EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals

What's to Blame? Derogation or Perception?[1]

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Abstract

Given the cost of trade and availability of pharmaceuticals, the driving force for parallel trade is the price difference between the source (exporting) and the destination (importing) country. An increase in the price difference or in the availability of pharmaceuticals for parallel trade should increase price competition in the destination country. Using 2003-2007 data from Sweden we investigated whether EU enlargement in 2004, when new countries with low pharmaceutical prices joined the EU, increased competition from parallel imports. Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, EU enlargement is not found to have increased this effect, which might be explained by derogations and changes in consumer perceptions of parallel imports.

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Introduction

Pharmaceutical prices vary substantially across the European Union (EU) countries. For example, Lipitor is sold for €44.93 in Sweden, but for less than half that, just €20.30, in Greece (IHS Global Insight, 2010).[4] Such price differences lead to arbitrage or so called "parallel trade" which is allowed within the EU towards fulfilling the objective of creating a single market. Parallel traders can take advantage of price differences buying pharmaceuticals in low-price (exporting or source) countries such as Greece and reselling them in high-price (importing or destination) countries such as Sweden. Given the availability of drugs for parallel trade, and the cost of trade, the driving force for parallel trade is the price difference between the source and destination countries. An increase in the availability of drugs for parallel trade or in the price difference should increase the volume of parallel imports and hence competition in the destination country. Using 2003-2007 data from Sweden we investigated whether EU enlargement in 2004, when new countries with low pharmaceutical prices joined the EU, increased competition from parallel imports.

By the enlargement, Cyprus, Malta, and the Central and Eastern European countries − the Czech Republic, Hungary, Latvia, Lithuania, Estonia, Poland, Slovakia, and Slovenia − joined the EU on May 1, 2004. The prices of pharmaceuticals especially in the Central and Eastern European Countries were much lower than in the rest of the EU. Retail pharmaceutical price level was 71% of the OECD average in the Czech Republic in 2005; 70% in Slovakia , and 68% in Poland, while it was 73% in Greece and 77% in Spain, the two major source countries (OECD, 2008). Hence enlargement increased price differences between EU countries with a possible twofold effect: causing some not previously subject to competition from parallel imports to face it and increasing competition for those previously subject to it. That is, intra-EU price differences might have become sufficiently large for parallel traders to start importing drugs not previously subject to parallel trade, while the increased price difference and the increased availability of drugs for parallel trade might have increased competition for others. We here explore whether EU enlargement increased intensity of competition from parallel imports focusing on drugs already subject to it.

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[4] Greece is one of the main EU countries from which parallel traders source drugs to Sweden. Medartuum, the biggest parallel trader in Sweden, sourced 19% of all its 2008 drug imports from Greece making Greece its third largest source country. Ganslandt and Maskus (2004) list Greece, Spain, and Italy as the most important source countries, accounting for 74% of all Swedish approvals for parallel trade of pharmaceuticals in 1998.

Given availability of drugs, and the cost of trade, parallel traders, as rational agents maximizing profits, would naturally source drugs first from the lowest-price country, which − after the EU enlargement − is likely to be one of the new members. Availability of new source countries with lower prices would also stimulate new parallel traders to enter the market. Both the volume of parallel imports and the number of parallel imported versions of each drug might thus increase in the destination countries, increasing competition from parallel imports. The enlargement could even affect prices of drugs subject to competition from parallel imports not sourced from the new members, since the availability of drugs for parallel trade in the new members might increase the amount of parallel imports a parallel trader could source from the existing members. For example, a parallel trader importing drugs to Great Britain from Spain might instead start sourcing drugs from the new EU members, thus increasing the amount of drugs available in Spain for import to Sweden, in turn increasing competition from parallel imports in Sweden.

However, EU enlargement might not lead to any substantial increase in parallel imports, due to the "derogation" covering all accession countries except Cyprus and Malta. This provision was part of the Accession Treaty because the patent laws in the eight Central and Eastern European accession countries were not in line with those in the existing EU members.[5] The derogation restrains parallel trade by allowing the patent holder of a drug to prevent parallel trade of the drug if the intellectual property (IP) rights in the accession country were not comparable with those in the existing member states at the time of the product's launch. The applicability of the derogation is assessed on a case-by-case basis, and its effect erodes over time as more and more products reach the end of their patent or supplementary protection certificate (SPC) term in the pre-existent EU members (Tobin and Turner, 2003).[6] Despite the derogation, a substantial number, about 6%, of the drugs facing competition from parallel imports, in Sweden had been granted approval for parallel import from the new EU members.

Parallel imported drugs are legitimately produced and legally imported by parallel traders without the authorization of the patent holder. They have the same active ingredient, strength, and form (e.g. pill or fluid) as the locally-sourced drug supplied directly by its patent-holding manufacturer via authorized wholesalers. However, parallel imports might differ in packaging

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[5] All of the accession countries except for Cyprus and Malta have only had EU compliant patent laws and provided patent protection for pharmaceuticals since the early 1990s (see Tobin and Turner, 2003; von Uexkull, 2004). Patent laws in Cyprus and Malta had been comparable to those in the EU for longer, so they were exempted from the derogation.

[6] SPC is an extension of patent on drugs, introduced to compensate for the effective patent life lost during the review process for market authorization.

as, depending on the requirements of the importing country, they may be repackaged or relabeled, or even differ in brand name.[7] Consumers might thus consider parallel imports to be imperfect substitutes for the locally-sourced drugs. But, parallel imports are the main instrument for creating competition during the patent life of a drug. Unless parallel trade is allowed, on-patent drugs are only subject to competition from therapeutic alternatives − with different active ingredients but similar therapeutic effects − until the patent expires and generics enter the market.

Theoretical studies show that parallel imports should create competition, causing prices to fall in the destination country (Pecorino, 2002; Ganslandt and Maskus, 2004; Maskus and Chen, 2004; Jelovac and Bordoy, 2005; Chen and Maskus, 2005). Though few in number, empirical studies have found mixed results. Ganslandt and Maskus (2004) found supporting evidence from Swedish data, while Kanavos and Costa-Font (2005) found, on the contrary, that parallel trade did not create competition. Kanavos and Costa-Font (2005) examined whether a surge in parallel trade represented by the market share of parallel imports − taking into account the endogeneity of market share − has any effect on the prices of locally-sourced drugs in the six destination countries in the EU, namely Denmark, Germany, the Netherlands, Norway, Sweden and the UK. Using data from 30 countries covering all drugs in 36 therapeutic classes, Kyle (2010) examined both actual and potential entry of parallel imports finding statistically significant but economically small effects on prices of locally-sourced drugs, which could be due to the possible endogeneity of the entry decision. These studies all investigate the effect of parallel imports on the prices of locally-sourced drugs; while there have been only two studies on means to increase competition from parallel imports. Köksal (2009) examined theoretically the effect of reference pricing, promoting substitution in pharmaceuticals, on competition from parallel imports, while Granlund and Köksal (2011) analyzed this empirically for Sweden.

Using the difference-in-differences approach and data from Sweden from January 2003 through October 2007, this paper examines whether EU enlargement in 2004, despite the derogation, increased competition from parallel imports. We estimated the effects of facing competition from parallel imports on prices of on-patent locally-sourced prescription drugs,

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[7] Blisters of parallel imported Diovan Comp are marked both as "Diovan Comp" and "Co-Tareg" one of the many trade names under which it is available in the EU. Similarly, blisters of parallel imported Nexium are marked both as "Nexium" and "Axagon".

and how these effects changed with the EU enlargement.[8] Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, EU enlargement is not found to have increased this effect. For drugs always facing competition from parallel imports before and after the enlargement, there was no statistically significant effect of the enlargement.

