October 2001

Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals

A. Bryan Baer
University of Georgia School of Law

Follow this and additional works at: https://digitalcommons.law.uga.edu/jipl

Part of the Biomedical Engineering and Bioengineering Commons, Food and Drug Law Commons, and the Intellectual Property Law Commons

Recommended Citation
Available at: https://digitalcommons.law.uga.edu/jipl/vol9/iss1/4

This Notes is brought to you for free and open access by Digital Commons @ Georgia Law. It has been accepted for inclusion in Journal of Intellectual Property Law by an authorized editor of Digital Commons @ Georgia Law. Please share how you have benefited from this access. For more information, please contact tstriepe@uga.edu.
NOTES

PRICE CONTROLS THROUGH THE BACK DOOR: THE PARALLEL IMPORTATION OF PHARMACEUTICALS

I. INTRODUCTION

A. FOREIGN PRICE CONTROLS TRIGGER DOMESTIC LEGISLATION

As busloads of senior-citizens travel to Canada and Mexico to take advantage of cheaper prices on prescription drugs, U.S. lawmakers, eager to please their senior-citizen constituents, feast over proposals that would make pharmaceuticals cheaper here in the United States.1 In the fall of 2000, Congress overwhelmingly passed amendments to the Agricultural Appropriations Bill (H.R. 4461),2 intended to alleviate the need for the elderly, as well as all other consumers of prescription drugs, to travel abroad for lower prices.3 Were the 2000 amendments to take effect,4 pharmacists and drug wholesalers could buy Food and Drug Administration (FDA) approved, American-made drugs in foreign countries, where the drugs are cheaper, and then “reimport” them into the United States. The drugs could then be sold for less than current retail prices.5 Although Congress passed the bill as a “free market” solution to the high costs of prescription drugs, the primary

1 A Drug War of a Different Sort, CONG. DAILY, Apr. 7, 2000, 2000 WL 6431403.
2 Through the remainder of the Note, the two amendments to H.R. 4461 will be referred to as the “2000 amendments.”
4 A late provision added to the amendments mandated that they would not take effect unless the FDA certified that the drugs entering the U.S. were safe. According to the FDA, certification would require an additional $90 million per year which could not be appropriated until fiscal year 2002 at the earliest. John Carey, Medicines Without Borders: The Move is on to Reimport Foreign Drugs, BUS. WK., Oct. 9, 2000, at 130, 2000 WL 24485608.
5 Id.
reason prescription drugs are cheaper in foreign countries, particularly in Canada and Mexico, is because of government enacted price controls, not market forces.6

B. THE ISSUE: HOW SHOULD INTELLECTUAL PROPERTY LAWS WORK TO CONTROL THE GLOBAL FLOW OF GOODS

The above legislation goes to the very heart of an issue debated in intellectual property, international and economic circles: How should nationally granted intellectual property rights work in controlling the flow of goods on a global scale?7 The plan of this Note is to address this question with respect to pharmaceutical patents. First, this Note will put the issue in context by explaining the applicable intellectual property (IP) doctrines, outlining the resolution, or lack thereof, prescribed by the international community, and summarizing the laws of the United States and European Union on this issue. Then, this Note will address the economics of the pharmaceutical industry. Finally, this Note will analyze the wisdom of allowing drug wholesalers to purchase pharmaceuticals abroad and reimport them into the United States.

II. BACKGROUND

A. “EXHAUSTION OF RIGHTS” AND THE “FIRST SALE DOCTRINE”

The most fundamental limitation on an intellectual property right, whether it is a patent, trademark, or copyright, is exhaustion upon first sale.8 After a good or article containing an intellectual property right, or “IPR,” is sold, the IP owner can no longer control the fate of that good; his rights have “exhausted.” This is commonly known as the first sale doctrine.9 Conse

6 Id.
7 See Vincent Chiappetta, The Desirability of Agreeing to Disagree: The WTO, TRIPS, International Exhaustion and a Few Other Things, 21 Mich. Int’l L. 333, 335 (2000) (stating that the TRIPS negotiations completely broke down upon discussing this issue); see also Andreas Reindl, Intellectual Property and Intra-Community Trade, 20 Fordham Int’l L.J. 819, 819 (1997) (stating that the role of intellectual property rights in intra-Community trade has been the subject of passionate debate since the early days of the European Community).
9 Id. at 447. It is important to remember that the first sale doctrine only frees that specific good from
quently, after the first sale of a product with an IPR, "a purchaser can resell
the product without being liable for infringement." 10

B. "PARALLEL IMPORTS": THE RESULT OF APPLYING THE FIRST SALE
DOCTRINE INTERNATIONALLY

How the first sale doctrine is applied internationally is becoming of
increasing importance as trade barriers crumble and goods move freely
among nations. 11 Due to differing purchasing powers among nations,
varying labor and other production costs, as well as different governmental
regulations, the same product is often priced differently in different
countries. 12 These price differentials create powerful incentives for third
party distributors to purchase products in low-priced countries and then
resell them in high-priced countries, discounting the price routinely charged
by the IPR holder in the high-priced countries. 13 Consequently, interna-
tional application of the first sale doctrine can frustrate IPR holders' attempts
to maximize the value of their property rights. 14

Goods that are purchased abroad by an independent third party and then
resold domestically to compete against authorized goods are known as
parallel imports. 15 Parallel imports are genuine goods; they are not pirated
nor counterfeit. 16 Nevertheless, an IPR holder may be able to prevent their
sale if the IPR issuing nation does not apply the first sale doctrine to goods
sold in foreign countries. 17

further claims by the IPR holder. See also Chiappetta, supra note 7, at 341 n.32 (stating that the holder's IPR
can be used to prevent direct exploitation of the intellectual product such as production of additional
products or copies).

