

Chapter 13

PARALLEL TRADE IN PHARMACEUTICALS: FIRM RESPONSES AND COMPETITION POLICY

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I. INTRODUCTION

Parallel trade refers to the resale of goods between countries without the authorization of the owner of the intellectual property (IP) rights associated with those goods. It is a response to international price discrimination, whereby an identical product is sold at different prices in different countries. Changes in both trade regulations and intellectual property rights may affect the legality and prevalence of parallel trade, which in turn may impact the product market strategies of IP-intensive firms such as pharmaceutical manufacturers. Competition policy, in turn, may constrain how firms respond to parallel trade.

There have been proposals in the United States to permit parallel imports of pharmaceuticals from Canada (and other countries) in the last several years. The U.S. is not alone in considering changes to the legality of parallel trade; developed countries like Switzerland, New Zealand and Australia have also reconsidered or revised their policies, and parallel imports into developing countries is an increasingly contentious trade issue. Both the law and the strategies firms use in response to parallel trade are relevant not only to the pharmaceutical industry, but to all IP-intensive firms that are active in multiple countries. Concerns raised about access to treatments and the widespread use of price regulation for medical treatments, however, make the issue of parallel trade especially salient in pharmaceuticals.

The implications of parallel trade for social welfare, both static and dynamic, are theoretically ambiguous in most economic models. However, these models typically consider a limited range of responses by firms to the threat of parallel trade. There is a growing body of empirical evidence that documents the effect of parallel trade in pharmaceuticals within the European Union. This paper summarizes the theoretical and empirical literatures and discusses the implications for competition policy.

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II. LEGAL STATUS OF PARALLEL TRADE

Parallel trade depends on three policies: intellectual property, trade and competition. First, goods subject to parallel trade have intellectual property rights associated with them. These rights include patents, copyrights and trademarks, and are applied for, granted and enforced at the country level. Intellectual property rights allow the owner of those rights to restrict competition from imitators within a country.

Whether owners of IP can restrict competition from their own products first sold in other countries – i.e. from parallel imports – depends on whether a country considers the IP rights “exhausted” by first sale abroad. A policy of national exhaustion amounts to a ban on parallel imports. That is, the owner of the IP cannot prevent resale of products first sold within a country, but can prevent resale of products first sold outside. A policy of international exhaustion allows parallel trade from any foreign country. A policy of regional (or “community”) exhaustion, which applies within the European Union, treats IP as exhausted by first sale within a region, but not outside that region. Policies may differ by the type of IP; while patents are most important for pharmaceuticals, trademark protection on the brand name or logo and copyright protection on package inserts or clinical trial data also apply.

Membership in the World Trade Organization requires that countries provide a minimum level of intellectual property rights and enforcement standards, in addition to restricting the ability of members to use protectionist trade policies. The WTO leaves the determination of exhaustion of IP rights up to the individual members. This is stated in Article 6 of the TRIPS agreement:

Article 6 Exhaustion

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

Competition policy plays two roles in this context. First, it governs the extent to which the owner of IP may exploit his monopoly power, and in particular how this manifests in pricing decisions. Second, competition policy affects how IP owners may respond to parallel trade. For example, a common response is to restrict supply in a country that is a source of parallel traded products, or to use restrictive contracts with wholesalers and distributors to prevent resale. Such actions can be viewed as anticompetitive.

A. Parallel trade in the European Union

While parallel trade in pharmaceuticals remains illegal in most countries, it is now permitted within the European Union. This is part of the move to a single market for pharmaceuticals in the EU; other changes include harmonization of regulations for the approval of new drugs and the adoption of the Euro. In particular, Article 28 of the European Community (EC) Treaty bans most actions that would inhibit the free movement of goods between member states. Article 30 provides some exceptions. For example, a trademark owner may restrict resale of an imported product bearing his trademark if the original packaging has been substantially changed.

Court decisions by the European Court of Justice (ECJ) during the last 25-30 years have applied the principle of free movement of goods within the EU to establish a policy of "community exhaustion" of patent rights and other forms of intellectual property, such as trademarks and copyrights. This paper summarizes only a few that are especially relevant to conduct in the pharmaceutical industry today. The basic principle is that under Article 30, exhaustion of IP rights cannot be limited to one jurisdiction within the EU. That is, if rights are exhausted by first sale in one EU member, they must also be exhausted in all other member states. The ECJ explicitly stated in 1996 that such rights "are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between member states."¹

However, pharmaceutical firms have challenged parallel traders under IP law in a number of ways. The first concerns the definition of "sale," which is the point at which IP rights are typically exhausted. The chain of distribution between manufacturer and consumer can involve several intermediaries (distributors, wholesalers and retailers, for example) and can involve multiple countries. An important case concerning pharmaceuticals is *Glaxo Group v. Dowelhurst*.² Glaxo had sold a number of different drugs, including HIV treatments, at reduced prices to a buyer in Africa. The drugs first came into possession of the buyer at its shipping agent's location in France, and were eventually resold to a parallel importer (Dowelhurst). The case settled before trial at the ECJ, but in a different case involving parallel imports of apparel,³ the ECJ found that sale to a third party within the EU — even with a contract specifying that the goods should be sold outside the Community — exhausted trademark rights. This issue is less relevant to the ability of firms to price discriminate within the EU than to use differential pricing outside. If this definition of sale continues to hold, then firms will be required to sell to

¹ Bristol-Myers Squibb v. Paranova A/S Case C-427/93, 1996 ECR 3457.

² Glaxo Group Ltd. v. Dowelhurst Ltd. & Anor, Case HC 03 00464, 2003 EWHC 2015.

