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DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING THE EXHAUSTION OF PATENT RIGHTS

Document prepared by the Secretariat

INTRODUCTION

1. At its thirty-third session, held in Geneva from December 6 to 9, 2021, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would continue working on a draft reference document on the exceptions and limitations to patent rights in conjunction with patent protection, in accordance with the agreement reached at the twenty-sixth session of the SCP. In particular, it was agreed that the Secretariat would, *inter alia*, prepare and submit a draft reference document on the exception regarding the exhaustion of patent rights to the thirty-fourth session of the SCP (see document SCP/33/5, paragraph 24, first bullet point under “Exceptions and Limitations to Patent Rights”).
2. In accordance with the above decision of the SCP, the Annex to this document contains the said draft reference document for the Committee’s discussions at its thirty-fourth session to be held in Geneva from September 26 to 30, 2022. In the preparation of the draft reference document, the Secretariat made use of information provided by the Member States¹, including national/regional legislative provisions and court cases, as well as other information made

¹ Member States and Regional Patent Offices were invited, through its Note C. 9089, dated January 14, 2022, to submit to the International Bureau any additional inputs for the preparation of the draft reference document on the exception regarding the exhaustion of patent rights. The inputs received are published on the website of the SCP electronic forum at: https://www.wipo.int/scp/en/meetings/session_34/comments_received.html.

available through various SCP activities. In addition, the Secretariat consulted other sources of information in order to obtain supplementary material on the topic.

3. A few submissions from Member States in response to Circular Note C. 9089, dated January 14, 2022 also included information on how the exception regarding exhaustion is applied in the respective jurisdictions in the case of biological material. Taking into account the specificity of issues raised with respect to exhaustion of biological material, which is linked to the exception related to farmers' and/or breeders' use of patented inventions², this issue is not addressed in the current draft reference document.

4. This document contains the following sections: (i) Overview of the exception regarding the exhaustion of patent rights; (ii) Exhaustion – meaning and types; (iii) Objectives and goals of the exception regarding the exhaustion of patent rights; (iv) The exhaustion of patent rights - international legal framework; (v) Implementation of the exception regarding the exhaustion of patent rights; (vi) Challenges faced by Member States in implementing the exception regarding the exhaustion of patent rights; and (vii) Results of implementation of the exception regarding the exhaustion of patent rights. In addition, it contains an Appendix, in which various legal provisions on the exception regarding exhaustion of patent rights are compiled.

[Annex follows]

² See document SCP/21/6 (Exceptions and limitations relating to farmers' and/or breeders' use of patented inventions).

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APPENDIX

1. Overview of the Exception Regarding the Exhaustion of Patent Rights

1. The doctrine of exhaustion of intellectual property (IP) rights (also referred to as a “first sale doctrine”),³ is an important feature of IP systems. In essence, it limits the rights of IP owners to control the distribution of protected goods after their first lawful release in the market. Specifically, this doctrine holds that once the goods embodying the subject-matter under IP protection are put on the market by or with the consent of the right holder, such holder’s exclusive rights to control the use and sale of those goods are “exhausted”. Thus, the doctrine allows lawful acquirers to use or resell such IP protected goods without any fear that the IP owner might enforce their rights against such use or sale.

2. The main justifications for providing the exhaustion of patent rights are balancing patentees’ interests with those of the consumers, promotion of competition and price reduction, free movement/circulation of goods, and freedom of trade.

3. While it has been generally accepted that the first sale of the IP protected good triggers exhaustion of the IP rights domestically,⁴ in the context of international cross-border trade, application of the exhaustion doctrine to parallel imports (also called “grey market goods”) differs among countries. Parallel imports are genuine goods, legitimately put on the market of another country and imported by a third party through an unauthorized channel of distribution, i.e. a channel parallel to the one authorized by the right holder. As they are imported via unauthorized channels, they may be not carrying the original producer’s warranty, or may be packaged differently. Within one country, different exhaustion rules may apply to different IP rights, such as patents, copyright and trademarks.

4. With respect to patents, in general, national law determines the exhaustion of patent rights. Looking at the location of the first sale that triggers the exhaustion of rights, there are three types of exhaustion regimes most frequently found in various countries: national, regional and international exhaustion. While the national exhaustion regime is the most restrictive with respect to allowing parallel imports, the regional and international exhaustion policies, with varying degree, enable parallel importation from third country sources. Some countries, however, apply industry-specific exhaustion rules; whereas in other countries, different exhaustion rules apply in specific circumstances.

5. At the international level, there is no agreement that prescribes the specific exhaustion regime that its members have to apply. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), in its Article 6, precludes anything in that agreement from being used to address the exhaustion of IP rights in dispute settlement under the WTO framework, subject to the TRIPS provisions on the national treatment and most-favoured-nation principles. The Doha Declaration on the TRIPS Agreement and Public Health provided guidance on the interpretation of Article 6, and confirmed that each member is free to establish its own regime for such exhaustion without challenge, subject to the most-favored-nation and national treatment principles.⁵

6. Several regional instruments regulate the issue of exhaustion within their respective regional frameworks. Express legislative provisions are provided in Decision № 486 of September 14, 2000 of the Commission of the Andean Community⁶, the Patent Regulations under the Eurasian Patent Convention, and the Bangui Agreement Instituting an African

³ The term “first sale doctrine” is generally used to reference the concept of exhaustion of rights in the copyright context, principally, in the United States of America.

⁴ With the exception of the self-replicating goods (such as biological materials) in the area of patents (see document SCP/21/6).

⁵ Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, document WT/MIN(01)/DEC/2, November 20, 2001.

⁶ Hereafter “Andean Community Decision № 486”.

Intellectual Property Organization, Act of December 14, 2015⁷. In Europe, rules on exhaustion are largely the result of the jurisprudence of the Court of Justice of the European Union (CJEU).

2. Exhaustion – Meaning and Types

Meaning

7. The exhaustion doctrine is viewed as an important limitation on the exclusive IP rights conferred on the owner. When a patent holder has sold or authorized the sale of a patented device, when a copyright owner has sold a copy of the work to an individual consumer, or once a trademark owner has sold a trademarked good, the respective right to control the disposition of that device, copy or good is said to be exhausted. The consumer is free to make use of that item in any way it might choose: by enjoying the item for its intended use, by reselling the item, or even by destroying it.⁸

8. However, the term “exhaustion of IP rights” can be misleading if understood literally. In fact, the exhaustion only relates to one specific aspect of the exclusive rights: i.e., the right to control the use, resale and other distribution of the product protected by means of IP after it has been legitimately sold on the market. Thus, the concept of exhaustion should not be understood as an extinguishment of any other rights. Specifically, under the exhaustion doctrine, a patentee’s rights to prevent others from making and selling any new product embodying the claimed invention remains intact. So does its right to prevent others from using a product so made. Yet, when the patented good is legitimately sold on the market, the buyer acquires the right to undertake any acts in accordance with the applicable law (which typically includes the right to use and resale) only with respect to that specific good bought, however, the buyer typically cannot manufacture new copies of the patented good as it would violate the exclusive right of ‘making’ that the patent accords to its owner.^{9,10} Thus, “the exhaustion doctrine does not accept the premise that a patentee’s rights of use with respect to the particular product survive” after it has been sold legitimately.¹¹

Legal justification of the exhaustion

9. There are various reasons given to justify the concept of exhaustion. One of the reasons is that IP rights are of “ubiquitous” nature, the feature that distinguishes them from tangible property. They exist independently of the physical good in which they are incorporated. Yet, each and every copy of that good “contains” these IP rights. Thus, they will follow the product downstream, potentially controlling its use. To avoid such endless expansion of the IP protection, the argument goes, there is a need, at some point, to put an end to the effect of IP rights on the marketed product.¹²

⁷ Hereafter “the Bangui Agreement”.

⁸ Michael V. Sardina, Exhaustion and First Sale in Intellectual Property, 51 Santa Clara L. Rev. 1055, 2011.

⁹ For related discussions on the specific rights to be exhausted, see Section 4 of this document, in particular, paragraphs relating to Article 28 of the TRIPS Agreement.

¹⁰ See also submission of France to SCP/34 suggesting that there is a distinction “between the exhaustion of the right holder’s prerogatives with regard to goods...(product or process) put on the market and the patent right itself, which remains enforceable even after the goods have been voluntarily marketed the first time (*infringement ≠ exhaustion*)”; submission of the Czech Republic stating “by exhausting the rights of the patent owner, these third parties do not acquire general disposition rights to the invention as such and typically cannot manufacture the product which is the subject-matter of the invention or dispose of the patent in any way”.

¹¹ See reasoning of High Court of Australia in *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41. at para 75.

¹² F. Abbott, T. Cottier and F. Gurry, The International Intellectual Property System: Commentary and Materials, Part one, 1999, p.99.

10. Somewhat in contrast to the above, another suggested line of justification for exhaustion is that IP rights and their subject matter are distinct. For example, a patented good embodies in itself the subject matter of patent rights, i.e., the invention, but not the rights themselves. Thus, when the patented good is sold on the market, what is transferred is the ownership right in that tangible good, but not the patent rights. Thus, the patentees' rights should be limited so that they may not oppose to any acts the buyer may wish to practice with respect to the patented good purchased.¹³

11. Yet, the most frequently given explanation raised in case law and legal scholarship with respect to exhaustion is that once a patented good is sold, the patentee is duly "rewarded" and should be prevented from repeated future attempts to extract compensation for the same product.^{14,15} The further restrictions on the acts of the buyer would result in the expansion of the patent rights beyond the purpose of the law.¹⁶

12. While various justifications for the exhaustion principle are proposed, based on the great number of countries providing for this exception,¹⁷ it could be inferred that there is a general consensus among legal systems that some limit to the rights of the patentee should be established after the patented good has been legitimately released into the market.

Exhaustion and parallel importation

13. The concept of exhaustion is adopted by most of the legal systems, and the main point of distinction among them is not whether the rights should be exhausted upon first sale at all. The general question which distinguishes countries' policies on the issue of exhaustion is whether the IP rights are exhausted upon the first domestic sale authorized by the owner or whether they are exhausted upon first sale authorized by the patentee, regardless of the country in which it occurs. This question is generally considered important, because it has an impact on the possibility of parallel importation.

14. In economic terms, parallel imports are a form of a cross-border arbitrage. Typically, the IP owners try to profit from setting different prices for the same product sold in different markets, depending on, for example, the purchasing power and other local characteristics. Where the price of the patented product put on the market by the patentee or with its consent elsewhere is lower than the price of such product in a specific market, third parties are normally motivated to import these patented products from the lower-priced markets into the higher-priced markets in order to profit from such price differentials. In practice, whether market players can, and if so, whether they are motivated to engage in parallel imports depend on various complex factors

¹³ However, this generally does not cover the act of reconstructing the patented article, as it may go beyond the simple repair and violate the exclusive right of "making". For related discussions, see Section 5.C.3 of this document.

¹⁴ It is often said that the basic purpose of this limitation is to prevent IP rights owners from obtaining a "second bite at the apple". As the IP owner has received a compensation through the initial sale of that good, it does not deserve to benefit from, or to maintain any control over, a subsequent downstream transaction. See J. M. Mueller, *Patent Law 427* (Aspen Publishers, 3d ed. 2009), cited by Michael V. Sardina, *supra* note 8. See also responses of, e.g., Canada, Belarus and the United States of America to section 8 of the Questionnaire on Exceptions and Limitations to Patent Rights carried out within the SCP, available at: <https://www.wipo.int/scp/en/exceptions/> (hereafter "the Questionnaire").

¹⁵ See also Decision of the Third Petty Bench Supreme Court of Japan of July 1, 1997 (BBS Supreme Court case) stating: "[...] the patent holder has received payment including remuneration for making the patented invention publicly available by assigning the patented products by himself and receives a license fee for licensing the use of patents. Therefore, the opportunity for securing compensation for making the patented invention available to the public has been granted, and there is no necessity to allow the patent holder to profit again in the process of circulation of goods in the market from the patented products which have already been assigned by the patent holder or the licensee".

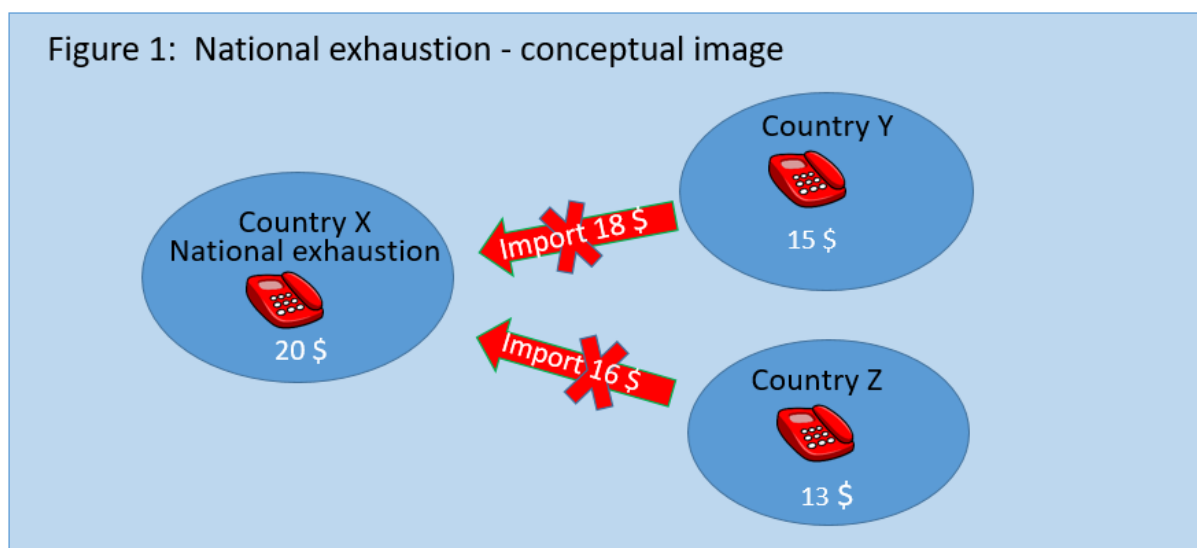
¹⁶ See also the US Supreme Court reasoning in *Impression Products, Inc v Lexmark Int'l, Inc* (2017) 137 S Ct 1523 discussed in Section 5.B of this document.

¹⁷ For the list of countries which provide a specific provision on the exception regarding the exhaustion of patent rights in their respective laws, see Appendix to this document.

and regulatory restrictions beyond an applicable exhaustion regime or the simple arbitrage theory, and one single factor alone would not automatically lead to parallel imports (see also Section 7, below).

15. Under the national exhaustion regime, the rights of the patentee with respect to the patented goods that have been legitimately put on the market are exhausted when these goods are put on the market of the country concerned, thus enabling the patentee to prevent parallel importation of genuine goods from third-country sources. In other words, the patentee's rights to control the use and distribution of the patented good is extinguished upon placing on the market of the protected product within the national territory only.

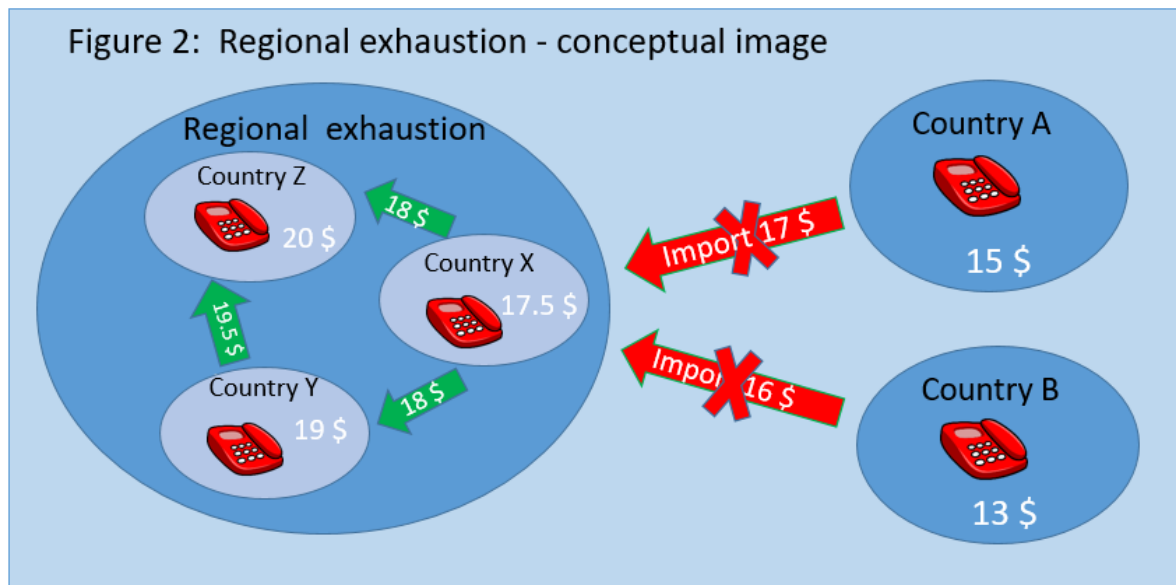
16. While the operation of the market involves complex transactions between multiple parties, the figures below aim to provide a simple illustration of the various types of exhaustion regimes. Figure 1 illustrates the principle of national exhaustion: country X applies the national exhaustion regime. The first legitimate sale of the patented good in country X exhausts the patent right with respect to that product, and the patentee will no longer be able to enforce its rights to prevent third parties from resale of that patented good within the territory of country X. At the same time, the patentee can prevent importation of the patented good that it legitimately placed on the market of countries Y and Z to country X.



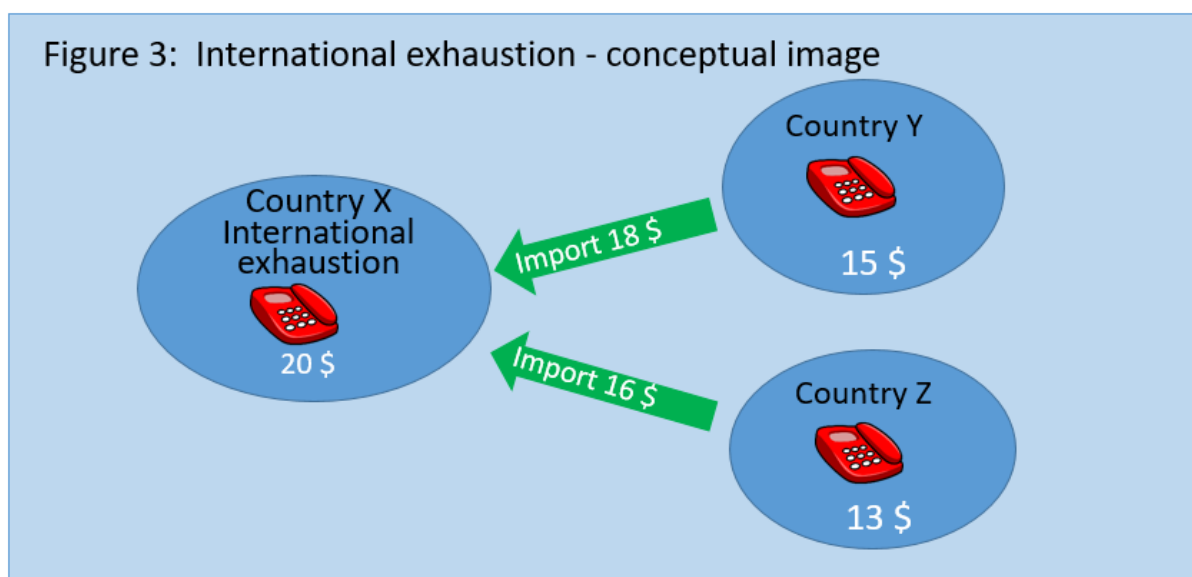
17. Under regional exhaustion, the patentee's rights are exhausted upon placing the good legitimately on the market of the defined regional territory of an integration arrangement, i.e. a regional single market or union. It means that once such goods are placed on such regional market, they may be imported to other countries within that region, and trading in such goods within that region would not constitute patent infringement, as the rights have been exhausted with effect to the whole region. Thus, regional exhaustion is triggered by the first sale of a product within the same regional market, and it has consequences in the territories of the several countries that form the regional market in question.

