Strategic Responses to Parallel Trade

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Abstract

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. 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 rivals' (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 parallel imports.

^{* &}lt;a href="mkyle@duke.edu">mkyle@duke.edu. I thank Amy Finkelstein, David Ridley, Kevin Schulman, John Van Reenen and seminar participants at the NBER Productivity Lunch, Lehigh, University of Toulouse, HEC Lausanne, London Business School, London School of Economics, Imperial College London, New York University, and Duke for useful discussions.

I. Introduction

Firms 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, 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.

Cross-national differences in pharmaceutical prices are the topic of much discussion in the press and in policy circles. Representative Henry Waxman (D-CA), a vocal critic of the pharmaceutical industry, maintains that: "A grandmother on the Westside has to pay more than twice as much for her drugs as a grandmother in France, in Canada, in Germany, in Italy, and in the United Kingdom. And for some drugs, seniors in Los Angeles are paying over three times more than seniors in other countries. This unconscionable gouging is unacceptable and has to end." Quite a few 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 price differences have persisted because of laws preventing arbitrage of drugs across borders. These laws include regulations on the right to sell a drug in a country as well as rights granted to patent-holders to prevent the sale of a product by other firms without authorization.

While arbitrage of drugs, or "parallel trade," 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, the adoption of the Euro, and the application of Articles 28-30 governing the free movement of goods within the EU. The EU has established a policy

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¹ http://www.democrats.reform.house.gov/investigations.asp?Issue=Price+Discrimination

of "community exhaustion" of most forms of intellectual property², 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. The combination of these changes has reduced the ability of firms in all industries to price discriminate across EU countries, but has been of particular concern to pharmaceutical firms, which face price controls in many EU countries.

The issue of parallel imports 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; re-importation of drugs was an important campaign issue in 2004 for Senator John Kerry and the subject of a Congressional Budget Office study. In addition, non-governmental organizations such as Doctors Without Borders/Medicins Sans Frontieres have lobbied extensively for a policy of "international exhaustion" of patent rights, which would remove the current barrier of IP rights to parallel trade in most countries. Both the law and the strategies firms use in response to parallel imports are relevant not only to the pharmaceutical industry, but to all IP-intensive firms that are active in multiple countries, some of which contend with illegal pirating that is not well-policed in addition to legal parallel trade.

This paper examines the extent of parallel imports of pharmaceuticals within the EU, and describes the strategic responses by firms to dampen the resulting profit losses. I

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² In the case of patent rights, community exhaustion is not the result of specific legislation, but rather the interpretation of laws on the free movement of goods by the European Court of Justice.

³ 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.

⁴ 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 (all?) others use national. In contrast, most countries have adopted international exhaustion of trademarks.

⁵ These industries include movies, video games, luxury goods, and others. The sources of the pirated copies are countries like China, India, Brazil, and Russia. See "US Moves to Stop Piracy of Intellectual Property," *New York Times*, Sept. 22, 2005.

find that parallel imports have not yet led to a large reduction in aggregate price dispersion across EU countries, consistent with other recent empirical studies of drug prices (Kanavos et al. (2004), Danzon and Chao (2002)). While the number of products experiencing parallel imports has been increasing, it is still a small fraction of the total number of pharmaceutical products. I find evidence that efforts by pharmaceutical firms to adjust to the threat of parallel imports may have moderated the impact. The setting examined in this paper is useful for understanding how firms adapt to a change in the legal environment that affects the ability to price discriminate. This research highlights the importance of considering all strategic options available to firms and the interaction of multiple policies when assessing the impact of parallel trade, or a change in trade and intellectual property laws more generally.

The paper proceeds as follows. Section II reviews the literature on parallel trade and describes the pharmaceutical market in the European Union. Section III presents a simple model of entry by parallel traders and describes what strategic options might be expected from pharmaceutical firms. Section IV describes the data, and Section V estimates the entry model and presents evidence of strategic responses. Section VI discusses and concludes.

Section II. Overview of the pharmaceutical industry in the EU and relevant literature

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 (EMEA) for an 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. 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 (2005), 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. 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. 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 parallel imports.

There are some 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. 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 repackaging costs. The cost of a license is approximately €1500 in most countries or €3480 for products approved through the EMEA. For additional detail, please see the EMEA's "Post-Authorisation Guidance on Parallel Distribution" and Arfwedson (2004).

In addition to securing a license and finding adequate supply, 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.

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 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 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), and Szymanski and Valletti (2005a, 2005b). 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. 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 dominant position, such as rationing supply to a low price market in an attempt to restrict exports, are legally problematic. 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.⁸

Pharmaceutical firms are therefore limited in their ability to use price and 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

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.

^{8 &}quot;European Pharma Lobby Group Complains To EU About Pfizer," Dow Jones Newswire, Oct. 17, 2005.

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.

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 the entry decision (Danzon et al. 2005, Kyle 2005, Lanjouw 2005), and a recent paper by Danzon and Epstein (2005) looks at both launch delays and pricing decisions in relation to price regulations in the EU. All these papers use a molecule or new chemical entity as the unit of analysis.

This research focuses on the threat of parallel trade in particular (separate from price controls), and considers additional strategic choices firms make: that of product characteristics. It follows a number of recent empirical papers exploring non-price strategic responses to competition. 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. 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 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. 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 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:

$$E(\Pi) = E|(p_H - p_L - c_T)q - L| > 0$$

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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.

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 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. Due to the limitations of my dataset, it is difficult for me to identify when rationing occurs with much certainty.

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

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.

which 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 limited their prevalence through at least the mid-1990s.

To illustrate how these various strategies work in practice, Table 1 contains package information and prices for Adalat (nifedipine, which is marketed as Procardia in the US), 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 reducing the volume of versions with competing parallel imports by introducing another version, in addition to responding with a price change. ¹³

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. Within a country, originators probably employ some

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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.

second degree price discrimination across packages, and I do not account for this. An interesting extension for future work may be to apply recent innovations in structural estimation of firms' product offerings, such as the model proposed by Draganska, Mazzeo and Seim (2005). I do not focus here on any strategic interaction between parallel traders. I assume that they are essentially undifferentiated and have low sunk costs (low exit costs). 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.

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 Table 2. 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 3. There are 1791 different chemicals (or unique chemical combinations) in these classes; 414 of them were introduced after 1990. This sample clearly 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 which 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.

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

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 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. 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

Figure 1 shows the share in terms of standard units of parallel imports within the set of drugs in my dataset, by country over time. The country with the highest penetration of parallel imports for this subset of drugs is Sweden, although the penetration has declined since 2002. Denmark, the Netherlands, Finland, Germany, and the UK are the other main destination markets for parallel imports. Figure 2 shows the average share gained by parallel imports at the product level, conditional on parallel trade taking place, and Figure 3 displays the average relative price of parallel import products to originator products. On average, an originator does not lose more than 10% of its sales to parallel imported versions. This could reflect difficulty in finding supplies of parallel imports, consumer tastes, or – based on the relative prices given in Figure 3 – rather small (if any) price discounts for parallel imported products. Note, though, that Figure 3 could

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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.

reflect price matching by originators to (initially) cheaper parallel imports. I explore this point further in Section 5.

Parallel trade takes place only if price differences exist across markets, so I now describe the general patterns of price dispersion of drugs in my data. I aggregate over all packages (and both original and parallel imported products) within a market so that the unit of analysis is a drug-period observation. There are often large price differences across different packages produced by the same firm, and averaging over them in this way obscures some important variation in price. However, it is difficult to do a meaningful comparison of prices at the *package* level across countries, because there is strikingly little overlap in the set of packages available in one country and in another. In addition, many drugs are not available throughout the EU, so the number of observations used to create measures of price dispersion varies. I compare patterns of price dispersion for all drugs in my dataset launched in at least two European Union member states as well as the subset for which any parallel importing took place.

Figure 4 compares the distribution of price differentials, measured as the percent difference between the price in country i and the average EU price or initial EU average, for ex-manufacturer prices within the EU and for countries outside the EU (the patterns are similar for retail and wholesale prices). Not surprisingly, the distribution of price differentials is much tighter within the EU than outside, but there are still many observations of prices that are half the EU average and of prices that are double the EU average. Figure 5 shows these distributions for the periods 1993-1994, 1995-1999 and 2000-2004. There is no obvious narrowing of price differentials over time either within the EU or outside of it. Figures 6 and 7 represent the distribution of price differentials measured as the difference between the current price in country i and the initial EU launch price. In all of these, the distribution is shifting to the left, which is indicative of prices falling over time. The variance of price differentials appears to be increasing over time in the EU, but note that this means that current prices are more divergent from the initial launch price, not necessarily an increase in differences across countries. For both measures of price differentials, the patterns are identical for the subset of drugs launched

in the US and if prices are weighted by quantity. Finally, Figures 8-10 show the movement of prices for one category of drugs (adenosine diphosphate receptor antagonist platelet aggregation inhibitors). Figure 8 shows the EU average, Figures 9a-b show the prices for each product across all countries in my dataset, and Figures 10a-b show the prices for EU countries only. These figures demonstrate that prices did not fall uniformly across products or countries, and also that price dispersion in this particular category seems to have increased.

