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# Strategic Responses to Parallel Trade

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# Strategic Responses to Parallel Trade*

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## Abstract

High prices for patented pharmaceuticals have prompted many governments to consider allowing competition from "parallel imports," or products first sold at lower prices in other countries. This paper examines how pharmaceutical firms have responded to changes in intellectual property rights and trade barriers that legalized parallel imports within the European Union (EU). The threat of arbitrage by parallel traders reduces the ability of firms to price discriminate across countries. Due to regulations on price and antitrust law on rationing supply, pharmaceutical firms may rely on non-price responses. Such responses include differentiation of products across countries and selective "culling" of product lines to reduce arbitrage opportunities, as well as raising arbitrageurs' costs through choice of packaging. Using a dataset of drug prices and sales from 1993-2004 covering 30 countries, I find evidence that the behavior of pharmaceutical firms in the EU with respect to their product portfolios is consistent with attempts to reduce parallel trade. This may at least partially explain why parallel trade has not yet resulted in significant price convergence across EU countries. Accounting for non-price strategic responses may therefore be important in assessing the welfare effects of competition from parallel imports.

**KEYWORDS:** parallel trade, pharmaceuticals, intellectual property, competition policy

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## I. INTRODUCTION

Cross-national differences in pharmaceutical prices are the topic of much discussion in the press and in policy circles. Several studies have documented these differences (Stuart et al. (2000), Danzon and Chao (2002), Danzon and Furukawa (2005)) and provided some explanations for their underlying causes, such as differences in patient demand, national income and the use of price controls by governments. Historically, these international price differences have persisted in part because of laws preventing arbitrage of drugs across borders. Concern over the prices of patented pharmaceuticals in the US and other countries has prompted suggestions that competition from "parallel imports" – that is, products first marketed abroad at a lower price -- would provide significant cost savings to patients or third-party payers.

Firms in many industry sectors often rely on trade barriers or intellectual property rights to charge different prices in different countries in response to local market conditions. This paper examines how European integration, which involved changes in both trade regulations and intellectual property rights that have led to legalization of parallel imports, has affected the product market strategies of pharmaceutical firms. In particular, it illustrates the importance of non-price responses, such as adjustments in product offerings or characteristics, to maintain price differences across borders. In IP-intensive sectors such as consumer electronics, college textbooks and software, such practices are common. However, non-price responses have received little attention in the debate over the welfare effects of parallel trade, which undermines the ability of firms to price discriminate across countries.

The issue of parallel trade is at the intersection of competition law, intellectual property (IP) law and trade law, and therefore is an important policy issue for governments and international organizations. There have been proposals in the United States to permit parallel imports from Canada (and other countries) in the last several years.[1] In addition, non-governmental organizations such as Médicins Sans Frontières have lobbied for a policy of "international exhaustion" of patent rights, which would remove the current barrier of IP rights to parallel trade in most countries.[2] 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-

[1] Congress passed a law allowing parallel imports from Canada under President Clinton, but the Department of Health and Human Services and the Food and Drug Administration declined to enforce it, citing safety concerns.

[2] Under the TRIPS agreement, each country can choose a policy of national (domestic) exhaustion (which would allow patentholders to prevent unauthorized imports) or international exhaustion of patent rights. Hong Kong and Argentina apply international exhaustion; most others use national. In contrast, most countries have adopted international exhaustion of trademarks. Kyle (2009) provides an overview.

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 (EMEA) for EU-wide 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, also known as international reference pricing. 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 (Danzon and Epstein (2005)). 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 (Danzon et al. (2005), Kyle (2007), and Lanjouw (2005)).

Besides changes in the approval process, pharmaceutical firms have experienced an important change in the protection afforded by patents they hold in the EU. Court decisions by the European Court of Justice during the last 25-30 years have established a policy of "community exhaustion" of patent rights and other forms of intellectual property, such as trademarks and copyrights. Once a patent holder has sold a product within the EU, subsequent buyers may trade it freely within the EU and without interference by the patent holder.[4] 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

[4] A "derogation" period was imposed for countries with relatively weak patent rights prior to joining the EU. These include Spain and Portugal before 1995, and the eight EU ascension members of 2004 (the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, the Slovak Republic, and Slovenia). During the derogation period, these countries could not serve as sources of parallel imports.

pharmaceutical firms to use intellectual property rights to prevent resale of their products has given rise to parallel imports.

There are some important restrictions on parallel imports. A parallel importer must obtain a license to import a product of identical chemical composition, dosage form, and strength from a country with a lower price. A 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 may incur re-packaging costs since he must ensure that the product has packaging appropriate for the country of resale. The cost of a license is approximately €1500 in most countries or €3480 for products approved through the EMEA. The EMEA's "Post-Authorisation Guidance on Parallel Distribution" and Arfwedson (2004) provide additional details.

In addition to securing a license and finding adequate supply (usually from wholesalers in a country with low prices), a parallel importer must find pharmacists willing to purchase their imports. This may seem simple enough; the parallel importer can offer the product at a lower price than that of the original product in the destination country. However, there are a host of country-specific regulations on pharmacists, in addition to pharmaceuticals. For example, a number of countries, including Denmark, Sweden and Germany, fix the profit margins of pharmacists. This reduces the incentive of pharmacists to seek out the lowest cost supply, and hence their demand for parallel imports. Germany has imposed a quota on the volume of parallel imports a pharmacist must dispense (now 7%), 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. Patients in all EU countries have government insurance coverage for most prescriptions, and are rather insensitive to price as a result.[5]

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, 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

[5] Mail order and online pharmacies are not yet widespread in the EU, with the exception of the Netherlands, in part due to country-level regulations on pharmacists and lobbying efforts by pharmacists to require that conventional pharmacies dispense drugs. See Taylor, Mrazek and Mossialos (2004) for additional details.

markets, although there remain persistent differences. 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. However, another study (Kanavos et al. (2004)) finds 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.

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). Malueg and Schwartz (1994) 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. 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). More recent research analyzes the additional welfare consequences for R&D, including Danzon (1998), Rey (2003), Szymanski and Valletti (2005, 2006), and Grossman and Lai (2008). These papers demonstrate 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. Most theoretical work does not explore the use of second-degree price discrimination.[6]

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.[7] 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

[6] Anderson and Ginsburgh (1999) consider the possibility that firms introduce versions of their products in a foreign country in order to price discriminate across consumers with different arbitrage costs, and find that under some circumstances, world welfare is increasing in the cost of arbitrage.

[7] These constraints include laws restricting the rate of price increases or requiring government approval to increase price. While pharmaceutical firms could seek a price increase in countries with price controls, they find it difficult to persuade governments facing their own EU-imposed limits on budget deficits to increase expenditures.

dominant position, such as rationing supply to a low price market in an attempt to restrict exports, are legally problematic.[8]

Price cuts and rationing are, for these reasons, problematic for pharmaceutical firms as responses to parallel trade. Price controls limit the extent (and direction) of price changes, and explicitly rationing supply entails legal risk.[9] A complete withdrawal of a drug from a low price market may be politically costly, and may trigger compulsory licensing by governments. Firms may not rely on intellectual property claims to prevent arbitrage across borders within the EU because IP is considered "exhausted" once the product is sold in any member state. Launch delays in response to price controls and parallel trade are studied in a number of papers (Danzon et al. 2005, Kyle 2007, Lanjouw 2005, and Danzon and Epstein 2005). All previous papers use a molecule or new chemical entity as the unit of analysis, and do not examine post-launch strategies.

