

## Standing Committee on the Law of Patents

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### EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: EXHAUSTION OF PATENT RIGHTS

*Document prepared by the Secretariat*

#### INTRODUCTION

1. At its twentieth session, held from January 27 to 31, 2014, the Standing Committee on the Law of Patents (SCP) agreed that, in relation to the topic “exceptions and limitations to patent rights”, the Secretariat would prepare, *inter alia*, a document, based on input received from Member States, on how exhaustion of patent rights was implemented in their countries or regional systems, without evaluating its effectiveness. The document should also cover practical challenges encountered by Member States in implementing them.
2. Accordingly, this document provides information on how exceptions and/or limitations related to exhaustion of patent rights have been implemented in Member States. It consists of three Sections: (i) Public Policy Objectives for Providing the Exception; (ii) The Applicable Law and the Scope of the Exception; and (iii) Implementation Challenges. The document aims at providing a comprehensive and comparative overview of the implementation of this exception under the applicable laws of Member States. Reference is made to the Questionnaire on Exceptions and Limitations to Patent Rights and the original responses submitted by the Member States and a regional patent office to clarify the scope of the exception in a particular jurisdiction (see the website of the SCP electronic forum at: <http://www.wipo.int/scp/en/exceptions/>).
3. The following Member States indicated that their applicable laws provided for exceptions and/or limitations related to exhaustion of patent rights: Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Belarus, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Bulgaria, Burkina Faso, Brazil, Canada, Chile, China, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, El Salvador, Finland, France, Gambia, Georgia, Germany, Greece, Honduras, Hungary, India, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lithuania, Madagascar, Mauritius, Mexico, Morocco, Netherlands, New Zealand, Norway, Oman,

Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Serbia, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Viet Nam and Zimbabwe (76 in total).<sup>1</sup>

## PUBLIC POLICY OBJECTIVES FOR PROVIDING THE EXCEPTION

4. Many Member States emphasized the balancing aspect of the exhaustion of patent rights.<sup>2</sup> For example, the public policy objective of providing the exhaustion of patent rights was to “achieve an appropriate balance of rights” (the United States of America), “provide balance between the IP owner and consumer” (Bhutan) and “establish the limits on the exercise of the industrial property rights with the aim of achieving balance in the system and promoting competition” (Chile). Similarly, in Viet Nam, the objective was to “[d]iversify sources of goods of competitive price”; in Spain, it was to “prevent the owner of a patent invoking his right to limiting later marketing of the protected products to observance of an imposed price or other clauses which restrict free competition”. Further, some Member States referred to the protection<sup>3</sup> or benefit of consumers.<sup>4</sup>

5. The policy objective sought in many Member States related to facilitating trade.<sup>5</sup> For example, the response of Romania stated that the objective was “[t]he interest of the free movement of goods and trade”. The response from the United Kingdom explained that the public policy objective was “[b]alancing patent holders’ rights with freedom of trade”. In the Russian Federation’s response, it noted that “[t]he basis of the provision on exhaustion of patent rights [...] is the idea of by-passing artificial barriers to free trade which may be erected by the owners of exclusive rights”. The public policy objective stated in the response from France was that the “exercise of the right in patents is restricted for the sake of the free circulation of goods on the territory of the European Union (EU)”. Similarly, other Member States noted that the applicable exhaustion regime reflected its membership in the European Union.<sup>6</sup> In its response, Switzerland noted that the “aim of the exception is to abolish the monopoly on the import of patented products for goods sold in the European Economic Area”.

6. Some Member States referred to public or societal interest, such as “public interest” (South Africa), “to make use of patent since it is in the public domain, share knowledge and experience, enhance R&D researches” (Jordan), “the interest of society that legal transactions be clear and sure” (Serbia) and “[e]nsuring the supply of medicine” (Poland). Likewise, the reply from Georgia noted that its exhaustion regime “is justified in line with the country’s economic, public health and social considerations”. The Republic of Moldova noted that its objective included the “dissemination of the information about the patented product”. The response from India stated that the objective was to “allow importation of patented products in the country from such markets where the product has been placed in duly authorized manner”.

