

## Standing Committee on the Law of Patents

**Twenty-First Session**  
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### EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: COMPULSORY LICENSES AND/OR GOVERNMENT USE (PART II)

*Document prepared by the Secretariat*

#### INTRODUCTION

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its twentieth session, held from January 27 to 31, 2014, the Secretariat, in relation to the topic “exceptions and limitations to patent rights”, prepared, *inter alia*, a document, based on input received from Member States, on how exceptions and limitations related to compulsory licensing have been implemented in Member States, without evaluating their effectiveness. (Part I, document SCP/21/4). The document also covered practical challenges encountered by Member States in implementing them.
2. This document is Part II and provides information on how exceptions and limitations related to government use have been implemented in Member States.
3. The 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.

#### GOVERNMENT USE

4. The following Member States (or territories) indicated that their applicable laws provided for exceptions and/or limitations related to government use: Albania, Algeria, Argentina, Australia, Austria, Azerbaijan, Bhutan, Bosnia and Herzegovina, Brazil, Burkina Faso, Canada, China and Hong Kong (China), Congo, Costa Rica, Croatia, Cyprus, Dominican Republic, Finland, France, Gambia, Georgia, Greece, Honduras, India, Indonesia, Israel, Kenya, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Mauritius, Morocco, Netherlands, New

Zealand, Norway, Oman, Pakistan, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, the Russian Federation, Sao Tome and Principe, Saudi Arabia, South Africa, Sri Lanka, Tajikistan, Thailand, Uganda, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Viet Nam, Zambia and Zimbabwe (62 in total).

### Public Policy Objectives for Providing the Exception

5. The laws of the above-listed Member States contain provisions that, in general, 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. Regarding the public policy objectives of such provisions, the following can be noted:

#### *Public interest*

6. Many responses stated that such government use is permitted if the public interest, such as national security, national emergency, nutrition, health or the development of other vital sectors of the national economy so requires, or if such use adequately remedies the anti-competitive practice engaged by the patentee or his licensee.<sup>1</sup> For example, in Burkina Faso, the government use provision “aims of strategic interest linked to public health, national defense or the national economy”. In Congo, the government use objectives relates to securing “vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the country’s needs”. Similarly, the response from France highlighted the “interest of the public” and “interest of the economy” in relation to the policy objectives of the exception.

7. In the response from Australia it was explained that “the Crown should not be impeded by patents (which are, in effect, Crown grants) from acting in the public interest, particularly in relation to matters of national defense; [...] unlike private traders, the Crown, through its departments and authorities is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position in regards to use of patented inventions.” The responses from Bhutan and India noted that the public policy objective for providing government use was to enable the government to use the invention whenever it is required. The response from the United States of America stated that the objective of the exception was to permit the government “to procure devices or services that it needs for its own governmental purposes [...]”. And the response from the United Kingdom noted that “Government departments should not be fettered by the existence of patents in the discharge of their functions”.

8. Some Member States’ responses on public policy objectives noted that the government use was specifically permitted to ensure the national security and defense, stating, for example, “to secure the government the right to full disposal of an invention, which has significance for the defense of the Kingdom”<sup>2</sup>, “providing the government a right to use [...] the patented technology for national security objectives”<sup>3</sup>, “to prepare for expected concerns that if inventions crucial for national security are monopolized by a certain person, it could adversely affect national security”.<sup>4</sup>

9. A few other Member States (or territories) focused specifically on the situations of emergency in responding to the question on policy objectives, stating that the purpose was to allow “immediate use of these inventions to meet the urgent needs of the community during a

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<sup>1</sup> See, for example, the responses from Algeria, Burkina Faso, Djibouti, Pakistan, Malaysia and Kenya.

<sup>2</sup> Norway.

<sup>3</sup> Netherlands.

