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## The Welfare Impact of Parallel Imports: A Structural Approach Applied to the German Market for Oral Anti-diabetics

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# The Welfare Impact of Parallel Imports: A Structural Approach Applied to the German Market for Oral Anti-diabetics\*

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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 anti-diabetic 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 markups. 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 drugs by 11% and do not have a significant effect on prices for generic drugs. This amounts to an increase in the demand-side surplus by €19 million per year (or €130 million in total) which is relatively small compared to the average annual market size of around €227 million based on ex-factory prices. The variable profits for the manufacturers of original drugs from the German market are reduced by €18 million (or 37%) per year when parallel trade is allowed, yet only one third of this difference is appropriated by the importers.

**Keywords:** parallel imports, pharmaceuticals, structural models, anti-diabetic drugs

**JEL Codes:** I11, I18, L13, L51

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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 (e.g., Ganslandt and Maskus, 2004; Dutta, 2011). The core of this policy debate is the tension between achieving price reductions that directly or indirectly benefit consumers in the short-run and long-run incentivising innovation into new products as well as securing the safety of drugs.

Since most drug manufacturers are active in international markets, both production and R&D activities are typically carried out at the global level. 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, 2014; 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 decreased R&D investments (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., Bennato and Valletti, 2014; 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.<sup>1</sup> Indeed, drug trade mostly emerges from low-price countries such as Portugal, Spain, and Greece 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

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<sup>1</sup>Parallel imported products are generally allowed in Europe and only differ in terms of packaging or colour, as the trading firms have to add package inserts and provide labelling in German either by a new package or by a sticker overlay. As an example, see Figures 1 and 2.

in 2010 from 24% in Denmark, to 11% in Germany, 10% in the Netherlands, and 7% in the UK (EFPIA, 2013). In the market for patented drugs, 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 analysing the effect of parallel trade in the German anti-diabetics market. We estimate a structural model of demand and supply for a large panel data set containing all oral anti-diabetic drugs sold between 2004 and 2010. We focus on this indication for four 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 anti-diabetics are prescribed exclusively for the treatment of this single disease, which makes a definition of the potential market size easier to identify. Finally, the prescription procedure for a particular drug package can be modelled 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). 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 the patients.

We build on Björnerstedt and Verboven (2012) and expand their approach to the estimation of different price coefficients for different chemical groups (Slade, 2004).<sup>2</sup>

While own price elasticities vary across chemical groups and active substances as well as over time, we estimate a mean own-price elasticity of -6.6 and mean cross-price elasticities that range from 5.082 to 0.002. Based on an oligopolistic model of multi-product firms, we then recover the marginal costs and, accordingly, relative markups on prices, which range between 22% and 86% depending on the specific drug type. 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 absent parallel trade.<sup>3</sup> According to our estimates, parallel imports strongly decrease the average price of patented drugs by 11% while they only imply a limited increase by 0.7% for the price of generic drugs that are sub-

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<sup>2</sup>For a general discussion on the benefits of alternative modelling alternatives for discrete choice models of demand see also Grigolon and Verboven (2014). However, Björnerstedt and Verboven (2012) conclude that – even in the specifically regulated pharmaceutical industry – the nested logit model seems to be strongly supported for use in competition analysis.

<sup>3</sup>We talk about demand-side welfare instead of consumer welfare because, given the structure of the German health care markets, this surplus is shared among the patients, physicians, and the statutory health care system.

ject to intense competition also without parallel imports. The overall increase in demand-side welfare due to parallel trade is estimated to be €130 million over seven years, which amounts to an increase by around 4% of the total demand side surplus calculated in the market for oral anti-diabetics absent parallel trade. The corresponding decrease in variable profits in Germany due to parallel trade for the manufacturers of original drugs amounts to €125 million over the seven sample years.<sup>4</sup> Parallel importers only appropriate a small fraction (€41 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.<sup>5</sup> While some of these studies find that parallel trade achieves only limited 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 of price increases after the entry of parallel imports in 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.<sup>6</sup> Yet, all of these studies are mostly descriptive price or entry regressions and/or based on reduced-form price equations, which neither allow a careful modelling 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 analyse the market entry of generic and “me-too” drugs in the U.S. (Ching, 2010; 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, there seems to exist substitutability not only across brand-names and generics or “me-toos” of the same molecule but also among different 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

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<sup>4</sup>This number must be taken cautiously since our data does not contain information on profits original producers gain by selling their drugs to parallel traders outside of Germany (compare Subsection 3.5).

<sup>5</sup>For an overview of studies about parallel trade see the EU Report “Competitiveness of the EU Market and Industry for Pharmaceuticals” (European Commission, 2009).

<sup>6</sup>In an earlier study, Kyle (2007) found fewer market entries of innovative products in low-price countries where parallel import is allowed and concluded that parallel trade indeed hinders innovation activities.

cheaper copies from other producers are not available in markets for patented drugs. 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 anti-diabetics. Furthermore, it constitutes the first attempt to estimate a structural demand model for the German pharmaceutical market.

The paper is organised as follows. Section 2 describes the institutional details of the regulations in the German drug markets and the characteristics of the market for oral anti-diabetics. Section 3 describes our data, while Section 4 sets up our modelling 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 Diabetes and the German market for oral anti-diabetic drugs

Diabetes is a metabolic chronic disease in which either the body does not produce enough insulin (type 1 diabetes) or it does not respond to the insulin that is produced (type 2 diabetes). Usually, the disease results in hyperglycaemia, or high blood sugar, and leads to damages of the body's systems, e.g., nerves and blood vessels (WHO, 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 large 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 for oral anti-diabetic drugs is large. In 2010, it amounted to about €572 million in pharmacy selling prices and €249 millions in ex-factory prices (own calculations). The treatment of type 2 diabetes ranges from dietary nutrition and physical activity to oral anti-diabetic drugs and, in severe cases, insulin. Seven chemical groups of oral anti-diabetics 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*), increase the physiological function of insulin (*thiazolidinediones*), or decrease blood glucose levels indirectly by increasing incretin levels (*Dipeptidyl peptidase 4 (DPP-4) inhibitors*). 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 that can be divided into either off-patent markets with free access for generic products or markets for patented drugs with strictly regulated access. However, independently of the specific regulation of reimbursement and disposal, all firms are free to set prices.

