WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

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SCP/28/3
ORIGINAL: ENGLISH
DATE: MAY 14, 2018

Standing Committee on the Law of Patents

Twenty-Eighth Session
Geneva, July 9 to 12, 2018

REFERENCE DOCUMENT ON EXCEPTION REGARDING ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES (SECOND DRAFT)

Document prepared by the Secretariat

INTRODUCTION

1. At its twenty-seventh session, held in Geneva from December 11 to 15, 2017, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would continue working on a draft reference document on exceptions and limitations. In particular, it was agreed that the Secretariat would, *inter alia*, submit a second draft reference document on exception regarding acts for obtaining regulatory approval from authorities to the twenty-eighth session of the SCP. In addition, it was agreed that the Secretariat would invite Member States to send any additional inputs with respect to, for example, challenges faced by Member States in implementing the exception and results of the national/regional implementation (see document SCP/27/9, paragraph 25, 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. 8728, dated February 9, 2018, to submit to the International Bureau any additional inputs for the preparation of the second draft reference document on exception regarding acts for obtaining regulatory approval from authorities (hereafter "exception").

3. Accordingly, Annex I to this document contains the said draft reference document for the Committee's discussions at its twenty-eighth session to be held in Geneva from July 9 to 12, 2018. As mandated by the Committee, in the preparation of the second draft of the reference document, the Secretariat made use of information submitted by the Member States to the twenty-eighth session of the SCP, available on the website of the SCP electronic forum at: http://www.wipo.int/scp/en/meetings/session_28/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 regulatory review exception; (ii) objectives and goals of the regulatory review exception; (iii) the regulatory review exception and international legal framework; (iv) regional instruments and their implementation; (v) national implementation of the regulatory review exception; (vi) challenges faced by Member States in implementing the exception; and (vii) results of implementation of the exception. In addition, it contains an Appendix, in which national legal provisions on the regulatory review exception are compiled.

[Annex follows]

REFERENCE DOCUMENT ON EXCEPTION REGARDING ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES (SECOND DRAFT)

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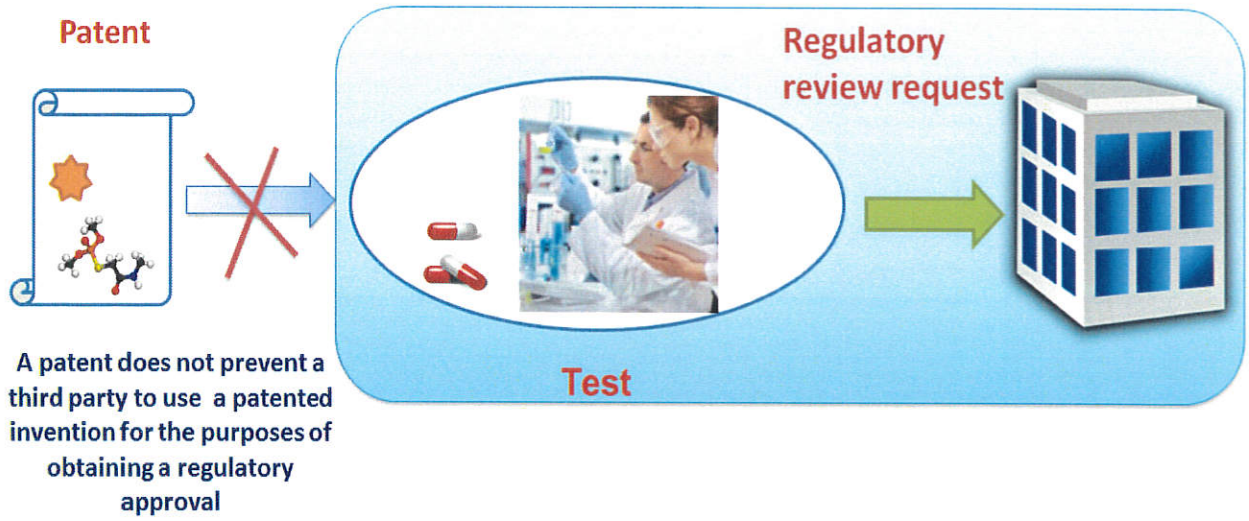
APPENDIX

1. Overview of the Regulatory Review Exception

1. Some products, typically pharmaceutical products, cannot be marketed without obtaining a marketing approval from a competent regulatory authority. The underlining rational for such approval is to ensure the safety, efficacy and quality of such products, thereby protecting consumers. Requirements for obtaining marketing approval differ from one country to another or from one sector to another, or even within the same sector, depending on various factors.[1] In general, in order to obtain a marketing authorization, an applicant needs to produce and test samples of the product so that he/she can collect and submit the required information to the relevant authority. If the product is under patent protection, such production, testing and other related use of that product for developing the data necessary for regulatory approval may be considered an infringement of the patent, if the applicant is not authorized to do so by the patentee.

2. Depending on the national regulatory requirements and the product specificities, the regulatory approval may take several years. If a third party has to wait the expiration of the patent until he/she can use the patented invention in order to obtain such regulatory approval, market entry of competitive products, such as generics and biosimilars, would be delayed.[2] To mitigate this situation, many patent laws provide for the regulatory review exception which, in general, entitles a third party to use a patented invention, without the consent of the patent holder, before the end of the patent protection, if such use is for the purposes of developing information to obtain a marketing approval.

Figure 1: Regulatory review exception – conceptual image



1 For example, the authorization for new chemical entities is much more complex than the authorization for an "equivalent" one for which abbreviated, simplified procedures are applied.

2 For example, it has been estimated that procedures for marketing authorization for generic products would delay their commercialization by 2-3 years or more in countries with generic pharmaceutical manufacturing capability. See, e.g., Jayashree Watal „Bolar exception to patent rights: Some Economic Implications" SCP Seminar on Exceptions and Limitations to the Rights, 03.11.14, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_ref_watal.pdf.

3. The list of products that require regulatory approval for putting them on the market varies from country to country. While pharmaceutical sector remains highly regulated in many countries, and therefore subject to the exception in many of those countries, the need to undergo a regulatory approval process is not unique for this sector. Other sectors like plant protection products, herbicides and pesticides, animal foodstuffs, flavoring substances and medical equipment are also highly regulated. Thus, in some countries, the regulatory review exception may also cover any of such regulated products.[3]

Box 1. "Bolar" Exception in the United States of America

The regulatory review exception is also known as the "Bolar exception", after a well-known 1984 case in the United States of America, *Roche Products v Bolar Pharmaceuticals*[4]. The Court of Appeals for the Federal Circuit ruled that the experimental use exception in the United States of America did not cover Bolar's acts to carry out equivalency tests for the regulatory approval of generic medicines before the expiration of the relevant patent owned by Roche. The court held that "Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" and that it "[...] cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes." As regards to Bolar's argument that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow drug testing required for the regulatory approval, the court stated that it was not a proper forum to debate the issue and that it would not engage in legislative activity proper only for the Congress.

Subsequently, The U.S. Congress addressed the lack of any exemption for generic drug testing. The Drug Price Competition and Patent Term Restoration Act (informally known as the Hatch-Waxman Act), introduced an explicit exception to the patent rights, i.e., acts 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, other than those products primarily manufactured using certain genetic manipulation techniques, were not infringement acts.[5] The general view of the Congress was that it was not appropriate to prevent generic pharmaceutical manufacturers from starting to prepare and obtain regulatory approval for their generic products only after the expiration of the relevant patent, since it would delay the entrance of generic medicines on the market for a substantial period, extending the effective protection period beyond the patent term.

2. Objectives and Goals of the Regulatory Review Exception

4. The public policy objectives and the goals of the regulatory review exception in many countries are aimed at avoiding a *de facto* extension of the patent term due to the time taken for a regulatory approval process, and thus facilitating the marketing of competitive products, such as generic medicines, immediately after the expiration of the patent term. For example, in the response from Australia to 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"), the policy

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3 For further information on products covered by the exception in various countries, see section "National and Regional implementation" in this paper.

4 *Roche Products v Bolar Pharmaceutical Co.*, 733 F.2d. 858 (Fed. Cir. 1984).

5 35 U.S.C. §271(e)(1).

objectives of the exception 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". 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".[6] Consequently, the regulatory review exception is used as a mechanism to encourage competition in the market as soon as patent is expired. As competition often lowers prices,[7] this exception is considered to promote the affordability of off-patent medicines, and to reduce the cost of treatments and improving access.[8]

5. As it is illustrated in section 5.6 of this paper, in some countries, the scope of the regulatory review exception covers testing for marketing authorization of new or innovative medicines in addition to testing for marketing authorization of medicines that are equivalent to those already sold in the market. The underlying public policy of such provisions is also to prevent *de facto* extension of patent term by accelerating the regulatory approval of new and improved medicines and facilitating their marketing just after the expiration of the patent term thus allowing patients to have early access to such new medicines.[9]

6. Like any other exceptions to the patent rights, the fundamental consideration underpinning the policy objective of the regulatory review exception is to maintain a balance between the interests of the right holders and third parties for the public interest at large. In other words, it is intended to balance the conflicting interests of producers and users of technological knowledge for the mutual benefits of all parties (for example, the pharmaceutical industry which is engaged in research and development and the generic pharmaceutical industry), in a manner that is conducive to social and economic welfare. In this regard, the response from Brazil to the Questionnaire explained that "The legislation aims at avoiding the extension of patent terms beyond twenty years from the filling date [...], thus establishing a reasonable balance of interests between right holders and users of intellectual property rights, as well as protecting public interests". [10] As regards the interest of patent holders, in the response from Lithuania to the Questionnaire, it is stated that the performance of acts, as provided in the Law on Pharmacy, for the purposes of submitting an application for marketing authorization [...] "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".[11] Similarly, in the responses of Costa Rica and the Dominican Republic to the Questionnaire, it is noted that the relevant exceptions would apply, provided the actions do not unjustifiably harm the normal working of the patent or cause undue harm to the legitimate interests of the patent holder.[12]

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6 See the responses of Australia and Mexico to the Questionnaire on Exceptions and Limitations to Patent Rights (hereafter "the Questionnaire"), available at: http://www.wipo.int/scp/en/exceptions/. See also the responses to the Questionnaire received from Chile, China, Israel, Kenya, Netherland, New Zealand, Poland, Portugal and Spain.

7 See section 7 "Results of implementation of the exception" of this paper.

8 Coenraad Visser, *Patent Exceptions and Limitations in the Health Context*, Annex V, SCP/15/3, p. 26.

9 See, e.g., the response to the Questionnaire by the United Kingdom, available at: http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/uk_2.pdf.

10 See also Jayashree Watal „Bolar exception to patent rights: Some Economic Implications" SCP Seminar on Exceptions and Limitations to the Rights, 03.11.14, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_ref_watal.pdf.

11 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).

12 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.

7. The use of the regulatory review exception as a mechanism to increase competition has been frequently highlighted by experts,[13] who recommend policymakers in developing countries to introduce this exception in their patent laws, among other policies.[14] Particular attention was given to countries that were actual or potential producers of generics.

Box 2. Policy objectives of the exception in Israel and Japan

The third amendment of Israel Patent Law (1998) created a new regime in patent protection of medicines, in order 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" (the explanatory memorandum to the third patent law amendment). According to the Jerusalem District Court Decision,[15] 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, mostly academics, with the public benefits derived from a competition at the pharmaceutical market and the price reduction as a result of the competition.

In Japan, the Supreme Court, in decision concerning generic drugs,[16] recognized that: (i) if any clinical investigations needed for getting approval of manufacturing generic drugs were not able to be conducted during the time when the patent rights are effective, this would substantially result in third parties not being freely able to use the patented inventions for a considerable length of time, even after the patent rights have expired; and (ii) patent right holders can ensure their economic benefits based on the exclusive licensing of their patented inventions.

3. The Regulatory Review Exception and International Legal Framework

8. No international treaty expressly addresses the regulatory review exception. Article 30 of the TRIPS Agreement, however, lays down general principles regarding the exceptions and limitations to the rights which may be provided by the WTO Members. According to Article 30, Members are allowed to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

9. The consistency of the regulatory review exception with Article 30 of the TRIPS Agreement was examined by a WTO Dispute Settlement Panel in *Canada - Patent Protection of Pharmaceutical Product* case.[17] The dispute was initiated in February 1999 by the European Communities and their member States against certain provisions in Canada's Patent Act. Specifically, the dispute concerned the regulatory

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13 For example, see Carlos M. Correa "The Bolar Exception: Legislative Models and Drafting Options", South Centre, Research Paper 66, March 2016; see also Jayashree Watal, supra note 10.

14 Some publications generally recommend countries to use to the "full flexibilities contained in the TRIPS Agreement". For example, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property urges member states to consider implementing TRIPS flexibilities by incorporating them into their national laws (Element 5.2a).

15 The Jerusalem District Court Decision (M.A. 223/09 (Jerusalem),H. Lundbeck A/S vs. Unifarm LTD, (2009) Nevo). See the response to the Questionnaire received from Israel available at: http://www.wipo.int/scp/en/exceptions/.

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

17 WTO document WT/DS114/R.

review provision (Section 55.2(1)) and the stockpiling provision (Section 55.2(2)) of the Patent Act of Canada that allowed generic drug manufacturers to override, in certain situations, the rights conferred on the patent owner. In particular, Section 55.2(1) permitted the generic manufacturers of pharmaceuticals to produce samples of the patented product for the purposes of the regulatory review process. Whereas Section 55.2(2)) of the Patent Act allowed producers of generic drugs to make the drugs and begin stockpiling them six months prior to the expiration of the patent.