18. For example, in Figure 2, if countries X, Y and Z are members to a regional agreement adopting the regional exhaustion regime, the first sale of the patented good in country X by the patentee or by a third party with its consent will prevent the patentee from blocking importation of that good into the markets of countries Y and Z, based on the alleged infringement of its patents in countries Y and Z. On the other hand, if the legitimate first sale of the patented good took place in a country that does not belong to that regional agreement (country A or B), the respective patents in countries X, Y and/or Z are not exhausted. Consequently, the patentee

can prevent importation of that patented good into these countries in which the patent rights has not been exhausted.



19. Finally, the rule of international exhaustion provides that the patentee's right to control the use and distribution of the patented good is exhausted upon placing the product on the market legitimately anywhere in the world. Thus, in a country applying the international exhaustion, patented products put on the market by the patentee or with its consent in any country may be imported into that country without constituting an infringement of the patent. In Figure 3, country X applies the international exhaustion regime. The importation of the patented products by third parties from country Y or Z to country X does not constitute patent infringement in country X, since the applicable patent in country X has been exhausted as far as these products legitimately put on the market of country Y or Z are concerned.¹⁸



¹⁸ It is to be noted that the availability of parallel imports may depend on other rules such as the regulatory approval regimes as well as contractual restrictions on parallel importation imposed by the patentee on sale.

3. Objectives and Goals of the Exception Regarding Exhaustion of Patent Rights

20. While in practice great variations of exhaustion regimes and thus variations in the treatment of parallel imports exist, the following policy objectives are found to be commonly shared across different countries, irrespective of the different exhaustion regimes that they apply.

21. In many countries, it is considered that such limitation on the rights of the patentee would achieve a balance among various private and public interests in the patent system,¹⁹ promote free movement/circulation of goods,²⁰ and protect the interest of consumers.²¹ In addition, the exhaustion is noted to serve the purpose of maintaining the “normal economic order”,²² and that the restriction on the alienation of goods legitimately sold on the market would run counter the goals of patent law. Moreover, it is often stated that the patentee should be prevented from receiving further compensation for the same product once it has sold it and thus been rewarded.

22. For example, with respect to the regional exhaustion doctrine in the EU, a Notice of the European Commission²³ states:

“The exhaustion of rights doctrine intends to balance the protection of industrial property rights with the free movement of goods. Derogations are only allowed in so far as they are justified for the purpose of safe-guarding the specific subject-matter of that property.”^{24,25}

23. The Supreme Court of Japan explains that patent rights are exhausted because:

“[...] (1) while the protection of invention under the patent law must be realised in harmony with the social and public interest, (2) in assignments, the assignor transfers all the rights to the assignee and the assignee acquires all the rights which belonged to the assignor, and when the patented products are placed in the market for circulation, transactions are effected on the assumption that assignees acquire the right to freely use and reassign the products as business, independent of the exercise of the rights by the patent holder on the product. If authorisation of the patent holder is required every time the products are assigned, free circulation of goods in the market will be obstructed, smooth circulation of patented goods will be inhibited, and will result in harming the interest of the patent holder himself, and thus will be against the goal of the Patent Law, which is to ‘promote invention and contribute to the development of industries by pursuing protection and utilisation of inventions [...]’, and (3) [...] there is no necessity to allow the patent holder to profit again

¹⁹ See responses of, e.g., Australia, Belarus, Chile and Japan to question 61 of the Questionnaire.

²⁰ See response of Colombia, Germany and France to Note C. 9089, published at: https://www.wipo.int/scp/en/meetings/session_34/comments_received.html. See also the responses from Cyprus, Denmark, Italy, the Netherlands, Portugal, Romania and Sweden to the Questionnaire.

²¹ See responses of, e.g., Zimbabwe and Sri Lanka to question 61 of the Questionnaire.

²² Response from China to the Questionnaire. See paragraph 25 of this paper.

²³ Commission Notice, Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) (Text with EEA relevance) (2021/C 100/03), available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0323\(03\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0323(03)&from=EN).

²⁴ A regional exhaustion regime is applied in the EU. For further information on the EU regional exhaustion, see Section 5.A.3 of this document.

²⁵ Similarly, the submission of Spain to SCP/34 explains: “[t]he exhaustion of industrial property rights serves to limit in particular such monopolies as may result from the exclusive rights conferred on patentees, should they lead to behavior or practices restraining trade or adversely affecting other competitors. It then becomes essential to find a balance between the general interests of the market and the individual interests of those holding industrial property rights. Rules are thus required to limit such rights, including exhaustion. Exhaustion serves to resolve cases where the territorial character of patent rights conflicts with the principle of free circulation of goods within the Community, and specifically, to prevent the use of patents to create monopolies contrary to Article 101 of the Treaty on the Functioning of the European Union”.

*in the process of circulation of goods in the market from the patented products which have already been assigned by the patent holder or the licensee”.*²⁶

24. The policy underlying the exhaustion doctrine was recently explained by the US Supreme Court:

*“The Patent Act “promote[s] the progress of science and the useful arts by granting to [inventors] a limited monopoly” that allows them to “secure the financial rewards” for their inventions. [...] But once a patentee sells an item, it has “enjoyed all the rights secured” by that limited monopoly [...]. Because “the purpose of the patent law is fulfilled when the patentee has received his reward for the use of his invention,” that law furnishes “no basis for restraining the use and enjoyment of the thing sold.””*²⁷

25. The submission from China²⁸ states on the objectives of the exception:

“This is seen as a reasonable limitation on patents, serving the purpose of maintaining the normal economic order by avoiding restrictions on the circulation and use of the patented products in the marketplace.”

26. One scholarly article also notes in this respect:

*“This doctrine was developed in the nineteenth century to balance the rights of IP owners to prevent the inappropriate use of their IP rights with the rights of retailers, second-hand dealers, and consumers to freely display, advertise, and resell the products that they lawfully purchased in the market, even if those actions directly compete with the IP owners’ business activities in the same market.”*²⁹

27. In addition, fostering competition and diversification of sources of goods of competitive price and, consequently, bringing benefits to the consumer is a policy behind the exception relating to exhaustion of patent rights. While welfare argument may be especially strong in countries which adopt international exhaustion,³⁰ it is also valid with respect to countries which operate under the national exhaustion regime. For example, the response from Mexico, which applies the national exhaustion, states in this respect:

*“The main objective of this exception is to guarantee the free transit of goods that have been introduced lawfully onto the market in the country. This will improve competition within the national market, benefiting consumers through lower prices and, above all, clearly demonstrating the prerogative of the patent holder [...]”*³¹

²⁶ Third Petty Bench Supreme Court of Japan of July 1, 1997 (BBS Supreme Court case, No.1995(O)1988), p.5.

²⁷ *Impression Products, Inc v Lexmark Int’l, Inc* (2017) 137 S Ct.

²⁸ Response from China to the Questionnaire. China applies international exhaustion with respect to patents.

²⁹ Irene Calboli, The intricate relationship between intellectual property exhaustion and free movement of goods in regional organizations: comparing the EU/EEA, NAFTA, and ASEAN, *Queen Mary Journal of Intellectual Property*, Vol.9, No.1, 2019, p.23.

³⁰ See, e.g., Susy Frankel and Daniel J. Gervais, *International Intellectual Property Rules and Parallel Imports in Research Handbook on Intellectual Property Exhaustion and Parallel Imports*, Edward Elgar Publishing Limited, 2016, p.87.

³¹ See response of Mexico to Note C. 9089. See also response of Viet Nam to section 8 of the Questionnaire.

4. The Exhaustion of Patent Rights - International Legal Framework

28. The issue of exhaustion of IP rights is not expressly regulated by any of the WIPO-administered treaties currently in force.³²

29. With respect to the TRIPS Agreement, the issue of exhaustion was one of the difficult issues during the negotiation of the Agreement and no single set of exhaustion rules was agreed upon. Some countries, including Switzerland and the United States of America, favored the TRIPS Agreement to establish a national exhaustion regime, whereas other countries, including Australia, Brazil, India, and New Zealand, defended international exhaustion, or at least the freedom for each WTO member to decide on this issue.³³

30. Eventually, a compromise solution reached was to simply exclude the matter from the dispute settlement. Specifically, Article 6 of the TRIPS Agreement provides:

“For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

31. The exclusion of the exhaustion issue from the dispute settlement procedure has been generally understood to imply that under the TRIPS Agreement, countries have freedom to adopt any scheme of exhaustion of rights and, consequently, allow parallel importation,³⁴ provided they fulfil their obligations regarding the national treatment (Article 3) and most-favoured nation treatment (Article 4). The application of Articles 3 and 4 means that a WTO member cannot apply different exhaustion rules vis-à-vis nationals of other members.

32. Another TRIPS provision specifically dealing with the issue of exhaustion is Article 28.1. The provision enumerates the exclusive rights conferred by a patent on its owner. Among other rights, the exclusive rights of the patentee include the right to prevent unauthorized persons from the acts of “importing” the patented product from another country.³⁵ However, Article 28

³² Except the Washington Treaty on Intellectual Property in Respect of Integrated Circuits of 1989, which has not entered into force. Article 5(6) of the Washington Treaty provides for exhaustion of the rights when a layout-design has been put on the market by, or with the consent of, the right holder. In the area of copyright, WIPO Performances and Phonograms Treaty (WPPT) (adopted on December 20, 1996) and WIPO Copyright Treaty (WCT) (adopted on December 20, 1996) do not expressly prescribe exhaustion rules and reserve this issue to each government. See Article 8 and 12 of the WPPT and Article 6(2) of the WCT.

³³ Daniel Gervais, “The TRIPS Agreement: Drafting History and Analysis”, third edition, Sweet & Maxwell, December 2008, p.199.

³⁴ See discussions of WTO members with respect to Article 6 during the TRIPS Council Special Discussions on Intellectual Property and Access to Medicines (document IP/C/M/31, June 18 to 22, 2001). E.g. Zimbabwe (on behalf of the African Group) stated: “Article 6 allows each Member the freedom to incorporate the principle of international exhaustion of rights - the legal basis for parallel importation”; European Communities stated: “Much importance will also be attached to Article 6, which enables Members to allow for parallel imports of patent protected goods which have been put on a third market by the right holder or with its consent.”; Switzerland stated: “we recognize that Article 6 offers flexibility to developing countries in the search for patented medicines offered at a cheaper price elsewhere in the world.”; Malaysia (on behalf of ASEAN) stated: “Members also have the freedom to provide for the principle of the international exhaustion of rights in their legislation. We note that, since the TRIPS Agreement does not address the issue of exhaustion of rights, as stated in Article 6, this provides the right of import from third countries.”; Japan stated: “Article 6 allows Members’ discretion as to whether national or international exhaustion is to be taken in their national jurisdiction”; and India stated: “Article 6 relating to “exhaustion” in the TRIPS Agreement establishes that each Member has full freedom to incorporate the principle of international exhaustion of rights in its national legislation. Thus, it is clear that the TRIPS Agreement permits parallel imports”. However, the view of the United States of America differed from those above: “There is no question that Article 6 denies Members the ability to avail themselves of dispute settlement in relation to questions involving parallel imports, except when those questions involve national or most-favoured-nation treatment. However, Article 6 of the TRIPS Agreement does not, in our view, authorize parallel imports.”

³⁵ Article 28 of the TRIPS Agreement states: “1. A patent shall confer on its owner the following exclusive rights:

contains a footnote regarding the right to prevent importation, stating that this right, “*like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6*”. Accordingly, the possibility of enforcing the exclusive rights of patentee against the importation of patented products placed legitimately elsewhere is subject to the exhaustion regime with respect to patents adopted by the country in which the importation takes place.

33. It follows from the footnote to Article 28 that no other IP rights can be “exhausted” other than those related to “use, sale, importation or other distribution of goods”. Thus, the rights of the patentee to, e.g., prevent “making” of the patented good remains intact by the exhaustion principle.

34. Furthermore, Article 51 of the TRIPS Agreement provides that WTO members shall adopt judicial or administrative procedures to allow the right holder to require the suspension of the release by customs of counterfeit trademark or pirated copyright goods. Members may also apply this provision to other IPR, including patents.³⁶ However, Article 51 also has a footnote which clarifies that “[*it is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder*”. Accordingly, members may, but are not obliged to, apply such procedures of suspending the release of imported goods when the patentee or a third party with its consent put those goods in the market of another country.

35. Finally, in November 2001, the WTO members confirmed, in paragraph 5(d) of the Doha Declaration on the TRIPS Agreement and Public Health,³⁷ that the TRIPS Agreement permits members to adopt their own policies and rules on the subject of exhaustion, provided non-discriminatory obligations under the TRIPS Agreement are complied with. The paragraph reads as follows:

“d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”^{38,39}

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing^(a) for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.”

³⁶ The provision, in this regard, states “[...] Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. [...]”.

³⁷ Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, document WT/MIN(01)/DEC/2, November 20, 2001.

³⁸ With respect to the impact of the Doha Declaration on the interpretation of Article 6, two lines of arguments exist among commentators: (i) that the Doha Declaration provides a broad interpretation of Article 6 (See, e.g., Daniel Gervais, 2008, p.202, *supra* note 33), and (ii) that impact of the Doha Declaration on the interpretation of Article 6 is confined to measures concerning public health, and that paragraph 5(d) has to be read in light of paragraph 4 of the Declaration which makes it clear that the “exclusive target of the Declaration is protection of public health” (See e.g., Nuno Pires de Carvalho, “The TRIPS Regime of Patent Right”, 2002, pp. 95 and 96, Kluwer Law International).

³⁹ With respect to the WTO disputes on the issue of exhaustion, on May 30, 2000, the United States of America requested consultations with Argentina under the Understanding on Rules and Procedures governing Settlement of Disputes of WTO concerning Argentina’s legal regimes governing patents and in other related measures. Among issues raised, the United States of America considered that Argentina denied certain exclusive rights for patents, such as, *inter alia*, the right of importation. After round of consultations, on May 31, 2002, the United States of America and Argentina notified the DSB that they have reached an agreement on all of the matters raised in the requests for consultations and that the provisions of the Argentinian law on, *inter alia*, the exhaustion are consistent with the TRIPS Agreement. (See the summary of dispute DS196:

36. Furthermore, with respect to Article 31*bis* of the TRIPS Agreement,⁴⁰ the Annex to the TRIPS Agreement setting out terms for using the Special Compulsory Licensing System prohibits pharmaceutical products made for export under Article 31*bis* to be diverted into other markets. Specifically, paragraph 3 of the Annex states that “[i]n order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system [...]”. Paragraph 4 of the Annex further provides “Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions [...]”.

37. In addition, a Ministerial Decision on the TRIPS Agreement, adopted on June 17, 2022, which establishes a special regime on COVID-19 vaccines,⁴¹ requires that eligible members undertakes “all reasonable efforts to prevent the re-exportation of the products manufactured under the authorization in accordance with this Decision that have been imported into their territories under this Decision”. However, in exceptional circumstances, an eligible member may re-export COVID-19 vaccines to another eligible member for humanitarian and not-for-profit purposes.⁴² In addition, members shall “ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorization in accordance with this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement”.

5. Implementation of the Exception Regarding the Exhaustion of Patent Rights

38. This Section provides information on the implementation of the exception in national laws and regional instruments. In total, 142 countries have been identified to provide for the exception regarding exhaustion of patent rights under their respective legal frameworks. In most of these countries, there is a specific statutory provision prescribing the specific exhaustion rule. In common law countries, the exception is provided through case law. An Appendix to this document contains provisions of national and regional laws on the exception regarding the exhaustion of patent rights.

5.A Geographical Location of the First Sale

39. Exhaustion is a market-driven legal phenomenon, and in that context, it has been categorized in accordance with the geographical dimension of its triggering acts. As explained in Section 2, exhaustion can be national – when the first legitimate sale domestically leads to the exhaustion of rights within the borders of national jurisdictions – or international – when it is triggered by the first sale in another country. Exhaustion can also be regional when it affects a single market that extends over the borders of one or more countries members forming a regional agreement. In some countries, as a general rule, one particular exhaustion regime is applied; however, other exhaustion regimes apply to specific goods or under specific

Argentina — Certain Measures on the Protection of Patents and Test Data at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm. See the text of the Notification of Mutually Agreed Solution (document WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1) at: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:IP/D/22A1.pdf&Open=True>.)

⁴⁰ The introduction of Article 31*bis* in the TRIPS Agreement replaced the 2003 waiver for members who have accepted the amendment. Members who are yet to accept the amendment currently have until December 31, 2023 to do so (document WT/L/1122). For them, the waiver will continue to apply until the amendment is accepted and takes effect in their territories.

⁴¹ The text of the Ministerial Decision is available at: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True>.

⁴² See paragraph 3(c) and footnote 3.

circumstances. The following subsections provide information on implementation of such various types of exhaustion regimes, categorized according to the geographical location of the first sale.

1. National Exhaustion

(i) National Exhaustion Provided in a Regional Instrument

Eurasian Patent Convention

40. The Eurasian Patent Office grants Eurasian patents in accordance with the Eurasian Patent Convention, which have effect in the territories of all Contracting States.^{43,44} Disputes relating to the validity or infringement of a Eurasian patent in a given Contracting State is resolved by the national courts or other competent authorities of that State on the basis of the Eurasian Patent Convention. The decision has effect only in the territory of the respective Contracting State.⁴⁵

41. With respect to the exhaustion of patent rights, Rule 19 of the Regulations under the Eurasian Patent Convention⁴⁶ states that the following case of use of the patented invention, *inter alia*, shall not constitute an infringement of the Eurasian patent:

“use of a product after this product has been marketed by the patent owner himself or with his consent in a Contracting State where the Eurasian patent is valid and in which the product in question was marketed”.

42. While the Convention does not expressly use the term “exhaustion”, the practical effect of this provision is that Eurasian patents are exhausted nationally within the individual territory of each Contracting State upon marketing of the product by the patent owner or with its consent in that territory. To date, no judicial ruling appears to exist with respect to the exhaustion of Eurasian patents in any of the Contracting States of the Eurasian Patent Convention.

(ii) National Exhaustion Provided in National Laws

43. In total, 30 countries are identified to provide for national exhaustion of national patent rights under their respective legal frameworks. Table No.1 lists countries which provide for national exhaustion with respect to patents by statutory provisions in their respective laws.⁴⁷

⁴³ Article 15(11) of the Eurasian Patent Convention.

⁴⁴ Member States of the EAPO are Turkmenistan, Republic of Belarus, Republic of Tajikistan, Russian Federation, Republic of Azerbaijan, Republic of Kazakhstan, Kyrgyz Republic and Republic of Armenia.

⁴⁵ Article 13 of the Eurasian Patent Convention.

⁴⁶ Patent Regulations under the Eurasian Patent Convention (as amended on September 10-11, 2020).

⁴⁷ Countries which, in principle, provide for national exhaustion, but in some cases, international exhaustion, are placed under “Mixed exhaustion policies” in Section 5.A.4 of this document.

