine, Zidovudine and the combination of those drugs in Kenya and East Africa.

<sup>49</sup> The study highlighted that after a process brought before the Competition Commission of South Africa against GSK and Boehringer, based on charges of anticompetitive practices, both companies granted a voluntary license to the local ASPEN Pharmacare Holdings Limited and two other generic companies for the "production of the generic versions of Stavudine, Veriapine, Lamivudine, Zidovudine and combination thereof". According to the study, "Aspen appears to have effectively taken advantage of the voluntary license to successfully build and sustain a viable local ARV manufacturing company".

<sup>50</sup> The study reports that a local generic pharmaceutical company, DANADAMS, is actively looking to acquire voluntary licenses agreement with right holders of patents in force in Ghana, for example, an immunity-from-suit agreement with Bristol-Meyers Squibb for the production of the generic versions of Stavudine and Didanosine.

<sup>51</sup> W. R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Fourth Edition, p.295-296.

<sup>52</sup> With a few exceptions, developing countries provide for compulsory licenses in their national laws.

terms within a reasonable period; and dependent patents and other titles that relate to the protection of inventions.

50. Members are also bound by the Decision of the General Council of August 30, 2003,<sup>53</sup> on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 Decision); therefore, some national laws provide specific provisions in order to implement that Decision.
51. In addition to the above, a number of countries laid down explicit provisions in their national laws that entitle the government, or a third party who is authorized by the government, to use the patented invention without authorization of the patentee under certain circumstances.<sup>54</sup> In some countries, such government use is permitted if the public interest, such as national security,<sup>55</sup> nutrition, health or the development of other vital sectors of the national economy so require, or if government use adequately remedies the anti-competitive practice engaged in by the patentee or his licensee. As in the case of the grounds for the grant of compulsory licenses, the grounds for government use are stricter in some jurisdictions and more liberal in others.
52. As reflected in Annex I(1) and Annex II(1), the differences among national laws on this issue have made the work of categorization complex. Its main goal is to show the more or less frequent use of a given ground for a compulsory license. However, the dividing line between a compulsory license based on public interest and government use on public interest grounds is not always easy to identify in the laws consulted, except where express indications were given. Thus, there is space for more precise elaboration in the future, if Member States so wish.

**(b) Exhaustion of Rights**

53. Patent rights, like other intellectual property rights, are territorial in nature, which means that each patent provides its owner the exclusive right of exploiting the invention within the limits of the country or countries where the patent was granted. Thus, one single invention could be the object of patent protection in several countries, creating rights that are independent from each other (Article 4*bis* Paris Convention). Article 28 of the TRIPS

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<sup>53</sup> The Decision was designed to address the public health problems recognized in Paragraph 1 of the Doha Declaration on TRIPS and Public Health, which says that WTO ministers “recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” The Decision takes the form of an interim waiver, which allows countries producing generic copies of patented products under compulsory licenses to export the products to eligible importing countries. The waiver would last until the WTO’s intellectual property agreement is amended. The Decision covers patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits

<sup>54</sup> In the United States of America, a third party who uses a patented invention in the performance of a Government contract in effect obtains immunity to liability for patent infringement of the patent. This is based on 28 USC §1498(a) which states that: “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.”

<sup>55</sup> For example, in France, the Government may at any time obtain *ex officio*, in order to meet its defense requirements, a license to work an invention that is the subject of a patent application or a patent, whether the task is to be done by the Government itself or on its behalf.

Agreement (Rights Conferred) enumerates those rights. It includes among them the “right of importation” because the exclusive right derived from a patent could be affected by the importation of the patented product from another country.

54. Article 28 contains a footnote regarding the right to prevent importation, stating that this right, “like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6”.<sup>56</sup> This means that the possibility of enforcing the exclusive rights of patents against the importation of legitimate products varies according to the level of exhaustion of rights adopted by the country where the importation takes place.<sup>57</sup>
55. The doctrine of exhaustion (of patent rights) is linked to the issue of parallel importation. Under the exhaustion doctrine, once a patent-protected article (a patented product or a product made by a patented process) has been put on the market by the right holder or with his consent, the patent owner’s rights in respect of that product are terminated. This limitation assures free circulation of products.
56. In countries in which the law provides for a national level of exhaustion, the rights of the owner of the patent are exhausted only in respect to goods that have been put on the market in the country with his consent.<sup>58</sup> Attention has been drawn by the Commission on Intellectual Property Rights (CIPR) in its report<sup>59</sup> to the positive practical implications that a restriction on parallel importation may have in facilitating access to lower priced medicines to those that need it most:

“In principle, it is undesirable for there to be restrictions upon the free movement of products once placed on the market by a manufacturer. But in practice and strictly for the purpose of ensuring that lower priced products can be supplied to, and only to, those who need the lower prices, it may be necessary to derogate from that general principle. Therefore an important component in establishing a system of differential pricing is that markets need to be segmented to prevent low priced products undermining high priced markets. For that purpose, it is essential that developed countries put in place effective mechanisms that prevent parallel importing of medicines”.

