

Ganslandt, Mattias; Maskus, Keith E.

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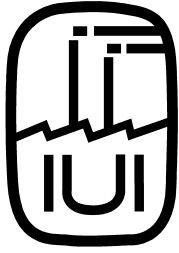
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**Parallel Imports and the Pricing of Pharmaceutical Products:
Evidence from the European Union**

by Mattias Ganslandt and Keith E. Maskus

IUI, The Research Institute of Industrial Economics
P.O. Box 5501
SE-114 85 Stockholm
Sweden

Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union¹

Mattias Ganslandt
The Research Institute for Industrial Economics

and

Keith E. Maskus
University of Colorado at Boulder

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We consider policy issues regarding parallel imports (PIs) of brand-name pharmaceuticals in the European Union, where such trade is permitted. We develop a simple model in which an original manufacturer competes in its home market with PI firms. The model suggests that for small trade costs the original manufacturer will accommodate the import decisions of parallel traders and that the price in the home market falls as the volume of parallel imports rises. Using data from Sweden we find that the prices of drugs subject to competition from parallel imports fell relative to other drugs over the period 1994-1999. Econometric analysis finds that parallel imports significantly reduced manufacturing prices, by from 12 to 19 percent. There is evidence that this effect increases with multiple PI entrants.

Keywords: Parallel imports, international arbitrage, drug pricing, pharmaceutical products

JEL Codes: F12, I11, L12

Ganslandt: IUI (The Research Institute of Industrial Economics), P.O. Box 5501, SE-11485 Stockholm, Sweden; email mattias.ganslandt@iui.se

Maskus: Department of Economics, UCB 256, University of Colorado, Boulder CO 80309-0256; email maskus@colorado.edu

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1. Introduction

Parallel imports (PIs) are legitimately produced goods imported legally into a country without the authorization of a trademark, copyright, or patent holder. The legal doctrine governing the permissibility of parallel imports is exhaustion, or the point of distribution at which rights to control further distribution are ended. Under national exhaustion the rights holder may prevent such importation. However, under international exhaustion PIs are legal. The essential purpose of such trade is arbitrage between countries with different prices.

For several years, parallel trade of prescription drugs has been an important issue for the pharmaceutical industry and numerous policy institutions in Europe, including the European Commission, the European Court of Justice, and member states of the European Union. Manufacturers prefer restraints on such trade in order to support higher prices in markets with weaker price controls. However, PIs exist and recent industry estimates suggest that lost sales in the EU currently amount to some \$3 billion per year.²

Parallel trade in prescription medicines has become a prominent issue in other parts of the world as well. For example, American consumers and policy makers have grown increasingly concerned about the relatively high prices of patented and brand-name drugs in the United States. Several measures have been proposed by U.S. policy makers, including direct regulation of drug prices and a policy to admit PIs. In an effort to reduce drug costs for consumers both the House and the Senate approved a measure in July 2000 that would have permitted pharmacists and wholesalers to import cheaper drugs from other countries.³ The Clinton Administration refused to implement the bill in December 2000, claiming that it could not guarantee the safety of such products. Nevertheless, high prices of patented and brand-name drugs in the United States remain

² See "Drug Makers Try to Curtail Cheap Imports," *The Wall Street Journal*, 11 April 2002.

an important policy issue and new legislation was introduced in 2003 to deregulate restrictions on parallel trade from Canada.

At the global level some analysts argue for establishing restraints on parallel trade in order to support low drug prices in poor countries (World Health Organization, 2001). It is argued that if tight segmentation could be maintained between rich markets and poor markets, drug companies might be willing to supply the latter with large volumes at marginal production costs. In August 2003, members of the World Trade Organization signed a waiver to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to permit developing countries to import generic substitutes of patented medicines in order to cope with national emergencies, such as HIV, tuberculosis or malaria.⁴ A key provision of this waiver is that beneficiary countries agree to control re-exportation of drugs they import in this fashion, for even generic drugs could be subject to parallel trade given the anticipated price differentials.

Parallel imports of pharmaceuticals are controversial because their welfare effects are generally ambiguous. First, there is a tension between two major public-policy objectives: innovation and development of new drugs, on the one hand, and short-run cost-containment strategies for the health care system and broad access to existing medicines, on the other.

The research-intensive pharmaceutical industry relies heavily on patents, the value of which depends in part on the scope for price differentiation. This scope depends critically on the existence of barriers to arbitrage. The value of a patent is, therefore, partly determined by the definition of the geographical area within which the product can be freely circulated and re-sold without the original manufacturing firm's consent. In the terminology of intellectual property law patent distribution rights are "exhausted" over a pre-defined area upon first sale. Once these rights

³ See "Senate Approves Measure on Import of Cheap Drugs," *The Wall Street Journal*, 20 July 2000.

are exhausted the patent holder can no longer restrict the circulation of the product. In other words, parallel trade is permitted over the geographical area where the rights to control distribution have been exhausted but not from regions or countries outside the area. One should, therefore, expect arbitrage to limit the scope for price discrimination within the area of exhaustion. The narrower the area of exhaustion, the greater is the scope for price differentiation. Consequently, countries with national exhaustion policies provide stronger incentives to innovate at the expense of higher consumer costs. In this context, permission of PIs could reduce incentives to innovate, even as consumers in high-price countries would gain due to lower prices for existing drugs.⁵

Second, there is an important conflict between divergent price regulations in different countries, on the one hand, and the consequences of parallel trade, on the other. Where PIs are permitted arbitrageurs can exploit regulated price differentials, leaving the original manufacturer with fewer alternatives to adjust its behavior. More specifically, patent holders may have an incentive to accommodate their pricing strategies to PIs while also taking measures to raise the trade costs of arbitrageurs. This accommodation would result in some price convergence but could expend considerable real resources on trade activities.

The tension between these multiple policy objectives is evident in EU policy.⁶ Under current EU law a member state has an exclusive right to define its health care policy, including price regulations and benefits, while the principle of free movement of goods allows individuals or firms within the EU to trade goods across borders without the consent of the producer.

The conflict between national price regulations, on the one hand, and mandates for EU-wide circulation of products, on the other, is recognized by the EU authorities. The Commission

⁴ See "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", 30 August 2003, WT/L/40 at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

⁵ Danzon (1998) argues that a segmented equilibrium with price-discriminating monopolies can be optimal from a welfare perspective.

notes in its *Communication on the Single Market in Pharmaceuticals* (1998) that, "Unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefits accrue to the parallel trader rather the health care system or patient." Even so the Commission concludes that "... parallel trade must equally be seen as an important driving force for market integration and, consequently, for achieving the Single Market."

Thus, while there are numerous issues concerned in the welfare tradeoffs, a central question for policymakers is the potential for PIs to generate significant price competition in higher-priced countries. Despite the importance of this question, there are no direct estimates of the price impacts of parallel trade in drugs. The aim of this paper is, therefore, to provide the first systematic economic investigation of these effects. More specifically, our focus here is on the price-integrating impact of PIs in pharmaceutical products within the European Union.