Table No. 1: Countries providing for national exhaustion

| Exhaustion Regime | Countries | Total Number |
|---------------------|---|--------------|
| National exhaustion | Albania, Barbados, Belarus, Belize, Bhutan, Bosnia and Herzegovina, Brazil, Dominica, El Salvador, Eswatini, Ethiopia, Gambia, Iran (Islamic Republic of), Kazakhstan, Madagascar, Mexico, Morocco, Mozambique, Nigeria, Papua New Guinea, Republic of Moldova, Saint Kitts and Nevis, San Marino, Sao Tome and Principe, Serbia, South Sudan, Sudan, Tajikistan, Trinidad and Tobago, United Republic of Tanzania. | 30 |

44. In the majority of countries that apply the national exhaustion with respect to patents, the applicable provisions stipulate that the rights conferred by a patent shall not extend to acts in respect of a patented product which has been put on the market of the respective country by the owner of the patent or with its consent. The reference to the market of the respective country implies that the rights are exhausted nationally, i.e., within the territory of the country concerned. In few countries with national exhaustion regimes, the relevant provisions are drafted in a way that specific acts, as defined in the applicable laws, on a patented article (typically acts of using and selling it), is deemed not to be patent infringement. This formulation seem to suggest that the patentee continue to hold its rights, but cannot enforce them because such acts do not constitute infringement.⁴⁸

45. Further, with respect to formulation of the provisions on national exhaustion generally, the provisions of laws differ in two aspects: (i) whether the authorized acts under the exception are expressly specified or not; and (ii) whether the national territory on which the first sale shall occur is expressly stated or not.

46. *Aspect (i)*. In many laws, the types of acts that can be carried out by third parties following patent exhaustion are not specified, although these acts are tied to the rights conferred by a patent. For example, Article 39 of the Law № 9947 on Industrial Property of Albania states:

“The rights conferred by a patent shall not extend to acts committed in the Republic of Albania with regard to a product protected by the patent after the said product has been put on the market in the Republic of Albania by the patent’s owner or with his consent”.

47. Similarly, Section 25(1)(c) of the Industrial Property Law of Ethiopia provides:

“1. The rights of the patentee shall not extend to:

[...]

*c) acts in respect of patented articles which have been put on the market in Ethiopia, by the owner of the patent or with his consent, or [...]*⁴⁹

⁴⁸ See the provisions of laws of Belarus, Kazakhstan and Tajikistan.

⁴⁹ This type of wording of the provision can also be found in the laws of, e.g., Barbados, Belize, Bhutan, Dominica, Eswatini, Ethiopia and Gambia.

48. In several other countries with national exhaustion regimes, the relevant provisions list the types of acts authorized under the exception. For example, Article 57, Section III of the Federal Law on the Protection of Industrial Property of Mexico states:

“Article 57.- The right conferred by a patent shall have no effect whatsoever against:

[...]

III. Any person who markets, acquires or uses the patented invention after the invention has been lawfully introduced onto the market in Mexico;” [Non-official translation]

49. Likewise, Article 116 (d) of the Law on Intellectual Property of El Salvador specifies that

“116. The effects of the patent do not extend:

[...]

(d) to the marketing or use of a product after it has been legally placed for the first time on the market within the national territory.”⁵⁰ [Non-official translation]

50. *Aspect (ii)*. In most of the countries with national exhaustion regimes, the reference to the national market with respect to first sale is expressly made. In few countries, the relevant provisions do not make a reference to any country: however, there is an understanding that the exhaustion type is national. For example, Article 30 of the Law of the Republic of Tajikistan on Inventions, which does not expressly indicate the geographical limitation of “commercial use”, is interpreted to mean a principle of a national exhaustion.⁵¹ The provision states:

“The following actions shall not be deemed infringements of a patent owners’ exclusive right:

[...]

- use of the devices incorporating inventions protected by titles of protection if such devices were put to commercial use on a lawful basis in accordance with the rights granted by a patent owner.”

Legitimate placement of the product

51. Further, while the laws of most countries that operate under the national exhaustion regime stipulate that the product must be placed on the market by the patentee or with its consent, in a few countries, the law does not specify a person who places the patented product on the market. Instead, the condition for the rights to be exhausted nationally is that the placement of the patented product on the market should be made lawfully. Specifically, the exhaustion applies after a patented product has been “lawfully introduced onto the market”, “lawfully sold in the country” and “put to commercial use on a lawful basis”.⁵²

⁵⁰ The example of this type of wording of the provision can also be found in the laws of Belarus, Serbia and Tajikistan.

⁵¹ See response of Tajikistan to the Questionnaire in which the application of the national exhaustion with respect to patents in that country is confirmed.

⁵² See the applicable provisions of the laws of Mexico, Madagascar and Tajikistan. No information has been received with respect to interpretation of these terms from the respective countries.

Other particularities regarding the scope of the exception

52. In some countries, the national exhaustion applies with some other conditions, providing a possibility for a patentee to exercise its rights, under specific circumstances, on the product after the first sale. For example in Montenegro, the placing on the market of the patented product by the patentee or with its consent exhausts the exclusive rights, “unless there are reasonable grounds based on which the patent holder retains exclusive rights deriving from the patent”.

53. As another example, in Nigeria, the patent holder’s rights do not extend to acts done in respect of a product covered by the patent after the product has been lawfully sold in that country, “except in so far as the patent makes provision for a special application of the product, in which case the special application shall continue to be reserved to the patentee notwithstanding this paragraph”.⁵³ Similar provisions are found in the laws of South Sudan and Sudan.⁵⁴

54. In Brazil, Law No.9.279 provides that the rights conferred do not extend to a patented product that has been placed on the “internal market” directly by the patentee or with its consent.⁵⁵ In addition, the law criminalizes importation of a patented product that has not been placed on the external market directly by the proprietor or with its consent for the purposes of, *inter alia*, exporting, selling or offering for sale in Brazil.⁵⁶ However, the law also appears to suggest an exception to this rule: in cases where a compulsory license is granted on the grounds of abuse of economic power, the parallel importation of the patented product is permitted if placed on the foreign market by the patentee or with its consent.⁵⁷

55. The Patent Act of Malaysia state that the rights under the patent shall not extend to acts in respect of products which have been put on the market by the patentee or its licensee, by the prior user, or the beneficiary of a compulsory license.⁵⁸

2. International Exhaustion

(i) International Exhaustion Provided in the Regional Instruments

Andean Community Decision № 486

56. Andean Community Decision № 486⁵⁹ provides rules on exhaustion applicable to the Member States of the Andean Community.⁶⁰ The Andean Community Decisions have a direct effect as domestic legislation of its Member States. With respect to the exhaustion of patent rights, Article 54 of the Decision 486 states:

“The patent shall not give the right to prohibit a third party from engaging in commercial acts in relation to a product protected by the patent after that product has been brought on to the market in any country by the owner of the patent, or by another person who has obtained his consent or is economically associated with him.

For the purposes of the foregoing paragraph, two persons shall be considered economically associated where one can directly or indirectly exercise a decisive influence

⁵³ See Article 54 (1) of the Law on Patents of Montenegro, and Section 6 (3) (b) of the Patents and Designs Act of 1971 of Nigeria, respectively.

⁵⁴ Section 23(2) of the Patents Act, 1971 (Act № 58 of 1971).

⁵⁵ Article 43, Paragraph IV of Law No. 9,279 of May 14, 1996 of Brazil (Law on Industrial Property, as amended up to Law No. 14.200 of September 2, 2021).

⁵⁶ Article 184 of Law No. 9,279 of May 14, 1996 of Brazil.

⁵⁷ See Article 68 of Law No. 9,279 of May 14, 1996 of Brazil. See also submission of Brazil to SCP/34.

⁵⁸ Section 37(2) of the Patents Act of 1983 of Malaysia (Act 291, as amended up to Act A1264).

⁵⁹ Article 54 of the decision № 486 of September 14, 2000 of the Commission of the Andean Community.

⁶⁰ The Andean Community is a customs union comprised of Bolivia, Colombia, Ecuador and Peru.

on the other concerning the working of the patent, or where a third party can exercise such an influence on both.”

57. Accordingly, with respect to patents, the Andean Community applies the international exhaustion regime.

58. The explanation given in a second paragraph with respect to a person “economically associated” with the patentee appears to suggest that parallel imports may be permissible even if no formal relationship exists between the “another person” and the patentee, provided that one can exercise a “decisive influence” on the other or a third party can exercise such an influence on both.⁶¹

59. With respect to this provision, the submission from Colombia clarifies that when the introduction to the market has been made by a third party duly authorized by the right holder, the link must be accompanied by proof or evidence that demonstrates the right holder’s will, whether this be a contract or another legal document. The response also clarifies that, according to the applicable legislation in Colombia, this principle of international exhaustion of patent rights is only applicable to product patents and that it does not apply to patents granted for methods or procedures.⁶²

60. As to date, the Court of Justice of the Andean Community, which has exclusive jurisdiction over, *inter alia*, the Andean Community treaties, has not ruled on the scope of Article 54 of the Andean Community Decision № 486.

Bangui Agreement

61. The Bangui Agreement Instituting an African Intellectual Property Organization (OAPI), Act of December 14, 2015, provides a system of international exhaustion for seventeen members of the OAPI.⁶³ The OAPI operates a uniform system for the protection of industrial property and serves as a national IP office for each Member State. However, disputes relating to the recognition, scope or exploitation of the rights provided for in the Agreement falls within the jurisdiction of courts in Member States.

62. Article 7(1)(a) of Annex I of the Bangui Agreement deals with the topic of exhaustion of rights. Specifically, the provision states that the rights conferred by the patent shall not extend to, *inter alia*:

“the offer, import, holding or use of the patented product on the territory of a Member State, after the product is legally placed on the market in any country by the owner of the patent or with his express consent”.

63. No judicial decisions have been documented with respect to the above provision in any Member State of the OAPI.

⁶¹ In this respect, the response from Colombia states that “it is clear that decisive influence with respect to the exploitation of the patent is an essential element when considering the link and the fact that, if the introduction to the market is carried out by that person with economic ties to the right holder, the right is exhausted with regard to future commercializations.” It also states that “in accordance with the patent law in force in Colombia, the cause of the exhaustion of the right is the introduction of the product in any country by its owner or by a third party that is authorized or has an economic link to the right holder. This means that the right holder will not be able to oppose any reimportations, even when the introduction has been made outside of Colombia.” See response from Colombia to Note C. 9089.

⁶² See response from Colombia to Note C. 9089.

⁶³ Member States of OAPI are Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo.

(ii) International Exhaustion Provided in National Laws

64. In total, 59 countries have been identified to provide for international exhaustion of patent rights either through a specific statutory provision within respective IP or patent legislation or case law. Table No. 2 lists countries which provide the international exhaustion regime with respect to patents.⁶⁴

Table No. 2: Countries providing for international exhaustion

| Exhaustion Regime | Countries | Total Number |
|--------------------------|--|--------------|
| International exhaustion | Antigua and Barbuda, Argentina, Armenia, Benin*, Bolivia ^x , Botswana, Brunei Darussalam, Burkina Faso*, Burundi, Cambodia, Cameroon*, Central African Republic*, Chad*, Chile, China, Colombia ^x , Comoros*, Congo*, Costa Rica, Côte d'Ivoire*, Cuba, Dominican Republic, Ecuador ^x , Equatorial Guinea*, Gabon*, Ghana, Guatemala, Guinea*, Guinea-Bissau*, Honduras, India, Jamaica, Jordan, Kenya, Kyrgyzstan, Liberia, Mali*, Mauritania*, Mauritius, Namibia, Nicaragua, Niger*, Pakistan, Paraguay, Peru ^x , Samoa, Senegal*, Seychelles, Sierra Leone, Thailand, Togo*, Tonga, Tunisia, Türkiye, United States of America, Uruguay, Viet Nam, Zambia, Zimbabwe. | 59 |

* International exhaustion is followed by virtue of application of the Bangui Agreement Instituting an African Intellectual Property Organization (OAPI), Act of December 14, 2015.

^x International exhaustion is followed by virtue of application of the Andean Community Decision № 486.

The formulation and the scope of the provisions on international exhaustion

65. In the majority of countries which apply the international exhaustion of rights with respect to patents, the applicable provisions stipulate that the rights conferred by a patent shall not extend to acts in respect of a patented product which has been put on the market of the respective country and/or “in any country”, “anywhere in the world”, “in a foreign country”, “abroad” or “outside” the country, by the owner of the patent or with its consent.

66. In few countries operating under international exhaustion, the relevant provisions are formulated to suggest that the patentee continues to hold its rights, but cannot enforce them because the third parties’ acts on the patented article, as defined in the applicable laws, are not considered as infringement of rights.⁶⁵

67. Further, similar to formulation of the provisions on the national exhaustion, the texts of the laws providing for international exhaustion of patent rights generally differ in two aspects: (i) whether the authorized acts under the exception are expressly stipulated or not; and (ii) whether the territorial limitation on which the first sale of the product shall occur is expressly stated or not.

⁶⁴ Countries that, in principle, provide for international exhaustion, but in some cases or circumstances, national exhaustion, are in Section 5.A.4 of this document. The analysis of international exhaustion regime as applied in the United States of America can be found in Section 5.B of this document.

⁶⁵ See provisions of laws of Armenia, Brunei Darussalam, China and India.

68. *Aspect (i)*. for example, with respect to a provision where the authorized acts under the exception are not specified, a reference is made to Section 11(4)(a) of the Patent Act of Ghana, which provides:

“(4) The rights under the patent shall not extend to: (a) acts in respect of articles which have been put on the market in any country by the owner of the patent or with the owner’s consent;”^{66,67}

69. The provisions where the authorized acts under the exception are specified typically includes acts of “sale”, “use”, and/or “importation”. In some other countries, “advertising” and “stocking” are also listed within authorized acts. For example Article 47(d) of the Patents Law of Tunisia states:

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

[...]

(d) the advertising, import, stocking or use of the patented product or the product obtained using a patented process, done on Tunisian territory after the product has been lawfully brought on to the market in any country by the owner of the patent or with his express consent;”^{68,69}

70. *Aspect (ii)*. In some countries, applicable provisions do not expressly state the territory on which the first sale of the product shall occur, however, the provisions are interpreted to provide for international exhaustion. For example, while the provision of the law of Türkiye does not expressly stipulate the market on which the product was put, the provision is understood to mean that if the product is put on the market anywhere in the world, the patentee’s rights on that product are exhausted:

*“After the products forming the subject of protection of industrial property right are put on the market by right owner or by third parties with his consent, actions related to these products shall remain outside the scope of the right.”*⁷⁰

71. Other specificities with respect to the formulation and the scope of the provisions on international exhaustion can be noted in the following paragraphs.

Legitimate placement of the product

72. According to the laws of many countries, in order to trigger the exhaustion of patent rights, the placement of the patented article on the market of any country must be made by the patentee or by the party acting with its consent. In few countries’ laws, however, no express reference is made to a patentee or a third party with its consent, but the requirement is that the importation of patented product has to be “lawful” or “duly authorized” under the law. For example, in India, Section 107A(b) of the Patent Act states that importation of patented products “*by any person from a person who is duly authorised under the law to produce and sell or distribute the product*”, shall not be considered as infringement of patent rights. While no judicial interpretation on Section 107A(b) exists, the argument has been made that importation

⁶⁶ Section 11(4)(a) of the Patent Act, 2003 (Act 657) of Ghana.

⁶⁷ This type of wording of the provision can also be found in the laws of, e.g., Jamaica, Kenya, Mauritius, Samoa, Seychelles and Sierra Leone.

⁶⁸ Article 47 (d) of the Patents Law № 2000-84 of August 24, 2000 of Tunisia.

⁶⁹ This type of wording of the provision can also be found in the laws of, e.g., Costa Rica, China, Dominican Republic, Kyrgyz Republic, Namibia and Thailand.

⁷⁰ Article 152 of the Law No. 6769 of December 22, 2016, on Industrial Property. See submission of Türkiye to SCP/34.

of products, *inter alia*, under a compulsory licensing, where there is no authorized first sale by the patentee, is validly covered by Section 107A.⁷¹ In this regard, the law of Pakistan expressly states that the patent rights do not extend to acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with its consent, by an authorized person, or “in any other legitimate manner such as compulsory licenses”.

73. In Argentina, the patent rights shall not have effect against any person who acquires, uses, imports or in any way commercializes the patented product, once the said product has been lawfully placed in the commerce of any country. With respect to the word “lawfully”, Article 36(c) of the Law on Patents and Utility Models of Argentina states that “*the placing in commerce is lawful when it is in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights [...]*”.⁷² The Corresponding Regulations further clarify with respect to this provision as follows: “*it shall be considered to have been lawfully placed on the market when the licensee authorized to commercialize it in the country proves that it has been done so by the owner of the patent in the country of acquisition, or by a third party authorized to commercialize it.*”⁷³

74. In Jordan, the patent rights shall not prevent anyone from importing any materials or goods from a third party that enjoys the legal protection of the same patent protected in Jordan, if such “*importation is lawful*” and also complies with “*the principles of commercial competition and fairly takes into account the economic value of the protected patent*”.⁷⁴ In addition, the patentee is entitled to prohibit parallel imports by means of clauses in licensing agreements.⁷⁵

75. The applicable provision of the law of the Dominican Republic states that the patent does not give the right to prevent: “*the sale, leasing, use, usufruct, importation or any means of marketing a product protected by patent or obtained by a patented process, once said product has been placed on the market in any country with the consent of the holder or of a licensee or in any other legal manner.*” The provision further clarifies that the products shall not be considered legally placed on the market “*if placed in violation of industrial property law*”.⁷⁶ The law of Uruguay also states that “*products or processes which infringe intellectual property rights shall not be considered as having been lawfully put on sale*”.⁷⁷

76. In some other countries, similar to the provision of the Andean Community Decision № 486, the rights conferred do not extend to acts in respect of products put on the market of any country by the patentee or with its consent but also by a third party “*having economic tie to a patentee*”.⁷⁸ In this connection, the law of Liberia clarifies that “*an economic tie shall exist between two persons where one of them may exercise on the other a decisive influence with*

⁷¹ See, e.g., Prakash Narayan “Exhaustion of Patent”, Pen Acclaims, Vol. 4, Dec. 2018, ISSN 2581-5504.

⁷² Article 36 (c) of the Law № 24.481 of March 30, 1995 on Patents and Utility Models of Argentina. With respect to this provision, the view has also been expressed that, in Argentina, parallel imports could be deemed admissible in cases where the supplier is a compulsory licensee. See C.M. Correa and J.I. Correa, Parallel Imports and Principle of Exhaustion of Rights in Latin America, in Research Handbook on Intellectual Property Exhaustion and Parallel Imports, Parts 3(11), edited by Irene Calboli, 2016.

⁷³ Corresponding Regulation to Article 36 of the Law No. 24.481, on Patents and Utility Models. [Non-official translation]. Some commentators note that it is unclear whether the Corresponding Regulation suggests that parallel imports can only be made by a licensee, thereby limiting the scope of the rule established in Article 36(c) of the Law № 24.481 on Patents and Utility Models of Argentina. See C.M. Correa and J.I. Correa (2016), *ibid*.

⁷⁴ Article 37(A) of Jordan Patent Law 32 of 1999, as amended.

⁷⁵ Article 37(B) of Jordan Patent Law 32 of 1999, as amended.

⁷⁶ Article 30 of Act No. 20-00 on Industrial Property of the Dominican Republic.

⁷⁷ Section 40 of the Law No. 17.164 of September 2, 1999, on Patents (as amended up to Law No. 19.924 of December 18, 2020).

