

A Limitation on the Patent Right to Exclude: International Exhaustion¹

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This chapter provides an important clarification to the usual patent rights that were first explained in Chapter One. In particular, this chapter explains that patent owners may sometimes lack the ability to exclude imports of patented drugs that they previously sold in another country. Whether or not the patent owner lacks this ability depends on whether a nation follows a legal doctrine called *international exhaustion* to exclude what are referred to as *parallel imports*. This chapter explains these terms, the controversy concerning this doctrine, and how well as how it impacts the commercial sale of drugs. Consistent with the focus of this book on presenting current realities, this chapter focuses on existing laws that are often driven by patent-owning companies; as will be explained, such companies are often opposed to international exhaustion, despite the fact that such a doctrine may have positive social effects. Understanding these issues provides helpful background to other chapters since the controversial issue is often at play in the development of international laws. This chapter answers some key questions concerning international exhaustion, such as the following:

- What is international exhaustion?
- What are the reasons for and against recognizing international exhaustion?
- Why are patent-owning drug companies generally opposed to international exhaustion?
- How do companies effectively market their drugs in a world where some countries recognize international exhaustion?

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I. Introduction

This chapter explains how patent laws may impact international trade in patented drugs, as well as profits of drug companies. While there are many things that impact free trade, the issue here is whether patent laws permit—or prevent—free trade of drugs first sold by the patent owner in another country. The relevance of this can be illustrated by considering the following scenarios:

- The owner of a patent on an HIV drug in Rwanda is considering selling the drug at below-market prices in Rwanda in recognition of the AIDS epidemic, poverty in the country, as well as public

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pressure. However, the patent owner is hesitant to do so for fear that some of these drugs could be purchased and resold in markets where the patent owner typically sells the same drug for a much higher price.

- A cancer drug is patented in both Canada and the United States. However, the drug costs less in Canada where drugs are subject to price caps. The patent owner should be able to sell the patented drug for a higher price in the United States—but only to the extent it can prevent the cancer drugs sold in Canada from being imported into the United States market for a lower price.

In both of the above scenarios, the patent-owning drug company has a clear interest in ensuring that lower-priced drugs in one market do not enter a higher priced market where the patent owner sells the identical drug—at a higher price. Consumers would prefer access to lower priced goods from a different market. Whether have such access depends on the the doctrine of international exhaustion.

One of the basic rights granted to a patent owner is the right to exclude imports of the patented product. So, it would seem that this basic right would protect the patent owner in the above scenarios. However, some countries have an exception to the usual right to exclude imports of a patented product. In particular, some nations’ patent laws bar a patent owner from excluding importation of a patented product the patent owner first sold in another country.² This is referred to as *international exhaustion* of patent rights because the first unrestricted global sale of the patented product is considered to have exhausted the patent owner’s rights to that product. Some suggest that exhausting the patent owner’s rights is fair since not only has the patent owner already received a profit, but consumers are also entitled to the lowest possible global price. On

² As discussed in Chapter One, a patent is granted by a nation and only has effect within that nation. Accordingly, in this scenario, the reference to a “patented product” is to a product that has been successfully patented in two separate countries, such that it is effective in both countries.

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the other hand, some suggest that exhaustion may reduce prices in the short term, but ultimately increase overall prices because companies would uniformly price goods higher, as will be explained later.

II. Explaining Exhaustion

Because international exhaustion can be confusing in addition to controversial, this Part begins with a brief review of patent rights, as well as the related and relevant concept of domestic exhaustion. International exhaustion will then be explained, followed by a discussion of terms that are frequently used in conjunction with discussions of international exhaustion.

A. Domestic Exhaustion

A patent owner's usual rights include the right to exclude others from making or distributing the patented product within the patent-granting nation. The right to control distribution covers a variety of activities including selling, offering for sale, and importing. However, when a patented product is first sold with the patent owner's authorization—either from the patent owner himself or his licensee with no contractual limitation—the patent owner generally loses the ability to control future sale of the sold product.³