This research focuses on the threat of parallel trade in particular (as distinct from price controls), and considers additional strategic choices that firms make: that of product characteristics. It follows a number of recent empirical papers exploring non-price strategic responses to competition. Qian (2008) studies how shoe manufacturers in China react to counterfeiters, and finds that investment in quality is among the responses to the threat from copycats. Mazzeo (2002) demonstrates that motels choose quality to soften competition. Dafny (2005a, 2005b) shows that hospitals, which also face constraints on price responses, find other means to respond to regulatory or competitive changes. This can be in their choice of how to classify a procedure (Dafny (2005a)), or in their investment in quality as a product characteristic (Dafny (2005b)). Duggan and Scott Morton (2006) find that in addition to raising prices for some buyers, pharmaceutical firms in the US introduce more new versions of their products at higher prices in response to Medicaid procurement policies. Ellison and Ellison (2007) examine whether pharmaceutical incumbents made strategic investments in advertising and product proliferation in anticipation of generic competition, in addition to adjusting price. In industries like consumer electronics or DVD distribution, firms exploit differences in product characteristics such as standards across countries for geographic market segmentation. Software firms change the characteristics of

[8] Several drug firms have made attempts to control supply; these were evaluated in Bundesverband der Arzneimittel-Importeure and Commission of the European Communities v. Bayer AG (C-2/01 P and C-3/01 P). In October of 2005, the European Association of Euro-Pharmaceutical Companies asked the European Union antitrust authorities to investigate Pfizer for using contracts in Spain that reward wholesalers for keeping products within the Spanish market. Source: "European Pharma Lobby Group Complains To EU About Pfizer," Dow Jones Newswire, Oct. 17, 2005. See Kyle (2009) for additional detail.

[9] The inflexibility of prices in Europe is an important difference with the US market. Scott Morton (1997a, 1997b) studies how pharmaceutical firms adjusted prices in response to changes in Medicaid laws.

their products sold in low-price countries to make them less attractive to buyers in high-price countries, by removing certain features, for example. In the case of pharmaceuticals, product characteristics such as brand name, dosage form, and strength for a particular molecule may serve a similar purpose. In general, these decisions are of second-order concern relative to the decision to launch a drug. However, they can be quite important in the context of parallel trade, and, in particular, for understanding why parallel trade has had relatively little impact on price convergence so far.

This research uses data on a wider variety of products than the Ganslandt and Maskus (2004) and Kanavos (2004) papers, so it is possible to study additional factors that might affect arbitrage. The detailed information on product characteristics – in particular, those characteristics chosen by drug firms after development costs are largely sunk – allows me to look for non-price responses to parallel trade. The data also covers 15 non-EU countries, enabling me to isolate strategic changes specific to parallel trade in the EU separately from general changes in product portfolios.

## III. CONDITIONS FOR PARALLEL TRADE AND STRATEGIC RESPONSES

I begin by considering the decision by a potential arbitrageur to begin parallel importing a particular product, conditional on having entered the business of parallel importing in general. A first requirement is that a match in chemical composition, dosage form, and strength exist between a lower price country and a high price country.[10] The owner of the original product, henceforth the originator, has some control over the number of matches between high and low price countries. One strategic response to the threat of parallel trade is to market the same chemical with different dosage forms and strengths in low price countries than in high price countries. For example, a drug might be sold as 30 mg pills in one country, and 25 mg capsules in another. The originator does face some constraints on its ability to introduce variations: in addition to incurring higher production costs, it must receive regulatory approval for each version. The cost of obtaining approval on a new version is significantly less than for obtaining

[10] The stringency of this requirement is unclear. The European Court of Justice ruled in Kohlpharma GmBH vs. Bundesrepublik Deutschland (Case C-112/02) that the products must be "substantially identical," and that there be no safety concerns related to the differences. Future litigation on this point is likely. In addition, the court ruled in Rhone-Poulenc Rorer (Case C-94/98) that when originators replace versions that face parallel import competition with new presentations, parallel importers may continue to sell the "old" version. However, differences in appearance might affect the willingness of buyers to substitute towards the parallel import. In practice, I identified only a handful of parallel imports without an exact match on all three characteristics in the country of resale.

approval for a new chemical entity, but additional clinical trials to justify a particular method of administration or strength may be necessary.

Assuming a product match exists, the entry condition for a parallel importer is that it expects positive profits:

$$E(\Pi) = E[(p_H - p_L - c_T)q - L] > 0 \quad (1)$$

where $p_H$ is the price of the product in the higher-price country, $p_L$ is the price of the matching product in the lower-price country, $c_T$ is the cost of transporting a product between the countries, q is the number of units the parallel importer supplies in the higher-price market, and L is the license fee. That is, a parallel importer will enter a product market if it expects to cover its fixed costs (L) with a high enough margin ($p_H - p_L - c_T$) on sufficient quantity (q).

The originator can influence the entry decision of a parallel importer through changes in some of these variables. As discussed above, originators are generally prevented from raising $p_L$ due to price controls, but they do have the option of lowering $p_H$ to narrow the price difference, and therefore the attractiveness of entry to a parallel trader. They can increase the transportation costs for a parallel importer by using different brand names in different countries and a variety of different package sizes; this requires the parallel trader to repackage the product for import. Finally, they may reduce the per-package volume of sales for a drug by splitting the total volume over many different versions. Since the parallel importer must obtain a license for each of these versions in the high price country, this has the effect of increasing its relative fixed costs. Rationing – or restricting supply to low price countries – is another strategic response that limits q. It is probably the easiest strategy for originators to implement, at least in the short run, but it is also of questionable legality.[11] Due to the limitations of my dataset, it is difficult for me to identify when rationing occurs with much certainty. As an alternative, I look for evidence of supply interruptions to countries that are likely sources of parallel trade.

Since at least the 1970s, pharmaceutical firms and others have challenged parallel imports under trademark law. While trademarks are usually internationally exhausted, trademark owners object to any changes made to packaging that might interfere with the trademark, usually arguing that such changes interfere with a buyer's ability to identify the manufacturer. The European Court of Justice has established the circumstances under which

[11] Firms may be sued for violating Articles 81 and 82 of the Treaty of Rome, which relate to competition law. The courts must determine whether rationing is an abuse of a dominant position and restricts parallel trade in practice (intent to restrict is not enough), or there is an agreement between the firm and wholesalers to restrict competition.

repackaging is permissible in a series of decisions;[12] most of these decisions did not result in as many restrictions on parallel trade as trademark owners would have liked. While I do not consider non-market strategies such as litigation in response to parallel trade, the uncertainty surrounding the legality of parallel imports probably limited their prevalence through at least the mid-1990s.

To illustrate how these various strategies work in practice, Appendix A contains package information and prices for Adalat (nifedipine), a calcium channel blocker that treats high blood pressure, in Finland. Bayer is the originator of Adalat, and has introduced 24 different versions (varying in form and strength) in EU countries. Paranova is the parallel importer of Adalat in Finland. Several points stand out. First, the price of Paranova's imports was generally less than US$ .03 below the Bayer price, or less than a 5% discount. Second, Bayer only faced parallel importing in three versions in Finland. Third, Bayer slightly reduced the prices of those versions that did face parallel import competition. Finally, Bayer discontinued two versions of Adalat that had matching products in Greece, and introduced a new version that did not have a match in Greece. In this particular case, Bayer seems to have responded to parallel imports by reducing the number of matches between Finland and countries with lower prices and by reducing the volume of versions with competing parallel imports by introducing another version, in addition to lowering its prices slightly.[13]

To summarize, this research examines some short-run responses to parallel trade (price reductions, rationing, and product withdrawal) and some longer-run responses (adjustment of brand names and differentiation in package and dosage). In a more complicated model, I would account for other important strategic considerations. For example, cutting price not only reduces the likelihood of entry by a parallel importer, but also may steal market share from substitute chemicals if physicians are sensitive to price differences (though in general, physicians have no incentive to even be aware of price differences, much less respond to them). Within a country, originators may employ some second-degree price discrimination across packages, and I do not account for this. I do not focus here on any strategic interaction between parallel traders, treating them as

[12] These include Hoffman-La Roche vs. Centrafarm (C-102/77); Bristol-Myers Squibb vs. Paranova (C-427/93); Boehringer Ingelheim vs. Paranova (C-429/93); Bayer vs. Paranova (C-436/93); Pharmacia & Upjohn vs. Paranova (C-379/97); Boehringer Ingelheim vs. Dowelhurst (C-143/00); Merck, Sharp and Dohm vs. Paranova (C-443/99); and Aventis Pharma vs. Kohlpharma (C-433/00).