10. The Panel examined whether the above provisions under the Patent Act of Canada were justified, *inter alia*, under Article 30 of the TRIPS Agreement. According to Article 30, exceptions to patent rights shall meet three conditions, namely, (i) the exceptions to the exclusive rights must be "limited"; (ii) the exceptions do not unreasonably conflict with a normal exploitation of the patent; and (iii) the exceptions do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

11. The Panel held that Canada's regulatory review provision was justified under Article 30 by meeting all these three cumulative criteria. Specifically, in the Panel's view, this exception was "limited" for the following reasons:

> "[...] because of the narrow scope of its curtailment of Article 28.1 rights. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded. Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products [...]".[18]

12. As regards the second condition of Article 30 which prohibits exceptions that "unreasonably conflict with a normal exploitation of the patent", the Panel considered that:

> "[...] Canada was on firmer ground, however, in arguing that the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization should not be considered "normal". The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights [...]".[19]

13. As regards the third condition, the Panel concluded that the exception contained in Section 55 2(1) of the Patent Act of Canada did not prejudice the legitimate interest of the patentee within the meaning of Article 30 of the TRIPS Agreement, subject to the following considerations:

> "On balance, the Panel concluded that the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest" within the meaning of Article 30 of the TRIPS Agreement. Notwithstanding the number of governments that had responded positively to that claimed interest by granting compensatory

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18 Paragraph 7.45, page 158, WT/DS114/R.
19 Paragraph 7.57, page 161, Ibid.

patent term extensions, the issue itself was of relatively recent standing, and the community of governments was obviously still divided over the merits of such claims [...]"[20]

14. Further, regarding the stockpiling provision contained in Canada's Patent Act, the Panel found that the measure was not justified under Article 30. This was because there were no limitations on the quantity of production for stockpiling which resulted in a substantial curtailment of extended market exclusivity, and, thus, was not "limited" as required by Article 30. Accordingly, the Panel concluded that the stockpiling provision was inconsistent with Article 28.1, as it constituted a "substantial curtailment of the exclusionary rights" granted to patent holders.[21]

4. Regional Instruments and Their Implementation

15. Two regional instruments exist addressing, *inter alia*, the regulatory review exception at the regional levels. These are European Union (EU) Directives 2001/82/EC and 2001/83/EC[22] and Andean Community Decision N° 689.[23]

4.1 European Union (EU) Directives

16. At the EU level, the regulatory review exception is governed by Article 13(6) of Directive 2001/82/EC and Article 10(6) of Directive 2001/83/EC. These provisions provide a common framework in relation to the regulatory review exception for EU Member States. In general, in order to give force to the Directives, the EU Member States have to transpose them into their national laws. While the provision on the regulatory review exception can be found in the laws of the EU Member States, the transposition and the implementation of the exception at the national level has not been uniform. Specifically, the analysis of national provisions and case law on the regulatory review exception of various EU countries shows that, the language, scope and interpretation of the exception vary.[24]

17. For instance, differences are found as regards the products covered under the exception. In particular, in some EU countries, the exception is limited to activities relating to marketing approval of generic medicines and biosimilars. In some other countries, the exception is applied also in relation to acts relating to new and innovative medicines, which are non-generic drugs, falling within the scope of the patent or requiring comparative studies with a known patented drug.[25] In addition, the regulatory review exception in some EU countries is also available for plant protection products and other regulated products, [26] while in other countries the coverage of the exception appears to be limited to medicinal products.[27]

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20 Paragraph 7.82, page 168, Ibid.

21 Pages 156 and 157, ibid.

22 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products; and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

23 Decisión N° 689 de 13 de agosto de 2008, sobre la Adecuación de Determinados Artículos de la Decisión 486 por la que se establece el Régimen Común sobre Propiedad Industrial, para permitir el Desarrollo y Profundización de Derechos de Propiedad Industrial a través de la Normativa Interna de los Países Miembros.

24 For the provisions of the laws, see Annex II of this document.

25 For example, in the United Kingdom, Section 60(5)(b) of the Patents Act of the United Kingdom covers, *inter alia*, "innovative products". Similarly, in Norway, the regulatory review exception contained in Section 3(3) No.5 of the Patents Act applies, *inter alia,* to "further developed, or newly developed medicines".

26 See, e.g., the responses to the Questionnaire from Hungary, Latvia and Portugal.

27 See, e.g, the responses to the Questionnaire from Germany, Greece and Netherlands.

18. Further, national laws vary as to whether this exception applies to tests and studies for the purposes of seeking a marketing authorization in other countries. For example, the regulatory review exception provisions in Denmark, Germany, Norway and Spain expressly state that studies and experiments necessary for obtaining authorization in non-EU countries are allowed under the exception. However, in other EU countries, such as Greece, the Netherlands and Sweden, the language of the relevant provisions suggests that the exception applies in relation to marketing authorization in the EU only.

19. Furthermore, there has been some uncertainly as regards to which specific acts are exempt from infringement according to the Directives. While it is widely accepted that the testing entity is allowed to manufacture the patented substance itself for its trials and studies, it remains unclear whether the substance could also be manufactured and sold by a third party manufacturer to the testing entity without infringing the patent according to the Directive. This question has been referred to the Court of Justice of the European Union (CJEU) in 2014 by the Dusseldorf Court of Appeal, but the case was subsequently closed without any guidance being issued by the CJEU.[28]

20. In order to maximize the benefits of the regulatory review exception in the EU, and to reduce fragmentation in the internal market associated with this exception, the European Commission has been studying the need for its related policy change.[29] In particular, the more harmonized interpretation of the regulatory review exception is expected to positively affect the pharmaceutical industry in terms of keeping the European pharmaceutical sector as a hub for clinical trials and bringing market opportunities to EU-based suppliers of APIs.[30]

4.2 Andean Community Decision N° 689

21. Another regional instrument, the Andean Community Decision N° 689, in Article 53, provides a regulatory review exception which is applicable to the Member States of the Andean Community comprising of Bolivia, Colombia, Ecuador and Peru. Specifically, Article 1 of Decision N° 689 states:

> "The Member Countries, through their internal regulations, will be empowered, under the terms expressly indicated in paragraphs a) to j), to develop and deepen only the following provisions of Decision 486: [...]
>
> e) Article 53: Include the faculty to use the object protected by a patent in order to generate the necessary information to support the marketing approval request for a product." (Note: this is not an official interpretation)."

22. In general, the Andean Community Decisions have direct effect as the domestic IP legislation of the Member States. However, as Decision N° 689 allows Member States to further "develop and deepen" the

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28 See discussion on *Astellas Pharma Inc v. Polpharma S.A. Pharmaceutical Works* case in section 5.4 of this paper.

29 See, Inception Impact Assessment "Optimizing the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations", European Commission, 15.02.2017, available at: http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf

30 For economic impact of such legislative changes, see chapter "Results of national/regional implementation" in this document.

provision concerning the regulatory review exception at the national level, the national laws of Colombia and Peru provide specific complementary provisions on this exception.[31]

23. As regards the scope of the exception in those two countries, the following can be noted: first, under the laws of both countries, the authorized acts include the "manufacture, use, sell, offer for sale or import" of the patented product by a third party for the purpose of generation of information to comply with the marketing approval requirements. Second, while the relevant provisions of both laws allow the exportation of the patented product outside the national territories, such exportation is permitted only to satisfy the requirements for marketing approval in their respective countries.[32] Thus, the language of the respective provisions in the law of Colombia and Peru suggest that under the regulatory review exception, third parties are not allowed to seek the marketing authorization in other countries.

24. As to date no extensive case law has been developed as regards Article 53 of Andean Community Decision N° 689, it remains to be seen what the exact boundaries of this provision are for its Member States. However, at least in one national case in Colombia, the third party has successfully relied on the regulatory review exception as a defense against infringement.[33]

5. National Implementation of the Regulatory Review Exception

25. Many countries have introduced the regulatory review exception in their laws, particularly since the issuance of the WTO Dispute Settlement Panel decision in the *Canada - Patent Protection of Pharmaceutical Products* case in 2000. The applicable laws of more than 65 countries[34] have been identified to provide for this exception.[35] Few countries are in the stage of introducing the exception to their respective law.[36] Relatively speaking, implementation of the regulatory review exception at the national level is a fairly new legal development in many jurisdictions.

26. In general, the regulatory review exception is described in a way that the exclusive patent rights do not extend to certain acts that are necessary to submit information to the relevant regulatory authority for the purpose of obtaining marketing approval of certain products. National laws therefore typically stipulate the scope of the third parties' acts that do not constitute patent infringement, and provide the types of products regulated by the regulatory approval (e.g., "pharmaceuticals", "medicinal products", or "any products") for which exploitation of a patented invention by third parties is allowed. The third parties covered by the exception are, in general, tied to the purpose of their use of the patented invention – to obtain a regulatory approval.

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31 See Article 3 of Decree 729 of 2012 of Colombia and Article 39 of Legislative Decree 1075 of June 27, 2008 of Peru.

32 Ibid.

33 See *F. Hoffmann- La Roche AG v Biotoscana Farma SA and Medical Pharmacy LTDa*. Judge Sixth of the Civil Circuit Court. Process No. 1101-31-03-016-2012-00013400. November 30, 2015.

34 See Appendix to this document.

35 As of April 26, 2018.

36 For example, such legislative amendments are taking place in the Republics of Belarus and Moldova (as of April 26, 2018). See information submitted to the SCP from these countries, available at: http://www.wipo.int/scp/en/meetings/session_28/comments_received.html.

27. While these are the essential common components that form the regulatory review exception, detailed analysis of national legislations indicates that there are certain differences among national laws in terms of their expression and interpretation as well as the coverage of the exception. Those elements typically relates to:

(i) in relation to permitted acts by third parties:

– in general, the exclusive right conferred by a patent extends to making, using, offering for sale, selling or importing for these purposes, the patented invention. Does the regulatory review exception apply to those acts?

– to what extent the act of exploiting a patented invention by a third party needs to be related or linked to the objective of obtaining regulatory approval? For example, if a third party imports patented compound, and supplies it to another company that produces test samples, and yet another company conducts testing to develop data for marketing approval, which acts are covered by the regulatory review exception?

– may a third party exploit the patented invention for the purpose of obtaining regulatory approval in foreign countries? If so, are there any conditions? Or, the regulatory review exception applies only if marketing authorization is sought in the same country where the patented invention is used?

– is there any time limit within which use of the patented invention by a third party should take place?

(ii) in relation to the types of regulatory approval:

– may a third party use the patented invention for the purposes of any regulatory approval? Or, is it limited to regulatory approval of certain products?

– does the regulatory review exception apply to generic products only (i.e., use of the patented invention is made for obtaining the regulatory approval of the product that is equivalent to brand name product which is already in the market)? Or, does it also apply to testing of a newly developed product that is covered by the claims of a valid patent, if such a test is made for the purpose of obtaining its marketing approval?

28. Furthermore, although it may be a matter of formality, countries provide the regulatory review exception under different legal frameworks, as they deem appropriate within their legal system and practice. The rest of this Section will describe those detailed elements found in the national implementation of the regulatory review exception.

5.1 Legal framework regulating the regulatory review exception

29. Countries take different approaches in providing the regulatory review exception under their respective legal framework. Table 1 summarizes how the regulatory review exception is introduced in each country's legal system.

Table 1. Classification of source of law	
Explicit provision on regulatory review exception in IP or patent legislation	Australia, Austria, Bolivia, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Finland, France, Germany, Iceland, India, Ireland, Israel, Italy, Jordan, Kenya, Latvia, Malaysia, Malta, Morocco, Namibia, Netherlands, New Zealand, Norway, Oman, Pakistan, Paraguay, Peru, Philippines, Poland, Singapore, South Africa, Spain, Sweden, Switzerland, Thailand, Tunisia, Turkey, United Republic of Tanzania, United States of America and Zimbabwe.
Regulatory review exception as part of the research or experimental use exception (stated explicitly)	Bosnia and Herzegovina, Croatia, Czech Republic, Hungary, Iceland, Portugal, Republic of Korea, Serbia, Slovakia, Slovenia, The Former Yugoslav Republic of Macedonia, United Kingdom and Uruguay and Viet Nam.
Regulatory review exception as part of the research or experimental use exception (through case law)	Japan and the Russian Federation.
Explicit provision in other legislations (e.g., relating to health and/or pharmacy)	Argentina, Belgium, Greece, Lithuania and Mexico.

30. In many countries, there is a specific statutory provision on this exception within respective IP or patent legislation. For instance, the Intellectual Property Law of Egypt states:

> "The following shall not be considered as infringements of that right when carried out by third parties:
> [...]
> (5) Where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtaining a marketing license, provided that the marketing starts after the expiry of such a protection period."[37]

[37] Article 10 of Intellectual Property Law of Egypt.

31. In some other countries, the regulatory review exception and experimental/scientific research exception are expressly combined into a single provision.[38] For example, Article 21 of the Patent Law of Jordan[39] states:

> "[...]
>
> C. Notwithstanding the provisions of this Law or any other legislation, carrying out research and development, and submitting applications for obtaining approvals to market a product prior to the expiry date of the patent protection shall not be considered an act of civil or criminal infringement."

32. In some other countries, the regulatory review exception is considered as being covered by a provision regarding experimental use or scientific research exception. Consequently, no specific provision on the regulatory review exception has so far been considered necessary in those countries. For example, in Japan, the Supreme Court determined that any clinical investigations of generic drugs, which are performed for the purposes of obtaining the regulatory approval from authorities would be regarded to be "experiments or research" under Article 69(1) of the Japanese patent law.[40] Similarly, in the Russian Federation, while no statutory exception concerning the regulatory review exists, courts have recognized that use of the patented medicine for such purposes is not considered an infringement of rights as it falls within the scope of the provision concerning the research exception.[41]

33. The legislative history of the United States of America[42] and South Africa[43] shows that the courts had been asked to decide on whether the experimental use exception in the respective country covered a specific act for obtaining regulatory approval. In both countries, the courts held that such an act constituted a patent infringement. In response to the courts' ruling, the regulatory review exception was introduced in their law through a legislative amendment.

Box 3. Regulatory review exception in South Africa

In 2003, the Patents Act of South Africa was amended to provide the 'Bolar' type exception in order to expedite the availability of generic medicine on the market after the expiration of the patent. The amendment was made following the decision in Stauffer Chemicals v Monsanto,[44] which held that the experimental use of an invention amounted to infringement.