⁷⁸ See the provisions of laws of Botswana, Cuba, Guatemala, Liberia and Nicaragua.

respect to the exploitation of the patented invention, or where a third party may exercise such an influence on both persons".⁷⁹

3. Regional Exhaustion

(i) Regional Exhaustion in the European Union Law

77. The exhaustion principle in the Europe Union (EU) as extended to the European Economic Area (EEA)⁸⁰ has its basis in Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU).⁸¹ Article 34 of the TFEU prohibits "[q]uantitative restrictions on imports and all measures having equivalent effect" between Member States.⁸² Article 36 of the TFEU provides exceptions to this general principle where they are justified, *inter alia*, on the ground of "the protection of industrial and commercial property",⁸³ provided they do not constitute a means of "arbitrary discrimination or disguised restriction on trade between Member States".⁸⁴

78. The EU rules on exhaustion are largely the result of the jurisprudence of the CJEU interpreting the above-cited provisions of the TFEU and its predecessors. The CJEU has consistently interpreted the Treaty as meaning that the IP rights conferred are exhausted within the single market by virtue of putting the relevant goods on the market, by the right holder or with his/her consent, in the European Union. For example, in *Centrafarm and Adriaan de Peijper v Sterling Drug Inc.*,⁸⁵ the Court stated:

"The exercise, by the patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market."

79. Likewise, in *Merck and Co Inc. vs Stephar BV and Petrus Stephanus Exler*,⁸⁶ the Court ruled that:

"[t]he rules contained in the EEC Treaty concerning the free movement of goods, including the provisions of Article 36, must be interpreted as preventing the proprietor of a patent for a medicinal preparation who sells the preparation in one Member State where

⁷⁹ §13.11. of the Liberia Intellectual Property Act 2016.

⁸⁰ The European Economic Area (EEA) was established via the Agreement on the European Economic Area, an international agreement which enables the extension of the European Union's single market to three member states of the European Free Trade Association (Iceland, Liechtenstein and Norway) into an internal market governed by the same basic rules. These rules aim to enable free movement of persons, goods, services, and capital within the European Single Market. The EEA was established on January 1, 1994 upon entry into force of the EEA Agreement.

⁸¹ Consolidated Version of the Treaty on the Functioning of the European Union, March 30, 2010, 2010 O.J. (C83) (hereinafter TFEU), as amended following the entering into force of the Treaty of Lisbon on December 1, 2009. Treaty of Lisbon, December 13, 2007, 2007 O.J. (C 306).

⁸² Art. 34 of the TFEU states: "[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States."

⁸³ "Industrial and commercial property" generally refers to intellectual property rights such as patents, trade marks, designs, copyright and geographical indications.

⁸⁴ Art. 36 of the TFEU states: "The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."

⁸⁵ *Centrafarm and Adriaan de Peijper v Sterling Drug Inc* (C-15/74).

⁸⁶ *Merck and Co Inc. vs Stephar BV and Petrus Stephanus Exler* (C-187/80).

patent protection exists, and then markets it himself in another Member State where there is no such protection, from availing himself of the right conferred by the legislation of the first Member State to prevent the marketing in that State of the said preparation imported from the other Member State.”

80. With respect to the derogations prescribed in Article 36 of the TFEU, the Court clarified in several occasions that they are only allowed in so far as they are justified for the purpose of safeguarding the rights which constitute specific subject-matter of that property.⁸⁷ That principle makes it possible to determine, in relation to each category of IP, the conditions in which the exercise of the rights will be permissible under the EU law, although in a cross-border situation, such exercise impedes free movement by definition. As regards patents, the specific subject matter of industrial property is *inter alia* to ensure that “*the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements*”.⁸⁸ It is then for the patentee to decide under which circumstances it wishes to market the patented product, including the option of marketing in Member States where the product does not benefit from patent protection. If the patentee does so, it must accept the consequences of its choice as regards the free movement of the product within the single market. Permitting the patentee to invoke its patent in one Member State to prevent the importation of that product that it freely marketed in another Member State where that product was not patented, would cause a partitioning of national markets contrary to the aim of the Treaty.⁸⁹

81. Thus, under the EU law, once a good protected by a patent has been put by, or with the consent of, the patentee on the market anywhere in the EEA, the rights conferred by that patent in relation to the distribution of the good within the EEA become exhausted. Thus, the patentee cannot invoke its rights to prevent the further resale of the patented goods by third parties within the EEA. However, the patentee can oppose to the importation by a third party of such goods into the European single market in so far as such importation would constitute an infringement of the patent rights. This rule illustrates the principle of the regional exhaustion.

82. According to EU law, the patent rights on goods placed on the regional market do not become exhausted, if the goods are produced under a compulsory license, as “the patentee cannot be deemed to have consented to the operation of the third party” to which such license had been issued, and no “exclusive right of first placing the product on the market” has been exercised, allowing the patentee to obtain the reward. In particular, in *Pharmon BV v Hoechst AG*,⁹⁰ the Court stated:

“25 It is necessary to point out that where, as in this instance, the competent authorities of a Member State grant a third party a compulsory license which allows him to carry out manufacturing and marketing operations which the patentee would normally have the right to prevent, the patentee cannot be deemed to have consented to the operation of that third party. Such a measure deprives the patent proprietor of his right to determine freely the conditions under which he markets his products.

26 As the Court held most recently in its judgment of 14 July 1981 (Merck v Stephar, cited above), the substance of a patent right lies essentially in according the inventor an

⁸⁷ See, e.g., *Sterling Drug (C-15/74)*, and *Merck and Co Inc. vs Stephar BV and Petrus Stephanus Exler (C-187/80)*.

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ *Pharmon BV v Hoechst AG (C-19/84)*, [1985] E.C.R. 2281. The Court concluded that: “[a]rticles 30 and 36 of the EEC Treaty do not preclude the application of legal provisions of a Member State which give a patent proprietor the right to prevent the marketing in that State of a product which has been manufactured in another Member State by the holder of a compulsory licence granted in respect of a parallel patent held by the same proprietor.”

exclusive right of first placing the product on the market so as to allow him to obtain the reward for his creative effort. It is therefore necessary to allow the patent proprietor to prevent the importation and marketing of products manufactured under a compulsory license in order to protect the substance of his exclusive rights under his patent.

27 Consequently, in reply to Question 1 it must be stated that Articles 30 and 36 of the EEC Treaty do not preclude the application of legal provisions of a Member State which give a patent proprietor the right to prevent the marketing in that State of a product which has been manufactured in another Member State by the holder of a compulsory license granted in respect of a parallel patent held by the same proprietor.”.

Agreement on a Unified Patent Court

83. The Agreement on a Unified Patent Court⁹¹ provides for a European Union-wide exhaustion. Article 29 of the Agreement states that the rights conferred by a European patent shall not extend to acts concerning a product covered by a patent after it has been placed on the market in the EU by, or with the consent of, the patentee, unless there are legitimate grounds for the patentee to oppose further commercialization of the product. However, to date, the UPC Agreement has not entered into force.^{92,93}

(ii) Regional Exhaustion Provided in National Laws

84. Table No. 3 lists countries which provide the regional exhaustion with respect to patents.⁹⁴

⁹¹ The Agreement on a Unified Patent Court of 19 February 2013 (UPC Agreement) sets up a Unified Patent Court (UPC) for the settlement of infringement and validity disputes relating to European patents with unitary effect (unitary patent) and “classic” European patents. The UPC Agreement harmonizes the scope and limitations of the rights conferred by a patent and remedies available beyond EU Directive 2004/48/EC (Enforcement Directive).

⁹² Protocol to the Agreement on a Unified Patent Court on provisional application (PPA) entered into force in January 19, 2022. The entry into force of the UPC Agreement and start of operations of the UPC is expected to happen during the last quarter of 2022 or early 2023 (see <https://www.unified-patent-court.org/about>).

⁹³ A commentary by Jan Busche in a book edited by Winfried Tilmann and Clemens Plassmann on UPC Agreement, which does not provide an official interpretation of the UPC Agreement, notes with respect to this provision: “[b]y way of derogation, exhaustion of the rights under the patent does not occur if the patent proprietor has legitimate grounds to oppose further commercialization of the product after it has been placed on the market. Legitimate grounds are those that may impair the patent proprietor’s general commercialization interests. Since the application of the exhaustion principle is intended to prevent patent law from exerting an influence on further commercialization channels generally, only those grounds having a certain weight can be recognized as legitimate. Contractual obligations prohibiting deliveries outside a certain region do not stand in the way of exhaustion. [...] One thing that is conceivable is product or packaging manipulations and other things capable of causing reputational damage or hampering commercialization. In this regard, reference may be made to the decision practice on trade mark law (Art 13(2) CTMR, Art 7(2) Trade Marks Dir, s 24(2) MarkenG).”. Unified Patent Protection in Europe. Edited by: Winfried Tilmann and Clemens Plassmann, Oxford University Press (2018).

⁹⁴ Switzerland, which, in principle, provides for regional exhaustion, but national or international exhaustion in certain cases, is placed under “Mixed exhaustion policies” in Section 5.A.4 of this document.

Table No. 3: Countries providing for regional exhaustion

| Exhaustion Regime | Countries | Total Number |
|---------------------|---|--------------|
| Regional exhaustion | <p>Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden (EU/EEA exhaustion).</p> <p>United Kingdom (unilateral application of EU/EEA exhaustion regime).</p> <p>Saint Vincent and the Grenadines (exhaustion within Caribbean Community market).</p> | 33 |

85. In most of the countries listed in Table No. 3, the exception relating to exhaustion of patent rights is provided via statutory means. However, in Austria, Germany, Greece and Liechtenstein, there is no statutory regulation of the exhaustion principle in the respective patent laws. In few other EU countries, the texts of the national law provisions on exhaustion refer to the “national market”,⁹⁵ however, the regional exhaustion of rights established by CJEU case law is applicable to any EU/EEA Member.

The formulation of the provisions on regional exhaustion

86. In line with the regional exhaustion rules, discussed above, the provisions of laws of many EEA states provide that the rights conferred by the patent “do not extend” or “apply” to acts relating to a product after that product has been “placed” or “put” on the EU or EEA market by the patentee or with its consent.⁹⁶

87. Few other variations of the wording of the provisions have been identified in the laws: in the Netherlands, Article 53 (5) of the Patent Act provides that if a product has been put on the market lawfully in the Netherlands or the Netherlands Antilles or in one of the Member States of the EU or in a State party to the EEA by the patent holder or with its consent, the person who obtains or later holds the product “*shall not be deemed to have contravened the patent by using, selling, hiring out or delivering that product or by otherwise dealing in it in or for his business, or by offering, importing, or stocking the product for any of those purposes*”. In Poland, Article 70.2 of the Act on Industrial Property states that a “*patent shall neither be considered infringed by an act of importation into the territory of the Republic of Poland or other acts referred to in paragraph (1) in respect of a product that has earlier been put on the market on the territory of the*” EEA by the patentee or with its consent. Similarly, in Romania, the acts of “*marketing or offering for sale, within the territory of the European Union, of specimens of the product constituting the subject-matter of the invention that have been previously sold by the patent owner or with his express consent*” shall not constitute infringement of rights. Further, in Italy and Montenegro, the respective provisions state that the “rights are exhausted” once the

⁹⁵ See, e.g. provisions of laws of Belgium, Cyprus and Czech Republic.

⁹⁶ See, e.g., provisions of laws of Denmark, France, Latvia, Luxembourg and Poland.

protected product have been put on the market by the patentee or with its consent in the territory of EU/EEA.

88. Further, some laws place a condition to this limitation of rights by adding “unless there are legitimate reasons that justify the patent holder opposing the ‘further marketing’, ‘wider placing on the market’ of the product” or “there exist reasons in accordance with the rules of Community law for the rights conferred by the patent to extend to such acts”.⁹⁷ In Norway, the exclusive right shall not include exploitation of products protected by the patent put on the market in the EEA by the patentee or with its consent “if this is not determined differently by regulation laid down by the King”.

Legitimate placement of the product

89. Submissions of some countries provided further clarifications with respect to the EU/EEA regional exhaustion as applied in their countries. First, in order for the patent right to be exhausted, the product must have been placed on the market legitimately, a condition considered satisfied when so placed by the patentee or a third party with the patentee’s consent.⁹⁸ The submission of the Czech Republic notes that, in practice, this consent will in most cases be given in writing as part of the license agreement. If the product is placed on the market by the licensee, the rights are exhausted, regardless of whether the license is exclusive or non-exclusive. However, if the product is placed on the market in a manner that is contrary to the terms of the license agreement, the rights will most likely not be exhausted.⁹⁹

Applicability to process patents

90. In terms of the applicability of the exception, the submission from Germany clarifies that the exhaustion is applicable regarding the rights of the patentee in respect of a product which is the subject-matter of the patent and the rights of the patentee in respect of a product which is produced directly by a process which is the subject-matter of the patent. It however is not applicable regarding the rights of the patent holder in respect of a process which is the subject-matter of the patent.¹⁰⁰ In this respect, the submission from Spain also notes that the exhaustion applies to products only, not to processes *per se*. If the patent is for a product, the right is exhausted when the product is legitimately placed on the market for the first time. If the patent is for a process, the exhaustion will affect products only if they are directly obtained by the patented process and placed on the market by the patentee, or a third party with its consent. The submission of France clarifies that no distinction is made between product and process patents and that reference in its law to the “patented product” should be taken to mean an “industrial product” or a patented invention.

Legal consequences

91. According to the principle of exhaustion, a product is no longer subject to the patent holder’s exclusive right if it has been put on the market either by the patentee or by a third party with its consent. The occurrence of exhaustion is strictly object-related, i.e., it only takes effect for the specific object that has actually been put on the market by or with the consent of the patent holder. The lawful acquirers as well as subsequent third party acquirers - including

⁹⁷ See, e.g., provisions of laws of Hungary, Latvia, Luxembourg, Portugal and Spain.

⁹⁸ See submissions of Spain to SCP/34.

⁹⁹ See submission of the Czech Republic to SCP/34.

¹⁰⁰ See submission of Germany to SCP/34 with reference to BGH, judgement of 24 September 1979, ref: KZR 14/78, GRUR 1980, 38 – Fullplastverfahren, explains: “Exhaustion of patent rights does not occur when the patent holder puts on the market a device which itself is not protected, but which serves to carry out a process which is the subject-matter of a patent. However, in case of the supply of such a device, it can generally be assumed that the contract between supplier and buyer includes the grant of a licence for the appropriate use of the protected process.”

competitors of the patentee - are entitled to use these objects for their intended purpose, to sell them to third parties or to offer them to third parties for any of these purposes.¹⁰¹ In this respect, the submission from Germany explains that the intended use of these marketed objects includes maintenance and restoration of the usability when the functionality or performance of the concrete item is partially or wholly compromised or lost due to wear, damage or for other reasons. On the other hand, not included in intended use are all measures resulting in the new manufacture of a product as described by the patent.¹⁰²

92. The submission from France notes that the doctrine of exhaustion allows the purchaser of the products incorporating a patented invention to resell them after making modifications that affect elements outside the scope of the protection granted by the patent, without the right holder's consent.¹⁰³ In other words, the rights holders may not restrict the import or other types of distribution of such modified products and have no *droit de suite* on the exploitation, import, resale or use of their inventions in the EEA.¹⁰⁴

93. Furthermore, the submission from Spain explains that the words "placed on the market" used in the applicable provision¹⁰⁵ must be interpreted in the broadest sense: a product has been placed on the market when made fully available to third parties. For that reason, use of the patented item for personal, non-commercial purposes is not considered to exhaust the patent right. Furthermore, in the cases of contractual licenses or licenses of right,¹⁰⁶ marketing of the product is covered by the provision on exhaustion of rights. If the product has been placed on the market by a third party enjoying a right based on prior use,¹⁰⁷ the patent right is exhausted and the patentee would no longer be able to enforce its exclusive rights over the patented product. Finally, the exhaustion of rights does not occur if the patent owner has legitimate grounds to prevent marketing of the product thereafter e.g., if the products may have been manipulated or altered.

Box 1. Application of the exhaustion doctrine by Spanish courts

(i) Valencia Commercial Court (Decision n° 72/2018, April 5, 2018)¹⁰⁸

In this case, the plaintiffs, Mr. X and the company Hygro International Pty Ltd. allege that the defendant, the company Cultivo Manuel y Rafa 3000, S.L.U, committed infringing acts with respect to two patents owned by Mr. X: manufacturing and/or importing, offering, advertising, distributing and marketing of products protected by the said patents without his consent.

¹⁰¹ BGH, judgement of 24 October 2017, ref: X ZR 57/16, BGHZ 2016, 300 –Trommeleinheit. See submission of Germany to SCP/34.

¹⁰² For further explanations, see paragraphs with respect to Germany in Section 5.C of this document.

¹⁰³ The submission refers to discussions on the exhaustion of patent rights of Emmanuel PY, 2021, PIBD 2021, 1162-II-3 (Paris Court of Appeals, April 16, 2021, No. 16/16/16760).

¹⁰⁴ The submission refers to, *inter alia*, *Centrafarm v. Winthrop* (case No. 16-74).

¹⁰⁵ Article 61 (2) of the Law № 24/2015 of July 24, 2015 on Patents of Spain (as amended by Law № 6/2018, of July 3, 2018).

¹⁰⁶ Article 87 of the Law on Patents, *ibid*, defines a license of right as one resulting from a public offering of nonexclusive contractual licenses issued by a patent holder in accordance with the provisions of the Law.

¹⁰⁷ According to Article 63(1) of the LP, "Prior use rights", the owner of a patent in Spain is not entitled to prevent persons who, before the priority date of the patent and in good faith, have been exploiting what ultimately becomes the object of the patent, or have made serious and effective preparation to exploit the said object, commencing or continuing operations in the same manner as they have been doing up to that point, or for which they had made preparations and to the extent appropriate to meet the reasonable needs of their business. Exploitation rights are only transferable together with the companies that have been exercising them.

¹⁰⁸ Decision No. 72/2018, April 5, 2018 (Ground 7), Valencia Commercial Court, ECLI: ES:JMV:2018:4924.

The defendant argued that the plaintiff's rights had been exhausted, since the allegedly infringing products had been placed on the market with the consent of the patentee and were legitimately acquired by the defendant. The defendant acquired the products through three different distributors: two of them official, as recognized by the plaintiff, and the other not official, as demonstrated by the plaintiffs.

Based on the facts, the judge considered that in the case of the products acquired by the defendant from the official distributors, the rights had indeed been exhausted, since their acquisition from an official distributor constituted a legal acquisition with the patentee's consent. On the other hand, with respect to the products acquired from a non-official distributor, the judge found that the patent rights had not been exhausted, because no evidence had been presented that the acquisition was legitimate, made through official channels and thereby authorized; and because the distributor concerned was in fact not official.

(ii) Madrid Commercial Court, Decision No. 903/07, December 20, 2007¹⁰⁹

The plaintiff, the company Goizper, brought proceedings against the companies Alcampo, S.A., Sabeko Banaket, S.A. and Euraspa, S.A. Euraspa, accusing them of patent infringement and unfair competition, for having imported and marketed in Spain agricultural sprays under the name "Sulf Agro", reproducing technical characteristics claimed under patent No. 9200041, and for constituting confusing imitations of sprays manufactured by the plaintiff.

The defendants argued that the patent rights in question had been exhausted, since the plaintiff had placed the protected product on the market.

The judge's conclusion was that two conditions were required for the exhaustion of rights: the protected products must have been marketed in a country of the European Economic Area (EEA); and that act must have occurred with the consent of the patent owner.

