

## Standing Committee on the Law of Patents

**Twentieth Session**  
**Geneva, January 27 to 31, 2014**

### EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: PRIVATE AND/OR NON-COMMERCIAL USE

*Document prepared by the Secretariat*

#### INTRODUCTION

1. At its nineteenth session, held from February 25 to 28, 2013, 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 the following five exceptions and limitations were implemented in Member States, without evaluating the effectiveness of those exceptions and limitations: private and/or non-commercial use; experimental use and/or scientific research; preparation of medicines; prior use; use of articles on foreign vessels, aircrafts and land vehicles. The document should also cover practical challenges encountered by Member States in implementing them.

2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through Note C.8076, to submit information to the International Bureau additional to, or updating, the information contained in their responses to the questionnaire on exceptions and limitations to patent rights on the above five exceptions and limitations. In addition, Member States and Regional Patent Offices which had not yet submitted their responses to the questionnaire were invited to do so.

3. Accordingly, this document provides information on how exceptions and limitations regarding private and/or non-commercial use have been implemented in Member States. 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 original responses submitted by the above Member States and a regional patent office to clarify the scope of the exception in a particular jurisdiction. The Questionnaire as well as the responses received from Member States are available in full on the website of the SCP electronic forum at:

<http://www.wipo.int/scp/en/exceptions/>. With a view to assisting easier access to the information contained in the responses, the website presents all responses in a matrix format with hyperlinks to each section in each response.

4. This document 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.

5. The following Member States and patent Offices indicated that their applicable laws provided for exceptions and/or limitations related to the prior use exception: Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bosnia and Herzegovina, Brazil, Bulgaria, China, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, El Salvador, Finland, France, Georgia, Germany, Greece, Honduras, Hong Kong (China), Hungary, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lithuania, Madagascar, Mexico, Morocco, Norway, Oman, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Serbia, Slovakia, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, United Kingdom, Viet Nam, Zimbabwe and the Eurasian Patent Office (EAPO) (61 in total).

## **PUBLIC POLICY OBJECTIVES FOR PROVIDING THE EXCEPTION**

6. While multiple public policy objectives are pursued by the private and/or non-commercial use exception in some Member States,<sup>1</sup> most Member States provided responses which described the following objectives.

### *Balancing of legitimate interests*

7. Many responses stated that the policy objectives pursued by the private and non-commercial use exception were related to balancing legitimate interests. For example, the need to establish a balance of interest between private use and commercial use was stated by the response from Austria. The response from Brazil referred to the exception which did not unreasonably conflict with a normal exploitation of the patent and did not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties, in order to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The response from China specified that “[p]ersonal or non-commercial use [did] not affect the economic interests of neither the right holders nor the public at large, so one should not allow right holders to enjoy absolute exclusive ownership” in order to promote “the economic development or the well beings of the entire society”. Otherwise, “it would make the patent coverage excessively large, thus interrupting the normal activities of the public at large”.<sup>2</sup> In Hungary, private use, for example, is not considered as prejudicing “the normal exploitation” of patents.<sup>3</sup>

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<sup>1</sup> For example, the response from the Republic of Moldova stated the following public policy objectives: (i) promote research; (ii) avoid abuse of rights in cases of non-commercial (private) use; (iii) contribute to the dissemination of the patent information; (iv) provide a mechanism to use a patented invention in case that it is not utilized by the owner and the late refuses to grant a license; and (v) provide a mechanism to use a patented invention in force majeure situation which endanger public security and/or health.

<sup>2</sup> Similarly, the response from Japan noted that extending enforcement of patents to the individual use of patented inventions at home, which went beyond business use, was excessive with regard to the actual social conditions.

<sup>3</sup> Similarly, the response from Portugal indicated that the exception did not harm the right owner. In addition, the response from El Salvador stated that it should be “ensured that the normal working of the invention by the owner is not harmed”.

### *Rationale of the Patent System*

8. Some Member States indicated that private and/or non-commercial use by third parties is outside the *raison d'être* of the patent system. For example, the response from the Netherlands stated that the objective of the patent system, i.e., to “reward [the patentee] for his contribution to the state of the art, with an exclusive right to exploit the invention”, would not be applicable in case of private and non-commercial activities.<sup>4</sup> The response from the Republic of Korea noted that, since the objective of patent protection was to “develop industries, providing the exception of private or theoretical working of a patented invention is legitimate.” Norway responded that private and non-commercial activities were “outside the exploitation as a professional activity”.<sup>5</sup> Similarly, other Member States, such as Hungary, stated that “the incentive to innovate is not endangered” by the exception.