In that case, the Court confirmed the interpretation of section 45(1) entitled "Effect of patent" by finding that it entitled the patent owner to have and enjoy the whole profit and advantage of the invention, but that it does not prohibit the mere possession of an infringing article/product without an intention to use or dispose of it. However, the Court stated that even experimental use of a patented invention would amount to an infringement in that the experiment uses the patented invention. The Court found that the alleged infringer who used the patented invention during the term of the patent

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38 See, for example, applicable laws of Argentina, Bosnia and Herzegovina, Croatia, Hungary, Jordan, Portugal, the Republic of Korea, Slovakia and Spain.

39 Article 21 C of Law No. 32 of 1999 on Patents, as last amended by Law No. 28/2007.

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

41 Article 1359(2) the Civil Code of the Russian Federation. Specifically, in the Novartis AG case, the Supreme Arbitration Court of the Russian Federation confirmed that manufacturing and submitting drug samples to a scientific examination center for subsequent quality testing, as well as officially registering the drug with the Federal Supervision Service for Healthcare and Social Development (Roszdravnadzor), could not be deemed as an infringement of rights. See document SCP/20/13, p.19.

42 See Box 1 "Bolar Exception in the United States of America".

43 See Box 3 "Regulatory review exception in South Africa".

44 *Stauffer Chemicals v. Monsanto* 1988(1) SA 805(T).

to prepare for marketing registration of its own similar product in fact used the patented invention as a springboard to obtain an improper advantage and that it constitutes infringement. In order to address this situation, the Patent Act was amended to include Section 69A, which states:

"69.A(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

(2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection."

The exception applies to any patented invention in any field of technology in respect of which any law requires the submission of information for the manufacture, distribution or sale of a product. This would for example cover pharmaceutical and agrochemical products which require marketing authorization before such products may be put on the market.[45]

34. In some other countries, for example in Lithuania and Mexico, the exception is contained not in the law on patents but in the regulations relating to health and/or pharmacy. For example, in Mexico, the exception is provided in the Regulations on Health-Related Consumable Goods. In Lithuania, the Law on Pharmacy stipulates this exception to the patent rights.

35. The above differences in the national approach show that non-existence of an explicit regulatory review exception provision within a patent or IP law does not mean that the country concerned does not have a regulatory review exception. A similar legal provision may be found in another law, or there may be established jurisprudence in the country, recognizing such exception to the patent rights under another legal provision.

5.2 Permitted acts under the regulatory review exception

Making, using offering for sale, etc.

36. Generally speaking, the regulatory review exception allows a third party's "exploitation" or "working" of the patented invention, which are necessary to obtain the marketing approval. While some national laws do not elaborate on those acts,[46] clarifications on the types of actions permitted under this exception are given in some countries.

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45 South Africa's statement on the regulatory review exception in WTO TRIPS Council (February 2018).

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

37. Somewhat mirroring the rights conferred by patents, the law of the United States of America provides that making, using, offering for sale or selling within the United states of America, or importing into the United States of America, a patented invention for the purpose stipulated in the relevant provision of the law[47] is not considered patent infringement. Similarly, according to the law of South Africa, it shall not be an act of infringement of a patent to make, use, exercise, offering to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the regulatory review purposes.[48] In many Latin American countries, their laws state that patent rights shall not extend to "uses" of a patented invention for the regulatory review purposes.[49] In Brazil, "making, using; and acts performed by non-authorized parties regarding patented inventions" which aimed at obtaining regulatory approval, as provided in its law, are permitted acts.[50]

38. In Canada and India, reference was also made to "constructing" [51] the patented invention, and to a "loan and transfer" in the Republic of Korea.[52]

Importing and exporting

39. In some countries, permissible acts explicitly include "import"[53] and "export" [54]. Importation of the patented invention, if permitted, might occur where a third party requires importation of such invention for the trial of his/her future product, which will be subject to marketing authorization by either the regulatory authority in his/her country or, if permitted under the applicable law, the regulatory authority in another jurisdiction (see Figure 1).

40. Figure 1 (in page 16) shows examples of scenarios that might occur where a patented invention is imported from Country B to Country A in order for a third party to use that invention in Country A. The regulatory review exception of Country A, therefore, is invoked. Under scenario 1, a third party imports a patented invention from Country B to Country A in order to conduct tests and studies for the purpose of developing information necessary for filing a marketing authorization request with the regulatory authority in Country A. Under scenario 2, in a similar manner as in scenario 1, importation of a patented invention takes place from Country B to Country A; however, tests and studies are undertaken with a view to filing a marketing authorization request with the regulatory authority in Country B. Scenario 3 is similar to scenario 2; however, tests in Country A are conducted in order to file a marketing authorization request with another Country C.

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47 35 U.S.C. Section 271(e)(1).

48 Section 69A of the Patents Act No.57 of 1978, as last amended by Act No. 20 of 2005.

49 See the relevant legal provisions of, e.g., El Salvador, Colombia, Costa Rica, Paraguay and Peru in Appendix.

50 See the response of Brazil to the Questionnaire.

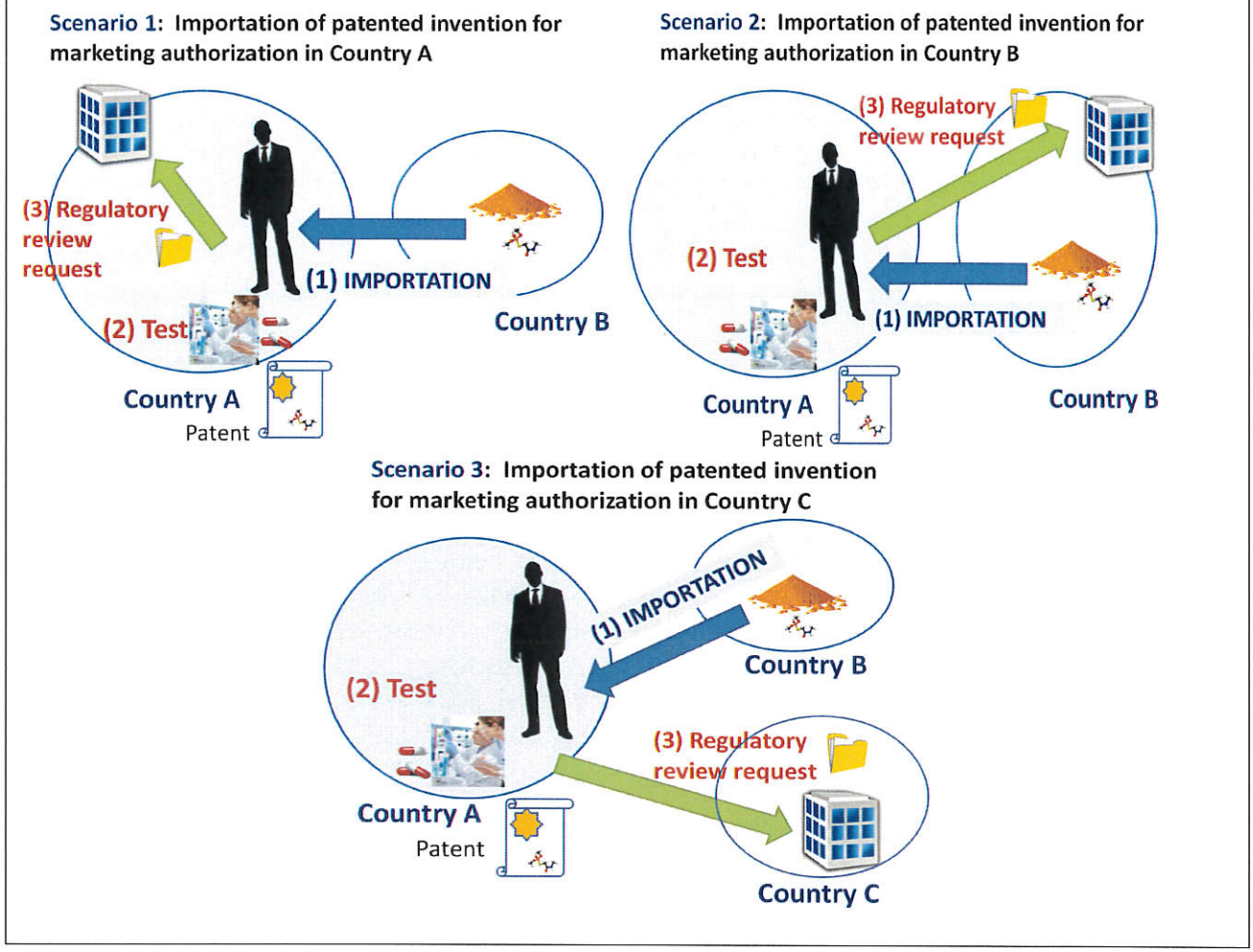
51 Section 55.2 (1) of the Patent Act of Canada reads: "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention [...]"; Section 107A(a) of Patents Act 1970 of India reads: "Certain acts not to be considered as infringement [...] any act of making, constructing,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

52 See the response of the Republic of Korea to the Questionnaire.

53 See, for example, the relevant legal provisions of China, Chile, India, the South Africa and the United States of America as well as the responses to the Questionnaire from the United Kingdom and Viet Nam.

54 See, for example, the responses to the Questionnaire from Chile, Israel, Latvia, Pakistan, Peru and the United States of America.

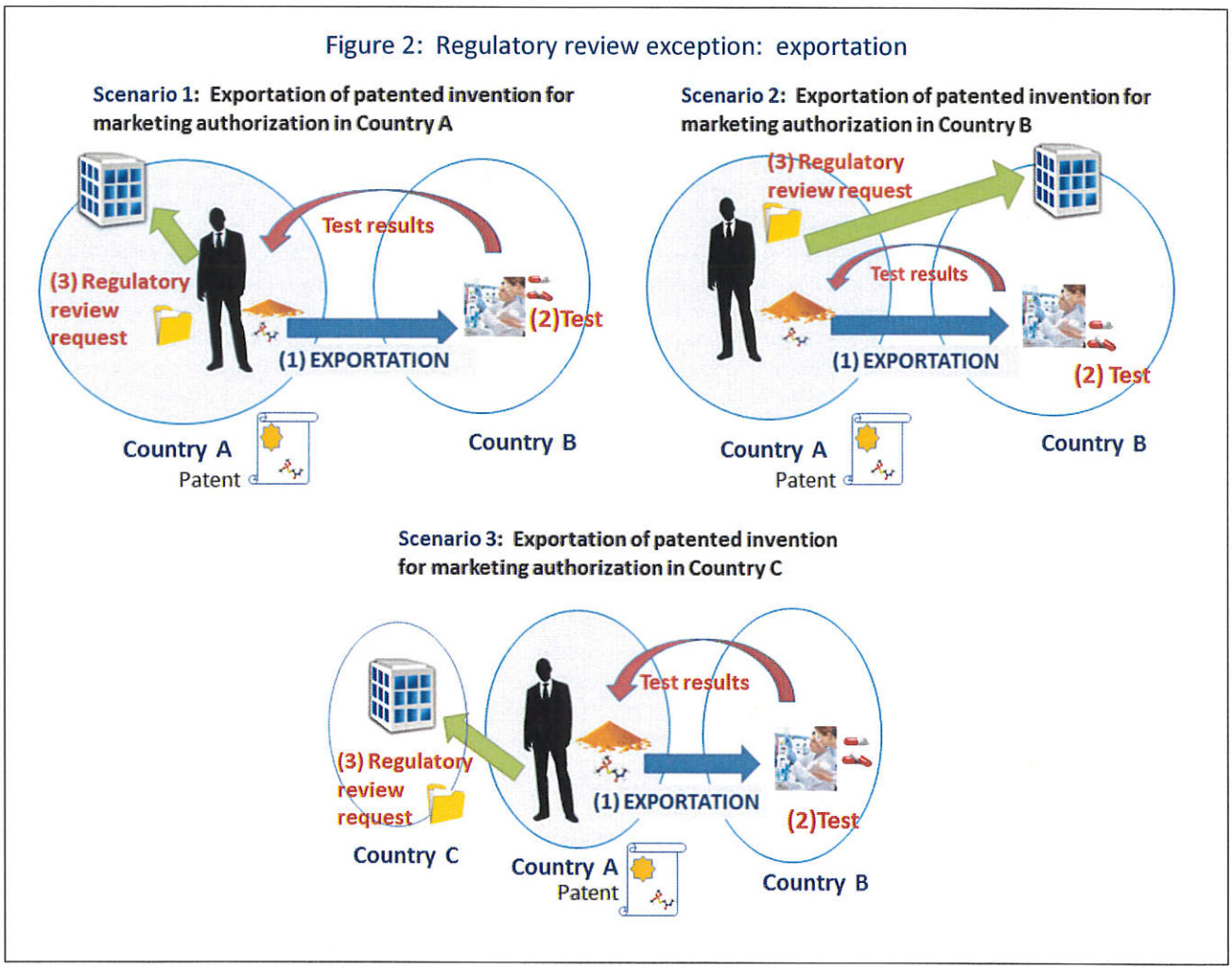
Figure 1: Regulatory review exception: importation



41. Similarly, a third party may export, if permitted by the applicable law, the patented invention to another country, when he/she seeks testing of its future product abroad, for the purpose of obtaining marketing authorization by either the regulatory authority in his/her country or, if permitted under the applicable law, the regulatory authority in another jurisdiction (see Figure 2).

42. Under scenario 1, a third party exports a patented invention from Country A to Country B in order to undertake tests using that invention in Country B for the purpose of developing information necessary for obtaining marketing authorization in Country A. Under scenario 2, exportation of the patented invention from Country A to Country B by a third party takes place for the purpose of undertaking tests and developing information necessary for obtaining marketing authorization in Country B. Under scenario 3, a third party exports a patented invention from Country A to Country B in order to undertake tests using that invention in Country B for the purpose of developing information necessary for obtaining marketing authorization in Country C.

Figure 2: Regulatory review exception: exportation



43. As those scenarios in Figures 1 and 2 illustrate, the jurisdiction in which the regulatory review exception is used, i.e., Country A, may not necessarily be the place where a request for regulatory review is eventually submitted. In addition, even if Country A allows importation or exportation of the patented invention under the regulatory review exception, it does not mean that all the Scenarios described above are automatically available and are compatible with the applicable law of Country A.