[13] Adalat was the subject of a long-running legal battle in the EU. In 1996, Bayer was fined for rationing supply between 1989 and 1993 to wholesalers in France and Spain, who were re-selling for parallel import into the UK. The claim was that Bayer had formed a cartel with its wholesalers, a violation of EU competition law. In January 2004, the European Court of Justice determined that Bayer had acted unilaterally and had not violated any competition law since it did not have a dominant position in the market.

undifferentiated and with low sunk costs.[14] Pre-launch strategies, such as delaying launch into low price markets, are assumed to be independent of the post-launch decisions I consider here. Finally, I do not model the choice(s) each firm makes, out of a menu of strategic options, although it is quite likely that not all firms respond to parallel trade in the same way and an individual firm may use multiple strategic responses. Because I have complete data on products within therapeutic classes across countries (described below), but not complete data on a firm's products across all therapeutic classes, I cannot analyze firm-level strategies across its entire portfolio of products. However, I can examine a firm's decisions about price, brand name and other characteristics for a specific product across 30 countries, while controlling for market conditions. I argue that despite the limitations of the dataset and reduced-form analysis, the pattern of results from many different analyses is consistent with efforts by originators to reduce competition from parallel imports.

**Table 1: Summary statistics for Midas data**

| | | | | | |
|---|---|---|---|---|---|
| Number of countries | | | | | 30 |
| Number of quarters | | | | | 47 |
| Number of unique dosage forms | | | | | 120 |
| Number of unique drugs (chemical combinations) | | | | | 1031 |
| Number of unique versions (drug-form-strength) | | | | | 9013 |
| Number of unique country-versions (drug-form-strength) | | | | | 21075 |
| | N | Mean | SD | Min | Max |
| Standard units shipped in quarter (1000s) | 957962 | 11.24 | 62.02 | 0.00001 | 3223.09 |
| Ex-manufacturer revenues, US$ | 957962 | 559487 | 4622218 | 1 | 726407713 |
| Ex-manufacturer price (wholesale purchase price) per standard unit, US$ | 957962 | 21.94 | 118.83 | 0.00001 | 13700.29 |

## IV. DATA

The data used in this research is a subset of the IMS Midas database, which is the most comprehensive source of information on drug prices and sales across countries. My dataset covers a total of 30 countries for all drugs assigned to 36 therapeutic classes (measured at the 4-digit Anatomical Therapeutic Chemical, or ATC, level) in five broader categories for 1993Q1-2004Q3. These are listed in

[14] In reality, parallel importers may be a heterogeneous bunch. The largest of them have sophisticated re-packaging factories, and certainly some (like Paranova) have been very aggressive in testing EU intellectual property and competition law as they relate to parallel trade.

Appendix B. The dataset contains information at the package (i.e. chemical(s), dosage form, strength, and pack size) level on the quantity sold within each country, as well as the ex-manufacturer, wholesale, and retail price per "standard unit" (typically a pill, capsule, vial, etc.) measured in US dollars at the current exchange rate in each quarter. Summary statistics are provided in Table 1. There are 1031 different chemicals (or unique chemical combinations) in these classes. This sample includes many products that are not "new chemical entities," but which appear to be herbal medicines marketed in only one or two countries, or products that are merely new combinations of existing chemicals. As a robustness check, I have run all the following analyses on the subset of chemicals that have been marketed in the US, and therefore meet FDA standards for safety and efficacy, and obtained similar results.

IMS identifies some products in the Midas data as parallel imports, though the source country is unknown. In the dataset provided to me, the only countries with a significant fraction of products flagged by IMS as parallel imports are Germany and the UK. Since other sources have named the Netherlands and Scandinavian countries as important destination markets, this suggests that IMS labels only a subset of parallel imports.[15] I therefore use additional criteria to identify parallel imports. If a manufacturer or corporation sold any product labeled a parallel import by IMS, I treat all its other products as parallel imports too (after checking that the manufacturer did not sell any product that would not be a candidate for parallel trade). To improve on this further, I tried to determine whether each corporation in the dataset is a parallel importer by looking at company websites, the membership lists of parallel import trade associations in the EU, and lists of approved parallel imports available from regulators in the UK and Denmark. The reclassification of products using this information led to a much more reasonable picture, consistent with other studies, on the penetration of parallel imports into Germany, the UK, the Netherlands, Denmark, Finland, and Sweden.[16]

Parallel trade occurs only if price differences exist across markets. In a related paper, Kyle et al. (2007) show that price dispersion for pharmaceuticals is both large and persistent throughout the time period I examine here. Roughly half of all price differentials at the drug level across the EU exceeded 50% (i.e., a given drug was 1.5 times as expensive in the priciest market compared to the

[15] I am forced to assume, for lack of a better data source, that IMS mislabels whether products are parallel imports but does include all product sales.

[16] Classification is not straightforward for all firms. For example, an entity called Delta Pharmaceuticals is a parallel importer of some products into the UK. A firm by the same name markets 2 drugs in Portugal, which are flagged as parallel imports using my rule. Delta does not market the same drugs in the UK, so these are probably two different firms. Fortunately, these classification issues affect few observations.

cheapest). As well, the distribution of price differentials did not fall dramatically after parallel trade became possible, and in fact fell less than across non-EU countries. At the aggregate level, therefore, parallel imports have had only a small effect, if any, on price dispersion. In contrast, Goldberg and Verboven (2005) find that EU integration has reduced price dispersion in automobiles, an industry that also historically had large price differences across countries.

## V. RESULTS

To begin, I estimate determinants of parallel trade entry. The purpose of this analysis is to establish that parallel importers respond to factors over which originators have some control, so that the strategic responses I suggest can be expected to have some effect on the behavior of parallel importers. Ideally, I would estimate entry into each source-destination product pair, since a parallel importer must specify the country from which it will obtain supply. However, I am unable to identify the source country of parallel imports in my data; I observe only the destination market. I therefore estimate entry by parallel importers into product j in country i using a logit. Based on the profit function for parallel traders described in Section III, I proxy for the terms related to price differences, availability of supply for parallel imports, demand for parallel imports, and transportation costs as follows:

*Price difference*: Average log price difference between originator price in country i and other EU countries
*Availability of supply*: Log of standard units sold in EU at a lower price, number of EU markets in which product is available, number of EU markets with a lower price, number of source countries with identical version, number of EU markets with parallel trade in this product
*Demand for parallel imports*: Log of standard units sold by originator in country i
*Transportation costs*: Number of EU markets with a different brand name than that in country i

Table 2 provides parameter estimates. I include country, time period and therapeutic class fixed effects to control for differences in the costs or benefits to entry related to regulation of pharmacists, storage requirements and other factors.

**Table 2: Results from entry regression**

| Y = 1 if parallel imports occur for version j in country i at time t | Coef. (StdErr) | dY/dX |
|---|---|---|
| Average log price difference between originator price in country and other EU countries | 0.028 (0.019) | 0.001 |
| Log of standard units sold by originator in market | 0.291** (0.006) | 0.008 |
| Log of standard units sold in EU at a lower price | 0.043** (0.007) | 0.001 |
| Number of EU markets in which product is available | -0.036** (0.006) | -0.001 |
| Number of EU markets with a lower price | 0.123** (0.005) | 0.003 |
| Number of EU markets with parallel trade in this product | 0.228** (0.009) | 0.006 |
| Number of EU markets with different brand name | -0.015** (0.002) | 0.000 |
| Number of "source" countries with identical version | 0.073** (0.011) | 0.002 |
| Intercept | -5.565** (0.202) | 0.027 |
| Number of Observations | 167086 | |
| Log Likelihood | -34918.318 | |
| Pseudo-Rsq | 0.3263 | |

* = significant at the 5% level, ** = significant at the 1% level. All specifications include country, therapeutic class and period fixed effects. Marginal effects are computed at the mean of all variables.