10 Donnelly, supra note 8, at 447.

11 David Perkins et al., Exhaustion of Intellectual Property Rights, in PLI'S FIFTH ANNUAL INSTITUTE
FOR INTELLECTUAL PROPERTY LAW at 41, 43 & 45 (PLI Patents, Copyrights, Trademarks, and Literary

12 Id. at 45.

13 Id. at 46.

14 Id.

15 Hillary A. Kremen, Note, Caveat Venditor: International Application of the First Sale Doctrine, 23

16 Perkins et al., supra note 11, at 47.

17 See Darren E. Donnelly, supra note 8, at 449 (explaining that whether an IPR holder has exhausted
her IPR depends on whether those rights are territorial or universal).
C. APPLICATION OF THE FIRST SALE DOCTRINE UNDER A REGIME OF INTERNATIONAL VS. NATIONAL EXHAUSTION

Because IPRs are granted and enforced at a national level, the IPR owner must seek protection in each country individually. Therefore, the patent owner acquires several parallel patents, one from each country in which she registers. If a country follows a rule of national exhaustion, the authorized distribution (first sale) of that good domestically will prevent the patent holder's further domestic enforcement of her patent against those “possessing, using or redistributing the particular good.” However, the patent holder would still be able to use her domestic patent to prevent the import or resale of authorized products sold abroad. Thus, under a national exhaustion regime the patent holder can use her parallel patent to prevent products first sold in one nation from entering another.

Under a regime of international exhaustion, on the other hand, the first sale of a product anywhere in the world by the patent owner or with her consent exhausts the holder’s parallel patents in all other countries. Consequently, a patent owner is powerless to stop parallel imports under a regime of international exhaustion.

The following example will illustrate how parallel imports, national versus international exhaustion and the first sale doctrine interrelate. Inventor “X” develops a new drug for the treatment of skin cancer. Due to the national nature of patent laws, “X” must submit a patent application in each country in which she desires to patent her drug. Say she wants to obtain a patent in the United States, the United Kingdom, and Japan. Assuming she is successful, she will have a separate but parallel patent in each nation. The protection she receives under each patent will vary according to the patent regime of that nation.

As a result of different market and regulatory conditions, the price of the drug may vary considerably among the three nations. For example, the price

---

18 Chiappetta, supra note 7, at 341-42.
19 Id. While for the purposes of discussing national and international exhaustion this Note references patent rights, the same concepts apply to copyrights and trademarks as well.
20 Id. at 341.
21 Id.
22 Id.
23 Id.
24 See Chiappetta, supra note 7, at 341 (providing a similar illustration on the exhaustion of IPRs).
in the United Kingdom may be substantially less than in Japan. Seizing the
opportunity, an independent trader purchases mass quantities of the drug in
the United Kingdom and then imports the drug into Japan for resale at less
than the price “X” charges for the drug in Japan.

What are the rights of the inventor? Under a national view of exhaus-
tion, each individual patent carries an independent right. Therefore, the sale
of the drug in the United Kingdom would not exhaust “X’s” right to prevent
the parallel importation of the drug into Japan. However, under an
international view of exhaustion, the parallel patents are interconnected.
The sale of the drug in the United Kingdom exhausts the rights under all
other parallel patents. Consequently, inventor “X” could not prohibit the
parallel importation of her drug into Japan.

III. THE LAW

A. EXHAUSTION UNDER THE “TRIPS” AGREEMENT

During the Uruguay Round negotiations in 1993, the international
community enacted the Agreement on Trade-Related Aspects of Intellectual
Property Rights (“TRIPS”). Although the TRIPS agreement did make
important steps to harmonize substantive IPRs across the international
community, the agreement failed to reconcile the exhaustion issue.
Proponents of international exhaustion argued that the free flow of parallel
imports would force market efficiencies and was in the spirit of free-trade
ideals embodied in the General Agreement on Tariffs and Trade (“GATT”)
and the World Trade Organization (“WTO”). National exhaustion
advocates argued that allowing for market divisions encourages research and
development of IP products and avoids intruding upon traditional national
sovereignty over intellectual property matters.

Article six reflects the deadlock that resulted: “For the purposes of
dispute settlement under this Agreement . . . nothing in this Agreement shall

27 Chiappetta, supra note 7, at 346.
28 Id.
be used to address the issue of the exhaustion of intellectual property rights.\textsuperscript{29} As a result, national and regional governments, like the European Union, have the exclusive authority to determine under what circumstances IPRs exhaust.\textsuperscript{30}

B. UNITED STATES CASE LAW: SOMEWHERE BETWEEN NATIONAL AND INTERNATIONAL EXHAUSTION

Current U.S. patent law provides that “whoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.”\textsuperscript{31} While on its face this statute would appear to provide a patent holder with the right to exclude parallel imports,\textsuperscript{32} case law indicates the statute is limited to an extent by a rule of international exhaustion.\textsuperscript{33}

The most recent Supreme Court case on the issue of parallel imports involved copyright law. In \textit{Quality King Distributors, Inc. v. L’anza Research International}, the plaintiff, who had copyrighted the label used on its goods, sold hair care products domestically and overseas.\textsuperscript{34} In the domestic market, the plaintiff engaged in an extensive advertising and distribution scheme allowing it to sell its products at prices 35\% to 40\% more than it sold them in overseas markets.\textsuperscript{35} Capitalizing on the price differential, a third party purchased the hair-care products overseas and imported them back into the United States.\textsuperscript{36} Plaintiff sued the third party for copyright infringement.\textsuperscript{37} A unanimous Supreme Court held that once an American made product had been sold overseas with the consent of the copyright owner, the owner of the copyright had no further control over that product’s fate.\textsuperscript{38} Since this

\textsuperscript{29} Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, art. 6, T.I.A.S. No. 6932, 33 I.L.M 86 [hereinafter TRIPS Agreement].
\textsuperscript{30} Id.
\textsuperscript{32} See Barfield & Groombridge, \textit{supra} note 26, at 198 (arguing that the statute provides full backing for U.S. patent holders to bar parallel imports, obviating the need to rely on previous court decisions).
\textsuperscript{34} Id.
\textsuperscript{35} Id. at 139.
\textsuperscript{36} Id.
\textsuperscript{37} Id. at 139-40.
\textsuperscript{38} Id. at 152.
decision, there has been considerable debate over whether and how this case applies to patents.39