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<sup>56</sup> Article 6 of the TRIPS Agreement allows each WTO Member to determine its own regime on exhaustion (whether national, regional or international), subject to the national treatment and Most Favored Nation (MFN) provisions of Articles 3 and 4, respectively, of the Agreement.

<sup>57</sup> This means that parallel importation of goods into a country will not be permitted where that country’s legislation provides for *national exhaustion*. Such importation will be permitted into a country with a *regional system of exhaustion* in so far as the goods were released in a country of the region by the owner of the patent or with his consent. In a country applying a system of *international exhaustion*, patented products put on the market by the owner of the patent or with his consent in any country may be imported into that country without constituting an infringement of the patent.

<sup>58</sup> It seems that this level of exhaustion has been adopted by several African countries, such as Ghana, Liberia, Madagascar, Morocco, Mozambique, Namibia, Tunisia, Uganda, and a certain number of Asian countries, such as the Philippines.

<sup>59</sup> The Report of the Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy* (2002), London (see also: [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm)).

57. In a system which provides for regional exhaustion once goods are released with the consent of the owner of the patent in any country member of a regional market or union,<sup>60</sup> the rights of the patent owner are exhausted and the goods may be imported to other countries of that regional market or union, and trading in such goods would not constitute an infringement. The elaboration of the regional exhaustion doctrine in the European Union goes back to a groundbreaking decision of the European Court of Justice (ECJ) in the early 1970s, where a distinction was made between the existence of IP rights and the exercise of those rights, particularly the way the exercise may be affected by the Treaty's prohibition against restrictions on the free movement of goods.<sup>61</sup> The derogation of the free movement of goods principle was considered by the ECJ justified only for the purpose of safeguarding rights which constitute the specific subject matter of this property, for instance, in the case of patents where the specific subject matter consists in:

“the guarantee that the patentee, to reward the creation effort of the inventor, has the exclusive right to use the invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well the right to oppose infringements.”<sup>62</sup>

58. Under a system of international exhaustion, goods put on the market by or with the consent of the patent owner anywhere in the world would result in the patent owner's rights being exhausted in the country concerned. Thus, goods imported into a country with a system of international exhaustion of rights cannot be considered as infringement so long as they were put on the market, originally, by the owner of the patent or with his consent.<sup>63</sup>
59. Article 6 of the TRIPS Agreement does not establish which level of exhaustion (i.e., national, regional or international) members shall adopt, subject to its provisions on national treatment and most-favored-nation treatment.<sup>64</sup> The decision about the level of exhaustion that is appropriate for a given country is a matter of policy consideration, in which some elements are not IP related, but based on certain market situations, as Cornish<sup>65</sup> has stated:

“In every intellectual property law it is necessary to decide which steps in the chain of production and distribution of goods require the licence of the right owner: manufacture, first sale by the manufacturer, subsequent sales and other dealings, export and import, use. In the past, legislators have often left the answer to the courts. In many cases, both in British and foreign laws, the rights are ‘exhausted’ after first sale by the right owner or with his consent. But often this is confined to the first sale to the territory covered by the

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<sup>60</sup> An example of regional exhaustion is that of the European Union, based on Articles 28 and 30 of the Treaty of Rome dealing with the free movement of goods.

<sup>61</sup> *Deutsche Grammophon, GmbH v Metro-SB-Grossmarket, GmbH & Co*, Case 78/70, [1971].

<sup>62</sup> ECJ, Case 15-74 [1974], *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.*

<sup>63</sup> Some examples of countries applying international exhaustion are: In Africa, Egypt (Section 10(1) of the Law on the Protection of Intellectual Property Rights no. 82/2002) and South Africa (Section 15c of the Medicines Act). Also several Latin-American countries have adopted international exhaustion, such as Argentina (Article 36 c) of the Patent Law), the Member countries of the Cartagena Agreement (Art. Decision 486), and Costa Rica (Section 16 of its Patent Law of 25/04/1983, No. 6867). In Asia, some examples are: India, Malaysia and China (it seems that Article 63 of the Patent Law, modified in 2009, provides an international exhaustion system).

<sup>64</sup> The Doha Declaration has reaffirmed that each member is free to establish its own regime without challenge.