## Cost-sharing and the distribution of parallel imports

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. These 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. Thus, off-patent markets face fierce competition by generic drugs and reference pricing (e.g., Herr and Suppliet, 2012). Rebate contracts do not play a big role in our analysis since they only became available in 2008 and not relevant for patented drugs or parallel imports.

In Germany, the distribution of parallel imports is supported by the regulator. Pharmacists need to fulfil a specific quota: the share of total turnover gained by parallel imports per patented active substance has to exceed 5% (BMG, 2013).<sup>7</sup> 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. However, in our data, these thresholds are only met by a small fraction of parallel imports and we observe both prices below and above them.

## 3 Empirical Strategy

To empirically analyse the extent of competition in the German market for oral anti-diabetic drugs, we follow the existing literature (e.g., Crawford and Shum, 2005; Dunn, 2012; Dutta, 2011; Kaiser, Mendez, Rønde, and Ullrich, 2013) and derive a demand function from the joint utility maximization of the two main agents – the patient and the physician – who participate in the decision process.<sup>8</sup> In this sense, the demand-side of our model is a reduced form of a more complex decision making structure. We approximate this process by using a two-level nested logit model described below.

### 3.1 Demand Model

We observe one geographical market (Germany) over  $t = 1, \dots, 84$  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 type 2 diabetes. The following specification of the demand estimation closely follows previous work from Berry (1994); Verboven (1996), and Slade (2004).

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<sup>7</sup>Additionally, this must hold for each health insurance and quarter.

<sup>8</sup>Potentially, pharmacists and health insurers also are involved in this decision process, yet their influence in the determination of the demand for specific drugs is expected to be limited.

## Joint utility maximization

The  $I$  agents,  $i = 1, \dots, I$ , in each market/month  $t$  choose one out of  $J_t$  products,  $j = 1, \dots, J_t$ .<sup>9</sup> In our setting, the agent's choice is represented by the joint decision of the two stakeholders: the patient and the physician.

The patient first provides information on her health status and, after discussing with the physician the most suitable chemical group and active substance, she finally chooses which specific product and package to buy at the pharmacy. We expect patients to show price-sensitive behaviour and have a preference for drugs that are fully exempt from co-payments. We also assume that patients respond to prices, as co-payments are a monotonic transformation of them, but to a smaller extent than doctors given the nature of the regulatory system and the limited amount of the co-payments.

The doctor is assumed to mostly decide in the patient's interest with respect to medical needs and other preferences, such as price sensitivity or taste. However, physicians are also assumed to pursue their own utility as they are encouraged to consider economic aspects in their prescription behaviour even though 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.

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. The agent  $i$ 's conditional indirect utility function for drug  $j$  is assumed to be:

$$u_{ijt} = -\alpha_{gj}p_{jt} + \beta x_{jt} + \xi_{jt} + v_{ijt}, \quad (1)$$

where  $p_{jt}$  is the price of product  $j$  in time/market  $t$ , and  $x_{jt}$  is the vector of other observed product characteristics, such as the active substance, the strength, or the package size. Among these other characteristics, we also consider whether the drug is exempt from co-payments. This should capture an important aspect of the patients' decision, i.e. the preference not to pay to get a drug. We use a more flexible specification compared to the standard nested-logit model and allow the price coefficients  $\alpha_g$  to depend on the characteristics of the product, namely on the chemical groups  $g = 1, \dots, G$  (Slade, 2004).<sup>10</sup> The first reason for this modelling assumption is that we assume preferences on

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<sup>9</sup>Discrete choice models such as the nested-logit do not allow modelling 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 combining different groups of active substances. We are therefore able to ease the complementarity problems by defining bundles of drugs which can be seen as substitutes to single drugs entailed in other nests.

<sup>10</sup>In a robustness check, we additionally insert the co-payments into this utility function to try to better disentangle the physician's and the patient's utilities. Yet, this is problematic from a theoretical viewpoint. Moreover, it would induce multicollinearity problems in almost all ATC4 groups. In the only sensible specification, where we do not estimate group-specific price and co-payment coefficients and after controlling for full co-payment exemption, the co-payment variable is not significant while the price is. Therefore, it does seem that the demand side's price sensitivity is mostly due to the physicians' economic incentives as well as patients' preference for full exemption. The results are available upon request.



prices and thus elasticities to differ by different patients’ medical needs, severity of illness, medical history, age, etc. which is reflected by the choice of different chemical groups. Second, this approach 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).<sup>11</sup> The vector  $\xi_{jt}$  contains characteristics that are observed by the firms, the patients, and the physicians but are unobserved by the researcher and might include brand perception, marketing expenditures, or publicly unknown interactions with other drugs. The random utility terms  $v_{ijt}$  reflect the influence of individual-specific taste. We assume that each agent maximises utility,  $u_{ijt}$ , given the characteristics of the product. The mean utility of product  $j$  in time/market  $t$  is:

$$\delta_{jt} = -\alpha_{gj}p_{jt} + \beta x_{jt} + \xi_{jt} \quad (2)$$

and the mean utility of the outside good  $j = 0$  in each time/market is normalised to zero:  $\delta_{0t} = 0$ .

### Nesting structure

In the market for oral anti-diabetics, there is a natural order of choices, which we exploit in our nesting structure. First, the physician chooses the chemical group and second the active substance suitable to the patients’ physical condition (e.g. body weight), individual preferences, medical history, co-morbidities, side-effects, and age. It is well understood that physicians make this choice in a hierarchical order with respect to both across and within chemical groups and active substances. For instance, the guidelines of the National Institute for Health Care and Excellence in the UK clearly advise initiating oral glucose control therapies for type 2 diabetes with *metformin*, followed by *insulin secretagogues* or *acarbose*, then other oral agents such as *exenatide*, and finally *thiazolidinediones*. When exactly the physician is expected to switch across groups depends on the patient’s health status.<sup>12</sup>

Based on the specific decision structure described above, 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 physicians’ and the patients’ decisions in these markets, while the product’s continuous characteristics play a less fundamental role (e.g., Grigolon and Verboven, 2014). They are mostly captured by the product fixed-effects in our setting.<sup>13</sup>

<sup>11</sup>The linear dependency results in larger elasticities for more expensive products, which is not consistent with economic intuition.

<sup>12</sup>For the German guidelines see [http://www.deutsche-diabetes-gesellschaft.de/fileadmin/Redakteur/Leitlinien/Evidenzbasierte\\_Leitlinien/EBL\\_Dm\\_Typ2\\_Update\\_2008.pdf](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.