Table 4 presents summary statistics of price differentials from the EU average. The top panel of the table includes all observations in the calculations and the bottom panel excludes extreme observations (those with price differentials greater than 20), which usually occur when sales are very low for a particular drug in a quarter. As was evident from the figures previously discussed, price dispersion is much greater in the set of non-EU countries. What is more clear from these tables is that while price dispersion fell during the 1995-1999 period relative to 1993-1994, the range and standard deviation increased within the EU during 2000-2004. Price dispersion is also greater within the subset of drugs for which some parallel trade took place, indicating that parallel importers enter markets with larger price differentials, on average, but do not result in price convergence; this can also be seen graphically in Figure 11. 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 which, like pharmaceuticals, historically had large price differences across countries. The focus of the rest of the analysis is at a micro level.

V. Results

To begin, I estimate the simple model of parallel trade entry presented in Section IV. The purpose of this analysis is mainly to establish that parallel importers respond to factors over which originators have some control. 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, and use proxies for the terms in the profit function related to price differences, availability of supply for parallel imports, demand for parallel imports, and transportation costs. Table 5 provides these variable definitions and 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.

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 largely robust to changes in the sample of drugs (results not shown 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 possible, 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 strategic price responses, I first estimate a regression that exploits this variation across countries and over time for each drug version, i.e.

$$Ln(Originator\ price_{ijt}) = \beta_0 + \beta_1 Threat_{ijt} + \beta_2 Entry_{ijt} + \beta_3 Competition_{ijt} + \lambda_j + \kappa_t + \epsilon_{ijt}$$

where i indexes country, j indexes a drug version (chemical/form/strength), t indexes quarters, λ is drug version fixed effect and κ is a time period fixed effect. I measure threat of entry as the number of markets with the identical product at a lower price that can serve as legal sources of parallel imports, conditional on no entry by parallel imports having yet occurred. Competition is measured as the number of competing drugs in the same therapeutic class launched in country i. I include it to control for any price changes that are the result of entry by competing chemicals, rather than entry by parallel imports.

I also estimate the regression equation:

$$Ln(Originator\ price_{ijt}) = \beta_0 + \beta_1 Threat_{ijt} + \beta_2 Entry_{ijt} + \beta_3 Competition_{ijt} + \varphi_{ij} + \kappa_t + \epsilon_{ijt}$$

where notation is the same as above, except ϕ is a country-drug version fixed effect. This regression relies on variation in the threat of entry or actual entry over time within each country-drug version pair to identify strategic responses.

Table 6 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 parameter estimate from the specification that relies on both cross-sectional and time variation (Column 1) indicates that products with parallel trade are priced higher than the average of identical versions in other countries without parallel trade. Threat of entry does not appear to constrain prices, either; the coefficient on the threat of entry variable is positive and significant. These

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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.

estimates suggest that products with parallel trade remain relatively expensive even after parallel importing begins. The results from the specification that relies on within country-drug version variation (i.e. only variation over time) in the second column of Table 6 show a statistically significant price reduction following entry by parallel imports. However, once again firms do not seem to respond to the *threat* of entry by reducing price differentials to make entry less attractive.

These parameter estimates imply that firms respond to entry by parallel imports by lowering prices about 4%, though not before parallel importing actually begins. In contrast, Goolsbee and Syverson (2005) show that airlines respond to the threat of entry by Southwest Airlines well before Southwest begins flying on a competing route. In this setting, the threat of competition from parallel imports does not appear to result in preemptive price cuts. Parallel trade does have an 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 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 drugs in Sweden, firms in their study also did not react immediately to potential competition from parallel traders.

2. Have originators reduced the number of matching products in both 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, S_{ijt} , as the number of versions available in both countries i and j in the period t divided by the number of versions available in only one of

the two countries. ¹⁸ The higher this number, the more similar the product mix. I calculate similarity based on a product being any version of a chemical for sale in a country (drug similarity), and again defining a product as a specific version (form and strength) of a drug (version similarity). I estimate the following regression equation:

$$S_{iit} = \alpha_0 + \alpha_1 Timetrend + \alpha_2 Market similarity + \alpha_3 Relationship_{iit} + \epsilon$$

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. When estimating this equation for version similarity, I include drug similarity as a control variable. Table 7 presents the results of this analysis for drug similarity, and version similarity results are in Table 8.

The parameter estimates in Table 7 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 (2005), 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

¹⁸ I experimented with other similarity measures, such as the simple matching coefficient and the Bray and Curtis coefficient, and found the same results.

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 8. However, the difference in similarity is mostly driven by pairs of "destination" countries (such as UK-Germany or UK-Finland). Pairs that include a source country and a destination country, like Denmark-Greece, are less similar than a random pair of other countries, despite both being in the "common market." This finding holds for a variety of similarity measures (not included). Interestingly, the interaction of drug similarity and the time trend is negative. This suggests that even as they launch drugs in more countries, firms have increased differentiation of versions available across countries.

Overall, these results are consistent with 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 logit for exit,

$$Exit_{ijt} = \beta_0 + \beta_1 Threat_Import_{ijt} + \beta_2 Threat_Export_{ijt} + \beta_3 Number of versions_{ijt} + \lambda_j + \kappa_t + \epsilon_{ijt}$$

where i indexes country, j indexes a drug version (chemical/form/strength), t indexes quarters, λ is drug version fixed effect and κ 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 t+1. I measure threat of entry as the number of markets with the identical product at a lower price that can serve as legal sources of parallel imports, conditional on no entry by parallel imports having yet occurred. Threat of export is defined as the number of markets with a higher price than the drug version and the price of the version in country i being in the lower quartile.

$$Exit_{ijt} = \beta_0 + \beta_1 Threat_Import_{ijt} + \beta_2 Threat_Export_{ijt} + \beta_3 Number of \ versions_{ijt} + \varphi_{ij} + \kappa_t + \epsilon_{ijt}$$

where ϕ is a country-drug version fixed effect and κ is a time period fixed effect. This specification relies on changes in import or export threat within a drug version-country, while the first relies on variation in import or export threat within a drug version across countries.

Results from regressions of exit are contained in Table 9. First, I estimate a logit for exit on the entire sample using a dummy variable for whether a country is an EU member, and therapeutic class and period fixed effects. Products in EU countries are more likely to be discontinued than in the average of the other 15 countries for which I have data. Within the EU, products that are likely to face competition from parallel imports (versions in relatively high price countries) or that are likely to be the source of parallel exports (versions in relatively low price countries) have a higher probability of being discontinued. Within a drug version-country observation, the change in the probability of exit associated with a change in the threat of import or export cannot be estimated with any statistical precision. (For now, I have results only for a linear probability model due to difficulties in obtaining convergence with a logit.)

These results provide limited evidence of product line "culling" in response to parallel trade. The EU overall has a higher rate of exit of versions than other countries,

and across EU countries, versions of products that are likely to be targets or sources of parallel imports are more likely to be discontinued.

3. 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, S_{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:

$$S_{ijt} = \alpha_0 + \alpha_1 Timetrend + \alpha_2 Market \ similarity + \alpha_3 Relationship_{ijt} + \epsilon$$

Results are presented in Table 10. 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. 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. 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 the firm: it means additional regulatory fees and higher production costs. An important question is whether these costs add any consumer benefit.

This paper illustrates one way firms adapt to changes in intellectual property and trade law. 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, including consumer electronics and software. Non-price responses such as these have received little attention in the debate over the welfare effects of parallel trade. 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 penetration of parallel imports if that is the goal.

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Table 1: 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 | 0.20 | 0.20 | 0.20 | 0.21 | 0.20 | 0.20 | 0.27 | 0.07 | 0.06 | 0.25 | 0.24 | 0.22 | 0.04 | 0.22 | 0.04 | 0.24 | 0.00 | 0.2.4 | 0.26 | 0.06 |
| 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 | o | 0.60 | 0.60 | | | | o | o | 0.60 | | | | | 0 = 6 | | | 0 = 4 | . =0 | 0.75 | 0.54 |
| 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 | 0.00 | 0.20 | 0.00 | 0.00 | 0.20 | 0.00 | 0.00 | 0.00 | 0.05 | 0.06 | 0.05 | 0.04 | 0.06 | 0.04 | 0.05 | 0.05 | 0.04 | 0.06 | | 0.00 |
| 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.