For this purpose we first develop a simple two-country model of parallel trade in which an original manufacturer maximizes profits in the high-price nation against a demand curve residual to import competition. In order to capture the effects of differing price controls, we assume that PIs come from a country in which price is capped. The number of parallel-importing firms is endogenous to market conditions and fixed costs under free entry, generating a prediction for price as a function of the number of entrants. In equilibrium the manufacturer sets a price in the high-price market that accommodates PIs, generating partial price convergence with the exporting country. We estimate this model using biweekly product-level data from the Swedish market from the first quarter of 1994 to the third quarter of 1999. We have compiled a unique data set consisting of prices for 50 major pharmaceutical products, the sales of patent holders, the wholesale prices of their drugs, the identity and time of entry of parallel importers, and the sources of PIs from within the EU.

⁶ See Ganslandt and Maskus (2000) for further details.

The Swedish market provides a natural test for our theoretical hypotheses. Before 1995 Sweden prohibited PIs of pharmaceutical products. However, Sweden's entry into the European Union on January 1, 1995 required that country to adopt the EU-wide exhaustion principle and permit such trade. Thus, we analyze the impacts of entry after an exogenous shock to the patented market. We find that prices in Sweden of drugs subject to competition from PIs declined relative to other pharmaceutical prices, with the effect concentrated at the end of the period. The econometric analysis shows that competition from the entry of parallel traders had a significant effect on the prices of original manufacturers in Sweden. We estimate the effect of such entry to be a reduction of between 12 and 19 percent of manufacturers' relative prices.

This result may be compared to other findings in the literature regarding competition from generic producers. Caves, Whinston, and Hurwitz (1991) found that in the United States the original innovator's price declined as the number of generic entrants rose, but the rate of price decline was small. Wiggins and Maness (1994) also reported that brand-name drug prices declined as generic entry expanded. Lu and Comanor (1998) found that the number of branded substitutes had a significantly negative effect on launch prices of new drugs in the United States. However, such findings are not universal. Grabowski and Vernon (1992) observed an increase in brand-name prices in response to entry. Frank and Salkever (1992, 1997) discovered that generic entry reduced the own-price elasticity of branded pharmaceutical products in the United States after patent expiration, permitting those prices to rise while generic producers targeted the higher-elasticity demand segments at considerably lower prices.

This issue remains unsettled and our results provide evidence for the hypothesis that entry through parallel imports exerts a significant downward influence on price by directly competing with the original producer in the same product. It should be noted that PIs are different from

generic products, for the former exist while the original product is on patent and the latter must await patent expiration. Further, because PIs are sourced from licensees or distributors of original manufacturers, they are identical to the patented product save for differences in packaging. Thus, they should be highly substitutable with the original goods.

The rest of this paper is organized as follows. We provide a brief overview of EU case law in Section 2. We present the theoretical model of PIs in section 3. In section 4 we develop the econometric approach and estimate the price effects of PIs from other countries in the EU to Sweden. We make concluding remarks in Section 5.

2. Current EU Case Law on Parallel Imports of Pharmaceutical Products

The European Court of Justice has held that free circulation of goods takes precedence over protection of intellectual property rights. In *Merck v Stephar* (C 187/80) the European Court of Justice held that a patent holder marketing its product in two different member states cannot prevent arbitrage between the two local markets, despite differences in intellectual property protection in the two countries. Thus, exhaustion applies upon first sale anywhere in the EU. Moreover, varying degrees of price control across countries do not justify prevention of parallel imports from countries with more rigorous regulations to markets with less rigorous regulations, as found in *Merck v Primecrown* (joined cases C-267/95 and C-268/95). Furthermore, parallel importers have limited rights to use original trademarks in marketing their products (*Dior v Evora*, C-337/95, and *BMS and Others v Paranova*, joined cases C-427/93, C-429/93, and C-436/93). Finally, manufacturers cannot partition the single market by introducing a new variety in member states, which could have the effect of replacing market authorization for the prior variety, where its product is subject to competition from parallel imports (*Rhone-Poulenc Rorer*, case C-94/98).

However, exhaustion in the European Union has important limitations. Most importantly, it does not extend to countries outside the common market (*EMI v CBS*, case C-51/75 and *Silhouette v Hartlauer*, case C-355/96). Thus, the ECJ has established a principle of "community exhaustion" but rejected the idea of international exhaustion. However, the principle of community exhaustion does not extend to cases where the goods are sold in a member state under a compulsory license, as established in *Pharmon v Hoechst* (C-19/84). To summarize, the EU system essentially mandates free parallel imports within its territory, despite the existence of national intellectual property regimes and price controls, so long as the manufacturer has placed the good voluntarily on the market.

In an important modification of EC policy, the European Court of First Instance ruled in 2000 that original manufacturers could impose supply quotas for foreign wholesalers so long as those quotas did not constitute contractual agreements prohibiting export of a product (*Bayer AG v Commission of the European Communities*, Case T-41/96, 26 October 2000). A literal interpretation of this ruling would be that it permits restraints on sales from manufacturers to licensed wholesalers but does not impede the ability of parallel importers to acquire drugs and ship them abroad. However, evidence suggests that manufacturers do limit supplies available for licensees within the EU that could escape into other markets in the region.⁷ As a consequence, parallel traders may encounter limits on the quantities available for their activity.

3. A Model of Parallel Imports

We develop a simple model of price arbitrage between two countries. The most important feature of this model is that parallel trading firms jointly choose the maximum amount of drugs they acquire for shipment to higher-priced markets. The notion that parallel traders do not acquire unlimited volumes is consistent with evidence that the share of such trade in total pharmaceutical

sales in high-price markets, such as Sweden, Germany and the UK, rarely exceeds ten percent except in a few major products. This situation occurs despite the existence of marked price differentials between these markets and EU member countries where prices are substantially lower.⁸ This may be because parallel importers find it difficult to locate distributors who are willing to supply their needs. Further, as just discussed, original manufacturers tend to limit their sales to foreign wholesalers, or to cap production levels permitted to foreign licensees, in order to restrict the volume of parallel trade.⁹ However, rather than relying on such constraints, in the model we derive the profit-maximizing quantity chosen by the PI firms.

The assumption of a quantity limit can be justified analytically on two grounds. First and foremost, our model is consistent with market conditions in Sweden. The model takes into account that PI firms are few and act strategically. The PI firms must order and ship the product from abroad prior to sale in Sweden and the quantity of PI firms is consequently pre-determined at the time when the manufacturing firm sets its price and markets clear.¹⁰ The ordering and shipping of PI products may therefore be considered a commitment mechanism for PI firms and the sequence of decisions in our model is consistent with these real-world conditions. Second, the quantity limit for PI firms is a convenient way to take into account the increasing marginal cost of PIs. As limited volumes of pharmaceutical products are available for parallel trade, PI firms use low-cost

⁷ See "Drug Makers Try to Curtail Cheap Imports," *The Wall Street Journal*, 11 April 2002.