7. The response of El Salvador indicated that “the owner may not exercise the right of the invention indefinitely”. Referring to remuneration to the patent holder, Belarus noted that the objective was the “exclusion of unfair repeated remuneration for the use of the same invention”,

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<sup>1</sup> In its response, the Eurasian Patent Office stated that the exhaustion rules were established according to the provisions of national laws of its Contracting States.

<sup>2</sup> See, for example, the responses from Australia, Bhutan, Chile, Kenya, Sudan and the United States of America.

<sup>3</sup> See the response from Sri Lanka.

<sup>4</sup> See the response from Zimbabwe.

<sup>5</sup> See, for example, the responses from Cyprus, Denmark, France, Germany, Italy, Mexico, the Netherlands, Portugal, Romania and Sweden.

<sup>6</sup> See, for example, the responses from the Czech Republic, Hungary and Latvia.

and Canada noted that the “patent holder has received compensation for the sale of the item on terms agreed to by the patent holder”.

## THE APPLICABLE LAW AND THE SCOPE OF THE EXCEPTION

8. The responses received from Member States can be roughly categorized into five types:

National exhaustion		27 responses
International exhaustion		19
Regional exhaustion		22
Mixed	In principle, national exhaustion; international exhaustion may apply in certain cases	3
	In principle, regional exhaustion; national or international exhaustion may apply in certain cases	1
Uncertain		4

Most of the Member States that indicated that their applicable laws regulated exhaustion of patent rights provided a specific statutory exception. However, in some Member States, this exception is provided under case law.<sup>7</sup>

### National Exhaustion

9. In some Member States, the national laws stipulate that the rights conferred by a patent shall not extend to acts in respect of articles which have been put on the market of the respective country by the owner of the patent or with his consent, thus adopting the national exhaustion.<sup>8</sup> The Brazilian law<sup>9</sup> provides that introduction of a product in the domestic market should be made “directly” by the patentee or his consent. The laws of El Salvador, Madagascar and Tajikistan state that the exhaustion applies after a product has been “legally placed on the market”, “lawfully sold in the country” and “put to commercial use on a lawful basis”, respectively.<sup>10</sup>

10. The issue of national exhaustion is not specifically dealt with in the statutory law of some Member States: rather, it is established through case law. Canada has a doctrine of implied license which indicates that when a patent holder sells the patented item (or item created due to a process patent), the buyer acquires a license to use and sell the item and all subsequent buyers receive the same license. Canadian case law established that “if the patentee sells the patented article that he made, he transfers the ownership of that article to the purchaser. This means that, henceforth, the patentee no longer has any right with respect to the article which now belongs to the purchaser who, as the new owner, has the exclusive right to possess, use, enjoy, destroy or alienate it”.<sup>11</sup>

11. In the United States of America, the case law that determines the exhaustion of rights states “[W]hen the patentee, or the person having his rights, sells a machine or instrument

<sup>7</sup> These Member States are: Australia, Canada, Japan and the United States of America.

<sup>8</sup> For example, Albania, Belarus, Bhutan, Bosnia and Herzegovina, Brazil, Croatia, El Salvador, Gambia, Madagascar, Morocco, Republic of Moldova, Russian Federation, Sao Tome and Principe, Serbia, Sudan, Tajikistan, Turkey, Uganda and Tanzania.

<sup>9</sup> Article 43, Paragraph IV, of Law n. 9.279 of 14 May 1996.

<sup>10</sup> Article 116(d) of the Law on Intellectual Property of El Salvador, Article 30.2. of the Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property (of July 31, 1989) of Madagascar, and Article 30 of the Law of the Republic of Tajikistan “On inventions”.

