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The welfare impact of parallel imports: A structural approach applied to the German market for oral antidiabetics*

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Abstract We investigate the welfare impact of parallel imports using a large panel data set containing monthly information on sales, ex-factory prices, and further product characteristics for all 700 antidiabetic drugs sold in Germany between 2004 and 2010. We estimate a two-stage nested logit model of demand and, based on an oligopolistic model of multi-product firms, we then recover the marginal costs and mark-ups. We finally evaluate the effect of the parallel imports' policy by calculating a counter-factual scenario without parallel trade. According to our estimates, parallel imports reduce the prices for patented and generic drugs by 39% and 0.05%, respectively. This amounts to an increase in the demand-side surplus by €11.4 million per year which is relatively small compared to the market size of around €470 million. Manufacturers of original drugs, instead, lose more than half of their variable profits when parallel trade is allowed and only a small fraction of these rents are appropriated by the parallel importers.

Keywords: parallel imports, pharmaceuticals, structural models, antidiabetic drugs
JEL Codes: I11, I18, L13, L51, D43

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1 Introduction

The controversial welfare effects of parallel trade in pharmaceutical markets have been critically debated in health economics and policy in the last few decades (e.g., Ganslandt and Maskus, 2004; Dutta, 2011). The core of this policy debate is the tension between incentivizing long-run innovation into new drugs and achieving price reductions that directly or indirectly benefit consumers in the short-run.

R&D activities in pharmaceuticals are typically carried out at the global level, as most drug manufacturers sell their products in international markets. Yet, intellectual property rights (IPR) on active substances are generally exhausted at the national level, which creates entry barriers across geographical (national) markets. These barriers try to eliminate arbitrage gains, which would be possible in pharmaceuticals since the prices for the same drugs differ across countries as a response to heterogeneous national demand and income conditions and as a reaction to different national regulations (Kyle, 2011).

In this context, parallel imports – i.e., a drug made or sold legally in other countries, which is imported without the permission of the intellectual property right-holder (e.g., the patent owner) by licensed trading firms – are expected to generate some downward pressure on price levels. In theory, the welfare effects of parallel trade are ambiguous and depend on the differences in the national price regulations (Bennato and Valletti, 2012; Jelovac and Bordoy, 2005), the patients' preferences (Jelovac and Bordoy, 2005) and the vertical integration of the trade firms (Ganslandt and Maskus, 2007) among other reasons. If the cross-country price differentials do not reflect true discrepancies in the efficiency of production and they are rather the outcome of different regulatory policies, parallel imports may lead to a price convergence that constitutes a mere welfare transfer from consumers in low-price countries to consumers in high-price countries and most likely benefits arbitrageurs (Danzon, 1998). Furthermore, the loss in profits for patent holders may lead to lower investments in R&D (Rey, 2003). However, even from a theoretical point of view, these mechanisms are not unequivocally clear. Parallel imports might well have positive effects on the innovation intensity due to the different incentives firms and regulators face when IPRs are internationally rather than nationally exhausted (e.g., Grossman and Lai, 2008). Hence, the assessment of the welfare effects of parallel trade is essentially an empirical issue. To identify causal effects, however, it is necessary to observe situations where parallel trade is allowed.

To this aim, the process of European integration provides a great policy experiment. The European Court of Justice commonly supports the community-wide exhaustion of IPR which allows free trade within the EU and prohibits the trade of patented products from and to non-European countries. Indeed, drug trade emerges from low-price countries – typically Portugal, Spain, Greece, etc.

– to high-price countries – such as the UK, Sweden, and Germany (Kyle, 2011; Grossman and Lai, 2008). In 2012, parallel trade amounted to about €5.3bn in the EU and to €2.9bn (based on ex-factory prices) in Germany (Murray and Weissenfeldt, 2013). The total market shares of parallel imports ranged in 2010 from 24% in Denmark, to 11% in Germany, 10% in the Netherlands, and 7% in the UK (EFPIA, 2013). In the in-patent market, parallel imports covered 25% of the sales in Germany in 2010 (Deutscher Bundestag, 2010), whereby Germany is by far the largest European market for pharmaceuticals and the heaviest parallel importer in the EU (Murray and Weissenfeldt, 2013).

Our paper aims at adding to this controversial discussion by analyzing the effect of parallel trade in the German antidiabetics market. We estimate a structural model of demand and supply for a large panel data set containing all oral antidiabetic drugs sold between 2004 and 2010. We focus on this indication for three reasons: First, changes in demographics and lifestyles made diabetes type 2 one of the most widespread diseases in Western countries. For instance, between 2000 and 2009 the number of German diabetes patients increased by 49% (Köster, Schubert, and Huppertz, 2012). Second, we observe the coexistence of original drugs, generics, and parallel imports across the different active substances. Third, oral antidiabetics are prescribed exclusively for the treatment of this single disease, which makes a definition of the potential market size easier to achieve. Finally, the prescription procedure for a particular drug package can be modeled more easily in this market than in other pharmaceutical markets.

The data that we use are provided by *IMS Health* and entail monthly information on sales, ex-factory prices, and further product characteristics such as package size, producer and re-seller names, and market entry. We model demand through a two-stage nested logit approach (e.g., Berry, 1994; Verboven, 1996; Stern, 1996), where the upper-nest corresponds to the chemical group (ATC4) and the lower-nest corresponds to the active substance (ATC5). We believe that this two-level structure based on the chemical groups and active substance covers the most relevant aspects of patient heterogeneity as well as the most relevant decisions' criteria of the physicians and pharmacists. We build on Björnerstedt and Verboven (2012) and expand their approach to the estimation of different price coefficients for different chemical groups (Slade, 2004).[1]

We obtain estimates of -7.6 for the mean own-price elasticity and estimates that range from 1.5 to 0.005 as mean cross-price elasticities. Based on an oligopolistic model of multi-product firms, we then recover the marginal costs and, accordingly, mark-ups, which range between 5% and 65% depending on

[1] For a general discussion on the benefits of alternative modeling alternatives for discrete choice models of demand see also (Grigolon and Verboven, 2013). Björnerstedt and Verboven (2012) conclude that – even in the highly and specifically regulated pharmaceutical industry – the nested logit model seems to be strongly supported for use in competition analysis.

the specific chemical group. Using these estimated demand- and supply-side parameters, we then simulate the new equilibrium prices, market shares, and changes in demand-side surplus and producers' variable profits that would result if parallel trade was not allowed.[2] According to our estimates, the existence of parallel trade strongly decreases the average price of patented drugs by 39% and it only implies a limited decrease by 0.05% for the price of generic products which are subject to intense competition. The overall increase in demand-side welfare due to parallel trade is estimated to be €80.1 million over seven years, which amounts to an increase by around 2.4% of the total demand side surplus calculated in the market for oral antidiabetics absent parallel trade. The corresponding decrease in variable profits due to parallel trade for the manufacturers of original drugs is quite severe and amounts to €92 million over the seven sample years which represent over 120% of their variable profits without parallel trade. Parallel importers only appropriate a small faction (€15 million) of this rent.

Our study contributes to the growing empirical literature on the effects of parallel imports on prices and welfare, whose results are still controversial.[3] While some of these studies find that parallel trade achieves only low price reductions (e.g., Ganslandt and Maskus, 2004; Granlund and Yesim Köksal, 2011; West and Mahon, 2003), Kanavos and Vandoros (2010) even identify a small tendency to price increases after the entry of parallel imports for six European countries. Kyle (2011) explains the relative small price reductions as the outcome of the strategic reaction of the original producer. Kanavos and Costa-Font (2005) and Enemark, Pedersen, and Sørensen (2006) conclude that in the early 2000s, parallel imports led to rather small cost reductions for the German health insurances but to high losses in market shares and profits for the original producers.[4] Yet, all of these studies are mostly descriptive price or entry regression and/or based on reduced-form price equations, which allow neither a careful model of the complex market structure nor an assessment of the effect of parallel trade on welfare.