³ Peak Holding v. Axolin-Elinor, Case C-1 6/03, 2004 ECR 11 3 1 3.

third parties outside the EU in order to prevent parallel imports of those products. That is, EU parallel trade undermines not only third degree price discrimination within the EU but also across other countries.

A more common legal challenge concerns trademark protection and repackaging. While an originator's trademark rights are exhausted once the product is placed on the market within the EU, the originator can object to the resale of a repackaged version of that product under certain conditions. This is particularly relevant in pharmaceuticals due to country-specific labeling requirements or standard package sizes, which require the repackaging of many parallel traded pharmaceutical products. Since repackaging changes the original condition of a product, trademark owners can claim that preventing such alterations is in their commercial interests because trademarks provide information to consumers about the origin and quality of a product. However, the ECJ ruled in *Hoffman-La Roche v. Centrafarm*⁴ and *Pfizer v. Eurim-Pharm*⁵ that trademark owners may not prevent the resale of repackaged goods for the purpose of restricting trade between EU countries, as this would violate Article 30. Subsequent decisions have clarified that repackaging must not harm the reputation of the trademark owner⁶ and related to the necessity of repackaging or changing trademarks to conform with standards of the importing market.⁷

To summarize, the EU has established a policy of "community exhaustion" of most forms of intellectual property, which means that once a firm has put the drug on the market in any EU country, it may not prevent the sale of that drug within the EU by any other firm by claiming a violation of patent rights or trademarks, under most circumstances. Note the patent holder may still prevent the sale of products first marketed outside the EU; it remains illegal to import drugs from Africa, for example, without the permission of the patent holder. But the combination of large price differences within the EU, some of which exist because of price controls, and the inability of pharmaceutical firms to use intellectual property rights to prevent resale of their products has given rise to a substantial market in parallel imported products, now estimated to be €5bn annually.⁸

B. Parallel trade in the United States

As a general rule, the U.S. does not allow parallel trade in pharmaceuticals, but no court decision has ruled specifically on the issue of national vs. international exhaustion of IP rights. According to Rebecca

⁴ *Hoffman-La Roche v. Centrafarm*, Case C-1 02/77, 1978 ECR 11 39.

⁵ *Pfizer v. EurimPharm*, Case C-1/81, 1981 ECR 2913.

⁶ *Bristol-Myers Squibb v. Paranova A/S* Case C-427/93, 1996 ECR 3457.

⁷ *Pharmacia & Upjohn v. Paranova A/S*, Case C-379/97, 2000 FSR 621.

⁸ See N. Tait & A. Jack, Brussels to relent on drugs packaging, *Financial Times* (November 20, 2008).

Eisenberg, “[t]he U.S.’ bargaining position, supported by the pharmaceutical industry, has been that every nation should follow a rule of national exhaustion. But it is not at all clear that this is the law in the U.S.”⁹

Exhaustion of IP rights is particularly unclear for copyright. Section 602(a) of the copyright statute in the U.S. reads “[i]mportation into the United States, without the authority of the owner of copyright under this title, of copies or phonorecords of a work that have been acquired outside the United States is an infringement of the exclusive right to distribute copies or phonorecords.” The U.S. Supreme Court limited the rights of copyright holders to prevent parallel trade in *Quality King Distributors, Inc. v. L’anza Research International, Inc.*¹⁰ by pointing to 109(a): “the owner of a particular copy or phonorecord lawfully made under this title, or any person authorized by such owner, is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord.” This case involved parallel trade in products first manufactured in the U.S. and then exported, and the decision is consistent with international exhaustion of copyright. However, the 9th Circuit Court of Appeals stated explicitly that the “first-sale” doctrine did not apply in *Omega, S.A. v. Costco Wholesale Corporation*,¹¹ which involved importation into the U.S. of watches manufactured in Switzerland (with U.S. copyright).

Section 526(a) of the Tariff Act of 1930 appears to give owners of trademarks the right to prevent parallel trade: “it shall be unlawful to import into the United States any merchandise of foreign manufacture if such merchandise or the label, sign, print, package, wrapper, or receptacle, bears a trademark owned by a citizen of, or by a corporation or association created or organized within, the United States, and registered in the Patent Office by a person domiciled in the United States.” Subsequent court decisions¹² have extended these rights to foreign firms with U.S. trademarks. *K-Mart Corp. v. Cartier, Inc.*¹³ qualified restrictions on parallel trade based on trademark ownership, stating that importing products from a foreign firm under “common control” of the U.S. IP owner is permitted. The IP owner cannot restrict the parallel importing of products manufactured by a foreign subsidiary unless the imported product is materially different from the domestic version.¹⁴

Section 271 of the Patent Law Act reads that “whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.” Thus, owners of U.S. patents can claim infringement by unauthorized importers

⁹ R. Eisenberg, Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development, 72 Ford. L. Rev. 477 (2003).

¹⁰ *Quality King Distribs. Inc., v. L’anza Research Int’l Inc.*, 523 U.S. 135 (1998).

¹¹ *Omega S.A. v. Costco Wholesale Corp.*, 541 F.3d 982 (9th Cir. 2008).

¹² *U.S. v. Eighty-Three Rolex Watches*, 992 F.2d 508, 517 (5th Cir. 1993).

¹³ *K-Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988).

¹⁴ 19 C.F.R. 133.23(3).

of their products. Court decisions in the United States have usually affirmed the rights of patent owners to restrict resale or parallel imports of their products, though not always. In *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*¹⁵ the court ruled that because the patent owner had not expressly forbidden resale into the U.S. by its licensee, the patent owner could not prevent parallel trade. *Jazz Photo v. International Trade Commission*¹⁶ reestablished that U.S. patent owners could claim infringement by the import of goods legally purchased abroad, stating that “[t]o invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent.”

