Intellectual Property Exhaustion and Parallel Imports of Pharmaceuticals: A Comparative and Critical Review

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Abstract This Chapter addresses the topic of intellectual property (IP) exhaustion in the context of the parallel trade of pharmaceuticals. These imports, which are controversial in general, are more complex with respect to pharmaceuticals, which require additional marketing and import authorizations. Nevertheless, individual countries remain free to accept these imports under the flexibility of Article 6 of the Agreement on Trade Related Aspects to Intellectual Property Rights (TRIPS Agreement). This Chapter reviews several national approaches—in developed, developing, and least developed countries (LDCs)—from the perspective of the exhaustion of patent rights as well as other IP rights. Through this review, it highlights that several countries today accept parallel trade. A large number of these countries are, however, developed countries, whereas several developing countries and LDCs instead prohibit parallel imports. This finding is perplexing, and the reasons for this restrictive approach are unclear as developing countries and LDCs need flexible policies and can largely benefit from parallel trade. In addition, despite the claim by the pharmaceutical industry that parallel trade would increase the price of medicines in these countries—as originator would increase prices due to the fear of parallel imports—medicines are sold at lower prices mostly because of governments' pricing or after the expiration of patent protection. Based on this review, this Chapter concludes that national legislations, which are not taking advantage of the flexibility in Article 6 of the TRIPS Agreement, may consider reviewing their policies and allow parallel imports.

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1 Introduction: The Relevance (and Resilience) of the Principle of Intellectual Property Exhaustion and Its Application to Pharmaceuticals

In this chapter, I explore the application of the principle of intellectual property (IP) exhaustion to the parallel imports of pharmaceuticals and the impact that different policies on exhaustion can have on these imports across selected jurisdictions. The legal treatment of IP exhaustion continues to represent one of the most debated and unresolved issues in international trade.[1] In addition, the debate regarding IP exhaustion and pharmaceuticals reflects the more complex debate on access to medicines and public health, and how domestic policies on IP exhaustion can be used to implement the existing IP-related flexibilities provided in the international system.[2] Several commentators have addressed this debate before, yet disagreements and uncertainty continue to characterize this important area of IP and international trade.

Moreover, domestic policies on IP exhaustion are not the only barrier to parallel imports of pharmaceuticals, as these imports are also subjected to national marketing approvals, import authorizations, and other formalities. In addition, in many instances, national governments exert price control on the sale of pharmaceuticals, in particular prescription medications. In other words, as commentators have noted, pharmaceuticals are traded, and parallel traded, in "distorted" markets due to the additional regulatory schemes and price control policies that apply to these products. National competition laws are also important in the context of parallel imports of pharmaceuticals, for example regarding excessive pricing or the validity of contractual clauses to block the products' redistribution after they have first been put into the market by the IP holders. Because of its limited scope, this Chapter only mentions and does not analyzes in detail this complex ecosystem of parallel trade in pharmaceuticals.[3] In practice, however, these factors remain very relevant, perhaps even more relevant than domestic policies on IP exhaustion in certain instances. In particular, in some countries, the actual impact of IP exhaustion on the admissibility of parallel imports of pharmaceuticals is certainly minimal, if not irrelevant due to the additional regulatory requirements and possible contractual limitations against these imports.

[1] For a detailed analysis and summary of the relevant debates, see the contributions in Calboli and Lee (2016). *See also* Ghosh and Calboli (2018); Fink 2004, p. 174); Maskus (2000), p. 1269; Abbott (1998), pp. 607–636; Abbott 2000) http://ssrn.com/abstract=1921856; Heath (1997), p. 623; Jehoram (1996), p. 280; Hilke (1988), p. 75.

[2] For a discussion of the flexibilities and applications to pharmaceuticals and health care, *see* El-Said (2010).

[3] For a comprehensive review of all these aspects, *see* Abbott (2016), p. 145 [hereinafter Abbott, *Parallel Trade in Pharmaceuticals*]. *See also* Kyle (2007), p. 88 and Maskus (2001).

In light of this, why then writing a chapter on this topic, if IP exhaustion may not matter, or matter considerably less than originally thought, for the admissibility of parallel imports of pharmaceuticals into national markets?

As I mentioned, the debate in this area remains complex and, even though domestic policies on IP exhaustion are not the only aspect to consider, these policies are still relevant, in particular when national governments are in favor of parallel imports and grant the pharmaceuticals the necessary marketing approvals and import authorizations. It is difficult to predict how often, in practice, national governments would approve these imports, but certainly in these instances domestic policies on exhaustion would make the difference in the legal treatment of the imports. Would these be treated as legitimate imports or IP infringements? Moreover, domestic policies on exhaustion not only can affect the imports of patented pharmaceuticals, but also generics. In particular, national rules on trademark exhaustion can be used to block parallel imports including of generics. While this may not affect countries with the ability to produce generics domestically, it could affect countries without manufacturing capacity. Instead, domestic policies favoring parallel imports could facilitate the supply of medicines at lower prices than branded versions, or even the supply of certain medicines altogether as originator companies often not directly distribute certain medicines in some countries.

The chapter proceeds as follows. Section 2 presents an overview of the principle of exhaustion in the context of international trade. This background leads to the discussion on the legal treatment of parallel imports of pharmaceuticals. Section 3 explores the domestic policies on patent exhaustion in selected developed and developing countries and elaborates on how different solutions—national, international, or regional exhaustion—impact the parallel trade of pharmaceuticals in these countries. Section 4 focuses on the impact of overlapping IP rights—notably trademarks and copyrights in addition to patents—to the parallel trade of pharmaceuticals. This Section highlights how parallel imports can be affected by these overlaps, in particular when a country adopts international patent exhaustion, but practices national exhaustion for copyrights or trademarks. It also highlights that overlapping rights can block parallel imports when the imported products, albeit genuine, carry small quality differences from the products distributed into the importing countries by IP holders.[4] Section 5 concludes and highlights that several developed countries adopt today more liberal policies on IP exhaustion, notably international exhaustion, than several developing and least developed countries (LDCs), which follow instead national exhaustion. This is certainly problematic for the latter countries and their access to pharmaceuticals.

[4] *See, e.g.* Calboli (2014a), p. 151 [hereinafter Calboli, *Avoidable Effects*]; Calboli (2011), p. 1241 [hereinafter Calboli, *Market Integration*] (addressing in details the legal treatment of quality differences in the context of trademark exhaustion).

2 Intellectual Property Exhaustion and Paralle Trade: General Considerations and Application to Pharmaceuticals

The doctrine of IP exhaustion is crucial in IP theory, as it limits the rights of IP holders to control the distribution of the products they have put in the market after their first lawful release.[5] This doctrine was developed in the nineteenth century to balance the rights of IP holders and to prevent the use of their IP rights against the lawful rights of retailers, second-hand dealers, and consumers to freely display, advertise, and resell the products they lawfully purchased in the market, even if those actions directly compete with the IP holders' business activities in the same market.[6] Generally, there are not major controversies regarding the application of this doctrine within national markets, at least regarding products whose quality has not been changed and are resold nationally.[7] In contrast, controversy has traditionally characterized the debate over the application of the doctrine of exhaustion in the context of international trade. In particular, the legal treatment of the phenomenon of parallel imports—the imports of genuine products, imported into a country from unauthorized third party importers after their first authorized sale by the IP holders abroad[8]—is one of the few aspect of IP that has never been internationally harmonized and discussion over the admissibility into national markets of these products continue to date. The tension between the application of the principle IP exhaustion and the movement of products across national border, in general and in the context of pharmaceuticals, is addressed in this Section.

2.1 The Principle of Intellectual Property Exhaustion in International Trade: An Overview

Professor Ghosh and I have extensively addressed the debates over the exhaustion doctrine and cross-border trade in our recent book, *Exhausting Intellectual Property Rights: A Comparative Law and Policy Analysis*.[9] The surge in global trade over the past century has heightened these debates, driven primarily by the concerns

[5] *See, e.g.*, Ghosh and Calboli (2018), pp. 22–40.

[6] *See* Kohler (1900), p. 452. An English translation of Josef Kohler's passages on exhaustion can be found in Heath (2014a), p. 419, 424.

[7] With the exception of the transfer of digital goods and self-replicating technologies—two recent phenomena that have been addressed by courts in several jurisdictions. *See, e.g.*, *Capitol Records, LLC v. ReDigi Inc.*, 934 F. Supp. 2d 640 (S.D.N.Y 2013); Case C-128/11, UsedSoft GmbH v. Oracle Int'l Corp., 2012 E.C.R. I-00000; *Bowman v. Monsanto Co.*, 133 S.Ct. 1761 (2013); Case No. C-428/09, Monsanto v. Cefetra, 2010 E.C.R. I-09961.

[8] Ghosh and Calboli (2018), pp. 41–64.

[9] *Id.*

expressed against and in favor of the arbitrage of consumer goods from low-cost to high-cost jurisdictions.[10] Although IP holders are interested in the benefits of free trade in reducing manufacturing costs and decreasing tariffs, quotas, and other trade restrictions, they generally oppose parallel imports because of the competition the imports create in the high cost domestic markets and the resulting loss of profits in those markets.[11] On the other side, supporters of parallel imports, including this author, point specifically to the inconsistency of the international IP system, which seeks harmonizing the IP system to eliminate barriers to trade and facilitate the registration and enforcement of IP rights worldwide, yet does not equally harmonize the free movement of products across jurisdictions to the same—in essence allowing IP rights to possibly operate as an invisible barrier to otherwise legitimate trade.[12]

The issue of IP exhaustion is not addressed in any of the agreements administered by the World Intellectual Property Organization (WIPO). Exhaustion, or lack of agreement thereof, is mentioned explicitly only in Article 6 of the Agreement on Trade Related Aspects to Intellectual Property Right (TRIPS Agreement), adopted under the auspices of the Word Trade Organization (WTO). The provision famously states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[13] Accordingly, the choice of exhaustion regimes depends on national decisions about desirable economic outcomes based on specific economic and trade-related factors, the size of national markets, the level of development, and possibly the pressure exerted foreign governments. Essentially, cross-border trade remains a form of national strategy, which may or may not include economic integration, and in which nation states maintain their political independence, while economic agents are permitted to engage in trade crossing their respective countries.[14]

[10] Parallel imports can be divided into two specified categories: passive and active parallel imports. *See* Fink (2004), pp. 171–188. The first category relates to the situation in which third party importers purchase products in one country and sell them in another. The second identifies the case of a foreign licensee, or authorized distributor abroad, who sell into the national market of the IP holders without her consent. The latter case is less frequent and is often prohibited through specific clauses in licensing agreements.

[11] For an excellent review of the economic studies on parallel imports, *see* Maskus (2016), p. 106 [hereinafter Maskus, *Economic Perspective*]. *See also* Saggi (2013), p. 131; Valletti and Szymanski (2006), p. 499; Valletti (2006), p. 314; Chen and Maskus (2005), p. 1; Malueg and Schwartz (1994), p. 187.

[12] *See* Ghosh and Calboli (2018), pp. 41–64. *See also* Calboli (2002), p. 47 (advocating for a change to international exhaustion in the EU).

[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instrument—Result of the Uruguay Rounds Vol. 31, 33 I.L.M. 83, 1869 U.N.T.S. 299 (1994), art. 6 [hereinafter TRIPS]. On the drafting of Article 6 of TRIPS, *see* Jehoram (1999), pp. 495, 508 (noting that this provision represents a compromise between two opposite approaches: "[t]he US Proposal [to introduce its own national system,] national exhaustion[,] and the [pleas of] developing countries . . . for the opposite," international exhaustion). S*ee also* Yusuf (2016) p. 23, 26; Taubman et al. (2012), pp. 18–20*;* Verma (1998), pp. 534, 539.

[14] Ghosh and Calboli (2018), pp. 44–48.