In this instance, the imported products had been manufactured in China, not in an EEA country. Referring to the CJEU case law, the judge ruled that the patent rights had not been exhausted, since, as reasoned by the CJEU, the exhaustion of rights must apply the Community jurisprudence. Moreover, even if the territorial condition had been fulfilled, the condition requiring consent of the patent owner, or of a third party with the owner's consent, remained unfulfilled, so the conclusion would be the same: the rights had not been exhausted.

94. In the United Kingdom, following the end of the implementation period on December 31, 2020, the United Kingdom ceased to be part of the EU/EEA and therefore the rights relating to goods put on the market of the United Kingdom are no longer considered exhausted by the EU law. However, although the United Kingdom is no longer part of the EEA, it continues to unilaterally apply the EEA regional IP exhaustion regime, i.e., the rights in goods put on the market in the EEA are considered to be exhausted in the United Kingdom. This

¹⁰⁹ Decision No. 903/07, December 20, 2007 (Grounds 2 and 3), Madrid Commercial Court, ECLI: ES:JMM:2007:808.

so-called a “UK+” exhaustion regime currently in place means that UK right holders cannot prevent the flow of goods from the EEA into the United Kingdom.^{110,111}

95. In Saint Vincent and the Grenadines, the Patents Act provides for a regional exhaustion of rights. In particular, the provision states that the rights conferred by a patent shall not extend to acts in respect of articles which have been put on the market in the Caribbean Community by the owner of the patent or with his consent.¹¹²

Burden of proof

96. Exhaustion constitutes an exception to the exclusive rights of the patent holder. The party invoking exhaustion has, in principle, the burden of proof as to the preconditions.¹¹³

4. Mixed Exhaustion Policies

97. In several national laws, one particular exhaustion regime is applied in principle; however, other exhaustion regimes apply to specific goods or under specific circumstances. Table No. 4 lists countries which apply mixed exhaustion policies with respect to patents.

Table No. 4: Countries providing mixed exhaustion regime

| Mixed Exhaustion Regime | Countries | Total Number |
|--|---|--------------|
| In principle, national exhaustion; international exhaustion may apply in certain cases | Andorra, Indonesia, Oman, Philippines, Rwanda, Russian Federation | 6 |
| In principle, regional exhaustion; national or international exhaustion may apply in certain cases | Switzerland | 1 |
| In principle, international exhaustion; national exhaustion may apply in certain cases | Singapore | 1 |

Different exhaustion rules with respect to specific goods

98. In the Philippines, while the national exhaustion regime applies with respect to patents, the international exhaustion regime applies to “drugs and medicines”. Section 72.1 of the IP Code¹¹⁴ states that the patentee has no rights to prevent third parties from “*[u]sing a patented product which has been put on the market in the Philippines by the owner of the product, or with*

¹¹⁰ The unilateral application of the EEA regional regime (UK+) derives from UK statutory instruments - The Intellectual Property (Exhaustion of Rights) (EU Exit) Regulations 2019 (as amended by The Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020). These statutory instruments were implemented following the UK Withdrawal Agreement from the EU.

¹¹¹ The UK is currently considering its future exhaustion regime, considering how the principle of exhaustion should work for the UK as a sovereign standalone nation. The UK Government held a consultation over summer 2021 to seek views on what the UK’s future exhaustion of IP rights regime should be. As of April 2022, the UK has completed an initial analysis of the consultation submissions and continues to explore the possibility of changes to the current regime and hopes to make a decision on the UK’s future exhaustion regime during 2022 (see submission of the United Kingdom to SCP/34).

¹¹² Section 28 of the Patents Act (Act № 39 of 2004) of Saint Vincent and the Grenadines.

¹¹³ See submission of Germany to SCP/34.

¹¹⁴ Section 72.1 of the of the Intellectual Property Code of the Philippines (Republic Act № 8293) (2015 Edition).

his express consent, insofar as such use is performed after that product has been so put on the said market: Provided, That with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: Provided, further, That the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party". In a 2009 decision in *Roma Drug vs. GlaxoSmithKline* case, the Supreme Court of the Philippines conferred the legality of private parallel importation of drugs.¹¹⁵

99. In Indonesia, there is a specific provision in the law which states that importation of a pharmaceutical product protected by a patent is exempted from criminal and civil lawsuits, provided the pharmaceutical product in question has been legally marketed outside the country and imported in accordance with the provisions of the law.¹¹⁶ However, the law appears to be silent with respect to the exhaustion policy regarding products in all other fields.

Box 2. *Roma Drug v GlaxoSmithKline, Philippines (2009)*

The petitioner Roma Drug was among the six local drugstores in Pampanga raided by the joint National Bureau of Investigation (NBI) and the Bureau of Food and Drugs (BFAD) inspectors where various medicines were found and seized upon the request of Glaxo SmithKline, a duly registered and authorized local distributor of the medicines seized from the said drugstores. The NBI proceeded in filing a complaint against petitioner for violation of Section 4 of the Republic Act No. 8203, also known as the Special Law on Counterfeit Drugs (SLCD), with the Office of the Provincial Prosecutor in San Fernando, Pampanga. The law prohibits the sale of counterfeit drugs, which include an "unregistered imported drug product". The term "unregistered" signifies lack of registration with the Bureau of Patent, Trademark and Technology Transfer of a trademark of a drug in the name of a natural or juridical person. The seized drugs are identical in content with their Philippine-registered counterparts. No claim was made that the drugs were adulterated in any way or mislabeled at the least. Their classification as "counterfeit" is based solely on the fact that they were imported from abroad and not purchased from the Philippine-registered owner of the patent or trademark of the drugs.

Petitioner Roma Drug challenged the constitutionality of the SLCD during the preliminary investigation but the provincial prosecutors issued a resolution recommending that Rodriguez, the owner of Roma Drug, be charged with violation of Section 4 of the SLCD. Thus, Roma Drug filed a Petition for Prohibition before the Supreme Court questing the RTC-Guagua Pampanga and the Provincial Prosecutor to desist from further prosecuting Rodriguez, and that Sections 3(b)(3), 4 and 5 of the SLCD be declared unconstitutional.

In responding to the question whether the contention of Roma Drug was correct, the Supreme Court referred to Section 7 of Rep. Act No. 9502 which amended Section 72 of the IP Code in that the law unequivocally grants third persons the right to import drugs or medicines whose patent were registered in the Philippines by the owner of the product.

In responding to the question whether Republic Act No. 9502 impliedly abrogates the provisions of the SLCD with which the petitioner is criminally charged, the Court stated:

"It may be that Rep. Act No. 9502 did not expressly repeal any provision of the SLCD. However, it is clear that the SLCD's classification of "unregistered imported drugs" as "counterfeit drugs," and of corresponding criminal penalties therefore are

¹¹⁵ *Roma Drug vs. GlaxoSmithKline* G.R. No.149907, April 16, 2009. See Box 2 for the summary of the case.

¹¹⁶ Article 167(a) of the Law of Republic of Indonesia Number 13 of 2016 on Patents.

irreconcilably in the imposition conflict with Rep. Act No. 9502 since the latter indubitably grants private third persons the unqualified right to import or otherwise use such drugs. Where a statute of later date, such as Rep. Act No. 9502, clearly reveals an intention on the part of the legislature to abrogate a prior act on the subject that intention must be given effect.”

The Supreme Court effectively decriminalized private parallel importation of drugs. In their discussion, the Supreme Court noted that – had they proceeded to directly confront the constitutionality of the assailed provisions of the Special Law on Counterfeit Drugs – it is apparent that it would have at least placed in doubt the validity of the provisions. “For a law that is intended to help save lives, the Special Law on Counterfeit Drugs has revealed itself as a heartless, soulless legislative piece,” the Court stated.

The Court added:

“Less urgently perhaps, but still within the range of constitutionally protected behavior, it deprives Filipinos to choose a less expensive regime for their health care by denying them a plausible and safe means of purchasing medicines at a cheaper cost”.

100. A hybrid approach is also followed in Singapore where, as a general rule, an international exhaustion to patent rights applies;¹¹⁷ however, the law does not allow imports of a patented pharmaceutical product if: (i) the product has not been previously sold or distributed in Singapore by the patentee or his licensee;¹¹⁸ (ii) the import of the product by the importer would result in the product being distributed in breach of a contract between the proprietor of the patent or any person licensed by the proprietor of the patent to distribute the product outside Singapore; and (iii) the importer has actual or constructive knowledge of the matters referred to in paragraph (ii).¹¹⁹

101. The recent amendments to the regulation of the exhaustion issue in the Russian Federation resulted in the change of the policy from the national exhaustion to a mixed-type exhaustion regime. Specifically on March 22, 2022, the Government of the Russian Federation issued a decree which allowed the government to establish a list of goods in respect of which the provisions of, *inter alia*, Article 1359(6) of Part IV of the Civil Code of the Russian Federation would not apply.^{120,121} On April 19, 2022, by Order No. 1532, such list has been established.¹²² The list includes a wide variety of goods, including cosmetics and perfumes, chemical products, clothing, footwear, cars, computer hardware and telecommunications equipment, household appliances, furniture and toys. According to the Order, Article 1359(6) of Part IV of the Civil Code with respect to the goods in the list will not apply, provided such goods have been legitimately introduced into circulation by the IP rights owners in other countries.¹²³

¹¹⁷ Article 66(2)(g) of the Patents Act of Singapore (Chapter 221)(Revised Edition 2005, as amended up to the Supreme Court of Judicature (Amendment) Act 2019).

¹¹⁸ Article 66(3)(a), *Ibid*.

¹¹⁹ Article 66(3)(b) and (c), *Ibid*.

¹²⁰ The decree can be found at the following website:
<http://publication.pravo.gov.ru/Document/View/0001202203300003>.

¹²¹ The text of Article 1359(6) reads: “The following are not deemed an infringement of the exclusive right to an invention, utility model or industrial design: [...] 6) the importation onto the territory of the Russian Federation, the application, offer for sale, sale, another introduction into civil-law transactions or storage for such purposes of a product in which the invention or utility model is used or of an article in which the industrial design is used, if the product or article has been earlier introduced into civil-law transactions on the territory of the Russian Federation by the patent holder or by another person by permission of the patent holder, or without a permit thereof, but upon condition that such introduction into civil law transactions was rightfully effected in the instances established by this Code”.

¹²² Order No.1532 can be found in the Appendix to this document.

¹²³ One drafting particularity about the Order can be noted: the Order does not limit IP rights with respect to parallel importation but exempts the application of the exhaustion of rights. If applied literally, this would mean that the IP rights owners have stronger rather than weaker protection against parallel imports. However, it is

On June 21, 2022, the above amendments were supplemented by the Law which states that it is not an infringement to use, *inter alia*, the results of intellectual activity expressed in goods (groups of goods), the list of which is established in the above-referred Order.¹²⁴ Thus, following these amendments, it could be inferred that, with respect to the goods in the list, the international exhaustion applies in the Russian Federation, while with respect to other goods not included in the list, national exhaustion continues to apply.

102. Switzerland also applies hybrid rules with respect to the exhaustion of patent rights. In principle, goods placed in Switzerland or the EEA by a patentee or with its consent can be imported, used or resold commercially in Switzerland (regional exhaustion).¹²⁵ However, if the patent-protected good was put on the market in a country outside of the EEA by a patentee or with his consent and if the patent protection for the functional characteristics of the goods is only of subordinate importance, the goods may be imported into the Swiss market (international exhaustion).¹²⁶ In addition, if the price of patent-protected goods in Switzerland or in the country in which they are placed on the market is fixed by the state, such as medicines, the goods may only be placed in Switzerland with the agreement of the patentee (national exhaustion).¹²⁷ Further, patented means of agricultural production and agricultural capital equipment, such as tractors and machines, can be imported into Switzerland from abroad (international exhaustion).^{128, 129}

Different exhaustion rules under specific circumstances

103. In few countries, the rules on exhaustion depend on the specific circumstances. Thus, for example, the general provision on exhaustion in the law of Oman illustrates that the regime applied in that country is a national exhaustion.¹³⁰ However, the Minister has the authority, *ex officio* or at the request of any interested party, of declaring the patent rights exhausted, and thus of authorizing others to import the patented product from another territory when that product: “*is not available in Oman or is available in Oman with unreasonably low quality standards or in a quantity that is not sufficient to meet the local demand or at prices that the Minister deems abusive or for any other reason of public interest, including anticompetitive practices*”. This provision is subject to the following conditions: (i) the product has been put in the channels of commerce in the territory from which it will be imported by the patentee or with his consent; and (ii) a patent claiming the product or the process for its manufacture is in force in the territory from which the product will be imported and is owned by the same person who owns the patent in Oman or by a person under his control.¹³¹ The Minister shall, *ex officio* or at the request of the patent owner, cancel the authorization if the importer fails to fulfill the purpose that justified the Minister’s decision. Further, if the conditions that gave rise to the Minister’s

understood that the intention of the Order was to introduce the international exhaustion of rights with respect to listed goods.

¹²⁴ The text of the adopted law can be found at: <https://sozd.duma.gov.ru/bill/127049-8>. The provisions also clarifies that “[t]he use of means of individualization with which such goods are marked shall also not constitute an infringement.”

¹²⁵ Article 9a 1 of the Federal Act of June 25, 1954 on Patents for Inventions of Switzerland.

¹²⁶ Subordinate importance is presumed unless the proprietor of the patent provides *prima facie* evidence to the contrary. See Article 9a 4 of the Federal Act of June 25, 1954 on Patents for Inventions.

¹²⁷ Article 9a 5, *ibid*. See also a response of Switzerland to the Questionnaire.

¹²⁸ Article 27b of the Federal Act on Agriculture (910.1) states: “¹ If a patent holder has put aids to production or agricultural capital goods into circulation within Switzerland or abroad or has agreed to their being put into circulation, such aids or goods may be imported, sold on and used commercially. ² Agricultural capital goods are investment goods such as tractors, machinery, tools and installations and their component parts that are intended predominantly for use in agriculture.”

¹²⁹ Finally, Article 9a 3 of the Federal Act on Patents provides a specific exhaustion provision applying to the propagation of biological material with respect to farmers use for an agricultural purpose, See Article 9a 3 of the Federal Act on Patents.

¹³⁰ Article 11(4)(A) of the Industrial Property Rights Law of Oman (promulgated by the Royal Decree № 67/2008).

¹³¹ Article 11(5), *ibid*.

decision to consider the patent exhausted cease to exist, the Minister may cancel the authorization, provided that the legitimate interests of the importer are taken into account.¹³²

104. The IP Law of Rwanda contains a similar provision applying, in principle, a national exhaustion for patents, however giving the power to the Minister to authorize others to import the patented product from another territory on the same circumstances as described above in the law of Oman.¹³³

105. Yet, in Andorra, the rights conferred by a patent do not extend to acts in respect of a protected product after that product has been introduced to the market by the patentee or with its express consent, to the Principality of Andorra or to any other territory “specified by agreements of the Government by virtue of reciprocity criteria”.¹³⁴

5. Uncertain Exhaustion Policies

106. In some countries, the type of exhaustion is uncertain as the relevant statutory provision has not specified the place at which the exhaustion rule would be triggered, and interpretation by courts has not been established yet in this respect.¹³⁵ For example, Sri Lanka’s IP law states in Section 86(1)(iv) that the owners’ rights shall “*not extend to acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under licence*” without specifying whether the market is a national one or any market.¹³⁶ Likewise, the relevant provision of the law of Uzbekistan states that “*the use of means consisting of objects of industrial property protected by patents, if these means are legally introduced into civil circulation*” is not recognized as infringement of rights. However, no further explanation can be found with respect to the words “civil circulation”.¹³⁷

107. Similarly, in South Africa, while Section 45(2) of the Patents Act¹³⁸ recognizes the doctrine of exhaustion of rights, uncertainty remains as to whether it applies nationally or internationally.¹³⁹ The provision states generally “*[t]he disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article.*”. Another relevant legal instrument in South Africa is Medicines and Related Substances Act which authorizes the Minister to prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular “*notwithstanding anything to the contrary contained in the Patents Act [...], determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent*”.¹⁴⁰ This provision, in the absence of any authoritative guidance, also does not make it clear about the

¹³² Article 11(6), *Ibid.*

¹³³ Article 40 of the Law № 31/2009 of 26/10/2009 on the Protection of Intellectual Property of Rwanda.

¹³⁴ Article 33(1)(a) of the Law 26/2014, of October 30, 2014, on Patents of Andorra.

¹³⁵ These countries are: Algeria, Malaysia, Mongolia, Panama, South Africa, Sri Lanka, Uganda, Ukraine and Uzbekistan.

¹³⁶ See also a response from Sri Lanka to the Questionnaire stating that the exhaustion rule is uncertain in that country.

¹³⁷ Article 12 of the Law of the Republic of Uzbekistan № 1062-XII of May 6, 1994 on Inventions, Utility Models and Industrial Designs (as amended up to Law of the Republic of Uzbekistan № ZRU-446 of September 14, 2017).

¹³⁸ Section 4569A (21) of the Patents Act 1978 (Act № 57 of 1978, as amended up to Patents Amendment Act 2002). See also Article 18.2.1 of the Patent Law of Mongolia of June 25, 1993.

¹³⁹ See the submission of South Africa to SCP/27 at: https://www.wipo.int/scp/en/meetings/session_27/comments_received.html.

¹⁴⁰ Section 15C of the Medicines and Related Substances Act 1965 (Act № 101 of 1965, as amended).

geographical limitation of the word “market” and, consequently, whether the parallel importation of medicines could validly be pursued.^{141,142}

108. In the Republic of Korea, the Supreme Court in a decision of January 31, 2019¹⁴³ recognized the principle of exhaustion by stating “*if a patentee of a product invention or a licensee [...] receiving a license to practice a patent has legitimately transferred a patented product that has been implemented in Korea, the purpose of a patent right for the transferred product has already been achieved and therefore exhausted. Therefore a patent right has no effect on acts, such as the use or transfer of a product by a transferee or an authorized person [...].*”¹⁴⁴ However, in the absence of the Supreme Court’s precedent, it is unclear whether the parallel importation would be permissible in the Republic of Korea.

109. In few other countries and one territory, the position on the exhaustion is uncertain because the respective patent laws do not appear to provide such an exception to the exclusive rights in the first place.¹⁴⁵

5.B Exhaustion – Subject to Reservation of Rights

110. In some countries, the issue of exhaustion is not specifically dealt within the statutory law but established through case law. Specifically, this is the case in Australia, Canada, New Zealand, Japan, the Republic of Korea and the United States of America. Thus, in these countries, judicial decisions set the boundaries of what legitimate acquirers of a marketed product can do without infringing the patent rights, including whether parallel importation constitutes patent infringement. In general, in these countries, the effect of legitimate sale of the patented products is that the ownership of that product is transferred to the purchaser which, in principle, has the right to do with the product as it wishes, without fear of patent infringement, either as a consequence of application of the implied license doctrine or the exhaustion principle.¹⁴⁶ However, such ownership can be subject to restrictions and conditions as to the use of a patented product after its sale imposed by the patentee to the downstream purchaser.¹⁴⁷ Recently, the courts in few countries focused on, *inter alia*, whether such

¹⁴¹ In this respect, the IP Policy of South Africa finds that a narrow interpretation of section 45(2) of the Patents Act could potentially give rise to challenges to parallel importation being pursued. Thus, the Policy notes the need to clarify in the Patents Act that parallel importation of medicines in the manner prescribed in the Medicines Act does not constitute an infringement of the former legislation. Cabinet, the highest decision-making body of government adopted the Policy in 2018, and according to the official sources, the work on the implementation of the Policy is ongoing. See the text of the Policy at: https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf.