### *Promotion of private, creative and academic activity*

9. Some Member States highlighted the additional aspects of the policy objectives to be promoted, in particular, private and academic activity and creativity, personal and family use, research and teaching<sup>6</sup>, as well as dissemination of knowledge. For example, it was noted by Honduras that the exception was aiming at “eliminating barriers to trade, protecting the strictly personal or family/individual right of use and stimulating scientific research and teaching”. In Mexico, it was considered that activities in the private or academic sphere and for non-commercial purposes “promote[d] and foster[ed] inventive industrially applicable activity”. Similarly, the response from Cyprus stated that the exception aimed at “encourag[ing] private initiative, principally learning, in colleges and universities”, and non-commercial or not-for-profit use of patented inventions by third parties would not incur any harm to the patentees. In the same manner, the responses from Italy and Romania stated that patents were not intended to “intervene in the private sphere”. In addition, the response from Sri Lanka stated that the objective was to “promote creativity while protecting the rights of patent holders”.<sup>7</sup> As stated by the response from the United Kingdom, another aspect was that it “should be possible to carry out minor activities without hindrance by the threat of patent infringement”.

### *Knowledge sharing, experimental research and enhancing R&D*

10. Some Member States<sup>8</sup> emphasized that the exception aimed at promoting knowledge sharing, experimental research and enhancing R&D. The response from Mexico stated that “[p]urely experimental, scientific or technological research, testing or teaching activities, involving the manufacture or use of a product or a patented process, within the private or academic sphere and for non-commercial purposes, [were] activities which promote[d] and foster[ed] inventive industrially applicable activity, the technical improvements and the

<sup>4</sup> See the Netherlands Parliamentary Papers 197, 1904-1905, no. 3.

<sup>5</sup> The response from Norway stated as follows: “The term ‘exploit’ implies certain limitations regarding the kinds of activities comprised by the patent protection. Patent rights only aim to protect the right holder against commercial exploitation of the invention. There is a common interest in keeping non-commercial use in the public domain. The right holder is therefore not protected against exploitation of the invention as a knowledge base for research, experimenting or education. However, if the invention is aiming at use in connection with research or education, for instance a measuring device, such use of the invention will be included in the patent protection”. Similar points were raised by the Russian Federation and Spain.

<sup>6</sup> See, for example, the response from Spain.

<sup>7</sup> See response from Sri Lanka: “Hanzard (Records of Parliamentary Debates) dated 23.07.2003. The purposes of introduction of the new law in 2003 were the promotion of national creativity, attraction of investment, promotion of trade, protection of consumer interests and integration of the national economy into the knowledge driven global economic environment”.

<sup>8</sup> For example, responses from Honduras, Jordan, Kenya, Mexico, Republic of Moldova and the Russian Federation.

dissemination of technological knowledge within the productive and academic sectors”.<sup>9</sup> It was considered by the response from the Russian Federation that “members of the public have an interest in unfettered access to the protected results of intellectual activity.” The response from Jordan stated that the exception promotes sharing of knowledge and experiences, and enhances R&D.

#### *Other public policy objectives*

11. Some other Member States stated that the objectives for providing this exception were to conform to current or future regional or international law. The response from Latvia referred to Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Similarly, Denmark, Italy and the United Kingdom indicated that the exception was adapted to Articles 27(a) and 31(a) of the Agreement on Community Patents 1989 (not entered into force). In a similar manner, in Albania, its national law was aligned with the EPC 2000 and EU directives concerning inventions. According to the response from Portugal, the public and/or non-commercial use exception was introduced in its law in 1995 as a result of the accession to the EU and the EPC. In the response from Hong Kong, China, reference was made to the laws of other jurisdictions, in particular, Section 42 of the Irish Patent Act 1992.

### **THE APPLICABLE LAW AND THE SCOPE OF THE EXCEPTION**

12. Most of the Member States provide the private and/or non-commercial use exception under their statutes. Only the response from Australia informed that the exception was not included in its statutes, but provided by common law as a “non-commercial use defense”<sup>10</sup>.

