Early Entries and Trademarks – An Empirical Examination of Barriers to Generic Entry

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Abstract

As a fundamental appropriability mechanism in pharmaceuticals, patents allow innovators to obtain monopoly rents for a limited time period in return for huge R&D investments. Industry practices suggest that innovators have found ways to circumvent the loss of monopoly power as patents expire. This study investigates the relevant issue of generic entry deterrence examining the joint impact of early entries and trademarks. Estimating a bivariate probit model that accounts for the endogeneity of early entry, we establish evidence for generic entry deterrence. We show that early entry has a significant and sizeable negative effect on generic entry which trademarks intensify.

Keywords: Generic Entry, Early Entry, Trademarks, Pre-emption.
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1 Introduction

As a fundamental appropriability mechanism in pharmaceuticals, patents allow innovators to obtain monopoly rents for a limited time period in return for huge R&D investments. The question whether innovators' monopoly power truly ends with patent expiration such that generic competition can effectively set in, is crucial on regulatory grounds. This study attempts to investigate this question and is the first to tackle the issue of generic entry deterrence examining the joint impact of early entries and trademarks. We have assembled a dataset comprising pharmaceutical market, exclusivity and trademark data for the German pharmaceutical market which is the second largest generic market in the world and thus a very important market to look at. Estimating a bivariate probit model that accounts for the endogeneity of early entry, we establish evidence for entry deterrence. We show that early entry has a significantly negative effect on generic entry which trademarks intensify.

As blockbuster drugs loose patent protections and drug pipelines have run dry, "Big Pharma" seeks ways to limit profit erosion following generic entry. One practice has become the introduction of a generic version of the original drug prior to the loss of exclusivity – typically patent expiration–, either through a subsidiary or licensee partner (early entry). Early entries occur frequently in many pharmaceutical markets throughout the world but no clear empirical evidence has been established yet, to determine whether this pre-empts subsequent entry or not. First-mover advantages have, however, been shown to be eminent in the generic market segment (Caves *et al.*, 1991; Grabowski and Vernon, 1992; Hollis, 2002). Early entrants in turn often pursue a product differentiation strategy, i.e. they register trademarks and build up new brands for the generic drugs they launch up front. What bearing trademarks have on subsequent generic entry in this particular context is an important and yet unresolved question that requires an empirical investigation. For the empirical analysis, a unique data set has been created by a matching pharmaceutical market data, exclusivity data – patents and supplementary protection certificates (spc)[1] – and trademark data from the German patent and trademark office. 79 substances[2] experienced a loss of exclusivity, e.g. patent expiration, between 2002-2007. By the end of 2007, generic entry occurred in 49 markets, of which 16 were affected by early entry. Early entrants in turn embarked on a trademark strategy in 6 markets that gave opportunity to enter.

The distinctive features of competition in off-patent drug markets have attracted the attention of various economists. Previous empirical studies prove pre-entry market size (Morton, 1999; Saha *et al.*, 2006), firm and drug characteristics (Morton, 1999), the brand-name drug's goodwill stock (Hurwitz and Caves, 1988; Hudson, 2000) as well as pharmaceutical price regulation (Danzon and Chao, 2000; Moreno-Torres *et al.*, 2007) to be important influencing factors of generic entry. Few empirical studies (Hollis, 2003; Reiffen and Ward, 2005a; Berndt *et al.*, 2007a,b) explicitly deal with early entry and its potentially anti-competitive

[1] A certificate that allows for an extension of market exclusivity for up to 5 years after patent protection which – depending on the life cycle of the drug – is granted by the national patent office.

[2] Throughout the paper the term substance is equivalently used for mono-substance, i.e. a substance that contains one active ingredient only. As the correct allocation of all relevant patents and supplementary protection certificates to a mono-substance is by far not trivial, this analysis focuses on mono-substances.