Table 2A: Therapeutic classes

| Broad Classification | ATC-4 | Definition | # drugs |
|------------------------------------|-------|---|---------|
| Alimentary Tract and | A4A1 | Antiemetics and antinauseants serotonin | 11 |
| Metabolism | A4A9 | Antiemetics and antinauseants other | 203 |
| Blood and Blood | B1C1 | Cyclo-oxygenase inhibitor platelet aggregation inhibitors | 25 |
| Forming Organs | B1C2 | ADP (adenosine diphosphate) receptor antagonist platelet aggregation inhibitors | 3 |
| | B1C3 | GP IIb/IIIa (glycoprotein) antagonist platelet aggregation inhibitors | 3 |
| | B1C4 | Platelet cAMP enhancing platelet aggregation inhibitors | 9 |
| | B1C5 | Platelet aggregation inhibitors, combinations | 9 |
| | B1C9 | Other platelet aggregation inhibitors | 8 |
| | B1D0 | Fibrinolytics | 23 |
| Cardiovascular system | C3A1 | Potassium-sparing agents plain | 8 |
| | C3A2 | Loop diuretics plain | 14 |
| | C3A3 | Thiazides and analogues plain | 40 |
| | C3A4 | Potassium-sparing agents with loop diuretic combinations | 25 |
| | C3A5 | Potassium-sparing agents with thiazides and/or analogue combinations | 234 |
| | C3A6 | Other diuretics | 143 |
| | C7A0 | Beta-blocking agents, plain | 38 |
| | C7B1 | Combinations with anti-hypertensives and/or diuretics | 107 |
| | C7B2 | Combinations with other drugs of group C | 2 |
| | C7B3 | Combinations with all other drugs except those of group C | 2 |
| | C8A0 | Calcium antagonists, plain | 26 |
| | C9A0 | Ace inhibitors, plain | 27 |
| | C9B1 | ACE inhibitor combinations with antihypertensives (C2) and/or diuretics (C3) | 123 |
| | C9B3 | ACE inhibitor/beta-blocker combinations | 12 |
| | C9C0 | Angiotension-II antagonists, plain | 7 |
| | C9D0 | Angiotension-II antagonists, combinations | 163 |
| General anti-infectives (systemic) | J1D2 | Injectable cephalosporins | 65 |
| Antineoplastic and | L1A0 | Alkylating agents | 32 |
| immunomodulating | L1B0 | Antimetabolites | 36 |
| agents | L1C0 | Vinca alkaloids | 16 |
| | L1D0 | Antineoplastic antibiotics | 23 |
| | L1X1 | Adjuvant preparations for cancer therapy | 49 |
| | L1X2 | Platinum compounds | 11 |
| | L1X3 | Antineoplastic monoclonal antibodies | 9 |
| | L1X9 | All other antineoplastics | 38 |
| | L3A1 | Colony-stimulating factors | 9 |
| | L3A9 | All other immunostimulating agents excluding interferons | 59 |
| | Total | | 1612 |

Table 2B: 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 |

Table 3: Summary statistics for Midas data

| Number of countries | | 30 | | | | | |
|--|-------------------------------|---------------|------------|----------|-----------|--|--|
| Number of quarters | | | | 47 | | | |
| Number of unique dosage for | Number of unique dosage forms | | | | | | |
| Number of unique drugs (che | 1031 | | | | | | |
| Number of unique versions (c | 9013 | | | | | | |
| Number of unique country-ve | ersions (dru | g-form-streng | gth) | 21075 | | | |
| | SD | Min | Max | | | | |
| Standard units shipped in quarter (1000s) | 957962 | 11.24 | 62.02 | 0.00001 | 3223.09 | | |
| Ex-manufacturer revenues, US\$ | 957962 | 559487.28 | 4622218.48 | 1.00000 | 726407713 | | |
| Ex-manufacturer price (wholesale purchase price) per standard unit, US\$ | 957962 | 21.94 | 118.83 | 0.00001 | 13700.29 | | |
| Trade price (pharmacy purchase price) per standard unit, US\$ | 957962 | 24.12 | 129.00 | -0.02632 | 14852.14 | | |
| Public price (price to consumer) per standard unit, US\$ | 957962 | 32.23 | 175.72 | -1.46053 | 31783.57 | | |

Table 4: Summary statistics for price dispersion

| Sample | Era | N | Mean | Median | Range | IQR | Std Dev |
|-----------------------------|-----------|-----|----------|--------|------------|-------|-----------|
| Non-EU countries | 1993-1994 | 235 | 136.44 | 19.60 | 12655.00 | 95.52 | 944.67 |
| | 1995-1999 | 313 | 913.10 | 12.50 | 254682.00 | 74.44 | 14395.38 |
| | 2000-2004 | 329 | 34169.64 | 16.78 | 5610124.00 | 76.39 | 427341.39 |
| EU countries | 1993-1994 | 467 | -0.95 | 0.00 | 68.91 | 0.00 | 6.64 |
| | 1995-1999 | 757 | -0.64 | 0.00 | 60.35 | 0.00 | 4.84 |
| | 2000-2004 | 704 | -0.70 | 0.00 | 69.93 | 0.00 | 5.09 |
| Outliers removed | | | | | | | |
| Non-EU countries | 1993-1994 | 232 | 48.64 | 17.63 | 1043.00 | 93.73 | 116.23 |
| | 1995-1999 | 309 | 47.54 | 12.32 | 1009.00 | 73.73 | 128.92 |
| | 2000-2004 | 322 | 45.81 | 15.98 | 1072.00 | 73.03 | 129.86 |
| EU countries | 1993-1994 | 467 | -0.95 | 0.00 | 68.91 | 0.00 | 6.64 |
| | 1995-1999 | 757 | -0.64 | 0.00 | 60.35 | 0.00 | 4.84 |
| | 2000-2004 | 704 | -0.70 | 0.00 | 69.93 | 0.00 | 5.09 |
| Drugs with no parallel | 1993-1994 | 410 | -0.59 | 0.00 | 68.91 | 0.00 | 6.08 |
| imports | 1995-1999 | 642 | -0.15 | 0.00 | 60.35 | 0.00 | 3.81 |
| | 2000-2004 | 547 | -0.23 | 0.00 | 69.93 | 0.00 | 3.92 |
| Drugs with parallel imports | 1993-1994 | 57 | -3.53 | 0.00 | 52.47 | 7.18 | 9.44 |
| | 1995-1999 | 115 | -3.37 | 0.00 | 44.67 | 5.97 | 8.07 |
| | 2000-2004 | 157 | -2.33 | 0.00 | 60.74 | 5.01 | 7.71 |

Price dispersion is computed as the difference between the price in country i and the average across EU countries.

Table 5: Results from entry regression

| Logit regression of Y = 1 if entry by paralle | el imports | | | | |
|---|-------------------|-------|-------------------|--------|--|
| | Coef. (StdErr) | dY/dX | Coef. (StdErr) | dY/dX | |
| Average log price difference between originator price in country and other EU | 0.604** | .017 | 1.082** | .035 | |
| Countries Log of standard units sold by originator in market | 0.306** | .008 | 0.079) | .012 | |
| | (0.007) | | (0.012) | | |
| Log of standard units sold in EU at a lower price | 0.067** | .002 | 0.063** | .002 | |
| • | (0.005) | | (0.008) | | |
| Number of EU markets in which product is available | 0.230** | .006 | 0.351** | .011 | |
| | (0.009) | | (0.014) | | |
| Number of EU markets with parallel trade in this product | 0.039** | .001 | 0.032** | .001 | |
| • | (0.007) | | (0.011) | | |
| Number of EU markets with different brand name | | | -0.087** | -0.003 | |
| | | | (0.007) | | |
| Intercept | -5.666** | | -6.810** | | |
| • | (0.172) | | (0.357) | | |
| Number of Observations | 1094 | 78 | 49851 | | |
| Number of Entry Events | 119: | 52 | 5930 | | |
| Log Likelihood | -26194 | 1.281 | -11690.482 | | |
| Pseudo-Rsq | 0.32 | 93 | 0.35 | 72 | |

^{* =} 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.