<sup>65</sup> W. R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*.

right-it amounts to a domestic, rather than international, exhaustion. Accordingly, national rights that are subject to such limitation can still be used to prevent the importation of goods sold abroad by the national right-owner or good which come from an associated enterprise”.

60. Certain countries, such as Japan<sup>66</sup> or the United States of America,<sup>67</sup> have not adopted express legislative provisions on exhaustion, leaving it to jurisprudence to determine the evolution of this matter. The current situation shows almost the same number of countries with national, regional and international exhaustion (see Annex I(2) and Annex II(2)).

**(c) Research Exemption**

61. The terminology is not unanimous in how to call this concept: in some cases the expression used is “research exemption”, in others “research exception” and in others “experimental use exception”; it is thus proposed to use the expression contained in the law of a given country or in a cited case law.

62. A significant number of countries worldwide provide in their national laws the so-called research exemption<sup>68</sup> (see Annex I(3) and Annex II(3)). Others have developed this exception through their case law.<sup>69</sup> Therefore, it is not surprising that in the *Canada-Patent Protection of Pharmaceutical Product* case (DS114),<sup>70</sup> the WTO Dispute Settlement Panel has referred to the research exemption as “one of the most widely adopted Article 30-type exceptions in national patent laws”.

63. The panel in the *Canada-Patent Protection of Pharmaceutical Product* case,<sup>70</sup> defines the research exemption as follows:

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<sup>66</sup> In Japan, a recent decision of the Supreme Court seems to point to an international level of exhaustion (*Recycle Assist, Co. Ltd. v Canon, Inc.*, Japan Supreme Court, Heisei 18 (jyu) 826).

<sup>67</sup> In the U.S.A. the exhaustion doctrine has been developed since the 1873 case *Adam v Burke* in which the Supreme Court enunciated the principle according to which a patent’s monopoly ends with the first sale or disposition of an article embodying the claimed invention by the patentee, or by a licensee of the patentee acting within the scope of the license. Historically this doctrine seems more oriented towards national exhaustion, but openings to international exhaustion are found in a recent decision of a U.S. federal court of first instance, *LG Electronics Inc. v Hitachi, Ltd.* (No. 07-6511 CW, ND Cal, 13<sup>th</sup> March 2009).

<sup>68</sup> Albania, Armenia, Bahrain, Barbados, Belize, Brazil, Bolivia, Cambodia, Cameroun, Chile, China, Colombia, Costa Rica, Cote d’Ivoire, Croatia, Cuba, Cyprus, Dominica, Dominican Republic, Equator, Egypt, El Salvador, Gabon, Grenada, Guatemala, Guinea, Honduras, Iceland, India, Indonesia, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Korea, Kyrgyzstan, Lebanon, Malaysia, Mauritius, Mexico, Moldova, Mongolia, Morocco, Namibia, Nicaragua, Norway, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Qatar, St. Lucia, Saudi Arabia, Serbia and Montenegro, Singapore, Sri Lanka, Swaziland, Switzerland, Tanzania, Thailand, Tonga, Trinidad and Tobago, Tunisia, Turkmenistan, Turkey, Uruguay. Additionally the sixteen francophone countries members of the Bangui Agreement (Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Côte d’Ivoire, Gabon, Guinea Bissau, Guinea, Guinea Equatorial, Mali, Mauritania, Niger, Senegal, Chad and Togo). The majority of the EU countries provide a research exemption, with the influential role that the Community Patent Convention (CPC) has played in the development of the patent legislation in the EU members states (Art. 27 (b) of the CPC established the research exemption).

<sup>69</sup> These include Australia, Canada, New Zealand and the United States of America.

<sup>70</sup> [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds114\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm).

“the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement”.

64. Proponents of the research exemption base their arguments on a wide range of reasons, beginning with the idea that the exception for experimental use is implicit in the patent system’s *quid pro quo*, since no other reason would be able to explain the interest that the patent system places on the free availability of the disclosure of the invention.<sup>71</sup> Other arguments based on practical considerations have also been advanced, for example that because much research is cumulative in nature, negotiating and concluding multiple patent licenses before any actual research takes place could involve significant transaction costs.<sup>72</sup> Others believe that the exception has a negative impact on innovation, arguing that an efficient allocation of resources requires researchers to pay the full cost of any inputs they use, including knowledge developed by other researchers.<sup>73</sup> Along the same line, several submissions were made by participants in the consultation process conducted by the Advisory Council on Intellectual Property (ACIP) of Australia on Patents and Experimental Use.<sup>74</sup>
65. The rationale of the exception was explained in the *Canada-Patent Protection of Pharmaceutical Product* in the WTO Dispute Settlement Panel decision:
- “... this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a ‘legitimate interest’ in using the patent disclosure to support the advance of science and technology.”<sup>75</sup>
66. Although the general policy objectives of the experimental use/research exemption under national laws are more or less in line with the description above, the texts of those provisions are not always exactly the same, and, in addition, the interpretation of those texts varies from one country to another.<sup>76</sup> In order to better understand some of those

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<sup>71</sup> Rebecca S. Eisenberg, ‘Patents and the Progress of Science: Exclusive rights and experimental use’. *Chicago Law Review* (1989), Vol 56, p. 1017.