<sup>13</sup>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 considered here. Yet, as a robustness check, we consider the active substance’s concentration as an exogenous demand factor in the specification where we use firm-level fixed-effects (Firm FE.IV).

The first level of nests are  $G$  different chemical groups,  $g = 1, \dots, G$ . The second level of nests consists of  $H_g$ ,  $h = 1, \dots, H_g$ , 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,  $v_{ijt}$ . Following Verboven (1996), we derive the estimation equation for each period  $t$ :

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

where  $s_{jt} = q_{jt}/M_t$  and  $s_{0t} = 1 - \sum_{j=1}^J [q_{jt}/M_t]$  are the market shares of drug  $j$  and of the outside good, respectively,  $q_{jt}$  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  $s_{j|h_g,t} = \frac{q_{jt}}{\sum_{j \in H_g} q_{jt}}$  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 assumed to be known to the firms, the patients, and the physicians but not to the researchers, and they are captured by  $\xi_{jt}$ . 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. Thus, they are 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  $\xi_j$  is captured by 700 product fixed-effects and  $\xi_t$  is captured by 84 time dummies similar to Nevo (2001). The remaining error term  $\omega_{jt}$  is defined as a product-and-time-specific error term.<sup>14</sup> 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 systematic sources of correlation among prices and *the changes* in unobserved product characteristics. Yet, in order to assess the robustness of our findings, we adopt 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 the German prices for drug  $j$  at time  $t$  by means of the Danish prices for the same drug in the same time period.<sup>15</sup>

This strategy also has an additional advantage. Since we use ex-factory prices, one might claim that they are measured with error due to the existence of rebate contracts among generic producers and health insurance companies. This might in turn create endogeneity problems if the contracted rebates are systematically correlated with the temporal change in unobserved characteristics

<sup>14</sup>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 Rønne (2010).

<sup>15</sup>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 authorised pharmaceutical products marketed in Denmark are publicly available at <http://medicinpriser.dk/>.

of the products (our error term). While we do not think that this should be a major problem in our case, the IV approach would nonetheless allow us to obtain consistent estimate.<sup>16</sup>

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  $\sigma_1$  and  $\sigma_2$ . Following Berry (1994) and Dutta (2011) we use nine standard instruments which account for the crowdedness in the product space.<sup>17</sup> The identifying assumption is therefore that the instruments, which are correlated with the inner-group market shares and prices through the markups, 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) by calculating own-price elasticities and cross-price elasticities that 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 of elasticities.

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 asymmetry 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.

### 3.4 Supply Side

In our analysis, we assume that 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 branding. In our sample 68 firms sell 700 products either in the same or in different classes of active substances. Hence, we assume that all these drugs (patented, imported,

<sup>16</sup>Since first, rebate contracts in Germany only became used starting in 2008, second, they only play a major role for generic drugs and, third, among these, only for a small fraction of the largest companies, we do not think that measurement problems due to rebates are an issue in our sample. Furthermore in a robustness check, we restrict our sample to the years 2004 to 2007. Coefficient estimates are quite similar, but a bit less precise than in our preferred model. Only for two ATC4 groups (1 and 4) the price coefficients' estimates are smaller and not significantly different from zero since generic competition started later in these groups (results available upon request).

<sup>17</sup>Our instruments are: the number of different packages a firm offers per product, the number of firms active in the product specific ATC5 group and in all other ATC5 as well as ATC4 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-linearised (e.g., Björnerstedt and Verboven, 2012).

or generic) are, to some extent, substitutes one of the other. Indeed, our demand estimation approach enables us to recover all possible cross-price elasticities among them. Further, we use the observed ownership structure to account for the fact that multi-product firms internalise the competitive externalities that each of their products exerted on the demand of their other products.

Finally, we assume that firms compete in prices. This is the standard assumption made in the relevant literature (e.g., Dunn, 2012; Dutta, 2011) and reflects the observation that pharmaceutical firms do not compete in quantities when producing chemical drugs.<sup>18</sup> 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. In markets for patented drugs, like the one for *thiazolidinediones*, the patent holder is granted a short run monopoly. However, since in our model we explicitly allow for parallel imports and model the competition patented drugs face from similar active substances, we believe that Bertrand-Nash behaviour with differentiated goods is a reasonable approximation to describe the market for patented oral anti-diabetics.

The profit functions of the multi-product firm  $f$  ( $f = 1, \dots, 68$ ) active in time/market  $t$  that manufacture a subset  $F_{ft}$ , of the  $J$  products is:

$$\Pi_{ft} = \sum_{j \in F_{ft}} (p_{jt} - c_{jt})q_{jt}(\mathbf{p}_t) - C_f, \quad (4)$$

where  $q_{jt}(\mathbf{p}_t)$  is the sold quantity of product  $j$  in time/market  $t$  as a function of the vector of all prices,  $\mathbf{p}_t$ , here defined as  $q_{jt}(\mathbf{p}_t) = s_{jt} \times M_t$ . This definition allows us to include the market share of the outside good as well as 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). We assume constant marginal costs  $c_{jt}$  – yet we allow them to vary over time – and we denote the fixed costs with  $C_f$ .

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). In each time/market  $t$ , the price vector,  $\mathbf{p}_t$ , has to satisfy the following  $J_t$  first-order conditions (in matrix notation):

$$\mathbf{q}_t(\mathbf{p}_t) + (\Omega_t^F \otimes \Delta(\mathbf{p}_t))(\mathbf{p}_t - \mathbf{c}_t) = 0, \quad (5)$$

where  $\mathbf{q}_t(\mathbf{p}_t)$ ,  $\mathbf{p}_t$ , and  $\mathbf{c}_t$  are  $J_t \times 1$  vectors of quantities, price, and marginal costs, respectively.  $\Omega_t^F$  is the firms' product ownership matrix ( $J_t \times J_t$ ) with elements ( $\Omega_t^F(j, k)$ ) equal to 1 if product  $j$  and  $k$  are produced by the same firm in time/market  $t$ , and 0 otherwise. The ( $J_t \times J_t$ ) matrix of first derivatives  $\Delta(\mathbf{p}_t) = \frac{\partial \mathbf{q}_t(\mathbf{p}_t)}{\partial \mathbf{p}_t}$  is multiplied element-by-element with the ownership matrix. To identify the marginal cost  $\mathbf{c}_t$ , Equation (5) can be rearranged into

$$\mathbf{c}_t = \mathbf{p}_t - (\Omega_t^F \otimes \Delta(\mathbf{p}_t))^{-1} \mathbf{q}_t(\mathbf{p}_t). \quad (6)$$

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<sup>18</sup>Other ways to model conduct in this market would be to assume joint profit maximization due to collusion or a Stackelberg pricing game, where the producers of original drugs are the price leaders and generics are the followers. However, these would be also very particular assumptions, which had not been identified to hold in general for this market.