Results are consistent with expectations. The probability of entry by parallel importers is increasing in the average price difference between country i and other EU member states, the volume of sales in country i, and the availability of lower cost supplies elsewhere. Parallel imports are less likely when the product has many different brand names in the EU, since a parallel trader would have to incur additional repackaging costs to sell them in country i. The parameter estimates are robust to changes in the sample of drugs, such as restricting the analysis to drugs whose patents have not yet expired and to drugs launched in the US market (results not reported here). Having demonstrated that parallel

importers respond to factors over which originators have at least partial control, I now turn to evidence of strategic responses by originators to reduce entry by parallel traders.

1. Have originators reduced price differentials?

Since price controls restrict the ability of pharmaceutical firms to increase price, I focus here on whether firms decrease price in order to deter, or in response to, entry by parallel traders. To make entry by parallel traders less attractive, the originator can reduce the average price differential between a high price country and those with lower prices. Originators should be more likely to reduce prices of those versions for which parallel trade is most likely, i.e., those with matches in several other countries. They may also choose to reduce price on products facing parallel imports, in order to make substitution towards parallel imports less attractive to pharmacists or patients.

Products in non-EU countries face no threat of parallel imports, and products in the EU face entry by parallel traders only if there are other EU countries with a matching version at a lower price. Similarly, a given product does not experience entry by parallel traders in all countries. To look for a price response, I estimate the regression equation:

$$\text{Ln}(\text{Originator price}_{ijt}) = \beta_0 + \beta_1 \text{Threat}_{ijt} + \beta_2 \text{Entry}_{ijt} + \beta_3 \text{Competition}_{ijt} + \varphi_{ij} + \kappa_t + \varepsilon_{ijt} \quad (2)$$

where i indexes country, j indexes a drug version (chemical/form/strength), t indexes quarters, φ is a country-drug version fixed effect and κ is a time period fixed effect.[17]

I measure potential entry (or the threat of parallel imports) as the number of typical "source" countries for parallel trade in which an identical version is available. I define Greece, Italy, Spain, Portugal, and France as source countries based on the following evidence. First, the average price index for pharmaceuticals for each of these countries was below the EU average, with France and Portugal having the lowest price indices (Urch Publishing, 2001), in 1998. Second, Ganslandt and Maskus (2004), who have data on the source of parallel imports into Sweden, identify Spain, Italy and Greece as accounting for 74% of the total there.[18] Spain and Portugal became legal source countries only in

[17] Price is measured in constant US dollars for this analysis. This introduces some noise through exchange rate fluctuations and makes statistical significance less likely.

[18] I experimented with other measures of potential competition. The obvious candidate is the number of countries with an identical version at a lower price, or at a price below some threshold.

1995, when their derogation period ended, and I account for this in constructing my measure of potential entry. As well, three other countries became EU members during my sample period (Austria, Finland and Sweden).[19]

Competition takes two forms. I include the number of competing drugs in the same therapeutic class launched in country i to control for any price changes that are the result of entry by competing chemicals, rather than entry by parallel imports. I also include the number of other non-parallel trading firms that sell the same drug in country i to control for price changes that result from competition from either generic versions or branded versions marketed by other firms, separate from parallel imports.

Table 3 contains the results of the price response regressions, which are estimated using data from EU countries only (as only these observations would have any variation in actual or potential entry by parallel traders). The results show a statistically significant, but economically small, price reduction following entry by parallel imports: for all specifications, prices in the periods following entry by parallel traders fall by roughly 3%. The response to *potential* entry is even smaller. The coefficient on the number of potential source countries (those with an identical version, and which are typically cited as the sources of parallel trade) corresponds to about a 1% price reduction, and is not estimated very precisely. I also examine whether prices respond differently to potential parallel trade across countries by interacting country dummies and the number of potential source countries (all interactions are included, but only a subset are reported in the last column of Table 3). While prices in the Netherlands do appear to be constrained by the threat of parallel trade, in that prices are about 5% lower than for drug versions in other countries facing a similar threat of parallel trade, this is not a widespread pattern. In fact, prices in the UK appear to be higher.

These parameter estimates imply that firms respond to entry by parallel importers by lowering prices about 3%, to potential entry by about 1%, and the response varies across countries. In this setting, the threat of competition from parallel imports does not appear to result in large or widespread pre-emptive price cuts. Parallel trade does have a small impact on price once an importer enters the market, but since only 7% of products in the EU with at least one matching product actually experience entry by parallel traders, this has had a small effect in

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I found either a positive coefficient or a statistically insignificant one in most specifications. One explanation for this is that parallel traders must invest in some infrastructure in each country from which they export, and they have largely sunk this cost for the five countries I treat as "typical sources." While prices for products may vary widely and be significantly lower in other EU countries, parallel traders may not incur these fixed costs for only a few products.

[19] Arguably, these changes in EU membership are a source of exogenous changes in potential entry. However, these changes were clearly anticipated. For this reason, I do not believe this alleviates all endogeneity concerns. My approach is quite similar to that of Goolsbee and Syverson (2008), who examine competitor responses to entry by Southwest Airlines.

the aggregate so far. These results are consistent with Ganslandt and Maskus (2004). Though they find that parallel import competition reduces prices by 12-19% for their sample of top-selling drugs in Sweden, firms in their study also did not react much to potential competition from parallel traders.

2. Have originators reduced the number of matching products in high and low price countries?

To test whether pharmaceutical firms have adjusted their product offerings to reduce the potential for parallel trade, I examine the overlap of products between pairs of countries over time. Each country-period is an observation, with a vector of dummy variables indicating whether a product is available. I calculate the Jaccard similarity measure of any two country-period pairs, Product Similarity$_{ijt}$, as the number of products available in both countries i and j in the period t divided by the number of products available in only one of the two countries.[20] The higher this number, the more similar the product mix in the two countries. I estimate the following regression equation for both the similarity in drugs between markets and also for the similarity in versions of drugs (dosage form and strength combinations):

$$\text{Product Similarity}_{ijt} = \beta_0 + \beta_1 \text{Timetrend} + \beta_2 \text{Market similarity} + \beta_3 \text{Relationship}_{ijt} + \varepsilon_{ijt} \quad (3)$$

where market similarity is calculated as the correlation between a set of variables from OECD Health Data on demographics and pharmaceutical demand, and the relationship between countries i and j is defined as whether both are EU members and whether they are likely source or destination markets for parallel imports. Source countries are defined as above (Greece, Italy, Spain, Portugal and France), and destination countries are Sweden, Denmark, the Netherlands, Finland, Germany and the UK. (The remaining countries are Austria, Belgium, Ireland and Luxembourg.) These countries have the highest penetration of parallel imports in my dataset. When estimating the equation for version similarity, I include drug similarity as a control variable. Table 4 presents the results of this analysis for drug similarity, and version similarity results are in Table 5.

[20] I experimented with other similarity measures, such as the simple matching coefficient and the Bray and Curtis coefficient, and found the same results.