Swedish case is interesting to study the effect of EU enlargement on competition from parallel imports, since the reimbursement system promotes use of parallel imports. The mandatory substitution policy introduced in 2002 requires pharmacists − with the consent of the consumer − to dispense the cheapest available drug in a substitution group. Drugs with the same active ingredient − an off-patent drug and its generics, or an on-patent drug and its parallel imported versions − are grouped together and the price of the cheapest drug in each group is set as the reference price for reimbursement. Consumers, if they accept substitution pay only some percentage of the reference price; but if not, also pay the full price difference.

The next section describes the legal framework, how rules regarding parallel trade of pharmaceuticals were affected by the EU enlargement, while the following section describes the institutional structure of the pharmaceutical market in Sweden, with focus on parallel imports. Then a section presents the theoretical framework in which the possible effects of EU enlargement are discussed. The following section describes the data and the variables, and the next section discusses the empirical strategy and the econometric analysis. A penultimate section presents the results, and the last section summarizes and draws conclusions.

Parallel Trade and EU Enlargement – Legal Framework

Parallel trade of pharmaceuticals is legal within the EU based on the principle of free movement of goods laid down in Article 28 of the EC Treaty to create a single market.[9] However, it is subject to restrictions to protect industrial and commercial property and human life and health, according to Article 30 (for extensive discussion see COM, 2003). Any other

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[8] Out-patient prescription drugs, on average across the OECD countries, account for approximately 80% of total pharmaceutical expenditures (OECD, 2008).

[9] The legality of parallel imports stems from the territorial exhaustion of intellectual property rights (IPRs). Regional exhaustion applies in the EU, meaning that IPRs are exhausted upon first sale anywhere in the EU. So pharmaceuticals can be freely circulated – bought and resold – without the consent of the intellectual property right holder.

restriction, such as supply rationing or dual pricing – without appropriate justification - is appraised in accordance with the rules on competition in Articles 81 and 82 of the Treaty.[10]

An important exception to the rules emerged with the 2004 accession of Cyprus, Malta, the Czech Republic, Hungary, Estonia, Latvia, Lithuania, Poland, Slovenia and Slovakia to the EU.[11] A derogation preventing parallel import of some (but not all) drugs from these countries, except Cyprus and Malta, was included in Article 22 of the Accession Treaty because of lack of EU-compatible patent protection laws in these countries. All of the accession countries except for Cyprus and Malta have only had EU compliant patent laws and provided patent protection for pharmaceuticals since the early 1990s (see Tobin and Turner, 2003; von Uexkull, 2004). Patent laws in Cyprus and Malta had been comparable to those in the EU for longer, so they were exempted from the derogation. Annex IV.2 of the Treaty describes "Specific Mechanism" in the following terms (Van Bael and Bellis, 2005):

> With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovakia or Slovenia, the holder or his beneficiary, of a patent or supplementary protection certificate (SPC) for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the above mentioned new Member States for that product, may rely on the rights granted by that patent or SPC in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.[12]

The patent holder can thus prevent the parallel import of a drug from these eight countries if there was no equivalent patent protection in the exporting country at the time the patent or the SPC was filed in the destination country, one of the existing members. The following hypothetical example explains how the specific mechanism is triggered (Freshfields

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[10] See, for example, the Bayer AG (Adalat) case (European Court of Justice Judgment of 6 January 2004) at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0002:EN:HTML.

[11] Opening the gates to cheap imports, by the EU-enlargement, from accession countries to existing members created concerns about profits of researched-based manufacturers who would then be less able to re-invest in R&D of new products. The G10 high level group on Innovation and Provision of Medicines, in its final report to the Commission in May 2002, called for the Accession Treaty to include derogation on parallel imports to recognize differences in IP protection (Tobin and Turner, 2003).

[12] The derogation also requires the parallel trader intending to import a drug covered by the specific mechanism to give the patent holder one month's prior notice of that intention before applying for import approval (Van Bael and Bellis, 2005; Freshfields Bruckhaus Deringer, 2003; Arnold and Porter, 2004). On the basis of the mechanism, the patent holder has the right to object to the parallel import of the drug within this month.

Bruckhaus Deringer, 2003). Suppose a particular drug is sold by the patent holder in both the UK and Estonia. A patent application for the drug was filed in the UK in 1992, patent granted in 1998, and first marketing authorization in the European Economic Area (EEA) obtained in 2000. In Estonia, however, there was no patent protection for any pharmaceutical products in 1992, when the patent application was filed in the UK, so the special mechanism is triggered. The UK patent expires in 2012, and the UK SPC in 2015. The drug then may not be imported to the UK from Estonia until 2015. [13]

Derogation does not apply to all drugs but some *fixed and closed class* marketed in the accession countries. Besides, derogation erodes over time as patents/SPCs expire and the number of drugs covered thus falls.

Parallel Trade and Institutional Structure of the Swedish Pharmaceutical Market

Parallel trade of pharmaceuticals has been legal in Sweden only since it joined the EU in 1995. Sweden − where pharmaceutical firms' sales prices are above the median in Europe (Dental and Pharmaceutical Benefits Agency, 2009) − is among the main destination countries in the EU; parallel imports account for 12% of total pharmaceutical sales. Just like locally-sourced drugs, parallel imports need to be approved for sale either by Läkemedelsverket − the Medical Products Agency (MPA) − at national level or by the European Medicines Agency (EMA).

After getting this approval, manufacturers are free to set prices, but to get the drug included for reimbursement in the national health insurance system, they also need to get the price approved by Läkemedelsförmånsverket (LFN), the Pharmaceutical Benefits Agency.[14] To raise or lower the price later, they also need LFN approval. Requesting approval for a price increase incurs the risk of having the drug taken off the reimbursement list, since LFN processes applications for price increases as a new application for reimbursement. Manufacturers are required to first remove the drug from the reimbursement list and then apply again for reimbursement at the higher price (LFNAR 2006:1). Applications must include explanation for the price increase as well as information about prices and treatment

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[13] Derogations on parallel trade of pharmaceuticals were introduced when Spain and Portugal joined the EU, but then it was only for a limited period.

[14] The name of Läkemedelsförmånsverket (LFN) − the Pharmaceutical Benefits Agency − was changed to Tandvårds och Läkemedelsförmånsverket (TLV) − the Dental and Pharmaceuticals Benefits Agency − on September 1, 2008, since a dental care reform went into effect in July 2008.

costs of comparable drugs (LFNFS 2003:1). There are two cases where applications for price increase will be accepted without resubmission of the drug for reimbursement: if the requested price is the same or less than the price of the most expensive substitutable drug in the group; or if the following two criteria are fulfilled: (i) there is a considerable risk that the drug will disappear from the Swedish market if the price is not approved, and (ii) the drug treats a serious condition threatening the patient's life or health, and there are patients who risk being without similar treatment if the drug disappears from the market (LFNAR 2006:1).

Even though locally-sourced drugs facing competition from parallel imports are generally the most expensive drug in their substitution group, price increases may still be allowed, if they treat a serious condition and are very likely to otherwise leave the market. In such a situation patients may again face the risk of being untreated, since the supply of parallel imports is limited and sometimes even intermittent. Hence, LFN, in order to secure availability of treatment, might allow a price increase even though the drug faces competition from parallel imports.

The Medical Products Agency requires a drug for which parallel import approval is being sought to be sufficiently similar to the locally-sourced one with common origin, containing the same active ingredient, and having the same therapeutic effect (LVFS 2004:8).[15] However, parallel imports might differ from locally-sourced drugs in color, taste, or shape, in which case the outer package should have information making that clear. Due also to differences in country-specific labeling requirements or standard package sizes, parallel imports might thus be repackaged or relabeled. The Medical Products Agency requires that such repackaging or relabeling not affect the original condition of the product or the reputation of the trademark or its holder.[16]

During the study period, there were no financial incentives for Swedish pharmacists to dispense parallel imports, but the reimbursement system promoted use of parallel imports.[17]

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[15] The expression "common origin" refers, for example, to whether the holder of the marketing authorization for the parallel imported drug in the exporting country is the same, or represents the same group of companies, as the holder of the marketing authorization for the locally-sourced drug in Sweden (LVFS 2004:8).