⁸ In 1998 the share of PI sales was six percent of the total sales of pharmaceutical products in Sweden, though it was higher in certain products. The aggregate share was moderate despite price differentials of 21 percent between Sweden and such low-price countries as Italy and Spain (Ganslandt and Maskus, 2001). It should be noted that this situation, involving a limited share of PIs in the presence of significant international price differentials, is consistent with quantity limits but not unlimited arbitrage.

⁹ The President of the European Association of Pharmaceutical Full-line Wholesalers (GIRP) recently stressed "...the full-line wholesalers' concern that they will no longer be able to guarantee the reliable and timely distribution of all pharmaceutical products due to the practice of supply restrictions by several manufacturers." (GIRP Press release, 17 December 2003).

¹⁰ Pharmacy managers in Sweden report that there is often a shortage of PI products. Such products are frequently out-of-stock and wholesalers are unable to meet the demand from pharmacies. Quantity limits are consequently of significance for the Swedish market (Holmberg, Kiellberg and Andersson, 2003).

suppliers first and more costly distributors only second.¹¹ In addition, PI firms would take costly actions to circumvent supply restrictions imposed by manufacturing firms.¹² Accordingly, we expect an increasing marginal cost of engaging in parallel trade.

Consider a model with two markets (home and foreign) denoted h and f . We assume throughout that the home market is the high-income country and the foreign market is the low-income country. Demand for a specific pharmaceutical product in the home market is

$$D_h(p) = a - bp \quad (1)$$

where b is proportional to the marginal utility of money.¹³ We make the simplifying assumption that no substitute therapies exist so that only the own-price appears in this demand function.

The product is patented in both countries and produced by a single manufacturing firm at marginal cost c , which for simplicity we set equal to zero in markets h and f . There is an autonomous government in the foreign country that is able to set a cap on the price charged to retail outlets (hospitals and pharmacies) in its own market. The price cap is denoted \overline{p}_f and is always (strictly) binding in that market. The price in the home market is unregulated. The manufacturing firm consequently sells the product in the home and foreign market at prices p and \overline{p}_f , respectively.

¹¹ Recent evidence from Canada suggests that it is increasingly costly for cross-border retailers to find large volumes available for arbitrage. For instance, the supply control systems used by major pharmaceutical companies have changed the behavior of Canadian online pharmacies selling prescription drugs to US citizens. According to some sources online pharmacies increasingly turn to wholesalers unaffected by the supply control systems. However, unaffected wholesalers charge 30 percent higher prices due to the risk of supply cutoffs. See "Drugmakers Curb Canadian Outlets," *Detroit Free Press*, 6 September 2003.

¹² Tactics used by Canadian on-line pharmacies to circumvent supply restrictions include payments to storefront pharmacies in exchange for supplies as well as the establishment of own retail outlets, permitting on-line drugstores to move supplies between channels. See "Pfizer Moves to Stop Drugs from Canada," *The New York Times*, 14 January 2004.

¹³ This system of demand functions can be obtained approximately from a linear-quadratic utility function (ie, $\alpha x - \beta x^2/2 + v(y)$) so long as the expenditure on x is a relatively small share of the consumer's budget and we substitute $a = \alpha/\beta$ and $b = v'(m)/\beta$, assuming that $v'(m) > 0$ and $v''(m) < 0$.

Assume that there is a small number of symmetric parallel-importing firms permitted to engage in commercial arbitrage, while arbitrage by individual patients between the two markets is prohibited. The marginal cost of engaging in parallel trade is t per unit and the fixed cost is T . The PI product is a perfect substitute for the product sold by the manufacturing firm to retail outlets in the h market. It is assumed that the PI price is below the price set by the manufacturing firm, which ensures that the entire PI quantity shipped to market h is sold. Denoting this quantity by X , the manufacturing firm's residual demand in the home market is

$$D_h^m(p) = D_h(p) - X \quad (2)$$

The strategic interaction is modeled as a multi-stage game. In the first stage, n symmetric parallel importers enter the market, applying for an approval from the authorities in h to import the product from market f .¹⁴ PI firms will only enter the market if the expected profit is non-negative. In the second stage, each PI firm (indexed by i) simultaneously ships a quantity x_i from the wholesaler in the foreign market to the home market, incurring the variable trade cost t . The shipped quantity x_i is known to all firms. In the third stage, the manufacturing firm sets its price (p) in the home market and markets clear. Throughout the game the manufacturing firm takes the price in the foreign market (\overline{p}_f) as given.¹⁵ Furthermore, it is assumed that both markets will be served in equilibrium.

¹⁴ This assumption is motivated by the fact that in the Swedish market a parallel importer must have an approval by the Medical Products Agency before it can commence to import a pharmaceutical product.

¹⁵ Pecorino (2002) presents a model in which a monopolistic pharmaceutical firm is unconstrained in price in its home market but bargains with the price authority in the foreign market. In his setup the permission of parallel imports (or "reimports") into the home market generates a higher price in the foreign market due to a change in Nash bargaining positions, raising overall monopoly profits, while prices in both countries are integrated by trade. The result is driven both by the assumption that the countries share similar incomes and by the existence of a single firm. In our model there are different incomes and free entry of PI firms.

In the theoretical analysis we look for the unique sub-game perfect Nash equilibrium. We solve the game in the usual fashion, starting in the last stage and working backwards to the first stage. This procedure also allows us to discuss different aspects of parallel trade.

In the last stage, when solving for an optimal price for the manufacturing firm subject to a particular quantity of PIs, we identify a relationship between the volume of PIs and the price in the home market. Working backwards to the second stage, we solve the non-cooperative sub-game among the PI firms and find the equilibrium volume of imports. This yields a relationship among the volume of PIs and the number of PI firms, the size of the h market, and the price in the f market. Proceeding to the first stage we solve for the equilibrium number of PI entrants. This shows how the number of PI firms in equilibrium depends on the size of the home market, prices, as well as variable and fixed costs.

3.1 Unlimited Parallel Imports Lead to Price Convergence

Before we proceed to our analysis of the multi-stage game, it is worthwhile looking at a benchmark in which arbitrage is perfectly elastic.¹⁶ In this case PI firms import a product to the home market as long as the retail price difference is larger than the trade cost. If parallel imports were actually to happen, the manufacturing firm would achieve no sales in h . Thus, the only way it can sell in the home market is by setting a price in the home market that makes such trade unprofitable. We shall refer to this as an “arbitrage-free” price.