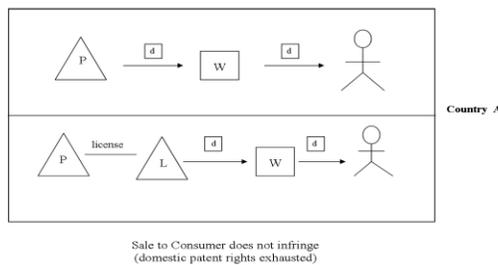
Figure 4 provides a visual depiction of two different scenarios of domestic exhaustion that occur in country A. In the first case, the patent owner (“P”) sells the drug (“d”) to a wholesale company (“W”). At this point, the patent owner's rights in the drug are exhausted. Accordingly, when wholesale company sells that drug to the consumer, there is no patent infringement. Although sale of a patented drug usually violates the patent owner's right, there is no such violation if the patent owner's rights have been exhausted, as in this case. In the second scenario,

³ A patent owner can arguably avoid the default rule of exhaustion by specifying a different rule in contract, although whether such contracts are legally enforceable raises additional issues. For the sake of simplicity, this chapter focuses on exhaustion issues without contractual limitations.

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the patent owner P does not sell the drug directly, but instead licenses a company (“L”) to make and sell the drug. L is thus a company authorized to sell the patented drug. When L sells the drug to the wholesale company, the patent rights are similarly exhausted. Accordingly, the end result is the same whether the patent owner originally makes and sells the patented good, or the patent owner authorizes a licensee to do the same—after the first authorized sale, the patent owner has no ability to control further distribution of the product.

Figure 4: Domestic Exhaustion



The reason that a patent owner’s right to domestically control his patented item is “exhausted” after the first legitimate and unrestricted sale is that the patent owner is presumed to have obtained an adequate economic return with the initial sale, such that further control of the patented item is not appropriate. The purchaser of the patented item is then free to use or sell the patented item to others—despite the fact that using and selling a patented invention typically gives rise to liability. This principle is enshrined in domestic laws and referred to as *domestic*

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exhaustion; alternatively, it is referred to as national exhaustion.⁴ After all, the rights of the patent owner are “exhausted” only with respect to goods that are sold domestically in the patent-granting nation.

Before proceeding further, let us consider an example of how domestic exhaustion works. Assume that patent owner Novexis sells a box of a patented drug for attention-deficit disorder to wholesaler X without any restrictions. Once the sale is completed, patent owner Novexis has exhausted its patent rights in that box and cannot control what X does with that box. X is free to use the drug or re-sell it.⁵ The patent owner’s usual right to exclude others from using or selling the patented invention does not apply to X because Novexis’ rights in that box have been “exhausted.”

However, Novexis *can* prevent X from *making* a duplicate of the drugs that X bought. Exhaustion of rights only applies to those specific goods sold by the patent owner. The right to exclude others from *making* goods is not impacted by the doctrine of exhaustion. Accordingly, the patent owner still retains the right to exclude X from making a new version of the patented good. If X makes the patented product without authorization, X would violate Novexis’ patent rights. In addition, the patent owner Novexis can and likely will make more of the patented drug—the exhaustion of its rights only apply with respect to goods the patent owner sold. Exhaustion has no impact on the patent owner’s ability to make and sell additional copies of the patented good. However, because patent owners know and expect that they will not be able to

⁴ Countries may provide an explicit exception in the same statute that provides patent rights, or recognize domestic exhaustion through case law.

⁵ Of course, there may be other laws that regulate whether it is permissible for a buyer of a patented drug to give the patented drug to another.

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control further distribution of their patented drug, they charge a high price for the first sale of the patented drug.

Before moving on to international exhaustion, the following questions should help recap the principles of domestic exhaustion:

Q: Does domestic exhaustion of patent rights bar the patent owner from suing others who make the patented drug?

A: No. Domestic exhaustion of patent rights only applies to sales of products from the patent owner himself (or those authorized by the patent owner).

Q: Does domestic exhaustion of patent rights prevent the patent owner from making more products like the one that is exhausted?

A: No. The exhaustion principle refers to rights in a *single product* (for example, a single box of Novexis' attention deficit disorder drug) that are exhausted when the patent owner sells it. The patent owner can make unlimited additional products—and sell them subject to the same domestic exhaustion principle.

B. From Domestic to International Exhaustion

Domestic exhaustion is the basis for the related, but more controversial doctrine of *international exhaustion*. Just as the first unrestricted sale of a patented product exhausts the patent owner's right to control the product domestically, *international exhaustion* limits the patent owner's right to control a product that has been sold without restriction anywhere in the world, i.e., the first *global sale*. The first global sale is considered to exhaust the patent owner's right to continue to control the product it sold. The patent owner is presumed to have received an adequate reward with the first global sale of the patented product, such that it should not be entitled to further control the item.

