

Standing Committee on the Law of Patents

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EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: COMPULSORY LICENSES AND/OR GOVERNMENT USE (PART I)

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 the following four exceptions and limitations were implemented in their countries or regional systems, without evaluating the effectiveness of those exceptions and limitations: (i) acts for obtaining regulatory approval from authorities; (ii) exhaustion of patent rights; (iii) compulsory licensing and/or government use; and (iv) exceptions and limitations relating to farmers’ and/or breeders’ use of patented inventions. 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. 8343, dated March 10, 2014, to submit information to the International Bureau in addition to, or updating, the information contained in their responses to the Questionnaire on Exceptions and Limitations to Patent Rights on the above four 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. In order to make the information more comprehensible, in relation to compulsory licensing and/or government use, the Secretariat prepared two documents: Part I - on compulsory licensing and Part II - on government use. Accordingly, this document is Part I and provides information on how exceptions and/or limitations related to compulsory licenses have been implemented in Member States. Information specific to government use can be found in Part II in document SCP/21/5. 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 Member States and a regional

patent office to clarify the scope of the exception in a particular jurisdiction. The Questionnaire and 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/>.

4. 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. With a view to facilitating 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.

COMPULSORY LICENSING

5. The following Member States (or territories) indicated that their applicable laws provided for exceptions and/or limitations related to compulsory licenses: Albania, Algeria, Argentina, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Belarus, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Bulgaria, Burkina Faso, Canada, Chile, China and Hong Kong (China), Congo, Costa Rica, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominican Republic, El Salvador, Finland, France, Gambia, Germany, Greece, Honduras, Hungary, India, Indonesia, Israel, Italy, Japan, Jordan, Kenya, Kyrgyzstan, Latvia, Lithuania, Madagascar, Malaysia, Mauritius, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Sao Tome and Principe, Saudi Arabia, Serbia, Slovakia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tajikistan, Thailand, Turkey, Uganda, Ukraine, the United Kingdom, the United Republic of Tanzania, the United States of America, Viet Nam, Zambia and Zimbabwe (87 in total).

Public Policy Objectives for Providing the Exception

6. The above-listed Member States indicated provisions in their national legislation that allow, in general, the government and/or third parties, under certain circumstances and conditions, to use a patented invention without the authorization of the right holder. While the public policy objectives that compulsory licensing provisions in the applicable laws of Member States pursue show some differences, most Member States provided responses which can generally be categorized into the following public policy objectives:

Balancing of interests

7. Many Member States underlined the balancing aspect of the exception, in particular, noting that the exception, as provided in their applicable law, aimed at striking a balance between the interest of patentees and of third parties and/or public interest and/or society. For example, the responses from Kenya and Saudi Arabia noted that public policy objectives of the compulsory licensing provisions were “to ensure a balance between the rights of the patentee and the public interest”.¹ Similarly, in El Salvador, the objective of the exception was to “balance between private interest and the interest of society”. In addition, the response from Chile stated that the objective of the exception was “to provide the industrial property system with balance, by providing tools that limit the right where committed higher interests exist”. The response from Canada stated that the overall purpose of the compulsory licensing provision

¹ In the response from Kenya the reference was made to a decision of the Industrial Property tribunal of Kenya in *Pfizer Inc. v Cosmos Limited* (IPT Case 49 of 2006), which ruled that the provisions on exceptions in the Industrial Property Act were to “balance between the rights of the patent holders vis-à-vis those of the public and third parties”.

was “to ensure a balance of rights is maintained by preventing anticompetitive behavior or other activities by patent holders that are not in the public interest”.^{2,3}

Preventing abuses of rights

8. Another public policy objective pursued by some Member States (or territories) is to prevent abuses which may result from the exercise of the exclusive rights. For example, the response from Germany noted that the objective of the exception was “to protect the public from any abuse of the exclusive right to which the patent owner is entitled”.⁴ The response from Hong Kong (China) stated that the objective underlying the grant of compulsory licenses was to “prevent abuse of monopoly rights by patent proprietors and to encourage manufacture”. The response also stated that compulsory licenses “ensure that patented inventions are applied practically to their fullest extent and patent rights are exercised without prejudice to the development of industry”.⁵ Similarly, a few other Member States noted the objective of “industrial development” or “establishment or development of industrial and commercial activities in the State” with reference to preventing abuse of rights.⁶

Promoting the public interest at large

9. Many other Member States in describing the public policy objectives of the compulsory licensing provisions, as provided in their applicable laws, focused on the interest of the State or the public at large, which are described as, for example, “public interest and interest of society”, “public interest considerations”, “urgent needs of the society”, “development of the economy and the well-being of the society”, “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” and “situations of public interest and emergency motivated by considerations of public health, nutrition and national security”.⁷

10. The response from Cyprus highlighted the importance of using patents “in order to encourage innovation and the further advancement of science and technology by other interested persons” and to “promote trade and to boost the economy of [the] country by using patents as a source of potential income not only to the patentees but also to the whole of [the] country”. The response of Netherlands stated that in the case of “exceptional circumstances and national security [...], the right of the patentee should be put aside”, it also noted that “innovation would be hampered if a patent holder could prevent, by not providing licenses [for dependent patents], the use and further improvements of an invention”.

² This policy objective was related, in particular, to sections 65 and 66 of Patent Act of Canada.

³ In addition, the following Member States also noted, *inter alia*, the balancing aspect of the relevant exception in describing its public policy objectives: Australia, Canada, India, Japan, Kyrgyzstan, Malaysia, the Russian Federation and the United States of America.

⁴ See also the responses from Austria, Italy, Poland, Portugal, Romania and Switzerland where public policy objectives for provision of compulsory licensing were, *inter alia*, to prevent “abuse of rights”.

⁵ In particular, this objective is pursued in relation to compulsory licenses granted on the grounds of non-working or insufficient working of patent. See a response of Hong Kong (China).

⁶ See, for example, the responses from the Republic of Korea and Qatar.

⁷ See, for example, responses from Burkina Faso, Congo, Gambia, Honduras, Hungary, Poland, the Republic of Belarus, the Russian Federation, the South Africa, Spain, the United Kingdom, Viet Nam and Zambia. See also responses submitted by France (stating that “the patentee’s monopoly may be restricted by economic or social imperatives of general interest, which are considered more important”), Norway (stating that “the main objective is to meet important public interests. The patented invention should benefit the technical development and society.”), Pakistan (stating that the objective of the compulsory license is “to curb monopolization and cartelization and to safeguard the national interest”) and the United Kingdom (stating that the objective is “to prevent the monopoly conferred by the patent working against the public interest. The Patents Act 1977 provides for the granting of compulsory licences as a way of correcting or remedying problems where certain conditions in the market are not being met or where licences are available but only under unreasonable terms.[...]”).

11. Many Member States pursued multiple policy objectives through provisions on compulsory licenses, including the above. For example, the response from Portugal stated that policy objectives of the compulsory licensing provisions were “to avoid abuse of the monopoly [...]; to avoid obstacles to technological and economical development; to promote public health; to guarantee national security”. In the response from China, it was stated that the policy objectives of the exception were “to prevent right holders from abusing their rights, to promote application of inventions and creations, to guarantee the normal operation of the patent system, and to safeguard the interests of the State and the public”. Similarly, the response from Mexico noted that such objectives were: “to avoid misuse on behalf of patent owners, [...] [to] contribute to the transfer and dissemination of technology [...]. The use of the technology for the benefit of the economy and [...] the preservation of national health and security as the supreme interest above and beyond all the rights of the patent owner”.⁸

12. Some other Member States also highlighted that the policy objectives for compulsory licenses included access to products and “consumer protection” so that the “businesses and consumers have reasonable access to patented products at reasonable prices” and products were “available to potential users”.⁹ The response from the United Kingdom stated that the compulsory licensing provisions, *inter alia*, could act as “an incentive for parties to negotiate and agree voluntary licensing agreements rather than go through what is essentially *inter partes* litigation in order to attempt to obtain a compulsory license” which could “prevent or repress anti-competitive behavior”.