When potential arbitrage is unlimited and perfectly elastic, blocking PIs with an arbitrage-free price in the home market is more profitable than accommodating the inflow. This strategy generates home sales at per-unit revenue equal to the foreign price plus trade cost, while under accommodation the manufacturer only sells in the foreign market with per-unit revenue equal to foreign price.

Compared to the segmented equilibrium, the threat of PIs results in price convergence (up to the level of trade cost) by virtue of a price decline in the home market. Thus, potential arbitrage is enough to induce price convergence but no actual PIs exist in equilibrium. It is worth noting that from a welfare standpoint, potential competition from PIs is more efficient than actual PI competition because in the former case no real resources are devoted to arbitrage (no trade costs are incurred), while they are in the latter.¹⁷

3.2 *The Effects of a Quantity Limit*

The impacts of PIs are sensitive to the existence of a maximum volume constraint, i.e. the supply elasticity of parallel imports. In particular, such a constraint gives the manufacturing firm an incentive to accommodate parallel trade rather than to set an arbitrage-free price in the home market.

Starting in the final stage, the manufacturing firm maximizes profits according to

$$\text{Max}_p (a - bp - X)p + X \overline{p}_f, \quad (3)$$

which gives the following first order condition

$$a - 2bp - X = 0. \quad (4)$$

The profit-maximizing price as a function of the total PI quantity is consequently

$$p(X) = \frac{(a - X)}{2b} \quad (5)$$

which shows that the price falls in the volume of PIs.

Working backwards to the second stage, we solve for the non-cooperative quantities chosen by the PI firms. These firms would face a downward sloping demand curve, recognizing that they all possess some (limited) degree of market power. Each symmetric PI firm maximizes

¹⁶ Ganslandt and Maskus (2001) offer proofs of these propositions.

$$\text{Max}_x [p(X)x - (\overline{p}_f + t)x] \quad (6)$$

where $p(X)$ is given by equation (5). The n interior first order conditions follow immediately and are symmetric:

$$\frac{(a - 2x - \sum_{-i} x_{-i})}{2b} - (\overline{p}_f + t) = 0 \quad (7)$$

where the subscript $-i$ refers to all PI firms other than i . The unique sub-game equilibrium is

$$x(n) = \frac{[a - 2b(\overline{p}_f + t)]}{n + 1} \quad (8)$$

which increases in the size of the home market (a) and decreases in the sum of foreign price and the unit trade cost. In the sub-game equilibrium with n PI firms, the total PI quantity is

$$X(n) = \frac{n}{n + 1} [a - 2b(\overline{p}_f + t)] \quad (9)$$

which increases in the number of PI firms. Accordingly, the equilibrium price as a function of n is

$$p(n) = \frac{1}{2b} \left[a - \frac{n(a - 2b(\overline{p}_f + t))}{(n + 1)} \right] \quad (10)$$

Thus, the equilibrium price in h falls in the number of PI firms. It is also worth noting that the equilibrium price in the home market converges to the foreign market price plus variable trade cost as the number of PI firms goes to infinity.

Working backwards to the first stage we find the equilibrium number of PI firms. It is assumed that a PI firm will only enter if the expected profit in equilibrium is non-negative. Thus, the free-entry equilibrium condition for PI firms is

¹⁷ It is theoretically possible from the global standpoint that a segmented equilibrium with international price differentiation is more desirable than an integrated equilibrium with partial or complete price convergence.

$$(p(n) - (\overline{p_f} + t)) x(n) - T \leq 0 \quad (11)$$

where $p(n)$ is the sub-game equilibrium price given by equation (10) and $x(n)$ is the corresponding sub-game equilibrium quantity given by equation (8). Assuming for simplicity that the number of PI firms is a continuous variable, we solve equation (11) for the equilibrium number of PI firms:

$$n^* = \frac{(a - 2b(\overline{p_f} + t))}{\sqrt{T}} - 1 \quad (12)$$

This expression is positive for sufficiently small fixed costs, i.e. $T < (a - 2b(\overline{p_f} + t))^2$. Accordingly, the equilibrium number of PI firms decreases in the foreign price ($\overline{p_f}$) and in the variable trade cost (t). It increases in the size of the market (a) and decreases in the fixed cost (T).

Finally, we can obtain the equilibrium price and the equilibrium volume of PIs by inserting the number of PI firms into equations (10) and (9), respectively. These various expressions constitute our accommodation equilibrium.

4. Empirical Analysis

We undertake an empirical analysis of the price effects of parallel imports. The analysis focuses on two issues. First, we quantify the average price impact of PIs in the import market (Sweden) by comparing products not subject to competition from that source with products subject to such trade. Second, we estimate an econometric model of the impact of arbitrage from parallel trade, accounting for the endogeneity of entry decisions. We consider both actual competition as PI firms enter and potential competition arising from the entry of Sweden into the European Union.¹⁸

For these purposes we collected detailed data about the pharmaceutical market in Sweden. The Swedish market provides a natural test for our theoretical hypotheses. When Sweden joined

the European Union on the 1st of January 1995 the policy on PIs was drastically changed. Before membership in the EU, parallel imports of pharmaceutical products were prohibited but when Sweden became a member they had to be allowed.¹⁹ Sweden is, therefore, a natural experiment for considering an exogenous change between two completely different policies.

4.1 Current Regulatory Structure

Our analysis is motivated by the differences in regulation that should sustain international price gaps as analyzed in the model. There is a significant difference between the pricing of pharmaceuticals in Sweden, on the one hand, and the pricing of drugs in strictly regulated markets such as Italy, Spain, Portugal and Greece, on the other. The system in Sweden can best be characterized as a negotiation between the national health-care authority and the pharmaceutical companies. When a new drug is introduced, the pharmaceutical company suggests a price and justifies its proposal by listing the benefits of the product, the expected patient volume, prices of comparable treatments and prices in other countries. After some negotiation, upon approval of the price by the authority the product is covered in the national health-insurance program. The pharmaceutical company is free to propose changes to the price at a later date, subject to an approval by the authority. Thus, this policy is sufficiently flexible that it constitutes a relatively moderate constraint when the manufacturing firm makes its pricing decisions.

The situation in Southern Europe is different. The prices of pharmaceuticals are strictly controlled in such countries as Italy, Portugal, Spain and Greece. In Italy the prices of reimbursed drugs are regulated with a price cap. The price of a drug eligible for reimbursement within the health system can be no higher than the average price in twelve EU countries. This maximum price cannot be exceeded else the product is removed from the reimbursement list. In Portugal the

¹⁸ As noted below, the endogeneity of entry precludes a sharp distinction in this regard.

¹⁹ Parallel imports are subject to a regulatory approval period, which effectively delayed the regime shift.

regulation is even broader in scope and the prices of all prescription drugs are regulated. The price must be equal to or lower than the lowest price in three reference countries (Spain, Italy and France). If the average price in the two remaining countries is more than 30 percent higher than the lowest price, 30 percent of the average in the two remaining countries is added to the lowest price. Spain also controls the prices of all prescription drugs. Prices are set based on cost, profit allowance and anticipated volume of sales. Finally, Greece regulates drug charges with a system of reference prices.