¹⁴² Some scholars argue that, in cases where no clarifications are provided in the statute with respect to the word “market”, given the territoriality of patents, an interpretation of this word would be limited to national markets. See, e.g., C.M. Correa and J.I. Correa (2016), *supra* note 72; see also Calboli, I. (2022), Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_2.

¹⁴³ Supreme Court decision No. 2017Da289903 of January 31, 2019.

¹⁴⁴ See submission of the Republic of Korea to SCP/34 also notes that this principle is also applied to the case where a product that has been manufactured by the patented process in Korea.

¹⁴⁵ See, e.g., the patent laws of Angola, Azerbaijan, Egypt and the Lao People’s Democratic Republic. See also response of Hong Kong China to the Questionnaire.

¹⁴⁶ The implied license doctrine refers to a notion that an unconditional purchase of a patented item grants an implied license to the purchaser to deal with the item without restriction. While the effect of the implied license doctrine and exhaustion is the same, the underpinning principles appear to be different: (i) the licensing is rooted in contract law, whereas the exhaustion doctrine in IP law; (ii) in the license model, the patentee retains all the exclusive rights during the patent term (i.e., the rights to not disappear or get exhausted upon the legitimate sale), whereas the exhaustion leaves no patent rights to be enforced. See, e.g., *United Wire Ltd v Screen Repair Services Ltd* [2000] UKHL 42. See also Olena Ivus, Patent Exhaustion in the United States and Canada, CIGI Papers No. 159 — January 2018.

¹⁴⁷ In some countries, the clause to permit the patentee to place contractual restrictions on the product stems from the provisions in the Free Trade Agreements (FTA) to which they are party. For example, the Australia –

expressed contractual restrictions placed by the patentee on goods should be enforced through a patent infringement lawsuit or whether this is a matter of contract law.¹⁴⁸

Canada

111. In Canada, while the term “patent exhaustion” is not used by courts, the treatment of patent exhaustion is essentially equivalent to national exhaustion while permitting express reservation of rights. In general, Canada applies a doctrine of implied license which indicates that when a patent holder sells the patented item (or the item created by using a patented process), the buyer acquires a license to use and sell the item and all subsequent buyers receive the same license.¹⁴⁹ In *Eli Lilly and Co v Novopharm Ltd* (1998)¹⁵⁰ the Supreme Court of Canada established that if the patentee sells the patented good, it transfers the ownership of that good to the purchaser, unless those rights are expressly reserved by contract and communicated to the purchaser.¹⁵¹ Were a purchaser to violate those express restrictions, the purchaser would be liable for patent infringement and the patent holder would have remedies in patent law.¹⁵²

Box 3. *Eli Lilly and Co v Novopharm Ltd* (1998)

In this case, the Supreme Court of Canada invoked public policy rationales to limit patent rights. Writing for the court, Justice Iacobucci quoted with approval the following passages from the judgment of the Federal Court of Appeal in *Eli Lilly and Co v. Apotex Inc* (1996):

“If the patentee sells the patented article that he made, he transfers the ownership of that article to the purchaser. This means that, henceforth, the patentee no longer has any right with respect to the article which now belongs to the purchaser who, as the new owner, has the exclusive right to possess, use, enjoy, destroy or alienate it. It follows that, by selling the patented article that he made, the patentee impliedly renounces, with respect to that article, to [...] his exclusive right under the patent of using and selling the invention. After the sale, therefore, the purchaser may do what he likes with the patented article without fear of infringing his vendor’s patent”.¹⁵³

United States FTA (Article 17.9.4) states that “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.” Similarly, Morocco – United States FTA (Article 15.9.4) states “Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory.” The footnote to this provision states that “[a] Party may limit application of this paragraph to cases where the patent owner has placed restrictions on importation by contract or other means.”

¹⁴⁸ It is to be noted that, according to the Questionnaire conducted in the SCP, in the majority of other countries (mainly civil law countries), the patentee is not permitted to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that could affect the exhaustion doctrine applied in respective countries. See responses to question 62 of the Questionnaire. However, these responses may be outdated.

¹⁴⁹ See *E.G. Signalisation de Montreal Inc. v. Services de Béton Universels Ltée* (1992), 46 C.P.R. (3d) 199, at 208 (F.C.A.), which states: “It is settled law that the purchaser of a patented article from a patentee acquires, at the same time, the right to use the article and the right to sell it, together with the same “right of use,” to another person. As long ago as 1871, this right was described as a “licence.””

¹⁵⁰ *Eli Lilly & Co. v. Novopharm Ltd.* [1998] 2 SCR 129.

¹⁵¹ For the Court’s reasoning in *Eli Lilly and Co v Novopharm Ltd.*, see Box. 3.

¹⁵² Olena Ivus, Patent Exhaustion in the United States and Canada, CIGI Papers No. 159 — January 2018.

¹⁵³ 2 SCR 129, para 99, quoting with approval Justice Pratte in *Eli Lilly and Co v. Apotex Inc.* (1996) 66 CPR (3d) 329 (FCA) at 343.

Justice Iacobucci further stated:

***“[U]nless otherwise stipulated in the licence to sell a patented article, the licensee is thus able to pass to purchasers the right to use or resell the article without fear of infringing the patent. Further, any limitation imposed upon a licensee which is intended to affect the rights of subsequent purchasers must be clearly and unambiguously expressed; restrictive conditions imposed by a patentee on a purchaser or licensee do not run with the goods unless they are brought to the attention of the purchaser at the time of their acquisition [...]. [I]n the absence of express conditions to the contrary, a purchaser of a licensed article is entitled to deal with the article as he sees fit, so long as such dealings do not infringe the rights conferred by the patent.”*¹⁵⁴**

United States of America

112. In the United States of America, the development of the exhaustion doctrine and its scope has also evolved through case law. Though the exhaustion principle has long been recognized by the courts,¹⁵⁵ it was not until the decision of the Supreme Court issued in 2017 in *Impression Products, Inc. v Lexmark Int’l, Inc.*¹⁵⁶ that the importation of a patented good that was sold outside of the country would not be considered as infringement of rights. In particular, the Supreme Court in this case held that after the sale of a patented good, the patentee exhausts all of its patent rights in that good, regardless of any restrictions it purports to impose, and even when the sale occurred outside the United States. These restrictions could be enforceable under contract law and not through a patent infringement lawsuit.

Box 4. Impression Products, Inc. v Lexmark Int’l, Inc. (2017)

Lexmark sold toner cartridges, the subject of its patents for use with laser printers, in the United States and abroad. The used cartridges were refilled by Impression Products for reuse and resale. In an attempt to meet this competition, Lexmark offered discounts to customers who agreed to use the cartridge only once and not to transfer the empty cartridge to anyone but Lexmark. It installed a microchip on each of such cartridge that prevented reuse. Its competitors, including Impression Products, developed methods to counter the microchip. Lexmark brought proceedings for infringement of its patent constituted by the refurbishment and resale of the cartridges. With respect to toner cartridges that Lexmark had sold abroad and that Impression Products imported into the country, Lexmark claimed that it never gave anyone authority to import these cartridges, so Impression Products infringed its patent rights by such importation.

The case presented two questions: (i) whether a patentee that sells an item under an express restriction on the purchaser’s right to reuse or resell the product may enforce that restriction through an infringement lawsuit; and (ii) whether a patentee exhausts its patent rights by selling its product outside the United States, where its patent law does not apply.

¹⁵⁴ *Ibid*, at para 100 and 101.

¹⁵⁵ See e.g. *Adams v. Burke*, 84 U.S. 453 (1873): “When the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use”. See also *Impression Products Inc. v Lexmark International Inc.* 137 S. Ct. 1523 (2017): “The Patent Act grants patentees the “right to exclude others from making, using, offering for sale, or selling [their] invention[s]. 35 U. S. C. §154(a). For over 160 years, the doctrine of patent exhaustion has imposed a limit on that right to exclude.”.

¹⁵⁶ *Impression Products Inc. v Lexmark International Inc.* 137 S.Ct. 1523 (2017).

A majority of the Supreme Court held that:

“Lexmark exhausted its patent rights in these cartridges the moment it sold them. The single-use/no-resale restrictions in Lexmark’s contracts with customers may have been clear and enforceable under contract law, but they do not entitle Lexmark to retain patent rights in an item that it has elected to sell.”¹⁵⁷

Roberts, C.J. explained that the exhaustion doctrine is not a presumption that arises on sale, rather it recognizes a limit on the scope of the patentee’s statutory rights. Acknowledging that the effect of a patent is to grant to a patentee a right to prevent others from using or selling their product, his Honour explained that the exhaustion doctrine regards that exclusionary power as extinguished when the product is sold. His Honour reiterated what had been said in the earlier cases – when a patentee chooses to sell a patented product, it is “no longer within the limits of the monopoly”. Instead, it becomes the “private, individual property” of the purchaser with all the rights and benefits of ownership. His Honour said that a patentee is “free to set the price and negotiate contracts with purchasers, but may not, “by virtue of his patent, control the use or disposition” of the product after ownership passes to the purchaser.”

With respect to Lexmark’s argument that all foreign sales are exempted from patent exhaustion, the Court stated:

“[...] exhaustion occurs because, in a sale, the patentee elects to give up title to an item in exchange for payment. Allowing patent rights to stick remora-like to that item as it flows through the market would violate the principle against restraints on alienation. Exhaustion does not depend on whether the patentee receives a premium for selling in the United States, or the type of rights that buyers expect to receive. As a result, restrictions and location are irrelevant; what matters is the patentee’s decision to make a sale.”

Thus, the Court concluded Lexmark could not sue Impression Products for infringement with respect to these cartridges. An authorized sale outside the United States, just as one within the United States, exhausts all rights under the Patent Act.

Australia

113. In Australia, while its Patents Act does not specifically deal with the issue, the exhaustion doctrine is applied to patent rights. The High Court of Australia recently found in *Calidad Pty Ltd v Seiko Epson Corporation* that the first sale of a patented product exhausts the patentee’s exclusive rights in that product and that approach was found to be preferable to the longstanding “implied license” doctrine.¹⁵⁸ The sale of a patented article in Australia would exhaust the patentee’s patent rights with respect to the particular product sold unless the patentee imposed restrictions or conditions on the buyer through a contract on the use of the patented product after its sale. These restrictions or conditions would be enforced through contract law or equity – not patent law.

114. That principle is subject to a qualification that importation of the patented article that was put into circulation outside Australia by the Australian patentee will be an infringement if, at the time of first putting the article into circulation, that patentee attached an express stipulation against bringing it into Australia.¹⁵⁹

¹⁵⁷ *Impression Products Inc. v Lexmark International Inc.*, *ibid*, at 1531.

¹⁵⁸ *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41.

¹⁵⁹ *Calidad Pty Ltd v Seiko Epson Corporation*, see Box 5 for the Court’s reasoning in this case.

115. Ultimately, the Court in this case discussed what type of modifications would amount to making a new product, thus constituting an infringement of the patent rights.

Box 5. *Calidad Pty Ltd v Seiko Epson Corporation (2020)*

The case concerned the “repurposing” the patented product for subsequent sale and importing such repurposed products into Australia for sale.

Seiko Epson Corporation (Seiko) manufactures and sells printer cartridges. Ninestar Image (Malaysia) SDN BHD (Ninestar) repurposed these printer cartridges by refilling used cartridges collected from consumers, which were then imported and sold in Australia by Calidad Pty Ltd (Calidad).

In the proceedings in the Federal Court, Seiko alleged that Calidad was in infringement of its patent rights. The Full Court of the Federal Court found that the implied license did not extend to the modifications made by Ninestar. Further, the modifications amounted to a “making” of a new patented product or a remaking of the original and infringed the patentee’s rights. Calidad appealed to the High Court arguing that the exhaustion doctrine should be applied in the cases of this kind.

There were two questions before the High Court: (i) whether a patentee’s rights with respect to the sale and use of a particular product should be regarded as exhausted when that product is sold or whether they continue; and (ii) whether modifications made to a product to enable its reuse amount to a making of a new product and infringes on that account.

With respect to question (i), the High Court held that a patentee’s rights with respect to a particular product are exhausted once that product is sold. In particular, the Court stated that:

“The exhaustion doctrine leaves no patent rights to be enforced with respect to the particular product sold. [...]

The exhaustion doctrine accepts that a patentee has special rights deriving from the patent which are given statutory effect, but holds that they are exhausted when the reward which is the object of those special rights is achieved by the patentee. The sale takes the product outside the scope of the patentee’s monopoly rights.”¹⁶⁰

With respect to the implied license doctrine, the High Court found that it is likely to cause confusion because it combines a “fictional licence” with the possibility of real restrictions. Specifically, the Court considered that:

“The exhaustion doctrine has the virtues of logic, simplicity and coherence with legal principle. It is comprehensible and consistent with the fundamental principle of the common law respecting chattels and an owner’s rights respecting their use. At the same time, it does not prevent a patentee from imposing restrictions and conditions as to the use of a patented product after its sale but simply requires that they be obtained by negotiation in the usual way and enforced according to the law of contract or in equity.”¹⁶¹

¹⁶⁰ *Calidad Pty Ltd v Seiko Epson Corporation* [2020] HCA 41., at para 74 and 75.

¹⁶¹ *Ibid*, at para 76.

On question (ii), the Court found that the modifications made to the cartridges were “within the scope of the rights of an owner to prolong the life of a product and make it more useful. They do not amount to an impermissible making of a new product.” Judges also found that modifications will amount to making a new product, which is an infringement of patent rights, where the modifications are of claimed features.^{162,163}

New Zealand

116. In New Zealand, the Patents Act 2013 is silent on the issue of exhaustion and the circumstances in which patent rights are exhausted will depend on the conditions under which the patentee has decided to make the patented product available. The applicable case law is *Betts v Wilmott* (1871)¹⁶⁴ where the court held that the exhaustion of rights is likely to depend on any conditions attached to the initial sale by the patentee.¹⁶⁵

Japan

117. In Japan, in accordance with the decision of the Third Petty Bench, Supreme Court of July 1, 1997,¹⁶⁶ if the patent holder or the licensee assigned the patented products in Japan,¹⁶⁷ the patent right has achieved its goal and has been exhausted, and the effect of the patent right does not extend to acts such as the use, assignment and rental of the product. As for the assignment of patented products overseas, the Supreme Court ruled that the patentee or an equivalent person may not exercise the patent right in Japan with respect to the importation of such assigned products. However, patentee may prevent importation of such products if the patentee agrees with the assignee to exclude Japan from the areas of sale or use of the products and the agreement is explicitly indicated on such products.¹⁶⁸

Box 6. Third Petty Bench, Supreme Court, Japan (1997)

This case is an action of the appellant seeking an injunction against import and sale of goods which were produced and sold in the Federal Republic of Germany by the appellant and claiming damages on the basis of a patent right vis-a-vis the appellee who imported these goods into Japan by parallel import and sold them. The appellee argued that the patent on the product had lost effect by the lawful sale of those products in the Federal Republic of Germany, and therefore, the import of these products into Japan and their sale in Japan do not constitute infringement of the patent.

In the international setting, the Supreme Court emphasized the need to balance the free movement of goods in the international market and the rights of patent owners. The

¹⁶² *Ibid*, at para 69 and 70.

¹⁶³ This issue is further discussed in Section 5.C.3 of this document (see paragraphs with respect to Australia).

¹⁶⁴ *Betts v Wilmott* (1871) 6 Ch App 240.

¹⁶⁵ In May 2019, the Ministry of Business, Innovation & Employment (“MBIE”) released a Discussion Paper, seeking submissions on various issues in relation to intellectual property laws, including whether the Patents Act 2013 (the “NZ Patents Act”) should be amended to provide for domestic and/or international exhaustion of patent rights. A review of the submissions received indicates that submitters were generally in favor of amending the NZ Patents Act to provide for international exhaustion. After reviewing the submissions, MBIE provided a recommendation to the Cabinet regarding amendments of New Zealand’s intellectual property laws. MBIE’s recommendations included a recommendation that the NZ Patents Act be amended to provide for international exhaustion of patent rights. The Cabinet agreed to these recommendations in June 2020. The next step is to draft a Bill to implement the recommendations agreed to by the Cabinet. This is now in progress. See <https://www.mbie.govt.nz/business-and-employment/business/intellectual-property/proposed-intellectual-property-laws-amendment-bill/>.

¹⁶⁶ Third Petty Bench Supreme Court of Japan of July 1, 1997 (BBS Supreme Court case, No.1995(O)1988).

¹⁶⁷ Under Article 68 of the Patent Act of Japan, the patentee has an exclusive right to work its patented invention as a business. Article 2(3) defines “working” of an invention, as applied to an invention of a product as “acts of producing, using, assigning etc. [...] or importing, or offering for assignment, etc. [...]” of such a product.

¹⁶⁸ For the Court’s reasoning in BBS Supreme Court case No.1995(O)1988, see Box 6.

Court stated that when a patent owner sells patented products overseas, it can be easily expected that a third party may buy such products from the buyer or intermediary seller and operate a business of importing, using, or distributing the products in Japan. The Supreme Court then held:

“(1) [...] when the patented product was assigned outside Japan by the patent holder, it is naturally expected that the products may be subsequently imported into Japan, if the patent holder assigned the patented products outside Japan without any reservation, it should be understood that the patent holder had implicitly granted the right to control the products to the assignee and the subsequent assignees without being restricted by the patent which the assignor has in Japan.

(2) On the other hand, if one looks at the right of the patent holder, the patent holder should be understood to be entitled to reserve the right of exercising his patent right in Japan at the time of the assignment of the patented products outside Japan, and if the patent holder, at the time of assignment, agrees with the assignee to exclude Japan from the area of sale or use of the patented products and expressly indicated this on the products, the person who had the products subsequently assigned from the assignee, even if there were intermediaries in the circulation process of the products, should be able to recognise that there was such a restraint on the product, and is capable of making a decision to purchase or not to purchase such products at his own will.

(3) The same shall apply in cases where the patented products were assigned outside Japan by subsidiaries or affiliated companies which can be regarded as an equivalent of the patent holder.

(4) The necessity of protecting the reliance of the assignee of the patented products on free circulation of the products does not depend on whether or not the patent holder has a corresponding patent in the place where the patented products have been first assigned.

Based on the above arguments, the Supreme Court ruled that, in the present case, the appellant has neither asserted nor proved that the appellant had agreed with the assignee at the time of the sale to exclude Japan from the area of use or sale, or had expressly indicated this on the products, and therefore, the appellant is not allowed to seek an injunction or claim damages based upon the patent right.

5.C Certain Legal Aspects Relating to the Exhaustion

118. This section focuses on some of the specific legal issues with respect to the exhaustion of patent rights.

1. Scope of Application

119. The analysis of national laws on the exhaustion of patent rights showed that there are some particularities in the applicability of exhaustion when the subject matter of a patent is not a product invention but a process invention. Since the exhaustion comes into play when a product protected by patent is placed on the market, the exhaustion is undoubtedly applicable to a *product* patent.