Hence, to make a more precise assessment of the welfare implications of different policy interventions, our approach builds on recent developments in the empirical health economic literature that estimates structural models of demand and supply. The most recent studies in this strand of literature analyze the market entry of generic and "'me-too" drugs in the U.S. (Ching, 2010;

[2] We talk about demand-side welfare instead of consumer welfare because, given the structure of the German health markets, this surplus is shared among the patients and the statutory health system.

[3] For an overview of studies about parallel trade compare the EU Report "Competitiveness of the EU Market and Industry for Pharmaceuticals" (European Commission, 2009).

[4] In an earlier study, Kyle (2007) found less market entry of innovative products in low-price countries where parallel import is allowed and concluded that parallel trade indeed hinders innovation activities.

Branstetter, Chatterjee, and Higgins, 2011; Arcidiacono, Ellickson, Landry, and Ridley, 2012; Bokhari and Fournier, 2013). Almost all these papers show that the entry of generic drugs benefits consumers more than it harms the producers by decreasing prices of the former patented drug. Furthermore, the demand seems to disseminate not only among brand-names and generics or "me-toos" of the same molecule but also across molecules (Branstetter, Chatterjee, and Higgins, 2011; Bokhari and Fournier, 2013). Since parallel imports are not allowed and patented drugs' prices are relatively high in the U.S., comparisons to Europe are difficult.

Probably the papers closest to our study are those by Dutta (2011) and Chaudhuri, Goldberg, and Jia (2006). They model the effects of stricter intellectual property rights on welfare in India. Both measure substantial loss in consumer welfare from patent enforcement and price deregulation but quite limited gains for foreign patent holders. These results cannot be transferred directly to the European case since in the EU patent enforcement is so strict that cheaper copies from other producers are not available in in-patent markets. Instead, parallel imports of the original drug from low-price to high-price countries exist. Hence, our research adds to this growing literature by looking for the first time at the welfare effect of parallel trade in the largest European market for oral antidiabetics and constitutes the first attempt to estimate a structural demand model for the German pharmaceutical market.

The paper is organized as follows. Section 2 describes the institutional details of the regulations in the German drug markets and the characteristics of the market for oral antidiabetics. Section 3 describes our data, while Section 4 sets up our modeling strategy. Section 5 presents the results of our estimation and simulation. Section 6 concludes with a discussion of the results and their policy implications.

2 The German Drug Market

In this section, we describe the salient characteristics of the German market for oral antidiabetics as well as some important institutional details on the working of the German health insurance markets that should help to understand our modeling assumptions.

2.1 Diabetes and The German Market for Oral Antidiabetic Drugs

Diabetes is a metabolic chronic diseases in which either the body does not produce enough insulin (type 1 diabetes) or the patients do not respond to the insulin that is produced (type 2 diabetes). Usually, the disease results

in hyperglycemia, or high blood sugar, and leads to damages of the body's systems, e.g., nerves and blood vessels (WHO, 2013). Diabetes is one of the major diseases afflicting developed countries, and increasingly so. According to the World Health Organization about 347 million people worldwide suffer from diabetes (WHO, 2013). The International Diabetes Foundation estimates a rise to about 552 million people and forecasts healthcare expenditures of $ 595 billion in 2030 (IDF, 2013). The causes of type 1 diabetes are unknown and the disease is unpreventable. The treatment includes medication with insulin. We focus on type 2 diabetes which accounts for 90% of all patients with diabetes (WHO, 2013). Type 2 diabetes differs substantially from type 1 diabetes and its causes include obesity, tobacco use, and physical inactivity. In Germany, 6 to 7 million patients are estimated to have suffered from type 2 diabetes in 2010 and a high number of unknown cases is assumed. Thus, diabetes type 2 is estimated to affect around 8% of the German population (Rathmann and Tamayo, 2012).

The German market of oral antidiabetic drugs is large and amounted to about €572 million in 2010 in pharmacy selling prices (own calculations). The treatment of type 2 diabetes ranges from dietary nutrition and physical activity to oral antidiabetic drugs and, in severe cases, insulin. Eight chemical groups of oral antidiabetics were available between 2004 and 2010 comprising 22 active substances. The drugs either suppress glucose production by the liver (*biguanide*), delay glucose absorption of the blood (*alpha-glucosidase inhibitors*), stimulate the production of insulin (*sulfonylureas*, *glinides*), or increase the physiological function of insulin (*thiazolidinediones*). Furthermore, a range of drugs that combine groups of active substances (so-called combinations, e.g., *biguanide* and *thiazolidinediones*) were also available in the market. Each chemical group comprises several active substances which can again be divided in either off-patent markets with free access for generic products or in-patent markets with strictly regulated access. However, independently of the specific regulation of reimbursement and disposal, all firms are free to set prices. In section 3.1, we will exploit this medical classification as a basis for generating our demand-side model which considers chemical groups (ATC4) and active substance (ATC5) as nests of closer substitutes (a complete classification of the drugs analyzed in this study is given in Table 1).

2.2 The German Statutory Health Insurance System: Decision Process and Regulations

We derive the demand-side of our model from the maximization of a unique utility function that encompasses the incentives and decisions of four major stakeholders, which are separately described in the following sub-sections. The underlying assumption is that the doctor, the pharmacist, and the health insurer always decide in favor of the patient. More specifically, we assume that the

physician, who makes a decision based on the patient's medical needs, acts as a perfect agent. However, we also assume that the physician partially accounts for her own interest by taking the drug's price into consideration when making their decision, as specific regulations – e.g., the introduction of prescription budgets for physicians – tend to make her price-sensitive.

2.2.1 Health insurance

More than 85% of the German population – around 69.8 million people – are covered by the statutory health insurance system (BMG, 2013). We only consider this group in our analysis. Those insureds face a co-payment of 10% per package (minimum €5, maximum €10) on pharmaceutical prices for prescription drugs, which are uniform across all German pharmacies as prices are. Moreover, most off-patent markets are regulated by reference pricing where the patient additionally pays the positive difference of the drug's price to the reference price, if applicable. Off-patent markets face fierce competition by generic drugs and reference pricing (e.g., Herr and Suppliet, 2012). Since 2007, the various health insurances may additionally contract on specific drugs' prices and quantities directly with pharmaceutical manufacturers (so-called rebate contracts). These drugs then have to be handed out as a first choice by the pharmacist only if the active substance is marked on the prescription.

2.2.2 The physician

At first, the physician chooses the chemical group suitable to the patients' physical condition (e.g. body weight), individual preferences, medical history, co-morbidities and age. It is well understood that physicians make this choice in a hierarchical order. For instance, the guidelines of the National Institute for Health Care and Excellence in the UK clearly prescribe initiating oral glucose control therapies for type 2 diabetes with *metformin*, followed by *insulin secretagogues*, *acarbose*, then other oral agents such as *DPP-4 inhibitors* and *exenatide*, and finally *thiazolidinediones*. When exactly the physician is expected to switch across groups depends on the patient's health status.[5] Hence, the choice of the chemical group can be seen as a good proxy of the unobserved individual characteristics, which we would not observe otherwise by using aggregated sales data.