4.2 *Data*

We employ three data samples. The primary data were provided by LIF, the Swedish Association of the Pharmaceutical Industry. The first data set includes the 50 molecules with the highest sales values in the Swedish market in 1994, 1995, 1996, 1997 and 1998. Approximately 35-38 percent of the Swedish pharmaceutical market in value terms is included in this data set. An observation is a "product", defined as a molecule with a specific anatomical therapeutic classification (ATC) code, form and concentration. More specifically, the data include 164 different forms and concentrations distributed over 50 molecules.²⁰ For each product there are quantities and prices for both original manufacturing firms and all PI firms on a yearly basis. Note that because we use data assembled on a detailed product level the price comparisons are not subject to the methodological problems with aggregated price comparisons discussed in Danzon and Chao (1995) and Danzon and Chao (2000).

²⁰ Whether a particular molecule is on patent in Sweden is not public information. Our best assessment is that 44 of the 50 molecules were protected by patents during the sample period because the time since initial launch was well within the average patent duration. Moreover, 49 of the 50 molecules were sold under a protected trademark.

Second, we have constructed a biweekly, unbalanced panel with prices for the 164 products in our sample from January 1, 1994 to September 1, 1999, for a total of 149 periods.²¹ We also have collected data on approvals to parallel-import the products in our sample for 1995-1999 and added this information to our biweekly panel. An approval is a formal decision by the Swedish Medical Products Agency and it allows a specific parallel importer to import a unique patented or trademarked molecule in a specific form and dose from a specified export country. Thus, in the biweekly panel we have information about the date when PI firms are approved as well as the date when they enter as actual competitors (the first-pricing date).

In a third sample we have detailed prices for subsets of the 50 molecules in France, Portugal, Spain, and Italy for 1994, 1995 and 1998. Spain and Italy are the two main parallel-exporting countries in the sample and we make particular use of their prices for 26 available molecules. These prices were obtained from IMS Health, a private consulting firm. The narrower sample was restricted to drugs that are precisely comparable on an international basis. Thus, they have the same ATC code, form, and concentration and originate from the same manufacturers across all markets.

4.3 *The Pharmaceutical Market and Parallel Imports*

Figures summarizing the Swedish pharmaceutical market are presented in Table 1. Pharmaceutical sales were approximately 0.8-0.9 percent of GDP valued at wholesale prices during the period 1995-1998. They ranged from 13.4 billion Swedish Kronor (SEK) in 1995 to 16.6 billion SEK in 1998. In 1998 the 50 top drugs accounted for 37 percent of total sales in the pharmaceutical market valued at wholesale prices.

²¹ The panel is unbalanced in the sense that new products and PI approvals enter the data set over the period, implying that the number of products differs over time. In particular, there were 196 products by the end of the period.

Parallel imports increased substantially after Sweden joined the European Union, both in terms of actual sales and approvals to engage in the activity. In 1995 no PIs occurred and no applications to import were filed. By 1998 PIs had grown to 1.0 billion SEK, which corresponded to six percent of the total market, and 226 approvals to import pharmaceutical products had been granted by the Medical Products Agency. Initial PI entry was gradual, for by 1996 only a single firm had been granted permission to start parallel trade. However, by 1997 the number had grown to four firms and in 1998 the number was ten. The largest PI firm accounted for 100 percent of total parallel trade in 1996, 85 percent in 1997 and 59 percent in 1998. The four largest companies accounted for 96 percent of all parallel trade in 1998. Parallel imports from 13 different countries had been approved by 1998. The sources of PIs were, however, heavily concentrated in a few low-price countries in Southern Europe. Two countries, Spain and Italy, were the exporters in approximately two thirds (63 percent) of all cases. The three most important export countries (Spain, Italy, and Greece) accounted for 74 percent of all approvals.

In 1998 parallel trade in Sweden was concentrated in the highest-volume products. Parallel imports accounted for 16 percent of the sales of the top 50 molecules, but the distribution of parallel trade as a share of total sales for these 50 molecules was not equal. Measured on an unweighted product basis the median share of parallel trade was zero percent and the maximum was 72.1 percent. Parallel imports existed in approximately 15 percent of all products. Ranking products from lowest to highest parallel-import shares, at the 95th percentile such imports accounted for 53.6 percent of total sales.

There is a similar picture for approvals on a product basis. Approvals to parallel-import drugs into Sweden in 1998 were concentrated in a few high-value products. For 68.3 percent of all

products on the top 50 list no entry of a PI firm had occurred. More than one approval had been granted for 21.9 percent of products.²²

To summarize this overview, our sample covers approximately 35-38 percent of the pharmaceutical market in Sweden. The growth of parallel imports from 1995 to 1998 was considerable and such imports accounted for 16 percent of sales of the top 50 molecules in 1998. A large and rapidly growing number of PI firms entered the market, in some cases to sell the same products as other firms already present. Overall, sales were achieved largely by four major parallel importers. Parallel trade was concentrated in a minority of the products in the sample and the share of PI was considerable for approximately 15 percent of the top-value products. Italy and Spain were the main source countries and were either individually or jointly specified as the export country in 63 percent of all PI approvals. A final observation is that because growth in PI activity seemed to be accelerating at the end of our sample, the data we have available presumably do not reflect a long-run equilibrium.

4.4 *Average Price Effects in the Import Market*

Next, consider the effects of parallel imports in the Swedish market. We start with a comparison between products that are subject to competition from PIs and products that are not. Note that this is not the fully appropriate counterfactual comparison, which would compare prices of those products facing PI competition with fictional prices of the same goods had there been no possibility of parallel imports. Unfortunately, this comparison cannot be made. Neither is it

²²Eighteen approvals had been granted for one specific product. That this number could be so large has two explanations. First, for some products a specific parallel-importing firm was approved to import the goods from several exporting countries. Second, more than one parallel-importing firm had an approval to import certain drugs, possibly from the same exporting country as other such firms.

possible to make a strict comparison between prices of patented drugs and those not on patent because exact information on patent status is not available.²³

We calculate the relative price change for all specific products between a base year (1994 or 1997) and 1998. The relative price change is defined as the price in SEK in 1998, divided by the corresponding price in the base year, minus one. We calculate the change for the average price including PIs as well as the change for the manufacturing firms' prices.

Table 2 reports the unweighted and weighted average price changes for all products. The unweighted average is a simple arithmetic mean. In the weighted average, however, product weights are computed as the product's sales in 1998 divided by the sum of sales for all products included in the average.