13. Some Member States (or territories) also noted specific public policy objectives on public health. Hong Kong (China) referred to the specific policy objectives which were “to make use of the system under the Protocol amending the TRIPS Agreement (adopted by the General Council of the WTO on December 6, 2005) to import medicine” and to “export pharmaceutical products to other WTO Members” in situations of a national emergency or other circumstances of extreme urgency. Similarly, the response from Canada stated the policy objective was to “to give effect to Canada’s and Jean Chrétien’s pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹⁰ The response from a few Member States, in responding to the question on public policy objectives, referred in general to obligations under the TRIPS Agreement and/or EU directives.¹¹

The Applicable Law and the Scope of the Exception

14. Out of 87 responses to the Questionnaire received from Member States, 86 responses indicated that the applicable laws provided for exceptions and/or limitations related to compulsory licenses through statutory means.¹²

⁸ Some other Member States also indicated multiple public policy objectives for the provision of compulsory licensing provisions in their laws, for example, see responses to question 68 of the Questionnaire from Djibouti, India, Poland and the Russian Federation.

⁹ See, for example, the responses from Netherlands, Serbia and Sri Lanka.

¹⁰ The reference was made to sections 21.02 to 21.2 of Patent Act of Canada. See also the response from Jordan.

¹¹ See responses of Israel, Latvia, Lithuania, Netherlands and Turkey to question 68 of the Questionnaire.

¹² In addition, some Member States reported the relevant case law (See, for example, the responses from Germany, Netherlands and South Africa to question 66 of the Questionnaire). The response from EAPO stated that the compulsory licenses were regulated by its Contracting States. In a particular, a reference was made to Article 12 of the Eurasian Patent Convention which reads: “(1) Compulsory licenses for the use of a Eurasian patent by third parties may be granted in conformity with the Paris Convention for the Protection of Industrial Property by the competent authority of a Contracting State with effect in the territory of that State. (2) A decision to grant a compulsory license may be contested in the courts or other competent authorities of the contracting State in the territory of which the compulsory license has been granted”.

15. In general, there are a number of common elements or requirements among compulsory license provisions in national laws. These include: (i) beneficiaries and the competent body (bodies) which grants compulsory licenses; (ii) the grounds on which compulsory licenses may be granted; (iii) prior efforts to be made by the requester of a compulsory license to obtain a voluntary license (with certain exceptions); (iv) limitation of the scope and duration of a compulsory license to meet the purpose of the authorization; (v) non-exclusive license; (vi) non-transferability, except with the business; (vii) authorization predominantly for the supply of the domestic market (with certain exceptions); (viii) remuneration to be paid to the patentee; and (ix) the possibility of review regarding the issuance of the compulsory license as well as decisions relating to remuneration.

Grounds for the grant of compulsory license

16. The vast majority of responses from Member States indicated several grounds on which compulsory licenses may be requested under the respective applicable law. The grounds to which many responses referred are: “non-working or insufficient working” of the patented invention found in 71 responses; “refusal to grant licenses on reasonable terms” found in 60 responses; “dependent patents” found in 57 responses; “public health” found in 56 responses; “national security” found in 52 responses; “anti-competitive practices and/or unfair competition” found in 47 responses; “national emergency and/or extreme urgency” found in 46 responses; and “other grounds” in 26 responses.

17. In addition to the above grounds, some Member States applicable laws provided for other grounds for the grant of compulsory licenses, such as: “development of other vital sectors of the national economy”¹³, “needs of national economy”¹⁴, “public interest”¹⁵, “public necessity”¹⁶, “serious public interest menace”¹⁷, “failure to meet market demand on reasonable terms”¹⁸, “non-exploitation of the patent for failure to manufacture or incomplete manufacture of the product [...] or commercialization that does not satisfy the needs of the market”¹⁹, “public non-commercial use; reasonable requirement of the public not satisfied; the patented invention is not available to the public at a reasonably affordable price”,²⁰ “sold at unreasonably high prices

¹³ See the response from Bhutan.

¹⁴ See the response from France.

¹⁵ This ground, *inter alia*, is provided in the applicable laws of Bulgaria, Peru, Spain and Turkey. In addition, in the responses from Austria and Czech Republic it was specified that a “public health” ground for the grant of compulsory license is applied in the framework of “public interest”.

¹⁶ See the response from Bulgaria. The response clarified that in case of public necessity no attempt by interested persons to obtain contractual licensing under fair conditions is required.

¹⁷ See response from Slovakia.

¹⁸ Section 30(1)(b) of the Patents Act of Uganda.

¹⁹ Article 68 of Law n. 9.279 of 14 May 1996 of Brazil.

²⁰ These grounds, *inter alia*, are found in the Patents Act of 1970 of India. The corresponding explanation from India stated that “[b]roadly speaking Compulsory Licenses are granted under four situations: (i) in the event the reasonable requirement of the public is not met or patented invention is not available to the public at a reasonably affordable price or the patented invention is not worked in India [...] (Section 84 of the Patents Act); (ii) in circumstances of national emergency, circumstances of extreme urgency or in case of public non-commercial use at any time after the grant of the patent, the Central Government may make a declaration in the official gazette that compulsory license can be granted for certain patents. Thereafter any person interested may make application to the controller of patents for the grant of compulsory license under such patents. (Section 92 of the Patents Act); (iii) [...] if a circumstance of national emergency or extreme urgency or in a case of public non-commercial use arise due to the epidemics like HIV/AIDS, TB, malaria or other such epidemics, the compulsory license can be granted by the Controller of Patents to any person interested any time after the grant of the patent pursuant to the notification by the Central Government [...] (Section 92 of the Patents Act); (vi) pursuant to Doha Declaration on the TRIPS Agreement and Public Health, the provision has been incorporated in the Indian Patents Act to grant a compulsory licence for exporting the patented medicine to the countries with no-manufacturing capacity or insufficient manufacturing capacity in the pharmaceutical sector to address the public health problems of that country with respect to the concerned pharmaceutical products (Section 92A of the Patents Act)”.

or not meet the public demand”,²¹ “a market for the patented invention is not being supplied, or is not being supplied on reasonable terms”,²² “where the working of a patented invention is particularly necessary for the public interest”,²³ “the use is necessary [...] for non-commercial public good”,²⁴ “overlapping rights of biotechnological patent owner and a plant variety owner”,²⁵ “compulsory cross-licensing when an invention is related to the protected plant variety”,²⁶ “compulsory license for plant breeder; compulsory license as a result of the Euratom Treaty”,²⁷ “plant varieties”,²⁸ “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”,²⁹ “environmental protection”,³⁰ “impeding the establishment or development of industrial and commercial activities”,³¹ “insufficient supply of appropriate goods, works or services on the market as a result of the specified non-use (insufficient use); the willingness of any person to use the patented subject matter specified”,³² “food and the development of other vital sectors of the national economy”³³ or the “specific provisions under the Clean Air Act, and under the rules of the Nuclear Regulatory Commission”.³⁴

18. In addition, some Member States (or territories) have reported specific provisions contained in their applicable laws that allow for a grant of compulsory license for the purpose of facilitating access to pharmaceutical products in countries with insufficient or no manufacturing capacities in the pharmaceutical sector.³⁵

19. In the United Kingdom, the grounds that apply differ depending on whether or not the proprietor of the patent is a “WTO proprietor” i.e. is a national of, or is domiciled in, a Member of the World Trade Organization, or has a real and effective industrial or commercial establishment in such a Member.³⁶

²¹ See the response from Malaysia to question 67 of the Questionnaire.

