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EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES

Document prepared by the Secretariat

INTRODUCTION

1. At its twentieth session, held from January 27 to 31, 2014, the Standing Committee on the Law of Patents (SCP) agreed that, in relation to the topic "exceptions and limitations to patent rights", the Secretariat would prepare, *inter alia*, a document, based on input received from Member States, on how the following four exceptions and limitations were implemented in their countries or regional systems, without evaluating the effectiveness of those exceptions and limitations: (i) acts for obtaining regulatory approval from authorities; (ii) exhaustion of patent rights; (iii) compulsory licensing and/or government use; and (iv) exceptions and limitations relating to farmers' and/or breeders' use of patented inventions. The document should also cover practical challenges encountered by Member States in implementing them.

2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through Note C. 8343, dated March 10, 2014, to submit information to the International Bureau in addition to, or updating, the information contained in their responses to the Questionnaire on Exceptions and Limitations to Patent Rights on the above four exceptions and limitations. In addition, Member States and Regional Patent Offices which had not yet submitted their responses to the Questionnaire were invited to do so.

3. Accordingly, this document provides information on how exceptions and/or limitations related to acts for obtaining regulatory approval from authorities have been implemented in Member States. The document aims at providing a comprehensive and comparative overview of the implementation of this exception under the applicable laws of Member States. Reference is made to the original responses submitted by the Member States and a regional patent office to clarify the scope of the exception in a particular jurisdiction. The Questionnaire and the responses received from Member States are available in full on the website of the SCP electronic forum at: http://www.wipo.int/scp/en/exceptions/.

4. This document consists of three Sections: (i) Public Policy Objectives for Providing the Exception; (ii) The Applicable Law and the Scope of the Exception; and (iii) Implementation Challenges. With a view to facilitating access to the information contained in the responses, the website presents all responses in a matrix format with hyperlinks to each section in each response.

5. The following Member States and Patent Offices indicated that their applicable laws provided for exceptions and/or limitations related to acts for obtaining regulatory approval from authorities: Albania, Argentina, Australia, Austria, Bosnia and Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, El Salvador, Finland, France, Germany, Greece, Hungary, India, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lithuania, Malaysia, Mexico, Netherlands, New Zealand, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, United Kingdom, United States of America and Viet Nam (52 in total).

PUBLIC POLICY OBJECTIVES FOR PROVIDING THE EXCEPTION

6. The exception related to acts for obtaining regulatory approval from authorities provided in the above listed Member States entitles, in general, a third party to use a patented invention during the patent term without the consent of the patent holder for the purposes of developing information to obtain marketing approval. The public policy objectives of such exception, in many Member States, was considered to be aimed at preventing a patentee from having a *de facto* extension of the patent term[1] and thus facilitating the marketing of generic medicines immediately after expiration of the patent term.[2] For example, in the response from Australia, it was explained that "without the exception, alternative manufacturers could not gain regulatory approval until the term has expired. These processes would take some time and amount to an extended period of exclusivity for the original patentee".[3] The response from Mexico stated that "the possibility that at the end of the patent's validity, the generic version of the medicine may enter the market and the validity of the patent may not be maintained artificially until such time as all the necessary tests are carried out in order to guarantee the bioequivalence, safety or effectiveness of the generic medicine".

7. In addition, some Member States also stressed the balancing aspect of the exception. For example, the response of Brazil, referring to the World Trade Organization panel "Canada - Patent Protection of Pharmaceutical Products"[4], noted that the exception established "[…] a reasonable balance of interests between right holders and users of intellectual property rights, as well as protecting public interests". Similarly, the response from Israel stated that the objective of the exception was to "balance the conflicting interests of the generic pharmaceutical industry on the one hand and those of the pharmaceutical industry which is engaged in research and development on the other hand".[5]

8. In addition, public policy objectives for providing the exception in Israel were discussed in court decisions which stated that "the public interest in the activities of generic companies combines the significant contributions in promotion of exports from Israel and providing an employment for large numbers of workers […], with the public benefits derived from a

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1 See, for example, the responses from Australia, Brazil, Chile, China, Israel and Portugal.

2 See, for example, the responses from Austria, France, Germany, Kenya, Netherlands, New Zealand, Poland and Spain.

3 The response from Australia noted that "[t]his type of exception was first introduced in 1998 (Intellectual Property Laws Amendment Act 1998) along with provisions for pharmaceutical extensions of term".