<sup>4</sup> The Republic of Korea.

period of extreme urgency” or to enable the government “to use the patented invention at epidemic complicated emergency situations”.<sup>5</sup>

10. In other Member States, government use is permitted to allow “for invention patents to be widely applied and exploited in order to safeguard the national and public interest”<sup>6</sup>, to ensure that “the public has access to patented products, and it has not been possible to obtain the product from the patentee”<sup>7</sup>, “to ensure the balance between the patentee right and the public interest”<sup>8</sup> “to safeguard consumer interests”<sup>9</sup>, and for the “safeguarding of matters of paramount importance to the country”.<sup>10</sup>

### The Applicable Law and the Scope of the Exception

11. 62 Member States reported that their applicable laws provided for exceptions and/or limitations related to government use. Most Member States’ laws provided a specific statutory provision on this exception. However, some Member States, in responding to the part of the Questionnaire on government use, referred to the provisions on compulsory licensing contained in their laws.<sup>11</sup> In addition, a few Member States reported the provisions concerning the “expropriation of a patent”, “assignment of invention”, “acquisition of a patent by the State” and “the Crown’s right to sell forfeited articles”.<sup>12</sup>

12. As regards the definition of government use, the provisions of many laws state that such use refer to situations in which a competent body, under the specific circumstances prescribed by the law, may grant a license without the consent of the patentee, authorizing a government entity or a third party authorized by the government to use the patented invention.<sup>13</sup> In India, the law provides the following meaning of “use of invention for the purpose of the Government”: “[...] an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking”.<sup>14</sup> In Australia, “[...] an invention is taken [...] to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia”.<sup>15</sup>

<sup>5</sup> See, for example, Hong Kong (China) and Kyrgyzstan, respectively.

<sup>6</sup> China.

<sup>7</sup> New Zealand.

<sup>8</sup> Saudi Arabia.

<sup>9</sup> Sri Lanka.

<sup>10</sup> Uganda.

<sup>11</sup> See, for example, the responses from Croatia, Qatar, the Republic of Moldova and Romania to question 81 of the Questionnaire.

<sup>12</sup> For example, Article 105 of the Industrial Property Code of Portugal reads: “1 – Anyone who is liable for obligations undertaken in relation to third parties or whose patent is expropriated in the public interest may be deprived of a patent under the law. 2 – Any patent may be expropriated in the public interest on payment of fair compensation, if the need for dissemination of the invention or use by public bodies so requires. 3 – The Expropriation Code is applicable, with the necessary adaptations”; Section 122 of the Patents Act of the United Kingdom provides “[n]othing in this Act affects the right of the Crown or any person deriving title directly or indirectly from the Crown to dispose of or use articles forfeited under the laws relating to customs or excise.” See also, Sections 171 and 172 of Patents Act 1990 of Australia; Article 106bis of the Korean Patent Act; and Chapter XIV of the Patent Act 57 of 1978 of South Africa.

<sup>13</sup> For example, Section 23 (1)(a) of the Patents, Industrial Designs and Trademarks Act 2002 of Mauritius states: “Where the competent authority is satisfied that the public interest including national security, nutrition health or the development of other vital sectors of the national economy so requires, it may upon a request made, authorize, even without the agreement of the owner of the patent, a Government agency to exploit the patented invention”; Section 29 of the Patents Act 29 of Uganda reads: “(1) Where the Minister is of the opinion that it is in the vital public interest to do so, he or she, in consultation with the registrar, and without the authority of the owner of a patent, may direct that a patented invention be exploited by a Government agent or other person designated by the Minister, on the following conditions [...]”.

<sup>14</sup> Section 99, Chapter XVII of the Indian Patents Act.

<sup>15</sup> Section 163(3) of Chapter 17 of the Patents Act of Australia.

13. In the United States of America, in case of government use, i.e., “[w]henver 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>16</sup>

14. In addition, the applicable laws of a few Member States provide that supply of products to foreign countries, required for the defense of those countries, are deemed “to be a use of the invention for the services of the Crown” or “to be use of the product or process by the Commonwealth for the services of the Commonwealth”.<sup>17</sup>

### *Grounds*

15. With reference to the grounds for obtaining the government use, the vast majority of responses mention several of them. The most common grounds referred to are: “national security” in 46 responses; “public health” in 38 responses; “national emergency and/or extreme urgency” in 35 responses; “other grounds” in 19 responses; “anti-competitive practices and/or unfair competition” in 16 responses; “refusal to grant licenses on reasonable terms” in 14 responses; “non-working or insufficient working of the patented invention” in 11 responses; and “dependent patents” in 5 responses.