As it is generally known, countries follow one of three systems: national, regional, or international exhaustion.[15] Under the principle of *national* exhaustion, IP holders' rights are exhausted after the first sale of a good or batch of goods, but only if this first sale has occurred in the national territory.[16] This regime is the least friendly for international trade and permits IP holders to stop parallel imports at the border or legitimately seize products after importation as IP infringements, even though these are genuine goods.[17] Instead, under the principle of *regional* exhaustion, a compromising solution between the international and regional exhaustion, the rights of IP holders are exhausted after the first sale of a good or batch of goods, but only if the sale has occurred in one of the member countries of a regional organization following this principle as a common rule for all members.[18] Under this system, the import of products originating from third countries from outside the region remains unlawful and can be stopped as infringement.[19] Finally, under the principle of *international* exhaustion, IP holders' rights to control the further distribution of a good or batch of goods exhaust after the first sale of the goods regardless of the country where this first sale has occurred.[20] Undoubtedly the friendliest approach for international trade, under this system parallel imports are considered lawful in the country of importation, even though the country from which the goods are imported may well apply a different system, i.e. national or regional exhaustion.[21]

National exhaustion should be contrasted with regional exhaustion, the rule that is currently established in the European Union (EU as extended to the European Economic Area, EEA)[22] and the *Organization Africaine pour la Propriete Intellectuelle* (OAPI).[23] What contrasts regional from national exhaustion is that regional exhaustion stems from the economic union of regions, but not necessarily the political union. Still, the principle is often the product of courts, treaties, or legislation.[24] In the EU, for example, much of the credit for the system's development is due to the EU Commission and the Court of Justice of the EU (CJEU).[25]

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[15] *Id.* at 10–11.

[16] *See* Rothchild (2016), p. 226. *See also* Ghosh and Calboli (2018), pp. 10–11.

[17] Ghosh and Calboli (2018), pp. 10–11.

[18] On the development of this principle in the EU, *see* Beier (1990), p. 131; Jehoram (1992), p. 622.

[19] *See, e.g.*, Calboli (2002), p. 47 [hereinafter Calboli, *Trademark Exhaustion in the EU*] (discussing the debate on the geographical extent of trademark exhaustion in the EU); Shea (1995), p. 463.

[20] Ghosh and Calboli (2018), pp. 10–11.

[21] *Id.*

[22] For a review, *see* Calboli (2019a), p. 22 [hereinafter Calboli, *Comparing IP Exhaustion*].

[23] *See Accord portant révision de l'Accord de Bangui du 2 mars 1977 instituant une Organisation Africaine de la Propriété Intellectuelle (Bangui (République centrafricaine), le 24 février 1999)* [hereinafter Bangui Agreement].

[24] Ghosh and Calboli (2018), pp. 63–64.

[25] *See* Jehoram (1992), p. 622; *see also* Beier (1990), p. 131. For example, the role of the Court of Justice of the EU (CJEU) was crucial in clarifying and enforcing the rule of regional trademark exhaustion in the EU. *See* Case C-335/96, Silhouette Int'l Schimed Gmbh & Co. KG v. Hartlauer Handelsgesellschaft mbH, 30 I.I.C. 920 (1998); Case-173/98, Sebago, Inc. v. GB-Unic SA,

Moreover, economic integration within the regional area generally arises prior to the decision among member states to adopt the rule of regional exhaustion.[26] It could be argued (and this author believes) that, in a harmonized international trade system, in which international organizations administer treaties, international exhaustion could be the logical step following from national and regional exhaustion. However, the TRIPS Agreement—and accordingly international trade construct supervised by the WTO—makes exhaustion a matter of territoriality and national choice.[27]

In our book, Professor Ghosh and I discuss at length the complex set of policy debates in this area.[28] We also highlight how a meaningful assessment of exhaustion policy needs to take into consideration economic implications, possibly through empirical analysis of the relationships among exhaustion policy, international trade, and IP. In this respect, we refer to several economic studies analyzing the effects of parallel importation on market prices, consumers, producers, and importers.[29] Through empirical studies, prominent economists found that in some instances, price differences are due to marketing decisions by IP holders.[30] These decisions reflect the seeking of price differences across countries to attract licensees and distributors in various jurisdictions that can take advantage of market conditions. In this scenario, parallel importers seek to take advantage of arbitrage possibilities arising from the ability to buy products at a low price and sell them at a high price, depending on the legal regime.[31] In other instances, however, price differences can arise from decisions in separate countries independent from the marketing decisions of the IP holders, for example because of higher product demand due to consumer tastes or regulatory differences that translate into higher or lower prices depending on the nature of the regulation.[32] The latter consideration is relevant regarding the

2 C.M.L.R. 1317 (1999); Joined Cases C-414-416/99, Zino Davidoff SA v. A & G Imports Ltd., Levi Strauss & Co. v. Tesco Stores Ltd., and Levi Strauss & Co. v. Costco Wholesale UK Ltd., 2001 E.C.R. I-8691.

[26] The principle of free movement of goods, for example, predates the adoption of the principle of regional exhaustion in the EU and was already enshrined into the Treaty of Rome in 1957. *See* Consolidated Version of the Treaty on the Functioning of the European Union, Mar. 30, 2010, 2010 O.J. (C 83) [hereinafter TFEU] as amended following the entering into force of the Treaty of Lisbon on December 1, 2009. Treaty of Lisbon, Dec. 13, 2007, 2007 O.J. (C 306). Several decisions were issued by the CJEU regarding the free movement of goods and the exercise of IP rights, before the official adoption of the principle of regional exhaustion. *See* Joined Cases 56 & 58/64, Costen & Grunding v. EC Comm'n, 1966 E.C.R. 299; Case 24/67, Parke Davis v. Centrafarm, 1968 E.C.R. 55; Case 40/70, Sirena v. Eda, 1971 E.C.R. 69; Case15/74, Centrafarm v. Sterling Drugs, [1974] E.C.R. 1147; Case 187/80, Merck & Co. v. Stephar, [1981] E.C.R. 2063. *See also* Saggi (2014), p. 125.

[27] Ghosh and Calboli (2018), pp. 63–64.

[28] *Id*. at 41–64.

[29] *See* Ganslandt and Maskus (2008), pp. 267–268; Ganslandt and Maskus (2004), p. 1035 [hereinafter Ganslandt and Maskus (2004)]; Roy and Saggi (2012), p. 262.

[30] Ganslandt and Maskus (2004), p. 29.

[31] *Id*.

[32] *Id*. *See also* Ghosh and Calboli (2018), pp. 48–51.

discussion of parallel imports in pharmaceuticals, which are subject to non IP-related regulations and whose price is often negotiated by governments and not private economic agents.[33]

Overall, looking at the spectrum of national solutions adopted on exhaustion and the various interests at stake, two observations can be derived from the existing studies. First, it seems the price differences of parallel imported products can be a social benefit for importers and, in several instances, for the importing countries. This could also be the case for parallel imported pharmaceuticals.[34] Price differences do matter for how national legal regimes on exhaustion are implemented both in a particular country or region—that is, whether a country chooses national, regional, or international exhaustion.[35] This first observation has implications for the second, notably that parallel importation is largely the result of price arbitrage arising from differences in prices. Importers see a profit-making opportunity and respond by buying low(er) and selling high(er). Here again, as empirical studies indicate, IP holders can nonetheless respond strategically to these importers either by pre-empting importation before it occurs through contractual clauses they can enforce through litigation[36] or marketing strategies—such as applying small differences in product quality in different countries or appealing to national tastes with varied products. IP holders can also lobby for changes in national laws favoring national exhaustion. Because of various strategic behaviors, the analysis of exhaustion is complicated and the policy responses become more challenging, as one size does not fit all. The approach under Article 6 of the TRIPS Agreement attempts to allows flexibility for individual national responses within this complexity.[37] However, as explained in the next Section, a system of international exhaustion does promote free trade. In turn, this can lead to access to lowered prices products, or access to products that would not be sold in certain countries altogether.[38]

[33] *See* discussion *infra* Part 2.2.

[34] Ghosh and Calboli (2018), p. 49.

[35] *Id*.

[36] *Id*., at 49–50.

[37] *Id.* at 63–64. *See also* Maskus (2016), p. 106; Chiappetta (2016), p. 125.

[38] For a relevant empirical study of the impact of parallel imports (although limited in geographical scope), *see* National Economic Research Associates, The Economic Consequences of the Choice of Regime in the Area of Trademarks: Final Report for DG XV of the European Commission 76-100 (1999). *But see* Kanavos et al. (2004) (finding neutral welfare effects as most of the benefits from producers went to the parallel importers and not to consumers). *See also* Kanavos and Costa-i-Font (2005), pp. 758, 772–775. A similar conclusion is supported by Ganslandt and Maskus (2004), p. 1035 (finding the actual cost savings were small in a study of Sweden because the wholesale price reductions were not passed on to hospitals and patients, instead the retailers and parallel importers made larger margins).

2.2 *Patent Exhaustion and the Debate on Parallel Trade of Pharmaceuticals*

Unlike most products, pharmaceuticals "are developed, approved, manufactured, traded, and used under complex and demanding regulatory schemes."[39] For strictly regulated markets such as the U.S. or the EU, these regulatory schemes apply all the way from the time of production of the active pharmaceutical ingredients.[40] Still, in all countries today, also developing countries, regulators must issue an official marketing approval before the pharmaceuticals are put in the market.[41] This approval may vary in standards for "new" pharmaceuticals and "generic" versions of previously approved pharmaceuticals.[42] For new medicines, elaborate lists of documents, including clinical trials and manufacturing, are necessary, while applicants for generics need to present details of the "bioequivalence" of the compound and manufacturing. Additionally, importers and distributors of pharmaceuticals are generally subject to import regulations and procedures for product recalling and other safety requirements.[43]

It is old news that bringing a new medicine to market is a costly and lengthy processes. On average, a successful drug costs over $1 billion to develop, and only one in several thousand compounds reaches the final approval stage.[44] Since it is relatively uncomplicated and inexpensive to copy the molecules of a new drug, patents are a fundamental part of the industry for the exclusive rights granted through patents. One of the main factors for the industry to obtain the maximum profitability is also the possibility to sell the medicines at differentiated prices across different countries. However, price setting for pharmaceuticals does not depend entirely on the industry international pricing strategy. Instead, many national governments control the prices pharmaceuticals are sold at nationally and later control these prices within hospitals, pharmacies, and other distributors.[45] Because of these negotiations, in countries offering national healthcare schemes, prescription medications are considerably less expensive than in other countries, while pricing of over the counter medications are left more to the market rules.[46] In some instances, national competition authorities have also determined when pricing was "excessive."[47] As noted before, this complex regulatory ecosystem makes it even more important, from the

[39] Abbott (2016), p. 145.

[40] *Id*. at 148–149.

[41] *Id*.

[42] *Id*. For the process of developing generics, see the contributions in Shargel and Kanfer (2014).

[43] Abbott (2016), pp. 149–150.

[44] The Drug Development Process, United States Food and Drug Administration, https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process.

[45] Abbott (2016), p. 150; Wasserman Rajec (2016), pp. 271, 283; Grabowski (2002), p. 533, 535.

[46] Abbott (2016), p. 150.

[47] *See* Abbott (2014), pp. 78–79.

pharmaceutical industry's viewpoint, that producers are able to prevent parallel trade from lower priced into higher priced markers.[48]

A rule of national patent exhaustion is the most effective rule to facilitate national price discrimination and block parallel imports of pharmaceuticals on the basis of national patent enforcement.[49] Representatives of the industry strongly support this rule. To justify their support, they have argued that price discrimination is advantageous not only for pharmaceutical producers, but also for developing countries, as this rule allows producers to set higher prices in more affluent markets while lowering prices in less affluent ones. This position has been supported by several economists.[50] Supporters of this view have argued that parallel imports could lead to a price increase, and not a price reduction, in lower priced markets (and possibly to a reduction of the supply of pharmaceuticals altogether) precisely to prevent possible trade diversion by parallel importers of pharmaceuticals first sold in these markets.[51] The industry also likes to point to the losses that parallel imports can bring to pharmaceutical companies and the fact that these losses would inevitably lead to less investments in R&D with consequential damage for pharmaceutical innovation.[52] The argument has been made that parallel imports also harbour counterfeited products, which are certainly a growing threat for public health, especially in developed countries.[53]

These positions have been largely rebutted, however, by proponents of international patent exhaustion and convincingly.[54] Supporters of international exhaustion have highlighted that it is difficult to assess whether price discrimination effectively benefits low income countries since many drugs are not sold at all in these countries[55] or they are sold for a small section of the affluent population at the same price as in higher-priced markets. Simply put, the assertions of the industry in this respect are speculative, as there are no data comparing the prices of the same pharmaceuticals in developed and developing countries, on a large scale and for a considerable number of products. Similarly, it has been correctly stressed that the industry has not presented compelling evidence that it would suffer severe losses and, in turn, these losses would affect reinvestment in R&D. Instead, supporters of international exhaustion noted that the industry spends large sums on the advertising and

[48] *See* Bale Jr (1999), p. 637 (arguing for the pharmaceutical industry).