## Table 3: Results from price response regression

| Y = ln(Originator price) | Coef. (StdErr) | Coef. (StdErr) |
|---|---|---|
| Intercept | 0.613** | 0.618** |
| | (0.029) | (0.029) |
| Post entry by parallel traders | -0.031** | -0.028** |
| | (0.006) | (0.006) |
| Post entry by parallel traders in other versions of the same drug | 0.003 | 0.003 |
| | (0.003) | (0.003) |
| Number of competing drugs in class | 0.004 | 0.004 |
| | (0.002) | (0.002) |
| Number of firms selling the same drug | -0.019** | -0.019** |
| | (0.003) | (0.003) |
| Total number of countries with identical version | -0.010** | -0.010** |
| | (0.002) | (0.002) |
| Number of source countries with identical version | -0.013 | -0.018 |
| | (0.008) | (0.012) |
| Germany * # sources | | -0.024 |
| | | (0.013) |
| Denmark * # sources | | -0.032 |
| | | (0.021) |
| Netherlands * # sources | | -0.057* |
| | | (0.024) |
| Sweden * # sources | | 0.013 |
| | | (0.011) |
| Finland * # sources | | 0.032* |
| | | (0.016) |
| UK * # sources | | 0.067** |
| | | (0.016) |
| Within Rsq | 0.387 | 0.390 |
| Number of observations | 251216 | 251216 |
| Fixed effects included | Period, product*country | |

* = significant at the 5% level, ** = significant at the 1% level. All country*number of source countries interactions are included in the regression, but the coefficients are reported only for likely "destination" countries (and are generally insignificant for the others).

**Table 4: Results from drug similarity regression**

| Y = Jaccard similarity of drugs | Model 1 Coef. (StdErr) | Model 2 Coef. (StdErr) | Model 3 Coef. (StdErr) | Model 4 Coef. (StdErr) |
|---|---|---|---|---|
| Time trend | 0.01226** | 0.01052** | 0.01275** | 0.00888** |
| | (0.00026) | (0.00028) | (0.00031) | (0.00031) |
| Pair of EU countries | 0.07590** | 0.04124** | 0.10117** | 0.04121** |
| | (0.00573) | (0.00483) | (0.00695) | (0.00533) |
| Time trend * Pair of EU countries | -0.00604** | -0.00353** | -0.01007** | -0.00520** |
| | (0.00077) | (0.00069) | (0.00093) | (0.00076) |
| Pair of source-destination countries | -0.05711** | -0.05721** | -0.00261 | -0.00268 |
| | (0.01517) | (0.01240) | (0.01838) | (0.01371) |
| Pair of destination countries | -0.00707 | -0.00647 | -0.00333 | -0.00332 |
| | (0.01790) | (0.01468) | (0.02170) | (0.01622) |
| Pair of source countries | 0.00579 | 0.00583 | 0.07577** | 0.07372** |
| | (0.01573) | (0.01280) | (0.01907) | (0.01414) |
| Time trend * Pair of source-destination countries | -0.00002 | -0.00013 | -0.00276 | -0.00308 |
| | (0.00203) | (0.00177) | (0.00246) | (0.00195) |
| Time trend * Pair of destination countries | -0.00332 | -0.00347 | -0.00630* | -0.00636** |
| | (0.00237) | (0.00207) | (0.00288) | (0.00229) |
| Time trend * Pair of source countries | 0.00240 | 0.00217 | 0.00295 | 0.00277 |
| | (0.00216) | (0.00187) | (0.00262) | (0.00207) |
| Similarity of OECD variables (Correlation) | | 0.00681** | | 0.01685** |
| | | (0.00128) | | (0.00141) |
| Intercept | 0.34610** | 0.37303** | 0.49653** | 0.54184** |
| | (0.00186) | (0.00205) | (0.00225) | (0.00227) |
| R-square | 0.116 | 0.120 | 0.092 | 0.089 |
| Mean of Y | 0.429 | 0.443 | 0.584 | 0.607 |
| Sample | All drugs | All drugs | US drugs | US drugs |
| Number of Observations | 20439 | 13215 | 20439 | 13215 |

* = significant at the 5% level, ** = significant at the 1% level. Source countries are Greece, Spain, Portugal, Italy and France. Destination countries are the UK, Germany, the Netherlands, Sweden, Denmark and Finland.

## Table 5: Results from drug version similarity regression

| Y = Jaccard similarity in versions | Model 1<br>Coef.<br>(StdErr) | Model 2<br>Coef.<br>(StdErr) | Model 3<br>Coef.<br>(StdErr) | Model 4<br>Coef.<br>(StdErr) |
|---|---|---|---|---|
| Time trend | -0.00222**<br>(0.00025) | -0.00019<br>(0.00041) | 0.00585**<br>(0.00087) | 0.00630**<br>(0.00095) |
| Pair of EU countries | 0.00273<br>(0.00155) | 0.00732**<br>(0.00179) | | |
| Time trend * Pair of EU countries | 0.00226**<br>(0.00021) | 0.00176**<br>(0.00025) | | |
| Similarity of drugs available (Jaccard) | 0.36379**<br>(0.00351) | 0.39443**<br>(0.00616) | 0.38640**<br>(0.01275) | 0.39238**<br>(0.01312) |
| Time trend * Similarity of drugs available (Jaccard) | 0.00335**<br>(0.00055) | 0.00025<br>(0.00090) | -0.00845**<br>(0.00181) | -0.00961**<br>(0.00198) |
| Similarity of OECD variables (Correlation) | | 0.00391**<br>(0.00047) | | -0.00418**<br>(0.00093) |
| Pair of source-destination countries | -0.00683<br>(0.00408) | -0.00543<br>(0.00457) | -0.00550<br>(0.00444) | -0.00502<br>(0.00463) |
| Pair of destination countries | 0.03101**<br>(0.00422) | 0.03047**<br>(0.00470) | 0.03109**<br>(0.00454) | 0.03191**<br>(0.00471) |
| Pair of source countries | -0.01584**<br>(0.00480) | -0.01812**<br>(0.00540) | -0.01482**<br>(0.00517) | -0.01584**<br>(0.00541) |
| Time trend * Pair of source-destination countries | -0.00033<br>(0.00055) | -0.00051<br>(0.00065) | -0.00101<br>(0.00060) | -0.00102<br>(0.00066) |
| Time trend * Pair of destination countries | 0.00041<br>(0.00058) | 0.00035<br>(0.00069) | 0.00064<br>(0.00062) | 0.00064<br>(0.00069) |
| Time trend * Pair of source countries | 0.00087<br>(0.00064) | 0.00137<br>(0.00076) | 0.00040<br>(0.00069) | 0.00062<br>(0.00076) |
| Intercept | -0.00454**<br>(0.00146) | -0.02577**<br>(0.00261) | -0.01381*<br>(0.00592) | -0.01366*<br>(0.00610) |
| R-square | 0.706 | 0.560 | 0.542 | 0.546 |
| Mean of Y | 0.1506 | 0.1556 | 0.177 | 0.175 |
| Sample | All countries, all drugs | All countries, all drugs | EU countries, all drugs | EU countries, all drugs |
| Number of Observations | 20439 | 13215 | 3401 | 3167 |

* = significant at the 5% level, ** = significant at the 1% level. Source countries are Greece, Spain, Portugal, Italy and France. Destination countries are the UK, Germany, the Netherlands, Sweden, Denmark and Finland.

The parameter estimates in Table 4 show that a pair of any two EU countries has more similar drugs than a pair of non-EU countries or an EU/non-EU pair, though the interaction between the time trend and the dummy for a pair of EU countries indicates the similarity of EU markets has increased less than the similarity of other markets over time. This may be somewhat surprising, since changes to the approval process in the EU should have reduced the cost of gaining regulatory approval in multiple EU countries. However, it is consistent with Danzon et al. (2005) and Kyle (2007), who show that pharmaceutical firms are avoiding or delaying launch in EU countries with price controls, which are likely to be source countries for parallel trade. Pairs that include a source country and a destination country, like Denmark-Greece, are roughly as close in the availability of drugs as a random pair of other countries, despite both being in the "common market." For the subset of US-launched drugs, pairs of source countries appear more similar. However, this reflects a common lack of US-launched drugs rather than common availability, and this result is not robust to the method of calculating similarity (results of alternative similarity measures are available on request).