44. For example, in order for Scenario 2 in Figure 1 and Figure 2 (or Scenario 3 in Figure 1 and 2) to be available, the regulatory review exception in Country A shall cover the cases where the patented

invention is imported/exported for the purpose of obtaining a regulatory approval in another country, that is, Country B (or Country C). However, as it will be further explained in Section 5.5, in some countries, the regulatory review exception can be invoked only for the purpose of obtaining a regulatory approval in the same country only, and not abroad. For instance, the regulatory review provisions of Colombia, El Salvador and Oman, state that while the exportation of the product outside the national territories is allowed, such exportation shall be permitted only to satisfy the requirements for marketing approval in their respective countries.[55]

45. In Australia, the regulatory review exception also applies to the cases where the patented invention is used for the purpose of obtaining regulatory approval in a jurisdiction outside Australia. However, for that purpose, while exportation of inventions covered by non-pharmaceutical patents is permitted without further conditions, with respect to pharmaceutical patents, exportation of patented goods is limited to the cases where: (i) the term of the standard patent on pharmaceutical substance has been extended under Part 3 of Chapter 6; and (ii) the goods consist of or contain certain pharmaceutical substance.[56]

46. Furthermore, whether the above scenarios can be legally operational or not depends on other factors applied in each specific case: for example, whether a valid patent also exists in Country B and whether the law in Country B provides for a regulatory review exception, and if so, what the scope of such exception is. As an illustration, in the case of Scenario 3 in Figure 2, if a valid corresponding patent also exists in Country B, depending on the scope of the regulatory review exception in Country B, importation of the patented invention to Country B and its use for testing before the expiration of the patent for the purpose of obtaining a regulatory approval in Country C may be considered as an infringement act in Country B.

47. Beyond the issue of patent law, in order for Scenario 2 (or 3) in Figure 1 to be available, the regulatory review authority in Country B (or Country C) should be in a position to accept the information generated by the test conducted in Country A. Furthermore, it goes without saying that the response to the question on whether market players would carry out the actions illustrated in each scenario also depends on their economic motivations and economic feasibility. In a nutshell, the above analysis shows that policy makers as well as third parties who use the regulatory review approval may need to consider variety of issues.

Studies, trials, tests etc.

48. Instead of articulating the third parties actions (such as making, using, offering for sale etc.), laws of some countries, particularly in Europe, provide the permitted acts by the type of the exploitation of the invention, such as "studies", "trials", "tests", "examinations" and/or "experiments", as well as "consequential practical requirements", "related practical needs" or "related procedures" necessary for

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55 Article 3 of Decree 729 of Colombia, Article 116 (e) of Law on the Promotion and Protection of Intellectual Property Rights of El Salvador, Section 11(4)(a) of the Industrial Property Rights and their Enforcement for the Sultanate of Oman (Royal Decree No. 67/2008).

56 Article 119A of Patent Act 1990 of Australia. The applicable pharmaceutical substances 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".

obtaining a marketing "authorization", "permission", "registration" or "marketing clearance" for a product, as defined in the applicable laws.[57]

49. For example, 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".[58] 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".[59]

50. In Germany, studies, experiments and any resulting practical requirements under Section 11 no. 2b of the Patent Act 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)".[60]

Quantitative element

51. In general, under the regulatory review exception, the use of the patented invention by third parties is allowed only for the purpose of obtaining the regulatory approval. As referred to in paragraph 37, the applicable law of South Africa clarifies that the regulatory review exception applies where the exploitation of the patented invention is made "on a non-commercial scale". In the United Kingdom, the UKIPO and the Medicines and Healthcare Products Regulatory Agency (MHRA) published their view on the regulatory review exception that the carrying out of chemical and biological synthetic processes suitable for the making, disposal or keeping of the active substance(s) should be in quantities sufficient to provide material for preparing investigative batches and to validate the processes to the satisfaction of the competent authorities.[61] However, the response from Norway to the Questionnaire stated that under the exception, a third party "can also produce any amount necessary to fulfill any documentation requirements needed to obtain the marketing authorization" in particular country.[62]

5.3 To what extent the permitted acts should be related to the marketing approval?

52. As its title "regulatory review exception" suggests, the acts permitted under the regulatory review exception are closely linked to its final objective of obtaining a marketing authorization of the product concerned. In many national laws, such a close link is expressed with the phrases such as "acts for regulatory approval", "acts solely for uses reasonably related to regulatory approval" or "acts exclusively aiming at regulatory approval".[63] In some countries, a direct relation between use of the patented invention by a third party for studies, trials and their consequential practical requirements, on the one

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57 See, for example, Section 22(1) of the Austrian Patent Act, 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, and Article 52.1(b) of the Law on Patents of Spain.

58 See a response of the Netherlands to the Questionnaire.

59 See a response of Switzerland to the Questionnaire.

60 See a response of Germany to the Questionnaire.

61 See UKIPO website at: http://webarchive.nationalarchives.gov.uk/20140603113939/http://www.ipo.gov.uk/pro-types/pro-patent/p-policy/p-policy-pharmaceutical/p-policy-pharmaceutical-activities.htm, and Annex A: Review of the EU Medicines Legislation, Proposals for Implementation, MHRA, p. 15.

62 See the response from Norway (question 56) at: http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/norway.pdf.

63 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.

hand, and the authorization by an authority to put the products on the market, on the other hand, is observed.[64]

53. In the United States of America, acts "solely for uses reasonably related to the development and submission of information under a Federal law" do not constitute patent infringement under 35 U.S.C. §271(e)(1). In interpreting this phrase, the Supreme Court of the United States held in *Merck KgaA v. Integra Lifesciences I, Ltd.*[65] that the exception broadly protects any pre-clinical testing of patented compounds that is reasonably related to the submission of information to a regulatory agency, and not just late-stage safety and efficacy testing in human subjects.

Box 4. Merck KGaA v. Integra Lifesciences I, Ltd.

In *Merck KGaA v. Integra Lifesciences I, Ltd.* Case, the United States Supreme Court decided on the range of permissible activities under 35 U.S.C. §271(e)(1), which creates an exemption from patent infringement for use of a patented invention "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."

Pharmaceutical companies investigate a great many compounds that do not turn out to have eventual application as medicines. Merck KGaA investigated some compounds patented by Integra Lifesciences but did not proceed with them further as they showed no promise for the indication that they were interested in. Integra filed suit against Merck for patent infringement. The question was whether the Bolar exception only covers activity relating to a compound for which regulatory approval is actually sought, or whether it covers activity relating to any compound for which it could reasonably be believed that regulatory approval could be sought.

The Court held that the exemption extends to preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. This includes both preclinical data pertaining to the safety of drugs in humans, and preclinical studies related to a drug's efficacy, mechanism of action, pharmacology, and pharmacokinetics.

The Court vacated a decision by the Federal Circuit, which had limited the §271(e)(1) exemption to research activities that supply information for submission to the FDA. The Court opined that the exemption is not categorically inapplicable to either (1) experimentation on drugs that are not ultimately the subject of an FDA submission, or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Nevertheless, the Court stated that the scope of § 271(e)(1) does not include all experimental activity that at some point, however attenuated, may lead to an FDA approval process. It does not cover basic research that is not done with the intent of identifying possible candidates for future FDA approval.

54. Further, in *Momenta Pharmaceuticals. v. Amphastar Pharma*,[66] the Federal Circuit held that if testing is carried out to "satisfy the FDA's requirements", it falls within the scope of the exception, even though the activity is carried out after approval and the information collected is never submitted to a regulatory agency, provided that the agency requires such testing or the retention of records for possible inspection.

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64 See the responses to the Questionnaire from Austria, Germany and Italy.
65 *Merck KGaA v. Integra Lifesciences I, Ltd,* 125 S. Ct. 2372, No. 03-1237 (June 13, 2005).
66 *Momenta Pharmaceuticals. v. Amphastar Pharma* (686 F.3d 1348 (2012).

5.4 Applicability of the regulatory review exception to third party suppliers

55. In general, in order to gather information necessary to obtain regulatory authorization, a requester of such authorization may need to produce and test a sample product, which could be technically complex. While, in some cases, the whole process may be conducted by a single party, in other cases, more than one party may be involved in this process. For example, one party may produce and/or supply a patented active pharmaceutical ingredient (API) to another party which conducts tests on that API. Several judgements have been rendered by the courts in Europe and the United States of America in relation to the question as to whether the activity of a third party supplying a patent-protected substance to a generic company for its use in tests for obtaining marketing authorization is exempted from patent infringement.

Europe

56. In Europe, the regulatory review exception relating to medicinal products for human use is governed by Article 10(6) of the Directive 2001/83/EC (as amended) which states: "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."[67] While it appears undisputed that a party wishing to carry out trials necessary to obtain marketing authorization for a generic medicine is entitled under the exception to manufacture the required product, [68] there has been some debate over the issue of whether a third party manufacturer which supplies a patent-protected substance to a generic company for its use in tests necessary to obtain marketing authorization should be exempt from patent infringement according to the Directive.

57. The national courts of Poland and Germany were recently called upon to consider this issue in *Astellas Pharma Inc v. Polpharma S.A. Pharmaceutical Works* case, which resulted in the Dusseldorf Court of Appeal referring that question to the Court of Justice of the European Union (CJEU) in 2014 (see Box 5).[69] The CJEU did not issue an interpretation on the subject, as the case was later withdrawn.

58. Nevertheless, in some EU countries, activities of such suppliers are included within the relevant exception. For example, the response to the SCP Questionnaire on exceptions and limitations to patent rights from the United Kingdom in this regard clarified that:

> "[...] Section 60(5)(i)(ii) provides that the exception also applies to any other act required for the purpose of such studies, tests and trials. This suggests that manufacturers and suppliers of materials for such studies, tests and trials would also be covered by the exception".[70]

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67 Directive No. 2004/27/EC of the European Parliament and of the Council of 31 March 2004 of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

68 The responses to the Questionnaire from Austria, Germany, Italy, Latvia and Netherlands stated that the manufacturers of pharmaceutical products, especially of generic medicines are entitled to use the relevant exception. See the responses to the Questionnaire provided by Austria (on Section 22 of the Austrian Patent Act), Germany (on Section 11 no. 2b of Patent Act), Italy (on Article 68(1)(b) of the Industrial Property Code), Latvia (on Section 20.3 of the Patent Law of Latvia), and the Netherlands (on Article 53(4) of the Netherlands Patent Act 1995).

69 Astellas Pharma Inc v. Polpharma S.A. Pharmaceutical Works (C-661/13), available at: http://curia.europa.eu/juris/liste.jsf?language=en&jur=C,T,F&num=C-661/13&td=ALL

70 In addition, the exception may be used by anybody seeking to obtain regulatory approval or carrying out health technology assessment for a medicinal product. See the response received by the United Kingdom to the Questionnaire.

59. In Germany, suppliers are exempt, if they are themselves involved in the process for obtaining a marketing authorization, i.e., they are co-organizer of clinical trials.[71]

Box 5. Astellas Pharma Inc v. Polpharma S.A. Pharmaceutical Works

In 2013, the Polish Supreme Court issued a decision in *Astellas v. Polpharma*[72] . The Court held that a third party supplier of an active pharmaceutical ingredient (API) to a generic manufacturer infringed the rights of the patent holder, because it had no control of whether the customer used the API for acts

related to obtaining a marketing authorization. The Court held that sale of a patented API, irrespective of its purpose, is not covered by the regulatory review exception and therefore constitutes patent infringement.

In the corresponding German proceeding, the Düsseldorf district court held that a third party supplier of API, such as Polpharma, will only be protected by the regulatory review exception when it is a co-organizer of the studies carried out by its customer.[73] On appeal, the Dusseldorf Court of Appeal felt that some clarification from the Court of Justice of the European Union (CJEU) is required on this issue. In particular, the German court has asked the CJEU whether a third party supplier can be exempt from patent infringement and under what conditions, particularly whether the third party supplier was bound to take measures to ensure the API is only used for the purpose of obtaining regulatory approval.[74, 75]

The United States of America

60. In the United States of America, some courts have ruled on the issue of whether the regulatory review exception under 35 U.S.C. §271(e)(1) applies to a third-party supplier.[76] The leading judicial opinion is Shire LLC v. Amneal Pharmaceuticals, LLC[77], which is a decision issued from the United States Court of Appeals for the Federal Circuit (see Box. 6).

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71 See a submission of Germany to the twenty-seventh session of the SCP to be found at: http://www.wipo.int/scp/en/meetings/session_27/comments_received.html.

72 CSK 92/13.

73 4a O 282/10, District Court Düsseldorf, 26/07/2012, to be found at: https://dejure.org/dienste/vernetzung/rechtsprechung?Gericht=LG Düsseldorf&Datum=26.07.2012&Aktenzeichen=4a O 282/10.

74 I-2 U 68/12, Düsseldorf Higher Regional Court order, December 5, 2013, to be found at: https://united-kingdom.taylorwessing.com/fileadmin/files/docs/Polpharma-Astellas_Beschluss_OLG-D%C3%BCsseldorf__ENG.pdf. The case was subsequently closed without any guidance being issued by the CJEU.

75 In this regard, it was explained in the submission of Germany that if a supplier is not a co-sponsor of clinical trials, he/she is obliged to take precautions against any infringing use of the supplied products and has to ensure that the protected products are only used within the scope of the exemption. See the submission at: http://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/germany_1.pdf.

76 See e.g., *SmithKline Beecham Corp. v. Geneva Pharmaceuticals, Inc.*, 287 F. Supp. 2d 576 (E.D. Pa. 2002); and *Shire LLC v. Amneal Pharmaceuticals, LLC* 802 F.3d 1301 (Fed. Cir. 2015).

77 802 F.3d 1301 (Fed. Cir. 2015).