Parallel trade in pharmaceuticals is further complicated in the U.S. by the Federal Food, Drug and Cosmetic Act and its amendments. The primary concern of this Act is safety, rather than exhaustion of IP, but there are a number of provisions relevant to the import of pharmaceutical products. Only the U.S. manufacturer of a pharmaceutical has the right to import that product into the U.S.¹⁷ Imports of foreign pharmaceuticals may not have FDA approval, which is specific to the manufacturer location, formulation, specification of the active ingredients, labeling, and many other features. This is one reason why, after Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 allowing pharmacists and wholesalers to import foreign drugs if certified by the Secretary of Health and Human Services (HHS), then-Secretary Tommy Thompson refused to provide the necessary certification.¹⁸

C. Parallel trade in other major markets

A complete survey of exhaustion regimes in other countries is beyond the scope of this paper, but it is worth noting the situation in several other developed nations. Many Asian countries are more open to parallel trade, particularly in copyrighted and trademarked products, though policies have been in flux over recent years. Japan historically applied international exhaustion in copyright, but changed the law in 2005 to ban parallel imports of music CDs. New Zealand, in contrast, liberalized parallel trade of copyrighted products in 1998. Japan, Australia and New Zealand treat patent rights as internationally exhausted. However, all of these countries make exceptions for products subject to price controls abroad, which is typically the case in pharmaceuticals.

¹⁵ *Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp.*, 266 F. 71 (2d Cir. 1920).

¹⁶ *Jazz Camera Photo v. Int'l Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001).

¹⁷ 21 U.S.C. § 381(d)(1).

¹⁸ See Report on Prescription Drug Importation, Department of Health and Human Services (December 21, 2004), available at <http://archive.hhs.gov/importtaskforce/Report1220.pdf>.

Switzerland treats copyrights and trademarks as internationally exhausted. Until 2008, Swiss law applied national exhaustion to patents. With the exception of pharmaceuticals, the Swiss now use a system of regional exhaustion (with the European Economic Area) for patent rights. As a result of its generally high prices, Switzerland is a destination for many parallel imports.

III. ECONOMIC MODELS OF PARALLEL TRADE

Most theoretical papers on parallel trade assume that the only strategic instruments firms have at their disposal are price, rationing of supply and exit from a market. The focus of these papers is the welfare impact of a move from international price discrimination to a uniform world (or regional) price, following Varian (1985).¹⁹ In the simplest model, which is a static analysis of two markets, moving from third degree price discrimination to uniform pricing has ambiguous effects on welfare. Consumers in the market with higher demand elasticity lose, because the uniform price is higher than that set under third degree price discrimination. Conversely, consumers in market with low demand elasticity are better off. Total welfare increases if and only if the total amount supplied increases, and this depends on the relative size of the two markets, the difference between profit margins in the two markets and the shape of the demand curves.

Malueg and Schwartz (1994)²⁰ show that parallel trade reduces global welfare if there are large differences in demand across countries, because firms will choose not to serve low-price countries. Thus, the empirical prediction is that the existence of parallel trade will reduce the availability of pharmaceuticals in countries with relatively low prices, whether due to price controls or to a high demand elasticity.

A limitation of applying the Malueg and Schwartz model to the pharmaceutical industry is that it does not explicitly consider how an inability to price discriminate affects incentives to invest in research and development (R&D).²¹ More recent research analyzes the additional

¹⁹ H. Varian, Price Discrimination and Social Welfare, *Am. Econ. Rev.*, 75(4), 870-75 (1985).

²⁰ D. Malueg & M. Schwartz, Parallel imports, demand dispersion, and international price discrimination," *J. Int'l Econ.*, 37(3-4), 167-95 (1994).

²¹ This is due to the fall in profits under uniform pricing compared to price discrimination that is a feature of most models. The logic is that if uniform pricing were more profitable, firms would not choose to price discriminate. An exception is Raff and Schmitt (2007), in which firms facing uncertain demand may realize higher profits when parallel trade is permitted. However, the conditions under which this is true in their model are unlikely to apply in the pharmaceutical industry. H. Raff & N. Schmitt, Why parallel trade may raise producers' profits, *J. Int'l Econ.*, 71(2), 434-447 (2007).

welfare consequences for R&D.²² These papers point out that parallel trade can reduce investment in quality or R&D as a result of reducing profits to patent-holders, so that even in cases where parallel trade benefits many consumers in the short run, welfare tends to be lower in the long run. If regulators are rational and recognize the total impact on R&D investment of setting a low price in their home country, they may increase prices and welfare is not necessarily reduced. In particular, Grossman and Lai (2008)²³ argue that parallel trade strengthens the bargaining position of pharmaceutical firms in their negotiations with governments over price, because countries that set prices too low risk products being unavailable and have less ability to free ride on the R&D investment incentives created by countries with higher prices. Their model predicts an increase in price in relatively low price countries.