Pairs of EU countries have more overlap of versions as well, and the version mixes are becoming more similar over time across EU countries, based on the results in Table 5. However, the similarity in the EU is mostly driven by pairs of "destination" countries (such as UK-Germany or UK-Finland). Though the coefficients on source-destination pairs are not significantly different from zero, they are significantly different from the coefficients on destination pairs. This finding holds for a variety of similarity measures (not reported). As well, pairs of source markets have less similarity of versions available than any other combination. This is consistent with originators taking steps to limit the number of source countries. Interestingly, the interaction of drug similarity and the time trend is negative within the sample of EU countries (Models 3 and 4). This suggests that even as they launch drugs in more countries, firms have increased differentiation of versions available across countries.

Overall, these results suggest an adjustment of product offerings to reduce the potential for parallel trade. Similarity of both drugs and versions of drugs is lower between pairs of source countries and destination countries than between other pairs of EU countries. In addition, similarity is greatest between pairs of destination countries, while pairs of source countries have less overlap of versions than any other EU pairing. This may indicate a strategy of producing versions for sale in all high price (destination) markets, and at the same time producing different versions in each of the likely low price (source) markets to limit both the number of arbitrage opportunities and the availability of supply sources.

As a second test for how product offerings change in response to parallel imports, I look for evidence of product line "culling," or selective exit of drug versions. That is, are firms more likely to discontinue versions of a drug that are

threatened by parallel imports or that may serve as a source of parallel imports into a higher price market? I estimate a conditional fixed-effects logit for exit,

$$\begin{aligned} \text{Exit}_{ijt} = {} & \beta_0 + \beta_1 \text{Source}_i + \beta_2 \text{Destination}_i + \\ & \beta_3 \text{Threat\_Export}_{ijt} + \beta_4 \text{Threat\_Import}_{ijt} + \\ & \beta_5 \text{Source}_i \times \text{Threat\_Import}_{ijt} + \\ & \beta_6 \text{Destination}_i \times \text{Threat\_Export}_{ijt} + \\ & \beta_7 \text{Controls}_{ijt} + \lambda_j + \kappa_t + \varepsilon_{ijt} \end{aligned} \tag{4}$$

where i indexes country, j indexes a drug version (chemical/form/strength), t indexes quarters, $\lambda$ is a drug version fixed effect and $\kappa$ is a time period fixed effect. Exit takes the value of 1 if the drug version is available in country i in period t but not sold in any period after that. I measure threat of import as the number of markets with the identical product at a lower price that can serve as legal sources of parallel imports. Threat of export is similarly defined as the number of markets with a higher price than the drug version. Control variables include the measures of competition defined earlier (number of competing molecules in the same therapeutic class, number of other firms making the same drug and number of other versions of the same drug) as well as the number of standard units of version j sold in the previous quarter.

Results from conditional fixed effects logits of exit are contained in Table 6 for both the entire sample of countries as well as the subset of EU countries. Most of the control variables have similar coefficients (in sign and order of magnitude) in both samples. I find that overall, if a version is withdrawn, the exit is less likely to occur in EU countries than in the non-EU subset. However, products are more likely to be withdrawn from destination markets than from mid-priced EU or source countries. The probability of withdrawal is increasing in the number of source countries with an identical match as well as the number of destination countries with an identical match, i.e., both the threat of competition from imports (number of source countries) and the threat of serving as exports (number of destination countries) increase the likelihood that a version is pulled from the market. The interactions of the source and destination market dummies with these threat measures are both positive, though estimated with less precision, for the EU subsample, implying that exit is particularly likely to occur from source countries when there are many potential destination markets, and from destination countries when there are many sources.

## Table 6: Results from conditional logit regressions of exit

| Y = 1 if version discontinued | All countries Coef. (StdErr) | EU countries Coef. (StdErr) |
|---|---|---|
| Source country | 0.396* | 0.375 |
| | (0.167) | (0.236) |
| Destination country | 1.895** | 2.350** |
| | (0.120) | (0.171) |
| Number of source countries with identical version | 0.659** | 1.037** |
| | (0.096) | (0.144) |
| Number of destination countries with identical version | 0.923** | 1.624** |
| | (0.069) | (0.108) |
| Source country*Number of destination countries | 0.095 | 0.224** |
| | (0.051) | (0.065) |
| Destination country*Number of source countries | -0.030 | 0.108 |
| | (0.048) | (0.069) |
| Number of competing drugs in class | -0.020* | -0.091** |
| | (0.009) | (0.018) |
| Number of other non-parallel trade firms selling the same drug | 0.022* | 0.056** |
| | (0.009) | (0.018) |
| Total number of countries with identical version | 0.624** | 0.411** |
| | (0.060) | (0.071) |
| Total number of unique versions worldwide | -0.007* | -0.018** |
| | (0.003) | (0.005) |
| Number of unique versions in country | -0.024* | -0.100** |
| | (0.009) | (0.024) |
| Units shipped in the prior quarter | -0.511** | -0.518** |
| | (0.010) | (0.017) |
| EU country | -0.535** | |
| | (0.084) | |
| Fixed effects | Version, period | Version, period |
| Number of observations | 243716 | 92061 |
| Log Likelihood | -9600.1 | -4095.9 |

* = significant at the 5% level, ** = significant at the 1% level. Source countries are Greece, Spain, Portugal, Italy and France. Destination countries are the UK, Germany, the Netherlands, Sweden, Denmark and Finland.

These results provide limited evidence of product line "culling" in response to parallel trade. Conditional on withdrawing a version at any time or in any country in my sample, firms appear to choose those that are likely to be targets or sources of parallel imports.

3. Have originators reduced supply to low price countries?

An originator may attempt to ration the supply of product to low price countries that parallel traders are likely to use as sources. While rationing is difficult for me to identify precisely, I can look for evidence of selective supply interruptions. That is, are firms more likely to interrupt the supply of versions of a drug that are that may serve as a source of parallel imports into a higher price market? I estimate a conditional fixed-effects logit for "temporary" exit,

$$\begin{aligned}\text{Temporary Exit}_{ijt} = {} & \beta_0 + \beta_1 \text{Source}_i + \beta_2 \text{Destination}_i + \\ & \beta_3 \text{Threat\_Export}_{ijt} + \beta_4 \text{Threat\_Import}_{ijt} + \\ & \beta_5 \text{Source}_i \times \text{Threat\_Import}_{ijt} \\ & + \beta_6 \text{Destination}_i \times \text{Threat\_Export}_{ijt} + \\ & \beta_7 \text{Controls}_{ijt} + \lambda_j + \kappa_t + \varepsilon_{ijt}\end{aligned} \tag{5}$$

where i indexes country, j indexes a drug version (chemical/form/strength), t indexes quarters, $\lambda$ is a drug version fixed effect and $\kappa$ is a time period fixed effect. Temporary exit takes the value of 1 if the drug version is available (units shipped are greater than zero) in country i in period t-1, not available in period t, but available again in some future period. Explanatory variables are defined as in Section V.2. Here, however, I expect only the coefficients on the source country dummy and threat of export variables (and their interactions) to be important, as there is no need to cut supply to high price markets.

Results from regressions of temporary exit are contained in Table 7 and are consistent with expectations. The coefficient on the dummy for source countries is positive and significant, but the coefficient for destination countries is closer to zero in magnitude and not estimated precisely. While the number of destination markets itself is not statistically significant, its interaction with the source country dummy is positive and significant. The corresponding interaction between the destination market dummy and the number of source countries is close to zero.