Box. 6 Shire LLC v. Amneal Pharmaceuticals, LLC

Shire brought a patent infringement suit against several generic drug companies and their third-party supplier. Each of the generic firms - the so-called "Abbreviated New Drug Application (ANDA) defendants"- had obtained the API of its proposed generic product from Johnson Matthey Pharmaceutical Materials, a chemical manufacturer. Johnson Matthey's role was limited to serving as a supplier, and it did not itself seek FDA approval to market a generic drug in the United States of America. The Court of Appeals reversed the district court's judgement that Johnson Matthey had induced infringement of the asserted compound claims, and concluded that the regulatory review exception applied to Johnson Matthey.
The court explained that:

> "Johnson Matthey is correct that it cannot be liable for the API it sold the ANDA defendants up to this point. Johnson Matthey, as an API supplier, has thus far done nothing more than provide material for use by the ANDA defendants in obtaining FDA approval. As the district court found, these sales, and the ANDA defendants' use of the API for filing the ANDA, were "reasonably related to the submission of an ANDA." [...] As such, Johnson Matthey's activities are protected by the safe harbor [...]".

Thus, the Court suggests that third-party suppliers are immunized from patent infringement, as long as their activity is limited to supplying material for use relating to obtaining the FDA approval.

5.5 Acts carried out to obtain regulatory approval in other countries

61. In some countries, the plain language of the relevant provisions in the laws is silent as to whether acts carried out for the purposes of obtaining the regulatory approval in other countries is included within the scope of the exception. However, such wordings should not necessarily infer that the scope of the exception in those countries do not include activities aiming at authorization in other countries.[78] In some countries, the wording of the relevant provision explicitly indicates that the exception applies to acts which are carried out for the purpose of obtaining the regulatory approval in those respective countries only.[79] Yet, in many other countries, the provisions on the regulatory exception expressly state that the activities made for the purpose of obtaining regulatory approval *in other countries* are also covered under the exception.[80]

62. As an example of the latter, the applicable law of India states:

> "Section 107A. For the purposes of this Act,-
> (a) any act of making, constructing, using or selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law

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78 For example, in China, Article 69(5) of the Patent Law provides that the acts, as defined in that provision, for the purpose of providing information required for administrative examination and approval, shall not be deemed to infringe patent right. It was explained in the submission of China that "Administrative examination and approval" is understood as covering the administrative examination and approval conducted by both Chinese and foreign drug administrations. See, the submission of China to the twenty-eighth session of the SCP, available at: http://www.wipo.int/scp/en/meetings/session_28/comments_received.html.

79 Article 3 of Decree 729 of Colombia; Article 116 (e) of Law on the Promotion and Protection of Intellectual Property Rights of El Salvador; Section 11(4)(a) of the Industrial Property Rights and their Enforcement for the Sultanate of Oman (Royal Decree No. 67/2008); and 35 USC § 271(e)(1) of the United States of America.

80 These countries are: Australia, Brazil, Canada, Denmark, Germany, India, Ireland, Israel, Italy, Malta, New Zealand, Norway, Oman, Philippines, Spain, Switzerland, United Kingdom, and the United Republic of Tanzania.

for the time being in force, in India, *or in a country other than India*, that regulates the manufacture, construction, use or sale of any product;
[...]
shall not be considered as an infringement of patent rights."(emphasis added)[81]

63. Likewise in Brazil:

"43. The provisions of the previous Article do not apply:
[...]
VII- to acts practiced by unauthorized third parties related to the invention protected by a patent, for the sole purpose of producing tests results, information and data in order to obtain the commercialization registration in Brazil *or abroad* for the exploitation and commercialization of the product that is the subject matter of the patent, after expiration of the terms set forth in Article 40."(emphasis added)[82]

64. In some countries, regulatory approval in foreign countries is covered by the exception under certain condition. In some countries, such condition is the membership to a certain international or regional treaty. 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 permitted.[83] 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".[84]

65. In Switzerland, regulatory approval in foreign countries is covered by the exception, only if they have regulations for pharmaceutical products comparable to those of Switzerland. [85]

66. As illustrated in Section 5.2 "Permitted Acts under the Regulatory Review Exception" above, operability of a particular scenario about the use of the regulatory review exception depends on many factors, and can be very complex, particularly where the whole process that starts from the use of a patented invention to submitting a request for marketing authorization by a regulatory authority is carried out in more than one country. Provided that all those other conditions are met, if the scope of the exception covers marketing authorizations in other countries, it may at least provide the possibility of submitting requests for marketing authorization in many jurisdictions on the basis of the result of a trial in one country, and thus avoid the need to duplicate such trial in multiple jurisdictions.[86]

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81 Section 107A(a) of the Patent Act of 1970 of India.

82 Article 43 (VII) of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001.

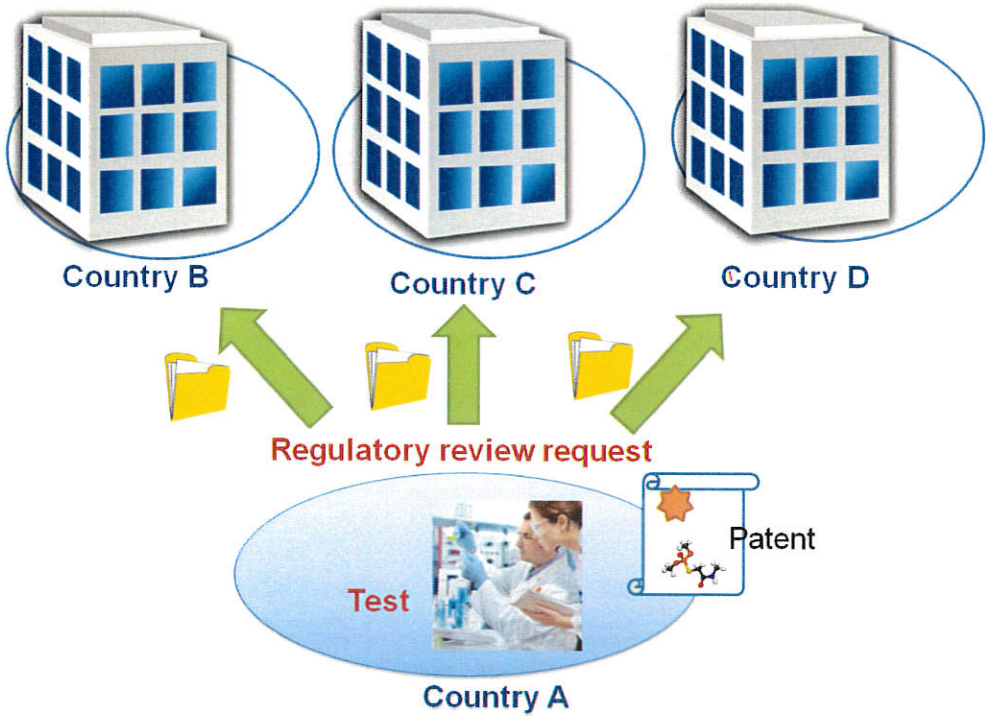
83 Section 3(3) No.5 of the Patents Act of Norway.

84 Section 11(2b) of the Patent Act of Germany.

85 Article 9(1) of the Federal Law on Patents for Inventions of Switzerland states: "The scope of protection conferred by the patent shall not extend to [...] acts necessary to obtain marketing approval for a pharmaceutical product in Switzerland or in countries with comparable regulation for pharmaceutical products."

86 See also the discussion under Section 7 "Results of implementation of the exception" in this paper.

Figure 3: One trial, multiple regulatory review requests



5.6 Products subject to the regulatory approval

67. In many countries, including Brazil, Canada, Hungary, India, Israel, New Zealand, South Africa and Viet Nam, the exception applies to exploitation of a patented invention for the regulatory approval of "any products".[87]

68. 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.[88] 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".[89]

69. However, in many other countries, the subject matter of the regulatory review exception is limited to certain products. Within one group of countries, the relevant provision limits the exception for the

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87 See also the relevant provisions of laws of the Dominican Republic, Italy, Jordan, Malaysia, Namibia, Pakistan and Portugal.

88 Section 119A of Patents Act 1990 of Australia.

89 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".

regulatory review of "reference medicine" [90]. Many countries' laws however use more general terms, broadly covering pharmaceuticals and medicines or medicinal products, for human and/or veterinary use. For example, the relevant provisions of Chile and Thailand refer to "pharmaceutical products"; in France, Greece and Norway the reference is made to "medicines" and in Finland, Germany and Switzerland to "medicinal product"; in El Salvador and Peru, the reference is made to "pharmaceutical and agricultural chemicals"; in Bosnia and Herzegovina and Croatia the reference is made to "medicine intended for humans or animals or a medicinal product". Yet in other countries, the laws refer to "allopathic medicines"[91], "drugs or veterinary biological products"[92], "medicinal products for human use or medicinal products for veterinary use"[93]. Some of them also cover medical devices and instruments. For example, in China, in addition to "patented drugs", the relevant provision refers to "patented medical apparatus and instruments". in the United States of America, in *Eli Lilly and Co. v. Medtronic*, the Supreme Court held that the exception under 35 U.S.C. §271(e)(1) not only applied to drugs but also to medical devices.[94]

Figure 4: Different types of products are covered by the regulatory review exception in various jurisdictions (non-exhaustive examples)
- Pharmaceutical and agricultural chemicals
- Drugs or veterinary biological products
- Reference medicine
- Medical apparatus and instruments
- Pharmaceuticals and non-pharmaceuticals
- Allopathic medicines
- Inventions for cosmetics, medical equipment, and agricultural chemicals
- Medicinal products
- Medicines
- Any product

90 Article 3(2) 2nd paragraph, 4 p of Patents Act of Sweden.

91 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 […]".

92 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)[…]".

93 Section 53 (4) of the Kingdom Act of 15/12/1994 of the Netherlands.

94 *Lilly & Co. v. Medtronic, Inc.* 496 U.S. 661 (1990).

70. In the United Kingdom, prior to October 1, 2014, the exception has been 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. On October 1, 2014, Section 60 of the Patents Act of the United Kingdom was amended to clarify that the exception also applies to innovative drugs.[95] Similarly, in Norway, the regulatory review exception contained in Section 3(3) No.5 of the Patents Act "applies regardless of whether the test in question relates to generic, further developed, or newly developed medicines".[96]

71. In Japan, the exception has been recognized through interpretation of more general exception under Article 69(1) relating to experimentation and research. Since the Supreme Court based its decision on the regulations under the Pharmaceutical Affairs Act, the scope of the decision may be extended to patented inventions for cosmetics, medical equipment, and agricultural chemicals, in addition to certain medicines and agrochemical products.[97]

5.7 Time to file a regulatory review request

72. In most countries, the use of the patented invention for the purpose of obtaining the regulatory approval from the competent authorities can take place anytime during the term of patent protection. Normally, competitors would start testing and research within a reasonable period before the expiration of the patent.

73. However, the laws of Mexico and Paraguay provide that the use of the patented invention by a third party shall take place within a specific time period in order to be covered by the exception. Specifically, Article 167bis of the Regulations on Health-Related Consumable Goods of Mexico states that "[...] the registration of a generic medicine may be requested, the active substance or ingredient of which is protected by a patent, in order to carry out the corresponding studies, tests and experimental production, within *the three years prior to expiry of the patent*. In this case, health registration shall be granted only when the validity of the patent ends." (emphasis added).

74. Likewise, Article 34 (d) of Law on Patents for Inventions of Paraguay states that the use of the invention *within thirty days before the expiration of the patent* term to gather information required for the approval of the product by the competent authority is not an infringement. (emphasis added).

6. Challenges Faced by Member States in Implementing the Exception

75. As regards the implementation of the regulatory review exception at the national level, in general, two types of challenges have been recognized by some Member States. The first type of challenge relates to the uncertainty about the scope of the regulatory review exception in the national laws. For example, when implementing Article 10(6) of Directive 2004/27/EC in the Netherlands, it is observed that the precise scope of "trials and studies" as well as "consequential practical requirements" referred to in that

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95 See the response from the United Kingdom to the Questionnaire, available at: http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/uk_3.pdf.

96 See the response from Norway to the Questionnaire (question 56), available at: http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/norway.pdf.

97 See submission of Japan in document SCP/23/3, p.5.

Article was considered unclear, in the absence of jurisprudence set by the European Court of Justice.[98] In Turkey, it was reported that the courts pronounced conflicting opinions as regards the scope of the exception.[99] Similarly, the court decisions are not unanimous on this issue in Portugal. [100]

76. The second type of challenge is lack of awareness about this exception among potential users who might benefit from it. For example, the UNCTAD Secretariat reported that even in countries that have enacted the regulatory review exception, it is not necessarily used by generic companies due to lack of their awareness of patent issues, among others.[101]

77. In addition, availability of patent status information on pharmaceutical patents may be important for the purpose of exercising the exception. Specifically, availability of the expiration data on pharmaceutical patents would assist third parties in their planning when to start studies and testing on the patented product to generate information for regulatory authorities. In general, various initiatives to improve the patent status data are being undertaken and discussed at the international[102] as well as national levels.[103]

78. In addition, even if the national law implements the regulatory review exception with clear boundaries and reflecting the interests of the country concerned, there are other issues that might affect the use of the regulatory review exception in practice. For example, absence of production capacity of generic medicines in the territory[104], inefficient administrative procedures of the regulatory authorities resulting in delay in processing applications for regulatory approval or protection of undisclosed test data were reported to be relevant to the intended outcome of the regulatory review exception and the issue of access to medicines in general.[105] While Member States may encounter various challenges after implementation of the regulatory review exception, [106] it appears that the issues raised in this paragraph

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98 See the response to the Questionnaire from the Netherlands. See also response from Spain which referred 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. See document SCP/21/3.

99 See submission of Turkey to the SCP 27 to be found at: http://www.wipo.int/scp/en/meetings/session_27/comments_received.html.