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International exhaustion has a similar effect as domestic exhaustion, but impacts a different patent right. Domestic exhaustion provides an exception from the patent owner's usual right to restrict domestic use or sale of patented products—when the products were first sold by the patent owner. In contrast, international exhaustion is an exception from the patent owner's usual right to exclude *imports*—when the first *global* sale is by the patent owner. In a country that adopts international exhaustion, if a patented product is imported into that country that has been first sold in another country by the patent owner without restriction, the importation does not constitute infringement.

Importantly, domestic and international exhaustion only limit some of the usual patent rights. Domestic exhaustion only limits the patent owner's right to control *some* sales and international exhaustion only impacts the patent owner's right to control *some* imports. For both types of exhaustion, the patent owner rights are limited only with respect to products that the patent owner himself sold or authorized to be sold. A patent owner always retains the right to exclude patented products made or sold by *others*. In the domestic context, the patent owner can exclude others from making the patented product. Similarly, a patent owner can always bar imports of a patented product made by another.

While domestic and international exhaustion have many similarities, one major distinction is that while domestic exhaustion is universally recognized, international exhaustion is not. A patent owner can not control a patented product it sold domestically – absent an agreement to the contrary. On the other hand, a patent owner's ability to control a patented product in global trade depends on whether the *importing* country recognizes international exhaustion. If the importing country recognizes international exhaustion, the patent owner cannot bar imports of a patented product it first sold elsewhere. On the other hand, if the importing country *rejects* the principle of

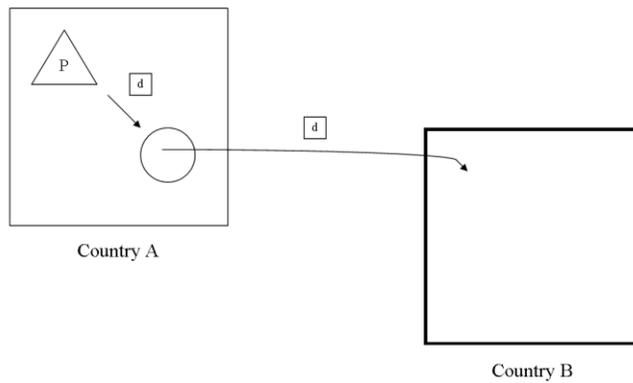
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international exhaustion, the patent owner will have the right to bar importation of its patented product it first sold in another country.

Figure 5 emphasizes that in evaluating international exhaustion, the focus is on the laws of the importing country, which is noted as “Country B.” As shown here, the patent owner first sells the patented drug, “d” in Country A. That same drug is then imported to Country B. Whether the importation in Country B constitutes patent infringement depends on whether Country B recognizes or rejects international exhaustion. The border of Country B is bolded to emphasize that only the importing country’s laws (not the exporting country) are relevant to this issue. If Country B recognizes international exhaustion, the importation does not violate any patent rights. On the other hand, if Country B rejects international exhaustion, the importation would constitute an infringement of the patent in Country B.

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Figure 5: International Exhaustion:
Look to Importing Country (B's) Law



FAQ on International Exhaustion:

Q: What do domestic and international exhaustion have in common besides using the word “exhaustion”?

A: They are both exceptions to the patent owner’s usual right to exclude all others from a host of activities relating to the invention. In addition, the policy reason is similar—in both cases, the patent owner is presumed to have received the full benefit of the patent with the first sale (whether that took place domestically or globally).

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Q: Do all countries recognize international exhaustion?

A: No! This is a highly contentious issue on which countries have been unable to agree.

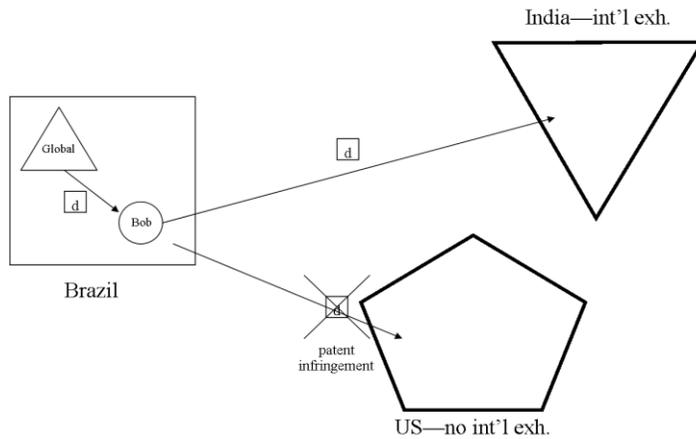
Q: Does international exhaustion only exist if recognized by both the exporting and importing country?