Supply interruptions occur more frequently in likely source countries, and are more likely to happen when a version has a match in many destination markets. Unlike permanent withdrawal, which affects both source and destination markets depending on the vulnerability to parallel trade, temporary exit is

confined to source markets. This is not surprising, given the explicit efforts of pharmaceutical firms to ration supply to these countries.

**Table 7: Results from conditional logit regressions of temporary exit**

| Y = 1 if temporary exit occurs (units shipped=0 at t, but positive in future) | All countries<br>Coef.<br>(StdErr) | EU countries<br>Coef.<br>(StdErr) |
|---|---|---|
| Source country | 0.747**<br>(0.083) | 1.263**<br>(0.124) |
| Destination country | -0.082<br>(0.078) | 0.172<br>(0.113) |
| Number of source countries with identical version | 0.152**<br>(0.045) | 0.252**<br>(0.070) |
| Number of destination countries with identical version | -0.039<br>(0.039) | -0.008<br>(0.062) |
| Source country*Number of destination countries | 0.071**<br>(0.023) | 0.077*<br>(0.033) |
| Destination country*Number of source countries | -0.052<br>(0.036) | 0.001<br>(0.048) |
| Number of competing drugs in class | -0.009<br>(0.006) | -0.017<br>(0.011) |
| Number of other non-parallel trade firms selling the same drug | -0.177**<br>(0.010) | -0.385**<br>(0.024) |
| Total number of countries with identical version | -0.033*<br>(0.016) | -0.057*<br>(0.024) |
| Total number of unique versions worldwide | -0.002<br>(0.001) | -0.002<br>(0.002) |
| Number of unique versions in country | 0.000<br>(0.006) | 0.043**<br>(0.015) |
| Units shipped in the prior quarter | -0.605**<br>(0.006) | -0.670**<br>(0.011) |
| EU country | -0.429**<br>(0.045) | |
| Fixed effects | Version, period | Version, period |
| Number of observations | 261360 | 94770 |
| Log Likelihood | -22560 | -8929.5 |

* = significant at the 5% level, ** = significant at the 1% level. Source countries are Greece, Spain, Portugal, Italy and France. Destination countries are the UK, Germany, the Netherlands, Sweden, Denmark and Finland.

## Table 8: Results from brand name similarity regression

| Y = Jaccard similarity in brand names | Model 1 Coef. (StdErr) | Model 2 Coef. (StdErr) | Model 3 Coef. (StdErr) | Model 4 Coef. (StdErr) |
|---|---|---|---|---|
| Time trend | -0.00027 | -0.00220** | -0.01160** | -0.01238** |
| | (0.00027) | (0.00035) | (0.00102) | (0.00108) |
| Pair of EU countries | 0.04195** | 0.05597** | | |
| | (0.00270) | (0.00298) | | |
| Time trend * Pair of EU countries | -0.00601** | -0.00833** | | |
| | (0.00036) | (0.00043) | | |
| Similarity of drugs available (Jaccard) | 0.45889** | 0.39380** | 0.51626** | 0.55307** |
| | (0.00591) | (0.00777) | (0.01541) | (0.01694) |
| Time trend * Similarity of drugs available (Jaccard) | 0.00860** | 0.02032** | 0.01184** | 0.00747** |
| | (0.00081) | (0.00110) | (0.00238) | (0.00262) |
| Similarity of OECD variables (Correlation) | | -0.00290** | | -0.01586** |
| | | (0.00082) | | (0.00175) |
| Pair of source-destination countries | -0.04089** | -0.04479** | -0.04005** | -0.03987** |
| | (0.00704) | (0.00751) | (0.00826) | (0.00856) |
| Pair of destination countries | -0.03893** | -0.04382** | -0.03670** | -0.03489** |
| | (0.00727) | (0.00771) | (0.00853) | (0.00880) |
| Pair of source countries | 0.01233 | 0.01437 | 0.00993 | 0.01475 |
| | (0.00831) | (0.00888) | (0.00973) | (0.01011) |
| Time trend * Pair of source-destination countries | 0.00235* | 0.00312** | 0.00250* | 0.00287* |
| | (0.00094) | (0.00107) | (0.00111) | (0.00122) |
| Time trend * Pair of destination countries | 0.00430** | 0.00497** | 0.00376** | 0.00412** |
| | (0.00100) | (0.00113) | (0.00117) | (0.00129) |
| Time trend * Pair of source countries | -0.00081 | -0.00105 | -0.00007 | -0.00103 |
| | (0.00110) | (0.00125) | (0.00129) | (0.00143) |
| Intercept | -0.00027 | 0.00438** | 0.05174** | 0.06365** |
| | (0.00116) | (0.00159) | (0.00435) | (0.00472) |
| R-square | 0.816447 | 0.814760 | 0.762802 | 0.768434 |
| Mean of Y | 0.129605 | 0.123012 | 0.156134 | 0.149289 |
| Sample | All countries, all drugs | All countries, all drugs | EU countries, all drugs | EU countries, all drugs |
| Number of Observations | 19082 | 12153 | 3402 | 3168 |

* = significant at the 5% level, ** = significant at the 1% level. Source countries are Greece, Spain, Portugal, Italy and France. Destination countries are the UK, Germany, the Netherlands, Sweden, Denmark and Finland.

4. Have originators taken steps to increase transportation costs?

I examine the overlap of brand names between pairs of countries over time to test whether firms use different brand names in across countries. Such differences require parallel traders to repackage products for import, and so increase their transportation costs. The approach taken is analogous to that of version overlap. Each country-period is an observation, with a vector of dummy variables indicating whether a given brand name is used in the country. I calculate the Jaccard similarity measure of any two country-period pairs, Brand Similarity$_{ijt}$, as the number of brand names available in both countries i and j in the period t divided by the number of brand names available in only one of the two countries. I estimate the following regression equation:

$$\text{Brand Similarity}_{ijt} = \beta_0 + \beta_1 \text{Timetrend} + \beta_2 \text{Market similarity} + \beta_3 \text{Relationship}_{ijt} + \varepsilon_{ijt} \quad (6)$$

Results are presented in Table 8. Interestingly, pairs of EU countries have lower similarity than pairs of other countries. As expected, source-destination pairs have even lower overlap of brand names. Over time, the overlap between source and destination pairs is increasing, but at a slower rate than the similarity between pairs of destination countries is increasing. While version similarity was greatest between destination countries and lowest between pairs of source countries, the opposite is true in the case of brand name similarity. This pattern is still consistent with increasing the cost of repackaging for parallel importers, however. The lack of similarity between source and destination markets means that parallel importers must relabel many of the products they ship to destination markets. In addition, while there may be substantial overlap in the versions of drugs available in destination countries, a parallel importer would be required to repackage a product for sale in each of them if they have different brand names. Thus, this use of brand names denies parallel importers significant economies of scale.

## VI. Discussion and Conclusion

Policymakers in the EU actively support the development of parallel trade as an important step towards a common market in pharmaceuticals. Some governments also hoped and expected that competition from parallel imports would lower drug

costs in countries with relatively high prices. The European Court of Justice has, in a series of decisions, generally sided against originators in lawsuits related to parallel trade. Despite all this, parallel trade has yet to reduce price dispersion across EU member states very significantly. This paper documents a number of patterns in product characteristics and availability that are, taken together, consistent with attempts by originators to limit competition from parallel imports. In short, firms have moved from using third-degree price discrimination to a form of second-degree, through increasing product differentiation.

In part, parallel trade may be limited as a result of policies set by national governments. Regulations on the profits of pharmacists inhibit incentives for pharmacists to seek low-priced drugs, so that many see little financial reason to stock parallel imports in lieu of original products. Patients and doctors in most countries are also rather insensitive to price, and probably see no benefit to using parallel imported versions of products. And although much has been done to facilitate parallel trade, parallel importers still face many regulations on their activities, including substantial documentation requirements due to concerns about drug safety.