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

### 3.5 Simulation

To quantify the welfare effects of parallel imports in Germany we compare the status quo market with parallel imports versus 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), for instance by not entering low-price countries or by offering slightly different versions (in package size or strength) in different countries. Furthermore, as Desogus (2010) shows discussing the Adalat Case, quantity restrictions on intra EU trade –limiting the availability of parallel imports– have been interpreted as a unilateral conduct by the EU. The situation is different in the U.S., where re-imports are prohibited mostly because of patient’s safety issues but also because they are expected to harm innovative firms.<sup>19</sup> 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, for example by stopping illegal imports from Canada or Mexico.

Hence, we assume that the choice set in the counterfactual situation is different to that in the status quo. Specifically, similar to the 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  $J_t^{sim} = J_t - I_t$ , where  $I_t$  is the number of parallel imports in time/market  $t$ . Accordingly, we define the  $J_t^{sim}$  nested-logit demand functions as:

$$q_{jt}(\mathbf{p}_t^{sim}, \hat{\delta}_t) = M_t \cdot s_{jt}(\mathbf{p}_t^{sim}, \hat{\delta}_t) \cdot s_{j|h,g,t}(\mathbf{p}_t^{sim}, \hat{\delta}_t) \cdot s_{h|g,t}(p_t^{sim}, \hat{\delta}_t) \quad (7)$$

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

$$\mathbf{q}_t(\mathbf{p}_t^{sim}, \hat{\delta}_t) + (\Omega_t^F \otimes \Delta_t(\mathbf{p}_t^{sim}, \hat{\delta}_t))(\mathbf{p}_t^{sim} - \hat{\mathbf{c}}_t) = 0, \quad (8)$$

We then determine the equilibrium simulated prices ( $\mathbf{p}_t^{sim}$ ) and simulated quantities ( $\mathbf{q}_t(\mathbf{p}_t^{sim})$ ) by using a Newton algorithm on Equations (7) and (8). With the new simulated equilibrium ( $\mathbf{p}_t^{sim}$  and  $\mathbf{q}_t(\mathbf{p}_t^{sim})$ ) and the estimated structural parameter ( $\hat{\delta}_t$  and  $\hat{\sigma}$ ) we calculate the demand-side surplus (e.g., Dutta, 2011):<sup>20</sup>

$$DS(\mathbf{p}_t^{sim}) = \frac{1}{\hat{\alpha}_g} \text{Mln} \left( 1 + \sum_{g=1}^g \left( \sum_{h=1}^{H_g} D_{h|g}^{\frac{(1-\hat{\sigma}_1)}{(1-\hat{\sigma}_2)}} \right)^{(1-\hat{\sigma}_2)} \right), \quad (9)$$

<sup>19</sup>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.

<sup>20</sup>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 directly to the consumers, we prefer to use the notation demand-side surplus.

where  $D_{h|g,t} = \sum_{jt \in h|g} \exp\left(\frac{\delta_{jt}}{1 - \sigma_1}\right)$  and the firms' variable profits are:

$$VP(\mathbf{p}_t^{sim}) = \sum_{j \in F_{jt}} (p_{jt}^{sim} - \hat{c}_{jt}) q_{jt}(\mathbf{p}_t^{sim}) \quad (10)$$

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

## 4 Data

Our data set contains monthly sales and prices of all oral anti-diabetic 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)<sup>21</sup>, thus allowing us to compare products with different active substances and presentations. Each of the drugs is characterised by the name, active substance, company name (either producer or parallel importer), package size, strength, defined daily dosages, 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 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 €0.01 to €0.27 and reflect the fact that some products are sold in markets for patented drugs 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 anti-diabetic drugs. We estimate our demand specification with the two- and threefold quantity of sold DDD as a robustness check and yield very similar results.

To ensure homogeneous market conditions, we only include in our sample products that are covered by the German SHI. A complete classification of the drugs analysed in this study is given in Table 1 in the Appendix. In our estimations, we only include packages with a market share within the subgroup of active substances (ATC 5) larger than 0.1%.<sup>22</sup> 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 inhibitors* (287 observations) and the combination of one of them (sitagliptin) with *metformin* (116 obs.) as well as *glimepiride* & *pioglitazone* and *gliquidone* since they form a special group of late innovations

<sup>21</sup>The WHO Collaborating Centre for Drug Statistics Methodology in Oslo provides a list of DDD for each active substance on a yearly basis.

<sup>22</sup>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. The reduced sample still covers 92% of the market in terms of sales in 2006.

with very high prices, which would constitute an extreme outlier not suitable for estimating a general model for the entire market (compare Table 1 in the Appendix).<sup>23</sup>

Table 2 in the Appendix gives an overview of the 24,603 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 ( $s_{jt}$ ), the market shares of the products within the inner nest ( $s_{jt|h}$ ) as well as the market shares of the inner nests within the outer nest ( $s_{ht|g}$ ). The variables are presented by firm type. In our preferred specification we control for the patients' preference not to pay for the chosen drugs. This is captured through the dummy *co-payment exemption* that takes on the value of 1 if drugs are fully exempt from co-payments. This happens when their price undercuts a certain threshold, which is set at 70% of the reference price. In our sample, it only occurs in one of the ATC4 groups (*sulfonylurea*).<sup>24</sup> Prices, sales per product, as well as market shares vary considerably across manufacturer 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 presented in Equation (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 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 by means of the Danish prices. The coefficients  $\sigma_1$  and  $\sigma_2$  measure the correlation of agents' preferences within the nests of active substances and chemical groups, respectively, and the six price coefficients [ $\alpha_g$ ] represent the average effect of the price on the market shares for each of the chemical groups. In

<sup>23</sup>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.

<sup>24</sup>Specifically, only 3,766 among the 10,504 observations in the ATC4 group *sulfonylurea* correspond to co-payment exempt drugs. Some drugs change status (from non-exempt to exempt and vice versa) across the sample periods which allows us to identify the effect of the co-payment exemption in our regressions with product-specific fixed-effects.



all specifications, all parameters (except of one) are significant and have the expected signs.