1. Application of the First Sale Doctrine Internationally in U.S. Patent Cases. The seminal patent case addressing whether the first sale doctrine applies internationally is Boesch v. Gräff, decided by the Supreme Court in 1890.40 There, the plaintiff owned parallel patents for lamp burners in the United States and Germany.41 Plaintiff sued to keep lamps lawfully purchased in Germany from being sold in the United States. Under German law at that time, a third party could manufacture and sell patented products so long as that party had done so prior to the patent owner’s submission of the patent application.42 Consequently, the plaintiff could not prevent a third party from selling his patented lamp burners in Germany.43

Basing its decision on national sovereignty, the Court held that the plaintiff could prevent a third party from importing the lamps lawfully sold in Germany into the United States.44

The right which [the third-party manufacturer] had to make and sell the burners in Germany was allowed him under the laws of that country, and purchasers from him could not be thereby authorized to sell the articles in the United States in defiance of the rights of patentees under a United States patent. A prior foreign patent operates under our law to limit the duration of the subsequent patent here, but that is all. The sale of articles in the United States under a United States patent cannot be controlled by foreign laws.45 (emphasis added).

Thus, Boesch v. Gräff established the rule that an unauthorized sale overseas of a patented good does not exhaust U.S. patent rights.46

39 See Barfield & Groombridge, supra note 26, at 199 (stating that the press has widely trumpeted the ruling as a triumph for unrestricted parallel trade in general).
40 Boesch v. Gräff, 133 U.S. 697 (1890).
41 Id.
42 Id. at 698.
43 Id.
44 Id. at 703.
45 Id. at 703.
46 Id.
How far the Boesch rule extends, however, is uncertain.57 Five years prior to Boesch, the District Court of New York in Holiday v. Mattheson held that parallel importation of patented goods first sold overseas under the authority of the patent owner did not infringe the United States patent.48 There, the owner of the patent sold his patented goods in England.49 The defendant acquired the goods in England and imported them back to the United States.50 The defendant did not have the plaintiff’s permission to import the patented product. Nevertheless, the court refused to grant the plaintiff an injunction.51 The court reasoned that there was a presumption upon the sale of a good that the seller intends to part with all his rights in the thing sold.52 It would be inconsistent with this presumption to allow the seller then to restrict the buyer’s use when no such restriction was made at the time of sale.53 Consequently, the court held that the plaintiff’s patent rights at home were exhausted after the goods were sold abroad.54 Unfortunately, the Supreme Court in Boesch ignored the Mattheson decision in its opinion.55

In Curtiss Aeroplane and Motor Corp. v. United Aircraft Engineering Corp., the plaintiff held thirteen U.S. patents for various improvements on airplanes.56 The plaintiff authorized the British government to practice its patents in Canada to build planes for military defense. A Canadian company was formed to build the planes.57 Included in the contract was a provision stating that the patent could not be practiced for any other manufacture, use, or sale, except by the British government.58 However, the contract contained no express restrictions on what the British government could do with the planes once it purchased them.59

The British government purchased the planes from the Canadian company. After the war, the defendant purchased the planes from the

57 Donnelly, supra note 8, at 451.
48 Holiday v. Mattheson, 24 F. 185 (C.C.S.D.N.Y 1885).
49 Id.
50 Id.
51 Id.
52 Id. at 185.
53 Id.
54 Id.
55 Boesch, 133 U.S. at 697-709.
56 Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng’g Corp., 266 F. 71, 72-73 (2d Cir. 1920).
57 Id. at 72-73.
58 Id. at 73.
59 Id. at 80.
British government and imported them into the United States. In its
decision denying the plaintiff an injunction, the court reasoned that a
purchaser of an authorized good containing a patent possesses an "absolute
property" in that article.

If a patentee or his assignee sells a patented article, that
article is freed from the monopoly of any patents which the
vendor may possess. If the thing sold contains inventions of
several United States patents owned by the vendor, the
article is free from each and all of them; and if the vendor
has divided his monopoly into different territorial monopolies,
his sale frees the article from them all. If the vendor's
patent monopoly consists of foreign and domestic patents,
the sale frees the article from the monopoly of both his
foreign and his domestic patents, and where there is no
restriction in the contract of sale the purchaser acquired the
complete title and full right to use and sell the article in any
and every country.

While holding that the first doctrine applied globally, the court distin-
guished this case from a situation in which a patent owner sold a license to
another entity limiting the patented product's manufacture and distribution
to a specific country. There, the owner grants a license to a third party to
manufacture and sell the good in a particular country. Consequently, the
owner's patent rights are not exhausted in countries where the third party
did not have a license to sell.

Other courts have distinguished a patent owner granting an exclusive
license to a third party to practice a patent in a foreign country from the
patent owner herself selling her product in another country. In Griffin v.
Keystone Mushroom Farm, Inc., the District Court of Pennsylvania held that the Boesch doctrine against exhaustion applied even when the overseas first sale was authorized by the patent owner. In Griffin, the plaintiff held parallel patents on farm equipment in Italy and the United States. He licensed his Italian rights to a company he formed to produce the equipment. The defendant purchased the equipment in Italy and imported it to the United States. The defendant argued that allowing the plaintiff to stop the importation of the equipment would amount to a windfall “double recovery” since the plaintiff had already received a royalty for the equipment from the Italian licensing agreement.

The court disagreed, stating that the underlying principles governing patent law were to allow patent owners to exclude others from making, using and selling the patented invention. One method of exclusion is to grant licenses to only those entities that the owner wants to practice the patent. Allowing the defendant to import the equipment sold under the Italian license would thwart the patent owner’s ability to exclude persons from practicing the patent in America.

The Griffin court also reiterated the principle expounded in Boesch, stating that the “sale of articles in the United States under a United States patent cannot be controlled by foreign laws.” Ruling for the defendant would violate that principle by allowing rights confirmed under an Italian patent to control the rights of an American patent holder.