<sup>72</sup> ‘Research use of patented knowledge: a review’, STI working paper 2006/2, OECD.

<sup>73</sup> Gans, J. ‘The Dynamic Effects of Intellectual Property Practices’, *Intellectual Property Research Institute of Australia* (2005) Working Paper and Rowe, E.A., ‘The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special treatment?’ *57 Hasting Law Journal* (2005).

<sup>74</sup> Advisory Council on Intellectual Property (ACIP) of Australia, ‘Report on Patents and Experimental Use’, October 2005.

<sup>75</sup> It is important to highlight that the Panel draws no conclusion about the correctness of the exceptions in terms of Article 30 of the TRIPS Agreement.

<sup>76</sup> In the United Kingdom, for example, it has been indicated by a court decision that the exception only covers experiments which generate genuinely new information, like trials carried out in order to discover something unknown or to test a hypothesis, or even in order to find out whether something which is known to work under specific conditions will work under different conditions as well. The exemption does not extend to experiments which are designed to verify existing knowledge, for example, or to demonstrate to a third party that a product works as claimed. While in Germany (in *Clinical Trial I* R.P.C.623 [1997]) the Court concluded that the scope of the experimental use defense include “checking of the utilisability of the subject-matter of the patented invention and checking possibilities of further development,” it explained that, in principle, the experimental use

differences, two elements of the exception should be highlighted: first, what constitutes the use of the patented product for scientific experimentation; and second, what is the need to ensure that, despite the fact that the patent is in force and that the user has not received consent from the right holder, the use of the invention is not considered an infringement.

67. Regarding the first element, some countries make reference to “acts for the purposes of *experimental use*” or “acts done for *experimental purposes* relating to the subject matter of the invention”,<sup>77</sup> while others make reference to research conducted for scientific purposes “acts carried out for *scientific research purposes*” or “the use of an invention for *scientific research only*”.<sup>78</sup> In other cases, both “experimental and scientific research” are covered,<sup>79</sup> and another group is represented by countries where reference is made to “technological” or “technical” activities.<sup>80</sup>
68. Regarding the second element, the law of some countries requires that relevant activities (experiment, research, or technical) be “without commercial or gainful intent”.<sup>81</sup> In other countries, the provision explicitly states that the experimental use exemption is applicable for acts anticipating a future commercial exploitation.
69. Regarding the acts of research or experimentation that are excepted, generally the drafting of this exception covers “experimentation/research related to” a patented invention, but in other cases reference is made to “experimentation/research *on*” a patented invention. This reflects an important distinction between, on the one hand, using the invention to explore the nature of the invention itself, and on the other hand, using the invention for its intended purpose.<sup>82</sup>
70. This distinction can be of significant importance, particularly because, in the view of some commentators, the nature of innovation has changed, in that many research tools have immediate commercial application as diagnostics or treatments, so that they qualify for patent protection, but at the same time they are of crucial importance for further research. As stated by Dreyfuss, “any scientist that would like to study the genetics of breast cancer needs to utilize the [patented] BRCA 1 test”.<sup>83</sup> Elaborating further on this point, research tools are gaining importance and relevance, particularly in fields such as biotechnology. Therefore, a cautious approach has been suggested by some experts, particularly on the definition of the appropriate scope of the exception, to avoid inconsistency with Article 30

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[Footnote continued from previous page]

exemption excludes all experimental acts as long as they serve to gain information, and thus the acts to support an application to a regulatory authority can be covered.

<sup>77</sup> Among others, the laws of Belize, Bhutan, Chile, Guatemala, Singapore, South Korea, Trinidad and Tobago, Tunisia and Turkey.

<sup>78</sup> Among others, the laws of Barbados, Egypt, Malaysia, Kenya, Lebanon and The Patent Regulation of the Cooperation Council for Arab States of the Gulf.

<sup>79</sup> Among others, the laws of Panama, China, Andean Countries, Costa Rica, Mongolia.

<sup>80</sup> The Brazilian Law and the Bangui Agreement are good examples.

<sup>81</sup> Among others, the laws of Argentina, China and Mexico.