<sup>11</sup> Eli Lilly and Co. v. Apotex Inc., [1998] 2 S.C.R. 129.

whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use".<sup>12</sup> The unauthorized importation in the United States of America of a patented device that was sold outside of the country is not shielded from infringement by the patent exhaustion doctrine.<sup>13</sup>

12. The response from Australia noted that, while the Australia Patents Act did not specifically deal with the issue, and there was little case law, national exhaustion seemed to apply to patents, "unless the patent owner had placed contractual restrictions to the contrary". That principle is part of the existing Australian law, subject to a qualification that importation of the patented article put into circulation outside Australia by the Australian patentee will be an infringement if, at the time of first putting the article into circulation, that patentee attached an express stipulation against bringing it into Australia. The general legal principle that applies in Australia is that it is not infringement of a patent for a purchaser to use or dispose of as the purchaser pleases, assuming the purchase was by way of an authorized sale of the product. In general, the sale of the product is the trigger for exhaustion. The response from Australia also referred to its obligation under the Free Trade Agreements, such as the Australia – United States FTA (Article 17.9.4).<sup>14</sup>

13. In Japan, in accordance with the decision of its Supreme Court<sup>15</sup>, the national exhaustion doctrine is applied. As for "assignment of patented products overseas", the Supreme Court ruled that "in a case where a patent holder in Japan or a person deemed to be equal thereto assigned a patented product overseas, it should be interpreted that the patent right holder is not allowed to execute his/her patent right in Japan, except that for an assignee, an agreement was made between a patent holder and the assignee that the areas for sale or use of the patented product excludes Japan, and that for the third party to whom the patented product was assigned by the assignee and subsequent acquirer, above-mentioned agreement was made between an assignee and said third party or acquirer, and it is explicitly indicated on the patented product".

14. The response from the Russian Federation referred to the application of the exhaustion rule to process patents. In accordance with the ruling of Its Constitutional Court<sup>16</sup>, it noted that "the limitation specified in the provision on exhaustion of rights extends only to patented industrial property which has a material form, and does not encompass patent holders' exclusive rights in relation to processes patented as inventions. Nevertheless, there are certain conditions under which the patented process, when used in conjunction with a device, is also exhausted, but only when performing the process with said device, the rights in relation to which have already been exhausted".

### International Exhaustion

15. National laws of some Member States state, in general, that the rights conferred by a patent shall not extend to acts in respect of articles which have been put on the market "in any country" by the owner of the patent or with his consent, thus adopting the international exhaustion.<sup>17</sup> In some Member States<sup>18</sup>, an article shall be "lawfully" placed on or introduced to the market. According to the response from Argentina, "the product shall be deemed to have

<sup>12</sup> Adams v. Burke, 84 U.S. 453 (1873).

<sup>13</sup> Fujifilm Corp v. Benun, 605 F.3d 1366, 1371-72 (Fed. Cir. 2010).

<sup>14</sup> "Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means".

<sup>15</sup> Decision of Third Petty Bench Supreme Court on July 1, 1997 (BBS Supreme Court case).

<sup>16</sup> Opinion of the Constitutional Court of the Russian Federation of October 16, 2001, No. 211-O.

<sup>17</sup> For example, Argentina, Armenia, Decision 486 of the Andean Community, Chile, Costa Rica, Dominican Republic, Kenya, Mauritius, Pakistan and Viet Nam.

<sup>18</sup> For example, Argentina, Armenia, Chile, Dominican Republic and Viet Nam.

been lawfully placed on the market when the licensee authorized to market it in the country shall prove that he has been so authorized by the owner of the patent in the country of acquisition, or by a third party authorized to market the product". Similarly, in Ukraine, "the introduction of a product that has been manufactured with the use of the patented invention (utility model) into the commercial circuit by any person who has obtained a product without violation of the patent owner rights" triggers international exhaustion. The phrase "obtained without the violation of the patent owner rights" applies to the cases where a product has been "manufactured by the patent owner and/or introduced into the commercial circuit by the patent owner or another person with a special permission (license) of the patent owner".