[49] *See supra* Sect. 2.1.

[50] *See* Bale Jr (1999), p. 648 (noting that "[t]he threat of parallel trade takes away any incentive of vaccine and pharmaceutical patent holders to make significant concessions to poorer countries"). *See also* Varian (1985), p. 870; *see also* Schwartz (1990), p. 1259; Singham (2000), pp. 363, 407.

[51] Bale Jr (1999), p. 637.

[52] *Id*. *See also* Danzon (1998), p. 293.

[53] *See, e.g*., Delepierre et al. (2012), p. 247; Kelesidis et al. (2007), p. 214; Harper and Gellie (2006).

[54] *See, e.g*. Abbott (2007) (providing of a detailed and very convincing rebuke to the various arguments called by the pharmaceutical industry in favour of national exhaustion and price discrimination) [hereinafter Abbott, *Economic and Social Welfare*]. *See also* Owoeye (2015), p. 359; Kumar Rai and Jagannathan (2012), p. 53.

[55] Abbott (2007), p. 8.

promotion of "lifestyle" (highly profitable) drugs rather than reinvesting all their profits in R&D.[56] The argument about fake medicines is increasingly important as the size of counterfeited medicines in developing countries has become a true issue.[57] This argument is not directly related to parallel imports, however, and again no evidence has been brought that parallel importers—who are subject to strict import controls and regulations no less than other imported medicines—are necessarily linked to the increase of counterfeited medical products in national markets.[58]

Accordingly, despite the pressure against parallel imports on the part of the industry, it cannot be disputed that parallel imports of pharmaceuticals can have beneficial effects for importing countries in terms of prices and access to pharmaceuticals. In particular, imports of lower priced pharmaceuticals can increase access to medicines and, in turn, assist both patients and national governments in saving costs, as several pharmaceuticals are provided through publicly funded health programs.[59] Certainly, for this advantage to be true, the cost savings from the lower point price of the medicines should be shared between importers, retailers, hospitals, and ultimately patients and cannot be pocked only by the importers and the distributors.[60] In this respect, the role of national governments remains crucial, as governments retain regulatory control on the importation of paralleled imported pharmaceuticals. Governments should (and generally do) exercise price control for these pharmaceuticals in order to impose that importers share the savings obtained through the arbitrage of the pharmaceuticals across different national markets.[61] It is thus advisable that individual countries—above all developing countries and LDCs—use the flexibility provided under Article 6 of the TRIPS Agreement and practice the type of domestic exhaustion that best suits national needs in terms of access to pharmaceuticals, thus international exhaustion.[62]

Opponents of parallel imports tried to argue soon after the adoption of the TRIPS Agreement that Article 28 grants patent holders the right to "prevent third parties from making, using, offering for sale, selling or importing" a product and thus it

[56] *Id*., at 8-9 (noting that "[this argument is based on the premise that higher levels of income will lead to increased investments in R&D . . . [but] originator companies on average invest about 15% of their gross income on R&D.]" Instead, it is noted that "[t]he industry spends a substantially higher percentage of income on advertising, promotion and administration. Much of the advertising and promotion costs are spent on "lifestyle" drugs such as Viagra. Considerable R&D spending is directed to lifestyle products and minor variations on existing therapies (so-called "me too" drugs).").

[57] United Nations Interregional Crime and Justice Research Institute, Counterfeit Medicines and Organised Crime (2012).

[58] Abbott (2007), pp. 9–10.

[59] *See* Ho (2011), p. 91.

[60] *But see* Kanavos and Costa-i-Font (2005), pp. 772–775; Ganslandt and Maskus (2004), p. 1035.

[61] Abbott (2007), pp. 9–10.

[62] *See* Musungu and Cecilia (2006).

limits the application of Article 6.[63] This argument was rebuked, however, and a footnote in Article 28 confirms explicitly that the provision of Article 28 is subject to Article 6.[64] This point was further addressed by the Declaration on the TRIPS Agreement and Public Health at the WTO Ministerial Conference held in Doha in 2001.[65] The Doha Declaration focused on accessed to health and reinforced the right of WTO members to take measures to protect public health, including issuing compulsory licenses. In particular, paragraph 5(d) of the Doha Declaration clarified that countries can adopt international exhaustion to allow the parallel importation of lower-priced medicines for public health purposes under Article 6 of the TRIPS Agreement and this cannot be challenged under the WTO dispute settlement system.[66]

One controversial point remained after the Doha Declaration: whether pharmaceuticals produced under compulsory licences could be imported into foreign countries. These imports may represent the only option for access to medicines for some of the LDCs, which cannot effectively avail themselves of compulsory licensing for lack of manufacturing capacity. In fact, most LDCs are still not obliged to implement pharmaceutical patents and clinical trial data protection, as the TRIPS Council agreed in 2015 to extend the waiver, which was set to expire on January 1, 2016, until 2033.[67] Hence, manufacturing capacity is the highest barrier in these countries. However, Article 31(f) of the TRIPS Agreement does not explicitly allow parallel imports of compulsory licensed medicines. Instead, the provision allows compulsory

[63] TRIPS, *supra* note 13, Art. 28. *See* Bale Jr (1999), pp. 641–648. *See also* Kodak SA v Jumbo-Markt AG, 4C. 24/1999/rnd, Dec. 7, 1999 (the Swiss Federal Supreme Court stated that: "Article 28 of the TRIPS Agreement gives the patent holder the right to prevent third parties from selling and importing patented products".).

[64] TRIPS, *supra* note 13, Art. 28 fn 6 ("this right [i.e. the right of importation], 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."). De Carvalho (2010), p. 173.

[65] *See* Abbott (2002), p. 469. For a detailed review of the TRIPS Agreement and public health, *see* Musungu (2016), p. 489. *See also* t'Hoen (2002), p. 27; Coriat and Orsenigo (2014); Velásquez et al. (2020).

[66] Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT/ MIN (01)/DEC/2 (20 Nov. 2001) ("5(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.").

[67] Council for TRIPS, Extension of the Transitional Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations With Respect to Pharmaceutical Products, IP/C/73 (Nov. 6, 2015). *See also* Daniel Benoliel & Timothy John Chirwa, *The Impact of Pharmaceutical Patents on Health Expenditures in Least-Developed Countries*, unpublished paper available at http://law.haifa.ac.il/images/Publications/BenolielChirwa.pdf (comparing LDCs in OAPI with other LDCs and noting that patents are not a primary obstacle to access to medicines in LDCs, as opposed to several other factors such as: rational selection and use of drugs, affordable prices, unsustainable and inadequate funding, and Reliable health and supply systems).

licencing to be granted "predominantly" for the domestic market.[68] Finally, in 2003, WTO members agreed to facilitate LDCs to import medicines made under compulsory licensing if they are unable to manufacture the medicines themselves. This resulted in the adoption of Article 31*bis* of the TRIPS Agreement in 2005.[69] The provision became effective in January 2017, after a sufficient number of countries ratified the provision,[70] even though the provision has not been invoked by any LDCs in the context of parallel imports of compulsory licensed pharmaceuticals to date.

3 National Solutions to Patent Exhaustion and Parallel Trade of Pharmaceuticals

Because of the flexibility of Article 6 of the TRIPS Agreement, countries worldwide can decide their national policy on patent exhaustion autonomously between national, international, or regional exhaustion. Some countries also apply a differentiated approach to the exhaustion of pharmaceuticals. In the following Section, I review the domestic policies of selected countries in various continents.[71] This information is necessarily limited due to the impossibility to comprehensively address all countries' policies in this Chapter. In addition, as mentioned above, the analysis does not extend to the national requirements each country applies regarding the regulatory schemes for the marketing approval and import authorization for the parallel imports of pharmaceuticals, which again remain a fundamental aspect of imports of medicines (both by originator companies and parallel importers).

3.1 Selected Jurisdictions in Asia

Several countries in Asia[72] follow a regime of international exhaustion related to patent rights. This choice can be explained by the fact that several countries in Asia are still developing countries or LDCs. For example, the two largest countries in Asia, India and China, both practice international patent exhaustion. India's

[68] TRIPS Agreement, *supra* note 13, Art. 31(f).

[69] *Id*., Art. 31*bis*. *See* Abbott (2005), p. 317; Abbott and Reichman (2007), p. 921.

[70] Zaheer Abbas and Riaz (2017), p. 451.

[71] For detailed overview in this respect, *see* World Intellectual Property Organization, Standard Committee on Patents Electronic Forum, Questionnaire on Exceptions and Limitations of Patent Rights, the database administered by the WIPO's Standing Committee on Patents https://www.wipo.int/scp/en/exceptions/ [hereinafter WIPO, Questionnaire on Patent Exceptions].

[72] Even if partially outdate now, a relevant resource for Asia is still Parallel Imports in Asia (Heath 2004).

approach is based on Section 107A of the Indian Patent Act, as amended in 2002, which provides that "[f]or the purpose of this Act, (b) importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights".[73] In China, Article 69 of the Chinese Patent Law provides that the following shall not be deemed to be patent right infringement "(1) after a patented product or a product directly obtained by using the patented method is sold by the patentee or sold by any unit or individual with the permission of the patentee, any other person uses, offers to sell, sells or imports that product."[74] Previously, under the rule of the Patent Law of China of 1985, the applicable rule was national patent exhaustion. This was changed, however, with the entry into force of new 2008 Patent Law, which provides for international patent exhaustion.[75]

Out of the ten members of the Association of South East Asian Nations (ASEAN),[76] three countries also practice international exhaustion. In particular, Cambodia follows international patent exhaustion under its Law on the Patents, Utility Model Certificates and Industrial Designs,[77] even though Cambodia does not currently provide patent protection for pharmaceuticals under the TRIPS Council's waiver for LDCs. International exhaustion is also adopted under the Patents Act of Malaysia[78] and the Intellectual Property Law of Vietnam.[79] Other ASEAN countries, such as Brunei,[80] Lao PDR[81] (also an LDC), and Thailand[82] do not have a specific rule on patent exhaustion. In these countries, whether the parallel importation of genuine products sold overseas with the proprietors' consent constituted infringement may depend on the contents of the contracts signed between the parties concerned. In Myanmar, a new Patent Law has been adopted in 2019, which is currently pending for approval, even though it remains unclear how the principle of

[73] Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India). *See also* Ghosh and Calboli (2018), pp. 108–109; Pai (2016), pp. 324, 327; Gopalakrishnan and Agitha (2012), p. 229; Basheer and Kochupillai (2009), p. 63.

[74] Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009) CN028 (China). *See also* Yu (2004), pp. 25–38.

[75] *See* Yu and Yin (2016), pp. 308, 311. *See also* Ghosh and Calboli (2018), p. 109.

[76] For a discussion on ASEAN, including the principle of exhaustion and free movement, *see*Calboli (2019b), pp. 363–391.

[77] Law on Patents, Utility Models and Industrial Designs, Art. 44 (Cambodia).

[78] Patents Act 1983, as amended by the Patents (Amendment) Act 2006, § 58A (Malay.).

[79] Law on Intellectual Property (No. 50/2005/QH11 of Nov. 29, 2005), art. 125(2)(b) (Viet.).

[80] Constitution of Brunei Darussalam, Patents Order, Art. 83(3) (2011) (Brunei).