[16] The leading case is Bristol-Myers Squibb v Paranova AS. It was in this case that the European Court of Justice (ECJ) first comprehensively formulated the five general conditions with which a parallel trader of repackaged drugs must comply (collectively, the BMS Conditions) to avoid infringing the re-applied trade mark (Galimberti and Pors, 2008).

[17] For example, the UK, the Netherlands, and Norway provide financial incentives for pharmacists to dispense parallel-imported drugs (Kyle, 2009). However, other than annual ex post payment by the county councils, which are responsible for reimbursement, to Apoteket (the Swedish state pharmacy monopoly) to compensate it for purchasing and dispensing parallel imports and generics, there are no explicit financial incentives to Apoteket to dispense parallel imports (Kanavos et al., 2005).

The Mandatory Substitution Policy introduced in 2002 requires pharmacists − with the consent of the consumer − to dispense the cheapest available drug, usually either a generic in the case of an off-patent drug, or a parallel import in the case of an on-patent drug. Drugs with the same active ingredient − an off-patent drug and its generics, or an on-patent drug and its parallel imported versions − are grouped together and the price of the cheapest in each group is set as the reference price. The Medical Products Agency defines a drug as a substitute if it has the same active ingredient, strength, and form as the prescribed drug and if its package size sums up to that of the prescribed drug as well. Consumers who accept substitution pay only some percentage of the reference price, but if they reject substitution, they also pay the full price difference.

Throughout the study period, retail pharmacies, owned by the state monopoly Apotek AB (National Corporation of Swedish Pharmacies), were the only legal entities to dispense the prescription pharmaceuticals for outpatient care. As both wholesale drug prices and the retail drug prices for reimbursable drugs are determined by the LFN, the state-monopoly pharmacies charged uniform prices nationwide. The pharmacy monopoly was abolished and private pharmacies were allowed to enter the market as of July 2009, but the retail prices of prescription drugs were uniform across the country during the study period.

A national health insurance system covers the whole population and has subsidized individual's pharmaceutical expenditures since pharmaceutical benefits scheme was introduced in 1955.[18] The subsidy increases in a stepwise fashion within any 12-month period. Since June 1999, consumers pay 100% of cost up to SEK 900; then 50% of cost up to SEK 1700; then 25% up to SEK 3300; then 10% up to SEK 4300; and finally, above SEK 4300, consumers are fully subsidized.

Price Difference and Parallel Trade - Theoretical Framework

Enlargement had two possible effects on competition from parallel imports: It might have increased the number of drugs subject to competition from parallel imports, and it might have increased the intensity of such competition. Both effects could result from increased price differences between countries. As prices in most of the new EU members were lower than in

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[18] Regarding cost containment of pharmaceutical expenditures, the Swedish health insurance system is structured by the law SFS (1981:49) and bills on subsequent changes listed at http://www.notisum.se/rnp/sls/fakta/a9810049.htm, accessed 30 October 2008.

most if not all pre-existent members, the new members were potential source countries. Price differences might then be large enough for parallel traders to import drugs that had not been subject to such competition before the enlargement. But even for drugs already subject to competition from parallel imports, the increased price differences and the increased availability of drugs for parallel trade might have increased the intensity of such competition. All else equal − e.g., product match and transportation costs − rational parallel traders using lowest-cost suppliers first would source drugs from the new EU members if possible. With lower costs, they might charge lower prices, thereby increasing the intensity of competition. Increased profit possibilities might also stimulate the entry of new parallel traders. Even if prices in the new EU members were the same as prices in the pre-existing source countries, increased availability of drugs for parallel trade might increase the volume of parallel imports in the destination countries which in itself might thus increase the price competition.

Köksal (2009) showed theoretically that the price difference between the source and destination countries should increase the intensity of competition from parallel imports. This result follows from the two-country model of third degree price discrimination with a monopolist manufacturer holding the patent for a particular drug, and supplying both countries. The monopolist price discriminates between the two countries since they differ in (i) consumer valuations of the drug, and (ii) the copayment rates that they pay. When parallel trade is allowed, drugs flow from the low-price to the high-price country. Since parallel imports differ in packaging or labeling, consumers may value them less than locally-sourced drugs. In a perfectly competitive market, parallel traders set the price of parallel imports equal to the price in the source country, with the cost of trade assumed zero.

This model is solved for both the benchmark case of autarky − where parallel trade is illegal − and the case of free trade, where parallel trade is legal. At equilibrium, the change in destination country price under free trade is a function of the initial price difference between the source and destination countries under autarky and the "rate of convergence". That is

$$p_{FT} - p_A = -\Theta\left(\gamma\, p_A - p_A^{*}\right)$$

where p_{FT} is the destination country price under free trade; p_A is the destination country price under autarky; p_A^{*} is the source country price under autarky; and $\Theta = \left[\dfrac{1}{\gamma}\dfrac{r}{r^{*}} + 1\right]^{-1}$ is the rate of convergence.

The initial price difference must be measured using prices quality-adjusted using a subjective value discount factor (γ) such that $\gamma \in (0,1)$. γ takes the value one if consumers perceive parallel imports as perfect substitutes of locally-sourced drugs. The more inferior consumers perceive parallel imports, the lower γ is. The rate of convergence (Θ) then depends on the relative coinsurance rates in the destination and source countries − r and r^*, respectively − and on γ. All else equal, the effect of parallel trade on the price of locally-sourced drugs in the destination country will be larger, the larger is the initial price difference between the destination and source countries. The effect will also be larger as γ converges towards unity. In other words, the prices in the destination country do not fall much, if γ diverges from unity.

Again in a two-country theoretical model, Ganslandt and Maskus (2004) showed that prices in the destination country fall as the number of parallel traders increases. They will enter the market if expected profit is positive, i.e., if revenue from parallel trade exceeds its cost. That is

$$E\left(\pi\right) = E\left[(p - p^* - t)q - F\right]$$

where p is the price in the destination country; p^* is the price in the source country; t is transport cost including repackaging; q is the quantity demanded of parallel imports in the destination country; and F is the fixed cost of getting approval for parallel trade. All else equal, if the price difference increases, the probability of entry by parallel traders also increases. Different from the model in Köksal (2009), the prices are here assumed regulated in the source country, and supply of parallel imports limited at level X, so that destination country demand for the locally-sourced drug is

$$D = a - bp - X$$

Given that the manufacturer first sets price in the destination country, and then the symmetric n parallel traders choose the amount to parallel import, equilibrium price is

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

which is a decreasing function of the number of parallel traders.

Data and Description of Variables

We used the same panel dataset from IMS Health as in Granlund and Köksal (2011), consisting of all prescription drugs sold in Sweden during the period from January 1992 through October 2007. The dataset consists of monthly observations except the period 1992-1994 for which we have only quarterly data. An observation represents a product with a certain active ingredient, form, strength, and package size, supplied by a certain firm and sold in a certain month. For each observation there is also information about the type of drug, i.e., whether it is brand-name or generic, locally sourced or parallel imported, as well as total units sold and total value during the observation period. To isolate the effect of EU enlargement on competition from parallel imports, we used only the part of this dataset covering January 2003 through October 2007. We did not use earlier data in order to avoid possible biases that might result from adjustments to the mandatory substitution policy introduced in October 2002 (described in Granlund and Köksal, 2011).

Prescription pharmaceutical sales constituted about 0.9% of GDP over the period 2003-2006. Both the share of parallel imports in total pharmaceuticals sales and the number of parallel traders increased substantially in 1998 (Table 1), because of the integration of Sweden in the EU (Ganslandt and Maskus, 2004). While the share of parallel imports was 2% in 1997, it was 6% in 1998, and the number of parallel traders increased from 2 in 1997 to 8 in 1998. After that both continued generally to increase through 2007. Starting from 2005 onwards, even though the share of parallel imports remained constant, the number of parallel traders gradually increased.