16. The Decision 486 of the Andean Community states that the exhaustion applies to an article "introduced into the commerce by the owner or another person authorized by the right holder or with economic ties to the patent owner". The "economic ties" between two persons are considered to be established "when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent, or when a third party is able to exert such influence over both persons". In Pakistan, the exhaustion applies where an article is "put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses".

17. The response from Chile explained that the doctrine of exhaustion was based originally on the rulings concerning Anti-trust Commissions, which had been replaced by the Court of Free Competition. It explained that during the period when the anti-monopoly bodies dealt with such cases, they "applied reasoning specific to the problems of parallel imports, and systematically sanctioned those industrial property right holders who exercised their rights in an abusive manner". For example, 1993 Ruling No. 886 of the Central Prevention Commission, which referred to trademark exhaustion, but is fully applicable to patents, stated that "the owner of a trademark that refers to articles or products of a certain manufacture may not lawfully oppose the trade of another person in genuine or authentic articles of the same origin" and "the exclusive distributor of a foreign product may not prevent importers that acquire the same product also abroad from marketing it in the country".

18. In India, the statutory provision<sup>19</sup> provides for the international exhaustion by allowing parallel importation as follows: "importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights". Similarly, in Jordan, the patent rights shall not prevent anyone from importing any materials or goods from a third party that enjoys the legal protection of that patent, if such "importation is lawful, complies with the principles of commercial competition and fairly takes into account the economic value of the protected patent".<sup>20</sup>

19. In Costa Rica, the international exhaustion applies, provided that it does not "unjustifiably harm the normal working of the patent, or cause undue harm to the legitimate interests of its owner or its licensee".<sup>21</sup> Further, Section 24A of the Patents Act of Zimbabwe stipulates that parallel importation is allowed "if the cost of importing such product is less than the cost of purchasing from the patentee".

20. The response from Georgia clarified that while the Deep and Comprehensive Free Trade Agreement with the European Union obliged Georgia to introduce a national exhaustion regime for IP objects, the international exhaustion regime applied exceptionally for patented products.

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<sup>19</sup> Indian Patents Act, Section 107A.

<sup>20</sup> Article 37 of Jordan Patent Law 32 of 1999, as amended.

<sup>21</sup> Article 16.2(d) of Law No. 6867 on Patents, Industrial Designs and Utility Models of Costa Rica (as last amended by Law No. 8632 of May 25, 2008).

21. The response from China, which applies international exhaustion, noted that the use by parties of patent exhaustion as an infringement defense in the judicial procedure was uncommon compared with other defense such as invalidation of the patent, or the alleged infringement action fell under the prior art or outside the scope of the patented claims. However, in some cases, the focus of the dispute was whether a defendant's allegedly infringing product had been sold by a patentee or his licensee and thus the patent rights were exhausted, or it had been manufactured by the defendant and consequently, the patent rights were infringed. The response from China also referred to the decision by the Supreme People's Court applying the theory of implied license.<sup>22</sup>

### Regional Exhaustion

22. Member States of the Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (February 24, 1999) apply the regional exhaustion regime, as it states that patent rights shall not extend to acts in relation to an article brought "on the market on the territory of a member State by the owner of the patent or with his consent".

23. Similarly, many Member States<sup>23</sup>, which are parties to the Agreement on the European Economic Area (EEA), apply the regional exhaustion regime, i.e., the patent right does not extend to acts in relation to an article put on the market in a country within the EEA by a patentee or with his consent. In other words, if a patented product is placed on the market outside the EEA, that does not exhaust the patent rights.

24. The United Kingdom in its response stated that a regional exhaustion doctrine applied within the EEA under Articles 34 and 36 of the Treaty on the Functioning of the European Union (the EU Treaty). The United Kingdom also has a "doctrine of implied license, which functions as an exhaustion doctrine". That doctrine was "established in *Betts v Willmott* (1871) LR 6 Ch App 239 where it was held that, on selling a patented product, the patentee transfers with the goods a license for the purchaser to sell or use the article. The principle applies regardless of whether the first sale is made in the UK or elsewhere".