As a second step, the physician together with the patient choose among the active substances within the chosen chemical group. For this choice the substance price, its side effects, and co-morbidity play an important role. In

[5] For the German guidelines see http://www.deutsche-diabetes-gesellschaft.de/fileadmin/Redakteur/Leitlinien/Evidenzbasierte_Leitlinien/EBL_Dm_Typ2_Update_2008.pdf p. 51-53 and for UK compare e.g., http://www.nice.org.uk/nicemedia/live/12165/44320/44320.pdf p. 13-18.

particular, physicians are also encouraged to consider economic aspects in their prescription behavior, yet they are not directly punished or compensated based on their decisions. Only if physicians exceed their individual drug budgets do they have to justify it to their supervising organization. Still, they should prefer to prescribe less expensive drugs such as generics (if available) to avoid audits and ease their overall budget constraint. While we generally assume that a physician prescribes an active substance, German doctors can, in principle, also prescribe a specific drug package if the patient's condition requires her to do so and if the patient is willing to pay a possibly higher co-payment.

2.2.3 The pharmacist

Based on the physician's prescription, which is required for prescription drugs such as oral antidiabetics, the patient and the pharmacist together choose one of the drugs containing the prescribed active substance. This can be either an original, parallel imported, or generic drug. This choice is restricted by the patient's health insurance or other hand-out rules. In general, the physician prescribes the original drug in in-patent markets and the pharmacist can then exchange this drug with its parallel imported version. This decision is again influenced by the patient's willingness to pay and parallel import quotas. In the off-patent market, if there is no rebate contract with the respective health insurance, the pharmacist has to hand out one of the three cheapest drugs if not marked otherwise on the prescription. However, the physician can still opt out of these rules and prescribe specific packages or brands.

In Germany, the distribution of parallel imports is supported by the regulator. Pharmacists need to fulfill a specific quota: the share of total turnover per patented active substance has to exceed 5% for each of the around 140 health insurances per quarter (BMG, 2013).[6] Furthermore, the parallel imported drug's price has to be at least 15% or €15 below the original product's package price to be considered as a parallel imported drug in the 5% quota. This regulation has two main economic effects. First, pharmacists tend to hand out parallel imported drugs as soon as the latter have fulfilled the requirements. Second, the parallel importing firms set the prices close to 15% (for prices below €100) or €15 below the original package price.

2.2.4 The patient

The most important stakeholder – the patient – first provides information on her health status and, after discussing with the physician the most suitable chemical group, she finally chooses which specific drug and package to buy at the pharmacy. While health insurances treat parallel imported products as

[6] The regulation applies to markets where parallel imported drugs are available. Revenues on drugs under a rebate contract are subtracted.

perfect substitutes in terms of their pharmaceutical identity, patients might have a specific non-medical preference for or against them, e.g., they may value higher non-German packaging or be worried about insecure repackaging and therefore ask in the pharmacy for the originator drug.[7] Furthermore, when an active substance in off-patent markets is marked on the prescription, patients can order a different drug to the offered generic drug if the price lies among the three cheapest prices for that active substance and if there is no rebate contract between one manufacturer and the patient's health insurer.

We also expect patients to show price-sensitive behavior, at least to some extent, as co-payments are highly correlated with prices. Moreover, price-sensitive behavior should also be observed if patients are rational and understand the long-term consequences of their purchasing decision on future insurance rates. Since the statutory health insurance is publicly financed, eventual profits coming from lower aggregated statutory expenditures can only be distributed to the insureds in the form of lower premia in the long-run.

3 Empirical Strategy

To empirically analyze the extent of competition in the German market for oral antidiabetic drugs, we derive a demand function by the joint utility maximization of the four stakeholders – health insurer, patient, physician, and pharmacist – who concur in the decision process described in section 2.2. We approximate this process by using a two-level nested logit model and we define hierarchical nests of products by using ATC4 as the upper nest and ATC5 as the lower nest. We believe that the nesting parameters for the groups and the subgroups cover some of the most relevant aspects of patient heterogeneity as well as the most relevant aspects of the physicists and pharmacists' decisions in these markets, while the product's continuous characteristics play a less fundamental role (e.g., Grigolon and Verboven, 2013).[8] They are mostly captured by the product fixed-effects in our setting. In particular, we believe that the use of the chemical group as an upper nest is particularly important for capturing those patient-specific characteristics which are not observable when using aggregated market data.

[7] Parallel imported products only differ in terms of packaging or color, as the trading firms have to add package inserts and provide labeling in German either by a new package or via new packaging or by a sticker overlay. As an example, see Figures 1 and 2.

[8] Since diabetes type 2 is a chronic disease, package size does not play an important role. The active substance's strength may be an important characteristic for the drug's choice, but there is not much variation within the active substances, which is why rather choose a product fixed-effect specification as discussed below. Yet, as a robustness check, we consider the active substance's strength as an exogenous demand factor in the specification where we use firm-level fixed-effects and time-invariant product characteristics (Firm FE.IV).

3.1 Demand Model

We observe one geographical market (Germany) over $t = 1, ..., 84$ months from 2004 to 2010. For each month, we calculate the potential market size, M_t, as the number of defined daily doses (DDD) for all diabetes patients in Germany. The potential market size is about twice as large as the actual market due to patients that either choose a non-prescription drug or other therapies to treat diabetes type 2. The following specification of the demand estimation closely follows previous work from Berry (1994); Verboven (1996), and Slade (2004).

The I agents, $i = 1, ..., I$,[9] in each market/time period choose one out of J_t products, $j = 1, ..., J_t$.[10] The model incorporates the option that agents might decide not to buy any drug or/and another product. This so-called outside good j_0 extends the choice set to $J_t + 1$ products. Because all agents buy in the same market t we can suppress the time/market subscript for simplicity. The agent i's conditional indirect utility function for drug j is assumed to be:

$$u_{ij} = -\alpha_g p_j + \beta x_j + \xi_j + \upsilon_{ij}, \tag{1}$$

where p_j is the price of product j and x_j is the vector of other observed product characteristics, such as the active substance, the strength, or the package size. Compared to the standard specification, we use a more flexible one and allow the price coefficients α_g to depend on the characteristics of the product, namely on the chemical groups $g = 1, ..., G$ (Slade, 2004). This helps to ease the well-known issue in logit models that elasticities –and thus markups and marginal costs c– depend on products' prices in a linear fashion (Berry, Levinsohn, and Pakes, 1995; Nevo, 2000).[11] The vector ξ_j contains characteristics that are observed by the firms, patients, physicians, and pharmacists but are unobserved by the researcher and might include brand perception, marketing expenditures, or publicly unknown interactions with other drugs. The random utility terms υ_{ij} reflect the influence of individual-specific taste. We assume that each agent maximizes utility, u_{ij}, given the characteristics of the product. The mean utility of product j is:

$$\delta_j = -\alpha_g p_j + \beta x_j + \xi_j \tag{2}$$

[9] In our setting, the agent's choice is represented by the joint decision of the four stakeholders: the patient, the physician, the pharmacist, and the health insurance.

[10] Discrete choice models such as the nested-logit do not allow modeling of complementary goods. In our context, this might be problematic since a mix of drugs is sometimes prescribed. However, we specifically consider a chemical group which contains drugs that combine different groups of active substances. We are therefore able to ease – though not completely solve – the complementarity problems by defining bundles of drugs which can be seen as substitutes to single drugs entailed in other nests.

[11] The linear dependency results in larger elasticities for more expensive products, which is not consistent with economic intuition.

and the mean utility of the outside good j_0 is normalized to zero: $\delta_0 = 0$.

Based on the specific market structure described above, products are grouped into nests. The first level of nests are G different chemical groups, $g = 1, ..., G$. The second level of nests consists of H_g, $h = 1, ..., H_g$, different active substances within the chemical group g. The specific composition of the nests is given in Table 1. We then apply a standard two-level nested logit model and assume a variance component error structure of the agent-specific error term, υ_{ij}. Following Verboven (1996), we derive the estimation equation for each period t:

$$\ln(s_{jt}) - \ln(s_{0t}) = -\alpha_g p_{jt} + \beta x_{jt} + \xi_{jt} + \sigma_1 \ln(s_{j|hg,t}) + \sigma_2 \ln(s_{h|g,t}), \qquad (3)$$

where the market shares $s_{jt} = q_{jt}/M_t$, and $s_{0t} = 1 - \sum_{j=1}^{J}[q_{jt}/M_t]$, q_{jt} are sales in defined daily doses [DDD] and p_{jt} is the price per DDD in EUR in month t. Inner-group market shares are defined as $s_{j|hg,t} = \frac{q_{jt}}{\sum_{j \in H_g} q_{jt}}$ and $s_{h|g,t} = \frac{\sum_{j \in H_g} q_{jt}}{\sum_{g=1}^{G} \sum_{j \in H_g} q_{jt}}$.

