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DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING COMPULSORY LICENSING

Document prepared by the Secretariat

INTRODUCTION

1. At its twenty-ninth session, held in Geneva from December 3 to 6, 2018, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would, *inter alia*, continue working on a draft reference document on exceptions and limitations to patent rights in conjunction with patent protection. In particular, the SCP agreed that the Secretariat would submit a draft reference document on the exception regarding compulsory licensing to the thirtieth session of the SCP. In addition, it was agreed that the Secretariat would invite Member States to send any additional inputs for the preparation of the draft reference document (see document SCP/29/7, paragraph 22, under "Exceptions and Limitations to Patent Rights").

2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through its Note C. 8828, dated January 7, 2019, to submit to the International Bureau any additional inputs for the preparation of the draft reference document on the exception regarding compulsory licensing.

3. Accordingly, Annex I to this document contains the said draft reference document for the Committee's discussions at its thirtieth session to be held in Geneva from June 24 to 27, 2019. As mandated by the Committee, in the preparation of the draft reference document, the Secretariat made use of information submitted by the Member States to the thirtieth session of the SCP, available on the website of the SCP electronic forum at: https://www.wipo.int/scp/en/meetings/session_30/comments_received.html, as well as other information collected though the SCP activities, as indicated in document SCP/27/3.

4. The reference document contains the following sections: (i) overview of the exception regarding the compulsory licensing; (ii) objectives and goals of the compulsory licensing; (iii) compulsory licensing and international legal framework; (iv) compulsory licensing

provisions in the regional instruments; (v) national implementation of the exception regarding compulsory licensing; (vi) challenges faced by Member States in implementing the exception regarding compulsory licensing; and (vii) results of implementation of the exception regarding compulsory licensing. In addition, it contains an Appendix, in which national and regional legal provisions on the compulsory licensing are compiled.

[Annex follows]

DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING COMPULSORY LICENSING

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APPENDIX

1. Compulsory Licensing - Overview of the Exception

5. In general, once granted, a patent confers on its owner, during the term of protection, the exclusive rights to prevent third parties from commercial exploitation (which includes making, using, offering for sale, selling or importing) of the patented invention without his/her authorization within the territory of the country/region where patent has effect. In addition, a patent owner has also the right to assign and conclude licensing contracts in respect of his/her invention. Such licenses that are granted by the patent owner are considered "voluntary" licenses.

6. Under certain circumstances and conditions, however, depending on a term used in a specific jurisdiction, a so-called "compulsory" or "non-voluntary" license may be granted by a competent national authority to a third party allowing the exploitation of the patented invention during the patent term without the authorization of the patentee. In particular, under a compulsory license authorization, a court or another competent authority grants a specific permission to a person or entity other than the right holder to produce, use, sell or import the patent-protected product, or use the patent-protected process, under specific circumstances.

7. This authorization may also be granted to a government agency or to a third party authorized to act on behalf of the government, in which case such authorization is referred to as "government use". While the beneficiaries of these two forms of licenses are different and such licenses may have operational distinctions, generally, the term "compulsory licensing" is often used to refer to both forms of authorization. Moreover, conditions to be respected in the grant of these both forms of licenses involve similar aspects.[1]

8. The provisions on compulsory licenses allowing the third parties and/or government, under certain circumstances and conditions, to use a patented invention without the authorization of the right holder are found in the national legislation of a large number of countries.[2] Though such provisions represent an exception to the rights of the patent owner, unlike other exceptions, the patent owners are entitled to a remuneration for use authorized under a compulsory license.

9. International treaties provide conditions to be respected for the grant of such licenses. In general, no international treaty restricts a freedom of countries to determine the grounds upon which compulsory licenses are granted under their respective national law. Therefore, a range of grounds have been set out in the national laws, reflecting the respective national policy. In general, provisions on compulsory licenses are considered as an instrument to safeguard public interest, prevent abuses of the patent rights, such as failure to work the patented invention, to ensure national security and to respond to national emergencies. While the use of compulsory licenses have been more frequent in relation to pharmaceutical patents, such licenses can also apply to patents in any field.

2. Objectives and Goals of the Compulsory Licensing

10. The policy objectives that specific compulsory licensing provisions pursue in the different laws may vary depending on the grounds available under the relevant laws. While such objectives can be generally categorized as provided in the following paragraphs, in many instances, they are interrelated.

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1 Yet, other terminology in relation to this exception may be used in some jurisdictions. For the purposes of this document, the term "compulsory licensing" is used to cover all other similar types of licenses.

2 See Appendix to this document.

Promoting the interest of the general public

11. In many countries, the public policy objective of the respective compulsory licensing provisions in the relevant laws is, *inter alia*, to safeguard the interest of the general public, including health, defense, and development of the economy. In this regard, the submission from Germany stated that the objective and goals of the compulsory license exception as provided in its law was to "protect the general public from the disadvantages of the monopoly position of a patent proprietor".[3] Similarly, describing the policy objectives, the response submitted by France to the Questionnaire on Exceptions and Limitations to Patent Rights stated that "the patentee's monopoly may be restricted by economic or social imperatives of general interest, which are considered more important".[4] In a similar manner, submissions from other countries describing the public policy objectives of the compulsory licensing provisions, as provided in the 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".[5]

12. In this regard, to explain the rational of exceptions which reflect countervailing individual and public interests, Professor Bently explains that:

> *"[Some] exceptions reflect the fact that incentivising innovation, while an important social goal, is sometime in conflict with other social goals or private interests, and the latter are regarded as of a higher rank or importance. The most obvious examples here are the exceptions and compulsory licence relating to national security and emergencies* [...] *for the purposes of "vital economic interest, public health, defence or the country's needs", subject to remuneration […]".*[6]

13. Similarly, in Norway, "the main objective is to meet important public interests. The patented invention should benefit the technical development and society. These objectives will not be met if the patentee represses the exploitation of the invention". The response from Pakistan stated that the objective of the compulsory license is "to curb monopolization and cartelization and to safeguard the national interest". In the United Kingdom, 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 […]". The response from Netherlands 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.[7]

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3 See the submission of Germany to the thirtieth session of the SCP referring to Hacker in: Busse/Keukenschrijver, 8th edition 2016, Sec. 24 marginal note 15; Rinken in: Schulte, *Patentgesetz*, 10th edition 2017, Sec. 24 marginal note 5, available at: https://www.wipo.int/scp/en/meetings/session_30/comments_received.html. The submission of Germany also notes that the exercise of the exclusive patent rights cannot in itself constitute an abuse of a dominant position.

4 The Questionnaire on Exceptions and Limitations to Patent Rights, carried out within the WIPO Standing Committee on the Law of Patents (SCP) (hereinafter referred to as "the Questionnaire"), available at: https://www.wipo.int/scp/en/exceptions/.

5 See, for example, responses to the Questionnaire 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.

6 Professor L. Bently et all. "Exclusions from Patentability and Exceptions and Limitations to Patentees Rights", SCP/15/3, p. 59, available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf.

7 See responses to the Questionnaire form these respective countries.

Box 1. Policy objectives of the exception regarding compulsory licensing in China and Mexico[8]
In China, the policy objectives of the exception are "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, in Mexico such objectives are: "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".

Balancing of interests

14. In addition to the above objectives, some counties' submissions underlined the balancing aspect of the exception. In particular, the relevant compulsory licensing provisions were aimed at striking a balance between the interests of patentees on the one hand and of third parties and/or public interest and/or society on the other hand. 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". 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 was to ensure that "a balance of rights is maintained by preventing anticompetitive behavior or other activities by patent holders that are not in the public interest".[9,10]

Preventing abuses of rights

15. Another public policy objective pursued in many jurisdictions in relation to the provisions on compulsory licenses is to prevent abuses which may result from the exercise of the exclusive rights conferred by the patent. For example, in relation to compulsory licenses granted on the grounds of non-working or insufficient working of a patent, 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".[11] 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.[12]

Box 2. Policy objectives of the exception in Portugal
"These compulsory licenses are provided to avoid abuse of the monopoly that is granted with a patent and obstacles to technological and economic development, but also to promote public health and guarantee national security".[13]

8 The responses to the Questionnaire from China and Mexico.
9 This policy objective was related in particular to sections 65 and 66, of the Patent Act of Canada.
10 In addition, the following Member States also noted, *inter alia*, the balancing aspect of the exception regarding compulsory licensing in describing its public policy objectives: Australia, Canada, India, Japan, Kyrgyzstan, Malaysia, the Russian Federation and the United States of America.
11 See a response of Hong Kong (China) to the Questionnaire.
12 See, for example, the responses to the Questionnaire from the Republic of Korea and Qatar, as well as a submission of Portugal to the thirtieth session of the SCP.
13 See the submission of Portugal to the thirtieth session of the SCP.

Specific public policy objectives on public health

16. Some Member States (or territories) responses also noted specific public policy objectives on public health. For example, as regards to the provisions on import and export compulsory licenses for patented pharmaceuticals, Hong Kong (China) referred to the specific policy objectives which were "to make use of the system under the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) (adopted by the General Council of the World Trade Organization (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 that the policy objective was "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."[14]

3. Compulsory licensing and International Legal Framework

17. Two international instruments, the Paris Convention for the Protection of Industrial Property, as well as the Agreement on Trade-Related Aspects of the Intellectual Property Rights (TRIPS Agreement) provide rules and conditions applicable to compulsory licenses.

3.1 Paris Convention for the Protection of Industrial Property

18. Article 5A of the Paris Convention provides certain rules concerning compulsory licenses in respect of patents and utility models. Specifically, Article 5A(2) of the Paris Convention recognizes the right of each country of the Union to take legislative measures providing for the grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. Member States are free to define the expressions "abuses which might result from the exercise of the exclusive rights conferred by the patent" or "failure to work".[15] Other examples of such abuses may be the refusal of granting a license on reasonable terms and conditions thereby hampering industrial development, or the failure to supply the national market with sufficient quantities of the patented product or demanding excessive prices for such product.[16]

19. Further, Article 5A(3) states that forfeiture of the patent shall not be provided for, except, in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. It further states that no proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

20. As regards compulsory licenses on the grounds of failure to work or insufficient working, Article 5A(4) provides that such licenses shall not be granted before the expiration of a period of four years from the filing date or three years from the date of the grant of the patent, whichever period expires last. Such period takes into account the time necessary for a patentee to organize the exploitation of the invention, either by himself or by a licensee. In contrast to paragraph (3), which concerns measures to prevent all abuses which might result from the exercise of the exclusive rights conferred by the patents, paragraph (4) applies only to compulsory licenses on the ground of failure to work or insufficient working.

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

15 Actes de la conférence réunie à Londres, 1934, p.174.

16 Actes de la conférence réunie à La Haye, 1925, p.434.

21. The competent authority of the country concerned shall refuse the compulsory license, if the patentee justifies his inactivity by legitimate reasons. Such reasons may be based on the existence of legal, economic or technical obstacles to exploitation of the patent in the country. The competent authorities of the country concerned have competence to decide on this question.[17]

22. The compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of sub-licenses, except with that part of the enterprise or goodwill which exploits the license. This requirement is intended to prevent the grantee of the compulsory license from obtaining a stronger position than it was warranted by the purpose of the compulsory license, namely, to provide a sufficient working of the patented invention.[18]

23. It should be noted that Article 5A does not deal with compulsory licenses other than those whose purpose is to prevent abuses of a patentee. In this regard, the "Guide to the Application of the Paris Convention for the Protection of Industrial Property" by G.H.C. Bodenhausen states that Member States are free to provide analogous or different measures under the applicable law, for example, compulsory licenses in other cases where the public interest is deemed to require such measures. It is further explained that this may be the case when patents concern vital interests of the country in the fields of military security or public health, or in case of "dependent patents". In such cases, the rules of paragraphs (3) and (4) of Article 5 do not apply.[19]

3.2 Agreement on Trade-Related Aspects of the Intellectual Property Rights

24. In accordance with Article 2.1 of the TRIPS Agreement, Members of the World Trade Organization (WTO) shall comply with Articles 1 through 12, and Article 19, of the Paris Convention, in respect of Parts II, III and IV of the Agreement. Accordingly, WTO Members have an obligation to comply, *inter alia*, with Articles 5A of the Paris Convention concerning compulsory licenses.

25. Further, Article 31 of the TRIPS Agreement provides that a Member may allow, under the stipulated conditions, other use than that allowed under Article 30 without authorization of the rights holder. Those other uses are typically compulsory licenses and government use without the authorization of the right holder. In addition, Article 31*bis* allows a special compulsory license permitting patented pharmaceutical products made under such license to be exported to countries lacking production capacity in the pharmaceutical sector.

26. According to Article 31, where the law of the Member allows for other use of the subject matter of patent without authorization of the right holder, the following conditions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other

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17 Actes de Bruxelles, pp. 316/7, 322/3, 325/6, 327/8.

18 G.H.C. Bodenhausen, "Guide to the Application of the Paris Convention for the Protection of Industrial Property", WIPO Publication No.611.

19 G.H.C. Bodenhausen, Ibid, p.70. However, it is to be noted that the Guide is not an official interpretation of the Paris Convention.

circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology, shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) the decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

WTO discussions leading to the amendment of the TRIPS Agreement

27. The Declaration on the TRIPS Agreement and Public Health,[20] adopted by the Fourth Session of the WTO Ministerial Conference at Doha on November 14, 2001, provides some guidance for the interpretation and application of Article 31 with respect to the grant of compulsory licenses and what constitutes a "national emergency or other circumstances of extreme urgency". The Declaration states that, in paragraph 4, the Members agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating the commitment to the TRIPS Agreement, the Members affirmed that the Agreement can and should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, the Members reaffirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

28. Paragraph 5 of the Declaration states that, in the light of paragraph 4, while maintaining the commitments under the TRIPS Agreement, Members recognize that these flexibilities include:

> "[…]
>
> (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;[21] and
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
> […]."[22]

29. Furthermore, in order to solve the problem of Members with insufficient or no manufacturing capacities in the pharmaceutical sector facing difficulties in making effective use of compulsory licensing, following up on paragraph 6 of the Declaration,[23] WTO Members decided, in 2003, on a "waiver" that removed limitations on exports under compulsory licenses to least-developed country Members and other Members that have insufficient or no manufacturing capacities in the pharmaceutical sector for the patented product in question. In particular, WTO Members waived the limitation in Article 31(f) of the TRIPS Agreement to predominantly supply the domestic market when generic medicines are produced under compulsory licenses. The special compulsory licensing system established by the decision allows exporting countries to grant compulsory licenses to generic suppliers exclusively for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.[24] It allows importing countries facing public health problems and lacking the manufacturing capacity to produce generic drugs to seek such medicines from third country producers under compulsory licensing arrangements.

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20 Declaration on the TRIPS Agreement and Public Health is available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

21 These clarifications dispelled a misconception that compulsory licences were only available in the situations of national emergency or other circumstances of extreme urgency.

22 These clarifications have practical relevance, because in such situations, the WTO Members may waive the requirement that a requester of a compulsory license shall first attempt to negotiate a voluntary license with the patent holder. See Article 31(b) of the TRIPS Agreement.

23 Paragraph 6 of the Declaration states "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

24 Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, available at: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

30. Following the Decision of the General Council of December 6, 2005, on the Amendment of the TRIPS Agreement,[25] an amendment to the TRIPS Agreement was formally built into the TRIPS Agreement on January 23, 2017, after acceptance of the Protocol amending the TRIPS Agreement by two thirds of the WTO membership. The amendment replaces the 2003 waiver for Members who have accepted the Protocol. Members to which the amended TRIPS Agreement applies may derogate from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products pursuant to Article 31*bis*, the Annex and the Appendix to the TRIPS Agreement.
For other Members that have yet to accept the Protocol, the waiver provisions established under the General Council decision of 30 August 2003 on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" continue to apply.[26]

4. Compulsory Licensing Provisions in the Regional Instruments

31. Several regional instruments contain provisions on compulsory licenses, laying down rules on such licenses at the regional level. These are: Decision № 486 Establishing the Common Industrial Property Regime for the Andean Community of September 14, 2000; Patent Regulation of the Cooperation Council for the Arab States of the Gulf; the Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), February 24, 1999); and at the European Union level - Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the legal protection of biotechnological inventions and Regulation (EC) No. 816/2006 of the European Parliament and of the Council of May 17, 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

32. In addition, Section 3(12) of the Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO) and Article 12 of the Eurasian Patent Convention (EAPO) provide the possibility of a grant of a compulsory license with respect to the patents issued by these respective Organizations, in accordance with the national law of the member country concerned.

Table 1. REGIONAL INSTRUMENTS	
Andean Community	- Chapter VII of Decision № 486 establishing the Common Industrial Property Regime for the Andean Community
Cooperation Council for the Arab States of the Gulf	- Articles 19 to 22 of the Patent Regulation of the Cooperation Council for the Arab States of the Gulf
African Intellectual Property Organization (OAPI)	- Articles 46 to 56 of Annex I of the Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), February 24, 1999)
European Union	- Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the legal protection of biotechnological inventions - Regulation (EC) No. 816/2006 of the European Parliament and of the Council of May 17, 2006, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

25 Decision of the General Council of December 6, 2005, on the Amendment of the TRIPS Agreement, available at: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

26 Members who are yet to accept the amendment currently have until 31 December 2019 to do so (document WT/L/1024).

33. Although grounds for the issuance of a compulsory license under these regional instruments differ, the general aspects concerning conditions for the grant of a compulsory license, its termination, remuneration and notification to the patentee generally reflect the requirements stipulated in the Paris Convention and the TRIPS Agreement. In addition, the competent authorities in charge of the grant of a compulsory license vary as does the procedural framework leading to the grant of a compulsory license.

4.1 Andean Community Decision № 486

34. Chapter VII of Decision № 486 establishing the Common Industrial Property Regime for the Andean Community provides rules regarding the compulsory licenses applicable to the Members States of the Andean Community comprising Bolivia, Colombia, Ecuador and Peru.

35. According to Article 61 of Chapter VII, at the request of any party, a compulsory license may be granted by the competent national office for the manufacture of the patented product or the use of the patented process where, at the time of the request, the patent "has not been worked" within the meaning of Articles 59 and 60,[27] or the working of the invention has been suspended for more than a year.[28]

36. As regards the "legitimate reasons" which would justify the inaction by the patentee and result in the refusal of the grant of the compulsory license, the Decision № 486 clarifies that this could be "reasons of force majeure" in accordance with the domestic provisions of each Member country.[29]

37. In addition, a compulsory license may be granted upon a declaration by a member country of the existence of "public interest, emergency or national security considerations".[30] Furthermore, a competent national office shall, either *ex officio* or at the request of a party, and after having obtained the consent of the national authority on free competition, grant compulsory licenses where practices that adversely affect free competition, especially an abuse by the owner of the patent of his dominant position on the market are noted.[31] In addition, Decision № 486 allows the grant of the compulsory license in case of dependent patents.[32]

38. The competent national office shall determine the scope or extent of the license, and in particular shall specify the period for which it is granted, its subject matter, the amount of the royalties and the conditions for the payment thereof. The said royalties shall be adequate, depending on the particular circumstances of each case, due regard being made especially to the economic value of the authorization.[33]

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27 Articles 59 and 60 state, respectively - "The owner of the patent shall be under the obligation to exploit the patented invention in any member country, either directly or through a person authorized by him." - "For the purposes of this Chapter, exploitation shall be understood to mean the industrial manufacture of the patented product or the full use of the patented process, including the distribution and marketing of the results thereof, in a manner sufficient to meet the needs of the market. Exploitation shall also be understood to mean the import of the patented product, including distribution and marketing, where it is done on a scale sufficient to meet the needs of the market. Where the patent relates to a process that does not result in a product, the requirements of marketing and distribution shall not be enforceable."