²² Section 46 of the Patents Act 1953 of New Zealand.

²³ Article 93 of the Japanese Patent Act.

²⁴ Article 22(A) of Jordan Patent Law 32 of 1999.

²⁵ Section 54 of Patent law of Latvia.

²⁶ Article 48 of the Patent Law of the Republic of Lithuania.

²⁷ Articles 57(5) and (6) and 60 of the Netherlands Patent Act 1995.

²⁸ Section 46a of the Patents Act of Norway.

²⁹ Section 58 and 59 of the Patents Ordinance 2000 of Pakistan.

³⁰ Article 82 of the Industrial Property Law of Poland.

³¹ Article 15 of the Decree Law No.30, 2006 of Qatar.

³² Article 1362 of the Civil Code of the Russian Federation. The corresponding explanation from the Russian Federation noted that “[...] under Article 1362 of the Code, the grant of a compulsory simple (non-exclusive) license for use of relevant patented subject matter within the territory of the Russian Federation is effected by bringing a court action against the patent holder while satisfying all the conditions listed (except dependent patents) simultaneously”.

³³ Article 7.6 and 8.2 of Law No. 4/2001 of Sao Tome and Principe.

³⁴ See response from the United States of America to question 67 of the Questionnaire.

³⁵ See, for example, Article 50(3) and (5) of the Law No.9947 on Industrial Property of Albania, sections 21.02 to 21.2 of the Patent Act of Canada, sections 72A-72J and sections 72K-72R of Patent Ordinance of Hong Kong (China) and section 92A of the Patents Act of India.

³⁶ Section 48A(1) reads: “In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are- (a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms; (b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms- (i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or (ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced; (c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.” Section 48B(1) reads: “In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are- (a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable; (b) where the patented invention is a

Non-working or insufficient working

20. With regard to the ground of “non-working”, the main elements to which Member States referred were that the patent was not worked within a certain timeframe in the territory or insufficiently worked to satisfy the demand of the market of the territory, without legitimate reasons. The applicable laws of many Member States define the beneficiary of such license as “a person”, “any person” or “any legal entity or natural person” or “any interested party”.³⁷ In few Member States, a compulsory license may be granted to a person who can demonstrate the capability to exploit the patented invention, provided all the requirements defined in the law are met.³⁸ For example, in Brazil “[a] license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent”.³⁹

21. In the law of the United Kingdom, in relation to the patented invention which may be subject to compulsory license on the ground of “not being so worked or is not being so worked to the fullest extent that is reasonably practicable” it is specified that a compulsory license may only be requested in relation to a patented invention owned by a non-WTO proprietor.⁴⁰

22. The applicable laws of most Member States did not expressly provide a definition of the terms “non-working” and “insufficient working”. However, the responses of few Member States explained that “abuse” or “non-working” occurs if the “exploitation”, or “working on a commercial scale” or “adequate use” or “sufficient and continuous working” of the patented invention did not take place within a certain period of time without a legitimate reason.⁴¹ Some other Member States (or territories), in defining what constituted a “non-working or insufficient working”, referred to situations where the demand for the patented product was not satisfied in local market on reasonable terms.⁴² Some other Member States (or territories) explained that non-working meant, *inter alia*, that “the reasonable requirements of the public with respect to the patented invention have not been satisfied”, or where the patented invention was capable of being commercially worked in the country, “is not being so worked or is not being so worked to

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product, that a demand for the product in the United Kingdom- (i) is not being met on reasonable terms, or (ii) is being met to a substantial extent by importation from a country which is not a member State; (c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked- (i) where the invention is a product, by the importation of the product from a country which is not a member State, (ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied; (d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms- (i) a market for the export of any patented product made in the United Kingdom is not being supplied, or (ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or (iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced; (e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.”

³⁷ See, for example, the responses of Argentina, Austria, Azerbaijan and Bolivia to question 65 of the Questionnaire.

³⁸ See Article 50 of the Law No. 9947 on Industrial Property of Albania, Article 40(1)(a) of Law No. 20-00 on Industrial Property of the Dominican Republic, and Articles 65 and 66 of Law on Industrial Property of Honduras, and the response from the Russian Federation to question 69 of the Questionnaire.

³⁹ Articles 68 of Law n. 9.279 of 14 May 1996 of Brazil.

⁴⁰ See Section 48B(1)(a) of the Patents Act 1977 of the United Kingdom, *supra* note 36.

⁴¹ See, for example, the responses received from Japan, Mexico, Portugal, Ukraine, South Africa, Zambia and Zimbabwe to question 69 of the Questionnaire.

⁴² See responses from Burkina Faso, China and Hong Kong (China), Greece, Israel, Poland, Republic of Korea and Spain to question 69 of the Questionnaire.

the fullest extent that is reasonably practicable”, or the patented invention is not available to the public at a “reasonably affordable prices”, and/or “sufficient quantities or quality”.⁴³

23. In few Member States, a lack of preparations to work is one of the grounds for compulsory licenses, for example, a compulsory may be granted where a patentee has “not started to work or to make effective and serious preparations to work”.⁴⁴ A few Member States, with reference to the definition of terms “non-working” and “insufficient working”, generally noted that the patentee was obliged to “exploit” or “manufacture” a patented invention directly or through a person authorized by him.⁴⁵

(i) Does importation constitute “working” of the patent?

24. Some Member States do not consider importation as working of the patent⁴⁶ or do not specify such issue in their applicable legal provisions⁴⁷ or the issue is *sub judice*⁴⁸. However, under most of the laws, importation is considered as working of the patent. Thus, the grant of compulsory licenses for “non-working” or “insufficient working” in those countries (or territories) cannot be obtained in the case of importation of a patented product or a product manufactured using a patented process.⁴⁹ However, conditions are applicable in some Member States. For example, in South Africa, an importation is only considered as working “as far as it is not involving excessive pricing”. In Oman, the unavailability of the invention “in sufficient quantities or quality or at predetermined reasonable prices in [internal market], either through manufacture in Oman or through importation”, constitutes “non-working”. In Denmark and Finland, “subject to reciprocity” the working of the invention in another country shall be equivalent to working in those respective Member States. Further, the responses from a few Member States, specified that importation of patented products into at least one Member State of the European Union and/or European Economic Area or Member of the WTO was considered “working” of the patented invention.⁵⁰ In Hungary and Poland, “the importation *per se* does not constitute ‘working’ of the patent; however, a legitimate import can mean that the patented invention is exploited in the territory of the country in order to satisfy the domestic demand”. In Norway, while import of the patented product from another country will not necessarily prevent the grant of a compulsory license, “in the case of import, the patentee may have legitimate reasons for the failure to work the invention”. Contrary to that, in Qatar, the law clarifies that “importing the product shall not serve as legitimate reason”. In Brazil, a compulsory license can be granted, *inter alia*, in case of non-exploitation of the patented invention within its territory for “failure to manufacture or incomplete manufacture” of the product or the patented process, “except cases where this is not economically feasible, when importation shall be permitted”.