In Sanofi v. Med-Tech Veterinarian Products, Inc., the District Court of New Jersey clarified under what circumstances parallel imports infringe and who may bring an infringement action. There, a French pharmaceutical company sold an exclusive license to American Home Products for its United States patent on acepromazine maleate, a tranquilizer for the treatment of animals. Sanofi continued to produce and market the drug

67 Id.
68 Id. at 1284.
69 Id.
70 Id. at 1285.
71 Id.
72 Id.
73 Id.
75 Donnelly, supra note 8.
in Europe. The defendant purchased the drug in Europe and then imported it to the United States. 77 Both Sanofi and its exclusive licensee, American Home Products, sued for patent infringement citing Boesch and Griffin. 78

The court held that while American Home Products had a valid claim, its licensor, Sanofi did not. 79 Discussing Sanofi’s claim, the court distinguished Boesch and Griffin on the ground that neither of the plaintiffs in those cases had sold the product overseas. 80 Sanofi sold the drug throughout Europe. 81 Consequently, the court analogized Sanofi’s case to Mattheson where the U.S. patent holder sold the patentable articles overseas. 82 Like the court in Mattheson, the District Court of New Jersey found that allowing Sanofi to impose restrictions against the defendant’s use would be inconsistent with the defendant’s expectation of full ownership. 83

Moreover, the plaintiffs in Boesch and Griffin had authority to sell their product in the United States. 84 Here, Sanofi granted an exclusive license to American Home Products for all United States sales. 85 Therefore, the court determined that it could not enforce an injunction on behalf of Sanofi, because Sanofi had no rights to sell the drug in the United States. 86 On the other hand, American Home had exclusive rights to practice the patent in the United States. 87 Thus, the defendant’s lawful purchase of the drug from Sanofi in Europe did not give the defendant the right to ship it to the U.S. because Sanofi had no right to sell the drug in the U.S. A purchaser, though acquiring the “whole right of the vendor in the thing sold,” 88 still may only do with that product what the vendor could have lawfully done and acquires no right greater than that possessed by the owner. 89 Thus, American Home’s infringement claim was valid.

(D.N.J. 1983).

77 Id. at 937.
78 Id.
79 Id.
80 Id.
81 Id. at 937-38.
82 Id.
84 Id. at 939.
85 Id. at 938.
86 Id. at 939.
87 Id.
88 Id. at 938 (quoting Holiday v. Mattheson, 24 F. 185, 185 (C.C.N.Y. 1885)).
89 Id. at 939.
The court also addressed the differences between exclusive and non-exclusive licenses.90 The court stated that a non-exclusive license confers only the privilege to sell the patented product without infringing the patent.91 Because the owner of a non-exclusive license could not prevent the patent owner from granting other licenses, he could not bring a claim for patent infringement.92

On the other hand, an exclusive license conveys the promise that others will be excluded from practicing the patent in the field of use for which the patent was granted.93 Consequently, the owner of an exclusive license may bring a claim against those who infringe upon it.94 But that right is restricted to the field of use in which the exclusive license has been given; therefore, the original patent owner does not have an actionable claim.95

In sum, the courts have laid down the following rule: parallel imports are not infringing when the one authorized to practice the patent right domestically makes the first sale abroad. However, where the patent owner grants an exclusive license to practice the patent in the United States, the exclusive licensee’s rights are not exhausted when another entity sells the product abroad.

Assuming this correctly states the rule,96 then even if L’azna is applied to patents, it would not alter the current state of the law. In L’azna the seller overseas was the entity authorized to practice the patent in the United States.97 Consequently, were the case to have arisen as a patent infringement dispute, the Court probably would have allowed parallel imports of the L’azna product based on existing patent law.

90 Id. at 936.
91 Id.
92 Id.
93 Id. at 937.
94 Id.
96 At least two commentators on the topic believe courts disagree whether sales abroad exhaust United States patent rights, and, if so, under what circumstances. See Donnelly, supra note 8, at 454; see also Barfield & Groombridge, supra note 26, at 190 (stating that the TRIPS agreement created confusion regarding the ultimate position of IPRs and competing non-pirated imports). However, under this author’s analysis, the cases seem to harmonize.
PARALLEL IMPORTATION OF PHARMACEUTICALS

C. PRESCRIPTION DRUG MARKETING ACT: A COMPLETE BAN ON PARALLEL IMPORTS FOR PHARMACEUTICALS

In the case of prescription drugs, prior to the 2000 Amendments, Congress had passed the Prescription Drug Marketing Act of 1987 (PDMA) completely banning parallel imports of pharmaceuticals. Passed due to concerns for the health and safety of consumers, the PDMA prohibits the re-importation of pharmaceuticals into the United States unless done by the original manufacturer. For example, should a foreign licensee receive bulk shipments of a drug from an American manufacturer, it would be prohibited from importing that drug back into the United States. This provision, however, does not prohibit the general importation into the United States of FDA approved drugs manufactured in foreign countries.

Despite this legislation, the FDA allows consumers to purchase prescription drugs in Mexico or Canada so long as the drugs purchased are for personal use only. The "personal use" exception authorizes persons to return to this country with limited quantities of drugs—even drugs not approved by the FDA—for their own use, so long as they pose no serious health hazard.

D. PARALLEL IMPORTATION OF PHARMACEUTICALS IN THE EUROPEAN UNION

Parallel importation of pharmaceuticals is allowed among Member States of the European Union. Article 30 of the European Economic Community establishes the general rule prohibiting national laws that restrict the

98 See Lars Noah, NAFTA's Impact on the Trade in Pharmaceuticals, 33 Hous. L. Rev. 1293, 1308 (quoting statements in the Congressional record noting that "[t]he ready market for re-imports has... been a catalyst for the perpetration of a continuing series of frauds against American manufacturers, and has provided the cover for the importation of counterfeit pharmaceuticals in several cases." H.R. Rep. No. 100-76, at 7 (1987)).
100 Noah, supra note 98, at 1308.
101 Id.
102 Id. at 1312.
103 See id. at 1314 (citing Food & Drug Administration, Regulatory Procedures Manual § 9-71-30(C) (Feb. 1, 1989)).
104 See generally Reindl, supra note 7 (criticizing the ECJ’s application of the EU’s free movement rule).
free flow of goods. However, Article 36 provides an exception allowing restrictions for intellectual property related goods provided that they are not disguised restrictions on intra-EU trade. Nevertheless, the following case law sets out the general rule that exclusive rights of intellectual property holders are exhausted when an article is lawfully sold with the consent of the IPR owner in any country within the EU.