[81] Lao People's Democratic Republic Intellectual Property Laws (Law No. 01/NA of 20 Dec. 2011) (Lao PDR) [hereinafter Lao PDR Law].

[82] Patent Act B.E. 2522, as amended by the Patent Act (No. 2) B.E. 2535 and the Patent Act (No. 3) B.E. 2542 (Thai.).

patent exhaustion is addressed in the new law. Myanmar can also be exempted from implementing patent protection for pharmaceuticals until 2033 (as an LDC).[83]

Other Asian countries follow a hybrid system. In particular, the 2016 Patent Law of Indonesia[84] grants patent owners the exclusive right to prohibit other parties from "importing" the patented products or the products derived from the patented products.[85] Yet, this provision does not apply, explicitly, to the imports of patented pharmaceuticals that have been lawfully marketed outside Indonesia and have been imported into Indonesia by third parties.[86] Similarly, the Philippine Intellectual Property Code[87] includes the right to oppose unauthorized imports,[88] but again this provision does not apply to the imports of pharmaceuticals.[89] Singapore also follows a hybrid approach, but opposite to the approach adopted by Indonesia and the Philippines. Notably, Singapore does not allow imports of patented pharmaceuticals if the products have not been previously sold or distributed in Singapore by the patent owner or with her consent.[90] After the products have been marketed in Singapore by the originator companies, then parallel imports are theoretically allowed. However, also after the first released in the Singaporean market by the patent holders, imports can still be blocked when the pharmaceuticals have been parallel imported because of a breach in the contract between the patent holder and her licensees, including outside Singapore.[91] As parallel imports are often the results of genuine products diverted from their original distributors into the distribution channels of parallel importers, this principle effectively nullifies the possibility to parallel imports pharmaceuticals into Singapore. This principle was introduced after the US-Singapore trade agreement. On the other side, Singapore practices international patent exhaustion for all other products.[92]

The remaining largest economies in Asia, Japan and Korea, do not have a specific statutory policy on patent exhaustion, and their respective case law has led to diverging position. In Japan, courts have largely recognized international patent exhaustion.[93] In particular, the Supreme Court stated that enforcing Japanese patents would not be consistent with international trade, even though the Court did not

[83] At this time, the author could not locate the pending draft of the 2019 Patent Law (Myanmar), as the draft is not published not available in any known database.

[84] Law of the Republic of Indonesia No. 13 of July 28, 2016, on Patents (Indon).

[85] *Id*. at art. 19(1)-(2) and art. 160.

[86] *Id*. at art. 167. This exception is based directly on the need to "to ensure a reasonable price and satisfy the justice of a pharmaceutical product is necessary for human health." *Id*. at Explanation to art. 167.

[87] Intellectual Property Code, Rep. Act 8293, as amended by Rep. Act 10372 (Phil).

[88] *Id*. at § 72.

[89] *Id*.

[90] Patents Act (Ch. 221, 2005 Rev. Ed.) § 66(3)(a) (Sing.).

[91] *Id*. at §§ 66(3)(b) & (c).

[92] *Id*. at § 66(2)(g).

[93] Heath (2004), p. 51.

directly acknowledge that Japan practices international exhaustion. The Court recognized the patent owner could prohibit the importation of goods through contractual restrictions and by indicating on the product that the patented item is not intended for sale in Japan.[94] In Korea, the Patent Act also does not elaborate on the issue of patent exhaustion and judicial decisions led to an opposite interpretation—national exhaustion. This position makes of Korea one of the few Asian countries choosing national patent exhaustion and it probably consistent with the level of technological development of the country[95] (even though the same could be said for Japan). However, in 1981, precisely in a case related to the imports of Italian pharmaceuticals from Switzerland into Korea, the Seoul District Court said the foreign sale had also exhausted the rights in Korea.[96] Still, the court fell short of explaining the reasoning for the decision in that case and no later case confirmed nor denied this position. It thus remains unclear if this decision changed the general view in favor of national patent exhaustion in Korea, or if it could be supported that also Korea decided through caselaw to follow a differentiated regime for the exhaustion of pharmaceuticals (international) versus other patented products (national).[97]

3.2 Canada, United States, Australia, and New Zealand

Today, international patent exhaustion is the system of choice also in Canada and the U.S., based on judicial precedents.[98] Specifically in Canada, in the 1998 decision in *Eli Lilly & Co v Novopharm Ltd.*, the Supreme Court confirmed that, when a patentee sells a patented product, the rights of the products exhaust as long as the seller did not impose any restrictions on the subsequent distribution.[99] Thus, the key inquiry in Canada is today not where the goods were first sold, whether in or outside Canada, but whether the products were sold with or without restrictions.[100]

The U.S. follows a very similar position. Notably, the traditional interpretation on patent exhaustion was recently changed in favor of international exhaustion by the 2017 Supreme Court decision *Impression Products v. Lexmark.*[101] Like in several other countries, the U.S. Patent Act does not elaborate on the geographical extent of the exhaustion of a patented product, or a product embodying patented process, after

[94] *Id*. at. 52–58.

[95] Byung-Il (2004), p. 73.

[96] *Id*. at 76–77 (citing the decision of the Seoul District Court in the case *Ildong Pharmacie v. Farmatalia Carlo Erba S.p.A*., Mar. 14, 1981).

[97] *Id*. at 77.

[98] *See* Calboli, *Comparing IP Exhaustion, supra* note 22, at 32.

[99] Eli Lilly & Co. v. Novopharm Ltd., [1998] 2 S.C.R. 129.

[100] *Id*.

[101] *Impression Prods., Inc. v. Lexmark Int'l, Inc.,* 581 U.S. 1523 (2017). *See* Ghosh and Calboli (2018), pp. 88–102.

the first sale of the products. In the past decades, several decisions by U.S. courts adopted the position that the sale of an article in a foreign country does not exhaust the U.S. patent.[102] In its February 2016 decision in the *Lexmark* case, the U.S. Court of Appeals for the Federal Circuit repeated this position. However, to the disbelief of many in the U.S., the Supreme Court reversed and stated that the first sale of products anywhere in the world exhausted the rights also in the U.S. Still, the Court did not exclude that contractual restrictions could prevent the import of gray market goods after the decision in *Lexmark*.[103] Thus, also in the U.S., the key inquiry may still be whether the products were sold with or without restrictions. Moreover, regardless of the change in national policy, the imports of pharmaceuticals remain subjects to the US regulatory schemes and the impact of *Lexmark* on these imports is, in practice, non-existing.

On the other side, Australia follows a less trade friendly national policy and favors national patent exhaustion. Also in Australia, however, the Patents Act does not specifically address the issue.[104] Notably, the Patent Act states that patent holders have exclusive rights to exploit their inventions in Australia.[105] The definition of "exploitation" is provided in the Patent Act and includes importation, similar to the TRIPS Agreement and other national laws.[106] This leads to the interpretation that Australia practices national exhaustion. Patent law in Australia is also constrained by the obligations under the Australia–United States trade agreement, whose 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."[107]

Similarly to Australia, also New Zealand does not allow parallel importation of patented products.[108] Here again, we have a hybrid system, however, as the Crown has the authority to order parallel importation of pharmaceuticals under the Medicines Act of 1981, notwithstanding the Patents Act.[109] Of course, provided that the products are in line with the requirements imposed under the country's regulatory schemes and import authorizations.

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[102] *See* Ghosh and Calboli (2018), at 88-102 (citing *Boesch v. Graff*, 133 U.S. 697 (1890); *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001); *Lexmark Int'l, Inc. v. Impression Prods. Inc.*, 816 F.3d 721, 771 (Fed. Cir. 2016)).

[103] *Impression Products, Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 1523 (2017).

[104] *See* Ghosh and Calboli (2018), pp. 107–108.

[105] *Patents Act* 1990 s 13 (Austl.).

[106] *Id*. at Schedule 1 (Austl.).

[107] Free Trade Agreement, U.S.-Austl., May 18, 2004, art. 17.9.4.

[108] *See* Ghosh and Calboli (2018), pp. 107–108; Susy Frankel, Test Tubes for Global Intellectual Property Issues: Small Market Economies 178 (2015).

[109] Frankel, *supra* note 108, at 178 (citing Section 32A of the Medicines Act 1981, introduced by the Medicines Amendment Act 1989). *See also* Patents Act, pt 2 (N.Z.).

3.3 Selected Jurisdictions in Latin America

Like in Asia, most countries in Latin America follow the principle of international patent exhaustion. There are important exceptions, however, to this rule.

The first exception is Mexico, which is surprising as both its partner members in the North American Free Trade Agreement (NAFTA), Canada and the U.S., follow now international patent exhaustion. Instead, Mexico practices national exhaustion. Also, in Mexico, no specific language related to the exhaustion of patent rights is found under the Mexican law. The Mexican Industrial Property Law clarifies, however, that the rights conferred by a patent cannot be asserted against "any person who markets, acquires or uses the patented product or the product obtained by means of the patented process, after said product has been lawfully placed on the market."[110] In the absence of a provision stating the opposite, the majoritarian interpretation of the wording "the market" is that it only includes "national market."[111]

National patent exhaustion is also the system adopted in Brazil. This position is particularly perplexing in light of Brazil's role in the parallel importation of pharmaceuticals in the 1990s. Notably, Article 43 of Law 9.279 of 1996 provides national exhaustion for patent and trademark rights regarding products "manufactured in accordance with a process or product patent that has been placed on the internal market directly by the patent holder or with his consent."[112] However, under Article 68(4) of the same law, if the exploitation of the patent (and use of the trademark) is made through importation of the product—that is, in the case where the products are not manufactured in Brazil, third parties are allowed to import these products after they have put them into the "market", which is interpreted in this instance as anywhere in the world.[113] Accordingly, in this case, parallel imports are admitted in Brazil.[114]

On the other side, Chile follows a system of international patent exhaustion as per Article 49(5) of Law No. 19.039, according to which a "patent shall not confer the right to prevent third parties from marketing the patent protected product, which such parties have acquired lawfully after that product has been lawfully introduced into the market of any country by the right owner or by a third party with the owner's

[110] Mexican Industrial Property Law, art. 22. Ley de la Propiedad Industrial, Diario Oficial de la Federación [D.O.F.] 27-06-1991, amended by D.O.F. 02-08-1994 (Mex.).

[111] *See* Correa and Correa (2016), p. 206.

[112] Lei No. 9.279, de 14 de Mayo de 1996, art. 43(4) (Braz.) [hereinafter Brazilian IP Law].

[113] *Id*., at art. 68(4). *See also* Correa and Correa (2016), p. 206.

[114] This provision finds its origin of the requirement of "local manufacture obligation" for patent holders that was originally provided under Brazilian law. As this requirement could have been challenged as incompatible with Article 27(1) of the TRIPS Agreement, the 1996 Law abolished the rule. Yet, Article 68(1), under the rubric "Compulsory Licensing," provides that the following can grant a decision of issuing compulsory licensing: "I. failure to work the subject matter of a patent on the territory of Brazil, failure to manufacture or incomplete manufacture of the product or failure to completely use a patented process, except for failure to work due to lack of economic viability, in which case importing shall be admitted. Brazilian IP Law, *supra* note 112, at art. 68(1).

consent."[115] As reported, legislative debates found this solution necessary "to provide a balance between the . . . right holders and . . . the citizens"[116] Argentina also adopts international exhaustion, according to Article 36(c) of Law No. 24.481 (consolidated text, 1996) on Patents and Utility Models and subsequent amendments "The right conferred by a patent shall not have any effect against: (c) Anyone acquiring, using, importing or in any way marketing the patented product or the product obtained by means of the patented process, after said product has been lawfully placed on the market in any country."[117]

The four members of the Andean Community—Bolivia, Ecuador, Colombia, and Peru—also practice international exhaustion.[118] Article 54 of Decision 486 of the Commission of the Andean Community establishes that the patent shall not confer the right "to proceed against a third party making commercial use of a product protected by a patent once that product has been introduced into the commerce of any country by the owner or another person authorized by the right holder or with economic ties to that patent owner."[119] Notwithstanding, the imports of these products can be further restricted by national laws providing for the import authorizations and other formalities.