Table 1. The Swedish Prescription Drug Market, 1997-2007

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
GDP	1927001	2012091	2123971	2249987	2326176	2420761	2515150	2624964	2735218	2900790	3063145
TPS	13984	16270	18148	19934	21301	22872	23301	23807	24819	25943	23067
PI	272	1008	1402	1754	2012	2090	2100	2527	3018	3012	2707
PI/TPS	2%	6%	7,7%	8,8%	9,4%	9,1%	9%	10,6%	12,1%	11,6%	11,7%
# PI Firms	2	8	10	9	9	10	11	11	9	12	14

Notes: GDP, TPS and PI are in million SEK expressed in nominal terms. TPS=total pharmaceutical sales; and PI=total sales value of parallel imports. PI/TPS is the share of parallel imports in total pharmaceutical sales. Source: Intercontinental Medical Statistics (IMS)

The dataset includes off-patent brand-name drugs and generics as well as on-patent drugs and parallel imports, but our empirical analyses focused only on locally-sourced on-patent prescription drugs. Data on off-patent brand-name drugs, generics, and parallel imports was used to create relevant variables for the analysis, but was not included in the final dataset. We had no information on patent expiration dates, so we defined drugs as off-patent starting from the first time any generic with the same active ingredient was sold in Sweden. This left us with 138,635 observations on 1,798 on-patent drugs with different active ingredient, form, or strength. Of these, 319 (about 18%) faced competition from parallel imports, of which about 6% had been granted approval by the MPA for parallel import from the new EU members. However, we had no information on parallel imports centrally approved by the EU-wide European Medicines Agency (EMA). But − considering the derogations − even the 6% approved in Sweden is a substantial number.

Table 2. Summary statistics for variables

Variable	Mean	Std. Dev.	Min	Max
ln$p$	5.9048	1.5953	1.9200	11.7041
Picomp	0.1601	0.3667	0	1
Pifirms	0.3722	1.0427	0	8
Mpi	6.7968	17.4634	0	118
Thcomp	0.8518	0.3552	0	1
Nthcomp	3.2421	2.6369	0	16
Thgencomp	0.2452	0.3524	0	1
Review	0.0243	0.1542	0	1
EU_Enlar	0.7116	0.4530	0	1
EU*Picomp	0.1186	0.3233	0	1
EU*Pifirms	0.2760	0.9170	0	8
EU*Mpi	5.3192	16.7301	0	118
Time	28.8636	16.7301	1	58
Timepi	4.7335	12.6790	0	58
EUR/SEK	9.2005	0.1233	8. 7986	9.5663
CZK/SEK	0.7116	0.4550	0	1.0685
Lnlong	4.1716	0.7975	-0.6931	4.6868

The variables used in the analysis and descriptive statistics are presented in Table 2. As in Granlund and Köksal (2011), the variable ln p_{it} is defined as the natural logarithm of the real price, the wholesale price in month t deflated by the consumer price index. *Picomp*$_{it}$ is an indicator of whether drug i is subject to competition from parallel imports (hereafter PI-competition), while *Pifirms*$_{it}$ is the number of parallel traders from which drug i faced

competition.[19] Mpi_{it} is the number of months drug i had faced competition from parallel imports before month t. $Thcomp_{it}$ is a dummy indicating whether drug i has any therapeutic competitors, drugs that have different active ingredients but the same therapeutic effect, while $Nthcomp_{it}$ is the number of therapeutic competitors, and $Thgencomp_{it}$ is the share of product i's therapeutic competitors facing generic competition.[20] $Review_{it}$ is a dummy indicating if drug i at month t belonged to a therapeutic group for which the review of reimbursement status had been completed by the LFN by then. EU_Enlar_t is a dummy taking the value one for the months after the enlargement in May 2004. The following three variables are interaction variables between EU_Enlar_t and the variables $Picomp_{it}$, $Pifirms_{it}$, and Mpi_{it}. $Time_t$ is the number of the months after December 2002 at month t, and $Timepi_{it}$ is an interaction variable between this variable and $Picomp_{it}$. The last three variables are instruments used in instrumental variable regressions: the Euro/SEK and the CZK/SEK exchange rates, and the logarithm of the number of months the product has been sold in Sweden ($Lnlong_{it}$).[21]

Table 3. Detailed summary statistics for key variables

Variable	Before EU Enlargement				After EU Enlargement			
	Mean	Std. Dev.	Min	Max	Mean	Std. Dev.	Min	Max
Picomp	0.1439	0.3667	0	1	0.1667	0.3727	0	1
Pifirms	0.3337	1.0427	0	8	0.3878	1.0669	0	8
Mpi	5.1239	17.4634	0	79	7.4748	18.6429	0	118
Thcomp	0.8454	0.3552	0	1	0.8544	0.3526	0	1
Nthcomp	3.1610	2.6369	0	12	3.2749	2.6365	0	16

Most of the drugs (85%) faced therapeutic competition, while only 16% faced competition from parallel imports (Table 2). The number of drugs facing competition from parallel imports after the enlargement is statistically significantly larger than that before the enlargement (Table 3). Almost all of the drugs facing competition from parallel imports (about 93%) faced therapeutic competition. Drugs facing competition from parallel imports accounted on average for 23% of total sales value, despite that they only constituted 16% of

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[19] A drug imported by a parallel trader is considered to be a competitor to the locally-sourced drug if it has the same active ingredient (i.e., the same 7-digit ATC code), strength, and form (e.g., pill or fluid) and both are sold in Sweden during the same month. Since, for example, a 100-pill package can substitute for two 50-pill packages, it is not required that the parallel-imported drug is of the same package size as the locally sourced drug.

[20] Following Brekke et al. (2008) and Pavcnik (2002), pharmaceuticals with the same 5-digit ATC code are classified as therapeutic competitors.

[21] In order to be able to take the natural logarithm, we defined $Lnlong_{it}$ as 0.5 for the first month a product was sold, and so on. The variable is truncated at 130.5 months due to lack of older data.

the population. Parallel traders thus targeted top-selling drugs that had also been subject to therapeutic competition from "me-too" drugs.

Empirical Analysis

We used a difference-in-differences method to examine how EU enlargement affected the price-effects on locally-sourced on-patent drugs of facing competition from parallel imports (hereafter PI-competition). This method was applicable because we had data, from both before and after enlargement, on drugs that had been either always or never subject to competition from parallel imports during the study period, as well as drugs that changed from being subject to such competition to not, or vice versa. Data on drugs that changed status allowed us to estimate the effect of competition from parallel imports, while data on all drugs allowed us to estimate the average effect of EU enlargement on competition from parallel imports. To isolate the effect of EU enlargement on the intensity of competition from parallel imports for drugs already subject to such competition, we also ran regressions on a restricted sample containing only the drugs that always or never faced such competition during the study period.

Estimating the effect of competition from parallel imports in general relies on changes in whether drugs face such competition or not. However, estimating the effect of EU enlargement on competition from parallel imports relies on comparison of changes in the prices of drugs always facing such competition with drugs never facing it both before and after the enlargement, as well as comparison of changes in the prices of drugs due to change in status (from being subject to PI-competition to not, or vice versa) before and after the enlargement.

This before and after comparison of differences in prices is attributed as the effect of the EU enlargement on PI-competition if possible biases have been removed by controlling for permanent differences between drugs as well as other factors that might have caused price changes. We thus included in the estimations drug specific fixed effects (α_i) controlling for time-invariant differences between individual drugs. We controlled for possible changes over time common to all drugs by including: a linear time-trend ($Time_t$); a dummy variable taking the value one after the enlargement (EU_t); and dummy variables for calendar months

$(Month_t)$.[22] We included the variables $Picomp_{it}$ to estimate the effect of being subject to competition from parallel imports, and $Pifirms_{it}$ to estimate the effect of the number of parallel traders importing the drug.