28 Article 61 of Chapter VII of the Decision No. 486 Establishing the Common Industrial Property Regime.

29 Ibid.

30 Ibid, Article 65.

31 Ibid, Article 66.

32 Ibid, Article 67.

33 Ibid, Article 62.

39. While no interpretation of Chapter VII of the Andean Community Decision № 486 has been issued to date by the Court of Justice of the Andean Community, on August 5, 2015, the General Secretariat of the Andean Community issued a Clarification on the Opinion No. 006-2015, in response to a request made by the Ecuadorian government. [34] It made a reference to the public interest ground required to issue a compulsory license, as follows:

> "[T]he Andean Community rules on compulsory licensing do not delimit the grounds of public interest which can justify the granting of such licenses. However, with respect to the relationship between industrial property rights and the right to health, experts in these areas have pointed out that the right to moral and economic protection resulting from scientific research constitutes a human right subjected to limitations of public interest.[2] Such limitations, only regulated as provided in Article 68 of Decision 486, do not cease to be difficult to define nor ensure certainty in the scope.
>
> The General Secretariat, in the light of the various existing positions worldwide on these dilemma, recognizes that the right to health includes a series of minimum and interrelated elements such as availability, accessibility, acceptability and quality (both goods/services as well as health programs)."[35] (Non-official translation).

40. Furthermore, the General Secretariat appears to note in the following paragraph the need to provide a balance between the issuance of compulsory license and protection of public health:

> "[The elements referred to above] would serve to delimit in a theoretical manner the reasons of public order that allow a Member State to grant a compulsory license in respect of a patent on a specific medicament". "[It is] essential to carry out a constant verification and analysis of such elements in order to obtain an adequate balance between the unauthorized use of industrial property rights and the adequate protection of public health."[36] (Non-official translation).

41. In general, the Andean Community Decisions have a direct application as the domestic IP legislation of the Member States. However, in order to give operability to the Andean Community legislation, member countries are entitled to adopt implementing rules at the national level.

Implementation of Chapter VII of the Andean Community Decisions № 486

Bolivia

42. In Bolivia, the Administrative Resolution No. 017/2015 of June 16, 2015, establishing the internal procedure on industrial property of the National Service of Intellectual Property (SENAPI), includes provisions regarding compulsory licensing. In particular, Article 168 of the Resolution states that in order to grant a compulsory license for reasons of public interest, emergency or national security, the declaration should be accredited by the Plurinational State of Bolivia.

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34 The background of the case: On February 6, 2015, Sugen Inc. filed a non-compliance claim against the Republic of Ecuador before the General Secretariat due to the issuance of a compulsory license on a patent owned by Sugen Inc. On May 29, 2015, the General Secretariat issued Opinion No. 006-2015 in which it emphasized that the compulsory license under question was still being disputed in the Ecuadorian Institute of Intellectual Property (IEPI) due to the administrative appeal brought by Sugen Inc. against such measure. Thereby, the General Secretariat stated that as the referred appeal was pending, it did not make any comment about the state of compliance of the Community obligations by Ecuador. On August 5, 2015, the General Secretariat issued a Clarification on the Opinion No. 006-2015 in response to a request made by the Ecuadorian government where it stated again that it would be counterproductive to make a statement in relation to the substance of the question being discussed, that is, compliance by the government of Ecuador with Decision 486, until a decision in respect of the appeal be issued. Therefore, Ecuador was urged to solve the pending appeal so that the position of the administrative organ was known.

35 *Sugen Inc v Ecuador* 011-FP-2015 (Clarification on the Opinion No. 006-2015, August 5, 2015).

36 Clarification on the Opinion No. 006-2015, August 5, 2015, p. 4.

Colombia

43. In Colombia, the Andean Community Decision № 486 is regulated through the Decree No. 1074 enacted on May 26, 2015 by the Ministry of Commerce, Industry and Tourism,[37] which establishes the procedure for the declaration of the existence of reasons of public interest. As provided in Article 2.2.2.24.3. of the Decree No. 1074, in order to seek the granting of a compulsory license on the basis of public interest, any interested person may apply for the declaration of this situation before the respective competent authority which shall proceed in accordance with the provisions of Chapter 24.[38] In particular, the competent authority, through a reasoned act, will decide to go forward or not with the administrative action and will communicate that order to the person concerned. [39]

44. Article 2.2.2.24.6 of the Decree provides that the respective Ministry or Administrative Department shall have a Technical Committee, which, after the corresponding evaluation, will recommend to the respective Minister or Director of Administrative Department to take the decision as regards the declaration of the existence of public interest.[40] Further, Article 2.2.2.24.5. provides some specific aspects that the declaration on the existence of public interest has to include. In particular, the provision states:

> "The resolution issued by the corresponding Ministry or Administrative Department which declares the existence of reasons of public interest that merit the issuance of compulsory licence(s) must identify the situation affecting the public interest; establish the circumstances that led to such declaration and the reasons why the patent must be licensed; in addition, indicate the measures or mechanisms necessary to be taken to prevent such affectation."[41] (Non-official translation).

45. Article 2.2.2.24. of the Decree further establishes that, following the publication of the corresponding declaration on the existence of public interest in the Official Gazette, the Superintendency of Industry and Commerce should go forward with the procedure for reviewing the issuance of compulsory license in accordance with the established procedure.

46. On July 16, 2008, the application for the issuance of a compulsory license on the grounds of public interest was filed by Mesa de Organizaciones con Trabajo en VIH/SIDA, Recolvih, Fundación Ifarma, Acción Esencial para la Salud AIS and Fundación Misión Social, seeking the declaration of the public interest over the combination lopinavir and ritonavir. [42] On May 8, 2009, the Ministry of Social Protection issued Resolution 1444, by which the application was declared inadmissible, because there were no reasons to declare that the access to the invention was of public interest. This decision followed the recommendation made by the Technical Committee, which concluded that there was no problem of access to that antiretroviral because such a medicine was included in the Mandatory Health Plan, which implied that, although high, the cost of the product was borne by the Colombian government's subsidized health insurance scheme and not by the consumers.

47. On November 24, 2014, the IFARMA Foundation petitioned the Ministry of Health to issue a declaration of public interest as a step toward granting a compulsory license for imatinib.[43,44] The request was based mainly on the high price of the pharmaceutical product and the budgetary constraints of the

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37 Decree No. 1074, available at: https://wipolex.wipo.int/en/text/489342

38 Decree No. 1074, art 2.2.2.24.3.

39 Ibid. art 2.2.2.24.4.(2).

40 Ibid, Article 2.2.2.24.6.

41 The provision further states "The aspects related to the specific scope of the compulsory license (s) that will be granted will be specified by the Superintendence of Industry and Commerce based on the provisions of the aforementioned resolution, within the procedure referred to in Article 2.2.2.24.7. of this Decree".

42 The combination was protected by the Colombian patent No. 28.401 in force until December 12, 2016.

43 Imatinib mesylate (polymorphic form β) protected by the Colombian patent No. 29270. Imatinib is a small molecule cancer drug that is used to treat leukemia.

44 The petition is available at: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/Solicitud-de-una-declaracion-en-el-acceso-al-medicamento-IMATINIB.pdf.

Colombian government. After analyzing all the information pertaining to the procedure, the Ministry of Health issued Decision No. 2475 of June 14, 2016, declaring the existence of reasons of public interest for imatinib and requesting, in the alternative, that the National Commission for Pricing of Medicines and Medical Devices (CNPMDM) consider including the product into the direct price control scheme.[45]

48. Decision No. 2475 was appealed by both the petitioners and the patent holder, however was upheld on appeal.[46] Consequently, the CNPMDM presented its general methodology applicable to medicines that are declared to be of public interest in exceptional cases (Circular No. 03 of 2016). [47]

49. Due to the opposing views between various governmental agencies over the reasons of public interest, it was decided not to grant the compulsory license on this product in Colombia. However, the CNPMDM issued a Circular no. 4 of 2016, whereby the price of the product was fixed at 206.42 per milligram, thus allowing for 43.9% price reduction compared to the previously authorized price.

Ecuador

50. As regards Ecuador, Section VII of the Intellectual Property Law[48] regulates the regime of compulsory licensing. According to Article 154 of the Intellectual Property Law:

> "Following a declaration by the President of the Republic as to the existence of reasons of public interest of emergency or national security and, only for as long as these reasons subsist, the State may subject a patent to compulsory licensing at any time and in such a case, the National Directorate of Industrial Property may grant licences for which applications are filed, without prejudice to the rights of the patent owner to be remunerated in accordance to this Section. The patent owner will be notified prior to the granting of the licence, so that he may assert his rights."[49] (Non-official translation).

51. Further, Executive Decree No. 118 on Declaration of Public Interest Regarding Access to Medicines for Human Use, enacted on October 23, 2009, by the Constitutional President of the Republic of Ecuador declared that "access to medicines used for the treatment of diseases which affect the Ecuadorian population and which constitute a priority in terms of public health" was a matter of public interest, and that compulsory licenses may be granted for "patents for medicines for use on human beings which are necessary for their treatment"."[50, 51]

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45 See submission of Colombia in document SCP/27/6.

46 Decisions Nos. 4008 and 4148 of 2016.

47 See submission of Colombia in document SCP/27/6. At the time of the submission, this Circular is the object of a request for nullity and restoration of rights before the Council of State which is still pending consideration.

48 Intellectual Property Law of Ecuador (consolidated version of February 10, 2014), available at: https://wipolex.wipo.int/en/text/444010.

49 The provision further states: "The decision of granting the compulsory license shall establish the scope or extension of the same, specifying in particular the period for which it is granted, the object of the license and the amount and conditions of payment of royalties, without prejudice to the provisions in article 156 of this Law.
The granting of a compulsory license for reasons of public interest does not impair the right of the patent owner to continue to exploit it." Intellectual Property Law of Ecuador (consolidated version of February 10, 2014), Article 154.

50 Article 1 of the Decree further clarifies that cosmetic and aesthetic medicines and bathroom products and, in general, those medicines that are not used to treat diseases, shall not be deemed to be a public health priority. The Executive Decree No. 118 on Declaration of Public Interest Regarding Access to Medicines for Human Use is available at: https://wipolex.wipo.int/en/text/281152.

51 The Decree establishes that the Ecuadorian Institute of Intellectual Property (IEPI), through the National Directorate of Industrial Property, is the competent national office for granting compulsory licenses to applicants, on the condition that they meet the requirements laid out in the relevant legislation and in the Decree, and that the authorization of compulsory licenses shall be considered depending on the specific circumstances of each case. Ibid, Article 2.

52. In addition, Article 8 of Resolution No. 10-04 P-IEPI of January 15, 2010, provided guidelines for issuing compulsory licenses on pharmaceutical patents. It provides that once the documentation is examined and the patent holder is notified, the Ecuadorean Institute of Intellectual Property (IEPI), through the National Office of Intellectual Property (Dirección Nacional de Propiedad Industrial, DNPI), will request the Ministry of Public Health to indicate whether the object of the request is a medicine that is used for humans for the treatment of diseases that affect the Ecuadorean population and such treatment is a priority for public health.

53. On April 24, 2010, the government of Ecuador granted its first compulsory license for ritonavir, an antiretroviral drug.[52] In order to grant this license, the Ministry of Health of Ecuador gave a technical opinion to the EIPI, by which it was asserted that ritonavir was an active substance which was used alone or in combination for the manufacture of drugs used in the treatment scheme of people living with HIV/AIDS, thus being a priority for public health."[53] On November 12, 2012, another compulsory license was issued by the IEPI for the combination of the antiretrovirals lamivudine and abacavir[54] after confirmation by the Ministry of Health that this was a priority medicine. Furthermore, it was reported that in Ecuador several other compulsory licenses were issued between 2013 and 2014.[55]

Peru

In Peru, Article 40 of the Legislative Decree 1075[56] amended by Law No. 29316,[57] incorporates a provision regarding the compulsory licensing regime, which reads:

> "Following a declaration, by the Supreme Decree, of the existence of reasons of public interest, emergency or national security; that is, national emergency or other circumstances of extreme urgency or in cases of public non-commercial use; and only for as long as those reasons subsist, the patent may be subjected to compulsory licensing at any time. In such a case, the licenses will be granted upon request. The holder of the patent subjected to the compulsory license will be notified when it is reasonable possible."[58] (Non-official translation).

54. According to the wording of this provision, the existence of "reasons of public interest, emergency or national security" is linked to "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".

55. While no compulsory license has been granted by the competent national authority in Peru to date on any of the grounds specified in the above legislation, the proposal to issue a compulsory license for an atazanavir[59] is currently considered by the Peruvian Congress, after being declared by the Congressional Health Commission in 2017 as a drug of public interest.[60]

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52 The compulsory license on the patent No. PI-97-1142 for "Retroviral protease inhibitor compounds, a process for repair and pharmaceutical compositions which include them" was granted through Resolution No. 1-DNPI-IEPI.

53 Resolution No. 1-DNPI-IEPI, available at: https://www.citizen.org/sites/default/files/access_attachment_3_0.pdf.

54 Source: https://www.keionline.org/22041.

55 See, e.g., Diego Sanabria "Compulsory licensing in Peru regarding right to health: Defining public interest in light of the Andean Community legal framework", MIPLC Class 2015.

56 Decreto Legislativo N° 1075 que aprueba Disposiciones Complementarias a la Decisión N° 486 de la Comisión de la Comunidad Andina que establece el Régimen Común sobre Propiedad Industrial (2006).

57 Law No. 29316 on the Amendment, Incorporation, and Implementation of the Miscellaneous Provisions on the Implementation of the Trade Promotion Agreement signed between Peru and United States, adopted January 13, 2009.

58 The provision further states: "The competent national leadership shall specify the scope or extent of the compulsory license, specifying in particular the period for which the object of the license, the amount and terms of financial compensation is granted. The grant of a compulsory license does not prejudice the right of the patent owner to continue exploiting it. Any decision on such license shall be subject to judicial review.".

59 Atazanavir is in antiretroviral medication used to treat HIV/AIDS.

60 The Declaration by the Congressional Health Commission is available at: http://www.leyes.congreso.gob.pe/Documentos/2016_2021/Dictamenes/Proyectos_de_Ley/00275DC21MAY20170607.pdf. See also: http://aisperu.org.pe/documentos/17-nota-de-prensa-declaran-atazanavir-de-interes-publico-ingles/file.

4.2 Patent Regulation of the Cooperation Council for the Arab States of the Gulf

56. Articles 19 to 22 of the Patent Regulation of the Cooperation Council for the Arab States of the Gulf regulate the grant of compulsory licenses in relation to patents issued by the Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office).[61] The grounds for the grant of a compulsory license are stipulated in Articles 19 to 21 of the Patent Regulation. According to Article 19, the Board of Directors may grant a compulsory license if the owner has never exploited or insufficiently exploited the patented invention within the meaning of Article 13 of the Patent Regulation.[62] Furthermore, according to Article 20/2, "state of emergency", "a dire public necessity", or "non-commercial use" also constitute grounds for the request for a compulsory license.

57. In addition, Article 20/3 of the Patent Regulation permits a government agency in a Council Member State to requests a compulsory license to exploit a patented invention, based on the public interest. In such a case, the Board of Directors may approve the grant of the license according to the terms of Article 19, with observation of clauses stipulated in Articles 20/1 and 2 of the Patent Regulation.

58. Article 21 of the Patent Regulation deals with the grant of a compulsory license in case of dependent patents. In particular, the provision states that should the exploitation of an invention is of a "significant technical advance and a considerable economic importance" which require use of another invention, the Board of Directors may grant one or both parties a compulsory license to exploit the other invention, unless they mutually agree on exploitation in an amicable manner.[63]

59. As regards the termination of the compulsory license, Article 22 of the Patent Regulation states such a license shall be cancelled in the following cases:

- If the beneficiary of the license fails to exploit it sufficiently in the Cooperation Council States within two years from the date of the grant of the license, renewable for another two years should the delay be found to be due to a legitimate reason;

- if the beneficiary of the compulsory license fails to pay the due amounts and the amounts stipulated in the Bylaws within three months from the date of maturity;

- if the beneficiary of the compulsory license fails to satisfy any other term that is stipulated in the decision granting the license; and

- if the circumstances due to which the license was granted end, and are unlikely to reoccur, provided the legitimate rights of the licensee are observed.

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61 The Cooperation Council for the Arab States of the Gulf comprises the State of the United Arab Emirates, the State of Bahrain, the Kingdom of Saudi Arabia, the Sultanate of Oman, the State of Qatar, and the State of Kuwait. The GCC Patent Office offers a unified patent granting system which provides patent protection in all six Member States.

62 Article 13 of the Patent Regulation states: "The Patent owner shall make sufficient exploitation of the patented invention in the Member States within three years from the date of grant. Should the prescribed grace period expire without sufficient exploitation, the provisions of Article (19) shall apply."

63 In such case, provisions of articles 19, and 20 of the Patent Regulation shall be observed.

4.3 Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), February 24, 1999)

60. The Agreement Revising the Bangui Agreement (Bangui Agreement) constitutes a uniform industrial property legislation for all the Member States of OAPI.[64] Patent matters are dealt with in Annex I of the Bangui Agreement. Articles 46 to 56 of Annex I of the Bangui Agreement[65] concerns "non-voluntary licenses". According to Article 46, at the request of any person made after the expiry of a period of four years from the filing date of the patent application or three years from the date of grant of the patent, whichever period expires last, a non-voluntary license may be granted where one or more of the following conditions are fulfilled:

- the patented invention is not being worked on the territory of a member State at the time the request is made;

- the working of the patented invention on such territory does not meet the demand for the protected product on reasonable terms;

- 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.

61. However, such a non-voluntary license may not be granted if the owner of the patent provides legitimate reasons for the non-working of the invention.[66]

62. Further, Article 47 of the Bangui Agreement regulates the grant of a non-voluntary license for a dependent patent. The conditions to be respected in case of dependent patents reflects Article 31(L) of the TRIPS Agreement, described above.

63. In addition, Article 56 provides for the possibility of *Ex-officio* licenses where certain patents are of "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 satisfaction of the country's needs". Such *Ex-officio* licenses shall be subject to the same conditions as the non-voluntary licenses granted under Article 46.[67]

64. Articles 48 of the Bangui Agreement clarifies the procedural aspects of the request for the grant of a non-voluntary license. The request for the grant of a non-voluntary license shall be made to the civil court of the domicile of the patentee or, if the latter is domiciled abroad, to the civil court of either his elected domicile or the place in which he has named an agent for the purposes of filing.[68] The request for a grant of a non-voluntary license shall contain, *inter alia*, evidence that the working of the patented invention on the territory of a Member State does not meet demand for the protected product on

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64 Article 4 of the Bangui Agreement states "(1) The Annexes to this Agreement contain, respectively, the provisions to be applied in each member State concerning – patents (Annex I) […] The Agreement and its Annexes shall be applicable in their entirety to every State that ratifies or accedes to the said Agreement."