3.2 Identification

The unobserved characteristics of product j at time t are known to firms and patients but not to the researchers, and they are captured by ξ_{jt}. When firms set their prices they most likely use this information, which in turn implies that prices and inner-group market shares are correlated with this structural error term and they are thus endogenous. To partially alleviate this problem, we assume a two-way error component model by $\xi_{jt} = \xi_j + \xi_t + \omega_{jt}$. We then capture part of the unobserved heterogeneity by means of a large set of fixed-effects: the component ξ_j is captured by 700 product fixed-effects and ξ_t is captured by 84 time dummies similar to Nevo (2001). The remaining error term ω_{jt} is defined as a product-and-time-specific error term.[12] In our main specification, the identification condition is therefore $E[p_{jt}|\omega_{jt}] = 0$.

This does not seem to be a particularly restrictive assumption since it is difficult to imagine of systematic sources of correlation among prices and *the changes* in unobserved product characteristics. Yet, in order to assess the robustness of our findings, we use a second identification strategy and estimate a specification where we use firm-specific fixed-effects together with product-specific, mostly time-invariant, characteristics and we instrument for the Ger-

[12] For a discussion of the inclusion of product fixed-effects see Dube, Chintagunta, Petrin, Bronnenberg, Goettler, Seetharaman, Sudhir, Thomadsen, and Zhao (2002); Kaiser, Mendez, and Rønde (2010).

man prices for drug j at time t by means of the Danish prices for the same drug.[13]

In our setting, inner group market shares are also potentially endogenous. Hence, we use an instrumental variable approach to obtain unbiased estimates for the parameters σ_1 and σ_2. Following Berry, Levinsohn, and Pakes (1995) and Berry (1994), we use nine standard instruments which account for the crowdedness in the product space (e.g., Dutta, 2011).[14] The identifying assumption is therefore that the instruments, which are correlated with the inner-group market shares and prices through the mark-up conditions, are uncorrelated with the product-specific error term.

Finally, to account for the potential serial correlation of the error terms due to the relatively high-frequency time structure of the data, we cluster the standard errors at the product-level.

3.3 Elasticities

We follow Berry (1994) and Verboven (1996) and calculate the own-price elasticities and cross-price elasticities which are different for drugs in the same sub-nest, H_g, of active substances, for drugs in the same nest, G, of chemical groups, and for drugs in different groups. The formulas we used to compute the elasticities can be found in the Appendix. We can compute one matrix of price elasticities for all products sold in each month. This results in 84 ($J_t \times J_t$) matrices. However, to retrieve the marginal costs and mark-ups as well as run the simulation we utilize only the elasticities calculated for June 2006 (month 42).[15] Even though the nested-logit model is restrictive in the representation of substitution patterns within or outside groups, it is quite flexible when it comes to the symmetry of cross-price elasticities across products or groups as these only depend on the structural parameters and the price and market shares of the substitute good/group. This is particularly important in our context where the substitution among different chemical groups is mostly hierarchical and cannot be assumed to be symmetric.

[13] This approach is similar to Hausman, Leonard, and Zona (1994) and Nevo (2001). It assumes that prices in different geographical markets are driven by common cost drivers that are independent of country-specific demand shocks. The prices of all authorized pharmaceutical products marketed in Denmark are publicly available at http://medicinpriser.dk/.

[14] Our instruments are: the number of different packages a firm offers per product, the number of firms in the own and all other groups of the active substances and the chemical groups, the number of products within each chemical group (total and by firm), and the number of products without the own firm's products within the same active substance and the same chemical group. All variables are inverted and log-linearized (e.g., Björnerstedt and Verboven, 2012).

[15] June 2006 is selected as the middle of the sample period in which the excluded new innovations have not yet entered. Furthermore, the last health reform took place at the beginning of 2004 while the discussions about the next reform (April 2007) only started in June 2006.

3.4 Supply Side

Firms in pharmaceutical markets sell a range of differentiated products and compete in prices. Typically, differentiation in drug markets stems from the active substance, strength, package size, and marketing activities. In our sample 68 firms sell 700 products either in the same or in different classes of active substances. Hence on the supply-side, we assume Bertrand-Nash price behavior among multi-product firms. We omit the time subscripts and define the profit functions of the F multi-product firms that manufacture a subset F_f, $f = 1, \ldots, 68$, of the J products as:

$$\Pi_f = \sum_{j \in F_f} (p_j - c_j) q_j(p) - C_f, \tag{4}$$

where $q_j(p)$ is the sold quantity of product j as a function of prices, p, here defined as $q_j(p) = s_j \times M$. This definition allows us to include the market share of the outside good and it allows us to keep the market size fixed in our simulation while at the same time enabling the total quantity of products sold to increase (Nevo, 2000). The marginal costs c_j are assumed to be constant and fixed costs are denoted with C_f.

In off-patent markets, such as *metformin*, market entry is a common phenomenon and demand-side regulation supports price competition, e.g., by reference pricing or co-payments. Thus, firms compete à la Bertrand-Nash in prices. In in-patent markets, like the one for *thiazolidinediones*, the patent holder is granted a short run monopoly. However, since in our model we explicitly allow for the entry of parallel imports and model the competition patented drugs face from similar active substances, we believe that Bertrand-Nash behavior with differentiated goods is a reasonable approximation to describe the in-patent market of oral antidiabetics as well. Furthermore, we also assume that a Bertrand-Nash equilibrium in prices exists and that the prices that support it are strictly positive (e.g., Nevo, 2000). The price vector, p, has to satisfy the following J first-order conditions (in matrix notation):

$$q(p) + (\Omega^F \otimes \Delta(p))(p - c) = 0, \tag{5}$$

where $q(p)$, p, and c are $J \times 1$ vectors of quantities, price, and marginal costs, respectively. Ω^F is the firms' product ownership matrix $(J \times J)$ with elements $(\Omega^F(j,k))$ equal to 1 if product j and k are produced by the same firm, and 0 otherwise. The $(J \times J)$ matrix of first derivatives $\Delta(p) = \frac{\partial q(p)}{\partial p'}$ is multiplied element-by-element $(\otimes)$ with the ownership matrix. To identify the marginal cost c, equation (5) can be rearranged as:

$$c = p - (\Omega^F \otimes \Delta(p))^{-1} q(p). \tag{6}$$

Clearly, the identification and estimation of the marginal costs relies on our demand estimates and on the assumption of Bertrand-Nash competition.

3.5 Simulation

To quantify the welfare effects of the parallel import policy we compare the status quo market with parallel imports vs. a hypothetical market without parallel imported drugs. We motivate this hypothetical situation by the fact that firms constantly try to avoid parallel trade (Kyle, 2007), e.g., by not entering low-price countries or by offering slightly different versions (in package size or strength) in different countries. Furthermore, re-imports are prohibited in the U.S. mostly due to patient's safety issues but also because parallel imports are expected to harm innovative firms.[16] Kanavos and Vandoros (2010) conclude that *"Drawing on the European evidence, [. . .] opening the US market to parallel imports will not necessarily lead to competition and enhance pharmaceutical cost containment."* Nevertheless, there is an ongoing debate in the U.S. about disadvantages and advantages, e.g., stopping illegal imports from Canada or Mexico.