effect on generic entry. The conclusions drawn are essentially conflicting, and a lot of the empirical evidence brought forward is descriptive in nature. Potential endogeneity issues with regard to the early entry decision are typically not accounted for. The generic entry literature has so far not touched on the subject of generic product differentiation despite the apparent relevance of trademarks for generic firms (von Graevenitz, 2006), in particular early entrants. Trademarks have been shown to be positively correlated with sales and market share (Griffith and Webster, 2004; Greenhalgh and Rogers, 2006), i.e. they appear to be a means of enhancing market positions. Given that generic advertising is rare (Scherer, 2000; Morton, 2000), we make use of trademark data to appropriately address product differentiation efforts on parts of early entrants, and to eventually disentangle the impact of early entries and trademarks – two potential, likely complementary barriers to generic entry. Treating early entry as an exogenous variable could give rise to a selection problem and an understatement of the early entry effect if early entry occurs in markets that are more attractive than given market characteristics would suggest. For this reason we estimate both a univariate and a recursive bivariate probit model and compare the estimates. In the recursive bivariate probit model generic entry and early entry are estimated simultaneously. A patent holder dummy serves inter alia as identifier in the early entry equation. Important influencing factors such as pre-entry market size and the number of off-patent substitute active ingredients are controlled for in all generic entry specifications. The effect of early entry on generic entry is found to be significantly negative in all bivariate probit specifications and it appears to be intensified by trademarks. We also find evidence for selection, i.e. an understatement of the early entry effect in the probit model. Pre-entry market size is a major drive of entry. The number of off-patent substitute active ingredients has a negative, yet small impact on generic entry. In turn, firms' therapeutic and drug forms experience influence generic entry decisions positively.

The organization of the paper is as follows. Section 2 provides an overview of previous empirical work on generic entry within the realms of early entry and product differentiation. It also outlines empirical results on the economic relevance of trademarks. Main aspects of the generic entry regulation and specificities of the German generic market are presented in Section 3. Section 4 describes the data and develops the empirical model. Section 5 presents and discusses the empirical findings. Concluding remarks follow in Section 6.

2 Literature Review

Early entries are not a new phenomenon neither in Europe nor the USA. Few empirical studies deal, however, with early entry – also known as authorized, branded or pseudo-generic entry – and its potentially anti-competitive effect on generic entry explicitly even though first generic entrant have been shown to have a long-lasting advantage over subsequent entrants (Caves *et al.*, 1991; Grabowski and Vernon, 1992; Hollis, 2002). Not only can the first generic entrant serve the market for a longer period of time – with fewer competitors and higher generic profits right after patent expiration – but it can also capture and sustain a substantially larger market share over a period of several years. Hollis (2003) argues that patients' uneasiness to switch between medications (even if the only difference is the label), search and

"persuasion" costs on parts of doctors, and the additional administrative costs of pharmacies when stocking several (identical) generic drugs result in switching costs. Hollis (2003) notes that switching costs are certainly not enormous, but not easy to overcome, either. First, there is little room for product differentiation given that generic drugs are therapeutically equivalent. Second, prices are matched as soon as one entrant lowers the price, resulting in overall little price dispersion[3] and only a transitory gain in market share when prices are cut. Based on previous empirical evidence showing first-movers advantages and the dynamics of generic competition, Hollis (2003) concludes that the introduction of brand-controlled pseudo-generics in Canada substantially lowered generic firms' expected profits and thus, incentives to enter. Morton (2002) examines the motivations of US pharmaceutical firms in the 90s to integrate generic activities. She finds no statistically significant synergy effects that would explain integration: generic entrants belonging to the cooperation that manufacture the original drug are not more likely to enter, to enter faster or to affect the number of generic entrants in a market. Given that the timing of brand-controlled generic entry – pre- or post-patent expiry – is not accounted for in her analysis, the last result should be interpreted with some caution, and not be generalized. The goal of the paper is to explain specialization tendencies among pharmaceutical firms' activities and not to test for strategic entry deterrence. Morton (2002) notes, however, that discouraging generic entry could have been one reason why US pharmaceutical firms integrated generic activities in the 90s. Reiffen and Ward (2005a) analyze the motivation of original drug manufacturers in the US to introduce an authorized generic pre-patent expiry, and explicitly deal with entry deterrence. Based on structural estimates from earlier empirical studies (Caves *et al.*, 1991; Reiffen and Ward, 2005b), they calculate the effect of authorized generic entry on generic industry profits and the number of generic entrants in equilibrium, which in turn affects generic and brand prices, and eventually original drug producers' profits. Their calculation shows that the anticipation of authorized generic entry crowds out between 1.7 to 2.4 entrants depending on market size. Reiffen and Ward (2005a) conclude that original drug producers introduce authorized generics in large markets fueled by rent-seeking motives, i.e. to capture generic profits without substantially affecting the number of generic entrants and generic prices. In small and medium-sized markets on the contrary, entry deterrence motives play a role as the impact on the extent of generic entry and prices is relatively large. Recent evidence on entry deterrence and consumer welfare effects of authorized generic entry in the US has also been provided by Berndt *et al.* (2007a,b). In both studies, the effect of authorized generics on the filing of ANDAs[4] with a paragraph IV certification (claim of patent non-infringement or invalidity) is examined. The first generic firm to file an ANDA with a successful paragraph IV certification is granted a 180-day exclusivity period where no other generic manufacturer (except for authorized generics) is allowed to enter the market with the same version of the drug. As such, those studies look at the change of generic entrants' incentives to enter early, not necessarily at the decision to enter or not, or related, the extent of generic entry. Berndt *et al.* (2007b) point out, that besides authorized generic entry, several factors may limit the