⁴³ See responses of Dominican Republic, India, Hong Kong (China), Oman, Poland and Morocco to question 69 of the Questionnaire.

⁴⁴ See responses from Argentina, Hungary and Morocco to question 69 of the Questionnaire.

⁴⁵ See responses from Portugal and Vietnam to question 69 of the Questionnaire.

⁴⁶ Responses from Uganda, United Republic of Tanzania and Zambia expressly indicated that importation did not constitute “working” of the patent under their applicable law.

⁴⁷ See responses from Bosnia, Croatia, Greece, Pakistan and Slovakia.

⁴⁸ See response from India.

⁴⁹ Responses from the following Member States expressly stated that importation constitutes “working” of the patent: France, Gambia, Honduras, Hong Kong (China), Israel, Japan, Malaysia, Mauritius, Mexico, Morocco, Netherlands, Portugal, the Russian Federation, Switzerland, Turkey and Ukraine.

⁵⁰ See responses from Italy, Spain and Sweden. In the United Kingdom “a compulsory license cannot be granted in respect of the ground mentioned in s.48B(1)(a) if demand in the UK is being met by importation of the patented invention from a member State of the European Economic Area (EEA) where the invention is being commercially worked”.

- (ii) Time period to be respected before the grant of a compulsory license in case of non-working or insufficient working

25. In most Member States, the time period during which compulsory licenses may not be granted on the grounds of non-working or insufficient working is three years from the date of the grant of the patent or four years from the filing date of the application. The applicable laws of many Member States further specify that the said time period lasts three years from the date of grant or four years from the filing date, whichever period expires later. In addition, in a few Member States, a compulsory license may be granted if the exploitation of the patented invention has been interrupted for more than one year⁵¹, and in two Member States, for more than three years.⁵² Some other variations found in the applicable laws are, for example, “three years from the date of the grant of the patent”,⁵³ “three” or “five” years from the date of publication of the mention of the grant⁵⁴, “3 years after sealing”,⁵⁵ or “three years of non-working”,⁵⁶ and “four years from the filing date of the application”.⁵⁷

26. In Zimbabwe, the compulsory license in case of, *inter alia*, insufficient use of patent rights may be requested “within a period of six months from the initial request for a voluntary license”.

- (iii) Definition of “legitimate reasons”

27. In the majority of Member States that allow grant of the compulsory license on the ground of “non-working or insufficient working” it is possible to justify such non-working or insufficient working with legitimate reasons. In this regard, some Member States made a reference to, for example, “legitimate grounds”, “reasonable ground”, “valid reasons”, “good reason”, “duly justified reasons” or “satisfactory reason” for failing to work the invention, or “acceptable reason for the non-use of the invention”.⁵⁸

28. Those legitimate reasons are, in most of those Member States, of a technical, economic, legal nature, or force majeure. For example, in the response from Turkey, it was stated: “technical or economic or legal reasons of an objective nature shall be deemed to constitute legitimate excuses for the inability to put the patent to use. The reasons accepted [...] are those which are beyond the control and will of the patentee.” Similarly, in Argentina, the legitimate reasons are explained as “objective difficulties of a technical and legal character, such as delays in obtaining registration for marketing approval from Public Bodies, which are beyond the patent owner's control and which make the exploitation of the invention impossible [...]”. In the Dominican Republic and Honduras, “force majeure, or circumstances independent of the will or beyond the control of the patent owner”, can “justify the non-working or insufficient working”. In addition, the response from China clarified that “for example, if the production, importing or marketing is prohibited by the Government, no compulsory license should be issued on the grounds of non-working or insufficient working”. In Brazil, in addition to a justification of non-use for “legitimate reasons” and based on “grounds of an obstacle of legal nature”, a compulsory license shall not be granted “if, on the date of the application, the titleholder proves that serious and effective preparations for exploitation have been made”. The response from Norway stated that even the “difficulties in providing raw material or has been struggling with lack of resources,

⁵¹ See Article 43 of Law No. 24.481 on Patents And Utility Models of Argentina, Article 41(1) of Law No. 20-00 on Industrial Property Dominican Republic and Article 18.1 of Law No. 6867 on Patents, Industrial Designs and Utility Models of Costa Rica.

⁵² Turkey and Ukraine.

⁵³ See, for example, Azerbaijan, Brazil, Honduras, Hong Kong (China), India, Netherlands, Qatar and the United Kingdom.

⁵⁴ Turkey, Ukraine, and Tajikistan

⁵⁵ Australia.

⁵⁶ Monaco.

⁵⁷ The Republic of Korea.

⁵⁸ See, for example, Brazil, China, Japan, Mexico, Pakistan, Serbia and Sweden.

this cannot be considered as legitimate reasons”; however, “if the working of the invention has been impeded by public regulations, there might be legitimate reasons”. In addition, in the responses of some Member States it was noted that the lack of financial resources or the lack of financial feasibility of the exploitation, did not constitute legitimate reasons.⁵⁹

29. Further, while the applicable law of many Member States provided that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons, the law in those Member States does not expressly define what those legitimate reasons are.⁶⁰ Some of those Member States (or territories) noted that that would be determined on a case-by-case basis, or by court.⁶¹ Some responses explained that the patentee had to provide “evidence that the circumstances made it impossible to remedy the lack or insufficiency of exploitation of his patent”, or “to prove the legitimacy of the reasons which resulted in the non-working of the patented solution”.⁶² In Cyprus, there is a specific test which takes into account the following factors: the nature of the invention; the time elapsed and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention; the ability of any person to whom a license would be granted under the order concerned to work the invention to the public advantage; and the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted. Yet, according to the applicable law of Jordan, the patentee may be granted an additional grace period if the Minister deems that reasons beyond the control of the patentee have prevented exploitation.

a. Compulsory license on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within “reasonable period of time”

30. With reference to the grant of compulsory license on this ground, the response from Germany stated that “in this case the public interest must, in addition, command the grant of a compulsory license”. Regarding the definition of the terms “reasonable terms and conditions” and “reasonable period of time”, the applicable law of most Member States did not provide any further explanations. Some responses stated that the expression “reasonable terms and conditions” and “period of time” would be decided, for example “based on the facts and circumstances of each case”, on “a case-by-case basis”, “on the conditions pursuant to the common practice” or “on such terms and conditions as are consistent with prevailing practice”.⁶³ The response from China noted that the reasonableness would be “determined by the specific circumstances”, such as “fields of technologies, marketing prospects, royalties of similar technologies, the funds invested in making the invention”. The response from the Dominican Republic referred to “the economic value of the authorization [...] bearing in mind the rate of average royalties for the sector in question, in relation to commercial license contracts between independent parties”. The response from Israel clarified that the conditions “are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent”.

31. In South Africa, the reasonableness “requires consideration of the patentee’s cost of production and marketing the article, the terms and conditions on which it negotiates with customers, and whether the trade can carry that price”.⁶⁴ The response from the United Kingdom explained that what constituted reasonable terms depended on “a careful

⁵⁹ See Argentina, Portugal, the Dominican Republic and Honduras.

⁶⁰ See the responses, for example, from Australia, Bhutan, Bosnia and Herzegovina, Croatia, Finland, France, Greece, Latvia, Madagascar, Morocco, Qatar, Switzerland and Zimbabwe.

⁶¹ See, for example, responses from Hong Kong (China), the Kyrgyzstan, Malaysia, Monaco, Romania, Tajikistan, Ukraine and United Republic of Tanzania to question 72 of the Questionnaire.

⁶² See, the response from Algeria and the Russian Federation, respectively.