The choice set in the counterfactual situation is different to that in the status quo. Hence, similarly to structural models that estimate the value of the introduction of new products (e.g., Petrin, 2002), we define the counterfactual choice set where parallel imported drugs are excluded as $J^{sim} = J - I$, where I is the number of parallel imports. Accordingly, we define the J^{sim} nested-logit demand functions as:

$$q_j(p^{sim}, \hat{\delta}) = M \cdot s_j(p^{sim}, \hat{\delta}) \cdot s_{j|hg,t}(p^{sim}, \hat{\delta}) \cdot s_{h|g,t}(p^{sim}, \hat{\delta}) \tag{7}$$

Similarly, the J^{sim} first-order conditions are:

$$q(p^{sim}, \hat{\delta}) + (\Omega^F \otimes \Delta(p^{sim}, \hat{\delta}))(p^{sim} - \hat{c}) = 0, \tag{8}$$

We then determine the equilibrium simulated prices (p^{sim}) and simulated quantities ($q(p^{sim})$) by using a Newton algorithm on equations (7) and (8). With the new simulated equilibrium (p^{sim} and $q(p^{sim})$) and the estimated structural parameter ($\hat{\delta}$) we calculate the demand-side surplus:[17]

[16] Golec and Vernon (2006) show that U.S. firms are more profitable, earn higher stock returns, and spend more on research and development (R&D) than manufacturers in the EU.

[17] The demand-side surplus corresponds to the typical consumer surplus calculated for a nested logit model. As we mentioned above, since only a part of this surplus goes to the consumers, while a part goes to the statutory health system, we prefer to use the notation demand-side surplus.

$$DS(p^{sim}) = \frac{1}{\hat{\alpha}_g} ln(1 + \sum_{g=1}^{g} (\sum_{h=1}^{H_g} D_{hg}^{\frac{(1-\hat{\sigma}_1)}{(1-\hat{\sigma}_2)}})^{(1-\hat{\sigma}_2)}), \tag{9}$$

and the firms' variable profits:

$$VP(p^{sim}) = \sum_{j \in F_f} (p_j^{sim} - \hat{c}_j) q_j(p^{sim}) \tag{10}$$

We finally compare them with the status quo welfare measures calculated by using the observed prices and quantities.

4 Data

Our data set contains monthly sales and prices of all oral antidiabetic drugs sold in Germany between January 2004 and December 2010. Price and sales data are available at the package level and at the level of defined daily doses (DDD)[18] which allows us to compare products with different active substances and presentations. Each of the drugs is characterized by the name, active substance, company name (either producer or parallel importer), package size, strength, defined daily dosages, presentation, market entry, and an indication if the drug was exempt from co-payments. All data were provided by *IMS Health*, a private marketing consulting firm, and extracted from their database *Pharmascope National* which is restricted to the German Statutory Health Insurance (SHI) market (IMS Health, 2012).

The size of the packages ranges from 21 to 200 (film)tablets per package. The strength, or concentration, varies considerably by active substances (in total from 0.5 mg to 1000g), which motivates the use of DDD as the basic metrics. The ex-factory prices per daily dose range from €0.02 to €2.5 and reflect the fact that some products are sold in in-patent markets while others are sold in off-patent markets.

To calculate the size of the potential market, M_t, we collect epidemiological data about the number of patients with diabetes in Germany from the German Diabetes Association (DDG, 2011; Giani, Janka, Hauner, Standl, Schiel, Neu, Rathmann, and Rosenbauer, 2004; Hauner, Köster, and Schubert, 2007). Annual information about diabetes patients are transformed into monthly values using average growth rates. For example, in 2010 about 8.4 million patients had a monthly demand of about 250 million DDD of antidiabetic drugs.

To ensure homogeneous market conditions, we include in our sample only products that are covered by the German SHI. In our estimations, we only include packages with a market share $> 0.1\%$ (within the subgroup of active

[18] The WHO Collaborating Centre for Drug Statistics Methodology in Oslo provides a list of DDD for each active substance on a yearly basis.

substances).[19] Furthermore, we exclude the chemical substance *Exenatide* due to its sub-dermal administration (pens, 158 obs.) and 83 observations of retard tablets (belonging to *gliclacides*). Finally, we also exclude *DPP-4 inhibators* (287 observations) and their combinations with *metformin* (580 obs.) since they form a special group of late innovations with very high prices, which would constitute an extreme outlier not suitable for estimating a general model for the entire market.[20]

Table 2 gives an overview of the 24,723 observations included in the final estimation by firm type (originator drug manufacturer, parallel importer or generic manufacturer) and chemical group. We observe quite heterogeneous competitive conditions across groups as the *Biguanides* and *Sulfonylurea* groups face severe generic competition while the other groups are much smaller and under patent protection, so that the competitive constraints are mainly those imposed by parallel imported drugs or potential market entry by innovations.

Table 3 reports the descriptive statistics for the most important variables used in this study, including the different prices, the overall market shares (s_j), the market shares of the products within the inner nest ($s_j|h$) as well as the market shares of the inner nests within the outer nest ($s_h|g$). The variables are presented by firm type. The variable *no copayment* captures the fact that some selected drugs can be exempt from co-payments when the price undercuts a certain threshold. The dummy *High strength* equals one if the product's strength exceeds the active substance's mean strength. Prices, sales per product, as well as market shares vary considerably across company types. In the lowest part of the table, we report the number of firms and products within groups and sub-groups, which are used to construct the instrumental variables for the inner-group market shares.

[Table 3 about here]

5 Results

5.1 demand-side Estimation

Table 4 displays the results of the two-level nested logit demand estimation (3). In the first two columns, we present the results for the specification that only includes product fixed-effects [FE], the following two columns then report the

[19] The preferred demand model leads to similar results when excluding all drugs with an overall market share below 0.001% or not excluding by market shares at all. However, it proved very difficult to correctly simulate very small market shares. We therefore decided to use the reduced sample which still covers 92% of the market in terms of sales in 2006.

[20] The demand estimation does yield similar results when not excluding this group but, again, it proved very difficult to predict the market shares and prices of such an extreme outlier using our average coefficient estimates.

instrumental variables estimation that accounts for the potential endogeneity of the inner group market shares [FE.IV]. Finally, model [Firm FE.IV] presents the results obtained including firm-effects and product characteristics (rather than product-specific fixed-effects) and instrumenting the prices with Danish prices. The coefficients σ_1 and σ_2 measure the correlation of agents' preferences within the nests of active substances and chemical groups, respectively, and the six price coefficients [α_g] represent the average effect of the price on the market shares for each of the chemical groups. In all specifications, all parameters (except of one) are significant and have the expected signs.

[Table 4 about here]

As expected, both coefficients for the two nests [σ_1 and σ_2] are considerably smaller after controlling for possible endogeneity and both are consistent with random utility theory ($0 \leq \sigma_2 \leq \sigma_1 \leq 1$) across all three models. The mean utility positively depends on the exemption from co-payments. Model Firm FE.IV additionally shows that the demand increases if the drug stems from the originator manufacturer as opposed to the generic manufacturer. Furthermore, above average strength is negatively associated with the market share.

From now on we will focus on our preferred specification [FE.IV]. The six price coefficients are negative and statistically significant from zero (except for the smallest chemical group 6). The coefficients cannot be interpreted as marginal effects but they show that substitution indeed differs by chemical group: group 2 represents an off-patent market with several generic competitors which results in a price coefficient of -5.2 and group 4 represents a market with patented active substances and a considerably lower price coefficient of -1.1.