A: No. International exhaustion refers to the *importation right*; accordingly, only the law of the importing country is relevant.

A hypothetical may be helpful to further reinforce how the doctrine of international exhaustion determines whether an imported product violates national patent laws. Assume that multinational drug company Global has patents over a drug in all relevant countries. Global sells a bottle of patented drugs in Brazil to businessman Bob. Whether those drugs may be exported to another country without patent liability depends on whether those other countries recognize international exhaustion. Technically, the issue is not about exporting the drugs (since there is no patent right to exclude exports), but, rather, about where the drugs may be imported. An individual or company in India that purchases the drugs from Bob will be able to import the drugs without any patent problem because India recognizes international exhaustion—the first global sale of the pills to Bob (in Brazil) exhausted Global’s right in those pills under Indian law as well. However, an individual or company in the United States that attempts to do the same thing will be subject to patent liability. In particular, because the US does not recognize international exhaustion, Global can legally block importation of those goods by suing for patent infringement and obtaining an injunction). A visual depiction of this scenario is show in Figure 6 with the box of patented drugs labeled as “d.”

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Figure 6: “Global” Example



Notably, whether Global can bar importation depends solely on the international exhaustion rule of the *importing* country. Accordingly, Figure 6 bolds the borders of the importing countries to underscore that it is the laws of those countries that is critical to this issue. It is of no relevance whether the exporting country (Brazil) recognizes international exhaustion since there is never a right to bar exports. Global’s patent rights can only control import, but not export of goods. There is never a patent right to exclude others from export. So, Global’s ability to control distribution of its goods will always focus on the importing country. Global can use its patent to bar importation of goods that it previously sold in another country if the importing country does *not* recognize international exhaustion.

While Global may not be able to bar importation of drugs at the border of every country, Global can always bar a variety of other activities that do not involve goods first made by the

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patent owner. In particular, Global may bar unauthorized others from making, selling, or offering to sell a duplicate copy of the patented pills. So, for example, even though international exhaustion exists in India, no one in India can make duplicate copies of the pills without permission from Global. International exhaustion of patent rights only applies to exhaustion of the usual import right—it has no impact on the patent right to exclude others from unauthorized making, using, or selling of the patented invention. Of course, once a product enters India, because India recognizes international exhaustion, the imported product may also be re-sold and used.

C. Deciphering Related Terms

Now that the implications of international exhaustion have been explained, this section will introduce related terms that are often used in conjunction or in lieu of the term international exhaustion. In particular, when goods first sold globally by a patent owner are imported into a second country without permission of the patent owner, those goods are referred to as *parallel imports*. The label “parallel” refers to the fact that these imported goods will be sold in parallel with those by the patent owner in that second country. Alternatively, parallel imports may be referred to as “gray market goods.” The word “gray” can be considered to refer to what is a gray legal area with respect to whether the goods are considered to infringe a patent right. This is in contrast to the term “black market,” which refers to illegal goods.

One important note to considering related terms is that they are not limited in application to patents. Rather, international exhaustion, as well as the related terms of parallel imports and gray market goods also apply to other types of intellectual property, such as trademark and copyright. The specifics of when parallel imports of goods protected by these other rights differ, but the concept is the same in all cases—whether importation is permissible depends on the importing nation’s rules on exhaustion.

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Labeling a good a parallel import or gray market good does not indicate whether the good infringes a patent. Whether the import actually infringes is a function of whether the import occurs in a country that recognizes international exhaustion. If it does, the parallel import is considered to not infringe the patent right. Alternatively, in a nation that does not recognize international exhaustion, the parallel import would infringe and the patent owner would be entitled to its usual panoply of remedies, including the ability to enjoin the importation and seek monetary damages.

Patented goods imported without the patent owner’s authority—whether labeled parallel imports or gray market goods—are not fake or counterfeit goods. In other words, while these goods may potentially infringe a patent, they are not *counterfeit* goods since all these goods were first sold by the patent owner. They are considered unwelcome imports to the patent owner not because they are inferior products, but because the patent owner prefers to segregate markets to attain the highest selling price in each market.

The following table provides a summary of terms that often arise in connection with discussions of international exhaustion.