25. The response from the Netherlands indicated that whether a product had been "put on the market lawfully" or not was decisive for the determination of exhaustion of the rights. The Supreme Court of the Netherlands ruled that products put on the market under a compulsory license or prior use were deemed to be lawfully put on the market.<sup>24</sup> In contrast, for the European Union, products put on the market in another country under a compulsory license are deemed not to be put lawfully on the market, and thus these products may only be imported with the consent of the patentee.<sup>25</sup>

### Mixed Exhaustion Regime

26. Some Member States provide for one particular exhaustion regime in principle, but apply other exhaustion regimes depending on the nature of the goods or circumstances of each case.

27. The Patent Act of South Africa stipulates that "the disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the

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<sup>22</sup> The Supreme People's Court held that "if the sole reasonable commercial use of certain item is to be utilized to exploit a patent, the sale of the said item by the patentee or by a third party authorized by the patentee means implied license on the part of the purchaser to exploit the patent".

<sup>23</sup> Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Germany, Hungary, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden and United Kingdom.

<sup>24</sup> Supreme Court, March 6, 1936, NJ 1936, 588 and Supreme Court, June 6, 1941, NJ 1941, 812.

<sup>25</sup> ECJ, July 9, 1985, NJ 1985, 456; BIE 1986/49 (Pharmon/Hoechst).

right to use, offer to dispose of and dispose of that article”.<sup>26</sup> In accordance with case law, the South African courts have adopted the following principles: “(i) where the patentee himself sells or disposes of the patented article, that article is freed from all restraint which the patentee’s monopoly had imposed upon it; (ii) where the patented article is disposed of by the patentee’s assignee or his agent within the scope of his authority, it is similarly freed from such restraints; and (iii) where the sale of the patented article is by a license of the patentee, the matter must depend on the extent of the authority conferred on the licensee by the licensor under the license agreement”.<sup>27</sup> The judge held that “provided the patentee of a South African patent is able and prepared to place limitations in a country of origin upon the sale in South Africa of his patented good imported into South Africa from that country of origin, purchasers in South Africa, from the likes of unauthorized jobbers, for resale in South Africa can be interdicted from so reselling on the basis of the protection afforded by South African patent”. Therefore, in principle, South Africa adopts the national exhaustion regime. However, the response of South Africa also noted that “the Minister of Health is empowered [...] to prescribe the conditions on which any patented medicine may be parallel imported into South Africa, regardless of the provisions of the Patents Act.”<sup>28</sup> A parallel imported medicine must have the same formulation, meet the same quality standards and is intended to have the same proprietary name as the medicine already available and registered in South Africa. A potential parallel importer shall obtain a permit to parallel import a medicine and a registration of a relevant medicine, and comply with other regulatory requirements with respect to parallel-imported medicines.<sup>29</sup>

28. Similarly, in the Philippines, while the national exhaustion mechanism applies in principle, the international exhaustion regime applies to drugs and medicines. Its law<sup>30</sup> states that “the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party”.

29. Oman, in general, adopts a national exhaustion regime. However, the Minister of Commerce and Industry has the authority, *ex officio* or at the request of any interested party, of declaring the patent rights exhausted, and thus of authorizing others to import the patented product or a product manufactured directly or indirectly by means of the patented invention (“the product”) from another territory when that product: (i) is not available in the territory of Oman; (ii) is available in the territory of Oman with unreasonably low quality standards or in a quantity that is not sufficient to meet the local demand or at prices that the Minister deems abusive; or (iii) for any other reason of public interest, including anticompetitive practices. Other conditions to be met are that: (i) the product has been put in the channels of commerce in the territory from which it will be imported by the owner of the patent or with his consent; and (ii) a patent in force in the territory from which the product will be imported and is owned by the same person who owns the patent in Oman or by a person under his control. The Minister shall, *ex officio* or at the request of the patent owner, cancel the authorization if the importer fails to fulfill the purpose that justified the Minister’s decision. Further, if the conditions that gave rise to the Minister’s decision to consider the patent exhausted cease to exist, the Minister may cancel the authorization, provided that the legitimate interests of the importer are taken into account.