For a clear interpretation of these estimates in terms of substitution patterns, we then need to calculate elasticities. Own- and cross-price elasticities of all products in the market (as a mean of June 2006) are presented in Table 5. The own price elasticities vary considerably across groups (-27 to -1.9, mean: -7.55), while the average cross-price elasticity within the same nest of active substances (0.33) is larger than within the upper nest of the respective chemical group (0.22) and indicates a strong substitution among products in similar nests. The mean cross-price elasticity for products outside the chemical group is small (0.002 on average) and reflects the low substitutability among drugs from different chemical groups.[21] The high correlation among drugs of the same chemical group is reasonable and reflects the fact that the grouped active substances differ only slightly in their molecule structure, which allows patients to easily substitute among them. The even larger correlation among drugs containing the same active substance might be driven by the same reasoning. Here, the drugs differ only in strength, dosage form, manufacturer,

[21] Qualitatively similar results are obtained by using the estimates from the [Firm FE.IV] model.

color, package size, etc. Furthermore, it is a common finding in the literature that patients tend to substitute toward similar drugs, (e.g., Ellison, Cockburn, Griliches, and Hausman, 1997; Dutta, 2011).

[Table 5 about here]

We can now use equation (6) to retrieve the marginal costs and the corresponding mark-ups. Table 6 presents marginal costs and markups as a mean percentage over all drugs marketed in period June 2006. On average, marginal costs are 42% of prices and tend to be higher for patented drugs and lower for generic products. This result, which is mostly driven by the chosen nested logit demand model to estimate elasticities, is a bit surprising as marginal costs are reported to be low in the pharmaceutical industry. A possible explanation is that high marginal costs for patented drugs reflect that innovative firms utilize more sophisticated production technology than generic companies. The reported marginal costs might also partially reflect investments in research and development that are not captured by fixed costs.

[Table 6 about here]

5.2 Simulation

The final step of our empirical analysis consists of simulating the new equilibrium in prices and quantities that one would observe, had parallel imports not been allowed. By comparing this counterfactual scenario to the status quo prices and corresponding demand-side surplus and variable profits, we can estimate the value of parallel imports.

Table 7 shows the estimated changes in prices and welfare measures due to the existence of parallel imports for those products available in period 42 (June 2006). This period should be less affected by changes in the regulatory framework as we discussed above. Prices of originator drugs decrease on average by 39% and prices of generic drugs decrease on average by only 0.5% when parallel imports are allowed in the German market for oral antidiabetics. Hence, the overall price level decreases by 6.9%. This result underscores that parallel imports indeed lead to price reductions, especially in in-patent markets, by increasing price competition.

[Table 7 about here]

We then calculate the change in demand-side surplus generated by the introduction of parallel trade. The savings generated by lower prices due to the parallel import policy amount to about €80.1 million in total (or 2.4% of the level without parallel trade) which amounts to about €11.4 million savings per year. These savings do not seem to be particularly large in comparison to the

total size of the market used in the estimation of €470 million in year 2006. However, one needs to keep in mind that the price difference between the originals' and their parallel imports is small since most of the products are priced close to the distribution rule's threshold of €15 or 15% below the original's price. Thus, we expect the competitive effects of parallel imports to be higher if, e.g., the substitution to the cheapest product within the active substance was implemented.

This average demand-side effect comes mostly from the overall lower price level, but is also strongly influenced by the behavior of the marginal consumer. A large part of the gains comes from the change in surplus from original products. First, the prices of original drugs are lower and, second, some patients substitute away from original products to parallel imports, which are even cheaper. However, these positive demand-side effects are partially outset by a decrease in demand-side surplus from generics. The price reduction for these drugs is minimal and several patients substitute away from the cheaper generic drugs to the more expensive parallel imports. These patterns are confirmed when we look at how the change in demand-side surplus breaks down among the different chemical groups. Large gains from parallel trade are observed in those chemical groups where generic competition is not severe, while surplus losses are measured in the *Biguanides* and *Sulfonamides* groups, where several generic products are sold. A side remark on this result is that, apparently, competition by generic entry does indeed work.

The final piece of evidence that we provide regards the gains and losses for manufacturers. Since we do not have a measure of fixed costs, we only analyze the effect of parallel trade on variable profits and hence measure an upper bound to the possible decrease in the incentive to invest in R&D for originators. On average, variable profits decrease by about €86.6 million over the seven sample years. This figure is mostly determined by the severe decrease in variable profits for the manufacturers of original drugs by €92.8 million, which represent over 120% of their variable profits without parallel trade. Only a small part of these lost profits, €15 million, is transferred to parallel importers. Furthermore, producers of generic drugs face a reduction of their variable profits by about 10%.

We cannot derive a complete welfare analysis, absent a reasonable measure of fixed costs. Yet, by comparing the figures above, and under the assumption that fixed costs would be the same in the status quo and simulated scenarios, we can measure a loss in welfare of about €6.5 million due to parallel trade. Therefore, our results are consistent with earlier, more descriptive studies, which find relatively small savings for the health insurances and the patients and big losses for the original producers due to parallel trade (e.g., Kanavos and Costa-Font, 2005). Clearly, these results are affected by the existence of other

extensive demand-side and price regulations which affect health care markets in Germany and might eventually reduce the ability of parallel trade to exert effective competitive pressure on prices. To this extent, one could try to simulate other counterfactual scenarios by changing other key parameters of the parallel imports policy – such as for instance the distribution rule's threshold.

6 Conclusion

In this paper, we study the effect of parallel trade on welfare in the German market for oral antidiabetics. To this aim, we develop and estimate the first structural demand model of the German pharmaceutical market. The estimated demand for antidiabetic drugs seems to be quite elastic, with an average own-price elasticity of -7.6. These results are in line with other studies for different pharmaceutical markets and are mostly driven by the broad availability of generic products in various chemical groups. Indeed, several demand-side policies –such as tiered co-payments and the reference pricing system– support generic competition in the off-patent market. Moreover, physicians and pharmacists are also made more price-sensitive through other specific cost-containment regulations. These findings contrast with the common wisdom that the broad insurance coverage of drug costs tends to generate quite price-inelastic behavior (e.g., Kaiser, Mendez, Rønde, and Ullrich, 2013). The estimated cross-price elasticities support the existence of some degree of market segmentation. Substitution seems to mainly take place across drugs within the same active substance and less within the same chemical group. The fact that patients barely substitute across chemical groups is very much in line with the physicians' behavior in oral glucose control therapies for type 2 diabetes.

The main focus of our analysis is the measurement of the welfare effect of parallel imports. We therefore need to simulate the situation where parallel imports are not allowed. By comparing the status quo to the simulated scenario we measure an average price decrease of +6.9% due to parallel trade. Several patients switch from the original products to the parallel imports, which increases demand-side surplus. Yet, this increase is limited to €80 million over the seven sample years since some patients who would consume generics in the absence of parallel imports switch to these more expensive drugs when they come to the market. Furthermore, the modest average price reaction is most likely driven by other institutional details of the existing parallel import policy in Germany (e.g., Kyle, 2011). In particular, it might be driven by the minimum parallel import quotas of 5% in pharmacy sales. Under this regulation, pharmacists do not have any incentive to hand out cheaper parallel imports other than those which undercut the price threshold to be counted in the quota (15% or €15 below the original's price). We expect the price effect to be larger, if there were other

distribution rules, e.g., if the rules were similar to those applied in the off-patent market where pharmacists have to hand out one of the three cheapest drugs if there is no rebate contract for the patient's health insurance drug combination and the physician has not ruled out a substitution of the prescribed drug. These alternative scenarios could be further investigated within our framework at the cost of imposing a more complex and potentially restrictive structure.