65 https://www.wipo.int/edocs/lexdocs/treaties/en/oa002/trt_oa002_2.pdf

66 Article 46(2) of the Bangui Agreement.

67 Article 56(3) of the Bangui Agreement.

68 Only requests made by persons domiciled on the territory of a Member State shall be considered. The owner of the patent or his agent shall be informed thereof without delay. Article 48(1) of the Bangui Agreement.

reasonable terms,[69] and a statement by the requester in which he undertakes to work the patented invention on the territory of one of the Member States in such a way as to meet the needs of the market.[70]

65. The civil court examines and takes a decision on the request for a grant of such non-voluntary license. If the non-voluntary license is granted, the decision of the civil court shall specify the scope of the license and the amount of the remuneration to be paid by the licensee to the owner of the patent which, in the absence of agreement between the parties, shall be equitable, due regard being given to all the circumstances of the case.[71]

4.5 European Union

66. A legal basis for granting compulsory licenses in the European Union is Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions (EU Biotech Directive),[72] and Regulation (EC) No. 816/2006 of the European Parliament and of the Council of May 17, 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

EU Biotech Directive

67. Directive 98/44/EC provides for the possibility to obtain a non-exclusive compulsory license in cases where a plant variety right cannot be exploited without infringing a prior patent, or a holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right. Article 12 of the EU Biotech Directive states in that regard:

> "1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.
>
> 2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention."

68. In order to obtain such a license, applicants referred above, i.e. a breeder or a patent holder, must demonstrate that:

> (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

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69 Article 48(1)(c) of the Bangui Agreement.
70 Article 48(1)(d) of the Bangui Agreement.
71 Article 49(1), (3) and (4) of the Bangui Agreement.
72 Directive 98/44/EC is available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044.

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.[73, 74]

69. In order to give force to the EU Directives, the EU Member States have to transpose them into their national law. The legislation of many European countries have included provisions implementing Article 12 of the EU Biotech Directive, although the exact wording differs.[75]

Regulation (EC) No. 816/2006

70. The Regulation aims to implement the system set up by the WTO Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of August 30, 2003.[76] It establishes a harmonized procedure for the grant of compulsory licenses in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems. Since the Regulation is a binding legislative act, it must be applied in its entirety across the EU.[77]

71. In addition to the above two legal instruments, the European Parliament adopted a resolution on March 2, 2017, on EU options for improving access to medicines, which includes the use of compulsory licensing by EU Member States.[78] In particular, paragraph 51 of the resolution notes the fact that the TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have effectively brought prices down, and that these flexibilities can be used as an effective tool in exceptional circumstances established by the law of each WTO member to address public health problems, in order to be able to provide essential medicines at affordable prices under domestic public health programs and to protect and promote public health.

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73 Article 12(3) of the EU Biotech Directive.

74 Further, Article 12(4) states that each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply. Regulation (EC) No 2100/94 was amended by Council Regulation (EC) No. 873/2004 of April 2004. Paragraph 5a of Article 29 of Regulation (EC) No 873/2004 states that: 5a. "On application, a compulsory licence for the non-exclusive use of a protected plant variety pursuant to Article 12(2) of Directive 98/44/EC shall be granted to the holder of a patent for a biotechnological invention, subject to payment of an appropriate royalty as equitable remuneration, provided that the patent holder demonstrates that:(i) he/she has applied unsuccessfully to the holder of the plant variety right to obtain a contractual licence; and (ii) the invention constitutes significant technical progress of considerable economic interest compared with the protected plant variety. Where, in order to enable him/her to acquire or exploit his/her plant variety right, a holder has been granted a compulsory licence in accordance with Article 12(1) of Directive 98/44/EC for the non-exclusive use of a patented invention, a non-exclusive cross-licence on reasonable terms to exploit the variety shall be granted, on application, to the holder of the patent for that invention, The territorial scope of the licence or cross-licence referred to in this paragraph shall be limited to the part or parts of the Community covered by the patent." Regulation (EC) No 873/2004 is available at: http://extwprlegs1.fao.org/docs/pdf/eur43018.pdf.

75 For example, see the relevant provisions of laws of the following countries: Austria, Belgium, Czech Republic, Croatia, Latvia, Lithuania, Netherlands, Norway and the Republic of Moldova.

76 Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health is available at available at: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. See Chapter on the TRIPS Agreement above.

77 Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems is available at: https://www.wipo.int/edocs/lexdocs/laws/en/eu/eu050en.pdf.

78 European Parliament resolution of March 2, 2017, on EU options for improving access to medicines (2016/2057(INI)), available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0061+0+DOC+XML+V0//EN.

5. National Implementation of the Exception Regarding Compulsory Licensing

5.1 Legal framework regulating the exception regarding compulsory licensing

72. In total, 156 countries/territories have been identified to provide for the exception regarding compulsory licensing under their respective legal frameworks. In most of those countries, there is a specific statutory provision on this exception within respective IP or patent legislation. In some other countries, the national law may not provide a specific provision on this exception; however, the provisions on compulsory licenses are applied to those countries through the membership in a regional agreement. For example, the provision on non-voluntary licenses in the Bangui Agreement is applicable in all Member States of OAPI. In some countries, the granting of a compulsory license in order to remedy an anti-competitive practice engaged in by the patentee is prescribed in the patent law and/or in the competition (antitrust) law. In the United States of America, in addition to 28 USC § 1498 (a), legislative provisions on compulsory licenses can be found in the Clean Air Act, and under the rules of the Nuclear Regulatory Commission. Appendix to this document contains provisions of national and regional laws on the compulsory licensing.

Table 2. List of countries/territories which provide for exception regarding compulsory licensing
Albania, Algeria, Andorra, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin*[79], Bhutan, Plurinational State of Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso*, Burundi, Cabo Verde, Cambodia, Cameroon*, Canada, the Central African Republic*, Chad*, Chile, China, Hong Kong (China), Colombia, Comoros*, Congo,* Costa Rica, Côte d'Ivoire,* Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea*, Estonia, Eswatini, Ethiopia, Finland, France, Gabon*, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea*, Guinea-Bissau*, Honduras, Hungary, Iceland, India, Indonesia, Iran, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kyrgyz Republic, Lao People's Democratic Republic, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Madagascar, Malaysia, Mali,* Malta, Mauritania,* Mauritius, Mexico, Monaco, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Netherlands, New Zealand, Nicaragua, Niger,* Nigeria, North Macedonia, Norway, Oman, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saint Lucia, Sao Tome and Principe, Saudi Arabia, Senegal,* Serbia, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, Togo*, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Uganda, Ukraine, United Arab Emirates, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Uzbekistan, Viet Nam, Zambia, and Zimbabwe (total: 156).

5.2 Scope of the compulsory licensing exception

73. While the national provisions on compulsory licensing differ among various jurisdictions as regards the specific details and procedural aspects, in general, there are a number of common elements or requirements among compulsory license provisions in national laws, reflecting Article 5A of the Paris

[79] "*" The Bangui Agreement provisions on, *inter alia*, non-voluntary licenses are applicable in Member States of the African Intellectual Property Organization (OAPI).

Convention and Articles 31 and 31*bis* of the TRIPS Agreement. Specifically, conditions described in paragraph 22, above, are commonly found in many national laws.

74. The following sections of the paper provide detailed information on how those elements are set out in the national laws.

(a) Nature of the license, its duration and the general licensing terms

75. The laws of many countries state that the grant of compulsory licenses shall be considered on "its individual merits", or "each application for a license shall be decided separately for its specific conditions and circumstances" or "after considering the merits of each individual case", or "such a use shall be based on individual peculiarities of the patent".[80]

76. Furthermore, the provisions on compulsory licensing found in the laws of many countries stipulate the condition that: (i) the scope of compulsory licenses must be proportional. i.e. limited to the purpose for which it was granted; and (ii) the compulsory license shall be non-exclusive and non-assignable – in the latter case, except with the part of the enterprise or goodwill in respect of which the license was granted.

77. As regards to the duration of the compulsory license, the national laws provide that such a license shall be terminated if, after hearing the parties, it is found that the circumstances which led to it ceased to exist and are unlikely to recur, subject to adequate protection of the legitimate interests of the authorised user. In general, the competent authority (typically, either the authority that granted the licence or judicial authorities) have the authority to review the existence of the circumstances that led to the grant of the license. In many countries, such a review process can be requested by the patentee. However, in some countries, such a request can also be made by "any interested party"[81] or "either party"[82] or "any person"[83]. Some countries' laws also state that the compulsory licenses may be revoked by the competent authority upon the agreement between the patentee and licensee.[84]

78. Some laws also state that the compulsory license can be terminated if the licensee has failed to comply with the terms of the decision.[85] In addition, some laws state that such a license can be revoked by the competent authority if the licensee did not undertake the necessary preparatory work or worked the invention during a specific period of time after the grant of such license.[86]

79. Furthermore, the laws also state that, except in cases where a compulsory licence is granted to remedy an anti-competitive practice, the compulsory license shall be used to ensure predominantly the supply of the patented product in the domestic market. In this regard, some laws provide the possibility to grant compulsory licenses in favor of generic suppliers, exclusively for the purpose of manufacturing and exporting pharmaceutical products to countries lacking production capacities in the pharmaceutical sector.[87]

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80 See, e.g. the provisions of laws of Cyprus, Iraq, Montenegro, Pakistan, Serbia and Tajikistan.

81 See, e.g., Bosnia and Herzegovina, Brunei Darussalam, Djibouti and India.

82 Australia

83 Ireland.

84 Australia, Costa Rica

85 Antigua and Barbuda, Barbados, Bhutan, Cambodia, Luxemburg and Malaysia.

86 See, e.g, Armenia and Luxemburg. In Armenia, the law specifies that the compulsory license is recognized as expired if the licensee did not undertake the necessary preparatory work to use the invention during a one-year period after the grant of such license. Article 69(3) of the Law of the Republic of Armenia.

87 E.g, Albania, Australia, Canada, Croatia, India, Jordan, Kazakhstan, New Zealand, Norway and Oman. See https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

(b) Prior efforts to obtain authorization on reasonable terms and conditions and within a reasonable period of time

80. Reflecting Article 31(b) of the TRIPS Agreement, one of the conditions stipulated in the national legislations for the grant of a compulsory license is that the party requesting such a license has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

81. The definition of the terms "reasonable terms" and "reasonable period of time", according to many laws, would be decided, in general, "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".[88]

82. In China, what constitutes reasonable terms 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". In the Dominican Republic reference is made 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". In Israel, as regards to the interpretation of the above terms, the reference is made to Section 119(2) of IPL which states that "the conditions attached by the patent holder to the supply of the product or to the grant of a license for its production or use 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". [89]

83. With regard to the reasonable time period to obtain a voluntary license, in few countries the reference is made to a 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"[90], whereas the law in Slovakia provided that a period of "three months from the request for the license" was a reasonable period.[91] 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.

84. In the Dominican Republic, the compulsory license can be issued if efforts to obtain a voluntary license have not been effective "after a period of two hundred and ten (210) days, counted from the date on which the respective license was applied for". 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.

85. In Germany, the requirement that the license seeker has unsuccessfully attempted within a reasonable period of time to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms does not necessarily have to be met by the date on which the action for a compulsory license is brought; under the general principles, it suffices if it is met at the close of the oral hearing.[92] However, from the requirement that the attempt must have extended over a reasonable period of time, it follows that it is not sufficient when the license seeker declares his willingness to pay an

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88 See, for example, the responses to the Questionnaire from Canada, the Dominican Republic, Hong Kong (China), Hungary, Kenya and Tajikistan to question 73 of the Questionnaire. See also a submission of Germany to the thirtieth session of the SCP.

89 See responses from these countries to the Questionnaire.

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

91 Article 27(1)(b) of the Patent Act of Slovakia.

92 BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR (journal of the German Association for the Protection of Intellectual Property) 2017, 1017 – *Raltegravir.*

appropriate license "at the last minute", as it were during the proceedings. Rather, he must have attempted over a certain period of time, in a manner appropriate to the specific situation, to reach agreement with the proprietor of the patent on a voluntary license.[93]

(c) Remuneration of the right holder

86. As provided by Article 31(h) of the TRIPS Agreement, one of the conditions to be respected for the grant of a compulsory license is that the patent owner shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.

87. In general, the national laws state that "reasonable", "adequate", or "equitable" remuneration or compensation shall be paid to the patentee, the amount of which shall be determined, taking into account "the merits of each individual case" or "the circumstances of each case"[94], and "the economic value of the authorization"[95] or "the economic value of the license".[96,97]

88. In general, the conditions of remuneration are determined by the court[98] or another competent body.[99] The court or another competent body would set the amount of remuneration, based on factors as provided in their applicable law, if parties would fail to agree themselves.[100] In addition, in the event of a substantial change in the circumstances, the competent authority may, upon request, revoke the license or lay down new licensing conditions.[101] In some countries, the conditions of compulsory licenses may be amended by the competent authority "upon agreement of the parties", "ex officio", at the request of "one of the parties" or "interested party" where new facts so warrant and, in particular, where a patent owner has granted a license to third parties on conditions more favorable than those accorded to the beneficiary of the compulsory license.[102]

89. Some laws provide further details as regards "the economic value of the authorization". For example, 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." In Hungary, the economic value of the authorization "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 reasonable royalty is "compatible with the successful working of the invention in Zimbabwe on a commercial scale and at a profit".

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93 BGH, judgement of 11 July 2017, *ibid*. In case 3 LiQ 1/18 of September 6, 2018, Federal Patent Court held that the applicant's licensing offer was not made within a reasonable period of time prior to the application for a compulsory license. According to the findings of the court, an offer to conclude a license agreement was only made three weeks before the Applicant applied for a compulsory license.

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

95 See responses to the Questionnaire, for example, from Argentina, Armenia, Costa Rica, Croatia, the Dominican Republic, Pakistan, the Philippines and the Republic of Moldova.

96 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".

97 As regards to whether the national laws provide 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. See, for example, the responses of Belarus, Chile and France to question 76 of the Questionnaire.

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

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

100 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.

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

102 See, for example, Costa Rica, Honduras and Nicaragua.

90. In Cyprus and Hong Kong (China), the patentee should receive reasonable remuneration, having regard to the "nature of the invention". In India, the remuneration is reasonable "having regard to the nature of the invention, 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 countries, "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.[103] 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.

91. In *Isentress II* case, the German Federal Patent Court ruled that if the persons applying for a compulsory license have made use of a provisional permission to use the invention granted to them in injunction proceedings, they must pay the legally specified remuneration for the duration of such (provisional) license grant even if the patent is revoked during the course of the (main action) of the compulsory license proceedings in which the decision is still pending.[104] The Court also ruled that aspects which are relevant for arriving at a reasonable royalty rate includes, among others, a general range of royalty rates, the market situation, the risk of patent revocation and the contribution of the patent to the development of a product under the compulsory license. [105]

92. In the United Kingdom, different provisions applied for WTO and non-WTO proprietors, i.e., the "remuneration adequate in the circumstances of the case, taking into account the economic value of the license" shall be paid to patent owners from WTO Members, and "reasonable remuneration having regard to the nature of the invention" is applicable to patent owners from non-WTO Members.[106]

93. In addition, in some countries, 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.[107, 108]

94. As regards to the specific provisions for the remuneration for compulsory licenses relating to import/export of patented pharmaceuticals, courts will take into account "the circumstances of the individual case", "the economic value of the the licence" to the importing country, "its level of development and the urgency in public health and humanitarian terms" and the "humanitarian or non-commercial factors relevant to the grant of the license".[109]

(d) Judicial or similar review

95. The national law provisions concerning the compulsory licensing state that the decisions relating to grant of such a license, its continuation or renewal as well as decisions concerning the level of the adequate remuneration of the right holder is subject to judicial review or other independent review by an authority higher than that which granted the license with the power to overturn the decisions of the granting authority.

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103 See, responses to the Questionnaire from the Czech Republic, Greece and Romania, respectively.

104 Federal Patent Court, judgement of 21November 2017, ref: 3 Li 1/16 (EP), GRUR 2018, 803 – *Isentress II*. See also the submission of Germany to the thirtieth session of the SCP.

105 Ibid.

106 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.

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

108 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.

109 See Section 21.08 of the Patent Act of Canada; Sections 72E and 72J of Patents Ordinance of Hong Kong (China); Article 177 of Patents Act 2013 of New Zealand; and Article 40e(5) of the Federal Act of June 25, 1954, on Patents for Inventions of Switzerland (status as of April 1, 2019).

(e) Grounds for the grant of a compulsory license

96. In many jurisdictions, compulsory licenses may be requested on one or more grounds. Table 3 provides examples of such grounds in a non-exhaustive manner.

Table 3. National laws provide different grounds for applying for a compulsory license, for example:
- Exercise of rights in abusive manner
- Non-working or insufficient working of the patented invention
- Dependent patents
- Anti-competitive practices and/or unfair competition
- National emergency or circumstances of extreme urgency
- Public interest
- Public non-commercial use
- Failure to meet market demand on reasonable terms
- The reasonable requirements of the public are not satisfied
- Compulsory licenses for patented pharmaceutical products for manufacture and export to countries with insufficient or no manufacturing capacities in the pharmaceutical sector
- Compulsory cross-licensing in case of interdependence between plant varieties and patented inventions

97. Furthermore, some laws provide more specific texts with regard to the grounds for the grant of compulsory licenses. For example, grounds available in some jurisdictions, include: "development of other vital sectors of the national economy"[110], "needs of national economy"[111], "public necessity"[112], "serious public interest menace"[113], "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"[114], "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",[115] "sold at unreasonably high prices or not meet the public demand without any legitimate reason",[116] "a market for the patented invention is not being supplied, or is not being supplied on reasonable terms",[117] "demand is not being met on reasonable terms"[118] "where patent has not been exploited in a manner which

110 See the response from Bhutan to the Questionnaire.
111 See the response from France to the Questionnaire.
112 See the response from Bulgaria to the Questionnaire.
113 See response from Slovakia to the Questionnaire.
114 Article 68 of Law n. 9.279 of 14 May 1996 of Brazil.
115 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.
116 See Section 49 of the Patents Act of Malaysia.
117 Section 46 of the Patents Act 1953 of New Zealand.
118 See, e.g., Article 49 of Patent Law of Cyprus.

contributes to the promotion of technological innovation and to the transfer and dissemination of technology",[119] "protection of natural environment"[120] or "the establishment or development of industrial and commercial activities is unfairly prejudiced"[121].

98. In addition, other grounds for the grant of compulsory license, although less frequently, are found in national laws. For example, in Switzerland, a compulsory license may be granted to any person who intends to use a patented biotechnological invention as an instrument or means for research according to Article 40b Patents Act. In Finland, "prior user" who was commercially exploiting an invention in Finland or has made substantial preparations for such exploitation and who had no knowledge of the application filed by a third party for that invention is entitled to a compulsory license for exploitation of the invention if the application results in a patent.[122] The application of grounds to different constituencies may also differ. For example, 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 WTO, or has a real and effective industrial or commercial establishment in such a Member.[123]

99. In case of semiconductor technology, some laws stipulate 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.[124]

100. The following sections describe further details on the grounds found frequently in national laws.

(a) Non-working or insufficient working

101. To justify the grant of exclusive rights, it is generally believed that the patented invention should be "worked" in the country where it was granted.[125] While the definition of "working" is generally a matter of national law, it usually means at least, in the case of a patent directed to a product, the making of the product and, in the case of a patent having been granted in respect of a process, the use of the process. As a rule, the working requirement may be fulfilled through the working of the patented invention either by the owner of the patent for invention or by another entity or person under a license contract.