The estimated coefficients of these variables, $Picomp_{it}$ and $Pifirms_{it}$, would be estimated without any bias if no variables not included in the specification caused price changes correlated with facing PI-competition. Since therapeutic competition could influence prices and might be correlated with PI-competition, we thus also included *Thcomp_{it}*, *Nthcomp_{it}*, and *Thgencomp_{it}* in the specification.[23] We also controlled for drugs whose reimbursement status was reviewed by the LFN for cost-effectiveness during the study period. The review, covering 49 therapeutic groups, started at the end of 2003, but only three therapeutic groups (migraine; diseases caused by excess stomach acid; and asthma, COPD, and coughs) were completed during the study period. These reviews could affect prices, since the drugs reviewed might lose reimbursement status (i.e., be de-listed) or be granted only restricted reimbursement. LFN might even directly recommend a reduction in the price of a drug, with which manufacturers would comply in order to retain the drug's reimbursement status. We controlled for these possible effects of the reviews on prices by including the dummy variable *Review_{it}* in the specification.[24]

To estimate the effect of EU enlargement on competition from parallel imports we included interaction terms between EU_Enlar_t and the variables controlling for PI-competition. Such specification would identify the effect of EU enlargement if no variables not included in the estimation influenced the price effect of facing PI-competition differently before and after the enlargement. This requirement is the reason for including Mpi_{it} and $EU * Mpi_{it}$ in the specifications. Since Mpi_{it} could affect prices − because the longer a parallel imported drug has been in the market, the more familiar with it will be consumers, physicians and pharmacists − and since its effect could differ before and after the enlargement, we included Mpi_{it} as well as $EU * Mpi_{it}$ in the specifications.

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[22] In order to control for common changes over time, we estimated, using fixed-effects OLS, a specification with the linear time trend replaced by year-month dummies, and obtained similar results. However, we did not include year-month dummies in the chosen specifications in order to use time-variation in the instruments (see below) for identification.

[23] The share of drugs facing therapeutic competition is statistically significantly larger among the drugs facing competition from parallel imports than among those not facing such competition. The difference is 9 percentage points.

[24] Of the 90 drugs in our dataset reviewed all but 15 had at least one therapeutic competitor.

Granlund and Köksal (2011) reported that the larger Mpi_{it} is, the more likely were patients to accept substitution of a parallel imported drug for the prescribed locally-sourced drug. This implies that over time parallel imports become stronger competitors for locally-sourced drugs, and that the latter therefore have to reduce their prices in order to keep sales up. Besides, a parallel imported drug, sold in Sweden for a long time without any supply shortages or even interruptions due to possible strategic response of the manufacturer like supply rationing in source country, might be considered as a reliable alternative by the LFN which may then be tougher when acting on applications for price increases for the locally-sourced drug. Mpi_{it} is thus expected to reduce the price of drugs facing PI-competition, an effect which might be strengthened after EU enlargement since parallel traders might switch to sourcing parallel imports from the new lower-price members for drugs that faced PI-competition for a long time and thus have a large Mpi_{it}. This would be the case if parallel traders first try to increase their profits in a secure market niche for parallel imports that have already gained consumers' acceptance. However, the effect of Mpi_{it} on the prices of drugs facing PI-competition might also be weakened by the enlargement, since the parallel imports sourced from the new EU members might differ in packaging or labeling, possibly causing confusion among consumers, especially the elderly and those with chronic diseases.[25] The perception of parallel imports among consumers might thus change after the enlargement.

We also included $Timepi_{it}$ in the specifications to capture changes over time in the effect of facing PI-competition *not* caused by the enlargement.[26] The main specification is then

$$
\begin{aligned}
\ln p_{it} = \ & \beta_1 Picomp_{it} + \beta_2 Pifirms_{it} + \beta_3 Mpi_{it} + \beta_4 Timepi_{it} + \beta_5 EU * Picomp_{it} \\
& + \beta_6 EU * Pifirms_{it} + \beta_7 EU * Mpi_{it} + \beta_8 Thcomp_{it} + \beta_9 Nthcomp_{it} \\
& + \beta_{10} Thgencomp_{it} + \beta_{11} Review_{it} + \beta_{12} Time_t + \beta_{13} EU\_Enlar_t \\
& + \sum_{n=2}^{12} \gamma_n Month_t + \alpha_i + \varepsilon_{it}
\end{aligned}
$$

The coefficients β_1-β_4 describe the effects of competition from parallel imports before EU enlargement. β_1 and β_4 describes the effect of facing competition at all and how this effect changed over time, while β_2 depicts how the effect relates to the number of firms, and β_3

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[25] Kanavos and Holmes (2005) discusses detailed evidence of confusion among patients.
[26] Before the enlargement, drugs subject to competition from parallel imports had a different time trend than drugs not subject to such competition. However, the difference in time trend was stable over time, so *Timepi_{it}* accounts for the difference in the time trend and corrects for any bias otherwise introduced.

describes the effect of the number of months a drug had faced competition from parallel imports before month t. The coefficients of the interaction variables, β_5-β_7 describe how EU enlargement influenced the price effect of competition from parallel imports. The coefficients β_8-β_{10} describe the effect of therapeutic competition on prices, while β_{11} depicts the effect of reimbursement reviews on prices, and β_{12} describes how the prices of drugs not subject to competition from parallel imports changed over time. Finally β_{13} describes how EU enlargement affected the prices of drugs not subject to competition from parallel imports.

We estimated the specification above with fixed-effects OLS-regression. However, the estimates would be biased due to the endogeneity of variables controlling for competition from parallel imports, which might arise since the entry decisions of parallel traders are determined by the prices of pharmaceuticals, or as a result of unobserved characteristics affecting both entry of parallel traders and the price of pharmaceuticals. We therefore also used an instrumental variables (IV) estimation method. Since we would otherwise have too many endogenous variables to instrument in the IV regression, we dropped $Pifirms_{it}$ and $EU * Pifirms_{it}$ from the specification and estimated it with both fixed-effects OLS and IV regression.

We estimate one of the three IV regressions using as instruments the Czech Koruna/Swedish Krona (CZK/SEK) exchange rate and the Euro/Swedish Krona (EUR/SEK) exchange rate (see column three of Table 4); another using the logarithm of the number of months the product had been sold in Sweden $(Lnlong_{it})$ (see column four of Table 4); and the other using all three instruments CZK/SEK, EUR/SEK, and $Lnlong_{it}$ (see column five of Table 4). The exchange rates are the instruments thought most likely to be exogenous, though $Lnlong_{it}$ should also be exogenous, since we controlled for therapeutic competition, and the instruments are powerful enough to explain the variation in endogenous variables. The exchange rates affect the probability of competition from parallel imports through their effects on price differences between locally-sourced drugs in Sweden and drugs in the source countries. Exchange rates between the currencies of other new EU members and the Swedish Krona could have been used as instruments as well, but most of the approvals granted by the MPA for parallel import of drugs from the new EU members have the Czech Republic as the source country. Since CZK/SEK does not account for much variation in PI-competition before the EU enlargement, we used EUR/SEK together with a transformation of CZK/SEK as instruments. We transformed the CZK/SEK exchange rate into an index which accounts for

the ineffectiveness of CZK/SEK before the enlargement by setting the value of CZK/SEK equal to 0 before the enlargement and normalizing CZK/SEK after the enlargement with the mean. With the exception that we used CZK/SEK as an instrument and truncated $Lnlong_{it}$ at a different value, we used the same instrument as in Granlund and Köksal (2011). $Lnlong_{it}$ affects the probability of facing pi-competition since pharmaceutical firms often launch their products first in high-price countries.[27] Thus during the first months a drug is sold in Sweden the probability of facing pi-competition is small since the drug is likely only sold in countries with higher or nearly equal prices, but as time passes it becomes more and more likely that the product is also sold in low-price countries.