Table 2: International Exhaustion—Definitions of Related Terms

Term	Definition
National Exhaustion	The general principle that a patent owner’s rights in a patented good end after the first legitimate and unrestricted sale in the patent granting nation. In other words, if patent owner Abbott sells a drug to distributor, Abbott cannot claim infringement against the distributor for selling the drug to a retailer or consumer. This is a universally recognized principle.
International Exhaustion	The first authorized and unrestricted sale of a patented product <i>anywhere in the world</i> exhausts the patent owner’s usual right to prevent import of the patented product.
Parallel Import (Good)	Importation of an authentic (non-counterfeit) product first legitimately sold in another country. The imported good is then

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	sold “in parallel” with products sold directly from the patent owner in the importing country. Parallel imports are imported without permission of the patent owner.
Gray Market Good	Parallel Import (see above definition)

The above terminology is often used in different combinations to refer to the same activity. International exhaustion refers to the legal principle regarding when a patent owner’s right to import is limited. However, there are alternative ways of stating the same thing. To help keep terms straight, the following table provides the different terminology used to refer to whether imported goods are exempt from patent infringement, or not by the importing nation.

Table 3: **Are Imported Goods Permissible?–Summary of Related Terms**

Imports of patented goods previously sold by patent owner in another country are NOT infringing	Imports of patented goods previously sold by patent owner in another country are INFRINGING
Int’l Exhaustion recognized	Int’l exhaustion <i>not</i> recognized
Parallel imports Permitted	Parallel imports <i>not</i> permitted
Gray market goods permitted	Gray market goods <i>not</i> permitted

Now that a full panoply of terms related to international exhaustion have been introduced, a few questions may help to reinforce key points:

Q: Are parallel imports counterfeit goods?

A: No. The word “counterfeit” means that goods are fake and illegitimate in that they are not authorized by the patent owner. However, parallel imports are legitimate goods made by the patent owner, or under authority of the patent owner.

Q: Do gray market goods violate patent rights?

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A: Not necessarily. The label gray market good only indicates that the good was not authorized for importation by the patent owner. However, it may nonetheless be permissible if the importing country recognizes international exhaustion.

Q: What does it mean that parallel imports are barred?

A: It means that the patent owner can block imports of patented goods that the patent owner previously sold in another country. Stated differently, parallel imports are barred from a nation that rejects international exhaustion.

III. Considering Principal Arguments

This section evaluates the arguments for and against recognizing a principle of international exhaustion for patents. Some of these arguments relate to international exhaustion of all types of intellectual property rights—not only patents, but also trademarks and copyrights. However, exhaustion of patent rights in drugs raise unique concerns because unlike other consumer goods, there are arguably safety issues at stake and patents are considered much more critical than other types of intellectual property rights to promoting an incentive for new research and development.

A. For International Exhaustion (and Parallel Imports)

The most often cited argument for international exhaustion is that it can be a means to lower drug costs. This is a major issue with respect to the supply of drugs since the same medicine—made by the same company—is often sold at different prices in different markets. Given the global environment of differing prices, permitting parallel imports should enable consumers’ access to the lowest priced drug. This can make drugs more accessible to consumers with less income and also reduce strain on national and local governments that would otherwise assist low-income consumers in purchasing drugs.

Some argue that universal international exhaustion is an optimal policy from the standpoint of efficiency. In particular, if all countries recognize international exhaustion, goods will flow freely in the

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global market. This would permit drugs to be produced in low cost regions (i.e. developing countries) and arguably result in an efficient allocation of resources. However, this is solely a theoretical argument that is unlikely to be tested in reality given strong opposition by some companies, as well as countries to international exhaustion.

Arguments for whether specific countries should recognize international exhaustion have become more important in recent years as more countries have been required to adopt patent laws pursuant to TRIPS. For a nation that has previously not provided patents and drugs and is philosophically opposed to doing so because of its impact on access to medicine, permitting parallel imports is a reasonable mechanism to comply with global laws permitting patent protection. Many have suggested that developing countries embrace international exhaustion of patent rights as one mechanism for promoting access to medicine in the wake of international obligations mandating patent rights.⁶ In addition, some suggest that even if international exhaustion were uniformly recognized, it would provide an adequate return to the patent owner who received profits with the first global sale.