[Table 4 about here]

As conjectured, the mean utility positively and significantly depends on the co-payment exemption which therefore confirms the importance to control for patients' preferences. Moreover, both coefficients measuring the correlation of preferences within the two nests [ $\sigma_1$  and  $\sigma_2$ ] are consistent with random utility theory ( $0 \leq \sigma_2 \leq \sigma_1 \leq 1$ ) across all three models. They are considerably smaller after controlling for possible endogeneity, as expected. Model Firm FE.IV additionally shows that the demand significantly increases if the drug stems from the originator manufacturer or a parallel importer as opposed to the generic manufacturer, capturing the preference for branded products. Furthermore, above average strength is negatively associated with the market share.

From here on we focus on our preferred specification [FE.IV]. The six price coefficients are negative and statistically significant from zero. 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  $-4.2$  and group 4 represents a market with patented active substances and a considerably lower price coefficient of  $-0.5$ .

For a clear interpretation of these estimates in terms of substitution patterns, we then need to calculate elasticities. The mean value of own- and cross-price elasticities of all products across all months are presented in Table 5. The own price elasticities vary considerably across groups ( $-37$  to  $-1$ , mean:  $-6.65$ ), while the average cross-price elasticity within the same nest of active substances ( $0.45$ ) is larger than within the upper nest of the respective chemical group ( $0.26$ ) and indicates a strong substitution among products in similar nests. The mean cross-price elasticity for products outside the chemical group is small ( $0.004$  on average) and reflects the low substitutability among drugs from different chemical groups. The high correlation among preferences for 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, colour, 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 markups for each of the 84 sample months. Table 6 presents marginal costs and markups as a mean percentage over all drugs across all time periods. On average, marginal costs are 33% 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 utilise 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]

The variation of margins and markups over time is also presented in Figure 3 aggregated at the year level to smooth out short term volatility. Marginal costs for all firms' types (original producers, importers, and generic manufacturers) seem to be quite constant over time. Interestingly, however, markups seem to substantially vary over time with a very striking decreasing trend of the mean value for manufacturers of original drugs. We interpret this finding as the result of the increasing overall availability of low-priced generic products as well as parallel import competition.

[ Figure 3: Marginal costs and markups over time 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 (mean) and quantities (total) due to the existence of parallel imports over all 84 months in our sample. Prices of originator drugs decrease on average by ca. 11% and prices of generic drugs increase on average by only 0.7% due to parallel trade in the German market for oral anti-diabetics. The overall average price in the market increases by ca. 10% because of the existence of parallel imports, which are more expensive drugs with respect to generics. Hence since the entire price distribution changes, one cannot make a clear comparison with respect to the situation without parallel trade. In order to do that, we also report the average price of original drugs and generics excluding parallel imports. Clearly, this average price decreases as a consequence of increased competition. Moreover, we observe an expansion of demand by 2.7% due to the introduction of new goods through parallel trade. Specifically, the reduction of over 218 million DDD generics (-0.5%) and over 7 million DDD original drugs (-2.5%) is overcompensated by the sales of 428 million DDD of parallel imports.

[Table 7 about here]

We then calculate the change in demand-side surplus and variable profits generated by the introduction of parallel trade, which are shown in Table 8. The change in demand-side surplus amounts to about €130 million in total (3.7% of the level without parallel trade) or ca. €19 million per year. These figures do not seem to be particularly large in comparison to the average annual market size of €227 million based on ex-factory prices.

[Table 8 about here]

The average demand-side effect comes mostly from the lower price level for original drugs, but is also strongly influenced by the demand expansion as well as the behaviour of the marginal consumer. 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 offset 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.<sup>25</sup> 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* (*metformin*) and *sulfonylurea* groups, where several generic products are sold. A side remark on this result is that, apparently, competition by generics does indeed work. When we look at the time evolution in Figure 4, we also observe some variation in the changes of demand-side surplus over time. Specifically, we observe a substantial jump in the change in demand-side surplus created by parallel trade after 2007.<sup>26</sup>

[ Figure 4: Demand-side surplus over time about here]

The final step of our welfare analysis regards the gains and losses for manufacturers. Since we do not have a measure of fixed costs, we only analyse the effect of parallel trade on variable profits realised in Germany and hence measure an upper bound to the possible decrease in the incentive to invest in R&D for originators. On average, as shown in the lower part of Table 8, variable profits decrease by about €102 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 €125 million (not taking into account sales in foreign countries, which would be (re-)imported).<sup>27</sup> Only a small part of these lost profits, €41 million, is transferred to parallel importers. Furthermore, producers of generic drugs face a reduction of their variable profits by about €18 million.

Unfortunately, we cannot derive a complete welfare analysis absent a reasonable measure of fixed costs as well as the profit effects of parallel trade in other countries where firms active in Germany also operate. Moreover, our results are clearly affected by the existence of other extensive demand-side and price regulations that affect health care markets in Germany and might eventually reduce the ability of parallel trade to exert effective competitive pressure on

<sup>25</sup>Please notice that the sum of the levels and differences of demand-side surplus across drugs types are not equal to the total. This is due to the fact that the demand-side surplus is calculated as a non-linear function of the mean utilities according to equation (9).

<sup>26</sup>We also compared the mean co-payment with and without parallel trade. Since we neither observe reference prices or contracted rebates for the two ATC4 groups with generic competition nor the exemption for specific individuals, this average co-payment potentially entails some measurement error. For the entire sample, the mean co-payments are on average around 2% lower in our simulated data (€5.46) than in our observed data (€5.56). This reflects the same logit as discussed above and it is driven by the fact that the price of parallel imports is higher than the price of generics. While the co-payments for generics are very similar in the two scenarios, the co-payments for original products are almost 50 EUR cents per package lower due to parallel trade.

<sup>27</sup>Notice, however, that parallel trade most likely increase the profits of these multi-national firms due to the increased sales of their products to parallel importers in other countries.

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. These simulations exceed the scope of this paper.