<sup>82</sup> It seems that many countries do not apply the research exemption to research made *with* the patented invention, although Belgium recently amended its Patent Act to extend the coverage of the exemption to “acts accomplished for scientific purposes *on* and/or *with* the subject matter of the patented invention” Article 28.1(b) of the Belgian Patent Act of 1984, as amended by the Law of April 28, 2005.

<sup>83</sup> Dreyfuss, R., ‘Protecting the Public Domain of Science: Has the time of an experimental use defense arrive?’ 46 *Arizona Law Review* (2004), 457.

of the TRIPS Agreement, in so far as any exception must not “unreasonably conflict with the normal exploitation of the patent”.<sup>84</sup>

71. Many experts and scholars believe that the general research exemption is important to promote innovation and improve the function of the patent system. Others argue that there is very little empirical evidence demonstrating the need for an exception applying to research tools as such.

**(d) Regulatory Review Exception**

72. In the majority of countries, various entities are vested with the power to authorize the commercialization of certain regulated products. This is particularly true for pharmaceutical products, but this phenomenon is not unique to this sector. Other sectors like plant protection products, herbicides and pesticides, animal feeding stuffs, flavoring substances and medical equipment are highly regulated.
73. The complexity of the related administrative processes, which has risen in recent times, varies from one country to another, or from one sector to another, or even within the same sector, depending on many factors. For example, the authorization for a new drug is much more complex than the authorization for an “equivalent” one.
74. Since this process of marketing authorization takes place in parallel with and independently of the process of protection for the invention of the product for which authorization is sought, it is possible that certain tensions will be created as a consequence of the delay in granting the authorization. Two major tensions could be mentioned. On the one hand, from the right holder's perspective, it may suffer a net loss of the effective time of patent protection, since the 20 year period protection starts from the patent application. This explains why some countries provide for the extension of the patent term as a matter of compensation for those delays. But on the other hand, even though the patent term is 20 years, counting from the filing of the patent application, competitors and consumers may be deprived of the possibility of an early entry into the market of non-patented products as soon as the patent expires, because competitors need to wait until the marketing authorization is granted for each one of their products, producing a *de facto* extended period of marketing exclusivity. Therefore, from the competitors' and users' perspectives, there is an interest that this administrative process for marketing authorization begin within the period of the patent protection, despite the fact that production and commercialization must wait until the patent expires.
75. These two aspects, patent extension for compensation of the patent owner's time lost waiting for marketing authorization, and use of the patented product for submission for regulatory authorization while the patent is still in force, are frequently discussed together in an exercise aiming to strike a balance between conflicting interests;<sup>85</sup> but in many

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<sup>84</sup> Correa, C., 'The International Dimension of the Research Exception'. AAAS/SIPPI Paper, January 2004.

<sup>85</sup> This was the case in the U.S.A., with the Drug Price Competition and Patent Term Restoration Act, also called the Hatch-Waxman Act after its sponsors Senator Hatch and Representative Waxman. Australia and Israel are also examples in which both topics are regulated jointly.

cases, countries have taken action in relation to one of the two issues in a separate manner.<sup>86</sup>

76. The regulatory review exception is also known as the “Bolar exception”, after a well known 1984 U.S. case, *Roche Products v Bolar Pharmaceuticals*.<sup>87</sup> The Court of Appeals for the Federal Circuit ruled that the research exemption did not cover Bolar’s acts to carry out equivalency tests for the regulatory approval of generic medicines before the expiration of the relevant patent owned by Roche.
77. Despite the fact that Bolar Pharmaceutical’s use was not considered covered by the general research exemption, and in consequence, it lost the case, the concern that this case generated was brought to the U.S. Congress. It decided that it was not appropriate to prevent generic pharmaceutical manufacturers from starting to prepare and obtain regulatory approval for their generic products, since it would delay the entrance of generic medicines on the market for a substantial period, extending the effective protection period beyond the patent term. Consequently, an explicit exception was introduced in the U.S. patent law (35 U.S.C. 271(e)(1)).
78. The regulatory review or *Bolar* type exception has been included in the national laws of many countries (see Annex I(4) and Annex II(3))<sup>88</sup> while in others it is considered to fall within the scope of the general research exemption<sup>89</sup> and in other cases has been developed through case law.<sup>90</sup>
79. The scope of the regulatory exception varies among national laws. First, in some countries, the exception covers the regulatory approval of any products, while in some other countries, it is limited to certain products.<sup>91</sup> Second, in some countries, the use of the patented product must take place in the country where the regulatory approval has to be requested, whereas in other cases, it is sufficient that the product be imported. In other countries, reference is made to the possibility of exportation, in which case the possibility of requesting marketing authorization in other countries is included; and in a few cases, express reference to import and export is made. Third, there is some room for interpretation in the different texts, for example, where expressions such as “acts for

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<sup>86</sup> The EU adopted legislation on Patent Term Restoration before the *Bolar* type exception was adopted, and the Canada Patent Law includes a *Bolar* type exception, but no provision on patent term restoration.