16. Other grounds for government use indicated by Member States include: “nutrition”<sup>18</sup>, “development of other vital sectors of the economy”<sup>19</sup>, “vital interest linked to the global economy”<sup>20</sup>, “national economic needs”<sup>21</sup>, “national defense”<sup>22</sup>, “public interest” such as “national security, nutrition, health, environmental conservation”<sup>23</sup>, “the preservation or realization of natural resources or the environment”<sup>24</sup> “any other public service”<sup>25</sup>, “vital interests of the State”<sup>26</sup>, “matters of “vital public interest” [...] including national economy, public order and morality”<sup>27</sup>, “public needs” and “development of economically important sectors”<sup>28</sup>, “where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology”<sup>29</sup>, and “the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community”.<sup>30</sup>

17. With reference to the grounds, the response from India stated that under its applicable law “there is no limitation with respect to the use by Government”.<sup>31</sup> The response from New Zealand noted that “while the applicable law refers to matters of national security or national emergency, it does not specifically exclude the other grounds”. In addition, in the United Kingdom, certain acts are exempt from infringement if they are carried out in the United Kingdom by a government department, or any person authorized in writing by a government

<sup>16</sup> Title 28, Section 1498(a) of the United States Code.

<sup>17</sup> Section 55(2)(a) Patents Act 1953 of New Zealand and Section 168 of Patent Act 1990 of Australia, respectively.

<sup>18</sup> Bhutan and Philippines.

<sup>19</sup> Bhutan, Philippines, Mauritius, Kenya and Sao Tome and Principe.

<sup>20</sup> Burkina Faso.

<sup>21</sup> Morocco.

<sup>22</sup> France.

<sup>23</sup> Kenya and Portugal.

<sup>24</sup> Thailand.

<sup>25</sup> Thailand and Viet Nam.

<sup>26</sup> Poland.

<sup>27</sup> Uganda.

<sup>28</sup> Lithuania.

<sup>29</sup> Pakistan.

<sup>30</sup> Zimbabwe.

<sup>31</sup> The reference was made to Chapter XVII and Section 47 of the Patents Act of India.

department, “for the services of the Crown” which includes “(a) the supply of anything for foreign defense purposes; (b) the production or supply of specified drugs and medicines; and (c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient”.<sup>32</sup> In the United States of America, government may practice any patented invention “for the government” and subject to its obligation to provide reasonable compensation to the patent owner. In Australia, the grounds stated are “for the services of the Commonwealth or the State”. In Burkina Faso, *ex-officio* licenses shall be subject to the same conditions as the non-voluntary licenses granted for non-working, i.e., “(a) the patented invention is not being worked on the territory of a member State at the time the request is made; (b) the working of the patented invention on such territory does not meet the demand for the protected product on reasonable terms; (c) on account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced”.<sup>33</sup>

*Grant of government use on the ground of national emergency or circumstances of extreme urgency*

18. Most of the Member States that provide for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency” do not provide definitions of those concepts and their scope of application.<sup>34</sup>

19. The response from Hong Kong (China) explained that a “period of extreme urgency may be declared where it is necessary or expedient in the public interest for the maintenance of supplies and services essential to the life of the community [...]” and that examples of such extreme urgency may include massive health crisis.<sup>35</sup> In Kyrgyzstan, the law stipulates “emergency is a situation that developed in a certain area as a result of a dangerous natural or man-made phenomena, accidents, disasters, natural or other disasters that may cause or have caused casualties, damage to human health or the environment, significant financial loss and deterioration of conditions of life people”.<sup>36</sup>

20. The applicable laws of some Member States, as regards the concepts of national emergency and/or extreme urgency, refer to war or similar situations. For example, the response from Norway stated that the term related to “war or danger of war and situations of crisis connected therewith”.<sup>37</sup> Similarly, in the Republic of Korea the concepts refer to situations “[w]here the non-commercial working of a patented invention is necessary for national defense in time of war, uprising, or other similar emergency or for the public interest.”<sup>38,39</sup>

<sup>32</sup> Sections 55(1) and 56(2) of the Patents Act of the United Kingdom.

<sup>33</sup> The response from Burkina Faso referred to Article 56 of the revised Bangui Agreement.

<sup>34</sup> See, for example, the responses from the following Member States to question 85 of the Questionnaire: Bhutan, Canada, Costa Rica, the Dominican Republic, India, Latvia, Malaysia, Mauritius, Oman, Pakistan and Zimbabwe.

<sup>35</sup> Section 68 of Patent Ordinance of Hong Kong (China).

<sup>36</sup> Article 1 of the Law of the Kyrgyz Republic “On Civil Protection”.

<sup>37</sup> Section 70 of the Patents Act of Norway.

<sup>38</sup> Article 106bis (1) of the Korean Patent Act.