120. However, the question as to how exhaustion applies to the patentee's rights in respect of a process patent is not as straightforward as in the case of product patents. In fact, a protected process as such cannot be placed on the market, since the function of the process is for it to be

used to achieve a particular end. Therefore, the patentee's rights are exhausted for a product created from the use of a patented process. Accordingly, the provisions of some countries' laws on exhaustion expressly state that where the subject matter of a patent is a *process*, the rights are exhausted when the *product which is produced directly by such process* is placed on the market legitimately.¹⁶⁹

121. Furthermore, submissions from some countries clarified that the exhaustion is not applicable regarding the rights of the patent holder in respect of a process as such.^{170, 171} In this respect, the submission from Germany explained the issue by bringing an example of a device that was put on the market by the patentee, where the device itself is not protected by a product patent, but serves to carry out a process that is the subject matter of a patent. In such a case, exhaustion of the process patent does not occur.¹⁷² However, if a person buys such a device from the owner of the process patent, that person cannot avoid practicing the patented process by using the purchased device. As it is in accordance with the purpose of the purchasing contract, the purchaser may use the device accordingly.¹⁷³ Specifically, the Federal Court of Justice stated:

"If the owner of a process patent sells to an industrial customer a device which, according to the purpose of the contract, is intended for the practice of the protected process, it would, however, contradict the meaning of the contract if the seller could now prohibit the acquirer of the device from using it as intended by invoking his process patent. According to the purpose of such a contract of sale, it must therefore be assumed as a rule that the seller has granted the acquirer permission to use the protected process with the aid of the device even if express agreements on such a license have not been made either in the contract of sale or otherwise [...]. However, this does not say anything about the more detailed conditions under which such a license may be granted, in particular whether it is granted against payment or free of charge. This legal consequence is based solely on the contractual agreements between the parties and has nothing to do with an exhaustion of the property rights relating to the process. The seller of the device is not prevented from making the licensing of the process dependent on a royalty payment [...]."
[Non-official translation]

122. It follows from the wording the Federal Court of Justice above, that the sale of the device that carries out the protected process does not result in exhaustion of rights, but relates to a (tacit) license. This, in particular, means that the parties could in the contract agree on a license fee for the use of the process patent in addition to the sales price for the device.^{174, 175}

¹⁶⁹ See, e.g., the provisions of laws of Bosnia and Herzegovina, China and Montenegro. See also submissions of Germany and Spain to SCP/34.

¹⁷⁰ See submissions of Colombia, Germany and Spain to SCP/34.

¹⁷¹ In this respect, the Constitutional Court of the Russian Federation noted that "the limitation specified in the provision on exhaustion of rights extends only to patented industrial property which has a material form, and does not encompass patent holders' exclusive rights in relation to processes patented as inventions." (October 16, 2001, No. 211-O).

¹⁷² See submissions of Germany to SCP/34.

¹⁷³ BGH, Judgment of 23.09.1979, KZR 14/78 mn. 15 – Fullplastverfahren

¹⁷⁴ The Court also stated that if the rights were exhausted, such a license contract could have been void due to violation of antitrust law (see BGH Judgment of 23.09.1979, KZR 14/78, guiding principle b, mn. 12 – Fullplastverfahren).

¹⁷⁵ This judgement confirmed by BGH Judgement 27.02.2007, X ZR 113/04, mn. 27 – *Rohrschweißverfahren*: "In the absence of agreements to the contrary, the delivery of the data carrier containing the welding data to third parties on the part of the patent proprietor or its licensees is to be regarded as (tacit) permission for the customers to use the protected process for the intended purpose (supplement to BGH, Urt. v. 24.9.1979 - KZR 14/78, GRUR 1980, 38 - Fullplastverfahren)."

123. In the United States of America, the Supreme Court in *Quanta Computer, Inc. v. LG Electronics, Inc.* (2008) case¹⁷⁶ confirmed that method patents are exhausted by the sale of an article that embodied the method.¹⁷⁷ Whether an article constitutes a “patented product” for the purposes of patent exhaustion depends on whether the article “substantially embodies a patent”.¹⁷⁸ Specifically, the Court stated:

*“Nothing in this Court’s approach to patent exhaustion supports LGE’s argument that method claims, as a category, are never exhaustible. A patented method may not be sold in the same way as an article or device, but methods nonetheless may be embodied in a product, the sale of which exhausts patent rights. Our precedents do not differentiate transactions involving embodiments of patented methods or processes from those involving patented apparatuses or materials.”*¹⁷⁹

*“The authorized sale of an article that substantially embodies a patent exhausts the patent holder’s rights and prevents the patent holder from invoking patent law to control post-sale use of the article. Here, LGE licensed Intel to practice any of its patents and to sell products practicing those patents. Intel’s microprocessors and chipsets substantially embodied the LGE Patents because they had no reasonable non-infringing use and included all the inventive aspects of the patented methods.”*¹⁸⁰

2. Legitimate Placement of the Product

124. In general, the placing on the market of the product protected by patent is a key precondition for exhaustion to occur. Furthermore, as follows from the wording of some national law provisions, in order for the rights to be exhausted, such product must be placed on the market by a patentee or with its consent. In some other countries’ laws, in this context, no express reference is made to the “patentee or with its consent”, but the condition is that such placement on the market shall be “lawful” or “legitimate”. Consent may result, for instance, from the grant of a non-exclusive or exclusive license, provided that the licensee does not go beyond the rights under the license.¹⁸¹ Thus, for the purposes of patent exhaustion, the licensee’s sale of the patented product is treated as if the patentee made the sale itself, i.e., such sale exhausts the patentee’s rights in that item. Furthermore, in countries of the Andean Community, exhaustion occurs when the protected product has been placed on the market (of any country) not only by the patentee, or with its consent, but also by another person who is “economically associated with him”.¹⁸²

125. Furthermore, with respect to the “legitimate” or “lawful” placement of the product, a question may arise with respect to whether patent rights are exhausted with respect to a product produced and placed on the market based on the prior user rights or those produced under a compulsory license. With respect to the compulsory license specifically, the following two opposing opinions have been found. One argument is that, since products placed on the market under a compulsory license are considered as “lawfully placed on the market”, the rights are exhausted.¹⁸³ On the other hand, it is argued that the “legitimate” requirement is only considered to be satisfied when the

¹⁷⁶ *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008). The issue was “whether patent exhaustion applies to the sale of components of a patented system that must be combined with additional components in order to practice the patented methods.” *Quanta Computer*, at 621.

¹⁷⁷ *Quanta Computer*, *ibid*, at 629.

¹⁷⁸ Court also stated: “*Eliminating patent exhaustion for method patents would seriously undermine the exhaustion doctrine. Patentees seeking to avoid patent exhaustion could simply draft their patent claims to describe a method rather than an apparatus.*” *Quanta Computer*, *ibid*, at 629.

¹⁷⁹ *Quanta Computer*, at 621.

¹⁸⁰ *Quanta Computer*, *ibid*, at 638.

¹⁸¹ See submission of the Czech Republic to SCP/34. See also Kraßer, *Patentrecht* (6th ed, 2009), §33Vb) 4, p. 797.

¹⁸² For the definition of “economically associated with him”, see paragraphs on the Andean Community Decision № 486 in Section 5.A.2 of this document.

¹⁸³ See C.M. Correa and J.I. Correa (2016), *supra* note 72.

goods are placed on the market by the patentee or a third party with the patentee's consent.¹⁸⁴ The argument goes that the compulsory license is opposite to the exercise of the free will and granted against the consent of the patentee, therefore the patent rights cannot be exhausted by the first sale of the products produced under compulsory licenses.¹⁸⁵

126. As demonstrated in the above sections of the document, the countries' approaches on these questions differ. In the European Union, the CJEU ruled that, in the case of compulsory licenses, the patentee cannot be deemed to have consented to the operation of a third party, thus the patentee can prevent parallel importation of such products.¹⁸⁶ In Pakistan, parallel importation of products placed on the market in "any other legitimate manner" such as "compulsory licenses" is expressly permitted. The provision of law of Malaysia also confirms that patent rights shall not extend to acts in respect of products put on the market, *inter alia*, by the beneficiary of a compulsory license, or by the prior user.¹⁸⁷ The submission of Spain, also clarified that if the product has been placed on the market by a third party enjoying a right based on prior use, the patent rights are exhausted and the patentee would no longer be able to enforce its exclusive rights over the patented product.¹⁸⁸

3. Post-sale Modifications / Refurbishment of the Product

127. In general, the effect of the exhaustion is that the legitimate purchasers of the patented product can use or resell the product in question without permission from, or control of the patentee. The legitimate purchasers are also, in principle, allowed to repair the purchased product so that it can continue serving its initial utility. However, as discussed in the above sections, the concept of exhaustion is not generally applicable in cases of manipulation of the product in so far as such modification would be considered 'making' of a patented product.

128. Thus, while there is no doubt that the exhaustion would not shield the activity of the party engaged in constructing a new copy of the product in question, courts have heard cases where patent holders sued commercial refurbishes who make business out of restoring and selling the patented products (e.g., recycling the purchased products, like in case of recycling ink cartridges, and repairing damaged goods). Such activities may fall in between the realm of permissibility under patent exhaustion and infringement of patent rights. While the circumstances of each case are different, the general approach taken by the courts in such cases is that, while the extensive modification can amount to patent infringement, some degree of modification is permissible under the doctrine of patent exhaustion. However, the courts differ in their reasoning and factors they apply in deciding such cases and, consequently, the extent of allowable modification under their respective jurisdictions.

United States of America

129. In the United States of America, in such cases, the courts generally focus on whether the defendants' activities constituted permissible repair or impermissible reconstruction (repair-reconstruction test). The principle of the distinction between permissible and prohibited activities was explained in *Wilson v. Simpson*,¹⁸⁹ where the Court distinguished the right of a purchaser of a patented machine to replace the machine's cutting-knives when they became dull or broken, from the patentee's sole right to make or renew the entire machine. The Court observed that the knives had to be replaced every 60-90 days whereas the machines would last for several years, explaining, "what harm is done to the patentee in the use of his right of

¹⁸⁴ See, e.g., the submission of Spain to SCP/34.

¹⁸⁵ See, e.g., Nuno Pires de Carvalho, *The Trips Regime of Patent Rights*, Kluwer Law International, 2002, p.99.

¹⁸⁶ See *Pharmon BV v Hoechst AG*, 19/84, 1985, cited in p. 22 of this document.

¹⁸⁷ Section 37(2) of the Patents Act of 1983 of Malaysia (Act 291, as amended up to Act A1264).

¹⁸⁸ See submission of Spain to SCP/34.

¹⁸⁹ *Wilson v. Simpson*, 50 U.S. (9 How.) 109, 13 L.Ed. 66 (1850).

invention, when the repair and replacement of a partial injury are confined to the machine which the purchaser has bought?"¹⁹⁰

130. This principle was elaborated by the Court in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*,¹⁹¹ where the patented combination was a fabric convertible top and the associated metal support structure. The Court explained that replacement of the worn fabric top constituted permissible repair of the patented combination, and could not be controlled by the patentee. The Court explained:

The decisions of this Court require the conclusion that reconstruction of a patented entity, comprised of unpatented elements, is limited to such a true reconstruction of the entity as to "in fact make a new article,"[...], after the entity, viewed as a whole, has become spent. In order to call the monopoly, conferred by the patent grant, into play for a second time, it must, indeed, be a second creation of the patented entity [...]. Mere replacement of individual unpatented parts, one at a time, whether of the same part repeatedly or different parts successively, is no more than the lawful right of the owner to repair his property.

131. In *Jazz Photo Corp. v. U.S. International Trade Commission*,¹⁹² United States Court of Appeals for the Federal Circuit clarified the line between reconstruction and repair, holding that it was not a patent infringement for one party to restore another party's patented "one-use" camera to be used a second time. This case concerns a dispute between Fuji Photo Film Co. and a group of camera refurbishes. Fuji asserted a portfolio of design and utility patents covering its disposable cameras in the International Trade Commission (ITC) against refurbishers outside the United States. These refurbishes collected used single-use cameras, loaded them with new film, sealed the back cover with tape and repackaged the single-use cameras in a new sleeve under their own trademark.¹⁹³ Although the ITC found the process infringing, the Federal Circuit disagreed and held that this reloading operation qualified as permissible repair in principle. The Court indicated that "[w]hile ownership of a patented article does not include the right to make a substantially new article, it does include the right to preserve the useful life of the original article." Referring to common law history of repair - reconstruction law, the Court stated that "reconstruction" requires a more extensive rebuilding of the patented entity.^{194,195} The Court appears also to note that the difference between a repair and reconstruction is a difficult question to be resolved on a case-by-case basis.¹⁹⁶

¹⁹⁰ *Ibid*, at 123.

¹⁹¹ *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961).

¹⁹² 264 F.3d 1094 (Fed. Cir. 2001).

¹⁹³ *Ibid*, at 1099.

¹⁹⁴ *Ibid*, at 1104.

¹⁹⁵ The Court of Appeals ruled that this decision applied to only to those cameras which were sold initially in the United States, refurbished abroad, and imported back into the United States. With respect to cameras initially sold abroad, refurbished abroad, and imported into the United States, Fuji retained the right to prevent importation (*Jazz Photo*, 264 F. 3d, at 1105). Following the decision of the Supreme Court in *Impression Products Inc v Lexmark International Inc* (2017), it could be inferred that this part of the decision of the Courts of Appeals is overruled. See Box 4 for Supreme Court's arguments in *Impression Products Inc v Lexmark International Inc* (2017).

¹⁹⁶ The Court of Appeals stated in particular: "*It is readily apparent that there is a continuum between these concepts; precedent demonstrates that litigated cases rarely reside at the poles wherein "repair" is readily distinguished from "reconstruction."* Thus the law has developed in the body of precedent, illustrating the policy underlying the law as it has been applied in diverse factual contexts. [...] ("It is impracticable, as well as unwise, to attempt to lay down any rule on this subject, owing to the number and infinite variety of patented inventions.")", *Jazz Photo Corp. v. U.S. Int'l Trade Commission*, at 1103.

United Kingdom

132. In the United Kingdom, in the *United Wire Ltd. v. Screen Repair Services Ltd. and Others*,¹⁹⁷ the question asked by the Courts of Appeal was whether an act of “making” has taken place within the meaning of section 60(1)(a) of Patents Act 1977. This case involved the refurbishment of a patented sifting screen used in the oil industry. In particular, the patentees had two patents relating to parts of oil rigs, coming into play to clean drill bits of cuttings on retraction. The defendants sold reconditioned screens by attaching new mesh to frames recovered from the patentee’s product. The trial court treated the case as a repair of the sold screen. The Court of Appeal reversed and rejected an analysis based on the “repair” argument:

“It follows that acts as prohibited by section 60 are infringing acts whether or not they can be categorised as repairs. It is therefore better to consider whether the acts of a defendant amount to manufacture of the product rather than whether they can be called repair, particularly as what could be said to be repair can depend upon the perception of the person answering the question. Even so, when deciding whether there has been manufacture of the product of the invention, it will be necessary to take into account the nature of the invention as claimed and what was done by the defendant.”¹⁹⁸

133. The Court of Appeal concluded on the facts that the defendants had made the screen assembly that was the subject of the first claim in each of the patents.

134. Supporting the judgement of the Court of Appeal, Lord Hoffman explained: “[r]epair is one of the concepts (like modifying or adapting) which shares a boundary with “making” but does not trespass upon its territory. I therefore agree with the Court of Appeal that in an action for infringement by making, the notion of an implied licence to repair is superfluous and possibly even confusing. It distracts attention from the question raised by section 60(1)(a), which is whether the defendant has made the patented product. As a matter of ordinary language, the notions of making and repair may well overlap. But for the purposes of the statute, they are mutually exclusive.” Lord Hoffman further stated that: “[t]he owner’s right to repair is not an independent right conferred upon him by licence, express or implied. It is a residual right, forming part of the right to do whatever does not amount to making the product.”¹⁹⁹ The correct test is: “whether, having regard to the nature of the patented article, the defendant could be said to have made it”.^{200,201}

Japan

135. The decision by the Supreme Court of Japan of November 8, 2007,²⁰² concerns the application of the exhaustion to the “re-used” patented article. Specifically, in this case, the plaintiff had a Japanese patent covering ink cartridge, and the defendant was a company that collected used ink cartridges, had them cleaned and refilled with new ink outside Japan, and sold the refilled cartridges in Japan. The Supreme Court stated that exhaustion restricts the

¹⁹⁷ *United Wire Limited v. Screen Repair Services (Scotland) Limited and Others*, July 20, 2000.

¹⁹⁸ *United Wire Ltd. v. Screen Repair Services Ltd. and Others*, on July 20, 2000, p. 14 of the transcript of the Court of Appeal judgment.

¹⁹⁹ Opinions of the Lords of Appeal for Judgment in the cause *United Wire Ltd. v. Screen Repair Services Ltd. and Others*, on July 20, 2000, accessed at: <https://publications.parliament.uk/pa/ld199900/ldjudgmt/jd000720/wire.htm>.

²⁰⁰ *Ibid.*

²⁰¹ Furthermore, Lord Bingham also explained the ambiguity of repair test: “I do not think that in a case such as the present this question is best approached by considering whether the defendant has “repaired” the patented product. For repair may involve no more than remedial action to make good the effects of wear and tear, involving perhaps no replacement of parts; or it may involve substantial reconstruction of the patented product, with extensive replacement of parts. Both activities might, without abuse of language, be described as repair, but the latter might infringe the patentee’s rights when the former did not. *Ibid.*”

²⁰² Case No. 2006 (ju) 826 of November 8, 2007.

enforcement of a patent only for a specific article itself sold by the patentee in Japan. Further, the Supreme Court recognized infringement when “*an article sold in Japan by the patentee is modified or its parts are replaced, and thus a patented article having an identity that is different from that of the patented article is considered to have been created, the patentee should be permitted to enforce the patent with respect to the new article.*”

136. The Supreme Court further stated that, in order to determine whether a patented article is newly constructed:

“it is appropriate to consider the totality of the circumstances including the attributes of the patented article, the details of the patented invention, the manner in which the article has been modified or its parts replaced, as well as the actual manner of the transaction, etc. The attributes of the patented article should include the article’s functions, structure and materials, intended uses, lifespan, and the manner in which it is used. The manner in which the article has been modified or its parts have been replaced should include the state of the patented article when it is modified, the nature and degree of the modification, etc., the lifespan of the replaced parts, and the technical function and economic value of those parts within the article.”²⁰³

137. Based on the fact of the case, the Supreme Court concluded that the defendant’s acts amounted to creation of a new patented article infringing the rights of the patentee.

Australia

138. In Australia, in *Calidad Pty Ltd v Seiko Epson Corporation* case (discussed in Box 5, above) which also concerns the “repurposed” printer cartridges imported into Australia, the judges found that modifications will amount to making a new product, which is an infringement of patent rights, where the modifications are of claimed features. However, no such modifications have been found to be made to by the defendant in this case. Specifically, the Court stated:

“When all of Ninestar’s modifications to each of the categories of cartridges were completed what remained were the original Epson cartridges with some modifications which enabled their re-use. The modifications did not involve the replication of parts and features of the invention claimed. There was no true manufacture or construction of a cartridge which embodied the features of the patent claim.

The modifications to the original Epson cartridges were consistent with the exercise of the rights of an owner to alter an article to improve its usefulness and enable its re-use [...] Regardless of whether it is said to be something done which is closer to “repair” than “making”, it clearly does not involve a manufacture or making.”

Germany

139. In Germany, the lawful acquirers are entitled to use purchased goods for their intended purpose²⁰⁴ which includes maintenance and restoration of usability when the functionality or performance of the concrete item is partially or wholly compromised or lost due to wear, damage or for other reasons. However, intended use does not include measures resulting in the new

²⁰³ *Ibid.*

²⁰⁴ BGH, judgement of 24 October 2017, ref: X ZR 57/16, BGHZ 2016, 300 –Trommeleinheit. See submission of Germany to SCP/34.

manufacture of a product as described by the patent.²⁰⁵ Two recent court cases in Germany clarify the delineation between intended use and new manufacture.