102. National laws of many countries provide that where a patentee fails to work a patent within a certain timeframe in their specific jurisdiction or where such working by the patentee is insufficient, without any legitimate justification by the patentee, a compulsory license may be granted to a third party, provided all other requirements under the applicable law are met.

103. In many countries, the relevant provisions reflect the wording of Article 5(4) of the Paris Convention with no further clarification. In other countries, the detailed provisions are provided clarifying the circumstances that may be applicable in case of "non-working". Those clarifications include the types of activities by the patentee that are considered as "working", in particular, whether importation of the patented invention is considered as "working", and the situations under which working by the patentee is considered "insufficient".

104. While the beneficiary of a compulsory license in general is defined as "any person", "any legal entity or natural person" or "any interested party" in many countries, beneficiaries of a compulsory license in case of "non-working" should normally demonstrate their ability to produce the patented product and to supply the market, since the purpose of such a compulsory license is to rectify the

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

120 Article 82 of the Industrial Property Law of Poland.

121 See, e.g., Article 49 of Patent Law of Cyprus, and Article 15 of the Decree Law No.30, 2006 of Qatar.

122 Section 48 of the Finnish Patents Act (550/1967).

123 See Section 48A(1) and B(1) of the Patents Act of 1977 of the United Kingdom.

124 See, e.g., Antigua and Barbuda, Argentina, Bahrain, Burundi, and the Republic of Moldova.

125 See, e.g., Section 83(a) of the Patents Act of India. See also the responses from Portugal and Vietnam to question 69 of the Questionnaire.

situation of non-working or insufficient working. Thus, the laws in some countries state that a compulsory license may be granted to, or requested by, a person who can demonstrate the capability to exploit the patented invention, provided all the requirements defined in the law are met.

105. 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".[126] In India, in considering the application filed for the grant of a compulsory license under this section, the Controller shall take into account, "[…] (ii) the ability of the applicant to work the invention to the public advantage; (iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted"[127] In Tunisia, "[the applicant] shall also supply proof that he is capable of exploiting the invention effectively and conscientiously".[128]

106. In many countries, the laws do not expressly provide a definition of the terms "non-working" and "insufficient working". In those countries, in general, an "abuse" or "non-working" occurs if the "exploitation", "working on a commercial scale", "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.[129]

107. In some other laws, in defining what constitutes a "non-working or insufficient working", a reference is made to the situations where the demand for the patented product was not satisfied in local market on reasonable terms.[130] In some other jurisdictions, a non-working means, *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 the fullest extent that is reasonably practicable". Furthermore, in some other countries, that expression means that the patented invention is not available to the public at a "reasonably affordable prices", and/or "sufficient quantities or quality".[131]

108. In many countries, a lack of preparations to work is one of the grounds for compulsory licenses, for example, a compulsory license may be granted where a patentee has "not started to work or to make effective and serious preparations to work" the patented invention.[132]

(i) Does importation constitute "working" of the patent?

109. Under most of the laws, importation is considered as working of the patent. Thus, in those countries, compulsory licenses on the ground of "non-working" or "insufficient working" cannot be obtained if a patentee has worked the patented invention through importation of a patented product or a product manufactured using a patented process, provided other requirements of the applicable law are met.

126 Articles 68 of the Law n. 9.279 of 14 May 1996 of Brazil.

127 Sections 84(6). Patent Act No. 39 of 1970 as last amended by the Patents Amendment Act No. 15 of 2005. See also Article 50 of the Law No. 9947 on Industrial Property of Albania, Article 40(1)(a) of the Law No. 20-00 on Industrial Property of the Dominican Republic, and Articles 65 and 66 of the Law on Industrial Property of Honduras, and the response from the Russian Federation to question 69 of the Questionnaire.

128 Article 70 Articles of the Patents Law No. 2000-84 of 24/08/2000.

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

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

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

132 See, e.g., the provisions of laws of Albania, Argentina, Bosnia and Herzegovina, Eswatini, Tonga and Uruguay.

110. For example, Section 14(1) of the Patent Act of Ghana states:

> "On a request […] the court may issue a non-voluntary licence if the court is satisfied that the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by *importation*, in the country." (emphasis added)

111. Similarly in Germany, Section 24(5) of the Patent Act states:

> "When a patentee does not work the patented invention or does not work it predominantly in Germany, compulsory licenses under the provisions of subsection (1) may be granted to ensure an adequate supply of the patented product to the domestic market. *Importing shall insofar be deemed to constitute working* of the patent in Germany." (emphasis added)

112. Likewise, Article 39 Law on Industrial Property of the Dominican Republic states:

> "For the effects of Article 41 of this law, exploitation of a patent is understood as follows:
> a) When the patent has been granted for a product or for a procedure for the obtaining of a product, supply to the internal market in reasonable quantity, quality and price, through production in this country and *importation*." (emphasis added)

113. However, few Member States do not consider importation as working of the patent[133] or do not specify such issue in their applicable legal provisions[134].

114. For example, Section 14(2) of the Industrial Property Act of the Gambia states:

> "Notwithstanding the provisions of subsection (1) of this section, a non-voluntary licence shall not be granted if the owner of the patent satisfies the Registrar General that circumstances exist (*other than importation*) which justify the non-working or insufficient working of the patented invention in The Gambia." (emphasis added)

115. In some countries, where importation is considered as working of the patent, certain conditions may be applicable. For example, 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. In South Africa, an importation is only considered as working as far as it is not involving excessive pricing in relation to the price charged in countries where the patented article is manufactured by the patentee. 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.[135]

116. 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".[136] 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

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133 Responses to the Questionnaire from Uganda, the United Republic of Tanzania and Zambia expressly indicated that importation did not constitute "working" of the patent under their applicable law.

134 See responses to the Questionnaire from Bosnia, Croatia, Greece, Pakistan and Slovakia.

135 See, e.g., the provisions of laws of Italy, Netherlands, Spain and Sweden. See also the responses to the Questionnaire from those countries. 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".

136 See responses to question 70 of the Questionnaire from those countries.

import, the patentee may have legitimate reasons for the failure to work the invention" which would bar an application for a compulsory license.[137] Contrary to that, in Qatar, the law clarifies that "importing the product shall not serve as legitimate reason".[138] 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".[139] In India, if the reasons why the patented invention could not be manufactured in India satisfies the authorities, then the patented invention could be considered as having been worked in that country even by importation.[140]

Box 3. India: Bayer Corp. V. Union of India, 2014[141]
This case discussed, among other issues, the requirement of getting the drug "worked in the territory of India". The Bombay High Court, in July 2014, ruled that when a patent holder is faced with an application for a Compulsory Licence, "it is for the patent holder to show that the patented invention is worked in the territory of India by manufacture or otherwise. Manufacture in all cases may not be necessary to establish working in India as held by the Tribunal. However, the patent holder would nevertheless have to satisfy the authorities under the Patent Act as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons but it would be for the patent holder to establish those reasons which make it impossible/ prohibitive for it to manufacture the patented drug in India. However, where a patent holder satisfies the authorities the reason why the patented invention could not be manufactured in India, then the patented invention can be considered as having been worked in the territory in India even by import. This satisfaction of the authorities is necessary particularly when the petitioner admittedly has manufacturing facilities in India. In the circumstances, the contention of Union of India that 'worked in India' must in all cases mean only manufactured in India is not acceptable."[142]

In December 2014, the Supreme Court upheld the grant of the compulsory license by dismissing a Special Leave Petition filed by the patentee.

117. Other specificities of laws as regards to the "non-working" can be found in some laws. For example, in the United Kingdom, under Sections 48-54 of the Patents Act, the grounds that apply are dependent on whether or not the proprietor of the patent is a 'WTO proprietor'. In particular, a compulsory license on the ground of "not being so worked or is not being so worked to the fullest extent that is reasonably practicable" is expressly mentioned only in relation to a request for a compulsory

137 See the response from Norway to question 70 of the Questionnaire.
138 See the response from Qatar to question 70 of the Questionnaire.
139 Article 68(1)-I of Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001.
140 See Box 3.
141 Background of the case: In 2008, Bayer was granted an Indian patent and regulatory approval for import and marketing for sorafenib tosylate sold in the local market under the name of Nexavar for cancer treatment. An application for a compulsory license was then filed by Natco, on the ground of non-working. This is based on the provision of Section 84(1) of the Indian Patents Act which states"(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India." On March 9, 2012, the Patent Controller of India granted a non-exclusive license to Natco, citing non-availability and non-affordability. It was concluded that the price charged by Bayer contravened the Patents Act as it was not available to the public at a reasonably affordable price with respect to the purchasing power of the public or in sufficient quantities. Bayer appealed against the Controller's order to the Tribunal, which, after hearing the parties, upheld the decision of the Controller to grant a compulsory license to Natco. That decision was appealed to the Bombay High Court.
142 The decision is available at: https://indiankanoon.org/doc/28519340/.

license to be made on a patent owned by a non-WTO proprietor.[143] In Belgium, as regards to what constitutes "exploitation of the patented invention", the law specifies, *inter alia*, that in the case of a patent whose subject matter is a machine, effective and continuous manufacture in Belgium by the patentee of products obtained by means of that machine may be deemed to constitute exploitation of the patented invention in Belgium, when such manufacture appears more important for the economy of the country than the manufacture of the patented machine itself."[144]

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

118. In most countries, 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 of those countries 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 countries, a compulsory license may be granted if the exploitation of the patented invention has been interrupted for more than one year,[145] and in two countries, for more than three years.[146] Some other variations found in the applicable laws are, for example, "three years from the date of the grant of the patent",[147] "three" or "five" years from the date of publication of the mention of the grant,[148] "3 years after sealing",[149] or "three years of non-working".[150]

(iii) Definition of "legitimate reasons" for non-working or insufficient working

119. In the majority of countries 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 which results in the refusal of a compulsory license. In this regard, the relevant provisions refer 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".[151]

120. Those legitimate reasons are, in most of those countries, of a technical, economic, legal nature, or *force majeure*. For example, in the response to the Questionnaire from Turkey, it is 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 this regard, 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

143 See Section 48B(1)(a) of the Patents Act 1977 of the United Kingdom.
144 Art. XI.37, Sec. 1(1) Code of Economic Law of Belgium.
145 See Article 43 of the Law No. 24.481 on the Patents and Utility Models of Argentina, Article 41(1) of Law No. 20-00 on Industrial Property of the Dominican Republic and Article 18.1 of Law No. 6867 on the Patents, Industrial Designs and Utility Models of Costa Rica.
146 Turkey and Ukraine. See the responses from those countries to question 71 of the Questionnaire.
147 See, for example, Azerbaijan, Brazil, Honduras, Hong Kong (China), India, Netherlands, Qatar and the United Kingdom.
148 Turkey, Ukraine, and Tajikistan.
149 Australia.
150 Monaco.
151 See, for example, the provisions of laws of Brazil, China, Japan, Mexico, Pakistan, Serbia and Sweden.

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 patentee has "difficulties in providing raw material or has been struggling with lack of resources, 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 some countries, the lack of financial resources or the lack of financial feasibility of the exploitation, does not constitute legitimate reasons.[152]

121. In general, the definition of the "legitimate reason" is determined on a case-by-case basis,[153] and the patentee has to prove the legitimacy of the reasons which resulted in the non-working of the patent by providing evidence that the circumstances made it impossible to remedy such non-working.[154] Further, while according to the laws of many countries, a compulsory license shall be refused if the patentee justifies his/her inaction by legitimate reasons, no specific definition of the term is found in those laws. [155]

(b) The reasonable requirements of the public are not satisfied

122. In some countries, a compulsory licence can be granted if the reasonable requirements of the public are not being satisfied with respect to a patented invention.[156] In general, the reasonable requirements of the public appear to relate, broadly speaking, to whether trade or industry in the country is unreasonably affected by the actions of the patentee in relation to the exploitation of the patent in the country concerned.

123. In this regard, some laws list circumstances in which the reasonable requirements of the public would be deemed not to have been satisfied. For example, Section 135 of the Patents Act of Australia states that:

> "[…]the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:
> (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure: (i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or (ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or (iii) to carry on the patented process to a reasonable extent; or (iv) to grant licences on reasonable terms; or (b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or
> (c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia."

124. Article 84(7) of Patents Act of India states that the reasonable requirements of the public shall be deemed not to have been satisfied –

> "(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or (ii) the demand for the patented article has not been met to an adequate

152 See the responses to the Questionnaire from Argentina, Portugal, the Dominican Republic and Honduras.

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

154 See, e.g, the responses from Algeria and the Russian Federation to the Questionnaire.

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

156 See, e.g., Australia, India and Zimbabwe.

extent or on reasonable terms; or (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or (iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, preventions to challenges to the validity of patent or coercive package licensing, or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by- (i) the patentee or person claiming under him, or (ii) persons directly or indirectly purchasing from him; or (iii) other persons against whom the patentee is not taking or has not taken proceeding for infringement." [157]

(c) Failure to meet market demand on reasonable terms

125. In some countries, the compulsory license can be granted specifically on the ground that "market for the patented invention not being supplied on reasonable terms" or "demand for the patented product is not being met on reasonable terms".[158]

126. In general, the definition of the term "reasonable terms" is decided on a case-by-case basis. Some laws provide further explanation of this term. For example, in the United Kingdom, what constitutes reasonable terms depends on "a careful 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".[159] A test applied by court in the United Kingdom is "how much are manufacturers who are anxious to make and deal with the patented article on commercial lines ready and willing to pay?"[160]

Box 4. South Africa: Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd 1992 BP 331 (CP)
This case relates to a patent on a device of paper diaper, which the applicant of a compulsory license alleged that it was able to sell the patented product at a lesser price than the patentee. The application for a compulsory licence is made based on Section 56 of the Patents Act of South Africa (Compulsory licence in case of abuse of patent rights), in particular Section 56(2)(c) "the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms."
The Court held that a charge of unreasonable terms is not established merely on proof that the applicant can sell the same sort of article at a lower price. Other relevant considerations need to be considered when deciding whether the patentee's prices are reasonable, such as the cost of producing and marketing the patented article, the terms and conditions on which it negotiates with customers, and whether the facts show that the trade as a whole can carry the price charged.
The Court held further that evidence of "reasonable terms" should be provided, as should the evidence that the patentee's prices were not reasonable. In particular, the Court stated that "on the charge of not granting a licence, the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are. […] as to the reasonableness of prices charged

157 See also Section 31(6) of Patents Act of Zimbabwe.
158 See, e.g., Trinidad and Tobago, the United Kingdom and the United Republic of Tanzania.
159 Section 48A.06 of the Manual of Patent Practice.
160 *Brownie Wireless Co Ltd's Applications 46 RPC 457*, was cited in the response from the United Kingdom to question 73 of the Questionnaire.

by the respondent, that "the applicants had not shown that, having regard to all the circumstances set out in the papers, the respondent had charged unreasonable prices. The applicants did little more than show that they could in certain sectors sell at lesser prices. That fell far short of showing that in all the circumstances the respondent's prices and method of fixing prices were not reasonable."

(d) Compulsory license on the ground of anti-competitive practices

127. Some national laws provide the possibility of granting a compulsory license to prevent abuses which might result from the exercise of the exclusive patent rights, other than non-working or insufficient working of the patent. Anti-competitive practices by patentees abusing the economic power derived from the exclusivity of the patent is one of the examples.

128. Some countries provide specific provisions under the patent law that allow the granting of a compulsory license in order to remedy an anti-competitive practice engaged in by the patentee. In some other countries, such a remedy can also be regulated in the competition (antitrust) law, under which compulsory licenses may be granted by a competition authority where it finds that it is an appropriate remedial action against an anti-competitive practice.[161]

(i) Definition of the term "anti-competitive practices"

129. As regards to what constitutes "anti-competitive practices", some countries' laws provide for a general wording, such as "any other act which national legislation characterizes as anti-competitive, limiting or restrictive of competition",[162] "if the patentee exercises his rights in such a way as to prevent others from competing fairly"[163] or "restraint of trade and contrary to public policy".[164] In Brazil, "a compulsory license may be granted if the patentee exercises his right in an abusive manner, or if the patentee engages in abuse of economic power by means of exploiting the patent, proven pursuant to law in administrative or judicial decision."

130. In some other countries, their legislations provide an enumerative list of anti-competitive practices to explain the term. For example, in Argentina, such practices are referred, *inter alia*, to:

> "(a) the 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;
> (b) the refusal to supply the local market under reasonable commercial conditions;
> (c) the obstruction of commercial or production activities;
> (d) any other act that falls into the category of behaviour deemed to be punishable under Law".[165]

131. Similarly, in Costa Rica, the following practices are considered to be anti-competitive:

> "(a) excessive or discriminatory pricing for the patented products;
> (b) failure to supply the market on reasonable commercial terms; and
> (c) hindrance of commercial or productive activities".[166]

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161 See Appendix to this document as well as document CDIP/4/4 Rev./STUDY/INF/5 for the national statutory provisions regarding compulsory licenses to address anti-competitive uses of IP rights, including antitrust laws and regulations.

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

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

164 Section 37(6)(f) of the Patents Act of Zambia.

165 Article 44 of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models.

166 Art. 2(f), amended by Law No. 7979 of January 6, 2000. See also provisions of laws of Algeria and the Dominican Republic.

132. Some countries patent legislation do not expressly define which practices are considered "anti-competitive".[167] In general, the determination or declaration of anti-competitive practices is 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".[168]

133. In Switzerland, a practice is held to be anticompetitive if it involves unlawful agreements that significantly restrict or even eliminate effective competition (including, among others, agreements to fix prices, limit quantities of goods or services and/or allocate markets geographically or according to trading partners) or unlawful practices by dominant undertakings (including, among others, refusals to supply, discrimination against trading partners and/or imposition of unfair prices).[169]

134. In the United Kingdom, the relevant authorities can apply for a compulsory license if a patent abuse is a factor contributing to an anti-competitive situation. In particular, Section 50A of the Patents Act allows the Competition Commission or the Secretary of State to apply to the comptroller to take action following a merger or market investigation to remedy, mitigate or prevent a competition matter that cannot be dealt with in any other way under the Enterprise Act. Section 51 makes provision for Government Ministers to apply to the comptroller to take action in response to a report by the Competition Commission "that a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest" or "that a person is pursuing a course of conduct which operates against the public interest". Applications under Section 50A or 51 must involve "conditions in licences 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 licences", or "a refusal by the proprietor to grant licences on reasonable terms".[170]

135. In some countries, the compulsory licenses on the ground of anti-competitive practices is specifically available in the area of health technologies.[171] For example, in France, *ex officio* licenses in the interest of public health, declared by a decree of the Minister for Intellectual Property for patents in this field (in particular medicines, medical equipment, production or manufacturing processes) are available when the patent in question is worked, *inter alia*, on conditions considered to constitute an anti-competitive practice.[172] In Switzerland, to correct anti-competitive practice, a compulsory license is available in the case of an invention relating to a human diagnostic product or process.[173] In accordance with the TRIPS Agreement, inventions in the field of semi-conductor technology, many laws stipulate that a compulsory license may only be granted for public non-commercial purposes or to remedy a practice declared anti-competitive following court or administrative proceedings.[174]

136. The provisions in some countries state that on the establishment of anti-competitive practice adopted by the patentee, applicant is not required to make "a prior efforts to obtain a license from the patentee on reasonable terms and conditions" and the authorized exploitation may go beyond the supply of the domestic market.[175]

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167 See, for example, the responses to the Questionnaire from Canada, Serbia, Sri Lanka and Zimbabwe.