3.4 European Union and Switzerland

Free movement of goods, including of pharmaceuticals, is allowed in the EU/EEA under the rule of regional exhaustion. Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU)—originally then the Treaty Establishing the European Economic Community (EEC Treaty)—are the applicable provisions to the exhaustion of patented goods within the EU. Notably, the distribution of a patented good by the consent of the patent owner into the market of any EU Member State exhausts the rights of distribution within the EU.[120] Exhaustion does not apply, however, if the product is a patented pharmaceutical manufactured

[115] Law No. 19.039 on Industrial Property of 1991, art. 49(5) (Chile). This provision has not been modified in the various amendment and updates of Law 19.039 that have been adopted since 1991.

[116] World Intellectual Property Organization, Standard Committee on Patents Electronic Forum, Questionnaire on Exceptions and Limitations of Patent Rights, Chile, Exhaustion of Rights, https://www.wipo.int/scp/en/exceptions/replies/chile.html#Q8.

[117] Law No. 24.481, Oct. 23, 1995, art. 36(c), [LV-C] A.D.L.A. 2948 (as amended by Law No. 24.572 [LV-E] A.D.L.A. 5892 (Arg.) [hereinafter Argentine Patent Law]. *See also* Correa and Correa (2016), p. 202.

[118] Decision No. 486 Establishing the Common Industrial Property Regime, Sept. 14, 2000, art. 54, WIPO CAN012, https://wipolex.wipo.int/en/text/223717 (Andean Community).

[119] *Id.*

[120] *See* Stothers (2007); Case15/74, Centrafarm v. Sterling Drugs, [1974] E.C.R. 1147; Case 187/80, Merck & Co. v. Stephar, [1981] E.C.R. 2063.

for the purpose of marketing approval rather than for commercialization.[121] Articles 34 and 36 also apply regardless of possible contractual limitations against further distribution of patented products. In particular, these limitations may be in conflict with Article 34 if they restrict or prevent importation into and distribution in another Member State.

An additional exception to the principle of free movement is found in the Act of Accession 2003[122] of new members from Eastern Europe, which provides that IP holders can rely on the "Specific Mechanism" and prevent the import and marketing of pharmaceuticals from new EU Member States into other EU Members States in which they have protection.[123] The reason for this exception was because patent protection and supplementary protection certificate (SPC) for pharmaceuticals was implemented later in time in these countries and at the time of accessions, several drugs were patented in the Western EU Member States but could no longer be patented in these countries. The "Specific Mechanism" additionally provides importers should demonstrate to the authorities in charge of issuing the permission to import they have notified the patent or SPC holder no less than a month earlier.[124] In 2005, the "Specific Mechanism" was later extended to Bulgaria and Romania, and in 2012 to Croatia.[125]

The only case in this area, *Merck v. Sigma*,[126] confirmed nonetheless a pro-exhaustion stance by the CJEU's interpretation of the provision. In particular, even though the Court accepted the Specific Mechanism provides for a specific derogation to the principle of free movement, it also stated that importers do not have "an obligation to obtain the express prior consent" from the rights holders.[127] Instead, rights holders have one month to oppose the imports and if they do not "take advantage of that period," importers "may legitimately apply to the competent authorities for authorisation to import the product and, where appropriate, import

[121] Case C-316/95, Generics v. Smith Kline & French Laboratories, [1997] E.C.R. I-3929.

[122] Act of Accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia, Apr. 16, 2003, 2003 O.J. (L236) 33 [hereinafter Specific Mechanism]. *See* Heath (2014b), p. 399; Stothers (2016), pp. 169, 178.

[123] Specific Mechanism, *supra* note 122.

[124] *Id*. Critically, in general, over this type of differentiated systems, see Jerome Reichman, Ruth Okediji, Ioannis Lianos, Robin Jacob, Christopher Stothers, The WTO Compatibility of a Differentiated International Exhaustion Regime Proposed by the Eurasian Economic Community, A Consultancy Report, Research Paper Series, Skolkovo-HSE International Laboratory for Law & Development (on file with author).

[125] Act of Accession of Bulgaria and Romania, 2005 O.J. (L157) 203, Annex V.1; Act of Accession of Croatia 2012 O.J. (L112) 21, Annex IV.1.

[126] Case C-539/13, Merck Canada Inc. v. Sigma Pharmaceuticals plc, [2015] R.P.C. 30. The importer provided advanced notification to Merck of its intention to import pharmaceuticals from Poland, where protection did not apply. Merck did not respond and the products were imported into the U.K. Merck objected and parallel imports were blocked. When Merck also sought damages, the issue was referred to the CJEU. *See* Stothers (2016), at 179.

[127] *Case C-539/13, Merck Canada,* ¶ 28.

and market it."[128] This should not be read as the rights holders have "forfeited the right to rely on the Specific Mechanism."[129] They simply cannot "obtain compensation for the loss" due to the imports "which he failed to oppose" in time,[130] but remain "free to oppose future importation and marketing of the pharmaceutical product protected by the patent or SPC."[131]

Not an EU Member State, Switzerland's example is worth noting as part of the European region. Until 2008, Swiss law applied national exhaustion to patents. The rule was then changed in favour of regional patent exhaustion and Switzerland now practices regional exhaustion with the countries members of the EU/EEA.[132] However, pharmaceuticals are still subject to national patent exhaustion in Switzerland, and parallel imports of pharmaceuticals first put into the market in a foreign country, including in the EU/EEA, cannot enter into the country. To be precise, Article 9 (a) paragraph 5 indicates that the principle of regional exhaustion does not apply and the consent of the holder of the patent of a product "is reserved" in the instances in which the price the product "in Switzerland or in the country in which they are placed" has been "fixed by the state."[133] This principle applies directly to prescription pharmaceuticals and all the medicines that are subjected to price control by national government. However, in the law, this principle is not directly referred to pharmaceuticals, but to all patented products that could be subject to price control.

3.5 Selected Jurisdictions in Africa

Access to medicines is a priority for most countries in Africa, the continent with the largest number of LDCs worldwide,[134] all of which are users of pharmaceuticals coming from foreign countries.[135] National practice on patent exhaustion varies

[128] *Id.* at ¶ 31.

[129] *Id.* at ¶ 32.

[130] *Id.*

[131] *Id.*

[132] Federal Act on Patents for Inventions (SR 232.14 LBI) art. 9a (inserted by No I of the Federal Act of June 22, 2007 (AS 2551 (2009); BBl 1 (2006)), *as amended by* No I of the Federal Act of Dec. 19, 2008, in force since July 1, 2009 (AS 2615 (2009); BBl 303 (2008)) (Switz.).

[133] *Id.* at art. 9a, ¶ 5 LBI ("Irrespective of the provisions of paragraphs 1–4, the consent of the proprietor of the patent for the placing on the market of patent-protected goods is reserved if their price in Switzerland or in the country in which they are placed on the market is fixed by the state."). *See also* Kyle (2009), p. 339, 345 (noting that, on the other side, "Switzerland treats copyrights and trademarks as internationally exhausted.").

[134] *See* United Nations, Committee for Development, List of Least Developed Countries, https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf (listing the 47 countries currently categorized as LDCs).

[135] Vawda and Shozi (2020); dos Santos and Lowé Gnintedem (2018), pp. 592, 593–594; Ncube (2016), p. 110.

across countries in the continent, however, with some countries practicing international exhaustion, while others national or regional exhaustion. The laws of several countries also remain silent on the issue.[136]

For example, the following countries do not seem to have a clear position on the issue as of today: Congo, Egypt, Nigeria, Swaziland, Angola, Lesotho, and Malawi.[137] South Africa's position is also unclear, even though several commentators support it following international exhaustion. In the late 1990s, South Africa implemented regulations authorizing parallel importation of medicines protected by patents and trademarks,[138] but the South African Patents Act remains unclear as to whether the doctrine of exhaustion of rights applies nationally or internationally.[139] Well-known by experts in this area, South Africa wanted to authorize parallel importation of retroviral pharmaceuticals for AIDS in the 1990s.[140] It was precisely in this occasion that patent holders argued that international exhaustion was precluded by Article 28 of the TRIPS Agreement.[141] The case was eventually dropped, but the ensuing criticism led to the adoption of the Doha Declaration.[142]

International patent exhaustion is instead directly adopted in the law of several countries in Africa. These countries include Ghana, which changed its previous regime of national patent exhaustion with the revision of the Patent Act in 2003, whose Section 11(4)(a) now states that "[t]he rights conferred under the patent shall not extend to 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."[143] Similarly, Article 43(1) of the 2012 Industrial Property Act of Namibia provides that "[t]he following acts do not constitute an infringement of the rights under a patent, namely: a) acts of importation of patented inventions which have been put on the market in any territory or country by the owner of the patent or with his or her authorization."[144] Kenya also explicitly permits the parallel imports of patented pharmaceuticals under the Industrial Property Act 2001, replacing the Industrial Property Act 1989, which prohibited parallel imports. Notably, Article 58(2) now recites, "[t]he rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya."[145] Additional

[136] *Id*. at 31–32. In general, *see also* McKeith (2013), p. 287.

[137] *See* WIPO, Questionnaire on Patent Exceptions (in which the respective countries may indicated that there is no clear national position of the issue).

[138] Abbott (2016), pp. 146–147.

[139] *Id*.

[140] *See* (Tayler 2004, p. 117).

[141] *See supra* Section 1.2.

[142] *Id*.

[143] Patents Act No. 657 (2003), § 11(4)(a) (Ghana). Vawda and Shozi (2020), p. 32.

[144] Industrial Property Act No. 1 (2012), § 42(1)(a) (Namibia). Vawda and Shozi (2020), p. 32.

[145] Industrial Property Act No. 3 (2001), § 58(2), *as amended* up to Act No. 11 (2017) (Kenya).

countries that explicitly follow international patent exhaustion are: Botswana,[146] Burundi,[147] Liberia,[148] Seychelles,[149] Sierra Leone,[150] Zambia,[151] Zanzibar,[152] and Zimbabwe.[153]

To the contrary, the following countries provide for national exhaustion: Madagascar, Mozambique, Rwanda, Sao Tome and Principe, South Sudan, and Uganda.[154] This choice is, at best, puzzling as all the countries in this list are LDCs.[155] Even though these countries may not protect pharmaceuticals with patents at this time because of the TRIPS Council's waiver—thus the impact of a national exhaustion regime ultimately does not affect imports of pharmaceuticals—this system can affect parallel imports of other products currently patented in these countries. Moreover, a system of national exhaustion may protect the business interests of the foreign patent holders more than the national interests, as most patents are filed by foreigners in the countries in question.[156] Another country practicing national exhaustion is Morocco under Article 55(d) of the Patent Law of 2000.[157] The provision was repeated in the US-Morocco FTA in 2004,[158] in which both the U.S. and Morocco subscribed to this position. As the U.S. later changed its national rule to international patent exhaustion,[159] Morocco could also consider a change in policy for public health reasons.

Finally, regional exhaustion is the system practiced by the seventeen members of the Organisation Africaine de la Propriété Intellectuelle (OAPI): Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Gabon, Guinea, Equatorial Guinea, Mali, Mauritania, Niger, Guinea Bissau, Senegal, and Togo. Its seat is in Yaoundé, Cameroon. In particular, OAPI operates a

[146] Industrial Property Act No. 8 (2010), § 25(1)(a) 2010 (Botswana). Vawda and Shozi (2020), p. 32 (recounting that Botswana utilized this flexibility when it declared HIV/AIDS a national emergency in 2000 and began importing cheaper ARV drugs).

[147] Industrial Property Law No. 1 (2009), art. 57 (Burundi).

[148] Liberia Intellectual Property Act, § 13.11(b) (2016) (Liberia).

[149] The Patents and Industrial Design Act, § 19 (2012) (Seychelles).

[150] Patents and Industrial Design Act, § 23(1)(a) (2012) (Sierra Leone).