Table 6: Results from price response regression

| Dependent variable = ln(Originator price) | Coef. | Coef. |
|---|----------|------------------|
| | (StdErr) | (StdErr) |
| Post-entry by parallel traders | 0.361** | -0.036** |
| | (0.003) | (0.003) |
| Threat of entry = # of markets with identical | 0.100** | 0.036** |
| product at lower price | (0.000) | (0.000) |
| Number of competing drugs in class | 0.001** | -0.001** |
| | (0.000) | (0.000) |
| Intercept | 0.268** | 0.394** |
| | (0.007) | (0.005) |
| Within Rsq | 0.31 | 0.32 |
| Between Rsq | 0.02 | 0.00 |
| Overall Rsq | 0.01 | 0.00 |
| Number of observations | 237468 | 237468 |
| Fixed effects included | Period, | Period, product* |
| | product | country |

^{* =} significant at the 5% level, ** = significant at the 1% level.

Table 7: Results from drug similarity regression

| Sample | All drugs | All drugs | US drugs | US drugs |
|-------------------------------|------------|------------|------------|------------|
| Number of Observations | 20439 | 13215 | 20439 | 13215 |
| | Coef. | Coef. | Coef. | Coef. |
| | (StdErr) | (StdErr) | (StdErr) | (StdErr) |
| Time trend | 0.00912** | 0.00694** | 0.01139** | 0.00703** |
| | (0.00024) | (0.00027) | (0.00031) | (0.00032) |
| Pair of EU countries | 0.05726** | 0.02223** | 0.08306** | 0.02514** |
| | (0.00539) | (0.00462) | (0.00688) | (0.00545) |
| Time trend * Pair of EU | -0.00608** | -0.00384** | -0.01019** | -0.00582** |
| countries | (0.00072) | (0.00066) | (0.00092) | (0.00078) |
| Pair of source-destination | -0.05377** | -0.05307** | -0.01662 | -0.01651 |
| countries | (0.01425) | (0.01188) | (0.01821) | (0.01401) |
| Pair of destination countries | 0.00437 | 0.00401 | 0.00832 | 0.00645 |
| | (0.01682) | (0.01406) | (0.02150) | (0.01658) |
| Pair of source countries | -0.01038 | -0.00916 | 0.04726* | 0.04617** |
| | (0.01479) | (0.01226) | (0.01889) | (0.01446) |
| Time trend * Pair of source- | -0.00050 | -0.00080 | -0.00192 | -0.00231 |
| destination countries | (0.00191) | (0.00169) | (0.00244) | (0.00200) |
| Time trend * Pair of | -0.00352 | -0.00347 | -0.00587* | -0.00554* |
| destination countries | (0.00223) | (0.00198) | (0.00285) | (0.00234) |
| Time trend * Pair of source | 0.00289 | 0.00228 | 0.00440 | 0.00386 |
| countries | (0.00203) | (0.00180) | (0.00260) | (0.00212) |
| Similarity of OECD variables | | 0.00748** | | 0.01750** |
| (Correlation) | | (0.00122) | | (0.00144) |
| Intercept | 0.33545** | 0.36583** | 0.47873** | 0.52637** |
| | (0.00175) | (0.00197) | (0.00223) | (0.00232) |
| R-square | 0.071458 | 0.061424 | 0.069283 | 0.057935 |
| Mean of Y | 0.395236 | 0.409451 | 0.553950 | 0.575532 |

^{* =} 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 drug version similarity regression

| Co (Std Time trend | 439 bef. lErr) 0087** 0025) 0539** | all drugs 13215 Coef. (StdErr) 0.00143** (0.00041) 0.01064** | 3401 Coef. (StdErr) 0.00658** (0.00080) | 3167 Coef. (StdErr) 0.00750** |
|------------------------------------|---|--|---|--|
| Co (Std) Time trend -0.00 (0.00) | oef. dErr) 0087** 0025) | Coef. (StdErr) 0.00143** (0.00041) | Coef. (StdErr) 0.00658** | Coef. (StdErr) 0.00750** |
| Time trend -0.00 (0.00 | 0087** 0025) 0539** | 0.00143** (0.00041) | 0.00658** | 0.00750** |
| (0.00 | 0025) | (0.00041) | | |
| |)539** | | (0.00080) | (0.00000) |
| Pair of EU countries 0.00 | | 0.01064** | | (0.00088) |
| 31 23 43 4141143 |)155) | | | |
| (0.00 | | (0.00177) | | |
| | 0219** | 0.00161** | | |
| countries (0.00 | 0021) | (0.00025) | | |
| \mathcal{E} | 5281** | 0.37120** | 0.36029** | 0.37179** |
| (Jaccard) (0.00 | 0376) | (0.00655) | (0.01376) | (0.01420) |
| Time trend * Similarity of 0.00 | 0242** | -0.00145 | -0.00968** | -0.01223** |
| drugs available (Jaccard) (0.00 | 0060) | (0.00096) | (0.00187) | (0.00204) |
| Similarity of OECD | | 0.00324** | | -0.00260** |
| variables (Correlation) | | (0.00047) | | (0.00091) |
| Pair of source-destination -0.01 | 1120** | -0.01085* | -0.01067* | -0.01026* |
| countries (0.00 | 0409) | (0.00455) | (0.00433) | (0.00452) |
| Pair of destination countries 0.02 | 2850** | 0.02837** | 0.02794** | 0.02894** |
| (0.00 | 0424) | (0.00468) | (0.00443) | (0.00460) |
| Pair of source countries -0.01 | 1673** | -0.01916** | -0.01580** | -0.01729** |
| (0.00 | 0482) | (0.00537) | (0.00504) | (0.00528) |
| Time trend * Pair of source- 0.00 | 0002 | -0.00012 | -0.00069 | -0.00074 |
| destination countries (0.00 | 0055) | (0.00065) | (0.00058) | (0.00065) |
| Time trend * Pair of 0.00 | 0083 | 0.00076 | 0.00108 | 0.00098 |
| destination countries (0.00 | 0058) | (0.00069) | (0.00061) | (0.00067) |
| Time trend * Pair of source 0.00 | 0072 | 0.00118 | 0.00030 | 0.00060 |
| countries (0.00 | 0064) | (0.00076) | (0.00067) | (0.00074) |
| Intercept -0.00 | 0130 | -0.01655** | -0.00038 | -0.00293 |
| (0.00 | 0148) | (0.00266) | (0.00581) | (0.00601) |
| R-square 0.65 | 55731 | 0.530862 | 0.493272 | 0.489006 |
| Mean of Y 0.14 | 42420 | 0.147309 | 0.163942 | 0.162451 |

^{* =} 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 9: Results from version exit regressions

| Y = 1 if version discontinued | Logit | Linear Probability Model | Linear Probability Model |
|-------------------------------|-------------------|--------------------------------|--------------------------------|
| | Coef. (StdErr) | Coef. (StdErr) | Coef. (StdErr) |
| Number of versions of drug in | -0.012** | -0.0032** | -0.0035** |
| country | (0.003) | (0.0001) (0.0003) | |
| EU country | 0.086** | (0.0001) | (0.0003) |
| , | (0.022) | | |
| Threat of parallel import | | 0.0006** | 0.0001 |
| | | (0.0001) | (0.0002) |
| Threat of parallel export | | 0.0070** | 0.0007 |
| | | (0.0010) | (0.0012) |
| Intercept | -4.582** | 0.0220** | 0.0102** |
| | (0.114) | (0.0026) | (0.0025) |
| Fixed effects | Class, period | Version, period | Version*country, period |
| Number of observations | 643849 | 241436 | 241436 |
| Log Likelihood | -43872 | | |
| Pseudo R-sq | 0.0196 | | |
| Within R-sq | | 0.0057 | 0.0067 |
| Between R-sq | | 0.0002 | 0.0006 |
| Overall R-sq | | 0.0021 | 0.0014 |

^{* =} significant at the 5% level, ** = significant at the 1% level.