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

169 See section on Switzerland in the Report by the European Patent Academy on Compulsory Licensing in Europe, 2018.

170 Sections 50A(1)(c) and 51(3) of the Patents Act of the United Kingdom. See response from the United Kingdom to question 74 of the Questionnaire.

171 See, for example, France, Switzerland and Ukraine.

172 Article L613-16 of the Code de la propriété intellectuelle.

173 Articles 40a and b of the Federal Law on Patents for Inventions (SR 232.14, LBI).

174 See, for example, Antigua and Barbuda, Argentina, Bahrain, Burundi, Germany and the Republic of Moldova.

175 See, for example, the provisions of laws of Albania, France and India.

(ii) Regulation of anti-competitive practices in the competition (antitrust) law

137. As stated above, in addition to patent law provisions, anti-competitive practices are regulated in the competition (antitrust) law.[176] The typical grounds under competition law for the grant of a compulsory license cover anti-competitive practices and abuse of monopolistic position and/or misuse of monopolistic rights in patents with the purpose of restraining or eliminating competition on the market. Under competition law, other sanctions (alternative or complementary) besides compulsory licenses can be issued by the competition law authorities to address anti-competitive uses of IP rights.[177]

138. In Germany, irrespective of Section 24 of the Patent Act, a claim to the grant of a license may come as a result of competition law provision. The submission from Germany explains that this is particularly the case if the refusal to grant a license or the enforcement of the patent constitutes an abuse of a market-dominating position or an unfair restraint or discrimination on the part of the market-dominating undertaking.[178] It further notes that the exercise of an exclusive intellectual property right forms part of the rights of the proprietor of such a right. Consequently, the exercise of the exclusive right, even if it is the act of an undertaking holding a dominant position, cannot in itself constitute an abuse of a dominant position. However, the exercise of an exclusive right linked to an intellectual property right by the proprietor may, in exceptional circumstances, involve abusive conduct. [179]

Box 5. United States of America: IP licensing as a remedy to address anti-competitive practices
In the United States of America, the regulatory Agencies have used IP licensing as a remedy in three different types of antitrust cases.[180] First, when the Antitrust Agencies have determined that a proposed merger is substantially likely to lessen competition, the Agencies may determine that an IP license to a particular purchaser of divested assets is necessary to maintain competition in a market, or the Agencies may determine that an IP license is necessary generally to lower a barrier to entry after the merger by making a license available on reasonable terms to all interested potential competitors. Second, the Agencies can seek compulsory licenses to remedy competitive harm arising from specific uses of IP rights. The third type involves cases in which IP licenses are used to remedy the effects of anti-competitive conduct, although the harm arises from such activities that do not involve IP rights. [181, 182]

(e) Grant of compulsory licenses on the ground of dependent patents

139. Many countries provide for the possibility of requesting a compulsory license where the exploitation of a patent (second patent) cannot be exploited without infringing another patent (first patent). Reflecting Article 31(I) of the TRIPS Agreement, the additional conditions stipulated in most of the national laws are:

176 For example, in Europe, the EU competition law, namely, Articles 101 and 102 of the Treaty on the Functioning of the European Union alongside with the relevant European case practice applies to antitrust cases. Article 101 of the EC Treaty refers to individual restraints to address anticompetitive practice which can also envisage IP rights. For further information, see document CDIP/4/4 Rev./STUDY/INF/5.

177 The discussion of such other sanctions is beyond the scope of this paper.

178 See the submission of Germany to the thirtieth session of the SCP.

179 Ibid.

180 It is to be noted that the competition law of the United States of America do not contain any language that specifically provided for or permitted the granting of compulsory licenses to address anti-competitive effects arising from the use of IP rights.

181 See the response from the United States of America to question 74 of the Questionnaire. See also document CDIP/4/4 Rev./STUDY/INF/5 p.14 for a detailed description of these three cases.

182 While the regulatory Agencies in the United States of America have used IP licensing as a remedy in mentioned three types of antitrust cases, the submission from this country to the SCP notes that 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.

– the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
– 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
– the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent".[183]

140. In general, the first condition serves the purpose of avoiding the situations where the patentee of the second patent files a request to grant a compulsory license to work an important invention claimed in the first patent by claiming dependency of its trivial inventions claimed in the second patent.

141. As regards to dependent patents, some laws refer to general conditions for granting a compulsory license, i.e., the party has to make efforts 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, [184] the granted license is not exclusive, or 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.[185]

142. In some countries, variations in wording were observed in relation to the description of the situation of dependency of patents, for example, "patent is included in the scope of another, earlier patent"[186]; "If the invention claimed in a patent may not be worked industrially in the country without infringing an earlier patent"[187]; "[…] 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".[188]

143. In Algeria and the Russian Federation, the relevant provisions are worded to provide two criteria for the second patent: (i) the second patent must represent an "important technical achievement/progress" and (ii) it shall have "significant economic advantages" over the first patent.[189] Different from this approach, in Brazil, the only substantive criterion applied in relation to the significance of the second patent is that it shall "constitute a substantial technical progress with regard to the earlier patent".[190]

Box 6. Russian Federation: Compulsory licenses in case of dependent patents
A plaintiff was a generic pharmaceutical company which owned a patent (the second patent) that could not be exploited without infringing a defendant's patent on Lenalidomide (the first patent). Following unsuccessful attempt to obtain a voluntary license, the plaintiff therefore lodged an action with the Russian Arbitration Court of the city of Moscow for the grant of a compulsory license, and in

183 See, for example, Article 46 of the Law No. 24.481 on the Patents and Utility Models of Argentina, Article 51(3) of Law No. 19.039 of Chile, Article 19.A.1 of the Law No. 6867 on the Patents, Industrial Designs and Utility Models of Costa Rica, Article 66 of the 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.

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

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

186 Bulgaria.

187 Costa Rica.

188 India.

189 See, e.g., Article 1362(2) of the Civil Code of the Russian Federation, and Article 47 of The Ordinance No. 03-07 of 19/07/2003 of Algeria.

190 Other criteria stated in Article 70 of the Industrial Property Law of Brazil, is that "there is a situation of dependency of one patent with regard to another; […] and the titleholder fails to reach agreement with the patent holder of the dependent patent on the exploitation of the earlier patent." Article 70 of the Industrial Property Law No. 9.279 of 14/05/1996 of Brazil, as last amended by Law No. 10.196 of 14/02/2001

June 2018, the Arbitration Court granted the compulsory license. This license represents the first compulsory license in the Russian Federation in the pharmaceutical area. The appeal against the grant of this compulsory license has been dealt with by the Appeal Arbitration Court, which, on September 17, 2018, took a decision to reject the appeal and to uphold the grant of a compulsory license.
Subject matter of the second patent was a new crystal form of Lenalidomide (polymorphic form ß). According to the pleadings made by the patentee of the second patent in the court proceedings, their polymorphic form ß would be obtained immediately in the desired particle size so that, in comparison to the conventional synthesis process used by the patentee of the first patent for the manufacturing of their own Lenalidomide, the process steps "milling" and "sieving" of the active ingredient could be omitted. According to the statements of the plaintiff, that represented a significant technological achievement. Moreover, due to the simplified manufacturing process, also an economic advantage over earlier patent was evident. The arguments continued that, as a consequence, in monetary terms the price of a generic version of Lenalidomide was about 20% below the price for which the patentee of the first patent offered that drug on the Russian market.
The Court came to the conclusion that the conditions for the grant of a compulsory license were fulfilled: "the dependent patent must represent an important technical achievement" and "shall provide significant economic advantages over the earlier dominant patent". Both court instances granted to the plaintiff a non-exclusive compulsory license to the full extent of the first patent. The amount of royalties to be paid to the owner of the first patent has been fixed by the court to 30% of the revenue.[191, 192]

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

144. Some other textual variations are 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".

145. Some national laws require that as an alternative to the requirement that the dependent patent shall involve an important technical advance in relation to the first patent, it must serve a different purpose from that of the first patent. For example, in Turkey, the owner of the second patent may request the court to grant a license for using the first patent owned by another person by bringing

191 Nativa v. Celgene, Ninth Arbitration Court of Appeal, case No. A40-71471/17.

192 The decision of the Appeal Arbitration Court can be appealed to the next court level, the Russian IP Court, within two months from the date of manufacture. Following this case, other cases on the issue of dependent patents have been heard by Russian courts. In case No. A40-141023/17-15-1263, decided by the Moscow Arbitration Court on February 8, 2019, a compulsory license has been granted on an active ingredient Sunitinib on the basis of dependent patents. One of the criteria looked by the court in deciding in favor of issuance of compulsory license was a price of a generic version of the drug which was about 20% to 60 % below the price offered by the holder of the first patent in the Russian market which overall would represent annual budgetary saving in the amount of 200 000 000 rub. This economic implication made a court to conclude that the dependent patent had a "significant economic advantages" over the invention of the holder of the first patent in the meaning of Article 1362(2) of the Civil Code of the Russian Federation. As regards the second condition that the dependent patent must represent an "important technical achievement"," the court stated that it was necessary to take into account the importance of the proposed technical solution to meet the public interest. In another case decided by the same court on the dependent patent, No. A40-141023/17-15-1263 of March 14, 2019, parties concluded an agreement during the court proceedings, in which the holder of the dependent patent agreed, *inter alia*, not to manufacture, use, offer to sell, sell, otherwise put into civil circulation or storage for any of these purposes any drug with active ingredient Gefitinib in the territory of the Russian Federation before the expiration of the term of the first patent on November 30, 2019 (patent No. 2153495).

evidence that his patent, with reference to the first patent, will serve a "different industrial purpose" or "achieves significant technical improvement".[193] Similarly, in the United Republic of Tanzania, the grant of a 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.[194] 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".

146. In the Netherlands, 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".[195]

147. In Brazil, the law clarifies that a process patent may be considered dependent on the respective product patent, and likewise, a product patent may be dependent on a process patent.[196]

Box 7. Hungary: Compulsory licenses in case of dependent patents

The only case on compulsory licensing in Hungary concerned dependent patents. The defendant was the patentee of an earlier product patent concerning an active ingredient (a pharmaceutical compound reducing blood pressure). The plaintiff was the owner of a later process patent, which according to claim 1, claimed the process for the preparation of the active ingredient protected by the defendant's earlier patent.

In Hungary, the condition for obtaining a compulsory license based on the dependency of patents is that the invention of the dependent patent shall constitute significant technical progress of considerable economic interest compared with the invention claimed in the earlier patent. The specificity of the case is that a process patent was compared with a product patent.

The court of first instance rejected to grant a compulsory license and established that the plaintiff had failed to provide an appropriate basis of comparison.

In 2006, at second instance, the Metropolitan Appeal Court annulled the decision of the Metropolitan Court and ordered the first instance court to reopen the case. The Metropolitan Appeal Court established that a product (a pharmaceutical active ingredient) and a process resulting in the same product shall be compared to each other from the perspective of the requirement of significant technical progress.[197]

148. In many countries, the compulsory licenses in case of dependent patents may be requested by "the owner of the second patent". [198] In few countries, such a license can also be requested by the licensee of the owner of the second patent, as well as the "the beneficiary of a compulsory license for the later

193 Article 101 of the 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".

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

195 Articles 57 (4) of the Patent Act of 15/12/1994 of Netherlands.

196 Article 70 of the Industrial Property Law No. 9.279 of 14/05/1996 of Brazil, as last amended by Law No. 10.196 of 14/02/2001.

197 The decision of the Metropolitan Appeal Court was not challenged by the Supreme Court because the basic patent's term had expired. A final decision was not reached by the lower court, so eventually there was no final decision on granting the compulsory license or not. See section on Hungary in the *Report by the European Patent Academy on Compulsory Licensing in Europe*, 2018.

198 See, e.g. the provisions of laws of Antigua and Barbuda, Austria, Barbados, Belize and Brunei Darussalam.

patent".[199] Similarly, the law in India provides that "any person who has the right to work any other patented invention either as a patentee or as a licensee thereof, exclusive or otherwise" may apply for the grant of a license for the related patent.[200]

(ii) Cross-license on reasonable terms

149. While, in most of the laws, 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, in some laws, some differences in the language are observed. 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 patentee of the first patent may also demand a compulsory license if inventions protected by dependent patents "serve the same industrial purpose".[201] 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.[202]

150. In few countries, a cross-license in respect of the second patent may be requested not only by the owner of that first patent, but also by his/her licensee or the beneficiary of a compulsory license for that first patent.[203]

151. In addition, in some counties, a compulsory cross-license can be issued 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.[204] In order to obtain such a cross-license, the breeder or the owner of the patent must prove that he has tried unsuccessfully to get a contractual license from the patent or plant variety owner, and the plant variety or the invention represents a significant technical progress of considerable economic interest, compared to the patented invention or the protected plant variety.

(f) Grant of compulsory licenses on the ground of public interest / national emergency or circumstances of extreme urgency / public non-commercial use / Government use

152. In various countries, reflecting different policy considerations, the compulsory licenses can be granted either on the grounds of public interest, and/or national emergency or circumstances of extreme urgency, and/or public non-commercial use, and/or Government use. While substantive nuances may exist in the interpretation of these terms among various jurisdictions, in general, it was observed that there is a close link between these grounds when it comes to situations under which they are invoked.

153. For example, in India, the circumstances of national emergency or extreme urgency or a public non-commercial use may arise, *inter alia*, in the cases of public health crises relating to some epidemics. In Peru, according to the text of Article 40 of the Legislative Decree 1075,[205] existence of "reasons of

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199 Article 45(3) of the Law No. 20-00 on Industrial Property of the Dominican Republic and Article 19.A.1 of Law No. 6867 on the Patents, Industrial Designs and Utility Models of Costa Rica.

200 Section 91(1) of the Indian Patents Act.

201 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".

202 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".

203 Article 45(3) of the Law No. 20-00 on Industrial Property of the Dominican Republic and Article 19.A.2. of Law No. 6867 on the Patents, Industrial Designs and Utility Models of Costa Rica.

204 See Article 28 of the Law 50/2008 on the Protection of Invention of the Republic of Moldova; Article 109 of the 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.

205 Decreto Legislativo N° 1075 que aprueba Disposiciones Complementarias a la Decisión N° 486 de la Comisión de la Comunidad Andina que establece el Régimen Común sobre Propiedad Industrial (2006).

public interest, emergency or national security" is linked to "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".[206] Yet, in some countries, the law may not expressly use the terms "national emergency" or "circumstances of extreme urgency", however, such situations can be implicit in the provisions relating, e.g., to national security and health in the framework of public interest.[207] Moreover, for national security purposes, depending on the national law, the compulsory license can be invoked on the grounds of either government use or public interest or on the ground of national emergency or circumstances of extreme urgency.

154. Taking into account the above observation, the following paragraphs provide general information as to the interpretation of these grounds in specific jurisdictions.

(i) Public interest

155. Many countries allow the granting of compulsory licenses on the grounds of "public interest".[208] The exact scope of the grounds relating to public interest considerations varies from one country to the other, reflecting different policy considerations among countries. In general, in many countries, with respect to public interest, the reference is made to the situations of national security, national economy, nutrition, environmental protection and public health in general.

156. For example, in Denmark, the situations of "public interest" may concern "national security, the population's access to medical products and food, power supply, communication lines etc."[209] In Brazil, public health, nutrition and environmental protection are considered to be of public interest, as well as the facts of primary importance for the technological or socioeconomic development of the country.[210] In Spain, the reasons of public interest are 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".[211]

157. In some countries, the meaning of the term has been clarified by a case law. In Germany, Section 24(1)2 of the German Patent Act states that a non-exclusive authorization to commercially use the invention shall be granted where "the public interest calls for the grant of a compulsory licence". In this regard, the court stated that the question of whether a public interest requiring the grant of a compulsory license is present must be answered by weighing all circumstances that are relevant in the individual case and the interests concerned,[212] and that there can be no universally valid definition of the term.[213] Since the grant of a compulsory license represents a significant encroachment on the patent holder's legal and constitutionally protected exclusive rights, the balancing of interests must be subjected to the principle of reasonableness.[214] Further, a case law in Germany clarified that public interest cannot be established merely on the basis of the exclusive position enjoyed by the patent holder, even if the latter enjoys an actual monopoly on the market. Public interest can only be affected if there are particular circumstances that subordinate the unrestricted recognition of the patent holder's exclusive

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206 Yet, in other countries, the reasons of public interest may not necessarily be linked to situations of national emergency. See, e.g., the decision of the Federal Court of Justice of Germany in Raltegravir case, p. 44 of this paper.

207 See, e.g, a response from Sao Tome to question 77 of the Questionnaire.

208 See, e.g., the provisions of laws on compulsory licenses of Austria, Bulgaria, Brazil, Colombia, Czech Republic, Finland, Germany, Netherlands, Norway, Peru, Portugal, Slovak Republic, Spain and Turkey. See also discussions and legislation of the member countries of the Andean Community as regards the term "public interest" above.

209 See response from Denmark to question 77 of the Questionnaire.

210 Article 2 § 2 of the Decree No. 3.201 of Brazil. The cases of national emergency or public interest are declared by the Federal Executive Power, through the Minister of State responsible for the matter in question. See submission of Brazil to the thirtieth session of the SCP.

211 See response from Spain to question 77 of the Questionnaire.

212 BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir.*

213 BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*.

214 BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon.*

right and interests to the interest of the general public in the exploitation of the patent by the party seeking a license. Only then, there is a justification for a major impairment of the patent holder's rights against his will in the form of a compulsory license. [215]

158. The Federal Court of Justice also stated that particular circumstances that justify the assumption of public interest, in addition to the abusive exploitation of patent right, may also include other circumstances of a technical, economic, socio-political and medical nature.[216, 217] In addition, the Court stated that a compulsory license in a pharmaceutical cannot be granted if the public interest can be satisfied with other more or less equivalent alternative products.[218] In 2017, in Raltegravir case, the Federal Court of Justice stated that a public interest prescribing the grant of a compulsory licence can be confirmed in the absence of alternative medicines on the market. The Court also stated that the public interest can exist even when only a relatively small group of patients is affected.[219] Accordingly, in another case involving a request for a compulsory license relating to a high cholesterol medicine, the Federal Patent Court dismissed the request in preliminary proceedings.[220] It did not recognize a public interest in the grant of a compulsory license because patients had access to medicines with substantially equivalent qualities, among other reasons.

Box 8. Germany: Federal Court of Justice, decision of 11 July 2017 – Raltegravir[221]
This is the first case in which Federal Court of Justice upheld the compulsory license granted by the Federal Patent Court.