An important discussion that we did not address in this study is how the policy of parallel imports affect investments in research and development. By definition, trade firms gain arbitrage profits and do not conduct any investments in R&D. Thus, the policy transfers profits from innovative firms that invest, at least partially, into R&D toward firms that do not invest in R&D at all. Our results partially confirm this view. The manufacturers of original drugs face severe losses by over €90 million due to the introduction of parallel trade. This loss in variable profit is, however, only partially (€15 million) transferred to parallel importers and it rather benefits the statutory health system. As the effect of parallel trade on innovations is one of the most prominent current debates in pharmaceutical markets, a natural extension of our framework would be to more carefully model the dynamics of innovation, drug introduction, and R&D.

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7 Appendix

7.1 Elasticities

We follow Berry (1994) and Verboven (1996) and calculate the own-price elasticities as:

$$\frac{\partial q_j}{\partial p_j}\frac{p_j}{q_j} = -\alpha p_j\Bigg(- \frac{1}{1-\sigma_1} + \left(\frac{1}{1-\sigma_1} - \frac{1}{1-\sigma_2}\right)s_{j|hg} + \left(\frac{\sigma_2}{1-\sigma_2}\right)s_{j|g} - s_j\Bigg). \tag{11}$$

The cross-price elasticities for drugs in the same sub-nest, H_g, of active substances are defined by:

$$\frac{\partial q_j}{\partial p_k}\frac{p_k}{q_j} = -\alpha p_j\left(\left(\frac{1}{1-\sigma_1} - \frac{1}{1-\sigma_2}\right)s_{j|hg} + \left(\frac{\sigma_2}{1-\sigma_2}\right)s_{j|g} - s_j\right). \tag{12}$$

Similarly, the cross-price elasticities for drugs in the same nest, G, of chemical groups are given by:

$$\frac{\partial q_j}{\partial p_k}\frac{p_k}{q_j} = -\alpha p_j + \left(\left(\frac{\sigma_2}{1-\sigma_2}\right)s_{j|g} - s_j\right). \tag{13}$$

Finally, we derive the cross-price elasticities to all drugs outside the own chemical group to be:

$$\frac{\partial q_j}{\partial p_k}\frac{p_k}{q_j} = \alpha p_j s_j. \tag{14}$$

8 Figures and Tables

Table 1: Anatomical Therapeutic Chemical (ATC) Classification System for the therapeutic class *Blood glucose lowering drugs, excl. insulin* (A10B) (= oral antidiabetics) marketed in Germany 2004-2010

ATC4: chemical (sub-) group	**ATC5: active substance / chemical substance**	**Total # of products**	**Total # of firms**
1. Alpha glucosidase inhibitors	Acarbose	63	20
	Miglitol	18	10
2. Biguanides	Metformin	121	37
3. Combinations of oral blood glucose lowering drugs	Metformin and Rosiglitazone	34	13
	Glimepiride and Rosiglitazone	19	6
	Metformin and Pioglitazone	11	9
	Glimepiride and Pioglitazone	4	1
	Metformin and Sitagliptin*	4	1
	Metformin and Vildagliptin*	17	3
4. Other blood glucose lowering drugs, excl. insulins (here: glinides)	Repaglinide	89	21
	Nateglinide	13	7
	Exenatide*	-	-
5. Sulfonylurea	Glibenclamide	51	28
	Glibornuride	14	8
	Gliquidone	2	1
	Gliclazide	4	2
	Glimepiride	170	30
6. Thiazolidinediones	Pioglitazone	36	12
	Rosiglitazone	15	7
Dipeptidyl peptidase 4 (DPP-4) inhibitors	Sitagliptin*	8	6
	Vildagliptin*	4	2
	Saxagliptin*	4	3

Oral antidiabetics (OAD) marketed in Germany between 2004 and 2010. Several OAD are not presented since they are not available in Germany. asterix [*]: excluded from our estimation.

Figure 1: Figure of the imported drug package of *Stilnox* produced by *Sanofi-Synthelabo* and marketed by *kohlpharma*. Source: Federal High Court of Justice [Bundesgerichtshof, Decision I ZR 173/04].

Figure 2: Figure of the original drug package of *Stilnox* produced by *Sanofi-Synthelabo*. Source: Federal High Court of Justice [Bundesgerichtshof, Decision I ZR 173/04].

Table 2: Number of observations used in final estimation by ATC4 and firm type, 2004-2010

ATC4	Orignator	Importer	Generic firm	Total
Alpha glucosidase inhibitors	505	2,821	184	3,510
Biguanides (metformin)	227	166	5,474	5,867
Combinations	399	1,263	0	1,662
Other (glinides)	489	2,439	485	3,413
Sulfonylurea	600	572	7,662	8,834
Thiazolidindiones	521	913	3	1,437
Total	2,741	8,174	13,808	24,723

Oral antidiabetic drugs in Germany over 84 periods (2004-2010). Final sample with data from *IMS Health*.

Table 3: Summary Statistics, oral antidiabetic drugs (2004-2010)

	Total		Originator		Importer		Generic manuf.	
	mean	s.d.	mean	s.d.	mean	s.d.	mean	s.d.
s_{jt} (%)	0.13	0.33	0.26	0.66	0.02	0.04	0.17	0.31
$s_j\|h$ (%) [product j in nest h]	3.3	8.2	12.9	18.9	2.8	5.4	1.6	3.3
$s_h\|g$ (%) [nest h in group g]	72.6	30.8	59.4	35.3	66.3	33.2	79.0	26.5
Price per DDD [EUR, ex-factory]	0.48	0.52	0.95	0.64	0.90	0.44	0.14	0.17
Price*: Alpha glucosidase inh.	0.90	0.24	1.12	0.32	0.87	0.21	0.82	0.20
Price*: Biguanides (metformin)	0.12	0.05	0.16	0.05	0.16	0.02	0.12	0.05
Price*: Combinations	0.94	0.49	1.21	0.64	0.86	0.40	-	-
Price*: Other (glinides)	0.97	0.44	1.22	0.52	0.95	0.42	0.80	0.34
Price*: Sulfonylurea	0.10	0.05	0.19	0.10	0.15	0.07	0.09	0.03
Price*: Thiazolidinediones	1.52	0.28	1.53	0.32	1.51	0.25	1.44	0.00
No co-payment	0.13	0.33	0.00	0.00	0.01	0.09	0.22	0.41
High strength within ATC5	0.54	0.50	0.48	0.50	0.48	0.50	0.58	0.49
# of firms within ATC5	17	9	7	8	11	5	23	5
# of firms within ATC4	21	8	15	9	14	6	27	3
# of products within ATC5	52	34	22	27	30	19	75	26
# of products within ATC4	76	42	51	38	47	25	101	34
Sales per product [in 1,000 EUR]	64	4	275	7	39	1	36	6
Danish prices in EUR	0.53	0.54	0.92	0.65	0.95	0.43	0.15	0.19

Descriptive statistics of the market of oral antidiabetic drugs $j = 1, \ldots, 700$ in Germany over 84 periods. Nest g: chemical groups (ATC4), nest h: active substances (ATC5). Own calculations with data from *IMS Health*. Price*: Price per DDD [EUR, ex-factory]. s_j: the overall market shares, $s_j|h$: the market shares of the products within the inner nest, $s_h|g$: the market shares of the inner nests within the outer nest