In Centrafarm v. Sterling Drug Inc., the Court of Justice of the European Communities (ECJ) first held that the marketing or sale of a patented product in a Member State with the consent of the patent owner exhausted national patent rights. Stating that “a product lawfully sold in the Community must be able to circulate freely within it,” the court established the “free movement” rule for goods first sold within the EU.

The ECJ extended Centrafarm with its holding in Merck v. Stephar. There, the court held that the doctrine of Community-wide exhaustion applied to those products that had been first marketed in Member States in which patent protection was unavailable. In Stephar, Merck owned patents in the Netherlands on the drug Moduretic, a diuretic. Merck also marketed this drug in Italy, which at the time did not offer patent protection. Stephar purchased the drug wholesale in Italy and sought to resell it in the Netherlands. Merck argued that since the purpose of patent protection was to allow the patentee to benefit from the exclusive right to first market the patented article, this right could not be exhausted when the

---

106 Article 36 provides that Article 30 shall not “preclude prohibitions or restrictions on imports, exports, or goods in transit justified on the grounds of . . . the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.” EEC TREATY art. 36.
108 Id. at 1173.
109 Id. at 1171.
110 Reindl, supra note 7, at 823.
112 Id.
113 Id. At the time the drug was marketed in Italy, there was a decree that no patent protection would be available. This decree was later held unconstitutional, but by that time the drug was no longer novel and thus, not patentable. Id.
114 Id.
first sale was in a state that did not afford such an exclusive right. Nevertheless, the court maintained that while a patent guaranteed the rights to first market a product, a patent did not automatically guarantee that the patentee would obtain a patent-like reward in all circumstances. Instead, the court focused on the patent holder's decision to market the product in a state that did not afford patent protection. Since Merck consented to the drug's sale in such a Member State, the court held that its patent protection on that article was exhausted throughout the Community.

The ECJ's reasoning in Stephar was challenged in Merck v. Primecrown. There, pharmaceutical products were first placed in Spain and Portugal at a time when no product patents were available for pharmaceuticals in those countries. Analogous to Stephar, these products were purchased wholesale in Spain and Portugal and imported into Great Britain. Despite the Advocate General's opinion to overrule Stephar, the ECJ affirmed, again noting the consent of the patentee to market the product in Portugal and Spain:

The substance of a patent right lies essentially in according the inventor an exclusive right to put the product on the market for the first time. It is for the holder of the patent to decide, in the light of all the circumstances, under what conditions he will market his product, and to decide whether or not to market it in a Member State in which there is no protection under the law for the product in question.

Moreover, the ECJ in Primecrown also concluded that the "free movement" rule applied despite imposition of price controls in a Member State.
Despite the ECJ's adherence to the "free movement" rule in *Stephar* and *Primecrown*, the court did not apply the exhaustion principle when a patented product is sold in a Member State without the consent of the patentee. 124 For instance, in *Pharmon v. Hoechst*, the ECJ held that sales under a compulsory license did not exhaust patent rights, because the patentee did not freely consent to market the product in a Member State that grants a compulsory license. 125

While the European Union allows parallel importation within the Community, the ECJ restricts parallel importation of goods first sold outside the EU. 126 In a recent trademark case, the ECJ found that the European Commission directive on trademarks mandated only an intra-community exhaustion rule. 127 Member States are required to uphold the rights of trademark owners to restrict parallel imports from outside the EU. 128 It is widely assumed this case would apply to patents as well. 129

In sum, within the European Community, patent rights are exhausted upon the first sale of the patented item with the consent of the patent holder. However, first sales outside the Community do not exhaust patent rights within the European Union.

IV. PARALLEL TRADE OF PHARMACEUTICALS IN THE UNITED STATES UNDER THE 2000 AMENDMENTS

Were the 2000 amendments to take effect, 130 the United States would be adopting a rule similar to that which currently exists within the European Union. So long as the drug complied with other FDA regulations, any patented United States drug sold overseas by the U.S. patent holder or its authorized licensee could then be imported back to the United States. Whereas, under current U.S. patent law a patent holder could prevent

124 Donnelly, *supra* note 8, at 476.
126 See Barfield & Groombridge, *supra* note 26, at 199 (stating that "the ECJ indicated that parallel imports from nations outside the EU would be treated differently and the territorial nature of IPRs would hold sway").
127 Id.
128 Id.
129 Id.
130 See infra note 4 (discussing that the FDA would require significant appropriations to effectively administer the new law and that the law would not take effect until those appropriations were made).
parallel imports contractually by establishing an exclusive U.S. licensee, the proposed legislation would allow parallel imports even in situations where there was an exclusive U.S. licensee. Consequently, entities with an exclusive domestic license for a pharmaceutical drug would be unable to prevent the parallel importation of that drug even when another entity was the one who sold it overseas.

V. RAMIFICATIONS OF PARALLEL IMPORTS ON THE PHARMACEUTICAL INDUSTRY

A. STRUCTURE OF PHARMACEUTICAL INDUSTRY

1. Dependence on a Strong Patent Regime. Drug innovation is an expensive, lengthy process in which pharmaceutical companies face a significant amount of financial risk. Since 1990, research based pharmaceutical companies have more than doubled their research and development expenditures. In 1999 alone, 20% of gross sales was poured back into to research and development of new pharmaceutical products. According to Gerald Mossinghoff, President of the Pharmaceutical Research and Manufacturers of America, it takes an average of $359 million and about ten to twelve years to bring one new pharmaceutical to the market.