<sup>39</sup> Similarly, in Sao Tome and Principe, while the law does not explicitly use the terms “national emergency” or “circumstances of extreme urgency”, they are implicit in the provisions relating to national security which could include a military attack or war, an epidemic or similar situations ( Article 7.6 of Law No. 4/2001 of Sao Tome and Principe). See also a response from Zambia which states: “The phrases are not defined in the Act; however, this may be inferred from section 41(2): “During any period of emergency the powers exercisable in relation to an invention by a Government department or a person authorized by the Minister under section forty, shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient- (a) for the efficient prosecution of any war in which the Republic may be engaged; (b) for the maintenance of supplies and services essential to the life of the community; (c) for securing a sufficiency of supplies and services essential to the well-being of the community; (d) for promoting the productivity of industry, commerce and agriculture; (e) for fostering and directing exports and reducing

21. In the United Kingdom, the Crown use provisions are applied, *inter alia*, “during any period of emergency” which is defined as “any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section”.<sup>40</sup>

*Competent body which grants government use and beneficiaries*

22. As regards the body authorizing government use, the laws of some of the Member States refer to “the Minister”, “the National Executive”, “the State”, “the Crown”, “the Commissioner”, “the Commercial Court”, the “competent authority”, or the “King”.<sup>41</sup>

23. Concerning the beneficiary, most Member States have designated “the government” or government agencies and third parties as beneficiaries of government use, for example, “Government Ministry, Department, agency or other person as the Minister may designate”, “government departments or [...] an enterprise or agency of the State”, “state or municipal institution, natural or legal persons to market” or “a persons”.<sup>42</sup> As regards the third parties, the law in the United States of America clarifies that “the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States”.<sup>43</sup> In the Dominican Republic, the “working license” is granted to “any person that so requests and has the capacity to carry out such working in the country”.<sup>44</sup>

24. The applicable law of Georgia does not expressly indicate the competent body which grants such license or the beneficiary stating, generally, the “use of invention in cases of natural disaster, catastrophe, epidemic or other emergency situations” shall not be considered a violation of exclusive rights.<sup>45</sup> Some Member States’ laws stipulate that government use is at the request of “anybody” or “any interested person or competent authority, or ex officio” or similar formulations.<sup>46</sup>

*Notification of the patentee or applicant*

25. Many Member States (or territories) that provide a government use exception stated that the patentee or applicant shall be notified where reasonably possible and must be informed about the grant of the government use and its scope.<sup>47</sup> Some Member States require such notification “unless National security requires otherwise” or “unless it appears to the relevant

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imports or imports of any classes, from all or any countries and for redressing the balance of trade; (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Her Britannic Majesty’s dominions or any foreign countries that are in grave distress as the result of war; [...]”.

<sup>40</sup> Section 59(3) of the Patents Act of the United Kingdom. It was noted in the response from the United Kingdom that “Section 59(4) requires that the draft of an Order under Section 59(3) must be approved by each House Of Parliament. To date, no Order under s.59(3) has ever been made”.

<sup>41</sup> See, for example, applicable laws of Albania, Argentina, Australia, Canada, Croatia and Madagascar.

<sup>42</sup> See, for example, Albania, Canada, Lithuania, Indonesia and Kenya.

<sup>43</sup> Title 28, Section 1498(a) of the United States Code.

<sup>44</sup> Article 46 of the Law No. 20-00 on Industrial Property of the Dominica Republic.

<sup>45</sup> Article 52(D) of the Patent Law of Georgia.

<sup>46</sup> See, for example, Section 36(5) of the Austrian Patent Act; Article 46 of Law No. 20-00 on Industrial Property of the Dominican Republic.

<sup>47</sup> See, for example, Article 51 Law No. 9947 on Industrial Property of Albania; Section 81.19.(3) of the Patent Act of Canada; Article 20 of the Law No. 6867 on Patents, Industrial Designs and Utility Models of Costa Rica; Section 69(7) of Patents Ordinance of Hong Kong (China); Section 84(2) of the Patents Act of Malaysia; and Article 1360 of the Civil Code of the Russian Federation.

authority that it would be contrary to the public interest to do so”.<sup>48</sup> In some Member States, the law stipulates that the decision to grant government use is made after hearing the owner of the patent and any other interested person.<sup>49</sup>