⁶³ See, for example, the responses from Canada, the Dominican Republic, Hong Kong (China), Hungary, Kenya and Tajikistan to question 73 of the Questionnaire.

⁶⁴ The response also noted that “evidence of “reasonable terms” should be provided, as should the evidence that the patentee’s prices were not reasonable” (*Afitra (Pty) Ltd v Carlton Paper of SA(Pty) 1992 BP 331 (CP)*).

consideration of all the surrounding circumstances in each case, e.g. the nature of the invention, the terms of any licenses under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a *bona fide* one and not one adopted to suppress or depress demand". A test applied by court in that state was "how much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay?"⁶⁵

32. With reference to the reasonable time period to obtain a voluntary license, few Member States refer to time period of three or six months. For example, the response from Oman stated "a period of up to a maximum of six months between the date on which the patent owner was informed by the proponent of the request and the proposed conditions for a voluntary license and the date on which the proponent of the voluntary license was informed by the patent owner on his final decision to refuse the proposal shall be deemed a reasonable time"⁶⁶, whereas the law in Slovakia provided that a period of "three months from the request for the license" was a reasonable period.⁶⁷ The response from China noted that what would constitute a reasonable period of time should be determined by taking into consideration the time needed by the right holder to make a decision after evaluating both the economic and technological aspects of the inventions. In Argentina, where efforts to obtain a license have not been successful following a period of "150 consecutive days as of the date on which the corresponding license was requested", a compulsory license may be granted. Finally, the response from Pakistan stated that it was the government which determined what constituted "reasonable terms and conditions and reasonable period of time".

b. Compulsory license on the ground of anti-competitive practices

33. As regards the grant of a compulsory license on the ground of anti-competitive practices, many Member States did not provide further explanations. The responses of few Member States noted that on the establishment of anti-competitive practice adopted by the patentee, it was not required to seek "an amicable agreement" or to make a prior "efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period"⁶⁸.

34. Some Member States, in explaining what constituted "anti-competitive practice" under their applicable laws, referred to an enumerative list of anti-competitive practices. For example, in some Member States such practices referred, *inter alia*, to: "the fixing of excessive or discriminatory prices for patented products"⁶⁹ and "the lack of market supply on reasonable commercial conditions".⁷⁰ Further, anti-competitive practices might be related to "denying a competitor access to essential facility"⁷¹ or "the lack of market supply on reasonable commercial conditions".⁷² Another type of anti-competitive practices related to the exclusion of competitors,

⁶⁵ *Brownie Wireless Co Ltd's Applications 46 RPC 457*, was cited in the response from the United Kingdom to question 73 of the Questionnaire.

⁶⁶ See also the response from India to question 73 of the Questionnaire.

⁶⁷ Article 27(1)(b) of The Patent Act of Slovakia.

⁶⁸ See, for example, responses from France and India, respectively.

⁶⁹ For example, the law in Argentina provides: "fixing of excessive or discriminatory prices for patented products in relation to average market prices; in particular, where offers of market supply exist at prices significantly lower than those offered by the owner of the patent for the same product". The response from Algeria refers specifically to "fixing, for patented pharmaceutical products, of excessive or discriminatory prices in relation to average market prices". Similarly, the applicable law of France envisages *ex officio* licenses in the interest of national public health, declared by decree of the Minister for Intellectual Property for a number of patents (in particular medicines, medical equipment, production or manufacturing processes) when these patented products "are made available to the public in an insufficient quantity or quality, or at abnormally high prices, or when the patent is worked in conditions contrary to the interest of public health, or constituting anti-competitive practices following an administrative or court decision made final".

⁷⁰ See, for example, the applicable laws of Argentina, Costa Rica and the Dominican Republic.

⁷¹ See the response from South Africa.

⁷² See the response from Costa Rica and the Dominican Republic.

for example, by “the obstruction of commercial or production activities”⁷³ or “engaging in an exclusionary act”.⁷⁴

35. Some Member States’ applicable laws also provide for a more general wording for the determination of anti-competitive practices, such as “any other act which national legislation characterizes as anti-competitive, limiting or restrictive of competition”,⁷⁵ “anti-competitive practice which operated or may be expected to operate against the public interest”,⁷⁶ “if the patentee exercises his rights in such a way as to prevent others from competing fairly”⁷⁷ or “restraint of trade and contrary to public policy”.⁷⁸

36. Some Member States’ applicable law did not expressly define which practices were considered “anti-competitive”.⁷⁹ The responses from some Member States indicated that the determination or declaration of anti-competitive practices was deferred to specific bodies, such as a “judicial or administrative body”, “any anti-monopoly agency or the judicial judgment by any court”, “administrative or court proceedings”, the “Federal Government and [a] judicial body”, the “Competition Commission, the Secretary of State or a Government Minister”, or the “Court of Free Competition”.⁸⁰

37. In the United Kingdom, a compulsory license “following a merger or market investigation to remedy, mitigate or prevent a competition matter [...]” may be applied for by the relevant authorities.⁸¹ In Germany, compulsory licenses may arise from the cartel law.^{82, 83}

38. Some Member States limited the grant of compulsory licenses on the ground of anti-competitive practices to the area of public health and/or semiconductor technology.⁸⁴ In case of a semiconductor technology, the response from a few Member States noted that a compulsory license may be granted only for a use for public non-commercial purposes or to remedy a practice declared anti-competitive following court or administrative proceedings.⁸⁵

c. Grant of compulsory licenses on the ground of dependent patents

39. Most of the Member States that allowed the grant of compulsory licenses on the ground of dependent patents, .i.e., where the exploitation of the patent (“the second patent”) was not possible without infringing the another patent (“the first patent”), stated that, in general, the following three conditions should apply: (i) the invention claimed in the second patent shall

⁷³ See the response from Argentina, Costa Rica and the Dominican Republic.

⁷⁴ See the response from South Africa.

⁷⁵ Article 42 of Law No. 20-00 on Industrial Property of the Dominican Republic.

⁷⁶ Sections 50A and 51 of the Patents Act of the United Kingdom.

⁷⁷ Article 22(C) of the Jordan Patent Law 1.11.1999.

⁷⁸ Section 37(6)(f) of Patents Act of Zambia.

⁷⁹ See, for example, the responses from Canada, Serbia, Sri Lanka and Zimbabwe.

⁸⁰ See responses of Australia, Chile, China, India, Lithuania, Pakistan, Romania, Sri Lanka and the United Kingdom to question 74 of the Questionnaire.

⁸¹ See Sections 50A of the Patents Act of the United Kingdom. In addition, under Section 51, a compulsory license may be applied in case “a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest”. The corresponding explanation from the United Kingdom states that: “Applications under s.50A or 51 must involve “conditions in licenses granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licenses”, or “a refusal by the proprietor to grant licenses on reasonable terms”. See response from the United Kingdom to question 74 of the Questionnaire.

⁸² Case No. KZR 39/06 – Orange Book Standard, published in IIC 2010, 269, May 6, 2009, the Federal Supreme Court of Germany. See a response from Germany to question 74 of the Questionnaire.

⁸³ In the United States of America, while the regulatory Agencies have used IP licensing as a remedy in three different types of antitrust cases, it is “in a few cases, the Agencies have sought compulsory licenses to remedy competitive harm arising from specific uses of IP rights”. See response from the United States of America to question 74 of the Questionnaire.

⁸⁴ See, for example, France, Germany, Switzerland and Ukraine.