30. In Switzerland, different exhaustion regimes apply depending on the place where the patented product was first put on the market and on the nature of the goods as follows: (i) in principle, goods placed in Switzerland or the European Economic Area by a patentee or with his consent can be imported, used or resold in Switzerland (regional exhaustion); (ii) if patent protection is of secondary importance due to the functional characteristics of the patented goods, the international exhaustion applies; and (iii) notwithstanding (i) and (ii), where “the

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<sup>26</sup> Section 45(2) of the Patents Act 1978 of South Africa, as amended.

<sup>27</sup> Stauffer Chemical co V Agricura Limited 1979 BP 168 (C).

<sup>28</sup> Section 15C of the Medicines and Related Substances Control Act of 1965, as amended.

<sup>29</sup> See the response of South Africa for further details.

<sup>30</sup> Section 72.1 of the Republic Act No. 8293, as amended by Republic Act 9052, of the Philippines.

price of the patented goods are set by the State in Switzerland or the country of commercialization”, such as medicines, the goods may only be placed in Switzerland with the agreement of the patentee. Further, international exhaustion also applies to patented means of agricultural production and agricultural capital equipment (such as tractors and machines).<sup>31</sup>

31. Further, some Member States noted that they provide for “a specific exhaustion provision applying to the propagation of biological material” with respect to farmers use for an agricultural purpose.<sup>32</sup>

#### Restriction to the Exhaustion by a Patentee

32. The majority of Member States<sup>33</sup> do not permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country. Some Member States stated that the situation was uncertain.<sup>34</sup>

33. The responses from some Member States indicated that patentees may be able to limit the exhaustion of rights through contractual restrictions. In the United Kingdom<sup>35</sup>, since the national exhaustion doctrine applied is one of implied license, it can be overridden if the patentee imposes conditions on the use/re-sale of the product when it is first sold. Such conditions place a limitation on the grant of the license to deal with the patented product and apply to all those who buy the product with knowledge of them.<sup>36</sup> The response from Australia noted that a provision under an Australia – United States FTA required each party to provide that the patent rights preventing the importation of a patented product “shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means”.

34. In Hungary, the EEA-wide regional exhaustion may be limited if “the patentee has legitimate interests in opposing the further marketing of the product”.<sup>37</sup> Similarly, in Italy, the EEA-wide regional exhaustion does not apply “when rightful motives subsist so as [a patentee] himself opposes to further marketing of products, namely when their condition is modified or altered after their putting in the market”.<sup>38</sup>

#### Uncertainty

35. The type of exhaustion is uncertain in some Member States, as the relevant statutory provision has not specified the place at which the exhaustion rule would be triggered, and interpretation by court on that respect has not been established yet.<sup>39</sup> The response from New Zealand noted that exhaustion was determined by case law, and “whether the rights are exhausted or not is likely to depend on any conditions attached to the initial sale by the

<sup>31</sup> Article 27b of the Law on Agriculture (RS 910.1).

<sup>32</sup> See document SCP/21/6 for further details.

<sup>33</sup> Algeria, Armenia, Austria, Bosnia and Herzegovina, Chile, China, Costa Rica, Croatia, Cyprus, Denmark, Dominican Republic, El Salvador, Finland, France, Georgia, Greece, India, Japan, Jordan, Kenya, Lithuania, Mauritius, Norway, Portugal, Republic of Korea, Romania, Sweden, Switzerland, Thailand, Ukraine, Tanzania and Zimbabwe.

<sup>34</sup> Australia, Gambia, Honduras, Israel, Latvia, Morocco, Netherland, Pakistan, Peru, Sao Tome and Principe, Slovakia, South Africa, Spain, Turkey, Switzerland, Tajikistan and Turkey.

<sup>35</sup> In the United Kingdom, the regional exhaustion doctrine cannot be overridden by a patentee since it derives from Article 28 of the EU Treaty which prohibits restrictions on imports between Member States.