The applicant distributes the medicine Isentress® for the treatment of HIV in Germany since 2008. It contains the active ingredient Raltegravir.
The defendant is the proprietor of a European patent called "Antiviral Agent" granted with effect for Germany and also distributes a medicine for the treatment of HIV that falls under the scope of protection of the aforementioned patent. In August 2015, the defendant filed an infringement action against the applicants before the Regional Court of Düsseldorf.[222] In 2016, the applicant filed an action for the grant of a compulsory license for the patent in dispute in an interim procedure. With regard to a public interest argument, the Federal Patent Court stated, *inter alia*, that there was a public interest in the continued availability of the active substance Raltegravir. Even though not every HIV or AIDS patient was dependent on being treated with Raltegravir, there were patient groups that needed the medicine containing the active substance Raltegravir in order to maintain safety and quality of treatment, in particular to avoid serious side effects and interactions. The associated reduction of the viral load would also protect the general public from new infections.
In its judgement of August 31, 2016, the Federal Patent Court therefore permitted the applicants to use the invention protected by the contested patent and to market the medicine Isentress®.

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215 BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of 11 July, 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir.*

216 BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of July 13, 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass.*

217 The submission from Germany further explained that, in applying the above principles, a public interest prescribing the grant of a compulsory license can be confirmed when a medicament used to treat serious illnesses displays therapeutic characteristics that the medicaments available on the market do not possess, or not in the same degree, or when its use avoids undesirable side effects that must be accepted with the administration of the other therapeutic medicines. See the submission of Germany to thirtieth session of the SCP.

218 BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon.* See the submission of Germany to thirtieth session of the SCP.

219 BGH, judgement of July 11, 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir.* See the submission of Germany to thirtieth session of the SCP.

220 Decision of September 6, 2018; docket No. 3 LiQ 1/18.

221 BGH, judgement of July 11, 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir.* See also a submission of Germany to the thirtieth session of the SCP.

222 The infringement proceedings were stayed, because at that time, an appeal was still pending before the Board of Appeal of the European Patent Office. Eventually, on October11, 2017, the patent in dispute was revoked by the Board of Appeal of the European Patent Office.

This decision was confirmed by the Federal Court of Justice in its "Raltegravir" decision of July 11, 2017. After having decided that the first requirement of Section 24(1) of the Patent Act was fulfilled, i.e. the applicants had made sufficient efforts in the previous unsuccessful negotiations in order to obtain a licence from the defendant, the Federal Court of Justice turned to the second requirement provided in Section 24(1)2 of the Patent Act which states that such a license shall be granted where "the public interest calls for the grant of a compulsory licence". The Court reviewed a public interest requirements in conjunction with the continued availability of the active substance Raltegravir. In particular, the Court stated that a public interest prescribing the grant of a compulsory licence can be confirmed when a medicament used to treat serious illnesses displays therapeutic characteristics that the medicaments available on the market do not possess, or not in the same degree, or when its use avoids undesirable side effects that must have to be taken into account in connection with the administration of the other therapeutic medicines. On the other hand, a compulsory license is unjustified if the public interest can basically be met with other, alternative substances.

The Federal Court of Justice stated, *inter alia*, that public interest could also be present if only relatively small groups of patients were affected. The Court considered it particularly important that Isentress® had been on the market for many years and had found widespread use. Thus, for a large number of patients, a change in therapy would be associated with a considerable risk of side effects. The Federal Court of Justice therefore confirmed that the public interest condition was met.

159. In South Africa, in considering the meaning of "public interest", the court quoted the statement of Luxmoore J in *Brownie Wireless* that the term must "be construed in its widest meaning, namely, the interest of the community including every class which goes to constitute that body, namely, the purchasing public, the traders and the manufacturers, the patentee and the licensees, and inventors generally, (and not) be construed simply with regard to the purchasing public."[223]

(ii) Grant of compulsory licenses on the ground of national emergency or circumstances of extreme urgency

160. Some laws provide for the possibility of compulsory licenses specifically on the grounds of "national emergency" or "circumstance of extreme urgency". [224]

161. In India and Hong Kong (China), the examples of such circumstances may include public health problems resulting from "HIV/AIDS, tuberculosis, malaria and other epidemics".[225] In the Republic of Moldova, the term "extreme situation" is 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".[226] In Serbia, the circumstances of "national emergency" or "circumstances of extreme urgency" were defined in the legislation as public emergency which "endangers the survival of the state or its citizens".[227] 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". In Mexico, "national emergency or security" includes "serious diseases declared as a priority by the General Health Council".[228] In Brazil, the term "national emergency" is understood as the imminent public danger, even if it happens only in part of the national territory.[229]

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223 *Sanachem (Pty) Ltd v British Technology Group PLC* 293.

224 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.

225 Section 92(3) of the 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.

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

227 See response to question 77 of the Questionnaire from Serbia.

228 Article 77 of the Law on Industrial Property of Mexico.

229 Article 2 § 1 of the Decree No. 3.201, available at: http://www.planalto.gov.br/ccivil_03/decreto/D3201.htm.

162. In some other countries, 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 […]",[230] "war, uprising, or other similar emergency",[231] "disasters, catastrophes or big accidents",[232]or "national security, public interest protection in the field of health, food supplying, environmental protection and improvement, specific commercial interest".[233]

163. In some laws, the requirement to make efforts to obtain authorization from the right holder on reasonable terms and conditions in cases of national emergency or other circumstances of extreme urgency is waived.[234] However, in such situations, according to the national provisions, the right holder shall be notified as soon as "reasonably practicable" or "possible".

(iii) Grant of compulsory licenses on the ground of public non-commercial use/Government use

164. In general, public non-commercial use refers to uses by (or for) governments for the purposes which benefit the general public and are non-commercial in nature, even if the patent is used by a private party.[235] Typically, such uses are referred to as "government use" under which the government, or a third party authorized by the government, uses a patented invention without authorization of the patent holder under certain circumstances.

165. 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".[236] 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".[237]

166. In the United States of America, in case of government use, i.e., "[w]henever 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".[238]

167. In many countries, government use is permitted if the public interest, such as national security, nutrition, health or the development of other vital sectors of the national economy so requires or if the government use adequately remedies the anti-competitive practice engaged by the patentee or his licensee.[239] For example, in the Russian Federation, the use of the patented invention by the government

230 Article 80 (1) of the Patent Law of Bosnia and Herzegovina.
231 Article 106(2)(i) of the Korean Patent Act.
232 Article 12 of the Patent Law of the Kyrgyz Republic.
233 Article 68(6) of the Patent Act of Croatia.
234 For example, India, Grenada, Iran and Kenya.
235 See, e.g., Daniel Gervais, "The TRIPS Agreement. Drafting History and Analysis", p. 395; Pier DeRoo "Public Non-Commercial Use' Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs", Michigan Journal of International Law, V. 32, Issue 2, 2011, p.351.
236 Section 99, Chapter XVII of the Indian Patents Act.
237 Section 163(3) of Chapter 17 of the Patents Act of Australia.
238 Title 28, Section 1498(a) of the United States Code. This provision acts as a codification of a defense in litigation between private parties. Consequently, where an infringement action is found in the performance of a Government contract, the recourse for the patentee is limited to a recovery of reasonable compensation through litigation against the US Government at the US Court of Federal Claims.
239 See, for example, the responses to the Questionnaire from Algeria, Burkina Faso, Djibouti, Pakistan, Malaysia and Kenya.

is allowed in the interest of national security.[240] In France, the State may at any time obtain *ex officio* license, in order to meet its defense requirements, a license to work an invention that is the subject of a patent application or a patent, whether the working is to be done by the State itself or on its behalf.[241] In Thailand, the relevant provision states "[i]n order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee".[242] The response from New Zealand, in relation to government use, noted that "while the applicable law refers to matters of national security or national emergency, it does not specifically exclude the other grounds".

168. In the United Kingdom, certain acts are exempted from infringement if they are carried out in the United Kingdom by a government department, or any person authorized in writing by a government 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".[243] In addition, the Crown use can be invoked during a period of emergency for any purpose "which appears to the department necessary or expedient –

> (a) for the efficient prosecution of any war in which Her Majesty 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 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 country or territory outside the United Kingdom which is in grave distress as the result of war; and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes."[244]

169. With regard to the objectives of government use provisions, 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." In the United States of America, the objective of the government use provision is to permit the Government "to procure devices or services that it needs for its own governmental purposes […]".[245] 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".

170. In Congo, the government use objectives relate 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".

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240 Article 1360 Civil Code of the Russian Federation.
241 Article L613-19 of the French Intellectual Property Code.
242 Section 51 of the Patent Act of Thailand 1979.
243 Sections 55(1) and 56(2) of the Patents Act of the United Kingdom.
244 Section 59 of the Patents Act of 1977 of the United Kingdom.
245 See response of the United States of America to question 84 of the Questionnaire.

171. In some laws, the requirement to make efforts to obtain authorization from the right holder on reasonable terms and conditions, *inter alia*, in cases of public non-commercial use is waived.[246]

172. 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".[247]

173. Concerning the beneficiary, most countries have designated "the government" or government agencies and third parties authorized by government 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 person".[248] 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".[249]

174. Many laws that provide a government use exception stated that the patentee or the patent applicant shall be notified where reasonably possible and must be informed about the grant of the government use and its scope.[250] Some national laws require such notification "unless national security requires otherwise" or "unless it appears to the relevant authority that it would be contrary to the public interest to do so".[251] In some countries, the law stipulates that the decision to grant government use is made after hearing the owner of the patent and any other interested person.[252]

175. Many laws stipulate that the government use may be granted "at any time" even at the pre-grant stage of a patent.[253]

6. Challenges Faced by the Member States in Implementing the Exception Regarding the Compulsory Licensing

176. Most of the challenges addressed in a study contained in document SCP/26/5 relating to the use of patent flexibilities in general may be relevant to the implementation of the exception regarding the compulsory licensing. The challenges relating to the implementation of this exception may be of dual nature: (i) the difficulties encountered by the governments in the implementation or transposition of international law at the national level; and (ii) challenges faced by individual stakeholders in using the national legal framework, resulting from the government's enactment of the national law.

246 For example, Dominica, Lithuania.
247 See, for example, applicable laws of Albania, Argentina, Australia, Canada, Croatia and Madagascar.
248 See, for example, Albania, Canada, Lithuania, Indonesia and Kenya.
249 Title 28, Section 1498(a) of the United States Code.
250 See, for example, Article 51 Law No. 9947 on Industrial Property of Albania; 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.
251 Section 106 of Israel Patent Law 5727-1967 and Section 164 of the Patents Act 1990 of Australia, respectively.
252 See, for example, Section 80 of Industrial Property Act 2002 of Kenya and Section 84(4) of the Patents Act of Malaysia.
253 See, for example, Article 51 Law No. 9947 on Industrial Property of Albania; 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.

6.1 The difficulties encountered by the governments in the implementation of international law at the national level

Constructive ambiguity of international treaties

177. Constrictive ambiguity and vagueness of certain clauses in international treaties can lead to different interpretations, with effect, in turn, on the perceived scope of provisions thereby affecting the national implementation process. The possibility of interpreting the texts of international treaties often lead to different understanding about the full range of options available for their implementation. [254] For instance, one researcher finds that clauses regarding, among others, the compulsory licensing in international treaties showed unclear definitions or the lack of adequate explanations, thereby affecting the national implementation.[255] As discussed above, with respect to the TRIPS Agreement, the Doha Declaration has provided a clearer context for specific operational choices for the use of policy options under the TRIPS Agreement, including on compulsory licensing. [256]

Complexity of practical implementation of the Special Compulsory Licensing System

178. In response to the problem identified in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the TRIPS Agreement has been amended by incorporation of the text of the decision of the WTO General Council on August 30, 2003 (as Article 31*bis*).[257] Since the system has been used only once as to date, some WTO Members have expressed the view that the System is overly complex and have questioned its practical applicability. [258] In addition, some academic publications also question the effectiveness and appropriateness of the system to address the problem it was intended to solve.[259]

179. In this regard, various views have been presented as regards to the operation of the system.[260] The entry into force of Article 31*bis* of the TRIPS Agreement has spurred a renewed discussion in the WTO TRIPS Council as to how to make effective use of the System and to overcome any constraints on its use.[261] While the reasons for the limited use of the System are still under consideration, it could be more

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254 See, for example, Bulletin of the WHO, *Access to AID Medicines Stumbles on Trade Rules*, available at: http://www.who.int/bulletin/volumes/84/5/news10506/en/; Anand Grover, *Promotion and Protection of all Human Rights, Civil, Political, Economic. Social and Cultural Rights. Including the Right to Developmen*t, Report of the Special Rapporteur on the Rights of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 2009; Monirul Azam, *Intellectual Property and Public Health in the Developing World*, 2016, p.16; Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005; and Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012.

255 Kyung-Bok Son et al., *The trends and constructive ambiguity in international agreements on intellectual property and pharmaceutical affairs: Implications for domestic legislations in low- and middle-income countries,* Global Public Health 13(4), June 2017. In particular, authors assessed constructive ambiguity in international agreements including the TRIPS Agreement, Korea-United States Free Trade Agreements, and Trans-Pacific Partnership Agreements on Intellectual Property.

256 WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 73.

257 See pages 9 and 10 of this paper.

258 TRIPS Council, Minutes of the Meeting, IP/C/M/84/Add.1, paragraph 64 and IP/C/M/83 Add.1, paragraphs 152, 154 and 169. As regards the views of some commentators, see UNDP, *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement*, 2010, p. 35-36; and Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, The International Bank for Reconstruction and Development (IBRD), The World Bank, 2008.

259 See, e.g., C. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, South Centre Policy Brief, No. 57, January 2019.

260 The views expressed by WTO Members on the operation of special export compulsory licensing system can be found in WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation, Intersections between Public Health, Intellectual Property and Trade*, 2012, p.179 and 180.

261 TRIPS Council Minutes of Meeting, IP/C/M/85.

widely used in the future, for example, following the introduction of the product patent regime in key potential exporting countries, or in the case of a pandemic or some other health security events where effective medicines may be patented in all major supplier countries.[262]

180. Another recent factor is the increasing number of countries, that are traditional exporters of medicines, have introduced new legislation to enable exports under the System. It is expected that those developments support demands from Members to look into how to make the System effectively work in practice. The WTO Secretariat notes that, setting aside the broader policy debate, compulsory licensing cannot function as a practical stand-alone tool for medicines procurement in the absence of other factors such as, production capacity, regulation for safety, quality and efficacy, economies of scale, and procurement policies.[263, 264] The absence of the economic incentives for generic manufactures to use the system is also pointed as a factor restricting its use in some academic publications. [265]

Operation of law and administrative framework

181. In general, national implementation of international treaties includes not only the passing of legislation, but also execution and operation of the law by administrative bodies and courts. For the operation of law, sufficient details are required in order to ensure legal certainty and predictability.

182. In addition, the successful operation of the law is most likely underpinned by simple, straightforward, inexpensive and transparent administrative and judicial procedures, which are available to those who need them to make use of the system, enforce their rights or, as third parties, defend their interests.[266] For example, it was noted that, in many instances, the high cost of litigation and the timeframes to reach finality on matters relating to compulsory licenses remained a deterrent to making use of this exception.[267]

183. In addition, where more than one administrative body is involved in the procedures for determining grant or refusal of compulsory licenses, the clarity of their responsibilities and mandates might be also important for a clear decision-making process.

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262 See submission of WTO summarized in document SCP/25/3.

263 Background note prepared by the Secretariat of the WTO to the UN Secretary-General's High-Level Panel on Access to Medicines: http://www.unsgaccessmeds.org/reports-documents/. Reviewing this question, the Trilateral Study observed: "The special export licence [under the TRIPS amendment] is one legal pathway that can be followed when it represents the optimal route to effective procurement, but, as for any compulsory licence, it does not in itself make the production of a medicine economically viable. Sufficient scale and predictability of demand are prerequisites for making it practically and commercially viable for companies to undertake the regulatory, industrial and commercial steps required to produce and export a medicine under such a licence. Regional approaches to procurement and joint notifications by countries with similar needs for accessible medicines may offer pathways to aggregating demand under the System, thus enabling an effective response to the needs identified."

264 Capacity building workshops organized by the WTO have also been focusing on how to make effective use of the System in practice. The summary of findings can be found at: https://www.wto.org/english/news_e/news16_e/trip_28oct16_e.htm.

265 See, e.g., Carlos M. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, South Centre, January 2019. The author states "The main hypothesis that may be advanced relates to the barriers that the system creates for potential suppliers to exploit economies of scale. Since the markets that may be supplied (in countries where there is insufficient or no manufacturing capacity in pharmaceuticals) are small, generic producers are unlikely to be interested in becoming involved in complex legal procedures when there are no chances for economies of scale to recoup the investment made and generate at least a reasonable profit."

266 See also Articles 41.2 and 62 of the TRIPS Agreement.

267 See submission of Companies and Intellectual Property Commission of South Africa to the twenty-seventh session of the SCP. The Yousuf A Vada paper also states "Another reason for the paucity of such applications may be the judicial procedure required, involving not inconsiderable cost, especially for relatively small entrepreneurs who may be precluded from challenging patent holders, particularly multinational corporations, by the risks entailed in entering the market and the high costs of litigation." *Compulsory Licensing Jurisprudence in South Africa: Do We Have Our Priorities Right?* South Centre, December 2018, p.19.

Institutional capacity

184. The insufficient local legal and technical expertise to incorporate and implement the flexibilities contained in international treaties into the national law is one of the major challenges in making use of those flexibilities, including compulsory licensing. For example, the Delegation of Algeria on behalf of the African Group stated that "[…] the majority of developing countries did not have the technical capacity to make use of those flexibilities, for example, compulsory licensing".[268, 269]

185. In addition, the effective use of compulsory licensing mechanisms in the health area may also depend on the existence of robust public health institutions which could monitor diseases burden, medicine sales, availability of medicines etc. It was reported that in many developing countries, there is no institutional mechanism to monitor the impact of patented drugs on access to medicines, allowing timely invocation of necessary measures, such as compulsory licenses.[270]

186. At the sixteenth and twenty-fourth sessions of the SCP, the African Group proposed a work program for the SCP under the agenda item, Patent and Health, which sought to enhance the capacity of developing countries and LDCs to adapt their patent regimes and make full use of flexibilities in the international patent system to address public policy priorities related to public health. One of the elements of the proposed work program is the provision of targeted technical assistance to Member States, particularly to developing countries and LDCs. [271]

187. The need to provide technical assistance and capacity building for using TRIPS flexibilities, tailored to a specific country's context, has been stressed in other international fora, including the WHO and WTO.[272] In addition, focusing on the use of flexibilities in general, a number of publications highlight that lack of capacity is one of the challenges in the use of such flexibilities, and stress the need to invest in national capacity building and technical expertise through various training programs, targeting various stakeholders in developing countries and LDCs. [273]

188. In accordance with Recommendation 14 of the Development Agenda[274], WIPO, has been assisting countries on the implementation of their intellectual property legal system and the understanding and use of TRIPS flexibilities, taking into account specific country's circumstances and needs.[275] In addition,

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268 Document SCP/19/8, paragraph 91.

269 Similarly, the Delegation of Nigeria also noted that "[…] the lack of capacity to fully comprehend the full range of the flexibilities that could be implemented raised concerns about costly violations of existing agreements". Document SCP/25/6/Prov., paragraph 165.