[151] Patents Act No. 40 (2016) § 76 (Zam).

[152] Industrial Property Act No. 4 (2008) § 11(4)(a)(i) (Zanzibar).

[153] Patents Act [Chapter 26:03], § 24A (amended by Act 9 of 2002) (Zimbabwe).

[154] Vawda and Shozi (2020), p. 32.

[155] *See* United Nations, *supra* note 134.

[156] *See* Graff and Pardey (2019) (for a survey of patent filing by foreigner and local inventors in Africa).

[157] Law No. 17-97 on the Protection of Industrial Property, art. 55 (Morocco).

[158] United States-Morocco Free Trade Agreement, 15 June 2004, 44 I.L.M. 544, art. 15.9 ("4. 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").

[159] *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 1523 (2017). *See* Ghosh and Calboli (2018), pp. 88–102.

unitary system for patents and OAPI member states do not have individual national laws. The Revised Bangui Agreement of February 1999 is the applicable patent law for all member states.[160] Article 8(1)(a) of Annex I provides that "The rights deriving from the patent shall not extend: (a) to acts in relation to subject matter brought on to the market on the territory of a member State by the owner of the patent or with his consent."[161] It should be noted, however, that even though thirteen of OAPI members states (excluding Cameroon, Congo, Côte d'Ivoire, and Gabon) are LDCs, the rights granted under the Bangui Agreement include pharmaceutical patents (as per Article 27 of the TRIPS Agreement).[162] Accordingly, LDCs in OAPI are de facto excluded from taking advantage of the existing TRIPS Council's waiver for patent protection for pharmaceuticals.[163] Moreover, these countries are bound by a system of regional exhaustion and not international exhaustion, whereas international exhaustion could likely a more favorable approach for all OAPI member states.[164]

4 Overlapping Intellectual Property Rights and Parallel Trade of Pharmaceuticals

In addition to patents, other IP rights can affect parallel trade, even when countries practice international patent exhaustion. This situation can arise when countries practice national exhaustion for trademark, copyright, or design rights.[165] In general, overlapping IP rights can apply to a product in its entirety or to different parts or features of it.[166] An example of the former is the overlapping trademark and copyright protection that can apply to the shape of a perfume bottle, the décor of a store, or the pictorial logo affixed to the packaging of consumer products, including pharmaceuticals.[167] An example of the latter is the cumulation of patent, trademark, and copyright protection that can cumulate on a pharmaceutical, the first protecting the compound/product and/or process of making the compound, the second protecting the shape and/or color of the pill made with the patented compound and

[160] Bangui Agreement, *supra* note 23.

[161] *Id*. at Art. 8(1)(a). *See also* Kongolo (2000), p. 717.

[162] Bangui Agreement, *supra* note 23, art. 2.

[163] Deere (2008), p. 240.

[164] Vawda and Shozi (2020), pp. 32–33. In addition, the same regime of regional exhaustion applies to trademarks, which may result in blocking, as possible trademark infringement, also trademarked generic medicines from foreign countries. *See* Calboli and Visser (2020), p. 102.

[165] *See* Calboli, *Avoidable Effects*, *supra* note 3; Ginsburg and Calboli (2020), p. 434. In this chapter, I do not focus on design rights, which nonetheless may remain a relevant area of investigation, even this overlap may be less relevant, in practice, due to the limited duration of design rights, which is generally comparable, or shorter in time than patents rights.

[166] Ginsburg and Calboli (2020), p. 434; Derclaye and Leistner (2011); Moffat (2004), p. 1473.

[167] Ginsburg and Calboli (2020), p. 434.

through the patented process, and the third being the written instructions accompanying the medicines' packaging, or the decoration of the packaging itself.[168] The problematic effects of these overlaps and their application to parallel imports is addressed in this Section.

4.1 Overview of Overlapping Rights and Enforcement of Copyright to Parallel Imports

Overlapping IP protection can apply simultaneously or sequentially. In the first case, two or more rights protect the same product at the same time. For example, a pictorial logo or the shape or color of a product—be this product a chocolate, liquor, or a pharmaceutical—can simultaneously enjoy trademark protection as distinctive signs and possibly copyright protection as independent artistic works, in addition to the protection the product may enjoy under patent or design law.[169] Likewise, the labels, instructions, and other literary parts of a products could be protected under copyright in addition to the protection that the products enjoys under patent law. Instead, in the second case, two or more types of protection apply to the same product at different times. For instance, the patent or design granted on a product, or copyright protection on its shape or logo, are set to be limited in time. Instead, trademark protection on a product's logo and possibly shape or color can continue without time limits.[170] Whether they are used simultaneously or sequentially, overlapping rights can prolog and/or enhance the scope of protection of the interested products.

In the context of pharmaceuticals, overlapping protection is often sought for different parts of the medicines or their packaging during or after patent protection. For example, in addition to protecting the names of the pharmaceuticals as marks, trademark registrations are often granted for the shape, colors, and other distinctive features of the medicines.[171] Similarly, logos and decorative or distinctive elements

[168] *Id*.

[169] *Id*. For a detailed list of examples, *see* Calboli (2014b), p. 52 [hereinafter Calboli, *Overlapping Rights*]. For examples of overlapping protection between trademarks and patents, in particular applied to pharmaceuticals, see the cases cited *infra* in Part IV.B. *See also* Calboli (2020), p. [hereinafter Calboli, *Trademark Protection for Medicines*]. *See also* the contributions in Overlapping Intellectual Property Rights (Neil Wilkof & Shamnad Basheer eds., 2012.

[170] Ginsburg and Calboli (2020), p. 434. For famous cases in the U.S., *see Frederick Warne & Co. v. Book Sales, Inc.*, 481 F. Supp. 1191, 1196 (S.D.N.Y. 1979); *Walt Disney Prods. v. Air Pirates*, 581 F.2d 751 (9th Cir. 1978) (finding that both copyright and trademark permissible on Disney comic book characters); *Universal City Studios v. J.A.R. Sales, Inc.*, 216 U.S.P.Q. 679 (C.D. Cal. 1982) (discussing the protection of the "E.T." motion picture character).

[171] For several relevant examples in the U.S., *see* U.S. Trademark Registration Nos. 2,593,407 (Pfizer Inc.; Viagra pill; diamond shape and color blue); 2,625,335 (Glaxo Group; Flovent HFA inhaler; tethered cap, mouthpiece covering shape, edge shapes); 2,679,181 (Gilead Sciences, Inc.; Viread pill; almond shape and color blue); 3,812,561 (Glaxo Group; Advair diskus inhaler; unique

applied to the packaging, or the labels, product instructions, or similar features of the pharmaceuticals could be protected as copyrighted works.[172]

The justification for overlapping IP rights rests on several elements: the broad definition of protectable subject matter (the item to be protected and the individual scope of protection of the type of products or individual product features); the lack of a comprehensive normative system prohibiting the possibility to cumulate separate types of IP protection in the same product, or different features of the same product; and the lack of a comprehensive system prohibiting, as misuse or abuse of rights, the enforcement of IP protection outside the traditional scope of protection.[173] Even though national variations subsist regarding the treatment of overlapping rights in individual nations, overlapping IP protection is generally accepted.[174] Some exclusions apply regarding the protection of the functional elements and additional protection under trademarks or copyright.[175] Still, in most countries, there are no

round design, color purple, color white, and wave patterns); 5,018,105 (Gilead Sciences, Inc.; Harvoni pill; diamond shape, light-orange color, and identification number); 5,018,106 (Gilead Sciences, Inc.; Sovaldi pill; oval shape, light-yellow color, and identification number); 5,030,567 (Gilead Sciences, Inc.; Truvada pill: oblong shape, color blue, word engraving); 5,298,494 (Eli Lilly and Co.; Olumiant pill; color light pink, oval/oblong shape, and word engraving); 5,435,196 (Teva Respiratory; AirDuo RespiClick inhaler; colors yellow and white); 5,614,245 (Glaxo Group; Seretide evohaler; color purple Pantone Matching System 2587). *See also* Calboli, *Trademark Protection for Medicines, supra* note 170.

[172] In the U.S., for example, the following are registered: U.S. Copyright Registration Nos. TX0004141715 (Pfizer, Inc.; Zyrtec (certirizine Hydrochloride) tablets for oral use; copyright registration for the product label); TX0004065039 (Abbott Laboratories; Advera, Specialized, complete nutrition, clinically proven effective nutritional management; copyright registration for the product label); TX0004068652 (Abbott Laboratories: Pedialyte oral electrolyte maintenance solution; copyright registration for the product label); TX0004862188 (Novartis Crop Protection, Inc.: AAtrex 4L herbicide : CGA 7L38BB 052 : 2/12 gallons, US standard measure: copyright registration for the directions for use and conditions of sale and warranty); TX0001650844 (Merck & Company, Inc.: Clinoril (selindac/ M S D:), copyright registration for the product information summary); TX0001135773 (Merck & Company, Inc.: Cosmegen (dactinomycin, M S D), actinomycin D, injection; copyright registration for the product label).

[173] *See* Calboli (2014b), p. 58.

[174] For example, in 2013, the United Kingdom eliminated the prohibition of cumulating copyright and design protection. The Enterprise and Regulatory Reforms Act 2013 extended copyright protection also to artistic works that have been reproduced more than 50 times. *See* Enterprise and Regulatory Reforms Act 2013, § 74 (U.K.) http://www.legislation.gov.uk/ukpga/2013/24/section/74/enacted.

[175] In the U.S., *see TrafFix Devices v. Mktg. Displays*, 532 U.S. 23, 32 (2001); see also McKenna (2012), pp. 823, 824 (advocating for a broader application of the doctrine of functionality and prohibiting overlaps). In the EU, *see* Case C-299/99, Philips v. Remington, 2002 E.C.R. I-05475, ECLI:EU:C:2002:377; Case C-48/09, Lego Juris v. OHIM, 2010 E.C.R. I-08403, ECLI:EU:C:2010:516; Case C-30/15, Simba Toys v. European Union Intellectual Property Office (EUIPO), 2016 EUR-Lex-62014TJ0687, ECLI:EU:C:2016:849. *See also* the contributions in The Protection of Non-Traditional Trademarks: Critical Perspectives (Irene Calboli & Martin Senftleben eds., 2018).

bright line rules also in this respect and the decision frequently falls with the courts.[176]

To date, several national decision related to overlapping rights in the context of parallel imports have focused on the mutual overlap between copyright or trademark rights, the use of copyright for incidental product features,[177] and the overlap between patent and trademark rights.[178] In the reminder of this section, I address the overlap between copyright and trademarks and the use of copyright on incidental feature, including the use copyright protection against generic pharmaceuticals. The use of copyright in this context is particularly pernicious. Copyright protection applies without the need of registration or other formalities across all members of the Berne Convention for the Protection of Literary and Artistic Works, which makes its enforcement with respect to pharmaceuticals both inexpensive and applicable worldwide without the need to market the product in the countries where protection is sought. Trademark protection is also useful, but is based on national registration and/or national use. Moreover, marks are deemed abandoned after a few years of non-use. Still, trademark protection's primary advantage remains the potential for perpetual protection as trademarks can be renewed for an unlimited number of times while copyright also expires.[179]

The overlap between trademark and copyright protection came to the attention of the courts first in Australia, a country practicing international trademark exhaustion but national copyright exhaustion.[180] In 1986, however, this strategy went too far when the parallel imports of liqueur bottles were stopped based on infringement of the copyright in the labels affixed to the bottles.[181] Considerable criticism followed this decision, and in turn the Australian Parliament deliberated to introduce Section 44C into the Copyright Act to prevent similar situations in the future. The new provision specifically prohibits against invoking copyright protection (and national copyright exhaustion) in the context of parallel imports. The provision reads that "[t]he copyright in a work a copy of which is, or is on, or embodied in, a non-infringing accessory to an article is not infringed by importing the accessory with the article"[182]—"accessory" being defined as: labels, packaging, containers,

[176] Australia, Singapore, and other parts of the Commonwealth practice a demarcation between copyright and design protection regarding artistic works that are reproduced in series. In particular, creators generally lose copyright protection in artistic works when the works are industrially applied (more than 50 copies of the work are made) or when the work is registered, or could be registered, as a design (the owner must then rely on the Designs Act). *See, e.g.,* Copyright Act 1968 (Cth) §§ 75, 77, and 77A (Austl.); Singapore Copyright Act of 1987, §§ 69, 70, and 74 (2006) (Sing.).