As in Granlund and Köksal (2011), we used a modified 2SLS instrumental variable estimation. First, a fixed-effects OLS estimation was employed to explain $Picomp_{it}$ using both the exogenous variables of the main specification and the instruments just discussed. We used those results to predict $Picomp_{it}$. However, as the instruments had no power to predict $Picomp_{it}$ for drugs that did not vary in $Picomp_{it}$ during the study period, we excluded those drugs in the first stage, instead used the observed values of $Picomp_{it}$ for these drugs as predictions. The predictions for $Picomp_{it}$ were then used to create predictions of the other four endogenous variables: Mpi_{it}, $Timepi_{it}$, $EU*Picomp_{it}$, and $EU*Mpi_{it}$. Predictions for all endogenous variables were then used as instruments for those variables in 2SLS estimation.[28] The main advantage with this method is that − compared to the standard two-stage IV − it yields robust estimates for the endogenous variables. Standard two-stage estimation, with the endogenous variables instrumented by the exchange rates or product longevity in the market, made clear that the instruments were weak in explaining at least one of the endogenous variables, which could have led to estimates sensitive to even small variations in the instruments.

To isolate the effect of EU enlargement on the intensity of competition from parallel imports, we restricted the analysis to drugs that always, or never, faced PI-competition during the study period. We did this analysis since these drugs constituted 83% of the full sample, and the effect of EU enlargement might differ for these drugs for two reasons. First, EU enlargement might have a larger effect on the prices of these drugs if parallel traders first

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[27] Danzon et al.(2005) argue that the risk of price spillovers due to parallel trade and external reference pricing is expected to make companies more willing to delay launch or forego launch entirely in low priced countries. In a cross-country analysis, they found that countries with lower expected prices tend to have fewer products launched and longer delays for those products that are launched, after controlling for per capita income.

[28] We used the *xtivreg2* command by Schaffer (2010) to run 2SLS estimation in Stata.

increased their profits in a secure market, where consumers were used to parallel imports, by sourcing the drugs they had already been parallel importing to Sweden from the new EU members. Second, in this sample more than in the full sample, the interaction variables between EU-enlargement and the variables controlling for PI-competition were likely to identify the effect of facing competition from parallel imports from the new EU members, in addition to facing competition from parallel imports from existing members. This would be the case if most drugs that faced steady competition from parallel imports from old members before the enlargement were more likely to face competition from parallel imports from these countries also after enlargement, compared to drugs that either faced intermittent PI-competition before enlargement or drugs that only started to face PI-competition after enlargement. In this estimation with the restricted sample, the dummy variable $Picomp_{it}$ was dropped since it was time-invariant and thus perfectly correlated with the fixed effects. $Timepi_{it}$ and Mpi_{it} would capture the same effect, so either could be included in the estimation. As $Picomp_{it}$ was time-invariant, there was no variable other than $Pifirms_{it}$ that varied endogenously, and so there was no problem of endogeneity in the estimation on the restricted sample where $Pifirms_{it}$ was excluded.

Results

Estimation results from the fixed-effects OLS regressions (with and without $Pifirms_{it}$ and $EU*Pifirms_{it}$) and the IV regressions are presented in Table 4, along with differentials indicating the average effect of the variables of main interest on prices. The differential dlnP/d$Picomp$ − representing the average effect of PI-competition on prices − was calculated using the estimated coefficients of all seven variables controlling for PI-competition (hereafter PI-variables) as well as the average values of these variables when the dummy variable $Picomp_{it}$ takes the value one.[29] IV regression with exchange rates as instruments (column 3), indicates that drugs facing PI-competition had on average 21% lower prices than what they would have had if they had never faced such competition. The magnitude of this effect depends on the choice of instrument in the IV regressions, however. That it is a lot larger in

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[29] As an example, the differential dlnP/d($EU*Picomp$) in estimations 2-7 was calculated as a linear combination of the estimates of β_5 and β_7. That is, $b_5 + b_7 * 37.41354$, where b_5 and b_7 are the estimates of β_5 and β_7, and 37.41354 is the mean of $EU*Mpi$ when $EU*Picomp$ equals one. Since the dependent variable is in logarithmic form, the exact change in price (in percent) should be calculated using the formula $100 * [exp(\beta) - 1]$.

the IV regressions than in OLS indicates that the variables controlling for the effect of PI-competition are endogenous. The positive estimates of *Pifirms*$_{it}$ and *EU*Pifirms*$_{it}$ (column 1) might be caused by endogeneity, but might also be caused by a generic competition paradox type situation as discussed in Frank and Salkaver (1992): In response to increased competition from parallel imports, manufacturers might increase prices to extract as much as possible from loyal (price-insensitive) consumers.

The differential dln*P/*d(*EU*Picomp)* based on the results from fixed-effects OLS regressions (columns 1 and 2) indicates that EU enlargement increased the effect of PI-competition, but by less than one percentage point. If enlargement had only affected the number of parallel traders, then dln*P/*d(*EU*Picomp)* would have been close to zero in estimation 1 where we controlled for *Pifirms*$_{it}$ and *EU*Pifirms*$_{it}$. That it is different from zero, suggests that EU enlargement might have also increased the intensity of competition (i) as a result of incumbent parallel traders importing more at lower price, and/or (ii) as a result of the price effect of parallel imports sourced only from new EU members being larger than that of parallel imports sourced only from existing members.

On the other hand, the differential dln*P/*d(*EU*Picomp)* based on the results from the IV regressions indicates that EU enlargement reduced the effect of PI-competition, but again less than one percentage point. The estimated average effect of EU enlargement was somewhat larger when exchange rates were used as instruments in the IV regression (column 3). The positive sign of dln*P/*d(*EU*Picomp)* in the IV regressions is because the reduction in the immediate effect of pi-competition − captured by *EU*Picomp*$_{it}$ − dominates the increase in the gradual effect − captured by *EU*Mpi*$_{it}$ − after EU enlargement.

The reduced immediate effect of facing PI-competition might be due to changed consumer perceptions of parallel imports, perhaps driven by those sourced from the new members. Consumers might simply perceive drugs sourced from the new members as inferior. Those drugs – even when imported by an incumbent parallel trader − might differ in packaging or labeling, and hence might cause confusion among consumers as discussed earlier. However, such concerns might vanish over time, as those drugs stay in the market and consumers get used to them. This gradual effect of competition from parallel imports is reflected as negative coefficients on *Mpi*$_{it}$ and *EU*Mpi*$_{it}$.

Table 4. Estimation results (multiplied by 100)