However, non-price responses by pharmaceutical firms may also be playing a role. Firms do cut prices in response to actual entry, but this affects a small number of products, and the price reduction itself is not large. In addition to rationing supply – a strategy that has faced a number of legal challenges – firms appear to adjust their product offerings in each country to minimize the potential for parallel trade. "Versioning" and "culling" limit the number of arbitrage opportunities. Such a strategy is, of course, costly to originators: it means additional regulatory fees and higher production costs. An important question is whether these costs add any consumer benefit. While the pharmaceutical industry differs from most others in the extent to which it is regulated, non-price responses are important for other IP-intensive sectors as well.

The possibility of non-price responses is typically ignored in policy debates, and indeed the effects on welfare are unclear. Firms should have higher profits than under perfect arbitrage, which may offset the negative effects of parallel trade on long-run incentives to invest in research. However, these strategies also offset the expected consumer gains from parallel trade. Understanding their impact may be important in evaluating whether to legalize parallel trade in other countries, and how to adjust other policies or regulations to achieve price reductions.

## Appendix A: Example of parallel trade in Finland: Adalat

| Year-Quarter | 98-1 | 98-2 | 98-3 | 98-4 | 99-1 | 99-2 | 99-3 | 99-4 | 00-1 | 00-2 | 00-3 | 00-4 | 01-1 | 01-2 | 01-3 | 01-4 | 02-1 | 02-2 | 02-3 | 02-4 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PARANOVA** | | | | | | | | | | | | | | | | | | | | |
| BBN RT.MEMB CT TAB | | | | | | | | | | | | | | | | | | | | |
| 0060MG | | | | | | | | | | | | | | | | | *0.54* | *0.57* | *0.61* | *0.62* |
| 0030MG | | | | | | | | | | *0.43* | *0.41* | *0.39* | *0.42* | *0.40* | *0.41* | *0.41* | *0.40* | *0.42* | *0.45* | *0.45* |
| BBC FILM-C TAB RET | | | | | | | | | | | | | | | | | | | | |
| 0020MG | *0.29* | *0.29* | *0.30* | *0.31* | *0.30* | *0.28* | *0.27* | *0.27* | *0.26* | *0.25* | *0.24* | *0.23* | *0.24* | *0.23* | *0.24* | *0.24* | *0.23* | *0.24* | *0.26* | *0.26* |
| **BAYER** | | | | | | | | | | | | | | | | | | | | |
| BBN RT.MEMB CT TAB | | | | | | | | | | | | | | | | | | | | |
| 0060MG | 0.67 | 0.68 | 0.69 | 0.73 | 0.70 | 0.66 | 0.65 | 0.65 | 0.63 | 0.59 | 0.57 | 0.55 | 0.59 | 0.56 | 0.57 | 0.57 | **0.56** | **0.59** | **0.63** | **0.64** |
| 0030MG | 0.50 | 0.50 | 0.51 | 0.55 | 0.52 | 0.49 | 0.48 | 0.48 | 0.47 | **0.44** | **0.43** | **0.41** | **0.44** | **0.41** | **0.42** | **0.42** | **0.42** | **0.44** | **0.47** | **0.47** |
| 0020MG | | | | | | | 0.37 | 0.36 | 0.35 | 0.33 | 0.32 | 0.31 | 0.33 | 0.31 | 0.31 | 0.32 | 0.31 | 0.32 | 0.35 | 0.35 |
| BBC FILM-C TAB RET | | | | | | | | | | | | | | | | | | | | |
| 0020MG | **0.29** | **0.30** | **0.30** | **0.32** | **0.30** | **0.29** | **0.29** | **0.28** | **0.27** | **0.26** | **0.25** | **0.24** | **0.26** | **0.24** | **0.25** | **0.25** | **0.24** | **0.26** | **0.27** | **0.28** |
| 0010MG | 0.17 | 0.17 | 0.17 | 0.18 | 0.17 | 0.16 | 0.16 | 0.16 | 0.15 | 0.15 | 0.14 | 0.14 | 0.15 | 0.14 | 0.14 | 0.14 | 0.14 | 0.14 | 0.16 | 0.16 |
| ACA CAPSULES | | | | | | | | | | | | | | | | | | | | |
| 0005MG | 0.09 | 0.09 | 0.10 | 0.10 | 0.10 | 0.09 | 0.09 | 0.09 | 0.09 | | | | | | | | | | | |
| 0010MG | 0.16 | 0.17 | 0.17 | 0.18 | 0.17 | 0.16 | 0.16 | 0.16 | 0.16 | | | | | | | | | | | |

Numbers in cells are the price per standard unit (pill) in US dollars. Yellow (italicized) cells are parallel imports of Adalat. Purple (bolded) cells are the original versions of Adalat facing parallel imports.

## Appendix B: Therapeutic classes

| Broad Classification | ATC-4 | Definition |
|---|---|---|
| Alimentary Tract and Metabolism | A4A1 | Antiemetics and antinauseants -- serotonin |
| | A4A9 | Antiemetics and antinauseants -- other |
| Blood and Blood Forming Organs | B1C1 | Cyclo-oxygenase inhibitor platelet aggregation inhibitors |
| | B1C2 | ADP (adenosine diphosphate) receptor antagonist platelet aggregation inhibitors |
| | B1C3 | GP IIb/IIIa (glycoprotein) antagonist platelet aggregation inhibitors |
| | B1C4 | Platelet cAMP enhancing platelet aggregation inhibitors |
| | B1C5 | Platelet aggregation inhibitors, combinations |
| | B1C9 | Other platelet aggregation inhibitors |
| | B1D0 | Fibrinolytics |
| Cardiovascular system | C3A1 | Potassium-sparing agents plain |
| | C3A2 | Loop diuretics plain |
| | C3A3 | Thiazides and analogues plain |
| | C3A4 | Potassium-sparing agents with loop diuretic combinations |
| | C3A5 | Potassium-sparing agents with thiazides and/or analogue combinations |
| | C3A6 | Other diuretics |
| | C7A0 | Beta-blocking agents, plain |
| | C7B1 | Combinations with anti-hypertensives and/or diuretics |
| | C7B2 | Combinations with other drugs of group C |
| | C7B3 | Combinations with all other drugs except those of group C |
| | C8A0 | Calcium antagonists, plain |
| | C9A0 | Ace inhibitors, plain |
| | C9B1 | ACE inhibitor combinations with antihypertensives (C2) and/or diuretics (C3) |
| | C9B3 | ACE inhibitor/beta-blocker combinations |
| | C9C0 | Angiotension-II antagonists, plain |
| | C9D0 | Angiotension-II antagonists, combinations |
| General anti-infectives (systemic) | J1D2 | Injectable cephalosporins |
| Antineoplastic and immunomodulating agents | L1A0 | Alkylating agents |
| | L1B0 | Antimetabolites |
| | L1C0 | Vinca alkaloids |
| | L1D0 | Antineoplastic antibiotics |
| | L1X1 | Adjuvant preparations for cancer therapy |
| | L1X2 | Platinum compounds |
| | L1X3 | Antineoplastic monoclonal antibodies |
| | L1X9 | All other antineoplastics |
| | L3A1 | Colony-stimulating factors |
| | L3A9 | All other immunostimulating agents excluding interferons |

## Countries in dataset

| | | |
|---|---|---|
| Argentina | Finland | Netherlands |
| Australia | France | Poland |
| Austria | Germany | Portugal |
| Belgium | Greece | South Africa |
| Brazil | Ireland | Spain |
| Canada | Italy | Sweden |
| China | Japan | Switzerland |
| Colombia | Korea | Turkey |
| Czech Republic | Luxembourg | United Kingdom |
| Denmark | Mexico | United States |

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