<sup>87</sup> *Roche Products v Bolar Pharmaceuticals*, 733 F.2d. 858 (Fed. Cir. 1984).

<sup>88</sup> The laws of Australia, Brazil, China, Costa Rica, Dominican Republic, Egypt, India, Jordan, Kenya, Malaysia, New Zealand, Nigeria, Thailand, Tunisia and Zimbabwe. The EU has decided to adopt at a regional level Directive 2001/82/EC for veterinary medicinal products and Directive 2001/83/EC for medicinal products for human use, as respectively amended by Directives 2004/27/EC and 2004/28/EC.

<sup>89</sup> In certain countries there is not a specific provision on the *Bolar* exception, but given the relation of the *Bolar* exception with experimental/scientific research, it is possible to argue that it is implied. Thorpe, P, [Study Paper 7] mentions as an example, Art.39 (d) of the Uruguay Law and Correa, C [2005] indicate Art. 21 (c) of the Patent Law of Croatia.

<sup>90</sup> In Japan, where the patent law does not contain a specific provision about regulatory review exception, this exception has been admitted by the Supreme Court of Japan, Case no. 1998 (ju) 153 (April 16, 1999).

<sup>91</sup> The US Supreme Court ruled that the *Bolar* exception was also applicable to all categories of FDA regulated products, such as medical devices, food additives and color additives. *Eli Lilly & Co. v Medtronic, Inc.*, 496 U.S.661 (1990).

regulatory approval”, “acts *solely for uses reasonably related to regulatory approval*” or “acts *exclusively aiming at regulatory approval*” are used.<sup>92</sup>

80. The *Bolar* type exception contained in the Canadian Patent Law (Art.55.2 (1)) has been studied by a WTO panel,<sup>93</sup> which found that this norm was in line with the TRIPS Agreement, and in particular with Article 30. In the panel’s view, this exception is “limited” for the following reasons:

“...because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner’s rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products...”.

81. The panel focused its attention on what constitutes a normal exploitation, to establish whether the exception “do[es] not unreasonably conflict with the normal exploitation of patents”. In this connection, the panel found:

“The Panel considered that Canada was on firmer ground, however, in arguing that the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization should not be considered “normal”. The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights...”.

82. The panel reached the conclusion that the exception contained in Article 55 2.(1) of the Patent Law of Canada did not prejudice the legitimate interest of the patentee within the meaning of Article 30 of the TRIPS Agreement, subject to the following considerations:

“On balance, the Panel concluded that the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a “legitimate interest” within the meaning of Article 30 of the TRIPS Agreement. Notwithstanding the number of governments that had responded positively to that claimed interest by granting compensatory patent term extensions, the issue itself was of

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<sup>92</sup> In *Merck v Integra, Merck KGaA v Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, No. 03-1237 (2005), the US Supreme Court confirmed that the *Bolar* exception applied to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDA, which includes preclinical studies of patented compounds that may be submitted to the FDA, studies that perform a risk-benefit analysis of a proposed clinical trial, safety-related tests that are not necessarily compliant with FDA regulations and studies to generate pharmacological, toxicological, pharmacokinetic and biological qualities of the drug in animals. The Supreme Court stated that the *Bolar* exception did not categorically exclude either experimentation on drugs that are not ultimately the subject of an FDA submission or use of patented compounds in experiments that are not ultimately submitted to the FDA.

<sup>93</sup> See WT/DS114/R.

relatively recent standing, and the community of governments was obviously still divided over the merits of such claims...”

83. The use of the regulatory review exception as a mechanism to increase competition has been frequently highlighted by experts and policymakers, and therefore the Report of the CIPR<sup>94</sup> recommended that policymakers in developing countries introduce this exception in their patent laws; particular attention was given to countries that were actual or potential producers of generics.