<sup>36</sup> *National Phonograph Company v Menck* (1911) 28 R.P.C. 229 Pat Ct; *Incandescent Gas Light v Brogden* (1899) 16 R.P.C. 179; and *Dunlop v Longlife Battery* [1958] R.P.C. 473.

<sup>37</sup> Article 20 of the Patent Act of Hungary. See also Article 16 of the Patent Act of Slovakia.

<sup>38</sup> Article 5, paragraph 2 of the Intellectual Property Code of Italy.

<sup>39</sup> Algeria and Sri Lanka.

patentee". In Israel, while an adoption of international exhaustion was suggested by the High Court of Justice<sup>40</sup>, the final decision was left for further interpretation.

## IMPLEMENTATION CHALLENGES

36. While most Member States responded that the exhaustion regime applied in their countries was adequate<sup>41</sup>, the response of Algeria noted that the applicable regime was not deemed appropriate, and that it had been contemplating revising its law. Similarly, Zimbabwe noted that since the regime was not adequate, the government had to put in place other exceptions such as compulsory licensing. Two Member States indicated that the applicable exhaustion regime had not yet been tested.<sup>42</sup>

37. A few Member States referred to discussions or envisaged amendments to the exhaustion regime. For example, El Salvador noted in its response that the exhaustion regime is under discussion by different national authorities and sectors. Additionally, in its response, the Russian Federation noted that amendments to Article 1359 of the Civil Code were envisaged in accordance with which the exhaustion would be triggered not only where a product has been introduced in civil circulation within the territory of the Russian Federation by a patentee or with his consent, but also where introduction of the product into civil circulation was performed lawfully, as to be prescribed by the Code. Similarly, Chile noted in its response that its patent exhaustion provision, together with all IP legislation, was being revised with a view to potential reform.

38. Many Member States responded that no challenges, or no significant challenges, had been encountered in relation to the practical implementation of the applicable patent exhaustion regime.<sup>43</sup> In its response, El Salvador noted that "in the area of health a restriction on parallel imports is being considered". The response from Kenya referred to a case<sup>44</sup> that addressed the issue of parallel importation. The response from Zimbabwe stated that challenges have been encountered regarding the importation into Zimbabwe of counterfeit pharmaceutical products. The response from China referred to design patent cases which examined the exhaustion of rights with respect to the use of recycled bottles under design patent protection.<sup>45</sup>

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<sup>40</sup> H.C.J. 5379/00, Bristol-Myers Squibb Company vs. the Ministry of Health, PD 55(4), 447.

<sup>41</sup> See the responses from Argentina, Belarus, Chile, China, Costa Rica, Cyprus, the Czech Republic, Hungary, India, Kenya, Latvia, Mexico, Morocco, Norway, Pakistan, Poland, Portugal, Sao Tome and Principe, Spain, Sweden and the United Kingdom.

<sup>42</sup> See the responses of Bhutan and Sri Lanka.

<sup>43</sup> See the responses of Bhutan, Bosnia and Herzegovina, Canada, China, Costa Rica, Croatia, Denmark, the Dominican Republic, Georgia, Hungary, India, Latvia, Portugal, Sao Tome and Principe and the United Kingdom.

<sup>44</sup> In Pfizer Inc. v. Cosmos Limited (IPT case 49 of 2006), the defendant claimed a parallel import defense, which was rejected by the court.

<sup>45</sup> Some courts held that "the used bottles purchased by the defendant are equivalent to raw materials for the new bottles, and the cleaning and disinfection processes are a form of processing in disguise, after which the used bottles embody the function of new bottles and become new products to reenter the circulation of bottles. It is therefore assumed that the using of used bottles for new alcohol by the defendant has gone beyond the traditional sense of use. Such activities in essence are manufacturing new bottles or the re-production of bottles, which should be deemed to be a violation of the plaintiff's patent right". Some other courts, however, rendered contradicting decisions on similar cases.