Table 10: Results from brand name similarity regression

| Sample | All countries, all drugs | All countries, all drugs | EU countries, all drugs | EU countries, all drugs |
|---|--------------------------|--------------------------|-------------------------|-------------------------|
| Number of Observations | 19082 | 12153 | 3402 | 3168 |
| | Coef. (StdErr) | Coef. (StdErr) | Coef. (StdErr) | Coef. (StdErr) |
| Time trend | 0.00144** | 00149** | 0.00417** | 0.00402** |
| | (0.00029) | (0.00051) | (0.00138) | (0.00154) |
| Pair of EU countries | 01404** | 00828** | | |
| | (0.00260) | (0.00299) | | |
| Time trend * Pair of EU countries | 00004 | 00092* | | |
| | (0.00035) | (0.00043) | | |
| Similarity of drugs available (Jaccard) | 0.44024** | 0.42994** | 0.73659** | 0.73613** |
| | (0.00568) | (0.00903) | (0.02081) | (0.02185) |
| Time trend * Similarity of drugs available (Jaccard) | 0.00579** | 0.01456** | 00112 | 00058 |
| | (0.00079) | (0.00134) | (0.00295) | (0.00330) |
| Similarity of OECD variables (Correlation) | | 0.00420** | | 00158 |
| | | (0.00079) | | (0.00140) |
| Pair of source-destination countries | 05561** | 05709** | 05275** | 05392** |
| | (0.00657) | (0.00722) | (0.00643) | (0.00677) |
| Pair of destination countries | 04321** | 04348** | 04773** | 04726** |
| | (0.00677) | (0.00741) | (0.00664) | (0.00695) |
| Pair of source countries | 01248 | 01448 | 0.00396 | 0.00378 |
| | (0.00776) | (0.00856) | (0.00767) | (0.00811) |
| Time trend * Pair of source- destination countries | 0.00198* | 0.00240* | 0.00249** | 0.00278** |
| | (0.00088) | (0.00103) | (0.00086) | (0.00097) |
| Time trend * Pair of destination countries | 0.00386** | 0.00351** | 0.00331** | 0.00327** |
| | (0.00093) | (0.00109) | (0.00092) | (0.00102) |
| Time trend * Pair of source countries | 0.00037 | 0.00112 | 00008 | 00001 |
| | (0.00103) | (0.00121) | (0.00102) | (0.00115) |
| Intercept | 01878** | 02295** | 16400** | 16331** |
| | (0.00202) | (0.00336) | (0.00967) | (0.01015) |
| R-square | 0.655803 | 0.586203 | 0.652188 | 0.650514 |
| Mean of Y | 0.156690 | 0.162605 | 0.184288 | 0.182244 |

^{* =} 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.

Figure 1: Share of parallel imports in total market over time

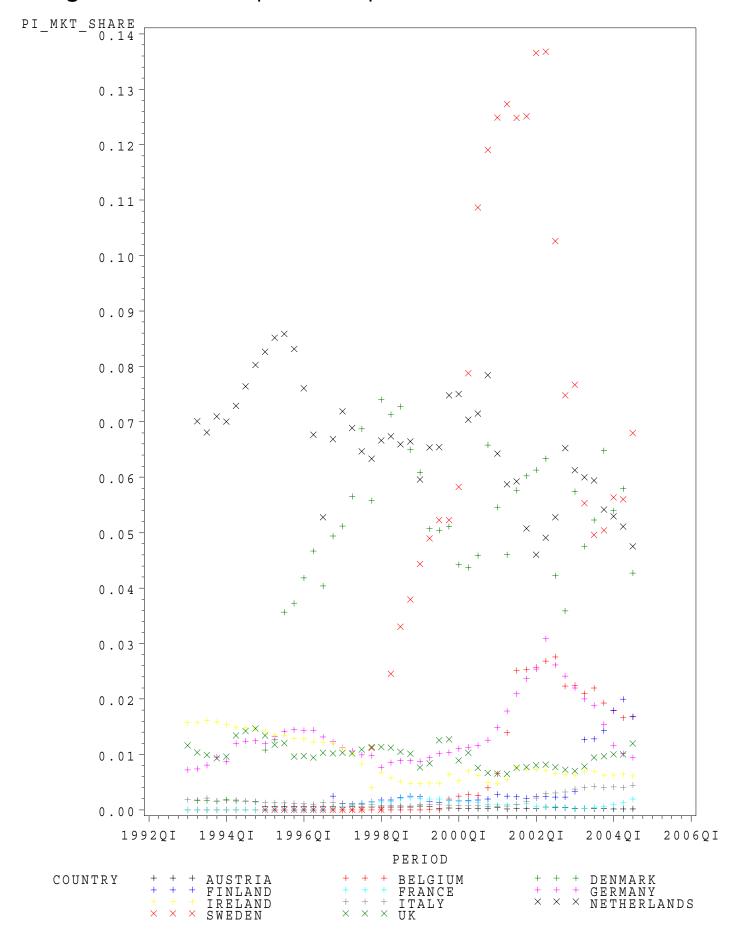


Figure 2: Average per-product share of parallel imports over time

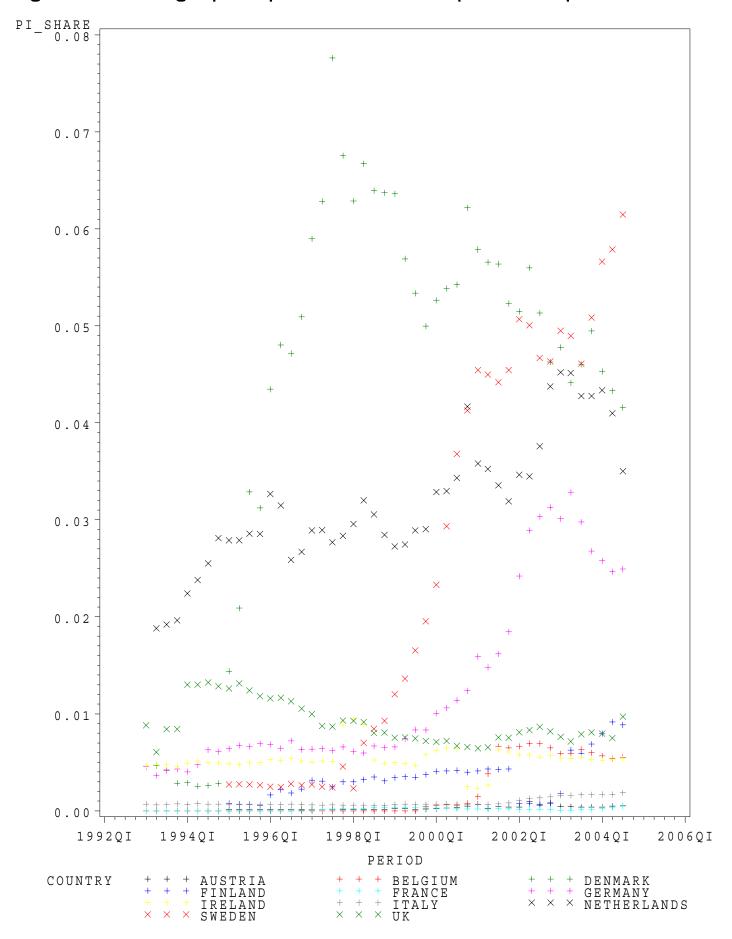


Figure 3: Average relative prices of parallel imports over time

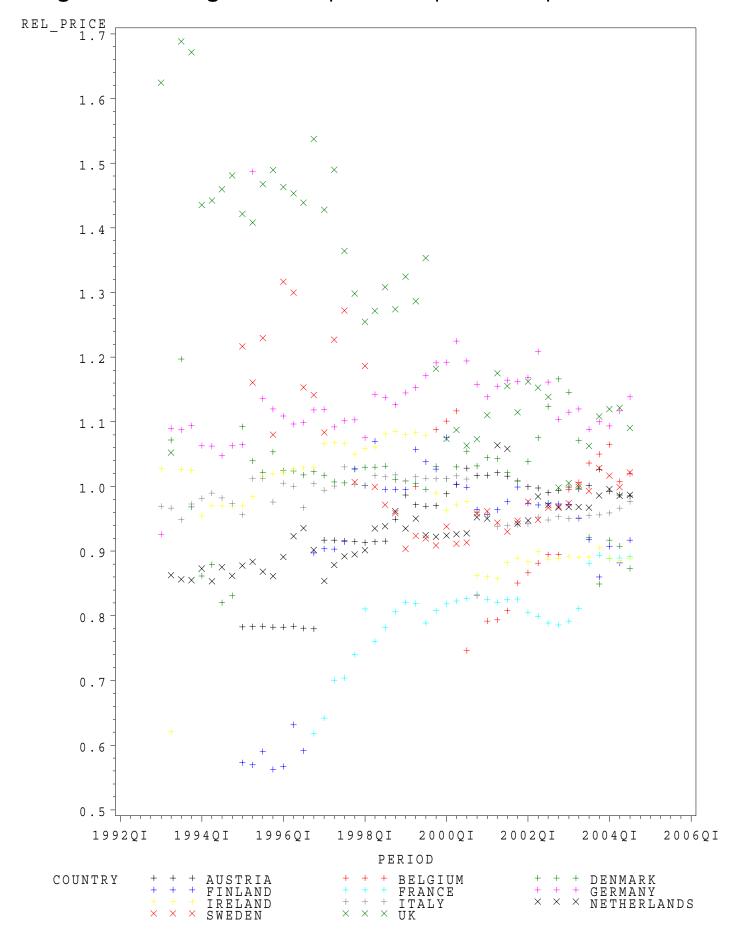


Figure 4: Distribution of price differentials (relative to EU average)