100 See a response from Portugal to the Questionnaire and document SCP/21/3, p.9.

101 See submission by UNCTAD in document SCP/25/3, p. 2.

102 For example, WIPO provides the Patent Register Portal, which facilitates the verification of legal status of patents and SPCs by compiling relevant information of national registers (see http://www.wipo.int/branddb/portal/portal.jsp). In addition, WIPO Standard ST.27 provides a recommendation for the exchange of patent legal status data. Furthermore, an information exchange session on publicly accessible databases on patent information status and data on medicines and vaccines was held at the twenty-seventh session of the SCP in December 2017, during which the Representatives of the World Health Organization (WHO) and the Medicines Patent Pool (MPP) made presentations (see http://www.wipo.int/meetings/en/details.jsp?meeting_id=42307).

103 For example, in Chile, the National Industrial Property Strategy, launched in December 2016 by INAPI and the President of the Republic, contemplates proposing a system that allows the expiration date of a pharmaceutical patent to be published in advance, so that the interested parties are aware of this fact and could make use of the regulatory review exception. See the submission of Chile to the twenty-eight session of the SCP, available at: http://www.wipo.int/scp/en/meetings/session_28/comments_received.html.

104 See submission by UNCTAD in document SCP/25/3. This point was also raised by the TWN with respect to use of exceptions and limitations in general. See document SCP/25/3, paragraph 6. The said document also contains, in paragraph 27, the following observation by TWN: "[…] 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." In addition, as regards the challenges, the submission from the Russian Federation stated in general that the producers of pharmaceuticals in that country face certain constraints and that various government bodies search for solutions. See the submission of the Russian Federation to the twenty-seventh session of the SCP.

105 See the submissions of Brazil and Chile to the twenty-eighth session of the SCP available at: http://www.wipo.int/scp/en/meetings/session_28/comments_received.html; response from South Africa to the Questionnaire, and document SCP/21/3, p.9.

106 For discussion on such general challenges, see document SCP/26/5.

are not within the realm of patent law in strict sense; although, they might affect the intended policy objectives of the exception.

79. As illustrated in various court cases also found in this paper, a patentee and a third party do not necessarily agree whether the act carried out by the third party is indeed within the scope of the regulatory review exception under the applicable law or not. In reality, it is probably not possible to fully eliminate such disputes arising between the interested parties. The submission by Brazil to the twenty-eighth session of the SCP states that where a third party purportedly used a patented invention under the regulatory review exception in Brazil, a patentee (i) sues the third party for alleged infringement of its patent and requests, and obtains, preliminary injunction order against the third party; or (ii) requests fast-track examination of the corresponding patent application to the patent office on the basis of the alleged infringement act by the third party. It was observed in the submission that such actions by the patentee undermine the use of the regulatory review exceptions by third parties.

7. Results of Implementation of the Exception

80. In general, it is recognized that in the absence of the regulatory review exception, competitive products, such as generic medicines, would not be able to enter the regulated product markets for prolonged periods following patent expiry. Thus, many countries reported that the implementation of the regulatory review exception in the national law has a positive effect on the timely regulatory registration and entry of generic versions of medicines into the market.[107] Similarly, in countries where the regulatory review exception also applies to marketing authorization of a new product that has not been on the market (but nevertheless the exception should be invoked, since the new product is within the scope of a valid patent), it is expected that the exception would support the earlier entry of the new product in the market.[108]

81. However, limited empirical evidence exists as regards the impact of the implementation of the regulatory review exception on the behaviors of various stakeholders and consequential economic effect of such behaviors. Few data was found focusing on Europe, where divergences exist in the implementation of the regulatory review provisions of the EU Directives.[109] One study produced for the European Commission found positive effect of broadening the scope of the exception in Europe. In particular, the study estimates that the extension of the regulatory review provision to cover *any medicines* and marketing authorizations in *any country* would benefit the European pharmaceutical industry by reducing legal costs, such as freedom-to-operate (FTO) studies, validity opinions, patent oppositions and costs of infringement proceedings. In particular, the study estimates, *inter alia*, that cost savings from FTO studies could amount between €23– €34.3 million per year.[110]

82. The study also states that the extension of the exception to cover authorization in any country would likely, *inter alia*, reduce the need to duplicate clinical trials to support marketing authorizations in non-EU countries. The study estimates that indicative cost savings of not having to conduct a clinical trial in another country would be up to €647,406 to €1.1 million per case. The cost savings of not having to run

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107 See, e.g., the submission of Mexico (document SCP/23/3), as well as Turkey's submission to the twenty-seventh session of the SCP.

108 See, e.g., the response to the Questionnaire by the United Kingdom, available at: http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/uk_2.pdf.

109 Article 10(6) of Directive 2001/82/EC and Artcile 13(6) of the Directive 2001/82/EC, as amended.

110 See, Charles River Associates "Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe". The study was prepared for the European Commission, February 2016.

clinical trials in four additional countries could be €2.6 million to €4.4 million per case. [111] In addition, the study suggests that the measures would positively affect incentive to innovate in the EU, by removing the legal uncertainty of trials; increasing the number of skilled jobs in a country which adopts wider scope of exemption; reducing delays associated with assessing the legal risks when conducting studies and trials in countries with narrow scope of exception; and benefiting the patient population of the country through faster introduction of innovative products.

83. The study also suggests that extending the scope of this exception to cover the third party supply of an API is likely to benefit EU-based API suppliers. It is estimated that sales by third party European generic API producers could increase by 7-29% (€45.2 million to €180.8 million additional annual sales by 2030), depending on the scenario. The additional EU API sales translate into 2,000 new jobs by 2030. EU-based generic producers will also benefit from more choice of locally produced APIs, reduction of transport cost and customs clearance and other delays associated with imports. [112]

84. In connection to the extension of the scope of the regulatory review exception in the United Kingdom to cover innovative product, the government made an impact assessment which estimated that the amendment would reduce the cost of undertaking trials in the United Kingdom (for example, by eliminating the cost of FTO investigations which would save companies between £3,000 to £135,000 per trial) and that would make the UK a more attractive place for companies to undertake research and development.[113]

85. As regards other empirical evidence, while not specifically focusing on the impact of the implementation of the exception, several studies have analyzed the effect of generics' entry on the prices of originator products and the cost of related treatments. In general, such studies have found the reduction of prices of brand-name medicines due to competition from generic manufacturers. [114,115] Similarly, in the WTO dispute *Canada - Patent Protection of Pharmaceutical Products,* Canada demonstrated that generic versions of innovative medicines traded at a significant discount to the innovative version of the medicine. It stated that on average: (i) the first and second generic versions of a previously patented product came on the market at just less than 75 per cent of the innovator's price; (ii) when a third and a fourth generic entered, the average price dropped about 20 percentage points to about 54 per cent of the innovator price; (iii) and when a fifth entered, the average fell another ten percentage points to just under 46 per cent of the innovator's price for the same medicine. At the same

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111 Depending on the per patient cost of the clinical trial. See p. 9 of the study, Ibid.

112 Ibid, p. 13.

113 "Experimental use and Bolar exemption" Impact Assessment No. BIS0402.

114 See, e.g., Joan Rovira et al., "The Impact of Biosimilars' Entry in the EU Market", stating that "[…] the entry of generics can reduce the drug's price by up to 80% of the originators pre-expiry price", January 2011. Another study focusing on the United States of America finds that, for drugs experiencing initial generic entry in 2011–2012, the market exclusivity period (MEP) was 12.6 years for drugs with sales greater than $100 million (in 2008 dollars) in the year prior to generic entry, 12.9 years overall. After generic entry, the brand rapidly lost sales, with average brand unit share of 16% at 1 year; 11% for new molecular entities with pre-generic entry sales of at least $250 million (in 2008 dollars). See brief report "Recent Trends in Brand-name and Generic Drug Competition", Journal of Medical Economics, 2013, 1-8.

115 Similarly, another study based on the Hatch-Waxman Act, finds that "since the Hatch-Waxman, almost all top-selling drugs not covered by patent face generic competition; whereas pre–Hatch-Waxman, only 35% had generics available. Similarly, today more than 70% of prescriptions are for generics, whereas pre–Hatch-Waxman generic prescriptions numbered 15%. At present, with rapid generic substitution […] the rate of generic penetration is accelerated, with 80% conversion within 6 to 8 weeks". See Martha M. Rumore, "The Hatch-Waxman Act--25 Years Later: Keeping the Pharmaceutical Scales Balanced", 2009. However, such studies should be treated cautiously as The Hatch-Waxman Act included a number of provisions aimed at facilitating approval of generic drugs by the Food and Drug Administration (FDA) and encouraging generic entry as well as other provisions, such as the extension of the patent term. Therefore, it is difficult to conclude what the specific attribution of the provision on the regulatory review exception in the Hatch-Waxman Act was on these findings.

time, Canada also explained that "while such discounts suggested substantial savings, the quantum of the savings realized would, of course, depend on the degree of market penetration that the generic products achieved. The quantum of the savings would also vary if the innovator adjusted its prices downward in an effort to retain market share".[116] In general, many policymakers view generic medicine competition as the principal method to contain costs of medicines. Therefore, numerous laws, regulations and legal precedents are employed to regulate the structure and competitive environment of this market.[117] The regulatory review exception is one of those elements which, if optimally designed, can be applied in shaping the competitive environment for both generic and originator products.

86. Nevertheless, it is to be noted that the findings stated in paragraph 85 are not specifically attributable to the implementation of the regulatory review exception under the relevant laws. Since the regulatory review exception may cover, depending on the applicable law, not only generic medicines but also other medicines or even other products that are subject to marketing authorization, discussions on the results and impacts of the implementation of this exception might require much broader considerations. However, as stated above, the empirical evidence focusing on the specific effect of the regulatory review exception on the behaviors of market players and its consequential economic effect is still limited at this point.

[Appendix follows]

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116 WT/DS114/R, footnote 112. Canada also explained that "while such discounts suggested substantial savings, the quantum of the savings realized would, of course, depend on the degree of market penetration that the generic products achieved. The quantum of the savings would also vary if the innovator adjusted its prices downward in an effort to retain market share".

117 Luke M. Oslon, Brett W. Wendling, "The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period", FTC. Working paper No. 317.

COMPILATION OF VARIOUS LEGAL PROVISIONS ON THE EXCEPTION REGARDING ACTS FOR OBTAINING REGULATORY APPROVAL FROM AUTHORITIES

COMPILATION DE DIVERSES DISPOSITIONS JURIDIQUES CONCERNANT L'EXCEPTION RELATIVE AUX MESURES PRISES EN VUE D'OBTENIR L'APPROBATION RÉGLEMENTAIRE DES AUTORITÉS

COMPILACIÓN DE LAS DIFERENTES DISPOSICIONES LEGALES SOBRE LA EXCEPCIÓN RELATIVA A LOS ACTOS REALIZADOS PARA OBTENER LA APROBACIÓN REGLAMENTARIA DE LAS AUTORIDADES

تجميع لأحكام قانونية مختلفة بشأن الاستثناء المتعلق بإجراءات الحصول على الموافقة التنظيمية من السلطات

关于从当局获得监管批准行为例外的各种法律规定汇编

КОМПИЛЯЦИЯ РАЗЛИЧНЫХ ПРАВОВЫХ ПОЛОЖЕНИЙ ОБ ИСКЛЮЧЕНИИ В ОТНОШЕНИИ ДЕЙСТВИЙ, СВЯЗАННЫХ С ПОЛУЧЕНИЕМ РАЗРЕШЕНИЯ ОТ ГОСУДАРСТВЕННЫХ РЕГУЛИРУЮЩИХ ОРГАНОВ

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ARGENTINA

Articulo 8°of Ley N° 24.766 de Confidencialidad sobre Informacion.

8° Cuando se trate de un producto o procedimiento protegido por una patente de invención, cualquier tercero podrá utilizar la invención antes del vencimiento de la patente, con fines experimentales y para reunir la información requerida para la aprobación de un producto o procedimiento por la autoridad competente para su comercialización con posterioridad al vencimiento de la patente.

AUSTRALIA

Section 119 A of the Patent Act 1990, consolidated as of February 24, 2017.

119A Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

(a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:

(i) are intended for therapeutic use; and

(ii) are not medical devices, or therapeutic devices, as defined in the Therapeutic Goods Act 1989; or

(b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

(2) Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain:

(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.

(3) In this section: pharmaceutical patent means a patent claiming:

(a) a pharmaceutical substance; or

(b) a method, use of product relating to a pharmaceutical substance, including any of the following:

(i) a method for producing a raw material needed to produce the substance;

(ii) a product that is a raw material needed to produce the substance;

(iii) a product that is a pro-drug, metabolite or derivative of the substance.

119B 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.

(2) This section does not apply in relation to a pharmaceutical patent within the meaning of subsection 119A(3).

AUSTRIA

Section 22 of the Austria Patent Act 1970, as last amended by Federal Law Gazette (BGBl) I No. 135/2009.

22 (1)

[...]

The effect of the patent shall not extend to studies and trials as well as to the consequential practical requirements, as far as they are necessary to obtain a permission, authorisation or registration for putting on the market pharmaceutical products.

BELGIUM

Article 6bis of the Belgium Medicines Act, 1964.

6bis § 1er.

[...]

La réalisation des études, des tests et des essais nécessaires en vue de satisfaire aux conditions et modalités prévues dans les alinéas 1er à 7 et les exigences pratiques qui en résultent, ne sont pas considérées comme contraires aux brevets et aux certificats complémentaires de protection pour les médicaments à usage humain.

[...]

BOLIVIA (PLURINATIONAL STATE OF)

Artículo 53 of Decisión N° 689 de 13 de agosto de 2008, sobre la Adecuación de Determinados Artículos de la Decisión 486 por la que se establece el Régimen Común sobre Propiedad Industrial, para permitir el Desarrollo y Profundización de Derechos de Propiedad Industrial a través de la Normativa Interna de los Países Miembros.

53 Incluir la facultad de usar la materia protegida por una patente con el fin de generar la información necesaria para apoyar la solicitud de aprobación de comercialización de un producto.

(Footnote to the Article: Los Países Miembros entienden esta facultad como la Excepción Bolar que facilita el otorgamiento de registros sanitarios.)

BOSNIA AND HERZEGOVINA

Article 73(b) of Patent Law of 2010.

73 The patent holder's exclusive right shall not apply to:

[...]