	(1) FE, OLS	(2) FE, OLS	(3) FE, IV[a]	(4) FE, IV[b]	(5) FE, IV[c]
$Picomp_{it}$	-1.703***	-1.272***	-25.477***	-19.612***	-21.094***
	(0.403)	(0.347)	(3.126)	(2.982)	(2.815)
$Pifirms_{it}$	0. 659***				
	(0.142)				
Mpi_{it}	-0. 252***	-0.226***	-0.064	-0.085	-0.184***
	(0. 016)	(0.015)	(0.070)	(0.064)	(0.056)
$Timepi_{it}$	0.057***	0.062***	0.119	0.088	0.186***
	(0.012)	(0.012)	(0.082)	(0.077)	(0.069)
$EU*Picomp_{it}$	-0.674**	0.939***	11.379***	9.272***	9.059***
	(0.293)	(0.296)	(0.960)	(0. 859)	(0.831)
$EU*Pifirms_{it}$	0.798***				
	(0.123)				
$EU*Mpi_{it}$	-0.044***	-0.049***	-0.277***	-0.228***	-0.223***
	(0.808)	(0.007)	(0.023)	(0.021)	(0.020)
$Thcomp_{it}$	1.530	1.218***	1.138***	1.164*	1.196***
	(0.253)	(0.242)	(0.278)	(0.262)	(0.259)
$Nthcomp_{it}$	-0.532***	-0.555**	-0.587***	-0.580**	-0.588***
	(0.055)	(0.055)	(0.061)	(0.059)	(0.058)
$Thgencomp_{it}$	-0.308*	-0.242***	1.010***	0.723***	0.651***
	(0.184)	(0.184)	(0.249)	(0.230)	(0.226)
$Revision_{it}$	-2.073***	-1.729***	-1.495***	-1.548***	-1.561***
	(0.417)	(0.418)	(0.434)	(0.427)	(0.426)
EU_Enlar_i	1.517***	1.515***	1.501***	1.467***	1.500***
	(0. 089)	(0. 089)	(0.097)	(0.096)	(0.096)
$Time_i$	-0.026***	-0.027***	-0.022***	-0.022***	-0.024***
	(0.002)	(0. 002)	(0.003)	(0. 003)	(0.003)
d ln$P$/d $Picomp$	-7.906***	-8.215***	-23.548***	-19.521***	-21.701***
	(0.446)	(0.463)	(2.917)	(2.798)	(2.601)
d ln$P$/d ($EU*Picomp$)	-0.464***	-0.895***	0.979***	0.719***	0.694***
	(0.249)	(0.252)	(0.275)	(0.265)	(0.262)
d ln$P$/d $Thcomp$	-0.582***	-0.968***	-0.806**	-0.836***	-0.855***
	(0.307)	(0.298)	(0.342)	(0.324)	(0.321)
Sample size	138635	138635	138635	138635	138635
Log likelihood	180,015.3	179,688	170,351.1	173,943.6	174,697.5

Notes: FE denotes fixed-effects regressions and IV denotes instrumental variable regressions.
IV[a] used CZK/SEK and EUR/SEK as instrument. IV[b] used $Lnlongevity_{it}$ as instrument.
IV[c] used CZK/SEK, EUR/SEK and $Lnlongevity_{it}$ as instrument.
F-values for significance of the instruments in the first-stage regression are 30.65, 451.09, and 173.10 for estimations 3, 4, and 5, respectively.
Asterisks ***, **, and * denote that coefficients are statistically significant at the 1%, 5% and 10% levels.
Standard errors robust against heteroskedasticity and autocorrelation are shown in parentheses. The differentials are evaluated at the mean of each variable when the relevant explanatory variable, i.e., *Picomp, EU*Picomp,* or *Thcomp,* takes the value one. Estimation results for calendar months are suppressed in order to save space, but are available from the authors upon request.

The estimated effect of EU enlargement on PI-competition could also be explained by the effect of PI-competition on prices of drugs that hadn't faced PI-competition before but became subject to such competition after the enlargement. For those drugs, if the price difference between the source country and Sweden was just large enough to engage in parallel

trade but still small, and if the supply of parallel imports was limited, then the price effect of PI-competition might be small, which would be reflected as positive coefficients on variables interacting with the dummy for EU enlargement.

The individual estimates for the PI-variables indicate that PI-competition both before and after the enlargement had a large immediate effect captured by $Picomp_{it}$ accounting for the main effect of PI-competition. The estimates for $Timepi_{it}$ from the fixed-effects OLS regressions (column 1 and 2) indicate that this initial effect fell in absolute value over time, while the estimates are not statistically significant in the IV regressions. On the other hand, the gradual effect of PI-competition was small in absolute terms before the enlargement, but larger after the enlargement.[30]

The estimated coefficients on the variables $Thcomp_{it}$, $Nthcomp_{it}$, and $Thgencomp_{it}$ provide evidence on how therapeutic competition affects prices. The differential $\mathrm{d}\ln P/\mathrm{d}Thcomp$ indicates that the average effect of facing therapeutic competition during the study period was a less than 1% price reduction. However, the estimates for the therapeutic competition variables indicate that the prices of drugs tended to rise if they faced such competition, but also to decrease as the number of therapeutic competitors increased. Besides, the IV regressions (columns 3-5) indicate that the prices of drugs facing therapeutic competition increased if the competitors were subject to generic competition. These results imply that a generic competition paradox type situation is likely to arise when drugs face therapeutic competition, unless prices fall as a result of increased number of therapeutic competitors. The estimates for $Review_{it}$ also indicate that prices, on average, fell about 1.5% due to the reimbursement reviews conducted by TLV. Since the vast majority of the drugs reviewed, about 90%, had therapeutic competitors; the reviews particularly affected the prices of drugs facing therapeutic competition.

The estimated coefficients on $Time_t$ indicate that the prices of drugs not facing PI-competition fell over time. However, the estimates for the dummy EU_Enlar_t indicate that the prices of drugs not subject to PI-competition increased after the enlargement. This result should be interpreted with caution, however, since this variable might capture something other than causal effects of the EU enlargement.

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[30] In specifications 3 and 4, the estimated coefficients on Mpi imply about 3% decrease in prices of drugs facing PI-competition with average Mpi of 32 months before enlargement, while the coefficient implies a relatively large decrease, around 11%, in prices of drugs facing pi-competition with average Mpi of 37 months after enlargement.

Table 5 - Estimation results with restricted sample (multiplied by 100)

	(6) FE, OLS	(7) FE, OLS
$Pifirms_{it}$	0.539*	
	(0.316)	
Mpi_{it}	-0.146***	-0.117***
	(0.030)	(0.024)
$EU*Picomp_{it}$	-1.118	0.699
	(1.110)	(1.023)
$EU*Pifirms_{it}$	0.412**	
	(0.188)	
$EU*Mpi_{it}$	-0.003	-0.018
	(0.014)	(0.017)
$Thcomp_{it}$	0.914	0.861
	(0.901)	(0.897)
$Nthcomp_{it}$	-0.713***	-0.728***
	(0.153)	(0.153)
$Thgencomp_{it}$	-0.884*	-0.921*
	(0.528)	(0.527)
$Revision_{it}$	-1.597***	-1.533***
	(0.475)	(0.485)
EU_Enlar_i	1.454***	1.459***
	(0.198)	(0.198)
$Time_i$	-0.017***	-0.017***
	(0.009)	(0.009)
d ln$P$/d $(EU*Picomp)$	0.112	-0.273
	(0.571)	(0.593)
d ln$P$/d $Thcomp$	-2.020**	-2.139**
	(0.986)	(0.981)
Sample size	117228	117228
Log likelihood	152,776.4	152,716.4

Notes: FE denotes fixed-effects regressions.

Asterisks ***, **, and * denote that coefficients are statistically significant at the 1%, 5%, and 10% levels.

Standard errors robust against heteroskedasticity and autocorrelation are shown in parentheses.

To disentangle the effects of EU enlargement on the intensity of competition from parallel imports, we also restricted the analysis to only drugs that were either always or never subject to PI-competition during the study period. Irrespective of whether we controlled for $Pifirms_{it}$, enlargement had no effect on the price effect of PI-competition for these drugs (Table 5). The estimated effect of enlargement using the whole sample, which indicated a 1% decrease in the absolute price effect of PI-competition, must then have been caused by the changes in the prices of drugs that had never faced PI-competition before but started to face such competition after the enlargement, and by drugs that changed from facing PI-competition to not, or (more likely) vice versa. The effect of PI-competition on the prices of drugs that started to face it after the enlargement could be smaller if the price difference between Sweden and the source country (one of the new EU members) was small and/or consumers

perceived the new parallel imports (sourced from the new members) as inferior. Besides, especially consumers with chronic diseases might become reluctant to accept parallel imports if each time they are offered a different version, sourced from a different country, or if they are offered parallel imports irregularly, due to problems in supply. Comparison of the estimates for PI-variables from the restricted sample with those from the whole sample indicates that the increase in the price effect of Mpi_{it} after enlargement was mostly driven by drugs changing status including drugs that started to face PI-competition.