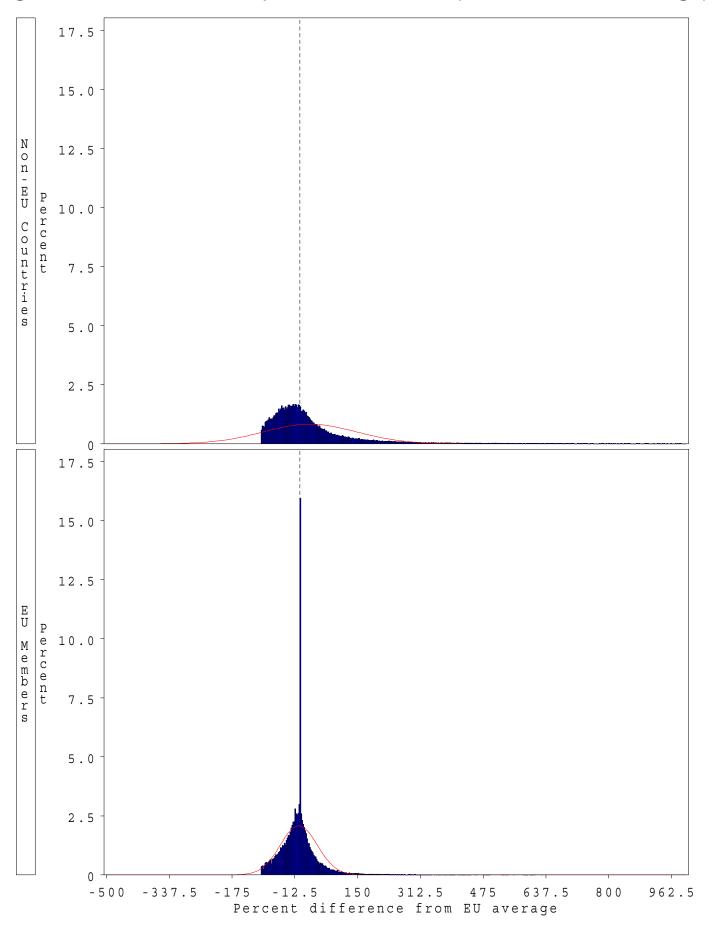


Figure 5: Distribution of price differentials (relative to EU average) over time

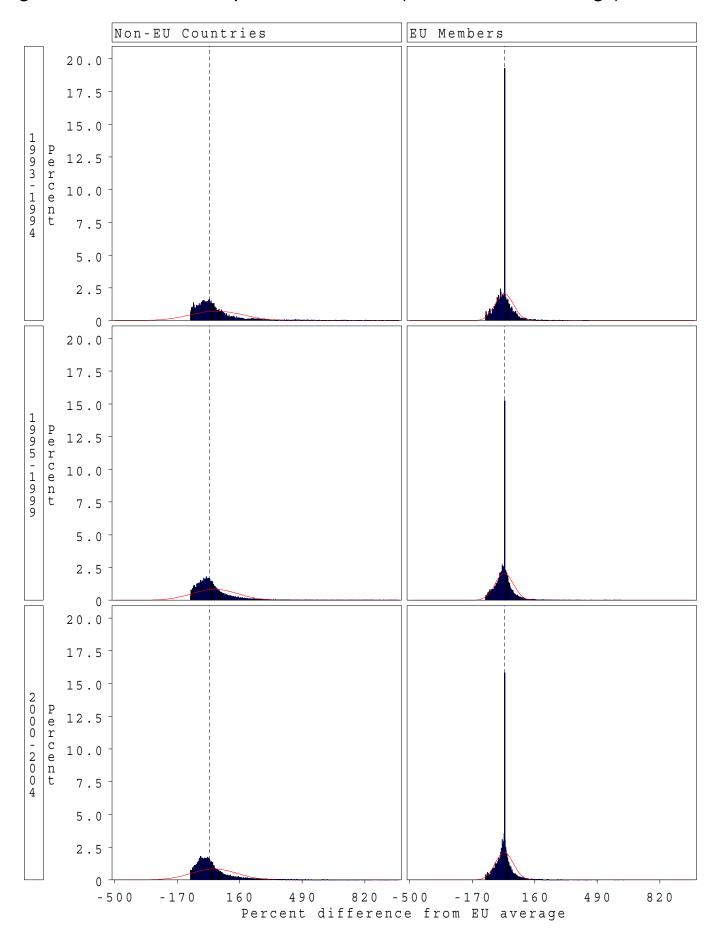


Figure 6: Distribution of price differentials (relative to initial EU average)

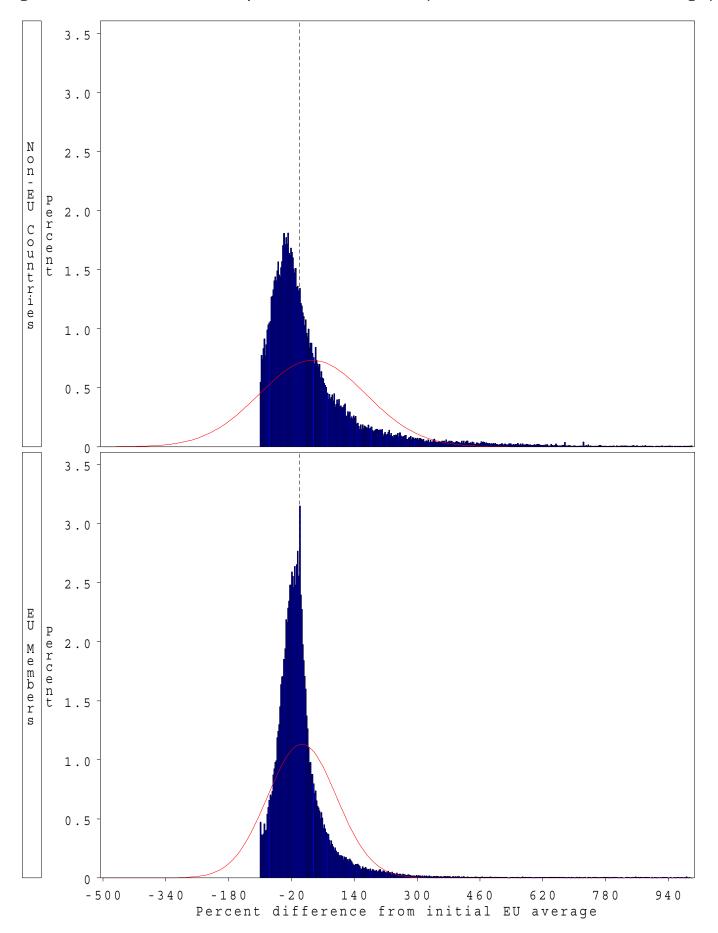


Figure 7: Distribution of price differentials (relative to initial EU average) over time