**(e) Utility Models**

84. Several countries provide for the protection of so-called “minor inventions”, through a system of protection the requirements of which are less stringent than those needed to obtain a patent, but which constitute an improvement in relation to the state of the art. With regard to the terminology adopted by national legislators for the title of protection, the term “utility model” is certainly the most widespread, but other expressions are also used, for instance: short term patent, petty patent, innovation patent, minor patent, utility innovation, consensual patent.
85. The policy space that countries enjoy in the implementation of this type of protection is quite broad, because even though it is mentioned in Articles 1, 4, 5 and 11 of the Paris Convention and is recognized as an industrial property right, there is no substantive provision about it within the Treaty.<sup>95</sup> Also, other multilateral treaties refer to utility models, such as the International Patent Classification<sup>96</sup> and the Patent Cooperation Treaty (PCT),<sup>97</sup> as well as the Paris Convention, without providing any substantive minimum standard of protection. Therefore, as there is no direct reference to utility models in the TRIPS Agreement, and as the usefulness of the system is not shared by all developed countries, there is no doubt that, for both developed and developing countries, as well as for LDCs, any decision on its national implementation derives exclusively from national policy choices. It goes without saying that the way through which those countries would wish to give shape to such a system, would be highly influenced by their own interest and no limitations would be imposed based on multilateral commitments, simply because there aren't any. For those who do not share the opinion that utility models are a complementary tool to promote local innovation, the flexibility they enjoy consist in simply not adopting a utility model system.
86. Considering the diversity of existing laws in this field, they can be categorized into two groups: The patent-type regime and the three-dimensional regime. In those countries categorized under the *patent-type regime*, in order to get utility model protection the applicant must fulfill the same requirements as under the patent system.<sup>98</sup> The main

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<sup>94</sup> CIPR Report [2002].

<sup>95</sup> Article 2, subsection 2, of the TRIPS Agreement contains a reference to the Paris Convention establishing that “nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention (...)”. The fact that this Treaty does not establish any minimum standard of protection for utility models leaves WTO Members free to formulate regimes for this category of IPR.

<sup>96</sup> The IPC covers not only patents for invention, but also inventors' certificates, utility models and utility certificates.

<sup>97</sup> In the framework of the PCT, references to an application for the protection of an invention shall be construed as covering applications for patents for inventions, inventors' certificates, utility, utility models, patents certificates of addition and utility certificates of addition.

<sup>98</sup> A typical example of this regime is the French “*certificat d'utilité*”.

difference between the patent and utility model system lies in the fact that the latter provides a shorter period of protection and a quick examination (instead of the normal substantive examination of patents). In those countries categorized within the group of the *three-dimensional regime*, inventions eligible for protection must be embodied in three-dimensional form.<sup>99</sup> Usually, the inventive step required is smaller than for patents, which allows protection to be extended to minor inventions.<sup>100</sup> Nevertheless, within this group, important differences exist from one country to another regarding substantive examination.<sup>101</sup> In the German legislation, any inventions of technical character that are new, based on inventive step and capable of industrial application are protectable through a utility model (mainly the requirements of the patent regime),<sup>102</sup> but the three dimensional requirement is also a condition.<sup>103</sup>

87. Concerning eligible subject matter, countries' legislation may be categorized as follows: first, countries that provide the same exclusions as in their patent laws, in which case there is frequently a general reference to the exclusion of patentability in the patent law or there is a detailed list that mainly reproduces the same exclusions that apply to patents.<sup>104</sup> Second, countries that add to the general exclusions of patentable subject matter in their patent laws exclusions specific to utility models, either because they are

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<sup>99</sup> This kind of system has been adopted by several civil law countries, such as Italy, Spain and several Latin-American countries.

<sup>100</sup> Klaus Fücksle, 'How Can Utility Models Help You in Europe?', *Patent World* (1998), no. 100, p.48.

<sup>101</sup> For instance, in Brazil, the procedure to obtain a utility model includes a substantive examination, while in Spain and Italy there is no such examination (in the latter country, however, a substantive examination is not provided in the case of patent applications either).

<sup>102</sup> For utility models the requirements are less stringent; the utility model requirement of *erfinderischer Schritt* (Art. 1 (2) and 3 (5) of the German Utility Model Act) that is translated as "inventive step" is less demanding than the patent requirement of *erfinderische Tätigkeit* that is translated into English as "inventive activity". Confusion may arise because the French and English wording of the patent law, as well as international convention, use the phrase "inventive step".

<sup>103</sup> Since the early stages of the utility model system in Germany in 1891, it was intended to promote minor inventions and avoid the copying of external configuration of certain hand tools, agricultural machinery and domestic appliances; therefore the "tridimensional requirements" have been always part of the German system.