Most theoretical work does not explore the use of second degree price discrimination. The use of second degree price discrimination involves adapting product characteristics to each local market, with the effect of making parallel imports a less attractive substitute to the original product in high price markets. The welfare effects of such adaptation are again ambiguous. As in the models discussed above, they depend on whether firms choose to supply more markets than under uniform pricing and on the responsiveness of R&D investment to profits. However, customizing products for individual countries may entail significant additional costs for firms. Opportunities for economies of scale may be reduced, for example, and there may be fixed costs associated with design. Welfare effects thus also depend on whether consumers value the customization. Fisher (2007)²⁴ suggests potentially welfare-reducing second degree price discrimination in the context of movie distribution. Movie studios use a “windowing” system in which movies are first released to U.S. movie theaters, then to foreign theaters and pay-per-view television, then to DVD. He states: “That system has substantial and well-known disadvantages from the standpoint of social welfare. Most importantly, it forces many consumers to wait long periods of time before they can watch films. Those harms may well be worse than the welfare losses caused by permitting more overt forms of discrimination.”²⁵

²² See P. Danzon, *The Economics of Parallel Trade*, *PharmacoEconomics* 13(3), 293-304 (1998); P. Rey, *The Impact of Parallel Imports on Prescription Medicines*, University of Toulouse working paper (2003); S. Szymanski & T. Valletti, *Parallel Trade, International Exhaustion and Intellectual Property Rights: A Welfare Analysis*, *Journal of Industrial Economics*, 54(4), 499-526 (2006); and G. Grossman, G. & E. Lai, *Parallel Imports and Price Controls*, *RAND J. Econ.* (forthcoming).

²³ Grossman & Lai, *supra* note 22.

²⁴ W. Fisher III, “When Should We Permit Differential Pricing of Information?” 55 *UCLA L. Rev.* 1 (2007).

²⁵ *Id.* at 26.

IV. EMPIRICAL EVIDENCE ON THE IMPACT OF PARALLEL TRADE

A. The EU experience in pharmaceuticals

The move to a European Common Market has directly affected the pharmaceutical industry in several ways. One major change is the process of obtaining approval to market a drug in the EU. Historically, a firm wishing to sell a new drug had to submit a separate application for marketing approval in each European country, and was to different regulatory standards in each. In an effort to form a single market for pharmaceuticals, the EU established two procedures for drug approval in 1995. The first of these, the Mutual Recognition Procedure, allows a firm to apply for marketing approval in one "reference member state" (RMS). Following approval in the RMS, the firm may launch the drug in other EU countries without additional applications unless another country raises a formal objection over concerns about safety and efficacy. The other procedure, which is required for biological products but optional for most others, involves an application to the newly created European Medicines Evaluation Agency (EMA) for an EUwide marketing approval. These processes have reduced the fixed cost of obtaining regulatory approval in multiple EU countries.

However, selling a drug in most EU countries involves more than approval through either procedure. In general, prices are not determined by market conditions: all but a few countries use explicit price controls on pharmaceuticals, necessitating a sometimes lengthy negotiation with health agencies responsible for providing health coverage to the local population. Many countries also specify that the launch price be set at the minimum or average of the price in a basket of other countries. Once a drug is marketed in several countries at different prices, therefore, any convergence towards a uniform price tends toward the minimum. For this reason, many firms attempt to launch at a uniform price, but this can lead to lengthy launch delays in countries where governments prefer to set a lower price.²⁶ Despite the reduction in the fixed cost of additional entry conditional on launch in one EU country, there are large differences in the set of drugs available across these countries, which are at least partly attributable to price regulation that lowers expected profitability and therefore the launch of a new drug.²⁷

²⁶ P. Danzon & A. Epstein, *Launch and Pricing Strategies of Pharmaceuticals in Interdependent Markets*, University of Pennsylvania working paper (2005).

²⁷ P. Danzon, R. Wang & L. Wang, *The Impact of Price Regulation on the Launch Delay of New Drugs*, *Health Econ.*, 14(3) (2005); M. Kyle, *Pharmaceutical Price Controls and Entry Strategies*, *Rev. Econ. & Stat.*, 89(1), 88-99 (2007).

Accompanying the harmonization of the approval process in the EU has been the tolerance and sometimes encouragement of parallel trade in pharmaceuticals. As noted in Kanavos et al. (2004), most of the benefits of parallel trade have gone to the arbitrageurs rather than to consumers or government payers.²⁸ However, several countries explicitly promote the use of parallel imported products. The UK, the Netherlands and Norway provide financial incentives to pharmacists to dispense parallel imported products, for example, and Denmark, Sweden and Germany require pharmacists to inform patients of their availability. There are some important restrictions on parallel imports.²⁹ A license (approximately €1500 in most countries) is required to import a product of identical chemical composition, dosage form and strength from another EU country. A single 10 milligram (mg) tablet of a chemical is not, by this definition, a perfect substitute for two 5 milligram tablets, nor is a 10 mg tablet identical to a 10 mg capsule. If the product has packaging in a different language, has a different brand name or has a different pack size, the parallel trader incurs repackaging costs. As noted in Section II, the extent of this repackaging and potential infringement of trademark rights has been a contentious legal issue.

In addition to securing a license and finding adequate supply (usually from distributors and wholesalers in a country with low prices), a parallel importer must find buyers in countries with high prices. Since patients in all EU countries face relatively low co-payments for pharmaceuticals, they tend not to be price-sensitive and do not actively seek out parallel imported versions of products that are reimbursed. Similarly, parallel importers may face some challenges in finding pharmacists willing to buy. Many countries regulate the profit margins of pharmacists and not all pharmacists have the incentive to minimize their supply costs and therefore may not be avid buyers of parallel imports. Germany has imposed a quota on the volume of parallel imports a pharmacist must dispense, but since his margins are fixed, the pharmacist has no strong motivation to find parallel imports that are any cheaper than the original product. The Netherlands and the United Kingdom use “clawback” mechanisms: any savings from the use of parallel imports are shared between the pharmacist and the government health authority, so pharmacists do have some incentive to find a low-cost supply.