Our discussion primarily focuses on the unweighted average. Over the whole period 1994-1998 prices increased on average 6.64 percent for all products and manufacturing firms' prices increased somewhat more at 7.34 percent. On average prices for products subject to parallel imports increased 2.88 percent while manufacturers raised their prices 6.38 percent for these products. In contrast, prices for products not subject to PI competition rose 7.57 percent.

The difference was even more pronounced over the shorter period 1997-1998. Average prices increased 0.25 percent among all products. Manufacturing firms' prices declined 0.34 percent for products subject to PIs, but rose 0.96 percent for products not facing this competition. Prices of products that were parallel imported fell on average by 3.12 percent. Thus, this data overview seems to confirm that the prices of PI products, and of products facing such competition, fell in the import market relative to the prices of products not subject to parallel trade, with much of the impact concentrated at the end of the period.

²³ However, note our assessment that most of the drugs were patented, including virtually all of the large-volume molecules. Thus, it is unlikely that these differential price impacts are associated with patent status.

We undertake simple tests of the hypotheses generated by our basic theory. First, to test whether the differences between the change in the manufacturing firms' prices for products subject to PIs and those not subject to PIs are significant, we perform t-tests, assuming unequal variances, of the hypothesis that the mean change is the same. The hypothesis that the manufacturing firms' price changes for goods facing PIs and those not facing such imports is the same cannot be rejected at the ten-percent level of significance for the period 1994-1998 ($t=0.43$). The hypothesis is, however, rejected at the five-percent level for 1997-1998 ($t=1.77$), which confirms that the manufacturing firms' prices increased significantly less for products subject to PIs than did prices of other products in the latter part of the period.

Our preliminary conclusion is that the data are consistent with accommodation of parallel trade by manufacturers for two reasons. First, the very existence of PI firms indicates that manufacturers choose not to block arbitrage. Second, the change in the manufacturing firms' prices is not significantly different between goods facing PIs and other goods over the period 1994-1998. However, the mean price of goods facing such competition, including both the PI volume and the original manufacturers' volume, increased significantly less than product prices of the manufacturing firms not facing such competition. Over the short period 1997-1998, the change of the manufacturing firms' prices was significantly lower for products facing import competition than for other drugs. This result suggests that manufacturing firms react to the volume of arbitrage with a lag, rather than reacting to parallel imports immediately upon their potential entry into the market.

4.5 *The Price Impact of Competition from Parallel Imports*

To investigate the price effect of parallel imports further we examine econometrically how changes in manufacturers' prices are affected by competition from that channel. For this purpose

we use our biweekly panel from January 1994 to September 1999 with original manufacturers' prices and PI approvals in Sweden. The manufacturing firm's price in Sweden for each product is normalized in each period of our biweekly panel compared with the price of the same product during the first period in which it was sold. That is, in the first period that a product is sold by the manufacturing firm in Sweden the relative price is defined as 1.0, while subsequent prices are computed relative to this basis. This variable is denoted PRICEMNF_{it} in period t , where subscript i refers to product i . It should be noted that these prices tend to remain constant for long periods and then change discretely over time in a piecewise-continuous process. In this regard, the estimated constant term provides the strongest explanation of prices in the panel.²⁴

We adopt two approaches to estimating the impact of entry by PI firms on relative manufacturers' prices in the panel. The first is an ordinary least squares (OLS) specification in which prices are affected by the number of PI entrants, the potential for PI competition, and a time trend. Thus, we define a variable DENTRY to take the value one if there are one or more PI firms active in the product at time t and zero otherwise. We also define DENTRY1 , DENTRY2 , DENTRY3 , and DENTRY3P as indicator variables for one, two, three, and more than three active PI firms in a period. These entry variables directly measure the presence of competition. In contrast, potential competition is measured by the variable D1995 , which is zero for the periods in 1994 and one after that. The notion here is that original manufacturers in principle needed to think strategically about the possibility of PIs after Sweden's entry into the EU, but not prior to that. Thus, D1995 is designed to capture the effect of the discrete change in policy facing manufacturers.

²⁴ We also estimated specifications with an AR(1) process within each product in the panel, finding that the lagged price coefficient was very close to unity and highly significant in the same way as the constant terms in the static specifications. However, we do not think that AR processes adequately capture price-setting in the data because, as noted earlier, the markets are not in long-run equilibrium during the period. Consequently we focus on the static specification of price changes.

An obvious difficulty is that entry decisions of PI firms are endogenous to changes in the manufacturer's price and OLS accordingly would generate biased and inconsistent estimates. Thus, our second approach is to estimate a series of instrumental variables (IV) equations, in which various instruments are used to explain DENTRY in the first stage, while predicted values for DENTRY are used in the second stage as a determinant of price changes, along with D1995 and the time trend. For this purpose, we selected combinations of the following instruments. First, we included the number of periods since initial launch of the manufacturer's product in Sweden (LAUNCHPER), which should capture the longevity of a product and the evident fact that PI competition acts with a lag. Second, we used the volume of drugs (by unit) sold by product in 1995 (QUANT1995) or the value of these sales (SALES1995) in Sweden. This variable reflects the idea that PI firms would focus on products with large markets. Third, we used also the one-year lagged volumes or sales (QUANTLAG and SALES1995, respectively) to account for growth in these markets.

We also wish to incorporate measures of the potential price gaps between export sources and Sweden, for these gaps directly account for the potential returns to PIs. Thus, a fourth instrument was the minimum price of matched available products in a set of potential exporters (France, Italy, Greece, Portugal, and Spain), defined relative to the contemporaneous Swedish manufacturer's price in Kronor (MINRELPR). Because these prices existed in our data for 1994 (and 1998) we used the 1994 local prices adjusted for changes in bilateral exchange rates over the estimation period. This wide definition of supply sources and biweekly price (exchange rate) changes permitted us to retain a relatively large sample size. However, to avoid any bias arising from attributing all price changes to exchange rates and to focus on key exporters, the next instruments were relative prices in Italy and Spain of these products in 1994 (RELIT94 and

RELSP94). This choice considerably reduced the available products for inclusion in the analysis. Finally, we included as instruments the bilateral exchange rates of the Swedish Kronor with the Spanish Peseta (ESP), the Italian Lire (ITL), and the Greek Drachma (GRD).

It is evident that foreign prices and exchange rates could be construed by original manufacturing firms as determinants of potential competition. Because we use these variables as instruments for entry decisions, it is difficult to differentiate between the impacts of actual and potential competition.²⁵ Thus, the IV approach can only test for the effect of total competition, which may be a mix of actual entry and potential competition.

Our approach is most consistent with that in Frank and Salkever (1997). They estimated first a fixed-effects OLS specification in which the number of generic entrants was considered to be exogenous. As noted above, they found that entry tended to raise the prices of brand-name products. Second, they developed a two-stage instrumental variables procedure with fixed effects, in which entry was predicted first on the basis of pre-patent volume, market age, years off patent, and a time trend. Their IV estimates discovered a larger impact of generic entry on brand-name prices.