(b) acts performed for research and development purposes, and for experiments relating to the subject matter of the protected invention, including the acts necessary for obtaining registration or marketing authorisation for the product which is a medicine intended for humans or animals or a medicinal product,
[...]

BRAZIL

Article 43 (VII) of the Industrial Property Law No. 9.279 of 14/05/1996, as last amended by Law No. 10.196 of 14/02/2001.

43 The provisions of the previous Article do not apply:

[...]

VII to acts practiced by unauthorized third parties related to the invention protected by a patent, for the sole purpose of producing tests results, information and data in order to obtain the commercialization registration in Brazil or abroad for the exploitation and commercialization of the product that is the subject matter of the patent, after expiration of the terms set forth in Article 40..

BULGARIA

Article 20 (7) of the Law on Patents and Utility Models Registration No. 27/2 of 1993, as last amended by Law no. 59/20 of July 2007.

20 The effect of a patent shall not extend to:

[...]

7. (new, State Gazette No. 64/2006, in force as from 09.11.2006; deleted, State Gazette No.31/2007, in force as from 13 April 2007) conduction of necessary researches and tests for the purpose of filing a marketing authorisation request for a generic medical product to be used in the human medicine or a generic medical product to be used in the veterinary medicine, as well as any other act related to subsequent practical requirements in connection with the filing of the request.

CANADA

Section 55.2 (1) of the Patent Act (R.S., 1985, c. P-4).

55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

CHILE

Article 49 of Law No. 19.039, as last amended by Law No. 20.160.

49

[...]

The patent shall not confer the right to prevent third parties from importing, exporting, manufacturing or producing the subject matter protected by a patent for the purpose of obtaining the registration or health authorisation for a pharmaceutical product. The above shall not entitle those products to be marketed without the authorisation of the patent owner

CHINA

Article 69 (5) of the Patent Act of 12/03/1984, as last amended on 27/12/2008.

Article 69 None of the following shall be deemed an infringement of the patent right:

[...]

(5) any person who produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any third party who imports patented drugs or patented medical apparatus and instruments especially for that person.

COLOMBIA

Artículo 53 of Decisión N° 689 de 13 de agosto de 2008, sobre la Adecuación de Determinados Artículos de la Decisión 486 por la que se establece el Régimen Común sobre Propiedad Industrial, para permitir el Desarrollo y Profundización de Derechos de Propiedad Industrial a través de la Normativa Interna de los Países Miembros.

53 Incluir la facultad de usar la materia protegida por una patente con el fin de generar la información necesaria para apoyar la solicitud de aprobación de comercialización de un producto.

(Footnote to the Article: Los Países Miembros entienden esta facultad como la Excepción Bolar que facilita el otorgamiento de registros sanitarios.)

Artículo 3° of Decreto 729 de 2012.

3° Excepción al derecho conferido por la patente. Además de los actos previstos en el artículo 53 de la Decisión Andina 486, el titular no podrá ejercer el derecho que le confiere la patente, respecto de los actos realizados con el fin de generar la información necesaria para presentar una solicitud de aprobación requerida, para que un producto entre al mercado una vez expire la patente. En tal sentido, los terceros estarán facultados para fabricar, utilizar, vender, ofrecer en venta o importar cualquier objeto de la invención patentada exclusivamente para el fin antes mencionado.

Parágrafo. Si un producto es fabricado, utilizado, vendido, ofrecido en venta o importado bajo la excepción del párrafo anterior, sólo podrá ser exportado con el propósito de cumplir los requisitos de aprobación en Colombia.

COSTA RICA

Article 16 (2) (e) of the Law on Patents, Industrial Designs and Utility Models No. 6867 of 25/04/1983, as last amended by Law No. 8632 of May 25, 2008.

16.2 Provided that the following exceptions do not unjustifiably harm the normal working of the patent, or cause undue harm to the legitimate interests of its owner or its licensee, the rights conferred by the patent shall not extend to:

[...]

(e) the uses necessary to investigate or process or any other requirements to obtain health approval for the purpose of commercializing a product after the patent protecting it expires.

CROATIA

Article 63(2) of the Patent Act No. 173 of 2003, as last amended by Act No. 76/2013.

63 The patent owner's exclusive right of exploitation of the invention shall not apply to:

[...]

2. acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for obtaining registration or authorisation for putting on the market a product comprising a medicine intended for people or animals, or a medicinal product,

[...]

CZECH REPUBLIC

Section 18(e) of the Patents Act No. 527 of 1990.

18 The rights of the proprietor of the patent shall not be infringed by use of the protected invention:

[...]

(e) in acts relating to the subject-matter of the invention done for experimental purposes including experiments and tests necessary, pursuant to the special legal regulation, before placing a medicine on the market.

DENMARK

Section 3(3)(iv) of the Consolidated Patent Act No. 221 of February 26, 2017.

3(3) The exclusive right shall not extend to

[...]

(iv) acts delimited to the subject-matter of the patented invention which are necessary for obtaining a marketing authorisation for a medicinal product for humans or animals in the EU, in an EU member state or in other countries or

[...]

DOMINICAN REPUBLIC

Article 30(g) of the Law on Industrial Property No. 20-00 of 18/04/2000, as amended by Law No. 424-06 on Implementation of the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR).

30 A patent shall not confer the right to prevent

[...]

(g) those uses necessary in order to obtain health approval and to market a product after the expiry of the patent that protects it.

ECUADOR

Artículo 53 of Decisión N° 689 de 13 de agosto de 2008, sobre la Adecuación de Determinados Artículos de la Decisión 486 por la que se establece el Régimen Común sobre Propiedad Industrial, para permitir el Desarrollo y Profundización de Derechos de Propiedad Industrial a través de la Normativa Interna de los Países Miembros.

53 Incluir la facultad de usar la materia protegida por una patente con el fin de generar la información necesaria para apoyar la solicitud de aprobación de comercialización de un producto.

(Footnote to the Article: Los Países Miembros entienden esta facultad como la Excepción Bolar que facilita el otorgamiento de registros sanitarios.)

EGYPT

Article 10 (5) of the Intellectual Property Law 82 of 2002.

10

[...]

The following shall not be considered as infringements of that right when carried out by third parties:

[...]

(5) Where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtaining a marketing license, provided that the marketing starts after the expiry of such a protection period.

[...]

EL SALVADOR

Article 116 (e) of Law on the Promotion and Protection of Intellectual Property Rights (Legislative Decree No. 604 of 15 July 1993) , as inserted by Legislative Decree No. 912 of December 14, 2005.

116 The effects of the patent shall not extend

[...]

(e) To the use by a third party of protected materials that are the subject of a valid patent, in order to generate the necessary information to support an application for a health certificate for a pharmaceutical or chemical-agricultural product submitted to the Supreme Council on Public Health or the Ministry of Agriculture and Livestock, an application that may be submitted once the patent protection term has expired; and if the product is exported outside the national territory, this export shall be permitted only to satisfy the requirements for marketing approval in El Salvador.

FINLAND

Section 3(3)(4) *of the Patent Act No. 550 of 15/12/1967, as last amended by Act 101/2013 of 31 January 2013.*

Section 3 The exclusive right conferred by a patent shall imply, with the exceptions stated below, that no one may exploit an invention, without the proprietor's consent, by:

[...]

(3) offering, putting on the market or using a product obtained by a process protected by the patent or importing or possessing such product for these purposes.

[...]

The exclusive right shall not apply to:

(4) examinations or experiments or measures arising from practical demands which are needed for an application to obtain a marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product (21.4.2006/295); or

[...]

FRANCE

Article L613-5 (d) of the Intellectual Property Code, Law No. 92-597 of 01/07/1992, as last amended by Law No. 2007-1540.

5(d) The rights conferred by the patent shall not extend to the studies and tests required with a view to obtaining a marketing authorisation for a medicine, or also to the acts necessary for them to be carried out or the authorisation to be obtained.

GERMANY

Section 11(2b) of the Patent Act, as last amended by Act of April 4, 2016.

11 The effects of a patent shall not extend to:

[...]

2b. studies, experiments and the practical requirements resulting therefrom which are necessary for obtaining authorisation to place medicinal products on the market in the European Union, or which are necessary for obtaining authorisation to place medicinal products on the market in the Member States of the European Union or in third countries;

GREECE

Article 11 par. 6 of Ministerial Decision No. DYG3 (A)/83657, Harmonization of the Greek legislation with that of the Community in the Field of Production and Marketing of Medicinal Products for Human Use, in Compliance with No. 2001/1983/EC Directive "on the Community Code for Medicinal Products for Human Use", as amended by No. 2004/27/EC, 2004/24/EC Directives on Traditional Herbal Medicinal Products and Article 31 of No. 2002/1998/EC Directive on setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components (2006).

11 (6) The realization of studies and the tests that are required for the application of paragraphs 1, 2,3 and 4 and the consequential practical requirements are not considered to infringe the rights which are protected by patents patent or supplementary certificates of protection for the medicines.

HUNGARY

Article 19(6)(b)of the Law on the Protection of Inventions by Patents No. XXXIII of 1995, consolidated text of 17.06.2017.

19 (6) The exclusive right of exploitation shall not extend to:

[...]

(b) acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorisation of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention;

ICELAND

Article 3(3) of the Patents Act No. 17/1991, as last amended by Act No. 126/2011.

3

[...]

The following are excepted from the exclusive right:

[...]

3. use of the invention for experiments which relate to the invention itself, [i.a. studies and trials and other related procedures that are necessary to make possible an application for marketing authorisation for e.g. a generic medicinal product and an improved pharmaceutical form];

INDIA

Section 107A(a) of the Patent Act of 1970, incorporating all amendments till 23-06-2017.

107A For the purposes of this Act,

(a) any act of making, constructing, using or selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;

[...]

shall not be considered as an infringement of patent rights.

IRELAND

Section 42(1)(g) and Section 42(1)(h) of the Patents Act 1992, consolidated unofficial version up to 19 May 2017.

42(1) The rights conferred by a patent shall not extend to —

[...]

(g) acts done in relation to the subject matter of the relevant patented invention which consist of

(i) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements of paragraphs 1, 2, 3 and 4 of Article 10 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004) for a marketing authorisation in respect of a medicinal product for human use, or

(ii) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements of paragraphs 1 to 5 of Article 13 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004) for a marketing authorisation in respect of a veterinary medicinal product, or

(iii) any other act which is required as a consequence of the acts referred to in subparagraph (i) or (ii) for the purposes specified in those subparagraphs, as appropriate.

(h) insofar as paragraph (g) does not apply, acts done in relation to the subject matter of the relevant patented invention which consist of—

(i) acts done in conducting studies, tests, experiments and trials (including clinical trials and field trials) with a view to satisfying the application requirements for a marketing authorisation or similar instrument (howsoever described) that is required by the law of the State or of any other state in order to sell or supply or offer to sell or supply—

(I) a medicinal product for human use, within the meaning of subsection (2), or

(II) a veterinary medicinal product, within the meaning of subsection (2),

or

(ii) any other act done which is required as a consequence of the acts referred to in subparagraph (i) for the purposes specified in that subparagraph, as appropriate.

(2) In this section (other than paragraph (g) of subsection (1))—

"medicinal product for human use" means—

(a) any substance or combination of substances having or purporting to have properties for treating or preventing disease in human beings,

or

(b) any substance or combination of substances which may be used on or be administered to human beings with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

"substance" means any matter of—

(a) human origin (including human blood and human blood products),

(b) animal origin (including micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts and blood products),

(c) vegetable origin (including micro-organisms, plants, parts of plants, vegetable secretions and extracts), or

(d) chemical origin (including elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis);

"veterinary medicinal product" means—

(a) any substance or combination of substances having or purporting to have properties for treating or preventing disease in animals, or

(b) any substance or combination of substances which may be used on or be administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

ISRAEL

Section 54a of the Patents Law 5727-1967.

54A An experimental act, which is part of an effort to obtain a license to market the product after the patent has lapsed, does not constitute "exploitation of an invention", if the following two conditions are met:

(1) the effort to obtain a license 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;

for purposes of this section, "license"-certification, permit or any other document required under Law in order to market the product.

ITALY

Article 68 of the Industrial Property Code, Legislative Decree No. 30 of 10/02/2005.

68 Limitazioni del diritto di brevetto

1. La facoltà esclusiva attribuita dal diritto di brevetto non si estende, quale che sia l'oggetto dell'invenzione:
[...]

b) agli studi e sperimentazioni diretti all'ottenimento, anche in paesi esteri, di un'autorizzazione all'immissione in commercio di un farmaco ed ai conseguenti adempimenti pratici ivi compresi la preparazione e l'utilizzazione delle materie prime farmacologicamente attive a cio' strettamente necessarie;

JAPAN

Article 69(1) of the Japanese Patent Act, as last amended by Act No. 55 of July 10, 2015.

69 (1) A patent right shall not be effective against the working of the patented invention for experimental or research purposes.

JORDAN

Article 21 C of Law No. 32 of 1999 on Patents, as last amended by Law No. 28/2007.

21

[...]

C. Notwithstanding the provisions of this Law or any other legislation, carrying out research and development, and submitting applications for obtaining approvals to market a product prior to the expiry date of the patent protection shall not be considered an act of civil or criminal infringement.

KENYA

Section 54 (2) of the Industrial Property Act No. 3 of 27/07/2001, as last amended by Act No. 11 of 2017.

54 Rights of owner of patent

[...]

(2) The rights conferred on the owner of the patent under this section shall not apply to acts by third parties necessary to obtain approval or registration of a product from the Institute, for the purpose of commercializing the product after expiry of the patent.

LATVIA

Section 20(3)of the Patent Law adopted on 15/02/2007.

20 The exclusive rights resulting from the patent shall not extend to:

[...]

(3) examination of the subject-matter of a patent, as well as to the research of patented or protected with a supplementary protection certificate medicinal products or plant protection means, which is carried out in order to obtain a permission for the placing on the market thereof;

LITHUANIA

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).

Article 11. Submitting an Application for Marketing Authorisation

[...]