In principle, the legalization of parallel imports, as well as the elimination of exchange rate fluctuations resulting from the Euro’s adoption, should reduce price dispersion across EU countries. However,

²⁸ P. Kanavos, P., J. Costa-i-Font, S. Merkur & M. Gemmill, *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis*, LSE Health and Social Care Special Research Paper (2004).

²⁹ Additional details are provided in J. Arfwedson, *Re-importation (Parallel Trade) in Pharmaceuticals*, Institute for Policy Innovation Policy Report 192 (2004).

empirical evidence of the effect of EU integration on price dispersion is mixed. Goldberg and Verboven (2005) find that prices for automobiles have become more uniform within the EU following the adoption of the Euro and other attempts to integrate the European markets, although there remain persistent differences.³⁰ Ganslandt and Maskus (2004) show that parallel imports have resulted in a reduction of the prices of original products for the top 50 drugs in Sweden.³¹ However, another study³² finds that parallel imports have had little effect on prices in the EU for the 20 top-selling drugs. By and large, parallel imports of these drugs were not sold at much of a discount to original products. The authors point out that parallel imports do not generate significant savings either to patients or to national health systems in most cases.

Price controls significantly constrain the ability of firms to increase prices, so it is not usually possible to set a uniform price at the average between the high and low price markets. Another important factor limiting the application of standard economic models of price discrimination is EU competition law. Practices that interfere with parallel trade or that can be shown to be an abuse of dominant position, such as rationing supply to a low price market in an attempt to restrict exports, are legally problematic.

Pharmaceutical firms are therefore limited in their ability to use price and, to some extent, rationing as strategic variables in response to parallel trade: in general, they cannot raise prices in the lower-price markets (though they should encounter little resistance to lowering prices in higher-price markets), and they may not explicitly ration supply. Withdrawing all versions of a drug from a low price market may be politically costly, and more importantly, could be interpreted by a government as a failure to "work" a patent and result in compulsory licensing — which may then also serve as parallel imports into other countries. Due to community exhaustion of intellectual property rights, firms may not rely on intellectual property claims to prevent arbitrage across borders. Decisions made about the timing of entry and initial price are crucial, given the constraints on ex post changes. A number of papers examine how price controls have affected launch delays and pricing decisions in relation to price regulations in the EU.³³ All these papers use a molecule or new chemical entity as the unit of analysis.

³⁰ P. Goldberg & F. Verboven, Market Integration and Convergence to the Law of One Price: Evidence from the European Car Market, *J. Int'l Econ.*, 65(1), 45-73 (2005).

³¹ M. Ganslandt and K. Maskus, The Price Impact of Parallel Imports in Pharmaceuticals: Evidence from the European Union, *J. Health Econ.* 23(5), 1035-57 (2004).

³² Kanavos, Costa-i-Font, Merkur & Gemmill, *supra* note 28.

³³ Danzon, Wang & Wang, *supra* note 27; M. Kyle, Pharmaceutical Price Controls and Entry Strategies, *supra* note 27; Danzon & Epstein, *supra* note 26.

Recent empirical work examining parallel trade in pharmaceuticals at the package level within the EU provides some evidence of the impact of parallel trade and how firms respond to it. The relevance of competition law to some of these responses is discussed in the following section.

Kyle et al. (2008) found no reduction in the price dispersion of a large sample of pharmaceutical products within the EU relative to a control group of countries without parallel trade.³⁴ This suggests that parallel trade did not induce originators to alter their pricing decisions on existing products very dramatically, nor did parallel imports substantially lower average (quantity-weighted) prices. Indeed, parallel trade did not occur in most products, despite large price differentials within the EU. When parallel trade did take place, the average share of arbitrageurs was less than 10%. While the impact is greater for the top-selling drugs, Kanavos et al. (2004) also found that parallel trade did not result in significantly lower prices in the UK, Germany, the Netherlands and other common destinations for parallel trade.³⁵

Kyle (2009) presented findings consistent with a number of non-price strategic responses.³⁶ In particular, pharmaceutical firms adjusted the portfolios of products sold in each EU country in a manner consistent with reducing the opportunities for parallel trade. Because parallel trade can occur only for identical products (same chemical, dosage form and strength), firms can differentiate products sold in countries that are typically sources of parallel exports from those sold in countries that would usually have parallel imports. Pharmaceutical firms also appear to reduce the similarity of brand names throughout Europe, particularly between countries that typically export, like Greece and Spain, and those that are usually large importers. This may reflect efforts to raise the repackaging costs for parallel traders or as a basis for legal challenges regarding trademark infringement. In addition, this paper showed some patterns of supply interruption to countries with low prices, like Greece, Spain and Portugal. A number of court cases involving supply restrictions have been brought in recent years, which are discussed in Section V. Finally, though not considered in the empirical papers previously mentioned, some pharmaceutical firms may respond by vertically integrating into distribution in countries that are sources of parallel exports.

In recent years, concerns about counterfeit pharmaceutical products led the European Commission to consider a ban on all repackaging, a move strongly supported by the pharmaceutical industry and opposed by

³⁴ M. Kyle, J. Allsbrook & K. Schulman, *Does Re-importation Reduce Price Differences for Prescription Drugs? Lessons from the European Union*, *Health Services Research*, 43(4), 1308-24 (2008).

³⁵ Kanavos, Costa-i-Font, Merkur & Gemmill, *supra* note 28.

³⁶ M. Kyle, *Strategic Responses to Parallel Trade*, University of Toulouse working paper (2009).

parallel traders.³⁷ Such a ban would enable originators to use small differences in packaging across countries to avoid the threat of parallel trade. However, the proposed ban was dropped in 2008.³⁸

As noted above, some efforts by originators to discourage parallel trade within the EU risk violating Articles 81/82 of the EC Treaty. Efforts to ration or use dual-pricing have been especially contentious. However, other non-price responses are possible and appear to be widespread. There is a possibility that the differentiation of products across EU countries is socially wasteful, unless consumers have very heterogeneous preferences that this differentiation appeals to. It may be that selling an identical product throughout the EU with rationed supply to low-price countries is preferable from a welfare standpoint, even if it violates competition law.