Table 3a provides summary data on the key variables used. Table 3b lists correlation coefficients among relative manufacturer's price, entry, the 1995 dummy, and central instrumental variables. Note first that PRICEMNF and DENTRY are positively correlated, suggesting that entry is associated with increases in relative prices. Next, the correlations of DENTRY with the instrumental variables are reasonably high with the exception of QUANT1995.²⁶ Most importantly, we believe that each of the instruments may be considered essentially exogenous to

²⁵ We are grateful to Thomas McGuire for this insight.

²⁶ This is true also of the correlations with the bilateral exchange rate variables.

the contemporaneous pricing decisions of manufacturers, making them asymptotically uncorrelated with the structural-equation residuals.

Turn next to the OLS results listed in Table 4. We estimate these equations using both fixed-effects and random-effects estimators to account for the product-specific influences. As may be seen the choice of fixed effects or random effects makes virtually no difference, except for reducing slightly the magnitudes of the constant terms. In models (1) and (2) we estimate simply the effect of any entry by PI firms (that is, by one or more firms) on relative manufacturers' prices over the period. As may be seen, entry reduced the average relative price by around 1.6 percent by these estimates, which was highly significant. However, our proxy for potential competition due to Sweden's EU-membership in 1995, D1995, had no effect on pricing behavior.²⁷ A more nuanced picture emerges from distinguishing between the number of entrants. Specifically, the entry of two PI firms had little impact on manufacturers' prices.²⁸ However, a third entrant tended to reduce average price by 4.6 percent, and additional entrants by another 4.9 percent. This result stems from the fact that multiple entrants existed in the highest-volume products. Thus, the average price impact over all products was modest but in the drugs with large market volumes the price-reducing effects of PIs were large and significant. These results are consistent with the simple calculations in Table 2. Note that the tendency for additional entrants to strengthen the reduction in prices provides additional support for the notion of accommodation as specified in our theoretical model.

As noted earlier, entry of PI firms is an endogenous choice and these OLS coefficients likely are misleading. Thus, Table 5 lists the results of various IV estimations, using different sets of instruments. In this regard, we could not estimate a system of first-stage equations for each of the differentiated entry variables (DENTRY1, DENTRY2, DENTRY3, and DENTRY3P). Thus,

²⁷ In other specifications, we used an indicator variable for the time between a PI approval and first-pricing date for that product in Sweden as a measure of potential competition, with similar results.

we were forced to estimate an IV equation only for DENTRY in each model, using its predicted values DENTRYHAT in the pricing equations shown.²⁹ Again, we use both fixed effects and random effects, the choice of which makes virtually no difference in the coefficients.

It is immediately obvious that the use of IV techniques generates considerably different results from OLS. First, the coefficients on DENTRYHAT are highly significant and negative, ranging from an impact of a 12 percent to a 19 percent reduction in manufacturers' prices, depending on the instruments and sample. Thus, the earlier OLS estimates were flawed in that they failed to account for the endogenous entry of PI firms. Specifically, because such firms tend to enter in products with otherwise significant pricing power, the OLS equations confound entry decisions (a positive association with price) with the price-reducing impact of entry. When instrumented, we find that entry has a sharply negative and significant effect on original manufacturers' prices.³⁰

Note also that with the IV approach the impact of Sweden's EU-membership, captured by D1995, becomes negative in models (5) to (10). However, at most the effect is 1.7 percent, far below the influence of entry by parallel importers later in the period. It is also interesting that the use of IV estimation reduces the coefficient on the time trend from 0.6 percent per year to 0.1 percent per year.

The results from our econometric analysis may be summarized in two points. First, both the OLS and IV equations demonstrate that competition from PIs had a significantly negative impact on the original manufacturers' prices in Sweden. Second, the OLS results are questionable

²⁸ DENTRY2 is significant at the 10-percent level but with this large a sample that inference is marginal at best.

²⁹ Similar estimation of a variable with the number of entrants was unsuccessful because our instruments could not well predict changes in entry decisions given such frequent data.

³⁰ In IV specifications using an AR(1) process in each product, we find even larger negative effects of PI entry when the coefficients are converted to "long run" impacts. As noted, however, we do not believe the data reflect a long-run equilibrium, making such estimates suspect.

in light of the evident endogeneity of entry by PI firms. Thus, we believe the IV estimates are more sensible and they show that the price-reducing impacts were substantial, ranging from 12 to 19 percent on average. Indeed, this price impact may be compared to the average price gap of 21 percent between Sweden and either Italy or Spain in available products in 1994 (Ganslandt and Maskus, 2001).

5. Conclusion

In this paper we developed a model of manufacturer behavior in the presence of parallel imports. We showed that the price of products facing such arbitrage should drop relative to prices of products that are not subject to it in the home market and for the manufacturing firm's price to fall as the volume of PIs (or the number of PI firms) rises.

The Swedish market provides a natural laboratory in which to investigate these effects. The growth of parallel imports from 1995 to 1998 was considerable and accounted for 16 percent of sales of major molecules in our sample in 1998. A large number of PI firms entered the market, in some cases to sell the same products as other such firms already present. Parallel trade was concentrated on a minority of the products in the sample but its share was considerable for up to 15 percent of major drugs.

The initial empirical analysis confirmed that prices of goods subject to import competition, including parallel-traded products themselves, fell approximately four percent in the import market relative to the prices of products not subject to parallel trade. Simple tests for differences in price changes suggested that the price effect came with a lag.

The econometric investigation discovered that when the endogeneity of entry is taken into account, the estimated effects of PIs becomes powerful, suggesting that original producers cut

prices by up to 19 percent, relative to other drug prices. Thus, we conclude that parallel imports represent a significant form of competition in markets such as Sweden.

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Table 1. The Pharmaceutical Market in Sweden 1995-1998

Sweden	1995	1996	1997	1998
Gross Domestic Product (MSEK)	1,649,922	1,688,200	1,738,859	1,816,042
Total pharmaceutical sales (MSEK)	13,393	15,808	14,263	16,567
Sales of top 50 molecules (MSEK)	4,576	5,977	5,201	6,203
Top 50 as share of total sales	34%	38%	36%	37%
Parallel imports (MSEK)	0	>0	269	1,007
Parallel imports of top 50 (MSEK)	0	>0	269	920
Parallel imports/Total sales	0%	0%	2%	6%
Parallel imports/Top 50 sales	0%	0%	5%	16%
Total number of PI approvals	0	1	45	226
PI approvals for top 50 molecules	0	1	31	131
Total number of PI firms	0	1	4	10

Sources: SCB, LIF, MPA

Table 2. Relative Price Changes of Pharmaceuticals in Sweden 1994-1998

		Unweighted Average		Weighted Average	
		1994-1998	1997-1998	1994-1998	1997-1998
Sweden					
All Products	Including PI	0.0664 (0.134)	0.0025 (0.035)	0.0080 (0.028)	-0.0137 (0.006)
	Manufacturer's price	0.0734 (0.133)	0.0073 (0.031)	0.0279 (0.022)	-0.0016 (0.003)
Products	Including PI	0.0288 (0.121)	-0.0312 (0.041)	-0.0438 (0.044)	-0.0385 (0.009)
Facing PI					
Competition	Manufacturer's price	0.0638 (0.120)	-0.0034 (0.035)	0.0031 (0.036)	-0.0067 (0.005)
Products not	Manufacturer's price	0.0757 (0.137)	0.0096 (0.030)	0.0365 (0.017)	0.0015 (0.004)
Facing PI					
Competition					
No. of Obs.		125	151	125	151

Source: Authors' calculations based on data from LIF. Figures in parentheses are standard deviations.