13. The performance of necessary studies and trials in order to submit an application for the marketing authorisation in the Republic of Lithuania of a medicinal product according to paragraphs 5, 10 and 11 of this Article or in the Community Code of Medicinal Products according to the requirements laid down in Regulation (EC) No 726/2004 or in other states according to legal requirements of those states and the related practical needs 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.

MALAYSIA

Section 37 (1A) of the Patents Act of 1983, as last amended in 2006.

37 Limitation of rights.

[...]

(1A) The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs.

MALTA

Article 27(6)(d) of the Patents and Designs Act, Chapter 417, of 01/06/2002, as last amended by Acts IX of 2003 and XVIII of 2005.

27(6) Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances:

[...]

(d) when an act is done for purposes which can reasonably be related to the development and presentation of information required by the law of Malta or any other country that regulates the production, use or sale of medicinal or phytopharmaceutical products;

MEXICO

Article 167bis of the Reglamento de Insumos para la Salud (Regulations on Health-Related Consumable Goods).

167 bis

[...]

Sin perjuicio de lo establecido en los dos párrafos anteriores, se podrá solicitar el registro de un genérico respecto de un medicamento cuya sustancia o ingrediente activo esté protegida por una patente, con el fin de realizar los estudios, pruebas y producción experimental correspondientes, dentro de los tres años anteriores al vencimiento de la patente. En este caso, el registro sanitario se otorgará solamente al concluir la vigencia de la patente.

MOROCCO

Article 55(d) of Loi n° 17-97 relative à la propriété industrielle, telle que modifiée et complétée par les lois n° 31-05 et n° 23-13.

55 Les droits conférés par le brevet ne s'étendent pas :

[...]

d. aux études et essais requis en vue de l'obtention d'une autorisation de mise sur le marché d'un médicament, ainsi qu'aux actes nécessaires à la réalisation de ces études et essais et à l'obtention de l'autorisation;

NAMIBIA

Article 43 of the Namibia Industrial Property Act, 2012 (Act No. 1 of 2012).

[...]

43. (2) It is not an infringement of a patent for any person to carry out acts, including testing, making, constructing, importing or using the patented invention solely for uses reasonably related to the development and submission of information required under any law of Namibia or any other country other than Namibia that regulates the manufacture, construction, distribution, use, import or sale of any product; except that it is not permitted to stock any products of the patented invention in any substantial quantities for any purpose other than for the development or submission of the information required.

NETHERLANDS

Section 53 (4) of the Kingdom Act of 15/12/1994, containing rules in respect of patents (the Dutch Patents Act).

53.4 The performance of necessary studies, tests and experiments in connection with the application of Article 10(1) to (4) of Directive 2001/83/EC on the Community Code relating to medicinal products for human use (Official EC Journal L 311) or Article 13(1) to (5) of Directive 2001/82/EC on the Community Code relating to veterinary medicinal products (Official EC Journal L 311) and the ensuing practical requirements shall not be deemed to constitute an infringement of patents relating to medicinal products for human use or medicinal products for veterinary use, respectively.

NEW ZEALAND

Section 145 of the Patent Act 2013.

145 It is not an infringement of a patent for a person to make, use, import, sell, hire, or otherwise dispose of the invention solely for uses reasonably related to the development and submission of information required under any law (whether in New Zealand or elsewhere) that regulates the manufacture, construction, use, importation, sale, hire, or disposal of any product.

NORWAY

Section 3(3)(5) of the Act No. 9 of 15/12/1967 on patents (The Norwegian Patents Act), as last amended by Act No.80 of 29/06/2007.

3(3)

[...]

The exclusive right shall not include

[...]

(5) Trials, experiments and similar of a patented medicine that are required to obtain a marketing authorisation for a medicine in a state that is a contracting party to the agreement of 15 April 1994 on the establishment of the World Trade Organization (The WTO Agreement).

OMAN

Section 11(4)(e) of the Royal Decree 67/2008: Promulgating the Law on Industrial Property Rights.

11

[...]

4 The rights under the patent shall not extend

[...]

e. to the acts of making, constructing, using, or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product, provided that any product produced under such authority shall not be made, used, or sold in Oman other than for referred purposes, and that the product shall only be exported outside Oman for purposes of meeting marketing approval requirements of Oman.

PAKISTAN

Section 30(5)(e) of the Patents Ordinance, 2000.

30(5) The rights under the patent shall not extend to

[...]

(e) acts, including tests, necessary for the approval of a product for its commercialization after the expiration of the patent;

PARAGUAY

Artículo 34(d) of Ley N° 1.630/2000 de Patentes de Invenciones, modificada por última vez por la Ley N° 2.593/2005.

34 La patente no dará el derecho de impedir:

[...]

(d) la utilización de la invención desde treinta días antes del vencimiento de la patente con fines experimentales y con el objeto de reunir la información requerida para la aprobación de un producto por la autoridad competente, para la comercialización con posterioridad al vencimiento de la patente; y,

[...]

PERU

Artículo 53 of Decisión N° 689 de 13 de agosto de 2008, sobre la Adecuación de Determinados Artículos de la Decisión 486 por la que se establece el Régimen Común sobre Propiedad Industrial, para permitir el Desarrollo y Profundización de Derechos de Propiedad Industrial a través de la Normativa Interna de los Países Miembros.

53 Incluir la facultad de usar la materia protegida por una patente con el fin de generar la información necesaria para apoyar la solicitud de aprobación de comercialización de un producto.

(Footnote to the Article: Los Países Miembros entienden esta facultad como la Excepción Bolar que facilita el otorgamiento de registros sanitarios.)

Article 39 of Resolution approving the Complementary Provisions to Decision 486 of the Andean Community Commission establishing the Common Regime on Industrial Property (Legislative Decree No. 1075 of June 27, 2008).

39 The patent holder shall not exercise the rights conferred by the patent where a third person uses the subject matter protected by the patent in force to generate the necessary information to support the application for approval to market a pharmaceutical product or agricultural chemical.

Any product produced in accordance with the preceding paragraph may be manufactured, used, sold, put up for sale, or imported into national territory for the generation of information for the purposes of meeting the requirements for the approval to market the product once the patent expires. Likewise, the product may be exported only for the purposes of meeting the requirements of the approval for marketing.

PHILIPPINES

Article 72.4 of Intellectual Property Code of the Philippines (Republic Act No. 8293) as amended by Section 7 of the Universally Accessible Cheaper and Quality Medicines Act of 2008 (Republic Act No. 9502).

72 The owner of a patent has no right to prevent third parties from performing, without his authorisation, the acts referred to in Section 71 hereof in the following circumstances:

[...]

4. In the case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product

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 not later than one hundred twenty (120) days after the enactment of this law;

POLAND

Article 69 (1)(iv) and Article 69(5) of the Industrial Property Law of 30/06/2000, as last amended by Act of 29/06/2007.

69 The following shall not be considered acts of infringement of a patent:

[...]

(iv) the exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorisation, being, due to the intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being pharmaceutical products;

PORTUGAL

Article 102(c) of the Industrial Property Code, as last amended by Law No. 46/2011 of June 24, 2011.

102 The rights conferred by a patent do not extend to:

[...]

(c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;

REPUBLIC OF KOREA

Article 96(1) of Korean Patent Act, as last amended by Act No. 11690 on March 23, 2013.

96(1) The effects of the patent right shall not extend to the following

1. Working of the patented invention for the purpose of research or experiments (including item permission or reporting on medicines under the Pharmaceutical Affairs Act, and research or experiments for registration of agrochemicals under the Agrochemicals Control Act):

[...]

SERBIA

Article 21(2) of the Law on Patents.

21 The exclusive rights of a right holder referred to in Articles 14 and 15 of this Law shall not apply to:

[...]

2) research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorisation from the competent authority for placing on the market a product which is a drug intended for use on humans or animals, or a medicinal product or plant protection products defined by the law regulating plant protection products;

SINGAPORE

Section 66(2)(h) of the Patents Act (Chapter 221), as last amended by the Statutes (Miscellaneous Amendments) Act 2014.

66.2 An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —

[...]

(h) it consists of the doing of anything set out in subsection (1) in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that anything produced to support the application is not —

(i) made, used or sold in Singapore; or

(ii) exported outside Singapore,

other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product;

SLOVAKIA

Article 18 (2)(f) of the Act No. 435/2001 Coll. on Patents, Supplementary Protection and Amendment of Some Acts (Patent Act), consolidated version in 2009.

18 Rights of a patent owner shall not be infringed if an invention is exploited:

[...]

(f) in activity conducted for experimental purposes which shall also be studies, exams necessary for registration proceedings pursuant to a special regulation. (According to footnote 8a this is Act No 140/1998 Coll. on Medicines and Medical Devices)

SLOVENIA

Article19(b) of the Industrial Property Act (ZIL-1-UPB3), as amended up to December 6, 2013.

19 The rights conferred by a patent within the meaning of Article 18 shall not extend to:

[...]

(b) acts done for research and experimental purposes of any kind relating to the subject matter of the patent irrespective of their final purpose;

SOUTH AFRICA

Section 69A of the Patents Act No. 57 of 1978, as last amended by Act No. 20 of 2005.

69A Acts of non-infringement.

(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

(2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.

SPAIN

Artículo 61(1)(c) of Ley N° 24/2015, de 24 de julio, de Patentes.

Artículo 61.1 Los derechos conferidos por la patente no se extienden:

[...]

(c) A la realización de los estudios y ensayos necesarios para obtener la autorización de comercialización de medicamentos en España o fuera de España, y los consiguientes requisitos prácticos, incluida la preparación, obtención y utilización del principio activo para estos fines.

SWEDEN

Article 3(2) 2nd paragraph, 4 p of Patents Act (1967:837).

3 From the exclusive right are excluded the following acts

[...]

2. studies, tests, examination activities and practical measures that refer to a reference medicine to the extent that these are necessary for obtaining a approval for the sale of a medicine pursuant to Article 8 a of the Act (1992:859) on Medicinal Products or for other proceedings for approval based on Article 10. 4 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as last amended by Directive 2004/27/EC, of the European Parliament and of the Council, or Article 13.1 – 13.5 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, as last amended by Directive 2004/28/EC of the European Parliament and the Council

[...]

SWITZERLAND

Article 9 (1)(c) of the Patent Law of 25/06/1954, version as on 01/01/2017.

9 Exceptions to effects of the patent

1. In general

The effects of the patent do not extend to:

[...]

(c) acts necessary for obtaining marketing authorisation for a medicinal product in Switzerland or in countries with equivalent medicinal product control;

THAILAND

Section 36(4) of the Patent Act B.E. 2522 of 11/03/1979, as last amended by Patent Act (No.3) B.E. 2542.

36

[...]

The preceding paragraph shall not apply to:

[...]

(4) any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term;

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Article 91(2) of the Law on Industrial Property adopted on 12/02/2009.

91 The right of the patent holder laid down in Article 89 of this Law regarding the exclusive utilisation of the invention shall not relate to:

[...]

(2) undertaking activities for research and development of the subject of the protected invention, in particular

manufacture, use, offer for sale, export or import of the protected invention, including also activities for obtaining approval for placing medications for human and veterinary medicine and products for protection of plants on the market; and

[...]

TUNISIA

Article 47 (e) of the Patents Law No. 2000-84 of 24/08/2000.

47 The rights conferred by the patent shall not extend to the following:

[...]

(e) acts necessary for the manufacture of generic drugs, provided that the commercial exploitation of the product of those acts may not be engaged in until the term of patent protection has expired;

TURKEY

Article 85(3) of the Law No. 6769 of December 22, 2016, on Industrial Property.

85

[...]

(3) The following acts are beyond the scope of patent rights:

[...]

Acts for experimental purpose relating to the subject matter of the invention subjected to market approval including the market approval of medicines and the tests and experiments required therefore.

UNITED KINGDOM

Section 60(5)(b) and Section 60 (5) (i) of the Patents Act of 1977, as amended, Unofficial consolidation up to 1 October 2014.

60(5) 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;

[...]

(i) it consists of –

(i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or

(ii) any other act which is required for the purpose of the application of those paragraphs.

[...]

Section 60(6D)

For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.

Section 60(6E)

In subsection (6D), "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—

(a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);

(b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;

[...]

Section 60(6F)

In subsection (6E) and this subsection—

"medicinal product" means a medicinal product for human use or a veterinary medicinal product;

"medicinal product for human use" has the meaning given by article 1 of Directive 2001/83/EC(2);

"veterinary medicinal product" has the meaning given by article 1 of Directive 2001/82/EC(3).

[...]

UNITED REPUBLIC OF TANZANIA

Section 12(4)(a) of the The Zanzibar Industrial Property Act, 2008 (Act No. 4 of 2008).

12(4)(a) The rights under the patent shall not extend

[...]

to an infringement of a patent for any person who make,construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Zanzibar or a country other than Zanzibar that regulates the manufacture, construction, use or sale of any product.

UNITED STATES OF AMERICA

35 USC § 271(e)(1).

§271. Infringement of patent

[...]

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States 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) 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.

URUGUAY

Article 39(D) of the Industrial Property Law No. 17.164 of 02/09/1999.

Artículo 39 El derecho que confiere una patente no alcanzará a los siguientes actos:

[...]

D) Los realizados exclusivamente con fines de experimentación, incluso preparatorios de una futura explotación comercial, realizados dentro del año anterior al vencimiento de la patente.

VIET NAM

Article 125 (2)(a) of the Intellectual Property Law No. 50/2005/QH11 of 29/11/2005.

125 Right to prevent others from using industrial property objects

[...]

2. Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts:

a) Using inventions, industrial designs or layout-designs in service of their personal needs or for noncommercial purposes, or for purpose of evaluation, analysis, research, teaching, testing, trial production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products;

ZIMBABWE

Article 24(5) of the Patents Act.

24 Extent, effect and form of patent

[...]

(5) The rights granted in subsection (4) shall not be construed as prohibiting any person from making, constructing, using or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law that regulates the manufacturing, construction, use or sale of any product.

EUROPEAN UNION

Article 13(6) of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

Article 13

[...]

6. 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.

Article 10(6) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

Article 10

[...]

6. Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 to 5 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.

[End of Appendix and of document]