B. Empirical evidence in other contexts

While few empirical academic studies examine parallel trade, in part due to difficulties in obtaining data, there is anecdotal evidence of non-price responses in other settings.

Sellers of software may change features of the products sold in different countries to segment markets and maintain large price differences. Microsoft sells “stripped-down” versions of its operating system and productivity software for \$3 in developing countries. These versions lack many features that appeal to users in countries with higher prices, thus limiting the opportunities for parallel trade. Software firms also use “licenses to use” rather than outright sale of their products, because many countries treat IP rights as exhausted by first sale but not by a license, though the effectiveness of this tactic varies across countries. Textbook publishers have responded to parallel trade in their products by selling “international editions” in addition to those sold in the U.S. The international versions may have some changes in content, such as using different currencies or systems of measurement. They are also sometimes of arguably lower quality; they may be printed on cheaper paper, in softcover, in black and white, and without supplementary materials.

The use of region codes in DVDs is one example of how manufacturers can introduce technological barriers to parallel trade. DVDs sold in Europe will not play on DVD players in the U.S., and vice versa. As then Competition Commissioner Mario Monti noted in a 2001 speech, his office received complaints “that such a system allows the film production companies to charge higher DVD prices in the EU because EU consumers

³⁷ A. Jack, EU to review drugs rules amid concern about fakes, *Financial Times* (May 22, 2007).

³⁸ Tait & Jack, *supra* note 8.

are artificially prevented from purchasing DVDs from overseas.”³⁹ Another example of a technological barrier is “locking” mobile phones (such as the iPhone) to a specific country.

Thus, liberalizing parallel trade may not necessarily result in a reduction of international price differentials or large benefits for countries with high prices. Responses by originators to sustain market segmentation undermine the price effect of competition from parallel imports. However, clearly the threat of parallel trade does have an effect: these responses might be costly, both in terms of production costs as well as consumer welfare in some markets.

V. PARALLEL TRADE AND COMPETITION POLICY

A. Competition law in the European Union

Competition law in the EU specifically promotes the free movement of goods between member states. Any attempt by an IP owner to limit parallel trade thus risks violating Articles 81 or 82 of the EC Treaty. Article 81 deals with cartels and collusive behavior (including both vertical and horizontal relationships) that impedes competition within the EU. Article 82 addresses the abuse of a dominant position, which IP owners may hold if a market is defined sufficiently narrowly. For example, responses such as the following may be considered anti-competitive: banning exports by downstream firms located in countries with relatively low prices, in an effort to restrict parallel trade to higher-price markets; charging different prices for goods intended for domestic consumption versus those intended for export; and restricting supply to distributors in countries that are often sources of parallel trade.

EU courts have repeatedly ruled that vertical agreements between manufacturers and distributors that prohibit parallel exports violate Article 81.⁴⁰ The agreement need not be explicit; implied threats to cut off supply as a punishment for selling to parallel exporters,⁴¹ or circulation of documents asking distributors not to sell to parallel exporters⁴² also constitute agreements between undertakings to interfere with the free movement of goods between member states. In a case involving pharmaceuticals, the Commission asserted that including the words “export prohibited” on invoices sent to customers formed an implicit

³⁹ M. Monti, Content, Competition and Consumers: Innovation and Choice (June 11, 2001), available at <http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/01/275&format=DOC&aged=1&language=EN&guiLanguage=en>.

⁴⁰ See, e.g., *Grundig-Consten*, OJ 161/2545 (1964); *GERO-fabriek*, OJ L16/8 (1977); *Johnson & Johnson*, OJ L377/16 (1980).

⁴¹ *National Panasonic*, OJ L/354/28 (1982).

⁴² *John Deere*, OJ L35/58 (1985).

agreement between the Italian subsidiary of Sandoz and its customers, i.e. was not unilateral conduct, and thus Article 81 applied.⁴³

Restricting supply in response to parallel trade has been the subject of many complaints to the European Commission and subsequent court cases. Commissioner Monti acknowledged that roughly 30 cases were pending in 2003. A particularly high profile case involved Bayer and its distributors in France and Spain.⁴⁴ In an effort to reduce parallel trade in its drug Adalat, Bayer tried to supply distributors in France and Spain only with adequate quantities for domestic consumption. In principle, the distributors could resell to parallel exporters to take advantage of higher prices in the UK. Distributors faced a requirement to supply their national markets, though, and supply restrictions thus limited their ability to divert products. The ECJ eventually ruled that unlike the *Sandoz* case, there was no agreement between Bayer and its distributors, so the supply restrictions did not violate Article 81.

However, even if supply restrictions to restrict parallel trade are permitted under Article 81, there remains the question of whether they constitute an abuse of dominant position under Article 82. What constitutes a dominant position depends critically on how the market is defined. Under a narrow definition, such as a molecule or chemical composition, most pharmaceutical firms indeed hold such a position for any product still under patent protection (not facing generic competition). Not surprisingly, parallel importers and wholesalers prefer this definition to a broader one based on therapeutic substitutes, which is more commonly used in merger analysis.