⁸⁵ See, for example, the responses from France and Moldova to question 74 of the Questionnaire.

involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to obtain a cross-license on reasonable terms to use the invention claimed in the second patent; and (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent".⁸⁶

(i) Definition of the term "dependent patents"

40. In relation to the term "dependent" different wordings were envisaged in the applicable laws of some Member States, for example, "If a patented invention cannot be exploited without infringing an invention patented with a better priority (earlier patent)"⁸⁷; "patent is included in the scope of another, earlier patent"⁸⁸; "If the invention claimed in a patent may not be worked industrially in the country without infringing an earlier patent"⁸⁹; "[...] the working or efficient working in Cyprus of any other patented invention which makes a substantial contribution to the art is prevented or hindered"; or the patentee/ licensee is "prevented or hindered without such license from working the other invention efficiently or to the best advantage possible".⁹⁰

(ii) Other details on conditions applied in case of dependent patents

41. Some variations also found in relation to the conditions applied in case of dependent patents. For example, in India, the license may be requested if, *inter alia*, "the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities" in that country. In Poland, the compulsory license may be granted if the holder of the earlier patent "prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent". In Portugal, if the two inventions are used "for different industrial purposes", a license may only be granted if the "first invention is essential to the exploitation of the second", and "only in the part necessary for said exploitation".

42. In addition, some responses noted that, in case of dependent patents, it was further required that the party was not able to obtain the patent owner's consent to exploit the invention under "fair conditions", "reasonable terms", "reasonable conditions usual in trade" "on the conditions that are in compliance with the common practice", within a reasonable period of time.⁹¹ In Japan, the person can request the patentee to hold consultations on the grant of a non-exclusive license.⁹² In Netherland, the law obliges the patentee at all times to grant a license required for the use of a second patent, as defined in the law; however the patent holder will be obliged to grant a license required for the use of a European patent "only after the term for filing an opposition to the European patent has expired or after opposition proceedings thus instituted have ended".

⁸⁶ See, for example, Article 46 of Law No. 24.481 on Patents and Utility Models of Argentina, Article 51(3) of Law No. 19.039 of Chile, Article 19.A.1 of Law No. 6867 on Patents, Industrial Designs and Utility Models of Costa Rica, Article 66 of Law No. 17-97 on the Protection of Industrial Property of Morocco, Article 67 of Decision 486 of Peru, Section 93 of RA No. 8293 of Philippines, Section 55 of the Patent Act of South Africa and Section 86(2)(g) of the Intellectual Property Act of Sri Lanka.

⁸⁷ Austria

⁸⁸ Bulgaria

⁸⁹ Costa Rica

⁹⁰ India

⁹¹ See, for example, the responses of Bulgaria, Cyprus, Germany, Hong Kong (China), the Kyrgyzstan, Morocco and Peru to question 75 of the Questionnaire.

⁹² The corresponding explanation from Japan stated that: "Yet, in a case where the grant of a non-exclusive license would unduly injure the other person or the patent right holder, the Commissioner of the Patent Office cannot render an arbitration decision ordering a non-exclusive license to be granted".

43. A few Member States also noted that a compulsory license granted in case of dependent patents “may not be exclusive”, or that such a license should be limited in the scope and volume that are necessary to exploit the invention by the owner of the second patent.⁹³

44. In addition, in construct with above-described three conditions applied by many Member States in case of dependent patents,⁹⁴ few Member States’ laws provided different criteria. For example, in Turkey, the owner of the second patent may request the court to grant license for using the first patent owned by another person by bringing evidence that his patent, with reference to the first patent, will serve a “different industrial purpose” or “achieves significant technical improvement”.⁹⁵ Similarly, in the United Republic of Tanzania, the grant of compulsory license may be requested if the second patent serves “industrial purposes different from those served by the invention which is the subject of the earlier patent”; or “constitutes substantial technical progress” in relation to that earlier patent.⁹⁶

45. The applicable laws of a few Member States stated that compulsory licenses in case of dependent patents may be requested by “the owner of the second patent”, “his licensee”, or “the beneficiary of a compulsory license for the later patent”.⁹⁷ Similarly, the law in India provides that: “any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise” may apply for the grant of a license.

(iii) Cross-license on reasonable terms

46. While, in most of the Member States, the owner of the first patent is entitled to obtain a cross-license on reasonable terms to use the invention claimed in the second patent, some differences were also found in some laws. For example, in Finland, the owner of a first patent may obtain a compulsory license to exploit the second patent “unless there are special reasons to the contrary”. In Portugal, the previous patentee may also demand a compulsory license if inventions protected by dependent patents “serve the same industrial purpose”.⁹⁸ In addition, the law in Portugal provides that with respect to an invention concerning a “process for preparing a chemical, pharmaceutical or food product”, and “whenever this process patent represents notable technical progress in relation to the previous patent” both the holder of the process patent and the holder of the product patent are entitled to request a compulsory license for the other holder’s patent.⁹⁹

47. In addition, few Member States noted a specific case of compulsory cross-licenses where a plant variety right could not be obtained or exploited without infringing the rights conferred by a previous patent, or a patent could not be exploited without infringing a prior plant variety right.¹⁰⁰

⁹³ See responses, for example, from Honduras and Netherlands.

⁹⁴ The conditions are described in paragraph 39 of the paper.

⁹⁵ Article 101 of Turkish Patent Decree Law. Similarly, in Ukraine, the patent owner of the first patent is obliged to grant the permission to use his invention to the owner of the second patent provided that that invention is “intended for other purpose” or has “significant technical and economical advantages”. See Article 30(2) of Law of Ukraine “On the Protection of Rights to Inventions and Utility Models”.

⁹⁶ Section 54 of the Patents (Registration) Act of the United Republic of Tanzania.

⁹⁷ Article 44(c) Law No. 20-00 on Industrial Property of the Dominican Republic and Article 19.A.1 of Law No. 6867 on Patents, Industrial Designs and Utility Models of Costa Rica.

⁹⁸ Section 54(2) of the Patents (Registration) Act of the United Republic of Tanzania also provides a compulsory cross-licensing if the first patent and the second patent “serve the same industrial purposes”.

⁹⁹ Article 89 of the Law on Patents of Spain also provides a cross-licensing possibility “where the subject matter of a patent is a process to obtain a chemical or pharmaceutical substance protected by a patent in force”.

¹⁰⁰ See Article 28 of the Law 50/2008 on the Protection of Invention of the Republic of Moldova; Article 109 of Industrial Property Code of Portugal; Article 47(5) of the Romanian Patent Law; Article 89 of the Law on Patents of Spain. See also document SCP/21/6.

d. Grant of compulsory licenses on the ground of national emergency or circumstances of extreme urgency

48. The applicable laws of most of those Member States (or territories) that provided for compulsory licenses on the grounds of “national emergency” or “circumstance of extreme urgency” did not provide for a definition of such circumstances.¹⁰¹ In some Member States, national emergencies were defined by listing examples, such as “state security, protection of public interest in the field of health and nutrition, protection and improvement of human environment, or special interest in a particular branch of economy [...]”,¹⁰² “war, uprising, or other similar emergency”,¹⁰³ “disasters, catastrophes or big accidents”,¹⁰⁴ “national defense, emergency or noncommercial public good”,¹⁰⁵ or “national security, public interest protection in the field of health, food supplying, environmental protection and improvement, specific commercial interest”.¹⁰⁶

49. The responses from India and Hong Kong (China) stated that examples of such circumstances may include public health problems resulting from “HIV/AIDS, tuberculosis, malaria and other epidemics”.¹⁰⁷ In the Republic of Moldova, the term “extreme situation” defined generally as “interruption of normal life and activity of the population [...] in a region as a result of accidents, disasters, natural or socio-biological calamities which resulted or could result within human and economic losses”.¹⁰⁸ In Serbia, the circumstances of “national emergency” or “circumstances of extreme urgency” were defined as public emergency which “endangers the survival of the state or its citizens”. The response from China, with reference to national emergency, referred to “wars or any emergency that endangers the country or any natural disasters or pandemic diseases”.