In addition to the costs and length of time it takes to bring a new drug to market, drug innovation is also a very uncertain. Recent studies show that only about one in 5000 compounds synthesized in pharmaceutical laboratories ever reaches the market. Of these drugs only three in ten cover costs of development after the deduction of taxes. Consequently, 20% of the products generate 70% of the profits.

112 Barfield & Groombridge, supra note 26, at 208.
113 See id. at 208 (citing Pharmaceutical Research and Manufacturing Association (PhRMA), Pharmaceutical Industry Profile: 1999 59, ch. 2 (1999)).
115 See Barfield & Groombridge, supra note 26, at 209 (citing R.S. Halliday et al., R&D Philosophy and Management in the World's Leading Pharmaceutical Companies, 1992 J. PHARMACEUTICAL MED. 139 (1992)).
116 See Barfield & Groombridge, supra note 26, at 209.
117 Id.
The benefits that make the risks and costs of innovation worthwhile are the exclusive rights afforded by patent protection once a new drug has been developed. Absent patent protection, third parties could "free ride" on the intellectual capital developed by the innovating company producing the same drug without the large research and development expenditures.

The exclusive right to market a drug afforded by patent protection allows pharmaceuticals to charge supra-competitive prices. Supra-competitive prices enable pharmaceuticals to recoup the cost of their investment on that drug and recover losses incurred from the development of countless other drugs which were not marketable. Therefore, without strong patent protection, pharmaceutical companies would have little incentive to develop new drugs.

Due to the high cost of research and development and small number of compounds that actually pay off, patent protection is the lifeblood of drug companies enabling them to continue innovating new drugs. A recent survey asked R&D executives of 100 U.S. firms what portion of inventions they developed in the past three years would not have been developed without patents. The pharmaceutical industry's response reveals its strong dependence on the patent regime. Pharmaceutical executives claimed that 60% of their drugs would not have been developed without patents versus only 17% for the machinery industry and 11% for electrical equipment.

Furthermore, the study found that pharmaceutical companies had sought patent protection for 80% of their patentable drugs as compared to only 50% among other industries.

2. The Pharmaceutical Distribution System. In order to capitalize on the benefits that patent protection affords, pharmaceutical companies must maintain an effective distribution system. The price for a particular pharmaceutical may vary considerably between countries due to a myriad of
factors: differences in consumer demand, the exchange rate, differing property regimes, as well as differing regulatory regimes concerning pharmaceuticals.\textsuperscript{147} Due to international price differentials, pharmaceutical producers often sign contracts with distributors authorizing them to market their drug only within a defined region.\textsuperscript{148} Such contracts are known as geographic territorial restraints. So long as there is a ban on parallel imports, geographic restraints allow pharmaceuticals to charge different prices to consumers based on their geographic location.\textsuperscript{149} In other words, pharmaceutical companies segment the world market into discrete geographic regions adjusting price accordingly to maximize their recovery of capital.\textsuperscript{150} Territorial price discrimination is entirely consistent with underlying patent rationale.\textsuperscript{151} By allowing the patentee to capture a larger part of the potential value attached to his invention, it increases a patentee’s incentive to develop new products.\textsuperscript{152} Moreover, territorial price discrimination allows a patentee to capitalize on distributional efficiencies, thereby offering pharmaceuticals to more regions of the globe.\textsuperscript{153}

B. EFFECTS OF PARALLEL IMPORTS ON THE PRICE OF PHARMACEUTICALS

Perhaps the biggest argument in support of the 2000 amendments is that allowing the parallel importation of drugs would reduce prices to United States consumers, particularly senior-citizens who spend a significant proportion of their income on pharmaceuticals.\textsuperscript{154} While the immediate effect of allowing the parallel importation of drugs would be to reduce the price within the United States, the long-term effect on the pricing of pharmaceuticals worldwide would be a move toward a single uniform price.

When prices across national markets differ widely, and parallel imports are allowed, a producer has three choices: (1) maintain price differentials, (2)
set a higher uniform price worldwide, or (3) market the drug exclusively in high price nations. Should a producer choose the first option, a parallel trader will purchase massive quantities of the good in low price countries and re-import them into higher priced markets, thus undercutting the price there. While prices will fall in the high price markets, prices will rise in low price markets due to increased demand for the product as a result of the entry of a new consumer, the parallel trader. Consequently, a uniform price emerges. The second option results in the same effect, just bypassing the parallel trader. Under the third option, not only do prices among wealthy nations converge, but consumers in less developed nations are unable to acquire much needed medicines.

C. CONSEQUENCES OF UNIFORM PRICING IN DEVELOPING NATIONS

Absent price controls, higher prices for pharmaceuticals in developing nations would be the necessary result of a new law allowing the parallel importation of pharmaceuticals. Consequently, this law could have tragic results for developing nations who no longer would be able to afford innovative therapies.

So long as a drug company can make up for reduced profits from sales in poorer nations with higher profits in richer countries, it can offer its drug at prices consumers in less developed countries can afford to pay. For example, in the case of drugs treating HIV/AIDS, pharmaceutical companies have been able to reduce the price by 50 to 75% of the medicines destined for

---

155 Donnelly, supra note 8, at 503. This scenario assumes the absence of government controls over prices which will be taken into account later in the analysis.
156 Id.
157 Id.
158 Id.
159 The ECJ foreshadows such a result in its two Merck opinions discussed infra Part III.D. In them, the ECJ states that the patent holder has the power to decide “under what conditions he will market his product.” Joined Cases 267 & 268/95, Merck & Co. v. Primecrown Ltd., 1996 E.C.R. I-6285, [1997] 1 C.M.L.R. 83 (1996). Thus, the ECJ insinuates that should a patent holder not like the market conditions of a certain nation, she should refuse to sell her medicines there. Nevertheless, were pharmaceutical companies to refuse to sell to poorer nations, the worldwide community would most likely clamor for compulsory licensing. Since compulsory licensing is beyond the scope of this Note, the possibility and ramifications of companies refusing to market medicines to poorer nations is not fully addressed.
161 Id.
developing countries. Allowing parallel trade reduces any incentives for pharmaceutical companies to make concessions to these nations.