## 6 Conclusion

In this paper, we study the effect of parallel trade on welfare in the German market for oral anti-diabetics. To this aim, we develop and estimate the first structural demand model of the German pharmaceutical market. The estimated demand for anti-diabetic drugs seems to be quite elastic, with an average own-price elasticity of  $-6.65$ . These results 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 behaviour (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’ behaviour 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 a price decrease of 11% for original drugs and no change for generics 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 €130 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. This is closely related to the ability to measure profits changes for innovative manufac-

turers. By definition, parallel traders gain arbitrage profits and do not conduct any investments in R&D. Thus, one effect of the policy is to transfer 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 in the German market by over €125 million due to the introduction of parallel trade. This loss in variable profit is, however, only to a small fraction (€41 million) transferred to parallel importers and it rather benefits the statutory health insurance. Yet, to get a complete picture of parallel trade's effects on manufacturers profits and incentives to innovate we would need to consider the global nature of production and R&D. While original drugs' manufacturers lose some profits in markets with parallel trade due to increased competition, they most likely increase their profits in other markets by selling their drugs to parallel importers. Which effect prevails is unclear especially because it seems that parallel trade, by decreasing the overall price level, also has the effect to expand overall demand. Hence to carefully answer these questions, we would need a much richer model of multi-country competition and a much more extensive dataset.

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## 7 Appendix

### 7.1 Elasticities

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

$$\frac{\partial q_{jt}}{\partial p_{jt}} \frac{p_{jt}}{q_{jt}} = -\alpha p_{jt} \left( -\frac{1}{1-\sigma_1} + \left( \frac{1}{1-\sigma_1} - \frac{1}{1-\sigma_2} \right) s_{jt|h_g} + \left( \frac{\sigma_2}{1-\sigma_2} \right) s_{jt|g} - s_{jt} \right). \quad (11)$$

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

$$\frac{\partial q_{jt}}{\partial p_{kt}} \frac{p_{kt}}{q_{jt}} = -\alpha p_{jt} \left( \left( \frac{1}{1-\sigma_1} - \frac{1}{1-\sigma_2} \right) s_{jt|h_g} + \left( \frac{\sigma_2}{1-\sigma_2} \right) s_{jt|g} - s_{jt} \right). \quad (12)$$

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

$$\frac{\partial q_{jt}}{\partial p_{kt}} \frac{p_{kt}}{q_{jt}} = -\alpha p_{jt} + \left( \left( \frac{\sigma_2}{1-\sigma_2} \right) s_{jt|g} - s_{jt} \right). \quad (13)$$

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

$$\frac{\partial q_{jt}}{\partial p_{kt}} \frac{p_{kt}}{q_{jt}} = \alpha p_{jt} s_{jt}. \quad (14)$$

## 8 Figures and Tables

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

<b>ATC4: chemical (sub-) group</b>	<b>ATC5: active substance / chemical substance</b>	<b>Total # of products</b>	<b>Total # of firms</b>
1. Alpha glucosidase inhibitors	Acarbose	34	12
	Miglitol	8	5
2. Biguanides	Metformin	173	45
	Metformin & Rosiglitazone	28	11
3. Combinations of oral blood glucosidase lowering drugs	Glimepiride & Rosiglitazone	19	6
	Metformin & Pioglitazone	10	8
	Glimepiride & Pioglitazone*	4	1
	Metformin & Sitagliptin*	4	1
	Metformin & Vildagliptin	15	3
4. Other blood glucosidase lowering drugs, excl. insulin (here: glinides)	Repaglinide	66	19
	Nateglinide	4	3
	Exenatide*	-	-
5. Sulfonylurea	Glibenclamide	53	28
	Glibornuride	3	3
	Gliquidone*	2	1
	Gliclazide	4	2
	Glimepiride	212	31
6. Thiazolidinediones	Pioglitazone	27	9
	Rosiglitazone	6	4
Dipeptidyl peptidase 4 (DPP-4) inhibitors	Sitagliptin*	8	6
	Vildagliptin*	4	2
	Saxagliptin*	4	3

Oral anti-diabetics (OAD) marketed in Germany between 2004 and 2010. Several OAD are not available in Germany and hence not reported in the table. The symbol [\*] denotes that the group is 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	Originals	Imports	Generics	Total
1. Alpha glucosidase inhibitors	338	1,434	48	1,820
2. Biguanides (metformin)	275	421	7,211	7,907
3. Combinations	353	988	0	1,341
4. Other (glinides)	322	1,586	312	2,220
5. Sulfonylurea	589	766	9,030	10,385
6. Thiazolidindiones	399	531	0	930
Total	2,276	5,726	16,601	24,603

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

Table 3: Summary statistics, oral anti-diabetic drugs (2004-2010)

	Total		Originals		Imports		Generics	
	mean	s.d.	mean	s.d.	mean	s.d.	mean	s.d.
Market shares								
$s_{jt}$ [in %]	0.03	[0.09]	0.09	[0.20]	0.01	[0.01]	0.04	[0.07]
$s_{j h,t}$ [in %]	0.03	[0.07]	0.13	[0.17]	0.03	[0.05]	0.01	[0.03]
$s_{h g,t}$ [in %]	0.78	[0.26]	0.66	[0.31]	0.74	[0.27]	0.82	[0.24]
Price per package	21.61	[29.74]	47.48	[47.15]	43.05	[39.25]	10.67	[10.22]
Price per DDD								
1. Alpha gluc. inh.	0.07	[0.24]	0.15	[0.38]	0.21	[0.38]	0.00	[0.04]
2. Big. (metformin)	0.04	[0.07]	0.02	[0.05]	0.01	[0.05]	0.05	[0.07]
3. Combinations	0.04	[0.18]	0.12	[0.30]	0.13	[0.30]	0.00	[0.00]
4. Other (glinides)	0.08	[0.29]	0.18	[0.50]	0.24	[0.43]	0.01	[0.11]
5. Sulfonylurea	0.04	[0.06]	0.05	[0.09]	0.02	[0.05]	0.05	[0.05]
6. Thiazolidinediones	0.06	[0.29]	0.27	[0.59]	0.14	[0.43]	0.00	[0.00]
No co-payment	0.15	[0.36]	0.00	[0.00]	0.02	[0.13]	0.22	[0.41]
# of firms in ATC5	23	[10]	13	[11]	12	[9]	27	[6]
# of firms in ATC4	25	[10]	17	[11]	14	[9]	30	[4]
# of products in ATC5	80	[48]	42	[45]	36	[38]	100	[37]
# of products in ATC4	99	[55]	58	[52]	46	[45]	124	[40]
Danish prices [in EUR]	0.37	[0.48]	0.84	[0.71]	0.87	[0.47]	0.13	[0.14]

We report the descriptive statistics for the 700 oral anti-diabetic drugs in Germany over 84 months (2004-2010). Nest  $g$  is defined at the chemical group level (ATC4), nest  $h$  is defined at the active substance level (ATC5). We use 6 different chemical groups (ATC4): 1. Alpha glucosidase inhibitors, 2. Biguanides (metformin), 3. Combinations, 4. Other (glinides) 5. Sulfonylurea, 6. Thiazolidinediones.  $s_{jt}$  is the overall market share of product  $j$  in month  $t$ ,  $s_{j|h,t}$  is the market share of the product within the inner nest (ATC 5),  $s_{h|g,t}$  is the market share of the inner nest (ATC5) within the outer nest (ATC4). All prices are ex-factory and in EUR. All values are based on our own calculations with data from *IMS Health*. 24,603 observations.