[3]Generic prices in are typically clustered around a certain "cut-off value" such as a reference price. A reference price is the maximum price the statutory insurance plan covers and reimburses.

[4]Abbreviated New Drug Approval: application process for generic entrants in the US, where therapeutic equivalence to the original drug and quality of the manufacturing process has to be proven.

profitability of the 180-day exclusivity period.[5] They also show that in spite of the increase in authorized generics since 2003, there is little change in the total number of paragraph IV certifications, paragraph IV certifications per drug, and timing of filings relative to approvals of new chemical entities. Thus, based on a review of descriptive statistics, they conclude that authorized generic entry and its recent increase has not delayed generic entry in the US. The conclusions drawn in the previous studies are conflicting, a lot of the empirical evidence brought forward is still descriptive in nature, apart from the fact that potential endogeneity issues with regard to the early entry decision are not accounted for.

Previous empirical work on generic entry has focused on the product differentiation activities of original drug producers, namely pre-patent expiry brand advertising (Grabowski and Vernon, 1992; Morton, 2000). The generic entry literature has so far not touched on the subject of generic product differentiation despite the apparent relevance of trademarks for generic firms (von Graevenitz, 2006), in particular early entrants. Trademarks have overall attracted little attention from researchers, compared to other intellectual property rights such as patents. The studies by Griffith and Webster (2004); Greenhalgh and Rogers (2006) are one of the first to contribute empirical research on the value of trademarks (Griffith and Webster, 2004; Greenhalgh and Rogers, 2006) demonstrating a positive correlation between trademarks, firms' sales and market share. Given that generic advertising is rare (Scherer, 2000; Morton, 2000), a closer look at generic firms' trademark activities is warranted. In the context of generic entry deterrence, we examine early entrants' trademark activities and their additional impact on subsequent independent generic entry.

3 Regulatory and Competitive Setting

With a market size of about €4.5 Bn. and a market penetration of 22% as of 2007, Germany is the second largest generic market in the world and the largest in Europe. Thus, it is an important market to examine closely, with respect to early entries and trademarks. Drug expenditures have steadily increased in Germany over the last couple of years. In the German statutory health-insurance system[6] alone drug expenditures amount to €25.6 Bn.[7], comprising the third largest cost factor. Given the demographic development in Germany, this trend is likely to persist. In order to limit the growth in medical expenses, several counteractive regulations have been introduced since 2000. Initiatives aim at creating cost awareness on parts of all actors in the healthcare system, and promote the use of high-quality, less cost-intensive medications such as generic drugs. Generic drugs are therapeutically equivalent or bioequivalent to off-patent, original drugs. They have the same active ingredient, identical quality and performance characteristics, the same strength and the same or a similar route of administration. Generic drugs are typically offered at a substantial price discount[8] as a consequence of price competition and lower R&D outlays. No safety and ef-

[5]Multiple entrants are awarded 180-day exclusivity given they apply for the same dose at the same day.
[6]The statutory health-insurance plan covers about 85% of the German population.
[7]BPI Pharma-Daten 2008; see also Commission (2008), p. 26.
[8]Generic price discounts are in the range of 20-80% of the original drug's price (WHO, 1999).