140. In case “Palettenbehälter II”²⁰⁶ the BGH decided on the question whether the intended use of a patented product put on the market by the patent holder or with his consent includes the replacement of parts of the product. Specifically, the BGH held that the replacement is considered as intended use if the identity of the product as manufactured is preserved. Whether this is the case or whether the measures taken do amount to remanufacturing the patented product depends, *inter alia*, on consumers’ expectation of the relevant parts to be replaced during the lifetime of the product, and the extent to which the replaced parts especially reflect the technical result of the invention. Whether the replaced parts specifically reflect the technical result of the invention is, as a rule, only decisive where consumers expect such parts to be replaced during the lifetime of the patented product. The decisive factor for this is whether there is a public perception that replacement is a normal maintenance measure that does not cast doubt on the identity of the overall product as a marketable asset.

141. In the judgement “Trommeleinheit”²⁰⁷, the BGH further specified the parameters for assessing the question of whether the replacement of parts of a product put into circulation with the permission of the patent holder falls under intended use or constitutes a new manufacture. The BGH clarified that the decisive point of reference is always the protected product. This also applies when the patent holder has put the protected product into circulation only as a component of an object comprising more components. The courts stated that the delineation between intended use and new manufacture in this case must be based solely upon whether the technical results of the invention are reflected precisely in the replaced parts.²⁰⁸

6. Challenges Faced by the Member States in Implementing the Exception Regarding the Exhaustion of Patent Rights

142. While no specific challenges have been reported by the Member States in relation to the implementation of this exception at the national level, the following paragraphs indicate general and specific issues relating to the national implementation of the exhaustion of patent rights. In addition, a reference is made to document SCP/26/5, which discusses constraints in making use of patent flexibilities in the context of public health, which may also be relevant to the exception on exhaustion of patent rights.

Ambiguity and uncertainty of national law

143. As indicated in Section 5.A.5 of this document, one of the challenges specifically relevant to the exception in question is the ambiguity and uncertain scope of the relevant provisions in the laws of some countries. Specifically, while exhaustion is a recognized concept in all the

²⁰⁵ The exclusive manufacturing right of the patent holder is not exhausted when the product is put on the market by the patentee or with his consent. See submission of Germany to SCP/34.

²⁰⁶ BGH, judgement of 17 July 2012, ref: X ZR 97/11, GRUR 2012, 1118 – Palettenbehälter II.

²⁰⁷ BGH, judgement of 24 October 2017, ref: X ZR 57/16, BGHZ 2016, 300 – Trommeleinheit.

²⁰⁸ With respect to exhaustion of, *inter alia*, patent rights in cases of recycling or repair of goods, the International Association for the Protection of Intellectual Property (AIPPI) has issued the resolution Q205: (i) Repair of a patented product, including maintenance work and minor interventions, should not constitute infringement. If patent rights in such product are exhausted before repair they are exhausted after repair; (ii) Reconstruction of a patented product, which involves changing or reproducing an essential component of such product should constitute infringement. The principle of exhaustion does not apply to such reconstructed product; (iii) Recycling of a patented product (where this involves acts whereby products that have served the use for which they were conceived are reused without being reduced to their constituent ingredients) should be addressed within the context of whether such recycling constitutes repair or reconstruction of such product. Resolution Q205, September 10, 2008.

countries reviewed in this document, a question remains with respect to its geographical application and its scope in some of those countries.²⁰⁹ To ensure effective operation of law and avoid legal uncertainty, the constitutive legal elements of the exception should be formulated in a clear manner without casting doubts on the scope of the exception. In general, once legal principles and underlining justifications are made clear, a sound interpretation by courts can be made on a case-by-case basis.

Various categories of IP rights on a product

144. It is often the case that a product put on the market is protected by different IP rights, such as patents, trademarks, copyright or industrial designs. For example, in the case of a pharmaceutical product, its chemical formula can be protected by patents, its brand name can be protected under trademarks, and the product instructions – under copyright law. In other cases, in some countries, computer programs can be protected by patents and copyright, or plant material can be protected by patents and plant variety protection systems.²¹⁰ While these different categories of IP relate to different features of the product and have different scope and duration of protection, during the period of time when all these IP rights on the same product are effective, the application of different exhaustion policies on different categories of IP and their enforcement can have an impact on the legality of parallel importation of the product. For example, this may occur if a country applies a national exhaustion regime for trademarks and an international exhaustion regime for patents or copyright (or *vice versa*).²¹¹ In such a case, IP owners may use their rights, invoking the national trademark exhaustion, to block parallel importation of patented goods to that country. While the differences in exhaustion policies for different IP categories may closely relate to the distinct policy justifications and rationales of each category of IP,²¹² policy makers may need to analyze the IP exhaustion in its totality in order to avoid any unintended consequences.²¹³

145. Although it does not specifically focus on the issue of the different categories of IP rights on a product, in the recent case in the United States of America, the Supreme Court explained the rationale for the application of the international exhaustion in the area of copyright and noted

²⁰⁹ In this respect, the UNCTAD Secretariat reported that with regard to patent exhaustion, “there appears to be a great degree of unawareness of the issue in many developing countries. Some countries’ laws include an express exception of the rights conferred under a patent, where the patented article has been commercialized in any country of the world with the consent of the patent holder. At the same time, these laws expressly include the right to prevent the importation of the patented good among the rights conferred by a patent.” See submission of UNCTAD in document SCP/25/3.

²¹⁰ To date, most of the judicial decisions concerning this issue of various categories of IP rights covering a product appear to relate to “overlap of rights” between copyright and trademarks. For discussion of such cases see Shubha Ghosh, Irene Calboli, “Overlapping Intellectual Property Protection and the Exhaustion Doctrine” in *Exhausting Intellectual Property Rights : A Comparative Law and Policy Analysis*, Cambridge University Press, 2018. Authors concluded that, to a large extent, the exercise of such overlapping intellectual property protection can constitute a misuse of intellectual property, be it copyright or trade-mark misuse. However, they note that courts have been generally reluctant to declare these practices as misuses.

²¹¹ At least in two countries which apply international exhaustion with respect to patents, the regime applied for trademarks appears to be a national exhaustion (see Art.6(3) of the Trademarks Act 2003 of Antigua and Barbuda and Art. 11 of Cambodia Law Concerning Marks, Trade Names and Acts of Unfair Competition of 2002. In addition, in the Andean Community, in contrast to the admission of parallel imports for patents, regimes for copyright and plant varieties allow the right holders to prevent imports of protected subject matter. See C.M. Correa and J.I. Correa, *Parallel Imports and Principle of Exhaustion of Rights in Latin America*, in *Research Handbook on Intellectual Property Exhaustion and Parallel Imports*, Parts 3(11), edited by Irene Calboli, 2016.

²¹² The policy reasons for such different rules on different IP are not the focus of this paper. For such discussions, see Viva R. Moffat, *Mutant Copyright and Backdoor Patents: The Problem of Overlapping Intellectual Property Protection*, *Berkeley Technology Law Journal*, Vol.19:1473, 2004. See also Shubha Ghosh, Irene Calboli, 2018, *supra* note 210.

²¹³ Shubha Ghosh and Irene Calboli suggest that a comprehensive solution in this respect would need to combine consistent positions on domestic policies for exhaustion with the adoption of the principle of mutual recognition of product quality and standards. See Shubha Ghosh, Irene Calboli, 2018, *supra* note 210.

why international exhaustion should also be applied in case of patents. The Court stated that “[d]ifferentiating between the patent exhaustion and copyright first sale doctrines would also make little theoretical or practical sense: The two share a “strong similarity . . . and identity of purpose,” [...] and many everyday products are subject to both patent and copyright protections”.²¹⁴

Other importation restrictions

146. Another issue has been specifically reported with respect to the exhaustion of patent rights in the area of pharmaceuticals. Although this issue does not seem to relate to the patent system as such, it can nevertheless affect the parallel importation of patented medicines. In particular, the submission of UNCTAD reported that some countries that allow for parallel importation of patented medicine lack guidelines for their regulatory agencies on how to authorize parallel imported pharmaceutical products, and that there was a need for coherence between the areas of patent law and drug regulatory law in this respect.²¹⁵ As discussed elsewhere, in some cases, the implemented policy options do not lead to the intended outcome²¹⁶ and the enactment of the policy allowing parallel importation may not necessarily result in the availability of parallel imported goods in the country concerned. Specifically, in the area of medical and agrochemical products, the regulatory approval regimes and product quality and safety regulations may affect the availability of such goods in the country.

7. Results of Implementation of the Exception Regarding the Exhaustion of Patent Rights

147. As reported in this draft reference document, there is a wide disparity in policies and attitudes towards parallel trade across the world suggesting that the interests and needs of countries on this topic are different and each country’s choice over a specific policy reflects its particular circumstances. However, none of the submissions by the Member States reported on the economic and social effects of the implementation of a specific policy on exhaustion in their respective countries.

148. In general, economists agree that the exhaustion doctrine has complex economic implications and it may be construed simply as a regulatory decision regarding whether to keep a market open or closed to parallel imports. While some countries tend to see national exhaustion as an important component of an IP owner’s right to control distribution across borders for the duration of its protection, other countries view openness to parallel imports as an important means of sustaining competition and of ensuring access to goods at a cheaper price.²¹⁷ However, researchers note that parallel trade is a fundamentally difficult area to quantify as there is a scarcity of data to back up either side’s argument. The only exception is in the pharmaceutical sector, where health authorities may keep track of the sources of traded medicines.

149. Given the data scarcity in this area, only a limited number of quantitative studies on the extent and effects of parallel imports across industries have been produced. Nevertheless, several economic studies on the subject, though not specifically limited to patents, provide useful insights. Commissioned by the UKIPO, an extensive review of such economic data and

²¹⁴ *Impression Products Inc. v Lexmark International Inc.* 137 S.Ct. 1523 (2017).

²¹⁵ See submission of UNCTAD in document SCP/25/3.

²¹⁶ See paragraphs 45 to 47 of document SCP/26/5.

²¹⁷ See, e.g., Maskus K. E. (2016), *Economic Perspectives on Exhaustion and Parallel Imports*. In: Calboli I, Lee E (eds.), *Research Handbook on Intellectual Property Exhaustion and Parallel Imports*, Edward Elgar, pp. 106 - 124.

literature on parallel trade has been conducted by Ernst & Young LLP in 2019.²¹⁸ The report reviewed over 30 economic studies by the prominent researchers in the field and based on such a review concluded the following: (i) Several factors may motivate parallel trade in a particular sector or region. Among those factors, one of the key drivers of parallel trade are price differentials between different markets which give rise to the potential to profit from redistributing goods between different markets (i.e. arbitrage);²¹⁹ (ii) In markets such as pharmaceuticals, where prices are controlled by governments, parallel trade will be persistent due to the inability of market forces to equilibrate prices in response to arbitrage opportunities.²²⁰ (iii) Another indirect driver of parallel trade is an exchange rate variation which can contribute to the price differentials and thus facilitate parallel trade.²²¹

150. Further, based on the literature review, the report concludes that the national exhaustion regimes are beneficial to IP right holders as they provide the incentive to innovate, whilst also removing the ability of parallel traders to easily benefit from investment by producers and authorized distributors. For example, supporting this argument:

- Bonadio (2011) finds that the national exhaustion regimes help preclude parallel imports which increases the degree of price discrimination and provides IP right holders with incentives to supply products at a lower cost in low-income countries, as they can be assured that these low price items will not go back onto the domestic market.²²²
- Fink and Maskus (2005) find that the national exhaustion regimes extend IPR holders' control over the international distribution of their products which helps to protect investments in marketing as well as after-sales services.²²³ Also, Palangkaraya and Yong (2006) found through use of a theoretical economic model, that both parallel imports, and the threat of such imports, reduced the domestic distributor's incentive to invest in market development.²²⁴

151. Also, some studies argue that the overall welfare under the national exhaustion regime is larger compared to international exhaustion systems. Thus, among the arguments made in favor of controlling parallel imports is that the price discrimination need not be harmful and under certain circumstances, it can raise economic well-being.²²⁵ Banning parallel trade results in international price discrimination, or one price set per market. By contrast, full parallel trade forces uniform pricing by the IP holder. Economies with inelastic demand would face higher prices under price discrimination than under uniform pricing. Countries with elastic demand,

²¹⁸ Ernst & Young LLP (2019), *Exhaustion of Intellectual Property Rights*. The objective of the study was to determine whether it would be possible to estimate the scale of parallel trade across the economy, and to suggest potential research methodologies for the future. This was commissioned to inform the Government's assessment and analysis of the options for the Intellectual Property Rights (IPR) exhaustion regime when the UK leaves the EU. For a literature review, see Section 3 of the report and Appendix A.

²¹⁹ E.g., NERA (1999), *The Economic Consequence of The Choice of A Regime Of Exhaustion In The Area Of Trademarks*; Ganslandt, Mattias and Maskus, Keith E. (2007), *Intellectual Property Rights, Parallel Imports and Strategic Behavior*; Bonadio, E. (2011), *Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?*. *European Intellectual Property Review*, 33(3), pp. 153-161.

²²⁰ *Ibid*, Ganslandt and Maskus (2007).

²²¹ Fink (2005), *Entering the Jungle of Intellectual Property Rights Exhaustion and Parallel Importation*, Washington, DC : World Bank, ISBN 0-8213-5772-7., p. 171-187.

²²² Bonadio, E. (2011), *Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?*. *European Intellectual Property Review*, 33(3), pp. 153-161.

²²³ Carsten Fink and Keith E. Maskus (2005), *Why We Study Intellectual Property Rights and What We Have Learned*.

²²⁴ Alfons Palangkaraya and Jongsay Yong (2006), *Parallel Imports, Market Size and Investment Incentive*, Melbourne Institute Working Paper Series, Melbourne Institute of Applied Economic and Social Research, The University of Melbourne.

²²⁵ Varian 1985, cited in a handbook "Development, Trade, and the WTO" by Bernard Hoekman et al., IBRD and the World Bank, 2002.

typically developing countries, would enjoy lower prices under price discrimination.²²⁶ In addition, a recent study by Bond Eric and Kamal Saggi (2020) reports that the national exhaustion leads to lower prices in the South, higher prices in the North, and larger incentives for investment in R&D.²²⁷

152. In contrast to the above literature, some researchers find that the international exhaustion regime facilitates competition and provides consumers with increased choice and potential benefits in the form of more competitive pricing. For example:

- Muller-Langer (2008) notes a study by Ganslandt and Maskus (2004) that found that between 1994 and 1999 parallel trade helped to reduce the prices of pharmaceutical products in Sweden by 12-19%. They attributed this to parallel trade as Sweden provided a natural experiment due to its switch from a national to regional regime after it joined the EU in 1995.²²⁸
- Dobrin and Chochia (2016) argues that parallel importers are able to secure lower prices for goods;²²⁹ while Fink and Maskus (2005) notes that the differences in the quality of parallel imports would also increase choice for consumers.²³⁰
- Bonadio (2011) notes that parallel trade can encourage IP right holders to reduce prices due to competition by parallel traders, which can act as a solution to potential anti-competitive behaviors by IPR holders.²³¹
- Three economic studies commissioned by the Ministry of Economic Development of New Zealand also confirmed that permitting the parallel importing has a net beneficial impact on New Zealand's economy by increasing the variety of consumer goods available and lowering of their retail prices.²³²

153. However, there is an argument that international exhaustion may cause consumer harm due to the potential to reduce the quality of products or cause consumer confusion:

- For example, Bonadio (2011) argues that parallel importers do not consider target market quality, and sell low quality products in countries with higher quality standards, which could harm consumers.²³³ In contrast, Sauer (2008) concluded there was insufficient support for the claim that parallel imports reduces the quality of products.^{234,235}

²²⁶ Bernand Hoekman et al., *ibid.*

²²⁷ Bond Eric and Kamal Saggi (2020), Patent protection in developing countries and global welfare: WTO obligations versus flexibilities, *Journal of International Economics*, Vol. 122.

²²⁸ Frank Mueller-Langer (2008), Does Parallel Trade Freedom Harm Consumers in Small Markets? *Croatian Economic Survey*, No. 11, pp. 11-41.

²²⁹ Dobrin, Samuel and Chochia, Archil (2016), The Concepts of Trademark Exhaustion and Parallel Imports: A Comparative Analysis between the EU and the USA, *TalTech Journal of European Studies*, vol.6, no.2, 2016, pp.28-57.

²³⁰ Carsten Fink and Keith E. Maskus (2005), *supra* note 223.

²³¹ Bonadio, E. (2011), *supra* note 222.

²³² See: <https://www.mbie.govt.nz/dmsdocument/12163-intellectual-property-laws-amendment-bill-policy-decisions-proactiverelase-pdf>.

²³³ Bonadio, E. (2011), *supra* note 222.

²³⁴ Katherine M. Sauer (2008), The quality of parallel imports, *Economics Bulletin*, *Economics Bulletin*, *AccessEcon*, vol. 6(44), pp.1-10.

²³⁵ In this regard, the submission of the Czech Republic to SCP/34 also notes that, in addition to the loss of profit of the patent owner, parallel imports can cause damage to the reputation of the manufacturer (patent owner), e.g., due to lack of control over the quality of sales and related services, or due to imminent infringements if, for example, products marketed in one market do not meet regulatory requirements in the second market.

154. With respect to a literature which argues that an international exhaustion regime would stifle innovation, the report by Ernst & Young LLP states that this argument is contested, and that absent empirical work, it is not possible to draw any firm conclusion in that respect.²³⁶

155. Given ambiguous economic results, it is difficult to prescribe a specific regime for a specific country or in a global context. Ultimately, the question as to whether the parallel imports are beneficial or harmful is an empirical question that depends on the circumstances. Each country is different and therefore should tailor its policy on exhaustion to its own needs. This needs to take into account a boarder national policy designed to maximize domestic innovation and development while taking into account welfare costs. The choice of exhaustion regime may have implications for international trade, for second hand markets, for consumer rights, and for distribution channels. Thus, one of the prominent scholars on the subject note that in deciding the policy which best promotes their national interests, consideration of the following factors must be included: the interests of IP owners, national and foreign, who desire control of the cross-border trade of their products, and the ability to set prices and exercise price discrimination in different jurisdictions; the interests of third party importers to sell and distribute goods lawfully purchased abroad; the interests of intermediaries, retailers, and other distributors to distribute goods lawfully acquired from parallel importers; the interests of consumers to access a higher number of goods, likely at lower prices, in national markets thanks to parallel imports; the interests of national governments in promoting local IP-intensive industries by protecting these industries from the additional competition of parallel imports; and the interests of national governments in increasing competition in the national market by opening it up to parallel imports.²³⁷

156. In conclusion, while there is no one-size-fits-all approach on the issue of exhaustion, availability of empirical evidence would help policy makers to take informed policy decisions. In this respect, noting the scarcity of data, appeal to authorities and international organizations has been made to devote more effort in gathering such data and making it available for research at least in sectors of considerable importance for public policy.²³⁸

[Appendix follows]

²³⁶ For ex., Maskus agrees that there is no econometric study available that considers the potential effects of parallel imports on decisions of firms owning IP rights to invest in R&D Maskus K. E. (2016), Economic Perspectives on Exhaustion and Parallel Imports. In: Calboli I, Lee E (eds.) Research Handbook on Intellectual Property Exhaustion and Parallel Imports. *Edward Elgar*, pp. 106 - 124.

²³⁷ Irene Calboli (2019), *supra* note 28, p.24.

²³⁸ See, e.g. Maskus K. E. (2016), *supra* note 217.