50. Some Member States’ responses referred in general to situations of “public interest”,¹⁰⁹ which were defined by Denmark as, for example, concerning “national security, the population’s access to medical products and food, power supply, communication lines etc.”¹¹⁰ Whereas the response from Spain explained that reasons of public interest were invoked when: “(i) the increase or generalization of working of the invention, or improvement of the conditions in which it is being worked, are of paramount importance for public health or national defense; and (ii) failure to work or insufficient quality or quantity of working leads to serious prejudice for Spain’s economic or technological development”.

51. In Mexico, “national emergency or security” included “serious diseases declared as a priority by the General Health Council”.¹¹¹ In Pakistan, the Federal Government was the authority to determine the grounds for national emergency or circumstances of extreme emergency. The response from Sri Lanka stated that the determination of such circumstances was within the competence of the court.

52. In addition, in relation to the grant of compulsory licenses on the ground of national emergency or circumstances of extreme urgency, the response from Hong Kong (China) referred to the provisions under its applicable law related to compulsory licenses to import

¹⁰¹ See, for example, responses from the following Member States to question 77 of the Questionnaire: Bhutan, Chile, China, Costa Rica, the Dominican Republic, El Salvador, Kenya, Latvia, Oman, Peru and Sudan.

¹⁰² Article 80 (1) of the Patent Law of Bosnia and Herzegovina.

¹⁰³ Article 106(2)(i) of the Korean Patent Act.

¹⁰⁴ Article 12 of the Patent Law of the Kyrgyz Republic.

¹⁰⁵ See response from Jordan to question 77 of the Questionnaire.

¹⁰⁶ Article 68(6) of the Patent Act of Croatia.

¹⁰⁷ Section 92(3) of Patents Act of India. The response from Zambia to question 77 of the Questionnaire with reference to national emergency also referred to HIV/AIDS pandemic.

¹⁰⁸ Article 1(2) of the Law 93/2007 on Civil Protection Service and Extreme Situations of the Republic of Moldova

¹⁰⁹ See responses from Check Republic, Finland, the Netherlands and Norway

¹¹⁰ See response from Denmark to question 77 of the Questionnaire

¹¹¹ Article 77 of Law on Industrial Property of Mexico.

pharmaceutical products into Hong Kong (China) and to export such products to other WTO Members.¹¹²

53. In addition, in relation to the time period to be respected before the grant of compulsory license on this ground, in the responses from few countries it was noted that where “public interest” requires, a compulsory license may be granted without observing any specific time limit.¹¹³

Policy in relation to remuneration

53. As regards to the question whether the applicable law provides a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee, some Member States responded in the negative.¹¹⁴ Many Member States (or territories) stated that “reasonable”, “adequate”, or “equitable” “remuneration” or “compensation” shall be paid to the patentee, the amount of which shall be determined taking into account “merits of each individual case” or “the circumstances of each case”¹¹⁵, and “the economic value of the authorization”¹¹⁶ or “the economic value of the license”.¹¹⁷

54. Regarding the economic value of the authorization, the response from Costa Rica specified that the competent body should bear “in mind the average rate of royalties for the sector in question, in commercial license contracts between independent parties.” With reference to the economic value of the license, the response from Hungary stated that “[i]n particular, it shall be commensurate with the royalty the holder of the compulsory license would have paid on the basis of an exploitation contract concluded with the patentee, taking into account the licensing conditions in the technical field of the invention.” In the Russian Federation, the total payment for a compulsory license should be “at a level no lower than the cost of a license determined under comparable circumstances”. In Zimbabwe, the patentee was provided with the reasonable royalty “compatible with the successful working of the invention in Zimbabwe on a commercial scale and at a profit”.

55. In Cyprus, Hong Kong (China) and India, the patentee should receive reasonable remuneration having regard to the “nature of the invention”. In addition to that, in India, the remuneration was reasonable “having regard to [...] the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors.” In other Member States, “the importance of the invention and the value of the license contracts in the relevant technical field”, “the extent of the industrial exploitation of the invention” or “the commercial value of the granted licenses” should be taken into account.¹¹⁸ In Canada, the Commissioner of Patents should ensure the maximum advantage for the patentee while permitting the licensee a reasonable profit, as well as the equality of advantage among the several licensees.

56. In the United Kingdom, different provisions applied for WTO and non-WTO proprietors, i.e., for patent owners from WTO Members, the “remuneration adequate in the circumstances of the

¹¹² The response from Canada to question 65 of the Questionnaire also provides provisions concerning the procedure to be followed by pharmaceutical manufacturers who wish to apply for a compulsory license to manufacture an eligible patented pharmaceutical product for export to an eligible importing country.

¹¹³ See, for example, the responses from the Djibouti, the Democratic People’s Republic of Korea and Sao Tome and Principe.

¹¹⁴ See, for example, the responses of Belarus, Chile and France to question 76 of the Questionnaire.

¹¹⁵ See responses, for example, from Jordan, Kenya, Norway, Serbia and South Africa.

¹¹⁶ See responses, for example, from Argentina, Armenia, Costa Rica, Croatia, the Dominican Republic, the Philippines and the Republic of Moldova.

¹¹⁷ See responses, for example, from Australia, Austria, Germany, Hungary, Kenya, Latvia, Morocco, Portugal and Serbia. The response from Jordan referred to “the economic value of the patent”.

¹¹⁸ See, responses from the Check Republic, Greece and Romania, respectively.

case, taking into account the economic value of the license” and for patent owners from non-WTO Members, “reasonable remuneration having regard to the nature of the invention”.¹¹⁹

57. In addition, in some Member States, in the cases in which the compulsory licenses had been granted to remedy anti-competitive practices, the need to correct such practices, among other factors, was taken into account in determining the amount of remuneration.^{120,121}

58. Some Member States stated generally that the conditions of remuneration were determined by the court¹²² or another competent body.¹²³ The responses of some other Member States noted that court or other competent body would set the remuneration, based on factors as provided in their applicable law, if parties would fail to agree themselves.¹²⁴ In addition, the responses of few Member States noted that, in the event of a substantial change in the circumstances, the competent authority may, upon request by one of the parties, revoke the license or lay down new licensing conditions.¹²⁵ Few Member States also noted that the decisions relating to uses not authorized by the patentee shall be subject to judicial review, along with the issues concerning the remuneration.¹²⁶

59. Few Member States (or territories) reported the specific provisions for the remuneration for compulsory licenses relating to import/export of patented pharmaceuticals. In particular, courts will take into account “the economic value of the use of the invention” to the relevant country and the “humanitarian or non-commercial factors relevant to the grant of the license”.¹²⁷ In addition, the law in Pakistan provided the patentee should be entitled to a payment “up to three percent remuneration by the licensee, on the basis of total sales of that chemical product taking into consideration its trade price [...]”.¹²⁸

Number and technological areas where compulsory licenses have been issued

60. With reference to the number of times and the technological areas in which compulsory licenses had been issued, most of the Member States (or territories) stated that they were not aware of such court decisions, had no data available or that no compulsory licenses have been granted in their territory.¹²⁹ The response from Japan stated that, “there were some cases where arbitration decisions were requested” but there had “been no cases where a non-exclusive license was granted by arbitration decision”. Few Member States reported that compulsory licenses had been very seldom used and in very few cases related to

¹¹⁹ In the decision of the United Kingdom Intellectual Property Office in *Montgomerie Reid’s Application* (BL O/145/83) in relation to the “reasonable remuneration” criterion, it was held that the royalty to be paid for a compulsory license under s.48 should be one which would be negotiated between a willing licensor and a willing licensee. See response from the United Kingdom to question 76 of the Questionnaire.