4 Report of the Panel on Canada – Patent Protection of Pharmaceutical Products (DS 114).

5 See also the response from the United States of America.

competition at the pharmaceutical market and the price reduction as a result of the competition". Further, it was explained that the exception was "intended to encourage development and licensing of competing products (generic and not generic, drugs and not just drugs) […]". Similarly, in Canada and Switzerland, the public policy objectives of the relevant provisions are to ensure the competition of patented and alternative products.[6] In New Zealand, in addition to facilitating the entry of generic products onto the New Zealand market when a patent expires, the exception intends to "ensure that New Zealand manufacturers of generic products could enter the export market promptly […]" upon expiration of the relevant New Zealand patent.

9. Noting, in general, the effect of the exception on the price of the product in question, some Member States suggested the following policy objectives of the exception: in Pakistan, the exception was provided in order to "[…] foster creativity and to provide quality and less expensive products through the local manufacturing units, aiming at helping the masses in general, and industrial development in particular"; in China, the objective of the exception is to "enable the public at large to obtain drugs or medical apparatus and instruments at a cheaper price after the expiration of the term of patent protection". The response from Hungary stated that enabling generic entry into the market in due time was important as "this can provide patients with quality medicines at reasonable price, and decrease the costs related to the financing of medicines covered by the health scheme of the state".

10. The response from Chile stated that the aim of the exception was to "incorporate flexibilities in the patent regime […]". Some Member States of the European Union responded that the exception was provided, *inter alia*, in order to comply with Directives 2004/27/EC and 2004/28/EC.[7]

THE APPLICABLE LAW AND THE SCOPE OF THE EXCEPTION

11. 52 Member States reported that their applicable laws provided for exceptions and/or limitations related to acts for obtaining regulatory approval from authorities. Most of Member States' laws provide a specific statutory provision on this exception. However, in some Member States, the regulatory review exception and experimental/scientific research exception are expressly combined into a single provision.[8] In Japan, the Supreme Court held that acts relating to obtaining regulatory approval from the relevant authority fell within the provision on experimental/scientific research exception found in the Japanese Patent Law and thus are not deemed patent infringement.[9] In Mexico, the exception is not included in the law on industrial property, but in the Regulations on Materials for Health. Similarly, in Lithuania, the Law on Pharmacy stipulates this exception to the patent rights.[10] In Bulgaria, the exception is provided in the Act on the Medicinal Products in the Human Medicine, the Act on the Veterinary-Medical Activities and the Law on Inventions and Utility Model Registration. The Romanian patent law does not expressly contain such provision: nevertheless, in the case of obtaining authorization to put a medicine or a plant protection product on the market, the exception is applied.

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6 In addition, in relation to Canada's public policy objectives for provision of the exception, the reference was made to the Panel Report on Canada-Patent Protection of Pharmaceutical Products (DS 114) of March 17, 2000.

7 These Member States are: Bulgaria, the Czech Republic, Denmark, Germany, Italy, Latvia, Lithuania, Norway, Portugal and Sweden.

8 These Member States are: Argentina, Bosnia and Herzegovina, Croatia, Hungary, Jordan, Portugal, the Republic of Korea, Slovakia and Spain.

9 Second Petty Bench of the Supreme Court, April 16, 1999 (Case No.153(ju) of 1998) (Minshu 53 (4) 627).

10 The Law on Pharmacy of the Republic of Lithuania (22 June 2006 No X-709; as last amended on 22 June 2011 No. XI-1506).

12. The below paragraphs describe details on the scope of the exception as provided in the applicable laws of Member States.