270 The submission of TWN, document SCP/25/3, p.6.

271 See documents SCP/16/7, SCP/16/7 Corr. and SCP/24/4.

272 Recently, the need to reinforce technical assistance and capacity building to Members of the WTO was raised by some Members during the WTO TRIPS Council extraordinary session on January 30, 2017, which was held on the occasion of the entry into force of Article 31*bis* of the TRIPS Agreement. Some Members referred to the WHO-WIPO-WTO Trilateral Cooperation as part of the increasing international efforts to improve the ability of developing countries and LDCs to have access to medicines and a source of technical assistance provided by international organizations and individual countries. TRIPS Council Minutes of Meeting, IP/C/M/84/Add.1.

273 See the Report of the United National Secretary-General's High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, 2016, p.24; Bulletin of the WHO, *Access to AID Medicines Stumbles on Trade Rules*, available at: http://www.who.int/bulletin/volumes/84/5/news10506/en/; Monirul Azam, *Intellectual Property and Public Health in the Developing World*, 2016, p.16; and Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005; Management Science for Health, *Managing Access to Medicines and Health Technologies*, 2012, p.3.11, available at: https://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf; Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012, p. 10; and Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, The South Centre, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/.

274 Recommendation 14 of the Development Agenda states that "[w]ithin the framework of the agreement between WIPO and the WTO, WIPO shall make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement."

275 See document SCP/18/5.

WIPO's technical assistance and capacity building activities cover not only drafting national legislations, but also aim at supporting judiciary and governmental agencies for their execution and operation of national law. They include staff of IP offices and health authorities as well as officials involved in IP discussions in various bilateral, regional and multilateral fora.

National governance and internal coordination

189. The implementation of various provisions contained in international treaties into the national law, in particular, on compulsory licensing, requires the involvement of various government departments and ministries, such as patent offices, ministries of health and trade, and drug regulatory authorities. In some countries, reportedly, their activities are not necessarily coordinated in order to pursue common policy goals, creating tensions between, for example, ministries responsible for the promotion of trade and the protection and enforcement of intellectual property and those responsible for public health.[276] Various publications have stressed the need to take a nationwide collaborative approach, involving all stakeholders for effective implementation of the TRIPS flexibilities into national laws.[277] In this regard, joint capacity building activities by the WHO, WTO and WIPO, involving government officials from health, trade and IPR sectors have been carried out with a view to facilitating interdepartmental coordination.

190. Additionally, one study concluded that policy approaches utilizing TRIPS flexibilities within low-income countries depend upon functioning governance, which requires the necessary administrative resources and authority to implement health policies and regulations. The authors found that developing countries often lack these basic capacities, making it difficult for them to meet basic public health needs.[278]

Extrinsic influences

191. During the SCP sessions, some Member States and non-governmental organizations reported on cases of political and economic pressure from some other countries and/or pharmaceutical industries which had intervened to the governments' decision making process to issue compulsory licenses.[279] Some publications also cite those cases, most of which are the cases of Brazil, India, South Africa and Thailand, and recently of Colombia.[280] [281]

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276 The Report of the United National Secretary-General's High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, p.24. See also a paper by Patrick L. Osewe et al., which reports that in most developing countries in Africa, national coordination systems on IP issues are generally weak or non-existent. Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, International Bank for Reconstruction and Development and World Bank 2008.

277 Ibid.

278 Cindy Bors *et al*., *Improving Access to Medicines in Low-Income Countries: A review of Mechanisms*, the Journal of World Intellectual Property (2015) Vol. 18, no. 1-2.

279 See, e.g., the statements made by the Delegation of South Africa at the 20th session of the SCP (document SCP/20/13), the Representatives of Knowledge Ecology International (KEI) at the 24th session of the SCP (document SCP/24/6) and the Representatives of Médecins Sans Frontières (MSF), KEI and Third World Network (TWN) at the 25th session (SCP/25/6 Prov., paragraphs 28, 52 and 53).

280 Anand Grover, *Promotion and Protection of all Human Rights, Civil, Political, Economic. Social and Cultural Rights. Including the Right to Developmen*t, Report of the Special Rapporteur on the Rights of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 2009; Monirul Azam, *Intellectual Property and Public Health in the Developing World*, 2016, p.17; Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012, p. 11; and Civil Society submissions to the United States Trade Representative (USTR) Special 301 hearing, available at: http://keionline.org/node/2735. See also a paper by Laurence R. Helfer et al., which reported on three cases where countries members of the Andean Community have faced pressure from the United States of America and pharmaceutical companies in the use of TRIPS flexibilities. Laurence R. Helfer et al., The *Influence of the Andean Intellectual Property Regime on Access to Medicines in Latin America***,** in Balancing Wealth and Health: Global Administrative Law and the Battle over Intellectual Property and Access to Medicines in Latin America (Rochelle Dreyfuss & César Rodríguez-Garavito, eds. 2013).

281 See document SCP/27/6.

192. However, one author, [282] while noting the concerns about possible negative reactions from developed countries' governments and their implications for trade or political relations, questions the true effect of such extrinsic influences.

6.2 Challenges faced by various stakeholders in using a national legal framework

193. Some Member States and academic publications point to challenges faced by various stakeholders in using a national legal framework once the government has implemented the policy options provided in the international agreements regarding the compulsory licenses. In particular, many of such debates relate to the challenges faced by individual stakeholders in obtaining and using compulsory licenses for manufacturing or importing a generic version of medicines, aiming at increased access to such medicines. Those challenges are described in the paragraphs below.

Ambiguity and uncertainty of national law

194. There is no doubt that clarity of national law, sufficient depth of implementing regulations, simplified and transparent administrative and judicial procedures, and a clear decision-making process positively affect the use of national legal framework by various stakeholders. Some academic publications refer to those aspects with respect to the use of compulsory licenses. [283]

195. For instance, while provisions on compulsory licensing are found in a great number of countries, it was observed that in many countries, the procedural aspects relating to such licenses are not spelled out in details under the national legal frameworks, or at least, are difficult to find . This issue was also highlighted in the submission of Costa Rica which stated that the challenge for the Industrial Property Registry is to establish the procedure to review the conditions under which the license may be granted, limitation of the scope of the license, its duration and the economic remuneration to be received by the right holder.[284] As regards the compulsory licensing provisions in the laws of least-developed countries, one paper notes that in some cases, conditions for the grant of such licenses as well as related procedural requirements are restrictive and burdensome.[285]

Technical capacity

196. The use of various provisions in the national/regional laws by various stakeholders at the practical level requires not only a supportive and coherent legal framework, but also technical resources and expertise of users.

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282 Carlos M. Correa, *The Use of Compulsory Licenses in Latin America*, The South Centre, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/. Referring to the cases of Ecuador and Indonesia, which had granted several compulsory licenses without any known negative repercussions, the author stated that such concerns might be exaggerated. The author noted that no complaints had been submitted against countries that granted such licenses under the WTO dispute settlement rules indicating their legitimacy under the TRIPS Agreement, particularly after the confirmation made by the Doha Declaration.

283 See also Mohammed El Said and Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy,* 2012, p. 9; Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, The International Bank for Reconstruction and Development (IBRD), The World Bank, 2008; and Sisule F. Musungu and Cecila Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?,* Commission on Intellectual Property Rights, Innovation and Public Health, WHO, August 2005.

284 See the submission of Costa Rica to the thirtieth session of the SCP. The submission therefore suggests that it is essential to study comparative law on this topic.

285 LDC Watch submission to the High- Level Panel on Access to Medicines, February, 2016, available at: http://www.unsgaccessmeds.org/inbox/2016/2/28/prerna-mingma-bomzan?rq=OAPI.

197. In addition to a good knowledge of the legal norms concerning compulsory licensing by the users of the system, the technical and technological knowledge of the product concerned, and practical legal expertise in other disciplines can be indispensable in order to steer the process. Particularly, where a compulsory license is sought for importation of the medicine, not only the laws pertaining to health and intellectual property but also trade law would be involved.

198. The responses from Uganda, the United Republic of Tanzania and Zambia, indicated that in their respective countries, the insufficient or lack of technological capacity on the part of local industries to produce generic pharmaceutical products is a challenge with regard to the use of compulsory licenses.[286,287]

199. Furthermore, issuing a compulsory license has often been insufficient on its own to ensure access to the product. As stated by the Representative of OAPI, "the description only needs to present the means necessary for carrying out the invention: there is no requirement for the description to reveal those indications for the practical execution of the invention, i.e., execution know-how." Oftentimes, patent applications do not disclose the know-how necessary to develop a protected product. Therefore, even if a compulsory license to make the patented product has been obtained, further technological knowledge and substantial amount of experimentation may be required for the manufacturing of the required product at the commercial scale. [288, 289]

Identifying relevant patents and their status

200. In order to determine whether a compulsory license is necessary to legally manufacture or import a patented product, first, relevant patents covering that product should be identified, and then, the legal status of such patents should be determined. Particularly, in developing countries and LDCs, such information may not be easily accessible.[290] In addition, even if legal status information is made available to the public by the respective national/regional patent office, the varied format of such information makes it difficult for the users to access the data. Furthermore, a good knowledge of patent procedures in a given country is necessary to fully understand the legal status of the patent concerned. The difficulty faced by those who do not have sufficient technical and IP expertise in unequivocally identifying patents covering a specific product has been fairly known.

201. Some examples show how the lack of patent status of specific products may affect use of compulsory licenses. In Zambia, it was reported that a request for a compulsory license on a HIV medicine had been filed, because a requester was not certain about the existence of the relevant patents or patent applications in that country.[291] Argentina, in 2005, announced plans to issue compulsory licenses for an antiviral medication to allow local production of the product. However, it was reported that the patent covering that particular medicine was never granted in Argentina.[292]

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286 See document SCP/21/4, paragraph 66. The Questionnaire as well as the responses received from Member States are available on the website of the SCP electronic forum at: http://www.wipo.int/scp/en/exceptions/.

287 See document SCP/25/6/Prov., paragraph 58, as well as document SCP/25/3, paragraph 6. This point was also raised by Indonesia and the TWN with respect to use of exceptions and limitations in general. The TWN stated: "[…] a lack of technological capacities, especially manufacturing capability, prevents many WIPO Member States from using exceptions and limitations to patent rights. For instance, the vast majority of the developing countries and all LDCs, except Bangladesh, lack the manufacturing capacity in the pharmaceutical sector."

288 Submission of the OAPI to the 22nd session of the SCP.

289 See the statements made by the Delegation of Brazil in documents SCP/21/12, paragraph 58 and SCP/25/6, paragraph 48. See also Eric Bond and Kamal Saggi, *Compulsory licensing, price controls, and access to patented foreign products*, Department of Economics Vanderbilt University, April 2012, page 5, available at: http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf .

290 See http://www.medspal.org/. The WHO published a guide on how to conduct patent searches for medicines: http://apps.who.int/medicinedocs/en/d/Js17398e/.

291 The statement made by the Representative of KEI (document SCP/25/6, paragraph 52).

292 See Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, p.72.

202. In some countries, patents may be granted by a national patent office as well as by a regional patent office. Synchronizing the national and regional patent status information would facilitate the provision of a complete picture of the patent status in a given country.[293]

203. The importance of establishing and maintaining publicly accessible databases with patent information status on medicines and vaccines has been highlighted in various fora, including in WIPO.[294] The Medicines Patents & Licenses Database (MedsPaL) as well as Patent Information Initiative for Medicines (Pat-INFORMED) are databases which allow users to obtain information on, *inter alia*, patent status of certain medicines in specific countries.[295, 296] The discussions on such databases are highly supported by the Member States, and they generally encourage various initiatives that would make the patent system more transparent and facilitate access to legal status information.[297]

204. In August 2017, The Committee on WIPO Standards adopted Standard ST.27: "Recommendation for the exchange of patent legal status data".[298] The Standard is intended to promote efficient exchange of patent legal status data in a harmonized manner between IP offices in order to facilitate access to the data by the offices themselves, IP information users, IP data providers and the general public.

205. As regards the Patent Cooperation Treaty (PCT), Rule 95.1 of the Regulations under the PCT require the notification by the designated Offices, within two months, or as soon as reasonably possible, of certain national phase processing events to the International Bureau. It allows access to timely and accurate information about national phase entry and other national phase events relating to the PCT international applications. The data collected is made available to the general public on the PATENTSCOPE website.[299]

Other aspects that affect the use of compulsory licenses

206. It was reported that the number of compulsory licenses granted not only in developed countries but also in developing countries and LDCs has been low. In some cases, the low number of such grants may not necessarily relate to constraints on its use as such, but may be due to other reasons described in paragraphs below.[300] Furthermore, some countries appear to find it appropriate to resort to this measure only in exceptional situations. For example, the submission of Brazil in this regard states that "despite being provided for in the TRIPS Agreement and Brazilian legislation, the compulsory license has been used as the last alternative of the Brazilian Government, only in extreme cases [when certain conditions are not satisfied]."[301]

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293 Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, 2008 The International Bank for Reconstruction and Development , The World Bank, p. 23.

294 See, e.g., the Report of the UN High-Level panel on Access to Medicines.

295 MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in developing countries.
See: https://www.medspal.org/?page=1.

296 Pat-INFORMED currently provides information on key patents for all small-molecule products submitted by the participants in the Initiative. The following therapeutic areas are covered: HIV/ AIDS, Cardiovascular diseases, Diabetes, Hepatitis C, Oncology, Respiratory conditions; and all products on the WHO Essential Medicines List (EML) that are not within these six areas. See: https://www.wipo.int/pat-informed/en/.

297 Delegations of Argentina, Brazil, Chile and Switzerland proposed a regular update on publicly accessible databases of patent status information concerning medicines and vaccines to be carried out in WIPO, which was supported by many Member States. See document SCP/28/10 REV. and SCP/29/8 Prov.

298 The standard was revised in October 2018.

299 For further information, see https://www.wipo.int/patentscope/en/data/national_phase/procedures.html.

300 Ellen F.M 't Hoen, in *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, presents data on compulsory licenses and government use authorizations granted between 2001 and 2014.

301 See a submission from Brazil to the thirtieth session to the SCP.

(i) No patents

207. Whether to file a patent application in a specific country or not is primarily an economic and business decision of the technology holder. Therefore, patent applications on a specific products and processes may be filed in some countries but not in others. In addition, since the patentability criteria are not exactly the same in all countries, a patent may be granted on a given invention in some countries, but not in others. One of the main reasons behind the low number of compulsory license grants in the East African Community was explained by the fact that all the pharmaceutical products produced and/or sold locally were generics.[302] Another study examining the use of compulsory licenses in Latin American countries noted that the reasons of limited use of such licenses in the region may relate to the fact that many medicines under patent protection in developed countries had not received protection in Latin America in the pre-TRIPS era and, hence, the need for compulsory licenses and/or government use may have not been so pressing.[303] Confirming that view, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) states that, in reality, most pharmaceutical companies either do not patent in developing countries and least developed countries (LDCs) or do not enforce their rights in those jurisdictions.[304, 305]

208. Similarly, in relation to the implementation of the special export compulsory licensing system under the TRIPS Agreement, a study focusing on Africa reports that most countries in the region procure their first-line treatment for HIV/AIDS from India, where most of those medicines were not patented.[306] However, some WTO Members have expressed their concern that the implementation of full patent protection for pharmaceutical products in India, coupled with the expiry of the transition periods in LDCs, could make it more difficult in the future to procure generic versions of new medicines.[307]

(ii) No need to resort to a compulsory license

209. Some Member States reported that the small number of granted compulsory licenses can be related to the fact that the general possibility of issuing such licenses can lead to price reductions for pharmaceuticals or making them otherwise available, for example, through the voluntary licensing.[308] In this regard, the submission from Brazil states that, in most cases, public interest declaration of a drug in itself promotes the intensification of negotiations for price reduction. This measure represents a signal from the Government of the importance of the medicine to the Brazilian health system and the possibility of granting a compulsory license if the cost of treatment exceeds the budget.

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302 The author noted that the situation may change in future as they were moving to new treatment regimes. See *Policy Coherence to Boost East Africa Pharmaceutical Industry*, available at http://www.ip-watch.org/2015/10/02/policy-coherence-to-boost-east-africa-pharmaceutical-industry/.

303 South Centre, *The Use of Compulsory Licenses in Latin America*, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/.

304 See document SCP/27/6, p. 6.

305 As regards pharmaceutical patents, the research conducted by the University of Ottawa on the WHO Model List of Essential Medicines (MLEM) found that, of the 375 items on the 2013 WHO MLEM, 95% are not under patent protection in most lower-income countries, meaning that patents with respect to these medicines have expired, or were not filed in the first place. Authors noted, however, that in the long-term, the proportion of patented products on the MLEM would likely increase. Reed F Beall and Amir Attaran, *Global Challenges Report: Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines*, WIPO, available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=334437.

306 Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, The International Bank for Reconstruction and Development, The World Bank, 2008.

307 WHO, WIPO, and WTO Study, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, 2012, p. 179, indicating observations made by the WTO members on whether the special export compulsory licensing system is fulfilling its intended function. Following a decision taken by the WTO General Council on November 30, 2015, the transitional period applies until January 1, 2033 (WTO document WT/L/971).

308 See the submissions of Germany and Brazil to the thirtieth session of the SCP.

210. Similar effect of compulsory licensing provisions have been reported in other countries. In Kenya, a local company applied for a compulsory license after taking measures to obtain voluntary licenses from the patentees. It led to the negotiations between the local company and the patentees, and to the conclusion of voluntary licenses, without having a need to issue a compulsory license.[309] In Latin America, some cases where the announcement of the intention to use compulsory licenses led to price reductions for medicines without the need to resort to compulsory licenses are also documented.[310]

211. Furthermore, it was reported that, in some cases, the governments may not see the need to issue compulsory licenses, because national treatment programs were being sustained by health financing mechanisms, such as the Global Fund and The U.S. President's Emergency Plan for AIDS Relief (PEPFAR).[311]

Other challenges where use of compulsory licensing provisions may not lead to intended policy outcomes

212. In general, implementation of the provision on compulsory licensing in national law and its use in specific circumstances is not a guarantee that it would achieve other important policy objectives such as public health and nutrition. In reality, various factors other than patents *stricto sensu* may affect the intended policy goals.

213. First, as reported by several Member States, the lack of technological capacity in developing countries was one of the issues that may be relevant to the use of technology in general. Some commentators note that not many developing countries have domestic technological, productive and regulatory capacity to reverse engineer and manufacture the pharmaceutical product without the assistance of the patent owner. [312]

214. In addition, developing and bringing a generic product to market requires a substantial investment, even if generic producers do not need to incur R&D costs. Economies of scale and associated marketing costs are just a few examples of economic factors that might affect return on investment and consequently, business decisions of generic producers.[313,314]

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309 Document SCP/20/13, paragraph 104.

310 Carlos Correa, *The Use of Compulsory Licenses in Latin America by* Carlos M. Correa, 2013, available at: https://www.southcentre.int/question/the-use-of-compulsory-licenses-in-latin-america/. See also Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, p.71.

311 The Report of the United National Secretary-General's High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, September 2016. The Report notes that as of September 2015, PERFAR was supporting antiretroviral treatment for nearly 9.5 million people worldwide and that as of mid 2015, the Global Fund has provided HIV/AIDS treatment to 8.6 million people. See footnote 120 of the Report, p.45. See also Patrick L. Osewe et al.,*Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, 2008 The International Bank for Reconstruction and Development, The World Bank, p. 14.