*The scope, duration and other conditions of government use*

26. Some Member States further require that “the scope and duration of the use shall be limited to the purpose for which the use was authorized”.<sup>50</sup> Further, some Member States expressly stated that “such use shall be non-exclusive”<sup>51</sup> and that “any use shall be authorized predominantly to supply the domestic market”.<sup>52</sup> Moreover, some Member States indicated that the authorization could not be transferred<sup>53</sup>, or could be transferred only “when the enterprise (or a part thereof) in which a patented invention is used”.<sup>54</sup>

27. Some Member States specifically indicated that it was necessary for the requestor to make efforts to obtain from the patentee a voluntary license on reasonable commercial terms and conditions within a reasonable period. In some Member States, this requirement is waived in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.<sup>55</sup>

28. In some Member States, the terms of the decision authorizing the exploitation of the patented invention can be changed upon the request of the patentee or a party authorized to exploit the invention, “taking into consideration the reasons” of request or “to the extent that changed circumstances justify such variation”.<sup>56</sup> Furthermore, some laws stipulate that authorization of such use shall be terminated when the circumstances which led to it cease to exist and are unlikely to recur.<sup>57</sup> In addition, in Lithuania, the Government may declare the resolution null and void, if “a person uses a patented invention for the purpose other than that in respect of which the resolution has been adopted”. In some Member States, such termination is subject to protection of “the legitimate interests of the authorized user” or “the legitimate interests of the Government or the third party”.<sup>58</sup>

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<sup>48</sup> Section 106 of Israel Patent Law 5727-1967 and Section 164 of the Patents Act 1990 of Australia, respectively.

<sup>49</sup> See, for example, Article 14(2) of Law No. 1733/1987 of Honduras; Section 80 of Industrial Property Act 2002 of Kenya; Section 84(4) of the Patents Act of Malaysia; and Section 29(a) of the Patents Act of Uganda.

<sup>50</sup> See, for example, Article 45 of Law No. 24.481 on Patents and Utility Models of Argentina; Section 81.19(2)(a) of the Patent Act of Canada; and Section 84(3) of the Patents Act of Malaysia.

<sup>51</sup> See, for example, Section 81.19.(b) of the Patent Act of Canada; Article 50(6) of the Patent Law of the Republic of Lithuania; Article 12 of the Patent Law of the Kyrgyz Republic. In this regard, Article 30 of Law of Ukraine on the Protection of Rights to Inventions and Utility Models state that “the permission for such a use shall not deprive the patent owner of the right to grant permissions for the use of an invention”.

<sup>52</sup> See, for example, Section 81.19.(2)(b) and (c) of the Patent Act of Canada; Section 84(8) of the Patents Act of Malaysia; Article 30 of Law of Ukraine On the Protection of Rights to Inventions and Utility Models

<sup>53</sup> See, for example, Article 12 of the Patent Law of the Kyrgyz Republic.

<sup>54</sup> See, for example, Section 81.19.(6) of the Patent Act of Canada; Article 50 (7) of the Patent Law of the Republic of Lithuania; Section 84(7) of the Patents Act of Malaysia; or Article 30 of Law of Ukraine On the Protection of Rights to Inventions and Utility Models.

<sup>55</sup> See, for example, Section 19.1(2) of the Patent Act of Canada; Article 80(3) of Patent Law of Bosnia and Herzegovina.

<sup>56</sup> See, for example, Article 50(3) of the Patent Law of the Republic of Lithuania and Section 84(9) of the Patents Act of Malaysia, respectively.

<sup>57</sup> See, for example, Section 165A of the Patents Act 1990 of Australia; Article 50(5) of the Patent Law of the Republic of Lithuania; Article 30 of Law of Ukraine On the Protection of Rights to Inventions and Utility Models.

<sup>58</sup> See, for example, Section 81.19.(5) of the Patent Act of Canada; Section 84(11) of the Patents Act of Malaysia; and Section 165A(2)(b) of Patent Act 1990 of Australia.