Entitlement

13. With regard to the question on the entitlement to use this exception, the vast majority of Member States responded that there are no restrictions as to who may use the exception, as the terms such as "any person", "any party", "any third party" or "any legal person" were found in the applicable laws.[11] Other responses referred to the "marketing approval applicant"[12], "person requesting the marketing authorization"[13], "enterprise that wants to register a new medicine"[14], or "the third importer, exporter, manufacturer or producer of the subject matter protected by a patent"[15]. In Thailand, the exception is applied to "those who wish to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term". The response from Brazil referred to the "non-authorized third parties […] whose acts aim exclusively producing information […] to obtain regulatory approval"[16], whereas the response from the United States of America stated that "those whose actions are "solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products" were entitled to use the exception.[17]

14. The response from the United Kingdom stated that the exception, as provided in its law, applied specifically to "those carrying out studies, tests and trials on generic medicinal products […]" including "manufacturers and suppliers of materials for such studies, tests and trials". Similarly, few other responses made a reference to "manufacturers of pharmaceutical products, especially of generic medicines"[18], or "companies producing generic medicines".[19] Few Member States' responses stated that their applicable laws did not expressly provide who is entitled to use this exception.[20]

Products covered

15. 15 Member States indicated that the exception applies to "any products" that require regulatory approval.[21] However, in a majority of Member States, the coverage of the exception is limited to certain products, such as "pharmaceutical products"[22], "human or a veterinary drug

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11 See, for example, Section 119A of the Patents Act 1990 of Australia, Article 73(b) of the Patent Law of Bosnia and Herzegovina, Section 55.2(1) of the Patent Act of Canada; Article 69 of the Patent Law of China; Article 63(2) of the Patent Act of Croatia, Section 3(3)(iv) of the Consolidate Patent Act of Denmark (Act no. 91 of 28 January 2009), Article 30(g) of Law No. 20-00 on Industrial Property of the Dominican Republic, Article 116(e) of the Law on Industrial Property of El Salvador, Article 19(6)(b) of Act XXXIII of 1995 on the protection of inventions by patents of Hungary and Section 54(2) of the Industrial Property Act 2002 of Kenya.

12 See the response from Switzerland (on Article 9(1) of its Federal Law on Patents for Inventions).

13 See the response from France (on Article L613-5(d) of its Industrial Property Code (CPI)).

14 See the response from Poland on Article 69(1)(iv) of its Industrial Property Law.

15 See the response from Chile (on Article 49 of Law No. 19.039 on Industrial Property of 1991).

16 Article 43, Paragraph VII, of Law n. 9.279 of 14 May 1996 (Industrial Property Law) of Brazil.

17 Title 35, Section 273(e)(1) of the United States Code.

18 See the responses provided by Austria (on Section 22 of the Austrian Patent Act), Germany (on Section 11 no. 2b of Patent Act) and Italy (on Article 68(1)(b) of the Industrial Property Code).

19 See the responses from Latvia (on Section 20.3 of the Patent Law of Latvia), and the Netherlands (on Article 53(4) of the Netherlands Patent Act 1995).

20 See, for example, the responses from Costa Rica (on Article 16.2(e) of its Patent Law), Norway (on Section 3(3) No.5 of its Patents Act) and Slovakia (on Article 18(1)(f) of the Patent Act).

21 These Member States are: Albania, Brazil, Canada, the Dominican Republic, Hungary, India, Israel, Italy, Jordan, Malaysia, New Zealand, Pakistan, Portugal, South Africa and Viet Nam. The response from Hungary noted that in that country, originally, the exception applied to medicines. However, that provision has been amended by Act XLVIII of 2001 in order to "bring it into conformity with Article 27(1) of the TRIPS Agreement and provide for technology neutral regulation".

22 Austria, Chile, Costa Rica and Thailand.

or a medical products"[23], "patented drugs or patented medical apparatus and instruments"[24], "medicines"[25], "medicaments"[26], "medicinal products"[27], "certain medicinal products"[28], "pharmaceutical and agricultural chemicals"[29], "certain medicines and agrochemical products"[30], "certain medicinal and plant protection products"[31], "allopathic medicines"[32], "drugs or veterinary biological products"[33], "medicinal products for human use or medicinal products for veterinary use"[34], "reference medicine"[35] and "generic medicines".[36]

16. In Australia, the Patents Act 1990 provides that the exception covered the regulatory approval of "pharmaceutical patents" relating to goods that "(i) are intended for therapeutic use; and (ii) are not medical devices, or therapeutic devices" as defined in its applicable law.[37] In addition, the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 introduced another provision providing an infringement exemption for acts for obtaining regulatory approval for non-pharmaceuticals.[38] In Norway, the exception only limits the exclusive rights regarding the patented medicine itself, and does not apply to "patented methods, equipment or other tools necessary to the process".[39] In the United Kingdom, the exception is applied in relation to "veterinary medicinal products and medicinal products for human use" which fall within the scope of the Directives 2001/82/EC and 2001/83/EC. The response from Kenya stated generally that the exception covered regulatory approval of "a product".