<sup>104</sup> In the case of the Philippines, it is provided in rule 2001 of the Patent Act that "the following shall be excluded from protection as utility models: (a) discoveries, scientific theories and mathematical method; (b) schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers; (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and compositions for use in any of these methods; (d) plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to microorganisms and non-biological and microbiological processes; (e) aesthetic creations; and (f) anything which is contrary to public order or morality."

derived from the application of the “tridimensional requirement”<sup>105</sup> or because there are some particular exclusions that apply exclusively to utility models.<sup>106</sup>

88. Even though there is a common understanding that the utility model system is an option for the protection of minor inventions that otherwise would not be able to pass the stringent test of patent protection, there are several differences among countries in relation to requirements and what they exactly mean. As an example, novelty is almost always considered as a requirement for protection, and despite the fact that the majority of countries apply this concept in a manner that is equivalent to the patent concept (universal novelty), certain countries apply it in a less stringent way, i.e., only local novelty is required.<sup>107</sup>
89. Inventiveness is sometimes not required;<sup>108</sup> while in many countries, there is such a requirement, but its meaning differs from the one applied to patents.<sup>109</sup> An example of the latter is Australia, where an “innovation patent system” was introduced in 2001, replacing the previous one on petty patents; the requirement of innovative step constitutes the main difference to the previous system. The idea was that a lower inventive threshold should be required for a second tier patent system, to encourage Australian businesses, particularly SMEs, to develop their incremental inventions and to market them in Australia.
90. There are other important features of the utility model system, for example the fact that there is no substantive examination in many countries, which reduces the time of the

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<sup>105</sup> For example, the Russian Federation’s Patent Act, in relation to inventions patentable through a utility model, stated that “A technical solution relating to a device shall be protected as a utility model” (Section 1351, subsection 1). In the case of Poland, it is stated that “Any new and useful solution of a technical nature affecting shape, construction or durable assembly of an object shall constitute a utility model”. In the Mexican Utility Model Law, protection would be given to “Objects, utensils, appliances or tools which, as a result of a modification in their arrangement, configuration, structure or form, offer a different function with respect to their component parts or advantages with respect to their usefulness...”.

<sup>106</sup> For instance, processes or chemical substances are excluded in the law of an important number of countries. Despite the fact that concern has been expressed in the sense that this back door could be used to protect non-patentable inventions, particularly, in sensible sectors as the pharmaceutical, it is clear that many solutions are available within the utility model system itself, for example, a definition could be adopted including the requirement of embodiment, but an exclusion from patentability for those products could also be provided.

<sup>107</sup> Art Law of Hungary.

<sup>108</sup> For instance, in Section 1351, subsection 1, of the Patent Law of the Russian Federation it is established that “A utility model shall be granted legal protection if it is new and industrially applicable”; no mention is made about any other requirement, similar to the situation of other countries such as Belarus, El Salvador, Kenya, Malaysia, Panama, Paraguay, Mexico, Philippines.

<sup>109</sup> Article 7(4) of the Australian Patents Act provides that “For the purposes of this Act, an invention has to be taken to involve an innovative step when compared with the prior art base unless the invention would, to a person skilled in the relevant art, in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, only vary from the kinds of information set out in subsection (5) in ways that make no substantial contribution to the working of the invention”. The major differences between an innovative step and an inventive step as used for a standard patent, apart from the invention needing to make a substantial contribution to the working of the invention, is that an innovative step cannot rely on common general knowledge *per se*. There is no requirement that an invention must be non-obvious, and even though the prior art base is the same, there is no limitation that the information has to have been “ascertained, understood and regarded as relevant to work in the relevant art”.

prosecution process and in consequence the administrative and maintenance fees. In some cases, examination is voluntary, and in others mandatory in case of conflict (opposition or enforcement). Another important difference compared with the patent system is the term of protection,<sup>110</sup> which is generally shorter.

91. The utility model system may serve as a policy instrument to address issues that some countries face when drafting their patent law. Some commentators believe that an overly generous patent system may lead to too many trivial patents and generate an undesirable increase of appropriation of knowledge. A system complementary to the patent system may be envisaged that would be designed mainly to answer the needs of local innovators, reserving appropriate levels of requirements to patents. Experience has shown that residents are generally those who use the utility model protection in countries where it exists.<sup>111</sup>

[Annexes follow]

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<sup>110</sup> In many countries this term consists of 10 years, but it could be longer or shorter. Certain countries provide for a minimum period of protection, renewable one or two times up to a maximum limit. For instance, Thailand, Portugal and Romania established a first period of protection of 6 years, renewable for two periods of 2 years each. Kazakhstan, Kyrgyzstan and Belarus provide for a first period of protection of 5 years, renewable for another 3 years. Usually the sum of all the periods is 10 years.

<sup>111</sup> In contrast to patents, resident applicants have a high share of the total utility model filings; the figures for the year 2007 show the following numbers for resident applications share: China 99.3%, Turkey 98.6%, Brazil 98.4%, Ukraine 98.2%, Republic of Korea 97.9%, Russian Federation 95.2%, Colombia 91.8%, Mexico 85.7%, Germany 82% and Japan 81.4%.