ficacy tests have to be conducted, only the less cost-intensive bioequivalence studies[9]. An increase in generic substitution has been achieved through the *Aut-idem* regulation which was introduced in 2002. If doctors have not excluded substitution, the pharmacists generally has to sell one of the three cheapest generic alternatives to the patient. If a more expensive product is sold instead, the pharmacist will have to incur the extra cost, i.e. the difference in price. Ever since 2004, dispensing fees on prescription drugs[10] consist to a great extent of a fixed component. The pharmacists receive a fixed amount of €8.10 on each medical product sold, plus 3% of the product's retail price. As a result, incentives to sell high-priced, identical drugs have been reduced. In the same year, reimbursement practices were also altered. Patients covered by statutory health insurance now have to make a co-payment for each drug product they purchase. The co-payment amounts to 10 % of the retail price, the minimum contribution is €5 and €10 is at the maximum. As most drugs are sold in packages priced below €50, patients are often inclined not to search for a cheaper drug with the same active ingredient (Accenture, 2005).

Given the nature of price competition, first-mover advantages are eminent in the generic market segment. Prices on generic drugs are indirectly regulated through reference prices.[11] In addition to the co-payment that patients covered by statutory health insurance must make, they receive a reimbursement up to the reference price only. As of July 2006, co-payments become obsolete if a drug product is priced 30% or more below the reference price. As a consequence, generic firms often set prices close to the reference price or 30% below[12], such that little price dispersion can be observed. Since April 2007, rebate contracts have been authorized and promoted, causing a major upheaval in the pharmaceutical industry. Statutory insurance providers may put out to tender several drugs and contract with the generic or pharmaceutical manufacturer that is able to offer the lowest price. Then, pharmacists are to provide the patient with the firm's drug that their insurance has contracted with. Except for rebate contracts, previous regulations seem to have created few incentives on parts of doctors, pharmacists or patients to switch between identical generic drugs as long as the price difference is a minor one. This may explain why first-mover advantages are also said to be substantial in the German generic market segment (Raasch, 2007).

Besides the advantages that generic first-movers have, there seem to be additional advantages of product differentiation. Generic drugs are most frequently marketed as INN-generics, i.e. the international-non-proprietary name (INN) of the active ingredient and a company suffix identifies the product. Some generic drugs are, however, sold under a new trade name which a trademark has been registered for. A trademark is an intellectual property right that is valid for 10 years and can in contrast to a patent, theoretically be extended indefinitely long. According to the World Intellectual Property Organization, "a trademark is a distinctive sign identifying certain goods or services as those provided by a specific person or

[9]Generic manufacturers eventually prove in bioequivalence studies that the rate and extent of absorption of the active ingredient is identical to that of the reference drug.

[10]Around 78% of pharmaceutical sales are made on prescription drugs (BPI Pharma-Daten 2008).

[11]To secure fair competition practices, manufacturers are prohibited from giving discounts in kind to pharmacies since 2005. Financial rebates are restricted to non-prescription drugs.

[12]AOK Press Release June, 2006 (accessed Dec 11th 2008); see also Accenture (2005).

enterprise". This comprises inter alia words, sounds, colors and graphics that have a distinguishing feature. Generic firms have been found to actively protect trademark portfolios and oppose trademark applications (von Graevenitz, 2006). Original drug producers in Germany also often cooperate with generic firms in order to optimize the product life cycle of their drugs.[13] Early entries, where a generic version of the original drug is marketed through a generic subsidiary or licensee partner pre-patent expiry, occur on a frequent basis.[14] The data at hand reveals that licensing was the preferred mode to arrange for an early entry between 2002-2007, and that early entrants often pursued trademark activities. In any case, the ultimate goal is to enter early enough – prior to patent or spc expiration – to capture and hopefully sustain a large market share in the long run. On the one hand, such a strategy lowers the expected profits of subsequent generic entrants and could thus potentially discourage entry.[15] On the other hand, it reduces the original drug producer's profits during the exclusivity phase. Original drug producer effectively face a trade-off between allowing for own product cannibalization and obtaining a possibly large share in the future generic market segment. The optimal timing of an early entry is undoubtedly crucial. Early entrants' trademark activities suggest, however, that generic firms are also well aware of the competitive edge that trademarks may additionally give.