#### *Mechanisms to regulate the private and/or non-commercial use exception*

13. In some Member States<sup>11</sup>, by definition, private use and non-commercial use are excluded from the scope of the patent right. The right conferred by a patent is primarily defined as the right to prevent others from using the patented invention for commercial/business purposes, for example, for “industrial or commercial purposes” (Algeria, Kenya and Madagascar), “purposes on a commercial basis” (Austria), “production or business purposes” (China), for exploiting “the invention commercially or operationally” (Norway), for activities “in or for his business” (Netherlands), for “industrial or commercial scale” (Uganda), for working “the patented invention as a business” (Japan) and for “profit or for professional purposes (Poland). According to the response from Israel, the definition of the phrase “exploitation of an invention” explicitly excludes acts which are “not on a commercial scale and not commercial in character”. The response from Norway stated that activities “outside the exploitation as a professional activity” were explicitly excluded from the scope of the exclusive rights.

14. Most of the Member States<sup>12</sup>, however, provide a broad definition of the scope of the patent rights which encompasses all kinds of activities, and explicitly stipulate that private use

<sup>9</sup> See Article 2(II) of the Law on Industrial Property of Mexico.

<sup>10</sup> Response from Australia, referring to the UK decision, *Frearson v Loe* (18760 9 ChD 48. (Genes and Ingenuity, Chapter 13, Report 99, Australian Law Reform Commission, June 2004).

<sup>11</sup> Article 12 of the Ordinance No. 03-07 of July 19, 2003 on Patents of Algeria; Section 22(1) of the Patents Act of Austria; Article 11 of the Patent Law of China; Article 18 of the Law on Industrial Property of Honduras contained in Decree No. 12-99-E; Article 68 of the Japanese Patent Act; Section 58 of the Industrial Property Act, 2002 (IPA) of Kenya; Article 30 of the Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property (of July 31, 1989) of Madagascar; Article 53 of the Patent Act of the Netherlands; Section 1(1) of the Patent Act of Norway; Article 66(1) of the Industrial Property Law of Poland; Article 94 of the Patent Act of the Republic of Korea; Section 28 of the Patents Act Chapter 216 Laws of Uganda.

<sup>12</sup> Article 38(a) of the Law No. 9947 on Industrial Property of Albania; Article 73(a) of the Patent Law of Bosnia and Herzegovina (Official Gazette No 53/10); Article 43 of Law n. 9.279 of 14 May 1996 of Brazil;

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for non-commercial purposes or private and non-commercial use is an exception to the exclusive patent rights. In formulating the exception, provisions of many national laws stipulate that it applies to acts carried out in the private sphere and for non-commercial purposes<sup>13</sup> or to use of a patented invention for personal needs with no purpose to make profits<sup>14</sup>. The response from the United Kingdom stated that the exclusion is provided for acts done “privately and for the purposes which are not commercial”. In Romania, the exception is restricted to acts done for “exclusively” privately and non-commercial purposes.<sup>15</sup> The patent law of Serbia clarifies that “the requirement for non-commercial and private use must be cumulatively met”. The national laws of some Members States, such as the Czech Republic and Finland, provided an exception for “acts done for non-commercial purposes”<sup>16</sup>.

#### *Definitions of the terms “private” and “commercial”*

15. Only few Member States provided information about the definition of the expressions such as “private use” or “non-commercial activities” in their jurisdictions<sup>17</sup>. Some Member States are interpreting commercial activities broadly in this context. In Hungary, the conceptual definition is provided by other laws, such as civil law and tax law.<sup>18</sup> The response from the Republic of Moldova noted that, in the absence of a definition, “in ruling such a case, a court would conduct itself by provisions of the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property”.