Permissible acts

17. Regarding the question on permitted acts in relation to a patented invention under the exception, many Member States responded that acts, such as "studies", "trials", "tests",

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23 Bosnia and Herzegovina and Croatia.

24 China.

25 France, Norway and Switzerland.

26 Germany.

27 Finland, Greece, Lithuania and Poland.

28 Denmark, Kenya, Slovakia and Turkey.

29 El Salvador and Peru.

30 Japan.

31 Latvia.

32 Mexico. Article 224 of the General Health Law of that country defines allopathic medicines as "[a]ny substance or mixture of substances of natural or synthetic origin, that has a therapeutic, preventive or rehabilitatory effect, that is pharmaceutical in form and is identified as such by its pharmacological activity, physical, chemical and biological characteristics, and is registered in the Pharmacopeia of Mexico for allopathic medicines […]".

33 The United States of America. In addition, Title 35, Section 273(e)(1) of the United States Code clarifies that the exception, as defined in that law, applies to a patented invention "(other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques)[…]".

34 Netherlands.

35 Sweden.

36 Spain.

37 Section 119A of Patents Act 1990 of Australia.

38 New Section 119B of Patents Act 1990 of Australia reads: "Infringement exemptions: acts for obtaining regulatory approval (non-pharmaceuticals): (1) A person may, without infringing a patent, do an act that would infringe the patent apart from this subsection, if the act is done solely for: (a) purposes connected with obtaining an approval required by a law of the Commonwealth or of a State or Territory to exploit a product, method or process; or (b) purposes connected with obtaining a similar approval under a law of another country or region. […]". The commentary from Australia stated that "This change effectively expands the pre-existing exemption (which was limited to pharmaceutical inventions) to all technologies; recognizing that technologies other than pharmaceuticals may also suffer delays in bringing products to market as a consequence of lengthy pre-market and pre-manufacturing regulatory approval processes".

39 It was explained that, "however, the exception applies regardless of whether the test in question relates to generic, further developed, or newly developed medicines. Under the exception, one can also produce any amount necessary to fulfill any documentation requirements needed to obtain the marketing authorization in the particular WTO Member. The party seeking authorization will have the burden of proof". See the response from Norway to question 56 of the Questionnaire.

"examinations" and/or "experiments", as well as "consequential practical requirements", "related practical needs" or "related procedures" necessary for obtaining a marketing "authorization", "permission", "registration" or "marketing clearance" for a product, as defined in the applicable laws, are permitted under the exception.[40] The response from Germany explained that "studies, experiments and any resulting practical requirements" means "any use under the patent's scope of protection that is intended to meet the prerequisites of a privileged study or a privileged experiment (for example: production or importation of the still protected active substance intended to be used in the experiment)". In the Netherlands, the permitted acts are the "necessary studies, tests and experiments for demonstrating the equivalence between a generic and reference medical product, the reference medical product being protected by a patent right or SPC". In Switzerland, the exception applies, *inter alia*, to "experiments and clinical trials in which a pharmaceutical product containing a protected active ingredient is tested to obtain the data required for marketing approval".

18. In El Salvador, Jordan and Spain "using" the patented invention is a permitted act under the exception.[41] In Albania, Japan, Poland and Portugal, "making" and "using" the patented invention under the exception are allowed. In China and Lithuania "making", "using" and "import" are permissible acts. In Brazil, "making, using; and acts […] regarding patented inventions" which aimed at obtaining regulatory approval, as provided in its law, are permitted acts. In some other Member States, all of the following acts are permissible under the exception: "making", using", "selling", "offering for sale" and "import";[42] and, in addition to those acts, in other Member States, "export" was also considered permissible.[43] In Canada and India, reference was also made to "constructing" [44] and, in the Republic of Korea to a "loan and transfer".[45] The responses from few Member States did not specify the acts authorized in relation to the exception as provided in their laws, stating generally "uses" or "acts" necessary to obtain the marketing approval".[46]