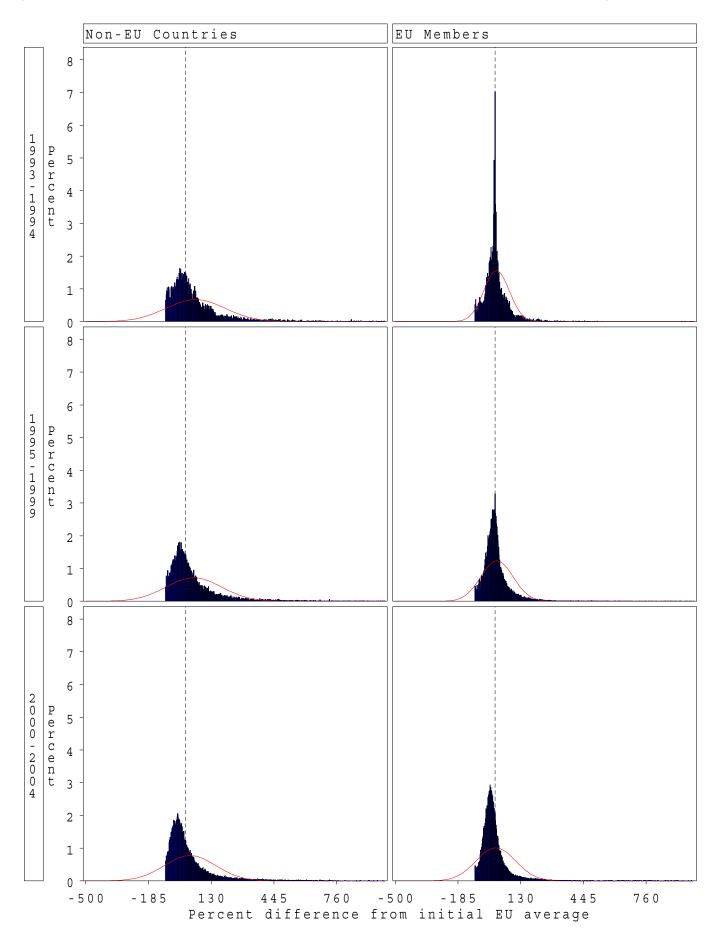


Figure 8: Average EU price over time for the B1C2 class

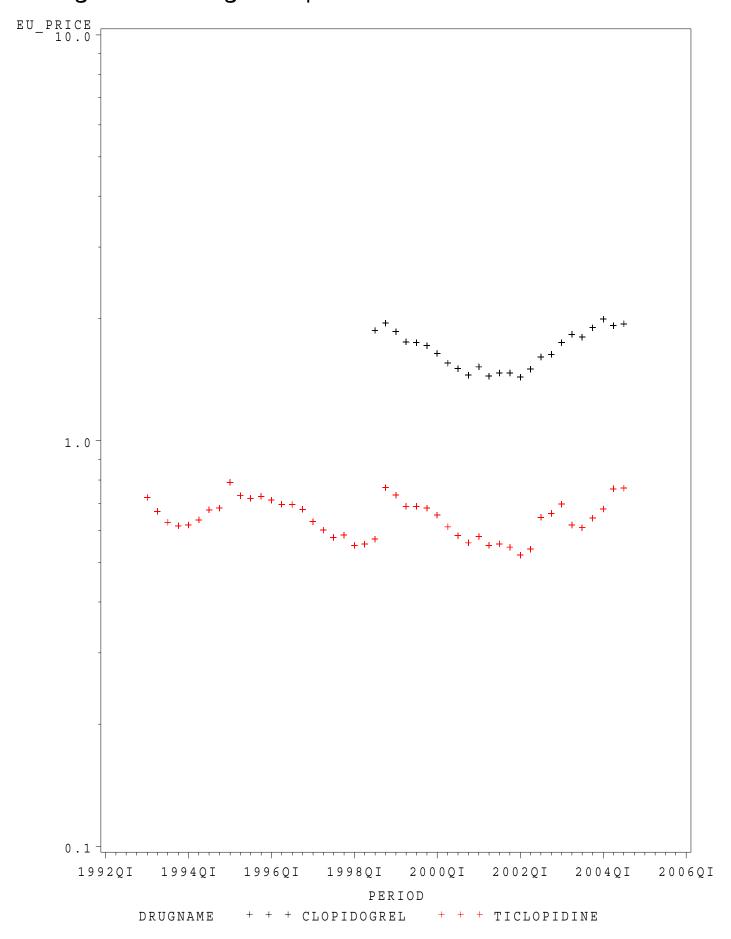


Figure 9: Average price over time for the B1C2 class, by country

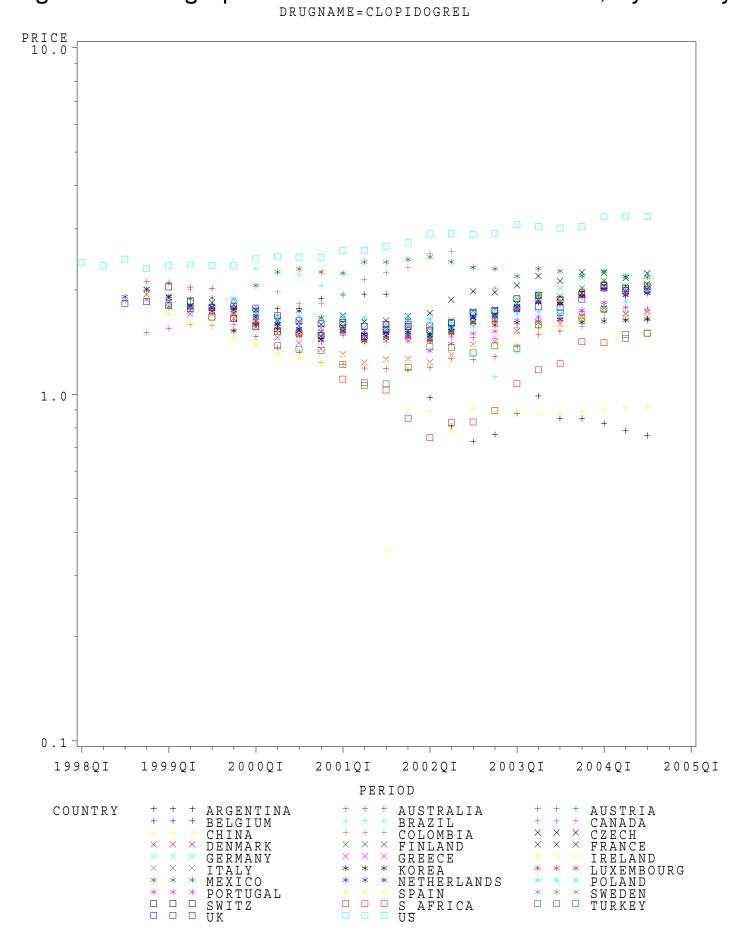


Figure 9: Average price over time for the B1C2 class, by country

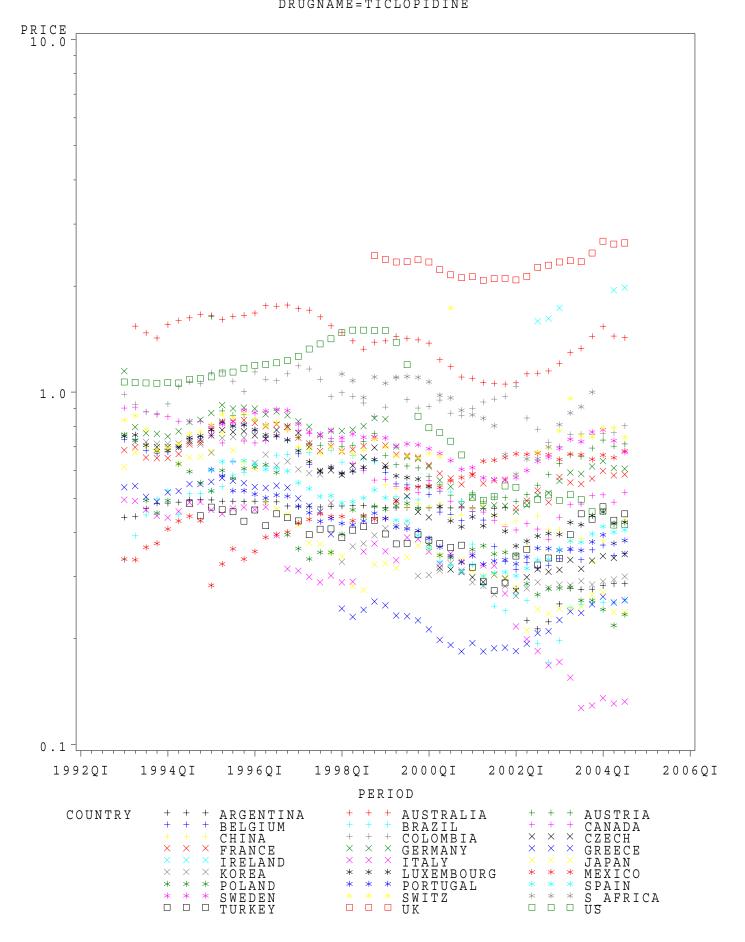


Figure 10: Average price over time for the B1C2 class, by country (EU only)