In two recent cases,⁴⁵ the pharmaceutical firm in question, Glaxo, was found to have a dominant position in some of the products it was rationing to its Greek distributors. However, the opinions of the ECJ and two Advocates General (AG) suggest that such supply restrictions do not amount to a per se violation of Article 82; as AG Jacobs stated in his opinion in *Syfait v. GlaxoSmithKline*, "a dominant pharmaceutical undertaking which restricts the supply of its products does not necessarily abuse its dominant position within the meaning of Article 82 EC merely because of its intention thereby to limit parallel trade."⁴⁶ He suggested that three factors are relevant. First, the existence of price regulation throughout the EU; second, the effect of parallel trade on the legitimate business interests of pharmaceutical firms given the economics of the industry; and third, the effect of parallel trade on the welfare of consumers and purchasers. He identified price regulation as a key difference from

⁴³ *Sandoz Prodotti Farmaceutici v. Comm'n*, Case C-277/87, 1990 ECR 45.

⁴⁴ *Bayer v. Commission*, Case T-41/96, 2000 ECR II-3383.

⁴⁵ *Syfait v. GlaxoSmithKline*, Case C-53/03, Joined Cases C-468/06 to C-478/06, 2008.

⁴⁶ *Syfait and Others v. GlaxoSmithKline AVEVE*, Case C-53/03, Opinion of AG of 28 October 2004.

other industries, and pointed out that price differentials within the EU were not necessarily the result of pharmaceutical firms' decisions, but rather imposed by national governments.

Though AG Ruiz-Jarabo Colomer agreed that these three factors were relevant, he maintained that price controls are the outcome of negotiations between member states and pharmaceutical firms, and that pharmaceutical firms do have some discretion in pricing.⁴⁷ Thus in his opinion, and in that of the ECJ, Glaxo did violate Article 82 by restricting supply.

An ongoing case⁴⁸ concerns the use of dual-pricing to thwart parallel trade and also depends critically on how price regulation is viewed by the court. In the late 1990s, Glaxo attempted to sell its products to Spanish wholesalers at one price for domestic resale, and a second (higher) price for sales outside Spain. Glaxo was open about its intention to discourage parallel trade, but argued that the price differences across Europe were not a result of its own efforts to segment the market, but rather a consequence of price controls. The European Commission ruled against Glaxo in 2001, finding that the use of dual pricing was a violation of Article 81, but this ruling was overturned in 2006 by the ECJ's Court of First Instance.⁴⁹ Similar complaints have been filed against other major pharmaceutical firms, including Pfizer, Sanofi Aventis, Lilly and Novartis.⁵⁰

Article 81 contains a requirement of particular importance to how pharmaceutical firms may respond to parallel trade. This is the obligation to supply:

The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

This obligation restricts the ability of pharmaceutical firms to withdraw from a national market (which economic theory predicts they would do in many circumstances). However, instead of a complete withdrawal from a market, pharmaceutical firms might instead selectively withdraw presentations or packages to exploit the regulatory requirement that authorizes parallel trade only for identical products; as noted in the

⁴⁷ *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEEV*, Joined Cases C-468/06 to C-478/06, Opinion of AG of 1 April 2008.

⁴⁸ *GlaxoSmithKline Servs. Unlimited v. Comm'n of the European Communities*, Case T-1 68/01, ECR II-2969, 2006.

⁴⁹ *Id.*

⁵⁰ See http://www.eaepc.org/admin/files/eaepc_press_release__parallel_distributors_file_complaint_against_dual-pricing_in_spain.doc

previous section, Kyle (2009)⁵¹ found aggregate evidence for this behavior. The Commission ruled that AstraZeneca had abused its dominant position in withdrawing some presentations from Denmark, Norway and Sweden and this case is still under appeal.⁵²

B. Competition Law in the United States

The U.S. has considered allowing parallel trade in pharmaceuticals several times in the last decade. Usually, the proposals would permit parallel imports (or “re-importation”) from Canada; some have included the EU and other countries as possible sources.⁵³ In the early 2000s, illegal cross-border trade (mostly through internet pharmacies) reached more than \$1 billion in value and was a prominent political issue in both the U.S. and in Canada.

Many products sold in the U.S. market are not approved for sale in Canada.⁵⁴ Allowing parallel imports from Canada may not result in trade in a large number of products, therefore. However, for products that are available in both countries, the impact depends largely on whether pharmaceutical firms may legally ration supply to Canada.

Anecdotally, pharmaceutical firms have already tried rationing supply to Canadian pharmacies.⁵⁵ In early 2004, Pfizer warned its Canadian distributors that it would refuse to supply them if it learned of sales to anyone exporting its products out of Canada. GlaxoSmithKline chose to supply retail pharmacies directly, in order to avoid selling to distributors or online pharmacies likely to engage in cross-border trade. AstraZeneca, Wyeth, Eli Lilly and Novartis also took steps to limit or control supply.

These rationing attempts triggered criticism from U.S. lawmakers and antitrust authorities. For example, Wisconsin Governor Jim Doyle sent a letter to then Attorney General John Ashcroft with the following:⁵⁶

My office has been notified that several major pharmaceutical companies have recently made what appears to be a concerted and coordinated effort to impose severe restrictions on how and to whom the wholesale drugs that they provide to Canadian distributors may be sold. Companies are also threatening to ration the supply of drugs to distributors who make their products available to Americans at more affordable prices. The

⁵¹ Kyle, *Strategic Responses to Parallel Trade*, supra note 36.

⁵² *Paranova Lakemedel v. Lakemedelsverket*, Case C-15/01, 2003 ECR-I-4175.

⁵³ HR-2427 and S-2328.

⁵⁴ Danzon, Wang & Wang, supra note 27; M. Kyle, *Pharmaceutical Price Controls and Entry Strategies* supra note 27; Danzon & Epstein, supra note 26.