B. Against International Exhaustion (and Parallel Imports)

⁶ E.g., WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH para.4.19 (2006); UK COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 42 (2002); UN General Assembly, Human Rights Council, Promotion And Protection Of All Human Rights, Civil, Political, Economic, Social And Cultural Rights, Including The Right To Development, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, A/HRC/11/12, at 11 (Mar. 31, 2009); see also Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre (2000)(providing model options for different versions of international exhaustion).

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Patent owning drug companies are strongly opposed to parallel imports; they would like all nations to universally reject international exhaustion in their patent laws. In essence, the doctrine of international exhaustion of patent rights presents a threat to their current business model of obtaining the highest price in each separate market. If a multinational drug company can block imports, it can maintain its desired business model of segregating different geographic markets. This market segregation is considered critical to maximizing patent profits since many countries have laws or regulations that restrict the price of drugs. A rational patent owner thus seeks to sell the same drug at the maximum possible price in each market. If a patent owner has an absolute right to exclude all imports—including imports of drugs it previously sold elsewhere in the world—the patent owner can effectively ensure that it has total control over the price in each market.

There are two primary reasons that (innovator) drug companies raise in opposing parallel imports of their patented products. First, they assert that geographic price discrimination actually benefits consumers by increasing the availability of locally lower-priced drugs and providing essential returns that fund the expensive development of new drugs.⁷ Second, they suggest that parallel imports threaten public health and consumer safety. Each of these arguments will be addressed and critiqued.

Does Price Discrimination Provide an Overall Societal Benefit?

Drug companies assert that the increased profits gained from price discrimination ultimately provide a social gain to consumers worldwide. In particular, they assert that price discrimination enables them to price drugs according to consumer ability to pay, with higher countries paying higher costs for the same

⁷ While this argument is couched in terms of consumer benefit, it can also be framed to focus more specifically on drug companies. In particular, companies sometimes assert that parallel imports are unfair to their ability to maximize profits—especially to the extent that some countries have price controls on products.

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drug. They suggest that without effective price discrimination, they will be forced to charge uniform prices globally, which would make drugs less available for lower-income regions. In addition, they suggest that the increased profits they gain from price discrimination is necessary to support the expense of research and development into new drugs that ultimately benefit all consumers.

While each of the above arguments sound plausible, a closer examination reveals some flaws. First, while companies may sometimes provide low cost drugs to the poorest countries, this is not always the case and in fact is seldom the case for so-called “middle income” developing countries that have low per capita income. Many consumers in poorer nations already can not afford drugs that are marketed in their countries not only because they often lack insurance, but also because they are paying equivalent prices as consumers in wealthier countries despite having less disposable income. While drug companies are generally not transparent about pricing, it would be in their economic interest to price drugs in middle-income countries so that only the wealthiest could purchase them since the poorest consumers that live on a few dollars a day are unlikely to afford most reduced prices. In addition, drug companies may be resistant to charging less because some large purchasers of medicine in rich countries may use existing prices in other countries to bargain down their purchase price.

The second is whether parallel imports undermine innovation. While drug companies do spend a substantial amount of their revenue on research, they actually spend more money on advertising and promotion of drugs. Moreover, many have questioned whether the research that drug companies focus on actually provides much of a social benefit. Most companies today focus more on developing new and often minor variations of existing drugs that are not likely to provide substantial new health benefits to consumers. In addition, companies often focus more on “lifestyle” conditions (such as depression and erectile dysfunction) that may yield a

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substantial profit in wealthy markets, rather than life-threatening diseases and conditions that predominantly affect poorer countries. While companies tend to present the issue in stark terms, there are more nuanced approaches. For example, regulatory laws could require licensed firms engaging in parallel trade to pay a fee that would go towards research and development.

Do Parallel Imports Harm Public Health and Safety?

Drug manufacturers suggest that international exhaustion is actually dangerous for consumers. In making this claim, companies emphasize that parallel imports are not sold by them, but an unauthorized distributor, such that the company cannot guarantee safety or efficacy. Companies suggest that while the imports are not fake, they may be of an inferior quality than goods sold directly by the company. First, the drug manufactures suggest that because they are/were not in control of the goods, they cannot guarantee that they will remain safe; they suggest that safety could be compromised if goods were tampered with, or because the product is fragile and needs special storage and handling. In addition they suggest that there may be a safety issue if consumers cannot read instructions written in a different language.