Purpose of the act − regulatory approval in other countries

19. While in many Member States, exception applies to acts which are carried out for the purpose of obtaining the regulatory approval in their countries, in some other Member States, activities made for the purpose of obtaining regulatory approval in other countries are also covered under the exception. For example, in Norway, the relevant acts carried out for the purpose of obtaining a marketing authorization in a "State that is a Contracting Party to the Agreement on the Establishment of the World Trade Organization of April 15, 1994" are

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40 See, for example, Section 22(1) of the Austrian Patent Act, Section 3(3)(iv) of the Consolidate Patents Act of Denmark, Section 3(3)(4) of the Patents Act of Finland, Section 11 no. 2b of Patent Act of Germany, Article 68(1)(b) of the Industrial Property Code of Italy, Section 54(2) of the Industrial Property Act of Kenya and Article 52.1(b) of the Law on Patents of Spain.

41 The response from Spain explained that "using" refers to "[…] studies and trials and the resulting practical requirements (to obtain authorization of generic medicines), including those providing for use, preparation and obtaining".

42 See, for example, the responses from the South Africa, the United Kingdom and Viet Nam.

43 See, for example, the responses from Latvia, New Zealand, Pakistan, Peru and the United States of America. See also, the response from Israel which stated that permitted acts under the exception "Any experimental act for obtaining a license to market the product, which may include making, using, import and export".

44 Section 55.2 (1) of the Patent Act of Canada reads: "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention […]"; Section 107A(a) of Patents Act 1970 of India reads: "Certain acts not to be considered as infringement […] any act of making, constructing, using, selling or importing a patented invention […]".

45 Section 55.2 (1) of the Patent Act of Canada reads: "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention […]"; Section 107A(a) of Patents Act 1970 of India reads: "Certain acts not to be considered as infringement […] any act of making, constructing, using, selling or importing a patented invention […]".

46 See the responses from Croatia, the Dominican Republic, Kenya and Thailand.

permitted.[47] In Germany, the relevant provision stipulates that the effect of the patent does not extend to studies, experiments and any related practical requirements that are necessary to obtain either marketing authorization for medicinal products "within the European Union" or authorization for medicinal products "within the Member States of the European Union or in third countries".[48] In India, the exception applies to acts carried out solely for uses reasonably related to the development and submission of information required under any law in India, or "in a country other than India" that regulates the manufacture, construction, use, sale or import of any product.[49,50]

20. Among Member States allowing exportation for the purpose of obtaining marketing approval in a foreign country or for the purpose of obtaining marketing approval in their own country, some provide other conditions that must be met. In Australia, the provision concerning the regulatory approval of non-pharmaceuticals stipulates that it is not an infringement if the act is done solely for purposes connected with obtaining a similar approval under the law of "another country or region",[51] whereas a provision concerning the pharmaceutical patent allows the exploitation of such patent solely for the purposes connected with obtaining a similar regulatory approval under the law of a "foreign country or of a part of a foreign country". However, the provision concerning the pharmaceutical patent "[…] does not apply unless the term of the patent has been extended under Part 3 of Chapter 6[52] and the goods consist of or contain […]" certain products.[53] In Switzerland, the applicable law provides that foreign countries shall be "with equivalent medicinal product control" for the exception to apply.[54] Further, the applicable laws of Oman and Peru, while allowing the exportation of the product outside the national territories, state that such exportation shall be permitted only to satisfy the requirements for marketing approval in their respective countries.[55]

Timeframe for the regulatory review request

21. The applicable laws of most of the Member States allow requests for a regulatory approval with the competent authorities to take place anytime during the term of patent protection. However, in Mexico, "the registration of a generic medicine may be requested […] within three years prior to the expiry of the patent […] and health registration shall be granted only when the validity of the patent ends".[56]

Conditions for the exception to apply

22. The applicable laws of some Member States provided for some conditions to be met for the exception to apply. For example, in Israel, "an experimental act […] does not constitute