Table 3a. Summary Statistics for Variables in Econometric Model

Variable	Obs	Mean	Std. Dev.	Min	Max
PRICEMNF	24751	1.0432	0.0944	0.6500	1.5620
DENTRY	24751	0.0448	0.2069	0	1
DENTRY1	24751	0.0169	0.1290	0	1
DENTRY2	24751	0.0103	0.1011	0	1
DENTRY3	24751	0.0059	0.0764	0	1
DENTRY3P	24751	0.0089	0.0940	0	1
D1995	24751	0.8200	0.3842	0	1
LAUNCHPER	24751	57.2	46.8	0	150.0
QUANTLAG (m units)	24751	0.0534	0.3363	0	5.4847
QUANT1995 (m units)	24751	0.0639	0.3657	0	5.0986
SALESLAG (m SEK)	24751	12.7000	32.3000	0	350.0000
SALES1995 (m SEK)	24751	14.1321	32.9084	0	281.3443
MINRELPR	16350	0.7045	0.1397	0.3952	0.9449
RELIT94	9450	0.8450	0.1758	0.5605	1.1840
RELSP94	11700	0.8335	0.1329	0.5951	1.0313
ESP (Kronor per 100 Peseta)	24751	5.4281	0.2459	5.0801	5.9926
ITL (Kronor per 100 Lire)	24751	0.4493	0.0149	0.4159	0.4883
GRD (Kronor per 100 Drachma)	24751	2.8825	0.1946	2.4775	3.2689

MINRELPR is from a sample of relative prices using data from France, Italy, Greece, Portugal, and Spain

Table 3b. Correlations among Key Variables

	PRICEMNF	DENTRY	D1995	LAUNCHPER	QUANT1995	QUANTLAG	SALESLAG	MINRELPR
PRICEMNF	1							
DENTRY	0.17	1						
D1995	0.14	0.10	1					
LAUNCHPER	0.32	0.46	0.49	1				
QUANT1995	-0.00	0.09	0.00	0.07	1			
QUANTLAG	0.06	0.14	0.07	0.11	0.81	1		
SALESLAG	-0.07	0.18	0.18	0.22	0.63	0.83	1	
MINRELPR	-0.26	-0.26	-0.00	-0.05	0.05	0.07	0.03	1

Table 4. Estimated Impacts of PI Entry on Original Manufacturers' Prices Using Ordinary Least Squares

Variable	OLS-FE	OLS-RE	OLS-FE	OLS-RE
	(1)	(2)	(3)	(4)
DENTRY	-0.0160	-0.0158		
	(-9.05)***	(-8.95)***		
DENTRY1			-0.0039	-0.0037
			(-1.55)	(-1.47)
DENTRY2			-0.0056	-0.0055
			(-1.77)*	(-1.72)*
DENTRY3			-0.0457	-0.0455
			(-10.9)***	(-10.9)***
DENTRY3P			-0.0494	-0.0492
			(-13.6)***	(-13.5)***
D1995	-0.0007	-0.0006	-0.0013	-0.0012
	(-0.55)	(-0.49)	(-1.03)	(-0.97)
TREND	0.0006	0.0006	0.0007	0.0007
	(59.14)***	(58.94)***	(60.4)***	(60.2)***
CONSTANT	0.9919	0.9825	0.9918	0.9825
	(1089)***	(189.4)***	(1095)***	(188.2)***
Observations	24751	24751	24751	24751
Products	196	196	196	196

Notes: figures in parentheses are t-statistics (for fixed effects) and z-statistics (for random effects). Associated p-values are significant at the 10-percent (*) or 1-percent (***) levels.

Table 5. Estimated Impacts of PI Entry on Original Manufacturers' Prices Using Instrumental Variables Estimation

Variable	IV-FE	IV-RE	IV-FE	IV-RE	IV-FE	IV-RE	IV-FE	IV-RE	IV-FE	IV-RE
	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
DENTRYHAT	-0.1890	-0.1796	-0.1913	-0.1735	-0.1715	-0.1663	-0.1300	-0.1208	-0.1661	-0.1386
	(-11.3)***	(-11.0)***	(-11.4)***	(-10.8)***	(-10.3)***	(-10.1)***	(-10.2)***	(-9.84)***	(-9.03)***	(-8.33)***
D1995	-0.0172	-0.0163	-0.0175	-0.0157	-0.0157	-0.0152	0.0033	0.0047	-0.0047	-0.0001
	(-7.99)***	(-7.70)***	(-8.06)***	(-7.51)***	(-7.35)***	(-7.20)***	(1.32)	(1.93)*	(-1.15)	(-0.02)
TREND	0.0010	0.0010	0.0010	0.0010	0.0010	0.0010	0.0008	0.0007	0.0011	0.0010
	(26.5)***	(26.5)***	(26.6)***	(26.6)***	(25.7)***	(25.7)***	(16.0)***	(15.8)***	(14.2)***	(14.0)***
CONSTANT	0.9844	0.9726	0.9843	0.9733	0.9848	0.9730	0.9875	0.9745	0.9763	0.9628
	(763.0)***	(113.6)***	(760.4)***	(175.7)***	(775.2)***	(91.6)***	(631.4)***	(110.0)***	(356.1)***	(103.5)***
Observations	24751	24751	24751	24751	24601	24601	13138	13138	7234	7234
Products	196	196	196	196	196	196	196	196	196	196

Notes: in Models (5) and (6) the instruments are LAUNCHPER, QUANTLAG, and bilateral exchange rates with Italy, Spain, and Greece. In Models (7) and (8) the instruments are LAUNCHPER, SALES LAG, and the same exchange rates. In Models (9) and (10) the instruments are LAUNCHPER, QUANT1995, and the same exchange rates. In Models (11) and (12) the instruments are LAUNCHPER, MINRELPR, and the same exchange rates. In Models (13) and (14) the instruments are LAUNCHPER, SALES LAG, the relative prices in Italy and Spain, and the same exchange rates.