While drug companies frequently suggest that parallel goods are not safe or of poorer quality, there is no substantial evidence for this assertion. Counterfeit goods may indeed be unsafe and parallel goods are sometimes discussed together with counterfeits, such that there may be an improper suggestion that parallel goods are unsafe. However, parallel goods are legitimate goods made and sold by the patent owner—even if the patent owner objects to their subsequent distribution, that does not necessarily mean they are unsafe.⁸ Drug companies may protest that they cannot vouch for distribution of parallel imports, but in the modern economy, drugs are manufactured worldwide. In addition, if safety is the issue, that can be addressed through

⁸ To the contrary, parallel goods may in fact be safe. E.g., CARY COGLIANESE ET AL., IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY 116 (2009).

regulatory laws, such as regulating either the parallel trade products, or those that promote such trade.

IV. Commercial Implications

This section addresses how drug companies currently operate in an environment where some, but not all countries recognize international exhaustion. This section aims to provide a picture of the current landscape of international exhaustion, including the extent to which it currently impacts corporate profits. In addition, this section explains how other laws and strategies beyond patents help to aid in the goal of market segmentation.

An important initial question is which countries currently recognize or reject international exhaustion of patent rights. Importantly, if the markets of major profitability reject this doctrine, drug companies will still be able to mostly maximize their profits. Basically, the current global landscape is in fact favorable to patent owning drug companies. In particular, the market of highest profits—the United States—rejects international exhaustion. Accordingly, drug companies can utilize patent laws to keep out parallel imports of lower-priced drugs from other countries. The European Union also rejects the principle of international exhaustion.⁹ Thus, drug

⁹ However, the EU recognizes *regional exhaustion*, which means that once a patented product has properly entered any EU member country, the patent owner has no control over subsequent sale or distribution of that product to another EU member country. Parallel trade accounted for about two percent of the pharmaceutical market in 2003, but varies tremendously by EU member country; parallel trade may be negligible or up to twenty percent. E.g., OECD, OECD HEALTH POLICY STUDIES, PHARMACEUTICAL PRICING POLICIES IN A GLOBAL MARKET 41 (2008). While some have studied parallel trade in the EU and suggested that cost savings do not get passed along to the consumer, the parallel trade in the EU is very different than potential parallel trade for developing countries since

companies can use patent laws to preclude low-cost drugs from a country, such as Rwanda, from entering the EU.

Not surprisingly, countries that presently recognize international exhaustion include a number of developing countries. For example, India, a number of Latin American countries, and South Africa all recognize international exhaustion. However, they are not the only ones. New Zealand, a developed country also recognizes international exhaustion. Notably for drug companies, New Zealand is a much smaller market than either the United States or the EU.

While the current global landscape concerning international exhaustion seems to largely preserve drug company interests in preventing infiltration of lower-priced imports from the wealthiest markets, drug companies are nonetheless vigilant in taking a variety of actions to protect their interests.

One way that drug companies aim to minimize trade in low cost drugs is to use contracts in conjunction with seeking changes in patent laws. As noted earlier, international exhaustion generally only applies with respect to the first *unrestricted* global sale. Accordingly, drug companies place contractual restrictions on further sales. In addition, drug companies—through their national government trade representatives—may aim to ensure that other countries agree that contractual restrictions will in fact be respected. For example, as discussed in Chapter Eight, the US has included provisions in some free trade agreements that require nations to bar imports of

most EU citizens have insurance. E.g., Robert C. Bird & Peggy E. Chaudhry, *Pharmaceuticals and the European Union Managing Gray Markets in an Uncertain Legal Environment*, 50 VA. J. INT'L. L. 719 (2010).

goods sold under contractual restriction. One important market that the US has imposed this obligation on is Australia.¹⁰

The following provides a snapshot of countries that currently recognize international exhaustion, as well as those who do not:

Table 4: International Exhaustion—Sample Countries

Int'l Exhaustion Recognized (Parallel Imports Permitted)	No International Exhaustion (Parallel Imports Barred)
India	US
Latin American countries (Andean Commission Decision 85)	EU (but, regional exhaustion ok)
South Africa	Australia (if contractual restriction)
New Zealand	
Japan (unless contractual restriction)	

Even in countries that already have desirable patent laws (that reject international exhaustion), drug companies may still seek protection of their goals through additional laws. As noted in Chapter One, drug companies seek to protect drugs from direct competition not only through patent laws, but through regulatory laws.¹¹ For example, in the most profitable market—the

¹⁰ U.S.-Austl. Free Trade Agreement, art. 17.9(1)(4), U.S.-Austl., May 18, 2004, T.I.A.S. No. 6422, available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text>.