47 See Section 3(3) No.5 of the Patents Act of Norway.
48 Section 11(2b) of the Patent Act of Germany.
49 Section 107A(a) of Patents Act 1970 of India.
50 Similarly, the applicable laws of Brazil, Canada, Italy, Israel, Lithuania, the Philippines and Spain expressly cover under the scope of the relevant exceptions, activities made for the purpose of obtaining regulatory approval in other countries.
51 Section 119B of the Patents Act 1990 of Australia. See supra note 38.
52 Part 3 of Chapter 6 of the Patent Act 1990 of Australia provides for the extension of the term of standard patents claiming pharmaceutical substances.
53 These products are "(a) a pharmaceutical substance *per se* that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or (b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification". See Part 3 of Chapter 6 of Patent Act 1990 of Australia.
54 See Article 9(1) of the Federal Law on Patents for Inventions of Switzerland.
55 See Section 11(4)(a) of the Industrial Property Rights and their Enforcement for the Sultanate of Oman (Royal Decree No. 67/2008) and Article 39 of Legislative Decree 1075 of Peru.
56 Article 167*bis* of the Regulations on Materials for Health of Mexico.

"exploitation of an invention", if the following two conditions are met: (1) the effort to obtain a license[57] is made in order to obtain a license in Israel or in a country, in which an experimental act on a patent protected invention for the purpose of obtaining a license is permitted before the patent lapses; (2) any product produced under the terms of this section is not used – both while the patent is in effect or thereafter – for any purpose other than obtaining a license as aforesaid". In Lithuania, the performance of acts, as provided in the Law on Pharmacy, for the purposes of submitting an application for marketing authorization in that country or in other states […] "shall be without prejudice to the rights granted by the medicinal product patent or by a supplementary protection certificate provided for in the Patent Law of the Republic of Lithuania and in other legal acts regulating the protection of industrial property".[58] In Poland, grant of the marketing authorization "shall be without prejudice to civil liability for putting on the market of a product without the patent holder's consent, where such consent is required". In Costa Rica, the relevant exceptions would apply, provided they "do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of its owner or its licensee". Similarly, in the Dominican Republic, the applicability of the exception shall "take into account the legitimate interests of third parties".[59]

23. Few Member States noted the requirement of a direct relation between studies, trials and consequential practical requirements, on the one hand, and the permission, authorization or registration by an authority, on the other hand.[60] Further, some other Member States stated that the relevant acts were to be made "to a necessary extent", "solely" or "exclusively" for the purpose of developing and submission of information to obtain regulatory approval.[61]

Protection of undisclosed information

24. Few Member States' responses noted that information submitted for regulatory approval is subject to protection against disclosure. For example, Article 167*bis* of the Regulations on Materials for Health of Mexico states that "[t]he information […] which is confidential or reserved in accordance with the provisions of the international treaties to which Mexico is a party and with the other applicable legal provisions, shall be protected against any disclosure to other individuals". In the Philippines, the relevant exception applies, provided that "in order to protect the data submitted by the original patent holder from unfair commercial use provided in Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary therein […]".[62]

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57 Article 54A of Israel Patent Law 5727-1967. For the purposes of that section, the term "license" means a "certification, permit or any other document required under the Law in order to market the product".

58 Article 11, part 13 of the Law on Pharmacy of the Republic of Lithuania (22 June 2006 No X-709; as last amended on 22 June 2011 No. XI-1506).

59 Article 16.2(e) of the Patent Law of Costa Rica and Article 30(g) of Law No. 20-00 on Industrial Property of the Dominican Republic.

60 See the responses from Austria, Germany and Italy.

61 See, for example, Article 43, Paragraph VII, of Law n. 9.279 of 14 May 1996 (Industrial Property Law) of Brazil, Article 69 (1) (iv) of the Industrial Property Law of Poland, Section 119A of the Patents Act 1990 of Australia, Section 55.2(1) of the Patent Act of Canada, Section 107A of Patents Act 1970 of India and Article 69A(1) of Patent Act 57 of 1978 of South Africa.

62 Section 72.4 of the Republic Act 8293 of the Philippines, as amended by the Republic Act 9502.

IMPLEMENTATION CHALLENGES

25. Most Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought and/or no amendments were foreseen. [63] Some Member States provided no answer on this question or stated that the question was not applicable.[64] In Chile, the relevant provision was being revised. In El Salvador, revision of the law was envisaged in the medium term. The response from Australia, with reference to applicable legal framework, stated that the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 expanded the existing exemption for pharmaceutical inventions to all technologies.