312 A paper by Beatrice Stirner and Harry Thangaraj notes in this regard that, Brazil which issued a compulsory license is a relatively affluent developing country, which has private and public sector reverse engineering capacities to manufacture antiretrovirals and other medicines. Not many developing countries can act under comparable conditions such as a domestic technological, productive and regulatory capacity to reverse engineer and manufacture the pharmaceutical product without the assistance of the patent owner. See Beatrice Stirner and Harry Thangaraj, *Learning from practice: compulsory licensing cases and access to medicines*, Pharm. Pat. Analyst (2013) 2(2), 195–213.

313 One paper also notes that "issuing a successful CL depends on a willing licensee who is able to develop the product, register it, and bring it to market. Companies might be willing to do this in larger and richer countries, but the economic incentives are weak in smaller and poorer countries. Single-country licenses are ineffective to incentivize robust generic competition by multiple licensee/entrants competing at efficient economies of scale producing sustainable cost savings". See a submission of the Health Global Access Project to the UN High-Level Panel on Access to Medicines.

314 The academic literature also notes other challenges. For example, one study notes that in addition to the issue of local capacity to manufacture or distribute AIDS medicines, more serious health policy problems exist in relation to access to such medicines: even non-patented drugs have not been easily accessible, they have expired in the central storage facilities or they have been misappropriated. See Ben Sihanya, *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya,* available at: https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm.

215. Furthermore, as regards the compulsory licenses in the area of medicines, as this area is highly regulated to achieve safe and quality-assured medicines, the manufacture of the medicines under compulsory license without meeting such quality standards, will not lead to the intended purpose of improving access to those medicines. For example, a couple of cases were reported from Kenya and Zimbabwe where, although a compulsory license had been issued, local production of medicines was not successful because of the difficulties in meeting the WHO prequalification quality standards.[315, 316]

216. In addition, in countries where test data protection in the form of data exclusivity is available, some measures may be necessary for the effective use of the compulsory license.[317, 318] Unless the national law specifies that data exclusivity may not be invoked when a compulsory license is granted, the needed products may be not authorized for commercialization.[319] This also applies to the situation where a country requires regulatory review of products destined for export under the special export compulsory licensing system.[320] Therefore, some countries provide for such explicit data exclusivity waiver in their laws, with a view to facilitating generic medicines registration. For example, Malaysia, Chile and Colombia do not provide data exclusivity if making, etc., of the product is allowed under a compulsory license.[321] In the European Union, data protection waiver exist in relation to products produced under compulsory licenses for export to countries with public health problems.[322]

7. Results of Implementation of the Exception Regarding the Compulsory Licensing

217. While there are inherent difficulties in collecting precise information on the number of compulsory licenses' requests and grants per country as reported by Member States, the mechanism has been rarely used, considering the total number of patent grants.[323] However, it does not mean that such requests

315 The statements made by the Delegations of Kenya and Zimbabwe during the sharing session on countries' use of health-related patent flexibilities, paragraphs 104 and 108 of document SCP/20/13, respectively.

316 Patrick L. Osewe et al., *Improving Access to HIV/AIDS Medicines in Africa, Trade-Related Aspects of Intellectual Property Rights Flexibilities*, 2008, The International Bank for Reconstruction and Development, The World Bank, p.xv. The author reports: "With respect to local production of HIV/AIDS medicines, country experiences in Ghana, Kenya and Zimbabwe reveal major challenges: the high cost of bioequivalence tests for each product, required for prequalification by the WHO; the high cost of active pharmaceutical ingredients (APIs) when purchased in small quantities; and the inadequate market share and lack of economies of scale. The latter, in turn, are related to an inability to supply under the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) when manufacturers lack WHO prequalification for their products. These factors have rendered local production unsustainable in the medium to long term."

317 In some countries a data exclusivity regime prevents, for a certain period of time, the regulatory authority from relying on the originator's clinical test data to approve a generic/biosimilar version of the originator product. In effect, it prevents generic drug manufacturers from cross-referring the data submitted by the originator.

318 See, e.g., Ellen F. M. 't Hoen et al., *Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation*, Journal of Pharmaceutical Policy and Practice, June 2917.

319 For example, in 2016, the issuing of a compulsory license was considered by the government of Romania for the hepatitis C medicine sofosbuvir, but the idea was reportedly not pursued because EU data exclusivity would expire only in 2024. See Ellen F. M. 't Hoen et al., ibid.

320 C. Correa, *Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?*, South Centre Policy Brief, No. 57, January 2019.

321 Section 5 of Malaysia 2011 Directive of Data Exclusivity, Article 91 of Law 19.996 of Chile, Article 4 of Decree 2085 of 2002 of Colombia.

322 Article 18 of EC Regulation No 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

323 According to the responses to the Questionnaire by the Member States, few or no requests for compulsory license had been made and licenses granted in most of the jurisdictions. See also the Report by the European Patent Academy on Compulsory Licensing in Europe, 2018, as regards to the information on the technological fields and number of such licenses granted in the Member States of EPO.

and grants are limited to a specific technology area in few jurisdictions.[324] During the last decade, the available data show that the use of compulsory licenses has been more frequent in relation to pharmaceutical patents.

218. Although the number of issued compulsory licenses per country may be low, some Member States pointed out that the overall assessment of the impact of the implementation of such provisions under the national law should take into account the fact that the existence of such provisions, or announcement of intention to invoke such provisions, promotes willingness on the side of the patentees to conclude licensing agreements. Thus, the potential to issue compulsory license can be part of the policy tool.

219. This happened in the case of Brazil in 2005, when the Government decreed public interest in the Kaletra® medicine. After two weeks of negotiations, the patentee accepted the proposal to reduce the price of Kaletra® and the granting of a compulsory license was no longer necessary. At the time, only for this product, the Brazilian Government was spending about 30% of the budget reserved for the purchase of antiretrovirals.[325] Similarly, it was reported that when Canada and United States of America had announced compulsory licenses relating to ciprofloxacin to respond to a possible anthrax outbreak in case of terror attacks in 2001, the patent holder responded with price discounts and commitments for the supply of stockpiles.[326]

220. Where compulsory licenses have been granted in the area of medicines, in many instances, they have been reported to have resulted in substantial reduced prices. For example, the following cases are some of the reported outcomes in some countries:

- Brazil: the compulsory license relating to antiretroviral drug efavirenz in 2007 reduced spending in 2007 by about 30 million US dollars, and that the estimated savings for the Brazilian government by 2012 had reached $236.8 million US dollars.[327]
- Ecuador: as a result of compulsory licenses granted in 2014 for the patents on antiretroviral drugs, Ecuador had achieved between 30% and 70% in savings for the Ministry of Health.[328]
- Thailand: the assessment carried out by the government on the effect of the compulsory license with regard to a cancer drug imatinib concluded that by 2009, the increased availability of that drug in the Thai health care system resulted in a gain of 2,435 quality adjusted life years.[329]
- India: the impact of the compulsory license issued in relation to sorafenib tosylate in 2012 is that the price charged for the drug produced under the compulsory license would not exceed $176 a month, which is about three percent of the price charged by the patentee.[330]
- Malaysia: a government use license issued for the patents covering HIV/AIDS medicines (didanosine, zidovudine, lamivudine and zidovudine combination) in 2004 expanded government program's treatment capacity from 1500 to 4000 by reducing the cost of three patented medicines by 81%. This reduced the monthly cost of HIV treatment in Malaysia from $315 to $58 per patient.[331]

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324 See, e.g, the Report by the European Patent Academy on Compulsory Licensing in Europe, 2018.

325 See submissions of Brazil and Germany to the thirtieth session of the SCP.

326 Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016.

327 Document SCP/21/12, paragraph 58.

328 Document SCP/21/12, paragraph 59.

329 See Ellen F.M 't Hoen, *Private Patents and Public Health, Changing Intellectual Property Rules for Access to Medicines*, 2016, pp.66-70.

330 Gibson Dunn, Compulsory License Granted by the Indian Patent Office, available at: https://www.gibsondunn.com/compulsory-license-granted-by-the-indian-patent-office/#_ftnref1.

331 WHO, *Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context*, 2014, p.4, available at: http://apps.searo.who.int/PDS_DOCS/B5144.pdf, and Chee Yoke Ling, (2006), *Malaysia's Experience in Increasing Access to Antiretroviral Drugs, Exercising the Government Use Option*, Intellectual Property Rights Series, Third World Network, Malaysia, p.14.

221. Various national and international instruments also recognize the effect of the compulsory licenses on the prices of patented medicines. For example, the resolution of the European Parliament of March 2, 2017 on EU options for improving access to medicines, includes the use of compulsory licensing by EU Member States. Paragraph 51 of the resolution notes, *inter alia*, the fact that the WTO TRIPS agreement provides flexibilities to patent rights, such as compulsory licensing, *which have effectively brought prices down* (emphasis added).[332] Executive Decree No. 118 of Ecuador states that in order to ensure universal access to essential medicines "one of the strategies being the use of compulsory licenses *as an instrument for reducing the cost of medicines*" (emphasis added).[333]

222. At the same time, the argument on the side of the research-based pharmaceutical companies is that the grant of a compulsory license can have a chilling effect on their research in terms of undertaking risky R&D, potentially hurting patients who may require new and innovative life-saving therapies.[334] It is reported that only one new chemical compound out of 10,000 studies in the laboratory ultimately became a marketed medicine, which frequently required over ten years.[335] The mean cost of bringing a new medicine to market, including regulatory processes was estimated at over $1 billion.[336] From the perspective of the research-based pharmaceutical companies, the ability to keep the innovation going depends on the existence of adequate incentives to help offset the high risks and costs inherent in R&D, which come primarily in the form of intellectual property, particularly patents, in the pharmaceutical industry.[337] Thus, they state that compulsory licensing is not a sustainable approach for access to quality medicines, as it creates disincentive to develop a new medicine, go through a regulatory process and market the new medicine, which deny or delay patients' access to innovative products and hinder the introduction of good quality generic versions in the longer term.[338] At least one case has been reported where a pharmaceutical company, in response to the grant of a compulsory license, decided not to register new pharmaceutical products in that country.[339]

223. In relation to compulsory licenses in the pharmaceutical sector, price reduction and impacts on incentives for R&D are often mentioned as the direct results of the grant (or the possibility of grant) of such licenses. However, what kind of results a compulsory license has delivered may depend on the circumstances of each case. In the *Raltegravir* case in Germany (see Box 8), the direct outcome of the compulsory license was continued access to a specific medicine, which would otherwise infringe the patent, for a certain patient group. In case of dependent patent situations, the direct outcome of a compulsory license would be availability of technically advanced products for consumers. Therefore, the result achieved by each compulsory license may need to be analyzed against the backdrop of each case, avoiding the generalization of the effects that compulsory licenses might bring. In theory, the results of the implementation of compulsory licensing provisions under each specific circumstances should be in line with the general policy objectives and goals of a compulsory licensing mechanism in each country, as described in Chapter 2 of this paper.

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332 European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)), available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0061+0+DOC+XML+V0//EN.

333 Executive Decree No. 118 of Ecuador on Declaration of Public Interest Regarding Access to Medicines for Human Use.

334 See http://www.businesswire.com/news/home/20070504005566/en/Merck-Statement-Brazilian-Governments-Decision-Issue-Compulsory; and *The campaign for use of compulsory licensing in Thailand*, available at: http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/.

335 Report of the 21st session of the SCP (document SCP/21/12, paragraph162), Representative of IFPMA.

336 Idem.

337 Idem.

338 Report of the 15th session of the SCP (document SCP/15/6, paragraph104), Representative of IFPMA.

339 *The campaign for use of compulsory licensing in Thailand: "*In defiance of the compulsory license, Abbott laboratories withdrew all their medications awaiting registration in addition to refusing to register any new pharmaceutical products in Thailand. This denied Thailand access to Aluvia, the new heat resistant formula Kaletra, as no generic equivalent was on the market at the time."

224. The economic studies on the relationship between compulsory licensing and welfare in general or specifically in relation to the changes in pharmaceutical R&D are limited. Nevertheless, some of such studies are introduced in the following paragraphs.

225. One study based on a theoretical two-country model on the role of compulsory licensing in pharmaceutical innovation found that, if broadly used, compulsory licensing undermined incentives for innovation; however, the study clarified that this finding did not necessarily entailed a decrease in welfare.[340] The study showed that there were circumstances in which welfare effects increased globally when compulsory licensing was used, even in light of its effect on innovation.[341] In another study that assessed whether a decrease in patenting activity followed six compulsory licenses issued by the United States of America in the 1980s and 1990s, the results indicated that, in five out of six cases, patenting activities had continued at the same or at an even higher pace than prior to the issuance of the compulsory licenses.[342] With respect to one case in which the patenting activities declined, the author concluded that the result of that case supported the theory that predictable or anticipated compulsory licenses in significant markets were likely to decrease innovative efforts.

226. Further, a 2017 paper examines the impact of compulsory licences on drug accessibility in developing countries by addressing the three main dimensions of accessibility (availability, affordability and quality) and proceeding to a literature survey of key arguments for and against compulsory licence. The paper concludes that compulsory licence inhibits neither the availability of essential drugs nor the affordability of life-saving treatments or the supply of high-quality drugs in developing countries, in particular antiretroviral drugs.[343] Another study generally examining the results of increased patent protection on the speed of drug launch, quantity sold and price found that, on average, access to new pharmaceuticals increased with the adoption of the TRIPS Agreement.[344] The study used data in 59 countries from 2001 to 2011, and found that the price premium for patented products was lower subsequent to the implementation of the TRIPS Agreement, possibly reflecting an increase in the use of price controls, governments' bargaining power or the threat of compulsory licensing.[345]

227. However, other studies demonstrate that biopharmaceutical innovation relies on the availability of strong IP incentives. A 2016 paper that examined challenges and opportunities for developing the biotechnology sector in Colombia shows that deterioration of the IP environment for biopharmaceuticals, including the continued use of, or the threat to use, compulsory licensing or unilateral ad hoc price reductions through a notice of public interest, may deter clinical trials' sponsors and future investments in

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340 Charitini Stavropoulou, Tommaso Valletti, *Compulsory licensing and access to drugs* (European Journal of Health Economics, 2014). The "welfare" is defined as the sum of consumer surplus and the firm's profit.

341 This study employed a two-country model to examine the interaction between a "North" country in which a company held patents on a medicine and a "South" country which purchases that medicine from the company in the "North". The study's global welfare analysis demonstrated that global welfare increased under compulsory licensing of what the study referred to as "lower quality drugs" (drugs for which consumers are less willing to pay and with reduced market coverage) even when the "South" country is relatively large and therefore negatively influences global pharmaceutical R&D.

342 Colleen Chien, *Cheap Drugs at What Price to Innovation – Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?* (Berkley Technology Law Journal, Vol. 18, 2003). The author reported that out of the six companies subjected to compulsory licenses in the study's sample, only one (Merieux with respect to a United States of America Federal Trade Commission order to lease a rabies vaccine) showed a decline in patenting subsequent to the license. The author also finds that developing countries care about two categories of drugs, "global" drugs that are created for rich markets, but are also useful in developing countries; and drugs specific to developing countries. The paper cites researches that suggest that if compulsory licenses are taken in less significant markets, their impact on innovation should be marginal. For global drugs such as AIDS therapy, this would imply that compulsory licenses that are limited to developing countries (i.e. ancillary markets) and do not impact the target markets for the drugs (i.e., rich countries) might not be detrimental to research efforts in the rich developed countries.

343 S. Guennif (2017), *Is Compulsory Licensing Bad for Public Health? Some Critical Comments on Drug Accessibility in Developing Countries*, Appl. Health. Econ. Health Policy Oct;15(5):557-565.

344 Margaret Kyle, Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (WIPO Meeting Doc. WIPO/IP/ECON/GE/3/13/REF/KYLE, 2013).

345 Ibid.

the biopharmaceutical sector. The paper estimates that under the pessimistic scenario, where Colombia's biopharmaceutical policy environment deteriorates by at least 25%, Colombia could expect a decrease of anywhere between 20 and 46 clinical trials a year and total economic losses of up to 119 million USD.[346]

228. Other stakeholders also argue that the voluntary technology partnering and technology transfer on mutually agreed terms is the approach that advances technological innovation as well as the deployment of new solutions. The arguments continue that, in contrast, policies that encourage non-commercial technology transfer can inhibit innovation investments, FDI, and knowledge sharing. In particular, it is noted that, policy tools like compulsory licensing can undermine the role that IP rights can play in facilitating the critical exchanges of knowledge that are most likely to boost absorptive capacity and economic development, especially in developing countries. Thus, it is argued that such instruments should be applied in specific, narrow contexts, as encouraging their broader use is unlikely to stimulate technology and knowledge flows. Rather, they discourage innovators, whether domestic or foreign, from sharing technology and know-how.[347,348] As regards the role of compulsory licensing in pharmaceutical technology transfer, another paper notes that, since the transfer of know-how not disclosed in a patent application could only be made by concluding voluntary licenses or through reverse engineering, compulsory licenses might be most effective when the technology was already known and only access to it was required.[349]

229. Considering the fairly general objectives and goals of the compulsory licensing mechanism, the limited number of studies and cases reported in this paper should be read in the specific circumstances of each case applied in a specific jurisdiction, and any generalized conclusions by no means could be drawn from them. While the debate on the use of compulsory licenses as a tool to access patented inventions will likely to continue, based on the issues discussed in this paper, one may probably be able to conclude that the effectiveness of the compulsory licensing provision to meet the intended policy objectives depends on various factors which may lie within and outside the realm of the patent system. As discussed above, the practical experiences show that the fact that a compulsory licensing mechanisms has not been used does not necessarily mean that the policy objective of the mechanism has been compromised. Conversely, use of a compulsory license alone may not necessarily lead to improved access to patented products in all cases.

[Appendix follows]

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346 Pugatch Consilium, *Challenges and Opportunities – Developing the Biotechnology Sector in Colombia*, 2016, p.61.

347 See submission of Innovation Insight in document SCP/25/3. See also, Daniel Benoliel and Bruno Salama, (2010) *Towards An Intellectual Property Bargaining Theory: The Post-WTO Era*, 32 U. Pa. J. Int'l L. 265. See also the submission of the Intellectual Property Owners Association in that document stating that: "Yet patent protection can only provide this support if patents are reliably obtainable and enforceable in local jurisdictions. The transfer of knowledge only works if innovators feel secure that patent rights will function as intended. Policies that encourage the weakening of patent rights create increased uncertainty. The use of exceptions and limitations to patent rights, for example exempting certain areas of technology from patent protection or imposing compulsory licensing, can impair innovators' desire and ability to collaborate with partners. These policies hinder the exchange of information and discourage investment and development, even if they are seldom implemented, and can leave countries without their much needed innovations.".

348 See also Pugatch Consilium, 2016, supra note 343, stating that "the repeated use of compulsory licensing tells patent owners that the country is not interested in cooperation and collaboration, and will lead them to also be less collaborative. Under these circumstances, compulsory licensing will be less effective and related objectives, such as lowering prices, enabling supply in areas of unmet need and facilitating sharing of know-how and technology, will be less achievable. Accordingly, compulsory licensing is intended primarily for public health and humanitarian emergencies, and not for commercial or political objectives, and to be used only after all other options for negotiating pricing and supply have been exhausted.".

349 See, for example, Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Oxford University Press, 2001).