29. In many Member States (or territories) the laws expressly stipulate that the government use may be granted “at any time” even at the pre-grant stage of a patent,<sup>59</sup> while in other Member States, the law provides the specific time frame, such as, for example, “three” or “four” years from the date of the grant of the patent.<sup>60</sup>

### *Remuneration*

30. Most Member States provide that the government use is subject to the payment of an “equitable remuneration”, “fair remuneration”, “equitable compensation” or “adequate remuneration” in the circumstances of each case.<sup>61</sup> Some laws further stipulate that such remuneration should take into account “the economic value of the authorization” or “the economic value of the use of the patent”.<sup>62</sup> Some other laws state that the royalties shall be determined by an agreement between the State and the patent owner (or the patent applicant). In the absence of an amicable agreement, the royalties shall be fixed by the competent body, such as a court.<sup>63</sup> In Honduras, “the amount of the compensation is determined in accordance with the extent of the industrial exploitation of the invention”. In Poland, the person whose invention is exploited for national purposes shall have the right to compensation payable from the State budget funds at an amount corresponding to the market value of the license.<sup>64</sup>

31. In the United States of America, the patentee whose invention had been used or manufactured by or for the government may sue the government “for the recovery of his reasonable and entire compensation for such use and manufacture. A reasonable and entire compensation shall include the owner’s reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action”.<sup>65</sup>

32. The laws of many Member States allow the decision authorizing the government use and/or terms of remuneration to be appealed against in the court.<sup>66</sup>

### *Number and technological areas where the government use exception has been applied*

33. As regards the number of times and the technological areas the government use exception has been applied, the response from Malaysia and Zambia stated that in each country such use was applied once to pharmaceutical products. In Thailand, since 2006, the

<sup>59</sup> See, for example, Article 46 of Law No. 20-00 on Industrial Property of the Dominican Republic; Section 69(4) of Patents Ordinance of Hong Kong (China); Sections 104 of Israel Patent Law; Article 37(2) of Ordinance No. 89-019 of Madagascar.

<sup>60</sup> See Article 15 of Qatar Decree Law No. (30) 2006 To Issue Patents’ Law and Section 49(1)(b) Patents Law of Cyprus, respectively.

<sup>61</sup> See, for example, Article 51 Law No. 9947 on Industrial Property of Albania; Section 12(6) of the Industrial Property Act of Gambia; Article 50 of the Patent Law of the Republic of Lithuania; Article 1360 of the Civil Code of the Russian Federation; or Section 29(b) of the Patents Act of Uganda.

<sup>62</sup> See, for example, Section 15 of the Industrial Property Act of the Kingdom of Bhutan 2001; Section 100 of the Indian Patents Act; Article 50 of the Patent Law of the Republic of Lithuania; or Section 84(3)(a) of the Patents Act of Malaysia.

<sup>63</sup> See, for example, Section 165 of the Patents Act 1990 of Australia; Annex I, Article 56, revised Bangui Agreement; or Article 37.2 of Ordinance No. 89-019 of July 31, 1989 of Madagascar.

<sup>64</sup> Article 69 (4) Industrial Property Law of Poland.

<sup>65</sup> However, “unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust”. (Title 28, Section 1498(a) of the United States Code).

<sup>66</sup> See, for example, Article 51(2) of Law No. 9947 on Industrial Property of Albania; Article 18 of the Law on Patent of the Republic of Azerbaijan, Annex I, Article 56, revised Bangui Agreement; Article 50(4) of Patent Law of the Republic of Lithuania; Section 84 of the Patents Act of Malaysia; Article 7.6 and 7.7 of Law No. 4/2001 of Sao Tome and Principe; Section 52(2) of Patent Act of Thailand 1979; Section 29 of the Patents Act 29 of Uganda; Section 62(1) of the Patents (Registration) Act of the United Republic of Tanzania further states that “[w]here the patentee prefers to appeal against the amount of remuneration fixed by the Registrar of Patents, such appeal shall not suspend the exploitation of the patented invention” for government use.

Ministry of Public Health of Thailand has announced the use of compulsory licensing under the government use provisions on seven patented drugs.<sup>67</sup>

34. However, in most Member States (or territories) the government use exception has never been invoked.<sup>68</sup> Some Member States stated that no data were available or that no record existed of such use.<sup>69</sup> The response from Australia noted that since none of the administrative bodies was involved in government use, it was difficult to assess its frequency, though it was expected that such use had been minimal. Similarly, the response from the United Kingdom clarified that patent offices did not generally get involved in “Crown use matters”, and that the relevant government department negotiated directly with the patent owner. However, according to their understanding, the Crown use provisions were invoked very rarely because the government preferred to negotiate a license like any other party would. It was also added that the need to determine and pay compensation for Crown use was likely to be a factor in deciding to conclude a conventional license.