⁵⁵ M. Korcak, *Internet pharmacy: the tug-of-war intensifies*, *Canadian Med. Ass'n J.*, 170 (6), 2004.

⁵⁶ http://www.wisgov.state.wi.us/docs/12.19.03_AshcroftLetter.pdf.

actions taken by these companies have caused at least one distributor, from whom the state of Wisconsin may have purchased prescription drugs at a considerable savings to taxpayers, to pull out of negotiations.

If there is collusion or other anti-competitive behavior taking place that deprives the citizens of Wisconsin and other states of the opportunity to purchase prescription medications at the lowest possible prices, it must be stopped immediately. Therefore, I call on you to initiate an investigation into these allegations to enforce the anti-trust laws and guarantee that the citizens of Wisconsin are able to bargain for the most competitive prices.

The unilateral decision of a firm to restrict supply is not a violation of the Sherman Act unless the firm is a monopolist. In pharmaceutical markets, that would generally require a market definition at the level of a patented chemical or biologic, which is quite narrow. However, this is not without precedent. The Federal Trade Commission defined pharmaceutical markets at the level of a molecule or formulation in a number of complaints against Abbott Laboratories,⁵⁷ Hoechst Marion Roussel⁵⁸ and Schering-Plough,⁵⁹ and in merger challenges involving Baxter International-Wyeth,⁶⁰ Glaxo Wellcome-SmithKline Beecham⁶¹ and Pfizer-Pharmacia.⁶² For broader market definitions, which have also been used in various cases by antitrust authorities, the actions of the pharmaceutical firms would indeed have to be coordinated in order to violate the Sherman Act.

As discussed above, a move from third degree price discrimination to uniform pricing through arbitrage tends to harm the market with lower prices due to reduced supply. Some in Canada recognized this potential. In a joint statement in late 2006, several Canadian interest groups reacted to the possibility of legalized parallel trade by asking for an export ban, citing the risk of supply shortages in Canada: "Canada needs to stop the cross-border drug trade before, rather than after, the United States legalizes drug imports from Canada. We need to protect Canadian patients and Canada's drug supply. As a responsible ally of the United States, the government must also act to protect Canadians and Americans against abuse of our system."⁶³

⁵⁷ Abbott Labs. & Geneva Pharm., Inc., FTC Docket Nos. C-3945, 3946 (May 22, 2000).

⁵⁸ Hoechst Marion Roussel, Inc. & Andrx Corp., FTC Docket No. 9293 (Mar. 16, 2000).

⁵⁹ Schering-Plough Corp., Upsher-Smith Labs. & Am. Home Prods. Corp., FTC Docket No. 9297 (Mar. 30, 2001).

⁶⁰ Baxter Int'l, Inc. & Wyeth, FTC Docket No. C-4068 (Feb. 3, 2003).

⁶¹ Glaxo Wellcome plc & SmithKline Beecham plc, FTC Docket No. C-3990 (Jan. 26, 2001).

⁶² Pfizer Inc. & Pharmacia Corp., FTC Docket No. C-4075 (May 27, 2003).

⁶³ http://www.pharmacists.ca/content/about_cpha/whats_happening/cpha_in_action/pdf/Consensusfinal.pdf.

IV. CONCLUSION

Parallel trade is at the complicated intersection of trade, IP and competition policy. This paper outlines the theoretical implications and empirical outcomes in the EU, where parallel trade in pharmaceuticals is most widespread. Strategic responses by pharmaceutical firms to parallel trade have moderated the price impact of this arbitrage, but have raised many questions in IP law and competition law. Of the latter, efforts to restrict supply and use dual pricing have been most important. This paper emphasizes that other non-price responses may also be used, particularly those that exploit IP rights. The application of antitrust law to these actions is not obvious. More generally, the welfare consequences of parallel trade are ambiguous, even when these non-price responses are ignored, and may depend to a large extent on the details of how parallel trade is regulated.

For example, should the U.S. liberalize parallel trade, pharmaceutical firms may adjust the characteristics of products sold in the U.S. from those in countries with lower prices. By doing so, they could rely on court decisions that uphold the rights of originators to prevent parallel imports of trademarked products that are materially different from those sold domestically. The definition of materially different would probably depend on how the Food and Drug Administration chose to regulate parallel imported products — whether, for example, the FDA insisted on identical dosage forms and strengths, as in the EU, or the amount of relabeling that is tolerated. Given the safety concerns in pharmaceuticals, it is likely that the FDA would require that parallel imports be identical to the originator products in the U.S. along most dimensions, particularly on ingredients and manufacturing location.

The EU experience suggests that pharmaceutical firms adjust such characteristics to limit the opportunities for parallel trade. The consequence may be a proliferation of package specifications and manufacturing facilities, which likely increase the total costs of production. Safety regulations in developed countries probably preclude strategies as extreme as those observed in software or textbooks, whereby products in some countries are clearly inferior quality. However, pharmaceutical firms may select a subset of countries for selling particularly convenient dosage forms, combinations or extended release formulations, while countries with low prices receive “basic” versions. Such responses have greater welfare implications for parallel exporting countries, but would also limit price reductions associated with parallel trade in the U.S.

Going forward, the issue of parallel trade is likely to remain of great importance to pharmaceutical firms and to antitrust authorities. The expansion of the EU to include central European countries with lower GDP per capita may exacerbate price differences and arbitrage

opportunities in pharmaceuticals. Parallel imports continue to be discussed in the context of TRIPS as well as bilateral trade agreements. While the resolution of a number of pending court cases may establish clearer guidelines for what responses antitrust authorities will tolerate, the social welfare implications of parallel trade remain murky.