[177] *See* Calboli (2014b).

[178] *See infra* discussion and cases cited in Part IV.B.

[179] Ginsburg and Calboli (2020), p. 434.

[180] *See, e.g.,* Calboli and LaFrance (2013), p. 1.

[181] R A & A Bailey & Co. Ltd. v. Boccaccio Pty. Ltd. (1986) 6 IPR 279.

[182] *Copyright Amendment Act (No. 1) 1998* (Cth.) [Austl.] (amending § 10(1) and adding ss. 44C, 112C).

instructions, warranties, "or other information," as well as instructional sound recording or films, "provided with the article."[183]

IP holders played a similar game in the U.S. and Canada, until the respective Supreme Courts called it off. In the U.S., the 2013 decision in *Kirtsaeng v. Wiley and Sons*[184] clarified that the Copyright Act provides for a system of international exhaustion. Previously, however, the majority of courts supported that the combined reading of Section 109(a) and Section 602(a)(1) of the Copyright Act prescribed national copyright exhaustion.[185] Before *Kirtsaeng*, IP holders used copyright protection to block parallel imports of otherwise legitimate products—famous examples were shampoos bottles[186] and sports watches.[187] Similarly, Canada practices international trademark exhaustion and national copyright exhaustion.[188] In *Euro-Excellence, Inc. v. Kraft Canada*, Kraft sued an importer for copyright infringement for the importation of chocolate bars.[189] The Supreme Court found the imports to be lawful, however, even though it reached its decision "on contractual grounds."[190] In 2013, Professor Mary LaFrance and I[191] proposed a legislative provision be implemented in the U.S. similar to the amendment approved in Australia in order to prohibit the enforcement of a claim for copyright infringement on "accessory copyright."[192] A revision of copyright law to this extent would prevent misuses of copyright law to block the parallel imports of otherwise legitimate products, in particular when the claim for copyright infringement refers to accessories or nonessential parts of the products.[193] Even though the US currently applies international exhaustion both for patents and copyrights, a similar

[183] *Id*. In 2003, the Australian legislature expanded this list, and added that a "computer program," "electronic literary or music item," or "sound recording" that is part of or combined with imported articles are also "accessories. *Copyright Amendment (Parallel Importation) Act 2003* (Cth.) [Austl.]. *See* Polo/Lauren Co. LP v. Ziliani Holdings Pty. Ltd. [2008] 75 I.P.R. 143 (F.C.A.) (applying the provisions and finding that parallel imports of polo shirts were not infringing). *See* Ghosh and Calboli (2018), pp. 148–152.

[184] *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351, 1358 (2013).

[185] For a detailed reconstruction of doctrine of copyright exhaustion in the U.S., *see* Calboli (2014c), p. 75; Ghosh and Calboli (2018), p. 116.

[186] *Quality King Distribs., Inc. v. L'Anza Research Int'l, Inc.*, 523 U.S. 135 (1998).

[187] *Costco Wholesale Corp. v. Omega, S.A.*, 131 S. Ct. 565 (2010).

[188] *See* Ghosh and Calboli (2018), p. 122.

[189] Euro-Excellence Inc. v. Kraft Canada Inc., [2007] 3 S.C.R. 20, 2007 SCC 37.

[190] *Id*.

[191] Calboli and LaFrance (2013), p. 1.

[192] *Id*. at 266-72 (referring also to the relevant case law in Australia).

[193] *See supra* note 172 listing examples of copyright registration for medicines in the U.S. For an example of attempt to enforce copyright against a generic pharmaceuticals producer, see SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc. 211 F.3d 21 (2d Cir. 2000) (holding that copyright liability does not attach to the use by the seller of a generic medicine of the label of the same medicine by the originator company, the Nicorette gum, after the generic seller had obtained FDA approval to sell the medicine).

amendment would prevent the opportunity for future strategic overlaps, should the law again be amended toward a system of national exhaustion.

Attempts by the pharmaceutical industry to use copyright law have been acknowledged in the U.S. and Australia, for example, even though this use was not with respect to parallel imports of genuine products but to block the introduction to market of generics nationwide. In 2000, the U.S., an originator company attempted to block the distribution of a generic claiming copyright infringement on the FDA-approved labelling that the generic manufactured used. This claim was rejected by the court based on the fact that the Hatch-Waxman Act requires the use of the "same" labelling and accordingly this requirement trumps the possibility to claim copyright infringement on pharmaceutical labels. Still, the court stated that copyright protection could be used, not regarding labels, but other materials such as advertising.[194] Similarly, in Australia, in 2008, an originator company claimed copyright infringement against a generic producer because of the reproduction of the legally required product information of the medicine. This claim was eventually also rejected and led to adoption of another amendment in Australia: the Therapeutic Goods Legislation Amendment (Copyright) Bill 2011, which was passed in 2001 and introduced Section 44BA to the Copyright Act.[195]

In Norway, however, the pharmaceutical industry attempted to claim copyright infringement against parallel imports within the EU/EEA. This attempt was also rejected.[196] Notably, the Norwegian Medicines Control Agency had provided notice to the industry that it would allow parallel importers to use the official Summaries of Product Characteristic (SPCs) given by originator companies for the purpose of seeking the importing authorization for intra EEA parallel imports. Astra Norge sued the Norwegian government on the claim that this infringed its copyright in the SPCs. The court of first instance ruled in favor of Astra Norge, but the court of appeal referred asked to the EFTA court if this decision would violate the EU Directive on marketing authorizations.[197] In conclusion, the EFTA Court ruled that indeed a finding of copyright infringement would represent a measure having equivalent

[194] *SmithKline Beecham,* 211 F.3d 21. *See* Tsien (2014), p. 334, 366.

[195] *Therapeutic Goods Legislation Amendment (Copyright) Bill 2011 (Cth)* [Austl.] (adding s. 44BA). According to the new provision the copyright infringement cannot be invoked: "2 . . .: (a) supplying, in Australia, some or all of any product information that is approved. . . in relation to medicine; (b) reproducing, in Australia, [this] information . . .; (c) publishing, in Australia, [this] information . . .; (d) communicating, in Australia, [this] information . . .; (e) adapting, in Australia, [this] information . . .; to the extent that the supply, reproduction, publication, communication or adaptation is for a purpose related to the safe and effective use of the medicine referred to in paragraph (a)." Moreover, "3. An act done in Australia that is ancillary or incidental to a supply, reproduction, publication, communication or adaptation referred to in subsection (2) is not an infringement of any copyright . . ." I am grateful to Luigi Palombi for pointing me to this specific amendment.

[196] This is reported by Stothers (2007), p. 426 (citing the decision Case E-1/98 Norway v. Astra Norge [1998] EFTA Court Reports 140).

[197] *Id.*

effect to a quantitative restriction and a disguised restriction to EU/EEA trade.[198] Once again, the principle of free movement in the EEA prevailed over the attempt to use copyright (or other IP rights) to block intra EU/EEA parallel trade. Ultimately these various attempts demonstrate that IP holder always try to use multiple avenues to pursue their interests, the enforcement of copyright to features of the packaging or information annexed to the medicines being also one of these avenues.

4.2 Enforcement of Trademark Rights to Parallel Imports of Pharmaceuticals

In addition to (attempting to) enforce copyright protection, an additional avenue to attempt to block the parallel imports of pharmaceuticals, and products in general, is the enforcement of trademark protection for products that may still be protected by patents or whose patent protection has expired.

The advantage of this overlap is obvious when the country of importation practices international exhaustion for patents but national exhaustion for trademarks, as the imports can then be blocked as a trademark infringement. For example, amongst the countries analyzed in Part III, several of the countries practicing international patent exhaustion have no clear policy in the area and apply instead national trademark exhaustion.[199] This is the case, for example in LDCs in ASEAN, Cambodia and Lao PDR,[200] which block parallel imports under trademark law. Also in Thailand, which does not have an express position on trademark exhaustion in general, it has been noted that trademark law can be invoked to block the imports of pharmaceuticals not imported directly by the trademark holders.[201] Another country practicing national trademark exhaustion is Brazil, with the exception of the instance where the trademark holder has not restricted in licensing agreements against parallel imports into Brazil or does not have a licensee in Brazil.[202] Unfortunately,

[198] *Id*.

[199] Ghosh and Calboli (2018), p. 65. *See also* Grigoriadis (2014).

[200] *See* Law Concerning Marks, Trade Names and Acts of Unfair Competition of the Kingdom of Cambodia, Art. 11(c) (Cambodia); Lao PDR Law, *supra* note 81, at art. 57(3) lit. 1.

[201] *See* Lifescience Asia-Pacific Network, A Comparative Overview of Distribution and Marketing of Drugs in Asia-Pacific:, p. 49. https://corrs.com.au/site-uploads/images/PDFs/Insights/article-IP-comparative-overview-of-distribution-and-marketing-of-drugs-across-asia-pacific.pdf (noting that, in Thailand, "parallel imports are not permitted in the pharmaceutical sector because it is mandatory for a company to preliminarily obtain an import license and product registration locally" and that "the FDA will not accept an application for a product with a trademark that is identical to other products in the Thai market, unless this product has the same manufacturer and the manufacturer has given its authorization to use and sell the product.").

[202] Brazilian IP Law, *supra* note 112, Art. 132 (III). *See also* Grigoriadis (2014), pp. 457–458 (highlighting that Brazil practices national trademark exhaustion even though it is a Member State of Mercosur, which establishes the principle of international exhaustion under Article 13 of the

information is not readily available at this time regarding the position several African countries, in particular LDCs, adopt on trademark exhaustion. Still, there are no doubts the effect of the limitations invoked under a system of national exhaustion are very relevant, as they can contribute to effectively blocking medicines from entering the countries allowing these imports under patent law.

IP holders have invoked trademark law to block the parallel imports also within regions that practice regional exhaustion, notably in the EU. However, the CJEU resisted the IP overlaps game and, in most instances, ruled in favor of parallel imports. As mentioned above, free movement of goods is one of the fundamental freedoms of the EU, and the CJEU long made it clear that the exercise of IP rights cannot trump free movement. Moreover, the CJEU designed the principle "mutual recognition" according to which Member States should accept "the sale in [their] territory of a product lawfully produced and marketed in another Member" even when the "technical or quality requirements . . . differ from those imposed on [their] domestic products."[203] In other words, genuine products of materially different quality cannot be blocked within the EU/EEA as long as they comply with national standards, which today have largely been replaced with EU standards. However, in the EU cases in question, parallel importers repackaged the pharmaceuticals—thus, the products carried differences in quality not because the trademark holder had produced them as such, but because the importers had altered the quality of the packaging. Yet, the CJEU still allowed the imports.[204]

In particular, the CJEU supported trademark rights could not be enforced against repackaged parallel imported medicines when "the repackaging did not adversely affect the original condition of the product" and that "the trade mark owner receives prior notice of the marketing of the repackaged product."[205] In *Bristol-Myers Squibb v. Paranova*,[206] the Court created a specific list of conditions for the repackaging and stated that: (1) it should be necessary to market the product in the country of importation; (2) does not affect the original condition of the product inside the packaging; (3) clearly states who repackaged the product and the name of the manufacturer; (4) does not damage the reputation of the trademark or of its holder; and (5) the importer gives notice to the trademark holder before the repackaged

Protocol on Harmonization of Norms on Intellectual Property in Mercosur in Matters of Trademarks, Indications of Source and Appellations of Origin adopted in 1995).

[203] Commission Communication No. C 256/2, Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 Feb. 1979 in Case 120/78, 1980 O.J. (C 256) 2, 2–3 (EC). The CJEU developed the principle of "mutual recognition" in Case 120/78, Rewe-Zentral AG v. Bundesmonopolverwaltung fur Branntwein, 1979 E.C.R. 649 (*Cassis de Dijon*).