16. Most of those Members States which provided for a definition explained the concept of commercial use by referring to activities for making profit. For example, the response from Austria stated that a commercial activity was an economic activity of “certain duration, following a unitary concept and suited for repetition, which - without necessarily being acquisitive - does not only serve the satisfaction of personal needs”. In Israel, according to its case law, the

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Article 20(1) of the Law on Inventions, Utility Model Registration (LPUMR) of Bulgaria; Article 63(1) of the Patent Act of Croatia (Official Journal Number 173/2003, 87/2005, 76/2007, 30/2009, 128/2010 and 49/2011); Consolidate Patents Act (Act no. 91 of 28 January 2009), Section 3(3)(i), of Denmark; Article 30 of Law No. 20-00 on Industrial Property of the Dominican Republic; L613-5 of the Intellectual Property Code of France; Section 11(1) of the Patent Act of Germany; Section 75(a) of 514 Patents Ordinance of Hong Kong, China; Article 19(6)(a) of the Patent Act of Hungary (Act XXXIII of 1995 on the Protection of Inventions by Patents); Section 68(1)(a) of the Industrial Property Code of Italy; Article 35 of the Patent Law of Lithuania; Article 55 of Law on the Protection of Industrial Property of Morocco; Section 11(4)(b)(i) of the Industrial Property Law 67/2008 of Oman; Article 102 of the Industrial Property Code (CPI) of Portugal; Law on Patents of Serbia, Article 21(1); Article 18(1)(e) of the Patent Law of Slovakia; Article 52 of the Law No. 11/1986 of March 20, 1986, on Patents of Spain; Article 9(1) of the Federal Law on Patents for Inventions (SR 232.14, LBI) of Switzerland; Article 75(a) of the Patent Decree Law of Turkey; Article 31(2) of the Law of Ukraine “On the Protection of Rights to Inventions and Utility Models”; Section 60(5)(a) of the Patents Act of the United Kingdom; Article 125(2) of the Law on Intellectual Property 2005, amended and supplemented in 2009, of Viet Nam; Article 52 of the Decision 486 of the Commission of the Andean Community.

<sup>13</sup> For example, see the applicable laws of Brazil, Costa Rica, Dominica Republic, France, Germany, Italy, Lithuania, Morocco and Romania. See also Article 53(a) of Decision 486 of the Commission of the Andean Community.

<sup>14</sup> Article 17(1) of the Law on Inventions, Utility Models and Industrial Designs of Armenia. Similar provisions are found in Article 23 of the Law on Patent of the Republic of Azerbaijan, Article 52 (b) of the Patent Law of Georgia and Article 40 of the Law on Inventions of Tajikistan.

<sup>15</sup> Article 34 of the Romanian Patent Law, no. 64/1991, as republished in 2007.

<sup>16</sup> Section 18(d) of the Patent Act of the Czech Republic; Section 3(3)(1) of the Patents Act of Finland. A similar provision is also found in Article 3 of the Swedish Patents Act (Swedish Statute Book, SFS, 1967:837).

<sup>17</sup> For example, the response from Peru explicitly stated that, in absence of a legal definition, “to date, no judicial or administrative ruling on the scope of this exception has been handed down.” The response from Zambia stated that in the current Act “the term ‘Commercial scale’ is not even defined in the Act and, therefore, the phrase should be given the ordinary grammatical meaning.”

<sup>18</sup> The response from Hungary stated that in accordance with Paragraph (1) of Article 6 of Act CXXVII of 2007 on Value Added Tax (VAT Act), economic/business activity means the performance of an activity in a professional manner either permanently or on a regular basis, if it aims at, or results in, achieving any value, and it is delivered in an independent way.

definition of the non-commercial use is an “unprofitable private use, such as exploitation of the invention for a home purpose”.<sup>19</sup>

17. Differently, in China, although the term is not defined by its law, it is widely understood as activities for the “purposes of industrial or agricultural production, or for commercial purposes”, independently from “being profitable or not” and from being a “profitable or non-profitable entity”. In the Netherlands, the term is understood as a broad concept, including “all kinds of professional activities, including universities and governmental/administrative activities”.<sup>20</sup>

18. In the Russian Federation, use of a patented invention for private, family, domestic, or other needs unrelated to business activity, where the purpose of such use is not to derive profit or revenue” does not infringe the exclusive patent rights.<sup>21</sup> The response from the Russian Federation noted that “a business activity shall be an independent activity conducted at one’s own risk, aimed at systematically deriving profit from the use of property, sale of goods, performance of work or rendering of services by persons registered in this capacity in the prescribed legal process”<sup>22</sup>. Further, it was explained that ‘commercial purposes’ meant use of a technical solution for deriving profit, while ‘non-commercial’ meant using the invention for other purposes (personal, socially beneficial, including in emergencies). Thus, the current Russian legislation does not treat use for needs unrelated to business activity and the generation of profit or revenue as an infringement of the exclusive patent rights.