Table 4: Demand estimation results

$ls_{jt} = \ln s_{jt} - \ln s_{0t}$	FE		FE.IV		Firm FE.IV	
$\sigma_1$ [active substance]	0.987***	(0.005)	0.854***	(0.031)	0.991***	(0.052)
$\sigma_2$ [chemical group]	0.609***	(0.045)	0.598***	(0.055)	0.604***	(0.069)
Price, ATC4, group 1	-4.450***	(0.492)	-4.407***	(0.478)	-11.586***	(2.273)
Price, ATC4, group 2	-4.145***	(0.245)	-3.992***	(0.308)	-7.503***	(1.002)
Price, ATC4, group 3	-6.636***	(1.164)	-7.989***	(1.322)	-7.591***	(1.653)
Price, ATC4, group 4	-0.508***	(0.134)	-0.789***	(0.213)	-4.805***	(0.388)
Price, ATC4, group 5	-1.493***	(0.303)	-1.421***	(0.400)	-5.680***	(1.138)
Price, ATC4, group 6	-0.523**	(0.177)	-0.952***	(0.265)	-2.938***	(0.291)
Co-pay exemption	0.038***	(0.005)	0.087***	(0.013)	0.017	(0.041)
Original					2.514***	(0.517)
Import					0.056	(0.079)
Constant	-1.297***	(0.065)			-1.854***	(0.261)
Observations	24,603		24,603		24,603	
Product fixed effects	yes		yes		no	
Time fixed effects	yes		yes		yes	
Firm fixed effects	no		yes		no	
Concentration dummies	no		no		yes	
IV ( $\sigma_1, \sigma_2$ )	no		yes		yes	
IV ( $p_{jt}$ )	no		no		yes	
Adj. R-squared	0.971		0.954		0.950	
$F$ -test excl. IV [ $\sigma_1 / \sigma_2$ ]			18.55 / 120.99		36.72 / 121.96	
$F$ -test excl. IV [ $p_{1t} / p_{2t}$ ]					2.15 / 25.31	
$F$ -test excl. IV $p_{3t} / p_{4t}$					2.21 / 82.51	
$F$ -test excl. IV $p_{5t} / p_{6t}$					137.00 / 0.89	

In the first two columns, we report the parameter estimates for the OLS (FE) and instrumental variable (FE.IV) estimations of equation (3). The specification (FE.IV) is used for the simulation. Column (Firm FE.IV) reports the results from an IV specification with firm fixed effects (without product fixed effects) and where the prices  $p_{jt}$  are instrumented with the corresponding Danish prices. The dependent variable in all specifications is  $ls_{jt} = \ln s_{jt} - \ln s_{0t}$ , where  $s_{jt}$  = quantity sold of drug  $j$  in month  $t$ /total market size in month  $t$  and  $s_0$  = market share of the outside option in month  $t$ /total market size in month  $t$ . The heterogeneous price coefficients  $\alpha_j$  are reported separately for the 6 different chemical groups (ATC4) listed in the Table 1: 1. Alpha glucosidase inhibitors, 2. Biguanides (metformin), 3. Combinations, 4. Other (glinides) 5. Sulfonylurea, 6. Thiazolidinediones). The clustered (product level) standard errors are reported in parentheses. The symbols \*, \*\*, \*\*\* represent significance at the 1%, 5%, and 10% levels, respectively.

Table 5: Product-level Price Elasticities

ATC-5	OPE	CPE, $\sigma_1$	CPE, $\sigma_2$	CPE, all
	mean [std]	mean [std]	mean [std]	mean [std]
Total	-6.652 [10.620]	0.452 [1.399]	0.258 [0.734]	0.004 [0.004]
ATC 4				
1. Alpha glucosidase inhibitors	-24.680 [6.751]	1.837 [1.198]	0.988 [0.078]	0.007 [0.007]
2. Biguanides (metformin)	-3.478 [1.049]	0.031 [0.001]	0.031 [0.001]	0.002 [0.000]
3. Combinations	-37.340 [16.280]	5.028 [3.275]	4.126 [1.584]	0.009 [0.002]
4. Other (glinides)	-4.818 [2.461]	0.300 [0.603]	0.142 [0.021]	0.003 [0.001]
5. Sulfonylurea	-0.991 [0.409]	0.023 [0.030]	0.011 [0.003]	0.003 [0.000]
6. Thiazolidinediones	-8.685 [2.409]	0.945 [0.527]	0.526 [0.115]	0.004 [0.001]
Original	-18.020 [14.22]	2.309 [3.166]	0.957 [1.320]	0.009 [0.007]
Import	-15.570 [14.63]	0.968 [1.280]	0.636 [0.706]	0.006 [0.006]
Generic	-2.321 [1.895]	0.030 [0.049]	0.025 [0.035]	0.002 [0.001]

We report the mean values and standard deviations over 84 period of the the product-level's own- (OPE) and cross-price elasticities (CPE) based on the estimated parameters from specification (FE.IV) of equation (3) and the formulas (11) to (14). 24,603 observations.

Table 6: Marginal costs and markups

	Total	Original	Import	Generic
	mean [std]	mean [std]	mean [std]	mean [std]
Marginal cost [EUR/DDD]	0.26 [0.40]	0.87 [0.39]	0.66 [0.41]	0.04 [0.10]
Marginal cost [% of price]	0.33 [0.59]	0.76 [0.18]	0.78 [0.25]	0.14 [0.59]
Markup [EUR/DDD]	0.11 [0.10]	0.28 [0.20]	0.1 [0.08]	0.08 [0.06]
Markup [% of price]	0.67 [0.59]	0.24 [0.18]	0.22 [0.25]	0.86 [0.59]

We report the absolute and and percentage mean values (with st.d.) over all 84 months of the estimated markups and marginal costs, which are based on the Jacobians calculated with the estimated parameters from specification [FE.IV] of equation (3). 24,603 observations.