¹²⁰ See responses from Australia, Argentina, Bosnia and Herzegovina, Croatia, the Dominican Republic and Philippines.

¹²¹ In this connection, it was also noted by few Member States that the termination of the authorization may be refused if it is considered that the conditions which gave rise to that grant of the license were likely to recur. See, for example, Argentina and the Dominican Republic.

¹²² See, for example, El Salvador, Greece, Monaco, Sweden and Uganda.

¹²³ For example, in Mexico the Mexican Institute of Industrial Property; in Poland, the Patent Office sets the conditions of remuneration.

¹²⁴ For example, in Australia, it is the Federal Court; in China, it is a patent administration department under the State Council. See also responses from the Czech Republic, Hungary and New Zealand.

¹²⁵ See, for example, responses from Germany and Sweden to question 76 of the Questionnaire.

¹²⁶ See, for example, responses from Argentina and Portugal to question 76 of the Questionnaire.

¹²⁷ See, Section 21.08 of the Patent Act of Canada and Sections 72E and 72J of Patents Ordinance of Hong Kong (China).

¹²⁸ Rule 44(1) of Patent Rules 2003 of Pakistan.

¹²⁹ These Member States (or territories) include: Algeria, Argentina, Republic of Armenia, Australia, Belarus, Bhutan, Bolivia, Bosnia and Herzegovina, Canada, Chile, China and Hong Kong (China), Costa Rica, Croatia, Cyprus, the Czech Republic, the Dominican Republic, El Salvador, Finland, Gambia, Greece, Honduras, Jordan, Kenya, Kyrgyzstan, Mauritius and Oman .

pharmaceuticals.¹³⁰ The response from Germany reported that the Federal Patent Court had issued one compulsory license in the period from 1961 to 2004¹³¹ and that this compulsory license had been revoked by Federal Court of Justice.¹³² The response from India stated that “[u]nder the Patents Act, 1970, only one compulsory license has been granted for a patent related to an anti-cancer medicine; the said decision has been challenged before the Court”. One compulsory license had been granted in the mining industry in Poland, one compulsory license concerning plant protection products in Portugal and one compulsory license was granted in the field of mechanical engineering in Turkey.¹³³ The responses from Brazil, Zambia and Zimbabwe reported that each country had issued one compulsory license related to pharmaceutical products.

61. A non-exclusive license related to a method of manufacturing Bis-thio benzene had been granted in the Republic of Korea in 1980, since it had not been commercially worked for the previous three years without justifiable grounds. The response from Switzerland reported two cases where courts had granted compulsory licenses on dependent inventions with respect to a school desk that allowed the user to work while standing or sitting and could be adapted to any height and on a convertor which could transform alternating current into direct current.¹³⁴ The response from the United Kingdom stated that no compulsory licenses had been issued during the last 10 years, and that very few requests for compulsory licenses, estimated to be less than one per year on average since the Patents Act 1977 came into force, had been received.

Implementation Challenges

62. Most Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought and/or no amendments were foreseen.¹³⁵ Some Member States provided no answer on this question or stated that the question was not applicable. The response from France and Switzerland, noting that in those countries the recourse to compulsory license mechanisms was rare, stated that the relevant provisions “appear to be satisfactory” or “seems adequate”. The response from Mauritius and Sri Lanka noted that the relevant provisions were “not yet practically tested”.

63. In Uganda, amendments were envisaged through the Industrial Property Bill. In Chile, while the compulsory licensing provisions had been considered to meet the policy objective, the relevant provision was being revised. Similarly, in El Salvador and Qatar, the laws were planned to be revised. The response from Burkina Faso stated that “a revision process [was] currently underway that takes into account [...] various aspects in the revised Bangui Agreement”. In Canada, a Private Member’s Bill to reform sections 21.01 to 21.2 of the Patent Act was considered by the parliament. Two Member States expressed the need to amend their laws specifically in order to implement the Protocol Amending the TRIPS Agreement adopted by the WTO General Council in December 6, 2005.¹³⁶

¹³⁰ See, responses from Austria and New Zealand.

¹³¹ Federal Patent Court judgment of 7 June 1991, case no. 3 Li 1/90, published in BPatGE 32, 184.

¹³² The Federal Court of Justice judgment of 5 December 1995, case no. X ZR 26/92, published in BGHZ 131, 247 – Polyferon.

¹³³ The response from Turkey explained that that license was granted on the ground of failure to put to use/work the patented invention in accordance with Article 96 of the Turkish Patent Decree Law.

¹³⁴ Federal Tribunal of Switzerland, Case No. ATF 29 II 564 and ATF 42 II 269, respectively.

¹³⁵ Member States (or territories) that expressly stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought and/or no amendments was foreseen were: Algeria, Belarus, Bosnia and Herzegovina, China and Hong Kong (China), Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, the Dominican Republic, Honduras, Hungary, India, Japan, Kenya, Latvia, Madagascar, Malaysia, Mexico, Morocco, Netherlands, Norway, Pakistan, Peru, Poland, Portugal, Republic of Korea, the Russian Federation, Sao Tome and Principe, Spain, Sweden, the United Kingdom and the United States of America.

¹³⁶ These Member States are New Zealand and the Republic of Moldova. It is to be noted that in New Zealand, sections 171 to 174 of the Patent Act 2013 concerning compulsory licenses for export of pharmaceutical products are already in force.

64. The response from Zimbabwe stated that the legal framework for the issuance of compulsory license was not adequate because Zimbabwe has yet to ratify the Protocol Amending the TRIPS Agreement. Similarly, in Zambia, the applicable legal framework is not considered adequate, therefore the circumstances for issuance of compulsory license had been broadened in the amended Draft law to be enacted.

65. Most of the Member States noted that they did not encounter any challenges in relation to the use of compulsory licensing system provided in their respective laws or provided no comments.¹³⁷ The response from some Member States, with reference to challenges, stated that the compulsory licensing system had not been or had been little used.¹³⁸ The response from Chile stated that, in the absence of cases of issuance of compulsory licenses, no challenges had been experienced.

66. The response from South Africa noted the “considerable burden of proof on the applicant for compulsory licensing” and the response from Uganda referred to “lack of technological capacity”, as a challenge. The responses from the United Republic of Tanzania and Zambia stated that the challenge in their respective countries was that there was insufficient or no capacity on the part of local industries to produce generic pharmaceutical products when the compulsory licenses were issued.

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¹³⁷ Member States (or territories) that expressly stated that no challenges have been encountered in relation to the use of compulsory licensing system provided in their respective laws were: Bhutan, Bosnia and Herzegovina, China and Hong Kong (China), Costa Rica, Croatia, Cyprus, Denmark, Dominican Republic, El Salvador, Hungary, India, Latvia, Malaysia, Mauritius, Mexico and the United Kingdom.

¹³⁸ See the responses from Czech Republic, Canada, Honduras, Norway, Pakistan, Portugal, Sao Tome and Principe to question 80 of the Questionnaire.