If concessions were made to poorer countries, consumers worldwide would be hurt as declines in research and development would bring fewer products to market. Since parallel importation of pharmaceuticals would reduce their profits, pharmaceutical companies would have both less money to devote to research and development and less incentive to innovate.

D. ATTACKING THE FREE TRADE ARGUMENT IN SUPPORT OF ALLOWING PARALLEL IMPORTS OF PHARMACEUTICALS

Proponents of the parallel importation of pharmaceuticals, and that of international exhaustion in general, disapprove of pharmaceutical companies' ability to price discriminate. They maintain that policies allowing parallel imports are in line with free trade principles established by the WTO.

According to Professor Abbott of the International Trade Law Committee (ITLC), "restrictions on the free movement of goods and services legitimately placed on the world market are inconsistent with the underlying objective of the GATT-WTO system . . .," the liberalization of markets.

This free trade argument when applied to the pharmaceutical industry is flawed for two reasons: (1) Different nations have different patent regimes, and (2) Government regulations on pharmaceuticals often include price controls artificially reducing the price of drugs. Consequently, price differentials are not the result of market forces. Thus, free trade via parallel imports is not truly free in the traditional "laissez-faire" sense and would not

163 Barfield & Groombridge, supra note 26, at 251. However, research has shown that pharmaceutical companies do take into account ethical considerations when deciding whether to supply needed drugs to low price nations: "To deny the sick medicines is not the way they act." Id. (quoting M.L. Burstall & L.S.T. Services, Undermining Innovation: Parallel Trade in Prescription Medicines 24, 66 (1992)).
164 Id. at 250.
165 Id.
167 See id. (supporting international exhaustion based on free trade principles, but making no reference to any specific U.S. legislation allowing the parallel importation of drugs).
improve world-wide welfare. To the contrary, allowing parallel imports could have drastic consequences on worldwide welfare.

1. Different Patent Regimes Across Nations. Allowing parallel imports from countries with different patent regimes has the effect of importing those regimes and controls on the U.S., thereby allowing foreign laws to control U.S. patent rights in violation of longstanding U.S. policy. As demonstrated in the discussion concerning patent protection of pharmaceuticals within the EU, patent regimes may differ from country to country. Consequently, patents that are current in the United States may not be current in all countries worldwide. Like certain states within the EU, some countries may not even offer protection at all. A law allowing parallel trade of pharmaceuticals in the U.S. would create a situation not unlike that which currently exists within the EU. However, the consequences would be much greater because parallel imports could come in from any country in the world.

In a country where a patented drug was not protected, either because it was no longer current, or the country did not offer patent protection, generic drugs of the same composition as the patented one would be allowed. Generic competition would then bring down prices for the patented drug in such countries. Parallel importation of the patented drug would cause prices to fall domestically since the drug was purchased in a nation that allowed generic competition. Consequently, the rights and benefits afforded under United States patent protection would be circumvented by foreign law.

A rule of exhaustion among nations with different patent regimes effectively exports the laws of the nation with the least protection to all

---

168 See id. at 193 (quoting economist Carsten Fink: "[T]he conditions surrounding parallel trade do not fit into the assumptions on which standard static (short-term effects) trade models supporting the case for laissez-faire trade are built." Carsten Fink, Does National Exhaustion of Intellectual Property Contradict the Principle of Free Trade? (Draft Paper for Conference on Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Switzerland) (Nov. 6-7, 1998)).

169 Barfield & Groombridge, supra note 26, at 251.

170 See Boesch v. Gräff, 133 U.S. 697 (1890) (stating that the sale of goods of products containing U.S. patents could not be controlled by foreign law).

171 See discussion infra Part III.C (comparing effects of policies either affording or refusing to afford patent protection).

172 The Trips agreement discussed infra Part III.A provides only a minimum of standards for intellectual property rights. It does not harmonize them completely across nations.

173 Barfield & Groombridge, supra note 26, at 246.

174 See Barfield & Groombridge, supra note 26, at 245-46 (discussing results of allowing parallel trade of pharmaceuticals in a general context).
other nations. As mentioned above, the European Union currently has a rule of exhaustion intra-community. In *Merck v. Primecrown*, the Advocate General criticized the logic of such a rule for patented drugs sold in Member States that did not afford patent protection precisely for this reason. According to the Advocate General, the free movement of goods among such states has the effect of exporting one Member State's patent regime into all the nations of the European Union. Therefore, the practical result is a Community-wide regime when such a regime does not exist.

Applying the logic of the Advocate General, a law allowing parallel imports of pharmaceuticals would have the effect of exporting the patent laws pertaining to pharmaceutical products of other nations into the United States. This would violate a fundamental principle of our patent regime by allowing foreign laws to control the sale of products in the United States under a United States patent. A pharmaceutical company that sells its drug in countries that do not afford patent protection must reduce its price to compete with generics. Allowing parallel imports from such a nation would reduce the price of the patented drug in the U.S. due to competition from the parallel import. Consequently, the resulting U.S. price would move toward that of the price of the drug in nations where no patent protection was afforded. Thus, the prices of patented drugs in the U.S. would effectively be dictated by foreign laws.

2. Price Controls on Pharmaceuticals. Applying the same argument, allowing parallel imports of pharmaceuticals would also have the effect of importing other countries' price controls into the United States. Price differentials are largely the result of price controls that numerous countries place on patented drugs. Were exhaustion in the U.S. to occur after the first sale in nations with price controls, the uniform price worldwide would

---

175 See discussion on EU law infra Part III.C (illustrating exhaustion within the EU).
177 Id.
178 Id.
179 Id.
180 See Reindl, supra note 7, at 833 (extending Advocate General Fennelly's argument to apply when Member States set different price controls on pharmaceuticals).
181 Barfield & Groombridge, supra note 26, at 246.
move toward that which exists in countries with the lowest government regulated price.