35. In India, a case was filed before the High Court of Delhi relating to use of invention by or on behalf of the Government “for the purpose merely of its own use”.<sup>70</sup> The case was subsequently withdrawn on October 2013. In Kenya, an application for government use order with respect to pharmaceutical products was made in 2004, however the parties negotiated and agreed on a voluntary license.

36. The response from the United States of America stated that the number and technological area where the exception was applied “cannot be easily determined since governmental use is not “issued” as such, but rather involves the government being sued for alleged patent infringement and found liable for infringement [...]”.

### Implementation Challenges

37. The vast majority of Member States responded that the applicable legal framework for the issuance of government use was considered adequate to meet the objectives thought and/or no amendments were foreseen.<sup>71</sup> The response from Morocco reported the following amendment would be introduced in the law shortly: “[w]here public health so requires, patents issued for medicinal products, for processes for obtaining medicinal products, for products necessary to obtain such medicinal products or for processes for making such products, may, where such products are not available to the public in sufficient quantity or quality or at unusually high prices, automatically be worked. *Ex officio* working is enacted by an administrative act on the request of the public health administration. The above provisions also apply to medicinal products for exportation to a country which does not have any manufacturing capacity or with insufficient manufacturing capacity in accordance with relevant international agreements in

<sup>67</sup> These patented drugs relates to: two antiretroviral drugs (Efavirenza and Lopinavir+Ritonavir), an antiplatelet drug (Clopidigrel), a lung cancer drug with generic name Erlotinib and trade name Tarceva®, a breast cancer drug with generic name Letrozole and trade name Femara®, a lung and breast cancer drug with generic name Docetaxel and trade name Taxotere®, a medication for chronic leukemia with generic name Imatinib and trade name Glivec®. See the response from Thailand to question 86 of the Questionnaire.

<sup>68</sup> See the responses from the following Member States (or territories) to question 86 of the Questionnaire: Bhutan, Canada, China and Hong Kong (China), the Dominican Republic, Gambia, Jordan, Kenya, Latvia, Mauritius, Morocco, New Zealand, Norway, Oman, Pakistan, Poland, Portugal, the Russian Federation, Sao Tome and Principe, Saudi Arabia, Tajikistan and Uganda.

<sup>69</sup> See, for example, the responses of the following Member States to question 86 of the Questionnaire: Argentina, Bosnia and Herzegovina, Costa Rica, Croatia, Netherlands and Qatar.

<sup>70</sup> *Chemtura Corporation v. Union of India & Ors.* (CS(OS) No. 930 of 2009).

<sup>71</sup> The following Member States (or territories) stated that the applicable legal framework for the issuance of government use was considered adequate to meet the objectives thought and/or no amendment were foreseen: Algeria, Australia, Bosnia and Herzegovina, Canada, China and Hong Kong (China), Costa Rica, Croatia, Cyprus, Djibouti, the Dominican Republic, France, India, Kenya, Latvia, Madagascar, Malaysia, Netherlands, Norway, Pakistan, Poland, Portugal, the Russian Federation, Sao Tome and Principe, the United Kingdom and the United States of America.

force”. The responses from Bhutan and Qatar also stated that the relevant provisions would be amended. Similarly, the response from Burkina Faso reported that “The Bangui Agreement is currently being revised [...]”. The response from the Republic of Korea stated that Article 73 of the TRIPS Agreement (Security Exceptions) was reflected in the legal framework to limit the issuance of government use only in time of war, uprising, or other similar emergencies.

38. Two Member States, Zambia and Zimbabwe, considered the current legal framework inadequate, because, in the former country, the legislation did not provide for “government use for research purposes” and in the latter “the circumstances for issuance of government use license have been broadened in the amended Draft law to be enacted by including exhaustion of patent rights (based on international principle)”.

39. The vast majority of Member States did not encounter any challenges in relation to the use of the government use mechanisms.<sup>72</sup> Australia noted that the main difficulty that had been tested by the courts was in defining which bodies could be considered to fall within the scope of the Crown. The response from Uganda stated that the challenge in that country in relation to government use was lack of technological capacity.

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<sup>72</sup> The following Member States (or territories) stated that no challenges had been encountered in relation to the use of government use mechanism: Bhutan, Bosnia and Herzegovina, Canada, China and Hong Kong (China), Costa Rica, Croatia, the Dominican Republic, India, Latvia, Malaysia, Mauritius, Pakistan, Portugal, Sao Tome and Principe, the United Kingdom and Zimbabwe.