19. In considering the applicability of the exception, whether a product was manufactured as a result of parallel, independent creative work, or using other people’s ideas (including directly using patent application materials) is not relevant in the Russian Federation. Use of a product or process in safeguarding an organization’s or entrepreneur’s business (e.g., office equipment, office furniture, vehicles, etc.) must be interpreted as purposes unrelated to “personal use”.<sup>23</sup> Personal use, however, might be applicable to legal entities. For example, use of a patented solution by a company to clean the snow inside its premises for the passage of employees could, in particular, be considered as personal use, while damp cleaning of floors in a shopping center should be deemed as safeguarding business activity.

20. In the United Kingdom, there is case law providing guidance on the interpretation of the terms “private” and “commercial”. In *Smith, Kline & French Laboratories Ltd v Evans Medical Ltd*<sup>24</sup>, the court considered that the word “privately” in Section 60(5)(a): (i) included commercial and non-commercial situations; (ii) was not synonymous with ‘secret’ or ‘confidential’; and (iii) was used as the opposite of “publicly”, denoting an act done for the person’s own use. In interpreting the meaning of “purposes which are not commercial”, the purposes of the act must be considered, i.e., there would be infringement if the purposes include any commercial ones in addition to the non-commercial ones. Further, experiments done for legal proceedings in the High Court or the UK IPO are not considered to be done for a “commercial” purpose.

21. Two Member States referred to the scale and purpose of the commercial activity. In the Philippines, the exception applies to acts done “privately and on a non-commercial scale or for a non-commercial purpose” and in Israel, acts pursued “not on a commercial scale and [...] commercial in character”.

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<sup>19</sup> Tel Aviv District Court Decision (C.S. 1512/93 (Tel Aviv) *The Welcome Foundation Limited vs. Teva Pharmaceutical Industries Ltd*, Takdin-DC, 94(2), 197)

<sup>20</sup> See District Court Alkmaar, December 2, 1991, BIE 1992/12: activities disbanding a bankrupt company.

<sup>21</sup> Article 1359(4) of the Civil Code.

<sup>22</sup> See Article 2(1) of the Civil Code of the Russian Federation.

<sup>23</sup> Paragraph 5 of Resolution No.18 of the Plenum of the Supreme Arbitration Court of the Russian Federation of October 22, 1997.

<sup>24</sup> *Smith, Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 513

*Inclusion of academic, experimental and research activities in the exception*

22. Mirroring their policy objectives of the exception, some Member States do not strictly distinguish the exceptions with respect to non-commercial use and academic/scientific research.<sup>25</sup> For example, in Mexico, patent rights do not extend to “a third party who, in the private or academic sphere and for non-commercial purposes, carries out purely experimental scientific or technological research, testing or teaching activities”.<sup>26</sup> In Kenya, Section 58 of the Industrial Property Act 2002 provides that “the rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research”.<sup>27</sup> In Israel, the Tel Aviv District Court decided that pure medical research for the discovery of medicinal properties of the patented material is not considered as a business activity even if it involves investment and experiments on a large scale, and therefore, it should be included in the exception.<sup>28</sup> The Court clarified that if the material would be further distributed for free to potential clients, such activity would be considered as a business activity.

23. As a private/non-commercial use exception, the response from South Africa referred to use of patented inventions “on a non-commercial scale and solely for purposes reasonably related to the obtaining, development and submission of information required under any law” that regulated the manufacture, sale etc. of any product.<sup>29</sup> It noted that the term “commercial scale” was not defined in its Patent Act, and the phrase should accordingly be given its ordinary grammatical meaning.<sup>30</sup>

*No prejudice to legitimate interest of patent holders*

24. Some Member States provide for the exception only under the condition that private and/or non-commercial use does not prejudice the legitimate interest of patent holders, and require, for example, that the use does not “prejudice the economic interests of the patent holder” (Brazil) or does “not cause significant material prejudice to the owner” (Bulgaria).<sup>31</sup>

**IMPLEMENTATION CHALLENGES**

25. Most Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought<sup>32</sup> and did not foresee any amendments to

<sup>25</sup> See also document SCP/20/4 (Exceptions and Limitations to Patent Rights: Experimental and/or Research Exception).