26. Most Member States stated that no challenges had been encountered in relation to the practical implementation of the exception.[65] In that regard, the response from Brazil stated that the Brazilian Government was "carrying out an evaluation on the implementation of the exception with a view to assessing its usefulness in light of the objective of ensuring a balanced patent system". The response from Portugal noted that patentees were not content about the exception: therefore, they "try to prevent the obtaining of regulatory approvals by setting up interim relief in the appropriate court". It further noted that "court decisions are not unanimous regarding this issue". The response from South Africa stated that no challenges had been encountered as far as patent law was concerned. It further noted that "challenges are encountered with the regulatory authorities such as Medicines Control Council where the delay in processing applications to register medicines delays access to the market". The response from Spain, referring to the amendment of the relevant provision of its national law implementing Directive 2004/27/EC and introducing the exception, questioned whether it had a retroactive effect or not.[66]

27. In the United Kingdom, proposals to amend Section 60(5) of the Patents Act were being considered by the Parliament so that activities relating to trials for human and veterinary medicines as well as health technology assessment would be acts which would fall within the scope of the research exception provided in Section 60(5)(b).[67] The response from the Netherlands noted that, in the absence of jurisprudence set by the European Court of Justice, the precise scope of "trials and studies" as well as "consequential practical requirements"

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63 Member States which expressly stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought and/or no amendments was foreseen were: Bosnia and Herzegovina, Canada, Chile, China, Costa Rica, Croatia, the Czech Republic, Denmark, the Dominican Republic, Hungary, India, Latvia, Malaysia, Mexico, New Zealand, the Netherlands, Norway, Pakistan, Peru, Poland, Portugal, Spain, Sweden and Turkey.

64 These Member States are: Albania, Argentina, Austria, Finland, France, Germany, Greece, Israel, Italy, Jordan, Lithuania, the Republic of Korea, Slovakia, South Africa, Switzerland, Thailand and Viet Nam.

65 Member States which expressly stated that no challenges had been encountered in relation to the practical implementation of the exception were: Bosnia and Herzegovina, Canada, China, Costa Rica, Croatia, Denmark, the Dominican Republic, Hungary, Latvia, Malaysia, Mexico, Norway and the United Kingdom.

66 The corresponding text explained that: "The Explanatory Memorandum of Law No. 29/2006 states that the only effects of [the amendment introducing the regulatory review exception] are for clarification purposes and that this is covered by the previous text of Article 52.1(b), which establishes that patent rights shall not extend to acts carried out for experimental purposes. However, Ruling No. 424/2010 of the Supreme Court, a chamber of the Civil Courts, of June 30, 2010, states that prior to the entry into force of Law No. 29/2006, the provision of samples to public health authorities was not covered by the "experimental use exemption". See the response from Spain to question 59 of the Questionnaire.

67 Section 60(5)(b) of the Patents Act currently reads "An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if (b) it is done for experimental purposes relating to the subject-matter of the invention". The response form the United Kingdom explained that "[t]he underlying policy for the proposed changes to section 60(5)(b) is that the patent system should not prevent a company from meeting the requirements of the regulatory approval system for medicinal products, and that activities carried out to meet such requirements should be exempt from patent infringement. Section 60(5)(i) addresses this concern in relation to generic drugs and the proposed amendments to the Patents Act will address it in relation to innovative drugs. This should allow patients to have earlier access to new drugs".

referred to in Article 10(6) of Directive 2004/27/EC[68] was unclear, for instance, with respect to "stock-piling or taking pre-orders". In addition, the Netherlands referred to the recent decision of the Hague Court of Appeal which had ruled that publication of a generic medicine in the G standard (a Dutch database for available medicines) prior to the expiry of the relevant patent constituted an act of infringement, notwithstanding the fact that the generic manufacturer had explicitly stated that the generic medicine would be available only after the patent expiry.[69] Finally, with reference to challenges, the response from Pakistan noted that the exception had never been invoked in the country. Some Member States responded that the question on challenges was not applicable or provided no answer.[70]

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[68] Article 10(6) of Directive 2004/27/EC reads: "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products".

[69] The Hague Court of Appeal (Case 105.007.171/01 of November 2, 2010).

[70] See, for example, the responses of Australia, Austria, India, Jordan, Kenya, New Zealand, Peru, Poland, Slovakia, the United States of America and Viet Nam to question 59 of the Questionnaire.