Figure 3: Marginal costs and markups of originals, imports and generic drugs over 28 quarters

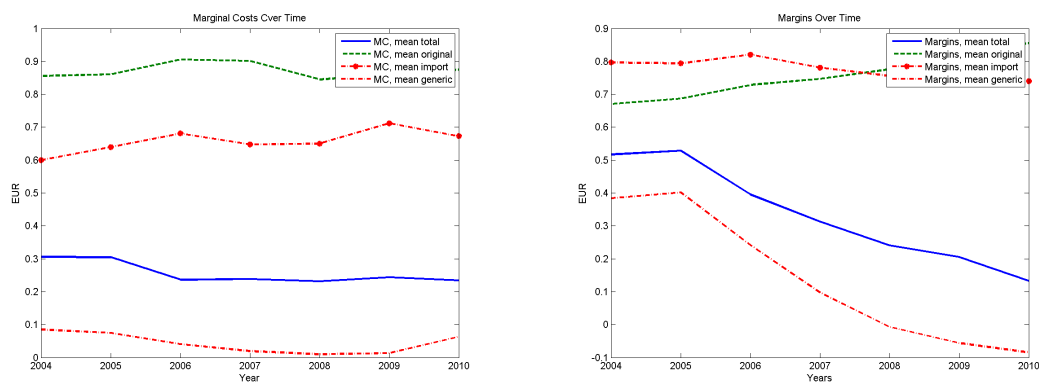
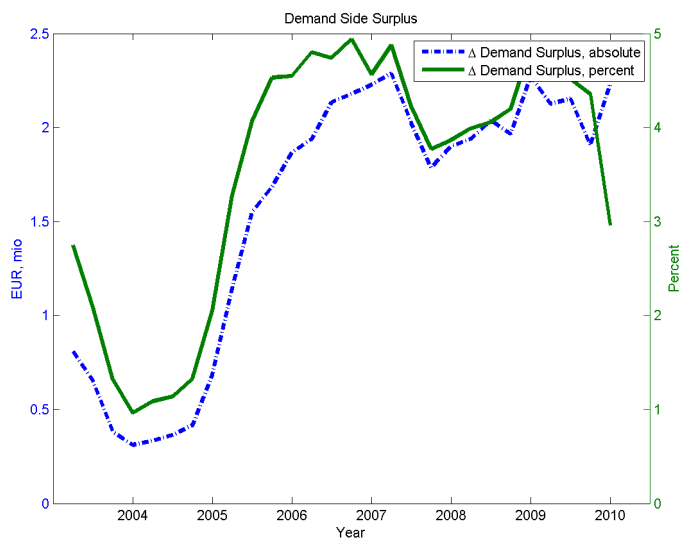


Figure 4: Absolute and relative difference between simulated and status quo demand-side surplus over 28 quarters



84 monthly values averaged to 28 quarters. Left axis in EUR, right axis in %.

Table 7: Effect of parallel imports on mean prices and total quantities by product types and chemical groups, 2004-2010

Price [EUR/DDD]	status quo mean	w/o imports mean	Difference in %
total	0.36	0.27	10.0
total, w/o imports	0.25	0.27	-5.9
original	1.15	1.29	-11.0
import	0.76	-	-
generic	0.128	0.127	0.7
ATC 4			
1. Alpha glucosidase inh.	0.88	1.09	-19.4
2. Biguanides (metformin)	0.13	0.13	1.7
3. Combinations	0.79	0.82	-3.6
4. Other (glinides)	0.95	1.64	-41.9
5. Sulfonylurea	0.11	0.10	4.8
6. Thiazolidinediones	1.48	1.66	-10.5
Cumulated quantity [DDD]	status quo in mio DDD	w/o imports in mio DDD	Difference in %
total	7,778.0	7,574.8	2.7
original	1,369.0	1,376.2	-0.5
import	428.7	0	-
generic	5,980.3	6,198.5	-3.5
ATC 4			
1. Alpha glucosidase inh.	139.9	71.0	97.0
2. Biguanides (metformin)	3,194.0	3,259.0	-2.0
3. Combinations	1,142.9	984.7	16.1
4. Other (glinides)	236.0	159.9	47.6
5. Sulfonylurea	2,813.3	2,897.5	-2.9
6. Thiazolidinediones	252.0	202.5	24.4

We report the mean values and percentage changes over all 84 months of the observed prices and total sum of quantities wrt. their simulated counterparts, based on the estimated parameters from specification [FE.IV] of equation (3). Column *status quo* reports the observed values from our data while column *w/o imports* displays our simulated results. 24,603 observations.



Table 8: Effect of parallel imports on demand-side surplus, and variable profits by firm types and chemical groups summed over 84 months (2004-2010)

Demand-side surplus	status quo in mio	w/o imports in mio	Difference in %
total	3674.0	3544.1	3.7
ATC 4			
1: Alpha glucosidase inh.	87.5	43.7	100.2
2: Biguanides (meformin)	1773.5	1773.7	0.0
3: Combinations	707.1	601.4	17.6
4: Other (glinides)	148.9	100.4	48.2
5: Sulfonylurea	1585.8	1597.6	-0.7
6: Thiazolidinediones	158.8	123.7	28.4
Variable profits	status quo in mio EUR	w/o imports in mio EUR	Difference in %
total	829.7	931.7	-10.9
original	208.3	333.5	-37.5
import	41.5	-	-
generic	579.9	598.3	-3.1
ATC 4			
1: Alpha glucosidase inh.	6.1	10.5	-42.2
2: Biguanides (meformin)	127.7	129.9	-1.7
3: Combinations	70.6	83.0	-15.0
4: Other (glinides)	62.6	107.0	-41.5
5: Sulfonylurea	451.7	460.7	-1.9
6: Thiazolidinediones	111.0	140.6	-21.1

We report the aggregated values and percentage changes over all 84 months of the demand-side surplus and variable profits due to parallel import. All figures are calculated based on the estimated parameters from specification [FE.IV] of equation (3). Column *status quo* reports values based on the observed data while column *w/o imports* displays values based on the simulated results. 24,603 observations.