<sup>26</sup> Article 22 of the Law on Industrial Property (LPI), published in the Federation Official Gazette on June 27, 1991, amended most recently June 28, 2010.

<sup>27</sup> A similar provision is found in Section 38 of the Patents (Registration) Act Cap. 217 R.E. 2002 of Tanzania.

<sup>28</sup> Tel Aviv District Court Decision (C.S. 881/94 (Tel Aviv) Eli Lilly and Company vs. Teva Pharmaceutical Industries Ltd, Takdin-DC, 1586(3), 98)

<sup>29</sup> Act 69a of the Patent Act 57 (1978) of South Africa.

<sup>30</sup> *Luxmoore J in McKenchnie Bros Ltd's Application* (1934) 51 RPC 461, 468; *Delta G Scientific (Pty) Ltd v Janssen Pharmaceutica NV and Another*, 1996 BP 455 (CP) AT 459G (in “Ordinary parlance the phrase is used in contradistinction to research work, or work done in the laboratory”).

<sup>31</sup> Similarly, the private/non-commercial use exception is applicable only where the use does not cause “unjustifiable harm to the working of the patent” (Costa Rica), not “significantly prejudice the economic interests of the owner of the patent” (Cyprus), not cause “undue harm to the legitimate interests of the patent holder” (Dominican Republic), or not “unreasonably conflict with a normal use of the patented invention and does not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties” (Republic of Moldova). The response from the Dominican Republic points out that the “actions stated in this Article shall be subject to the condition that those actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder, taking into account the legitimate interests of third parties”.

<sup>32</sup> Member States which expressly stated that the applicable legal framework of the private and non-commercial use exception was considered adequate to meet the objectives thought are: China, Croatia, Cyprus, Denmark, Dominican Republic, France, Hong Kong (China), Hungary, Latvia, Norway, the Russian Federation, Spain and the United Kingdom.

their legislation<sup>33</sup>. The response from Sri Lanka stated that no study regarding the adequacy of the exception had been undertaken, but it was estimated that “probably due to the existing level of R&D activities in the country, the exception had not been practically tested”.

26. In other Member States, amendments might be foreseen in the future or studies were undertaken. In Zambia, a new Bill plans to introduce a private and non-commercial use exception.<sup>34</sup> The response from Brazil noted that its government was carrying out an evaluation on the implementation of the private and non-commercial use exception “with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system”. In El Salvador, the law was planned to be revised in the medium term. The response from Madagascar noted that the statutory legal frameworks “may be subject to revision” in the future<sup>35</sup>, but considered it adequate at that moment. The response from Mexico stated that since there was no definition which indicated clearly the scope of the exception, “it would be advisable to amend the current legal framework”.

27. Many countries stated that no challenges had been encountered in relation to the practical implementation of the exception<sup>36</sup>. With reference to challenges, the response from the United Kingdom referred to its case law and the difficulties in distinguishing private use from commercial use in cases where activities have “dual purpose”<sup>37</sup>. In those cases, the private use defense would not apply if one of the purposes of those activities was “commercial in nature”.

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<sup>33</sup> Member States and a regional office which responded that no amendment to the law was foreseen are: Dominican Republic, Hungary, Japan, Kenya, Latvia, Honduras, the Netherlands, Peru, Portugal, the Republic of Moldova, Spain, Tajikistan, the United Kingdom and EAPO.

<sup>34</sup> The current Patent Act, Cap 400 of the Laws of Zambia does not provide for a private and/or non-commercial exception. The relevant section in the proposed Bill reads: the rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.  
<sup>35</sup> See Article 140.

<sup>36</sup> For example, responses from China, Croatia, Denmark, El Salvador, Honduras, Hong Kong (China), Hungary, Portugal, Republic of Moldova, Spain, Tajikistan and Zimbabwe.

<sup>37</sup> See response from the United Kingdom: “In *Smith, Kline & French Laboratories Ltd v. Evans Medical Ltd* [1989] FSR 513 and *McDonald v. Graham* [1994] RPC 407 at 431, it was considered that where there is a dual purpose to the activities carried out and one of these activities is commercial in nature, then the defense of private use will not apply”.