¹¹ While regulatory laws applicable to drugs are well known to ensure that marketed drugs are safe and effective, the regulatory laws of some countries go beyond these traditional goals in helping drug manufacturers attain commercial exclusivity beyond the patent system through measures called “data exclusivity” and “patent linkage,” as discussed in more detail in Chapter Nine.

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United States—regulatory laws also enable drug companies to exclude unwanted parallel imports from other countries, such as Canada.¹²

While there is an exception for limited supplies for personal use, this regulatory rule prevents large-scale imports.¹³ Although pharmaceutical countries have been very concerned about cross-border trade from Canada to the United States, the amount of such trade is very minimal compared to total sales in the United States.¹⁴

Another method companies use to supplement effective enforcement of desired patent and regulatory laws is through the use of trademarks. A trademark is a word, symbol, etc, that is used to identify and distinguish its source. For example, the word “Tylenol” is a trademark that identifies that the drug acetomenophin is made by a particular company. Drug companies can sell the same product with different names or different packaging. These differences would make it easier for drug companies to help identify products that should be seized by customs officials as infringing. In addition, drug companies themselves may use the differing trademarks to help them identify unauthorized products that they can try to block through private litigation.

Another approach patent-owning companies take is to limit drugs sold. A company may decide not to sell drugs in certain areas where expected sales (and profits) are low. The example

¹² 21 U.S.C. 331(t) (2006). Technically, the Medicare Modernization Act of 2003 permitted an increase of imports from Canada *if* the Secretary of Health and Human Service certified that such imports would not pose an additional risk to public health and would result in significant cost savings. 21 U.S.C. 384(b) (2006); *see also* RICHARD ABOODD, PHARMACY PRACTICE AND THE LAW 146 (6th ed. 2010). However, the Secretary of Health and Human Services has yet to make such a certification.

¹³ FDA Regulatory Procedures Manual, 9-12 (Mar. 2010); 21 USC 956 (2006); 2006 HR 5441, sec. 535.

¹⁴ In 2005, the total sales volume of goods represented 0.5% of US sales. OECD, *supra* note 7, at 41-42.

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provided in the introduction to this chapter illustrates this concept. As noted earlier, a drug company may be reluctant to sell its patented HIV drug in Rwanda for fear that it might be imported into wealthier markets—even though there are patent and possibly regulatory laws that should minimize this. While drug companies have provided some patented drugs at low cost to poor markets, such a decision is likely not made lightly. Rather, it must be balanced against the risk of undesirable imports. Even in countries with desirable laws that bar parallel imports, the patent owner may prefer to avoid taking legal action. The ideal situation for the drug company is to bar all possible imports, which can be enhanced if there are few drugs available to import in the first instance.

A drug company may also limit the sale of goods that have a high probability of becoming imports in a wealthier market—without regard to whether the initial market has low sales. For example, the same drug is often sold at a much lower price in Canada than the United States because Canada imposes price caps on drugs, but the United States does not. While there are already patent and regulatory laws that favor the drug company interests, the drug company may still need to take legal action to enforce the laws. Moreover, even legal action will not bar all imports. After all, a consumer who travels to Canada and imports a drug for personal use will not violate regulatory laws given the exception for personal use. Technically, the consumer who imports a small sample of drugs would violate the patent right of importation. However, drug companies are unlikely to sue individual consumers—the value of the drugs will be relatively low and the public relations impact would be very negative. Given all these factors, a drug company would want to limit sales of drugs in Canada as another tool to limit imports. Indeed, after cross

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border sales briefly increased after the development of Canadian Internet pharmacies, patent-owning companies limited supply to Canada to minimize this problem.¹⁵

V. Conclusion

Although most countries today must provide patent rights, differing prices of patented drugs will continue to provide an incentive for some to buy a cheaper version of the drug in one market to sell in a second market. This incentive does not exist in markets that bar parallel imports. Accordingly, patent-owning drug companies want to limit parallel imports. There is currently no uniform rule on whether parallel imports are permissible; in other words, countries currently take differing positions on whether to recognize international exhaustion of patent rights. While patent owners generally have the patent law they desire in important markets, they continue to lobby for a more uniform approach, as will be discussed in the Chapter on TRIPS-Plus. Moreover, fear that parallel trades hinders desired market segregation may also impact their approach to other patent concepts, such as compulsory licensing, as will be later explored.

¹⁵ E.g., OECD, *supra* note 7, at 42.