Conclusion

Ten new countries joined the EU by the enlargement in 2004. Given that parallel trade of pharmaceuticals is legal within the EU, and prices were lower in these new members, the enlargement raised concerns about parallel trade and price competition in pharmaceuticals. Parallel import of pharmaceuticals from eight of the new members – all except Cyprus and Malta - was "derogated" (restricted) due to lack of proper patent protection. The derogation hinders parallel import of a drug if it did not have equivalent patent protection in the source country at the time the patent was filed in the destination country. It covers thus just a fixed and closed set of pharmaceuticals. That is, there are drugs eligible for parallel trade, so EU enlargement might still increase competition from parallel imports. Despite the derogations, data on approvals granted by the Swedish Medical Products Agency show that at least 6% of drugs facing competition from parallel imports had competitors sourced from the new members.

Using Swedish data from 2003-2007 we examined whether EU enlargement increased the effect of competition from parallel imports on prices of on-patent prescription drugs. Drugs facing competition from parallel imports were found to have had on average 17- 21% lower prices than they would have had if they had never faced such competition. But, contrary to expectation, the enlargement was found to have reduced the effect of competition from parallel imports though slightly (at most one percentage points). The immediate effect of facing competition from parallel imports − which mainly determines the total effect − fell after the EU enlargement, while the gradual effect, taking place over ensuing months, rose. The immediate effect of PI-competition might have fallen after enlargement because of changes in consumer perceptions of parallel imports. Perhaps consumers perceive drugs sourced from the new members as inferior because of different packaging or labeling.

However, such concerns might vanish over time as the drugs remain in the market and as consumers got used to them.

The estimated effect of EU enlargement on competition from parallel imports might also capture the change in prices of drugs that became subject to such competition only after the enlargement. If the price difference between the source country and Sweden was small and the supply of parallel imports was limited, then the effect of facing competition from parallel imports might be small, which would be reflected as a decreasing effect of EU enlargement on competition from parallel imports.

The effect of EU enlargement on competition from parallel imports might then be due both to the derogation restricting the set of drugs that could be parallel traded and to changes in consumer perceptions of parallel imports. The study period covered a short transition during which both parallel traders and consumers were adjusting to the availability of drugs from new EU members. The results may bode well for increased competition from parallel imports over a longer period, since they indicate that the gradual effect of PI-competition was strengthened by the enlargement.

References

Arnold & Porter (2004), Accession Derogation – An Export Ban?, in *Parallel Trade: Update – Pharmaceuticals*, Advisory, February 2004: 6-7.

Brekke, K.R., A.L. Grasdal, and T.H. Holmås (2009), Regulation and Pricing of Pharmaceuticals: Reference Pricing or Price Cap Regulation, *European Economic Review* 53(2): 170-185.

Chen, Y., and K.E. Maskus (2005), Vertical Pricing and Parallel Imports, *Journal of International Trade and Economic Development* 14(1): 1-18.

COM (2003), Commission Communication on Parallel Imports of Proprietary Medicinal Products for Which Marketing Authorizations Have Already Been Granted, Commission of the European Communities, Brussels.

Danzon, P.M., Y.R. Wang, and L. Wang (2005), The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty-five Major Markets in the 1990s, *Health Economics*, 14(3): 269-292.

Dental and Pharmaceutical Benefits Agency (2009), Tillägg till uppdrag angående förberedande åtgärder med anledning av omregleringen av apoteksmarknaden [Amendment to commission on preparations for reregulation of the pharmacy market] (in Swedish).

Freshfields Bruckhaus Deringer (2003), EU Enlargement: Pharmaceutical Issues, Briefing, http://www.freshfields.com/publications/pdfs/practices/6777.pdf .

Galimberti, G., and W. Pors (2008), Parallel Imports of Pharmaceutical Products, in Pharmaceutical Advertising, Global Legal Group Ltd, London.

Ganslandt, M., and K.E. Maskus (2004), Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union, *Journal of Health Economics* 23(5): 1035-1057.

Granlund, D., and Köksal, M.Y. (2011), Parallel Imports and Mandatory Substitution Reform: A Kick or A Muff for Price Competition in Pharmaceuticals?, Scandinavian Working Papers in Economics 824, Umeå University.

IHS Global Insight (2010), Greek Drug-Price Reduction Progress As Electronic Prescription System Starts to Yield Results, Same-Day Analysis, 8 Sep 2010.

Jelovac, I., and C. Bordoy (2005), Pricing and Welfare Implications of Parallel Imports in the Pharmaceutical Industry, *International Journal of Health Care Finance and Economics* 5(1): 5-21.

Kanavos, P., D. Gross, and D. Taylor (2005), Parallel Trading in Medicines: Europe's Experience and Its Implications for Commercial Drug Importation in the United States, *AARP Public Policy Institute Issue Paper* 2005-7.

Kanavos, P., and P. Holmes (2005), Pharmaceutical Parallel Trade in the UK, Benedict Irvine (ed.), Civitas (Institute for the Study of Civil Society), London.

Kyle, M.K. (2009), Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy, Chapter 13 in *International Antitrust Law & Policy: Fordham Competition Law*, edited by B. Hawk, Juris Publishing, New York.

Kyle, M.K. (2010), Strategic Responses to Parallel Trade, *B.E. Journal of Economic Analysis and Policy* 11(2).

Köksal, M.Y. (2009), Reference Pricing-Making Parallel Trade in Pharmaceuticals Work, Scandinavian Working Papers in Economics No. 367, University of Gothenburg.

LFNFS 2003:1 Läkemedelsförmånsnämndens Föreskrifter om Ansökan och Beslut hos Läkemedelsförmånsnämnden [The Pharmaceutical Benefits Board's Regulations about Application and Decisions at the Pharmaceutical Benefits Board] (in Swedish).

LFNAR 2006:1, General Guidelines Concerning Price Increases of Pharmaceuticals from the Pharmaceutical Benefits Board, Läkemedelsförmånsnämnden (The Pharmaceutical Benefits Board, Stockholm, http://www.tlv.se/Upload/English/ENG-lfnar-2006-1.pdf.

LVFS 2004:8, The Medical Products Agency's Provisions and Guidelines for Marketing Authorisation of Parallel Imported Medicinal Products, Code of Statutes, Läkemedelsverket (Medical Products Agency), Stockholm.

Maskus, K.E., and Y. Chen (2004), Vertical Price Control and Parallel Imports: Theory and Evidence, *Review of International Economics* 12(4): 551-570.

OECD (2008), Pharmaceutical Pricing Policies in a Global Market, OECD Health Policy Studies, Paris.

Pavcnik, N. (2002), Do Pharmaceutical Prices Respond to Potential Patient Out of Pocket Expenses, *RAND Journal of Economics* 33(3): 469-487.

Pecorino, P. (2002), Should the US Allow Prescription Drug Reimports from Canada?, Journal of Health Economics 21(4): 699-708.

PPRI (Pharmaceutical Pricing and Reimbursement Information) (2007), Sweden Pharma Profile, submitted for the PPRI Project, Austrian Health Institute, Vienna.

Schaffer, M.E. (2010), xtivreg2: Stata Module to Perform Extended IV/2SLS, GMM, and AC/HAC, LIML, and k-class Regression for Panel Data Models. http://ideas.repec.org/c/boc/bocode/s456

Tobin, H., and N. Turner (2003), Boom or Gloom for Parallel Trade in the Enlarged EU?, PPR Communications, IMS Health.

Van Bael, I., and J.F. Bellis (2005), Competition Law of the European Community, 4th Ed., Kluwer Law International, The Netherlands.

Von Uexkull, A. (2004), The Impact of the EU Enlargement on the Pharmaceutical Industry, Online Publication Vossius & Partner, http://mobile.vossiusandpartner.com/pdf/pdf_22.pdf.