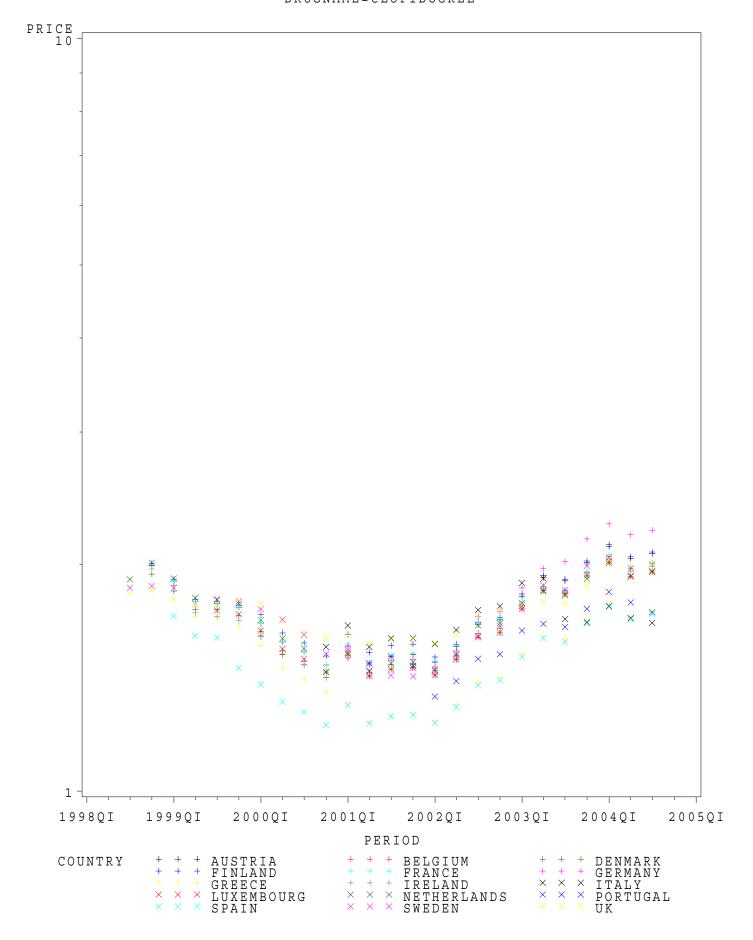


Figure 10: Average price over time for the B1C2 class, by country (EU only)

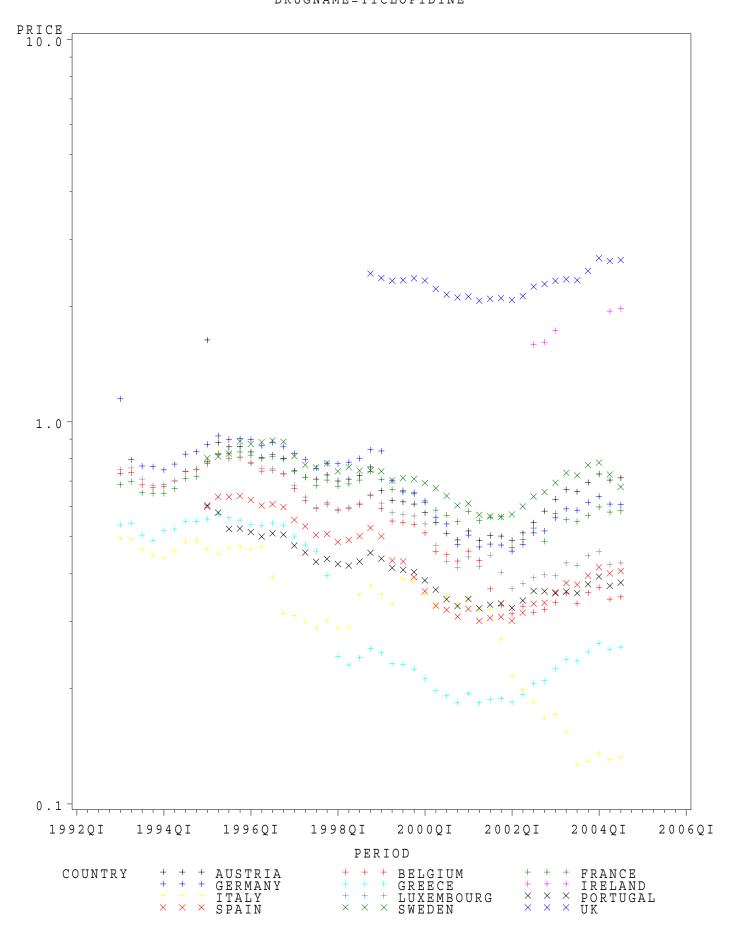
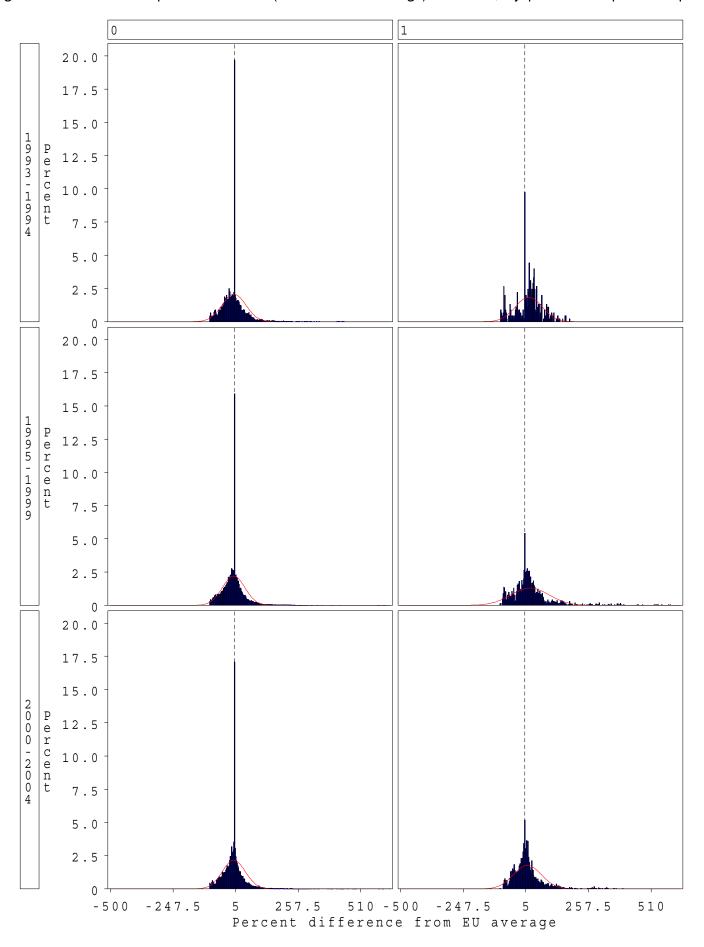
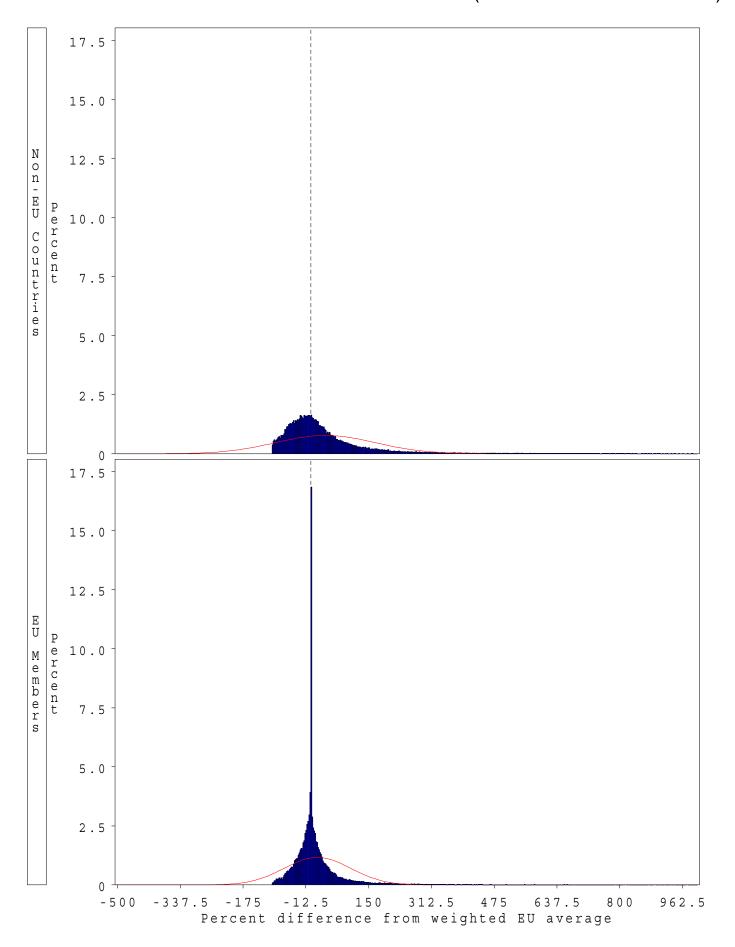


Figure 11: Distribution of price differentials (relative to EU average) over time, by presence of parallel imports



DISTRIBUTION OF WEIGHTED PRICE DIFFERENTIALS (RELATIVE TO EU AVERAGE)



DISTRIBUTION OF WEIGHTED PRICE DIFFERENTIALS (RELATIVE TO EU AVERAGE) OVER TIME