Table 4: Demand Side Results

$ls = \ln s_j - \ln s_0$	FE		FE.IV		Firm FE.IV	
σ_1 [active substance]	0.972***	(0.011)	0.878***	(0.024)	0.862***	(0.017)
σ_2 [chemical group]	0.811***	(0.025)	0.507***	(0.045)	0.763***	(0.009)
Price, nest 1	-2.854***	(0.465)	-2.611***	(0.438)	-3.798***	(0.054)
Price, nest 2	-4.410***	(0.328)	-5.239***	(0.368)	-0.898***	(0.208)
Price, nest 3	-6.955***	(1.598)	-4.531***	(1.203)	-1.672***	(0.057)
Price, nest 4	-0.493***	(0.124)	-1.068***	(0.277)	-2.856***	(0.049)
Price, nest 5	-0.547***	(0.446)	-2.203***	(0.526)	-5.294***	(0.262)
Price, nest 6	-0.630*	(0.356)	-0.457	(0.429)	-1.770***	(0.027)
No co-payment	0.054***	(0.007)	0.065***	(0.011)	-0.431***	(0.018)
High strength					0.296***	(0.035)
Original drug manuf.					-0.159***	(0.041)
Parallel importer					0.096***	(0.010)
Constant	-1.678***	(0.152)			-1.569***	(0.103)
Observations	25,769		24,722		23,689	
Product fixed effects	yes		yes		no	
Time fixed effects	yes		yes		yes	
Firm fixed effects	no		yes		no	
IV (σ_1,σ_2)	no		yes		yes	
IV (p_{jt})	no		no		yes	
adjusted R^2	0.94		0.93		0.92	
F-test excl. IV [σ_1 / σ_2]			15.29 / 51.43		223 / 2344	
F-test excl. IV [p_{1t} / p_{2t}]					2918 / 4009	
F-test excl. IV p_{3t} / p_{4t}					651 / 1127	
F-test excl. IV p_{5t} / p_{6t}					3747 / 2794	

Parameter estimates for the OLS (FE) and instrumental variable (FE.IV) specification shown in (3). (FE.IV) is used for the simulation. The column (Firm FE.IV) presents results of an IV specification with firm fixed effects (without product fixed effects) and additional instrumental variables for p_{jt}. Clustered (product level) standard errors in parentheses. The dependent variable is $ls = \ln s_j - \ln s_0$, where s_j = quantity sold of drug j/total market size and s_0 = outside market size/total market size. The results of the price coefficients α_j are presented by the 6 different chemical groups (ATC4) (1. Alpha glucosidase inhibitors, 2. Biguanides (metformin), 3. Combinations, 4. Other (glinides) 5. Sulfonylurea, 6. Thiazolidinediones) listed in the Table 1.

* $p < 0.1$, ** $p < 0.05$, *** $p < 0.001$

Table 5: Product-level Price Elasticities

ATC-5	OPE mean [std]	CPE, σ_1 mean [std]	CPE, σ_2 mean [std]	CPE, all mean [std]
Total	-7.55	0.33	0.22	0.003
	[5.02]	[0.31]	[0.21]	[0.001]
Alpha glucosidase inhibitors	-18.38	0.85	0.43	0.005
	[5.27]	[0.42]	[0.04]	[0.003]
Biguanides	-4.47	0.05	0.05	0.002
	[1.19]	[0.00]	[0.00]	[0.000]
Combinations	-27.48	1.50	1.50	0.001
	[9.47]	[0.13]	[0.13]	[0.000]
Other (glinides)	-8.67	0.40	0.18	0.003
	[4.25]	[0.55]	[0.03]	[0.001]
Sulfonylurea	-1.88	0.07	0.01	0.003
	[1.10]	[0.39]	[0.01]	[0.000]
Thiazolidinediones	-5.81	0.26	0.26	0.002
	[1.26]	[0.03]	[0.03]	[0.000]
Originator products	-13.09	0.80	0.36	0.004
	[9.56]	[0.79]	[0.35]	[0.002]
Parallel imports	-13.87	0.67	0.48	0.003
	[9.35]	[0.63]	[0.48]	[0.002]
Generics	-2.70	0.03	0.03	0.003
	[1.56]	[0.02]	[0.02]	[0.001]

Mean values and standard deviations of the the product-level's own- (OPE) and cross-price elasticities (CPE), based on the estimated parameters from specification (3) and by the formulas (11) to (14) for June 2006 (period 42), *310 observations*

Table 6: Marginal Costs (MC) and Mark-ups

ATC-5	Price mean [std]	MC mean [std]	Mark-up mean [std]	MC % [std]	Mark-up % [std]
Total	0.43	0.35	0.08	0.37	0.62
	[0.51]	[0.45]	[0.13]	[0.28]	[0.28]
Alpha glucosidase inhibitors	0.90	0.84	0.06	0.93	0.07
	[0.25]	[0.25]	[0.01]	[0.02]	[0.02]
Biguanides (metformin)	0.11	0.08	0.02	0.75	0.25
	[0.03]	[0.03]	[0.00]	[0.06]	[0.06]
Combinations	0.78	0.75	0.03	0.95	0.05
	[0.27]	[0.27]	[0.01]	[0.02]	[0.02]
Other (glinides)	1.03	0.86	0.17	0.82	0.18
	[0.48]	[0.44]	[0.12]	[0.09]	[0.09]
Sulfonylurea	0.11	0.05	0.06	0.35	0.65
	[0.07]	[0.06]	[0.02]	[0.21]	[0.21]
Thiazolidinediones	1.62	1.14	0.48	0.69	0.31
	[0.26]	[0.42]	[0.29]	[0.21]	[0.21]
Originator products	1.21	0.86	0.35	0.72	0.28
	[0.51]	[0.45]	[0.33]	[0.22]	[0.22]
Parallel imports	0.90	0.81	0.10	0.88	0.12
	[0.45]	[0.40]	[0.08]	[0.09]	[0.09]
Generics	0.10	0.05	0.05	0.48	0.52
	[0.03]	[0.04]	[0.02]	[0.26]	[0.26]

Absolute and and percentage mean values (with st.d.) of product prices and estimated marginal costs, which base on the Jacobians that are calculated with estimated parameters from specification (3) for June 2006 (period 42).

Table 7: Effect of PI on mean prices, total demand side surplus, and total variable profits by firm types and chemical groups

	status quo [EUR]	w/o imports [EUR]	Δ [%]
Price per DDD [Total]	0.43	0.45	-4,78
Price per DDD [Original]	1.21	1.69	-39.05
Price per DDD [PI]	0.90		
Price per DDD [Generic]	0.09	0.09	-0.05
Demand Side Surplus [Total]	3,310,943,043	3,230,807,800	+2.42
Demand Side Surplus [Original]	316,607,314	276,530,078	+12.65
Demand Side Surplus [PI]	233,358,458		
Demand Side Surplus [Generic]	2,760,977,270	2,954,277,722	-7
Demand Side Surplus [Alpha gl. inh.]	66,597,697	34,613,673	92.40
Demand Side Surplus [Biguanides]	1,501,867,501	1,635,692,008	-8.18
Demand Side Surplus [Combinations]	249,730,353	118,707,519	+110.37
Demand Side Surplus [Other]	107,627,048	69,565,255	+54.71
Demand Side Surplus [Sulfonylurea]	1,279,931,086	1,392,207,378	-8.06
Demand Side Surplus [Thiazolidinediones]	105,189,356	60,157,209	+74.86
Variable Profits [Total]	183,716,957	270,309,103	-47.13
Variable Profits [Original]	77,133,274	169,968,197	-120.35
Variable Profits [PI]	15,394,994		
Variable Profits [Generic]	91,188,688	100,340,905	-10.04
Variable Profits [Alpha gl. inh.]	3,207,739	8,357,889	-160.55
Variable Profits [Biguanides]	29,694,113	32,381,480	-9.05
Variable Profits [Combinations]	9,391,999	21,273,718	-126.51
Variable Profits [Other]	16,661,464	35,269,208	-111.68
Variable Profits [Sulfonylurea]	62,324,473	68,019,932	-9.14
Variable Profits [Thiazolidinediones]	62,437,167	105,006,874	-68.18

Mean values and percentage changes of the prices, demand side surplus and variable profits, based on the estimated parameters from specification (3) and on the simulations for June 2006 (period 42). The column *status quo* show figures from our data and the column *w/o imports* displays results from our simulation. PI: Parallel import.