Furthermore, allowing parallel imports from countries that place price controls on pharmaceuticals would have serious negative implications for pharmaceutical companies and consumers worldwide. Due to the huge costs associated with research and development, the pharmaceutical industry faces considerable fixed costs—costs that do not vary no matter how many drugs are produced or how many consumers or countries utilize a drug. However, marginal costs—the cost of producing additional pills of the same drug—are relatively small. Governments enacting price controls force the price of pharmaceuticals down to their marginal costs. Pharmaceutical companies are willing to continue to supply drugs to these nations since the mandated price control covers the cost of producing the additional drugs.

Nevertheless, basic economics dictates that in order to survive in the long run, firms must be able to cover total costs—marginal and fixed in all markets. Pharmaceutical companies are able to cover the cost of research and development by charging higher than marginal costs for drugs in free-market countries like the United States. In essence, governments enacting price controls are free-riding on consumers in the United States and other free market countries who pay the tremendous fixed costs associated with research and development.

3. Economic Implications of the 2000 Amendments. A law allowing parallel importation from countries with price controls would prohibit a pharmaceutical from ever recouping fixed cost, because U.S. prices would be roughly equal to those in countries where price controls existed. Absent price controls, prices would become uniform, somewhere between the price...
existing in poor and rich nations. Here, however, price controls would prevent the price from increasing despite an increase in demand. Therefore, drug prices in nations with price controls would remain at their artificially low levels, and prices in the U.S. would move toward these low prices. Consequently, prices would only remain greater than marginal cost, but never high enough for pharmaceutical firms to recoup their fixed innovative costs.

Since firms unable to recoup fixed costs cannot remain in business, there is a general consensus that it is sensible trade policy to exclude parallel imports that are subject to price controls. Even those who support international exhaustion in general make an exception when price differentials are the result of government regulation. For example, in his article supporting parallel trade, Frederick Abbot states:

One can envisage an exception to an open international parallel importation rule based upon government price controls directed at a specific industry, for example, the pharmaceutical industry. By setting a non-market price, the government subsidizes exports at the expense of the manufacturer.

As these comments indicate, even those who support international exhaustion based on free-trade principals recognize the negative consequences such a rule would have when price differentials are the result of governmental controls.

---

191 See discussion infra Part V.B (citing Donnelly, supra note 8, at 503).
192 Donnelly, supra note 8, at 503.
193 See id. (stating that global nature of the pharmaceutical industry combined with the high ratio of sunk research and development costs render the industry particularly vulnerable to the effects of parallel trade).
195 See Barfield & Groombridge, supra note 26, at 246-47 (citing Frederick M. Abbott, First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation, 1 J. INT’L ECON. L. 607, 623 (1998)).
196 Barfield & Groombridge, supra note 26, at 247 n.192 (quoting Abbott, supra note 195).
E. LONG TERM EFFECTS OF THE 2000 AMENDMENTS—WOULD POORER NATIONS BAN PARALLEL EXPORTS?

Firms who cannot recoup fixed costs cannot remain in business in the long run. Therefore, pharmaceutical companies could be forced to abstain from selling drugs in nations whose price controls only allow them to cover their marginal costs. This move would force these governments to either (1) lift price controls or (2) ban the exportation of pharmaceuticals. Since nations with price controls tend to be poorer nations whose citizenry would not be able to afford patented drugs otherwise, governments would probably not choose the first option. Ironically, the long run consequence of allowing parallel imports into the U.S. could be laws in poorer nations banning parallel exports.\textsuperscript{197}

Another reason why poorer nations might ban the export of pharmaceuticals is that demand for pharmaceuticals would outstrip supply. Were parallel importation allowed, there would be a vast increase in demand as distributors would compete with consumers for the purchase of drugs.\textsuperscript{198} Moreover, those realizing benefits of price controls would be unauthorized parallel importers and consumers in wealthy nations, not sick people in price control countries.\textsuperscript{199} As a result, there would be strong incentives for governments of poorer nations to effectively ban the export of pharmaceuticals.\textsuperscript{200}

VI. CONCLUSION

While a law allowing for the parallel importation of drugs may bring benefits to U.S. consumers in the short term, in the long run, it could have severe negative consequences for consumers in poorer nations, the pharmaceutical industry, and U.S. consumers.

Due to significant research and development costs and because the information resulting from this research and development is a pure public

\textsuperscript{197} Even if a price control nation did not place an outright ban on pharmaceutical exports, it would most likely enact a tariff high enough to eliminate any profits a parallel trader could recoup.

\textsuperscript{198} See Kremen, supra note 194, at 163 (stating that the threat of unauthorized importers taking advantage of price breaks offered to developing countries has a negative impact on international trade as nations will be encouraged to seek remedies such as quotas and tariffs).

\textsuperscript{199} \textit{Id.}

\textsuperscript{200} \textit{Id.}
good once it is acquired, pharmaceutical companies must have strong patent protection to remain viable. Only through this patent protection are pharmaceuticals able to charge prices significantly above marginal price in order to recoup the enormous fixed costs associated with research and development expenditures.

Allowing parallel imports of drugs thwarts the protection provided by U.S. patents. Though proponents argue that the 2000 amendments are in line with free trade principals, price differentials of pharmaceuticals are mostly the result of governmental intervention, not market forces. Consequently, not only are the patented drugs imported into the U.S., but the laws and regulations of the nations from which they come are imported as well. The result is that U.S. patent protection is effectively reduced to that offered in the nation with the least protection and the greatest price controls. This result runs contrary to well established patent principals since the late 1800's and makes it virtually impossible for pharmaceutical companies to recoup their fixed costs.

Faced with the possibility of insolvency, pharmaceuticals may stop supplying drugs to poorer nations, harming consumers who most desperately need innovative medicine. Should pharmaceuticals choose to continue to supply poorer countries, U.S. consumers and consumers worldwide would be harmed, because pharmaceutical companies would have few dollars and little incentive to embark upon research that would lead to improved medicine.

A. BRYAN BAER