[204] *See* Stothers (2016), pp. 171–175.

[205] Hoffmann-La Roche v Centrafarm, 1978 E.C.R at 1166. *See* Stothers (2016), pp. 171–172.

[206] Joined Cases 427, 429 & 436/93, Bristol-Myers Squibb v. Paranova 1996 E.C.R. I-3457. *See* Stothers (2016), pp. 172–173.

product is put for sale, and, on demand, supplies her with a specimen.[207] In addition, the CJEU ruled that even changing the mark on the packaging (with the mark used by trademark holders in the country of importation) was not grounds to prohibit parallel imports if the trademark holders deliberately used different marks in different EU countries.[208] This constituted, according to the Court, a "disguised restriction on trade between Member States" under the rule of Article 36 of the Treaty[209] as long as[210] the mark's replacement is "objectively necessary"[211] and not only for "the parallel importer . . . to secure a commercial advantage."[212] Still, despite these supportive rulings regarding parallel imports of pharmaceuticals, the CJEU also ruled a decade ago the unauthorized repackaging and relabeling of genuine products may constitute "legitimate reasons" against parallel trade within the EU/EEA when this may lead to consumer confusion or provoke unfair detriment to a mark's reputation.[213]

Using trademark protection can prove useful to block parallel imports not only when a country practices national exhaustion but also when it follows a system of international trademark exhaustion.[214] Notably, under the rule of several national trademark laws—the U.S., Canada, India, China, Korea, Singapore, amongst others—IP holders can oppose parallel imports under a regime of international exhaustion when the quality of the imported products is different of those sold nationally, even if the products are genuine and were first marketed by IP holders in foreign markets.[215] This principle is based on the idea trademarks indicate to

[207] Several cases followed from these "BMS conditions," which frequently were resolved in favor of parallel importers. *See* Stothers (2016), p. 172 (citing C-143/00, Boehinger Ingelheim v. Swingward, 2002 E.C.R. I-3759; Case C-348/04, Boehinger Ingelheim v. Swingward, 2002 E.C.R. I-3759, as applied by the English Court of Appeal in [2008] EWCA (Civ) 83; Joined Cases C-400/09 and C-207/10, Orifarm v. Merck Sharp & Dohme, 2011 E.C.R. I-7063). As we have seen in Section III regarding the Specific Mechanism, the requirement to notify the originator of the pharmaceuticals remains, however, an important condition to fulfil by parallel importers. Courts have rules that failure to notify will result in finding of infringement. *See Id*. at 173 (citing Hollister v. Medik Ostomy Supplies, [2012] EWCA (Civ) 1419, [2012] W.L.R 327 (Eng.)).

[208] Case 3/78, Centrafarm BV v. American Home Prods. Co., 1978 E.C.R. 1823.

[209] *Id.* at 1841–1842.

[210] Case C-379/97, Pharmacia & Upjohn v. Paranova, 1999 E.C.R. I-6927.

[211] *Id.* at I – 6967–6969.

[212] *Id. See* Stothers (2016), pp. 174–175 (citing Specialty Euro. Pharm. v. Doncaster Pharms. Ltd., [2015] EWCA (Civ) 54, [69], [2015] W.L.R.).

[213] Case C-59/08, Copad, SA v. Christian Dior Couture SA, 2009 E.C.R I- 03421 (stating that a trademark owner may oppose the unauthorized sale of luxury goods to discount stores by a licensee if the sale could damage the reputation of the mark). *See* Calboli, *Reviewing Trademark Exhaustion*, *supra* note 10, at 261–262.

[214] *See, e.g*., Calboli (2011), p. 1241; LaFrance (2013), p. 45.

[215] Ghosh and Calboli (2018), p. 65; Grigoriadis (2014).

consumers origin and consistent quality.[216] Accordingly, consumers could be confused when they rely on the mark affixed to the paralleled imported products, but these products are "materially different" in quality.[217] Small quality differences often apply to products marketed in different countries because of national standards or producers' choices (or marketing partitioning strategy by IP holders).[218] In some countries, like the U.S. and Singapore, this rule is mitigated by the use of disclaimers—in other words, the products can still be lawfully imported as long as the importers properly labels the products indicating their origin and quality dispelling the risk of consumer confusion.[219] Yet, in an action for infringement, it is up to national courts to decide the extent they could find these disclaimers weigh against a likelihood of consumer confusion. Courts in the U.S., for example, have interpreted the concept of "material differences" broadly, to include a large set of product features and accessories and have blocked parallel imports accordingly.[220]

In summary, it is not surprising that the pharmaceutical industry considers trademark protection as an important avenue to block parallel imports even though the courts have frequently denied their claims. Considering the expansion of trademark protection, that can protect today the packaging but also the color and shape of several pharmaceuticals, and the length that this protection grants due to the possibility to renew the protection indefinitely, we will certainly continue to see more activity in this respect.

[216] *See* Landes and Posner (1987), pp. 265–266 ("[T]rademark law . . . can best be explained on the hypothesis that the law is trying to promote economic efficiency."); *see also* Economides (1988), p. 523, 526; Kratzke (1991), pp. 199, 205.

[217] *See* Schechter (1927), p. 813, 818 ("The true functions of the trademark are, then, to identify a product as satisfactory and thereby to stimulate further purchases by the consuming public."); Sanders and Maniatis (1993), p. 406.

[218] Calboli (2011), p. 1271.

[219] Tariff Act, 19 U.S.C. § 1307 (1930). "This product is not a product authorized by the United States trademark owner for importation and is physically and materially different from the authorized product." The disclaimer must be "designed to remain on the product until the first point of sale to a retail customer in the United States." 19 C.F.R. § 133.23(b).

[220] In the US, for example, *see Societe Des Produits Nestle S.A. v. Casa Helvetia, Inc.*, 982 F.2d 633, 639 n.7 (1st Cir. 1992) ; *Lever Bros. Co. v. U.S.*, 877 F.2d 101, 103, 108 (D.C. Cir. 1989); *Dial Corp. v. Encina Corp.*, 643 F. Supp. 951, 952 (S.D. Fla. 1986); *Ferrero U.S.A., Inc. v. Ozak Trading, Inc.*, 753 F. Supp. 1240, 1243, 1247 (D.N.J.), *aff'd,* 935 F.2d. 1281 (3rd Cir. 1991); *El Greco Leather Prods. Co. v. Shoe World, Inc.*, 806 F.2d 392 (2d Cir. 1986).

5 Conclusion: A Call for a Wider Application of the Flexibility of Article 6 of the TRIPS Agreement in Developing and Least Developed Countries

In the light of the above, what conclusions could be derived from the comparative review offered by this chapter regarding domestic policies on patents exhaustion and the application of overlapping IP right to the parallel imports of pharmaceuticals?

At the outset, the analysis elaborated in this chapter confirms that the national treatment of the principle of IP exhaustion remains a highly complex legal question across different jurisdictions. This is even more true regarding pharmaceuticals considering how many countries apply differentiated rules or have recently changed their national laws to address these imports. As I anticipated in the Introduction, this review also confirms that the principle of IP exhaustion remains a relevant tool for countries' international trade policies, including for trade in pharmaceuticals. In turn, it is still important to engage in scholarly discussions on this area, even though other factors—from marketing approvals, to import authorizations, or contractual restrictions—can affect the admissibility of these imports into national markets. For example, domestic policies providing for national exhaustion can become the ultimate barrier against parallel imports of pharmaceuticals in the instances in which national governments do grant the necessary regulatory approvals (or recognize specific foreign approvals) to these products. To the contrary, domestic policies on international exhaustion would become the decisive factor to permit these imports into national markets. In addition to patent exhaustion, domestic policies on trademark or copyright exhaustion can also be used as effective barrier to the parallel imports of pharmaceuticals, including generics.

More specifically, the comparative review presented in this chapter highlights that, twenty-five years after the adoption of the TRIPS Agreement, a number of national governments are using more actively the flexibility offered by Article 6 of the TRIPS Agreements in order to frame national solutions on the application of the principle of IP exhaustion in ways that best fit their international and domestic trade-related interest. Several countries, developing and developed countries, have undergone specific revisions of their national laws in this respect, and the interpretation of the principle of exhaustion has been debated at large by national courts in the past several decades. In general, both national legislators and judges seem to have acquired a better understanding of the possible applications of this principle. National and international economic studies have also been prepared to assist policy makers in determining the economic implications of legislative choices in this area. Interestingly, several developed countries, including the US and Canada, have changed their national policies from national to international patent exhaustion—even though parallel imports may still be blocked in several countries through (enforceable) contractual restrictions and, with respect to pharmaceuticals, by the mentioned regulatory requirements.

To the contrary, legislative or judicial reforms in favour of more liberal policies on IP exhaustion are still not the case for several developing countries and LDCs.

Instead, as noted in this chapter, several of these countries continue to follow a system of national patent exhaustion. For example, this position is followed by several LDCs in Africa. Several developing countries and LDCs even allow for the enforcement of overlapping IP rights in their jurisdictions. As noted in this chapter, the LDCs countries members of OAPI follow a system of regional exhaustion, which remains more restrictive than international exhaustion. These findings, and the limited use of the flexibility of Article 6 of the TRIPS Agreement in these countries, are the most problematic conclusions from the comparative review in this chapter. The reasons for these choices are difficult to identify as the legislative history of these laws cannot be easily reconstructed, but most likely range from the lack of expertise of national legislators, to the lack of economic studies regarding these countries, or the absence of, or low quality technical assistance, or the pressure of foreign governments and business interests, including trade-offs accepted as part of trade agreements or foreign direct investments. Regardless of the reasons, these national policies are problematic as they undermine the possibility, for these countries, to import less costly products, including pharmaceuticals. In the case of pharmaceuticals, these national policies could essentially amount to block these countries from accessing life saving medicines for their citizens.

Simply put, it is almost paradoxical, and quite problematic, that several developed countries currently apply less restrictive IP exhaustion policies than a number of developing countries and LDCs, whereas the former have larger economic capabilities and access to products than the latter.

The last conclusion that can be derived from the comparative review in this chapter is the relevance of IP overlaps in this debate, in particular when countries practice different type of exhaustion—national instead of international. In particular, it is clear that only when countries practice international exhaustion for all IP rights overlapping IP protection cannot interfere with the general admissibility of parallel imports in that country—at least from the perspective of the enforcement of IP rights. As a result, pharmaceutical companies have attempted to invoke copyright and trademark rights to block the further circulation of their products or to block the introduction to market of generics. In the EU, in particular, companies have invoked both copyrights, and most frequently trademark protection to try to block the parallel trade of their products within the EU since the late 1970s. As mentioned in this chapter, copyright could be used to protect the packaging, the logos, and the instructions of the medicine. Likewise, trademark rights are granted today not just for the marks affixed to the pharmaceutical packaging, but also on the pills, the devices necessary to inhale the medicines, etc.

This finding, certainly not new but not frequently raised in the debate of scholars, which are experts on patents and pharmaceuticals, is also problematic. In particular, the enforcement of these additional rights can easily nullify the effects of domestic policies on international patent exhaustion, should countries practice national trademark or copyright exhaustion. The same applies, as this chapter illustrates, when IP holders can invoke differences in the quality of the products, even in the case of domestic policies providing for international exhaustion. Again, calling upon these rights may become a last resort for the pharmaceutical industries—which still

heavily relies on regulatory schemes to control the international distribution of pharmaceuticals—and courts seem to have rarely supported these claims. Yet, these disputes may not be representative of the number of claims actually used in cease and desists letters to parallel importers and distributors of these products nationally. As it is known, very few disputes reach the courts, due to the time and legal fees involved. Instead, most disputes are settles in highly secretive and nontransparent out-court proceedings where dubious claims and weak rights—such as copyright and trademark protection for pharmaceuticals—can be validated by the parties in the settlements. Ultimately, this large numbers of rights simply offers more arrows that IP holders to throw against parallel imports, and we can be sure that, should the occasion arise, the arrows will be used with full force.

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