Given the lengthy generic entry process where firms are uncertain about competitors' entry decisions, generic firms can only anticipate early entry and the likelihood that early entrants embark on a product differentiation strategy. Independent generic entry is generally permitted as soon as the original drug goes off-patent, i.e. 20 years after patent application. Original drug producers have the additional possibility to apply for a supplementary protection certificates which guarantees market exclusivity to the original drug producer for up to five years when granted by the national patent office. As noted earlier, generic drug manufactures do not conduct safety and efficacy but bioequivalence studies which take on average 2 years. In its abridged application for market approval, the generic firm refers to reviews of experts and clinical test results that were obtained in the course of the original drug's approval process. According to current law, the generic firm can access this type of data without notice or permission of the original drug producer eight years after the original drug's market entry[16] (data exclusivity period).[17] Thus, generic firms can start conducting bioequivalence studies while the reference drug's patent protection is still valid ("working under patent") and commit no infringement doing so given data exclusivity has elapsed. Not before 10 years after the original drug's market entry, the generic drug is allowed to be marketed ("marketing exclusivity"), though. Moreover, if the original drug producer files an application dossier for at least one additional indication within 8 years after market entry,

[13] See also Commission (2008), p. 11.

[14] With the permission of the original drug producer (patent holder) a generic drug can be approved at any time before patent or spc expiration.

[15] Of course, original drug producers have other options to cope with the threat of generic entry, such as to obtain a second patent for a reformulation (second generation products).

[16] Given time and cost-intensive clinical trials and a lengthy approval process, market entry of the original drug typically occurs 10-12 years after patent application.

[17] With the implementation of the *Bolar provision* in German law, "working under patent" became legal. For applications filed before November 2005 the data exclusivity period amounts to 10 years in Germany.

the original drug producer's market exclusivity period is extended for another year (8+2+1-Rule). A central application procedure has increasingly been used by generic firms that sought market approval between 2000-2007 (Commission, 2008). The centralized procedure is optional for generic firms and has the advantage that a community market authorization is obtained at once. Applications are submitted at the *European Medication Evaluation Agency (EMEA)*, which evaluates the application and gives a recommendation to the European Commission within a period of approximately 270 days, which finally grants market approval and informs the applicant. In summary, generic firms decide upon entry into a market roundabout 2-3 years before loss of exclusivity[18] and actual entry (WHO, 1999). Due to the disclosure[19] of generic applications dossiers, generic firms effectively sunk entry costs simultaneously and can only form expectations about competitors' actions.[20]

4 Data & Methodology

An empirical examination of the effect that early entries and trademarks have on independent generic entry requires the use of diverse data sets and sources. A detailed description of the data set construction and a data overview is given in the next sub-section. A motivation and presentation of the empirical model follows.

4.1 Data Set

Through a matching of national pharmaceutical market, exclusivity (patent and spc) and trademark data, a unique data set has been created tracking substances' losses of exclusivity and generic entries between 2002-2007. *Insight Health* provides pharmaceutical market data for the time period 1999–2007, in addition to data on patents and spc's[21]. The pharmaceutical market data comprise information on drugs (substances)[22], medical products and the retail forms that are available. Additionally, they give information on manufacturers, prices (producer, retail and reference prices), rebates in kind and the turnover and revenues that manufacturers in the German retail market achieve. As price, turnover and revenue data are available on a monthly basis for the years 2002 to 2007 only, the analysis is geared towards this time period. Moreover, it is focused on human medications and substances that contain one active ingredient only. The analysis is confined to data on retail revenues, i.e. the wholesale and direct purchase transactions of public pharmacies. Given data constraints, hospitals sales are neglected. In Europe, the turnover generated by prescription medication

[18] Expiry of patent protection (possibly extended through a spc), data and marketing exclusivity.

[19] See also Commission (2008), p. 15.

[20] Entry costs comprise the costs of conducting bioequivalence studies – $ 40.000-150.000 (WHO, 2005), market approval fees – at the EMEA, an annual fee of €21.700 in addition to a basic fee of €94.100 (Commission, 2008) – and legal costs in the event of litigation, settlements etc..

[21] *Insight Health* has obtained patent and spc data from national patent offices since 2005. Additional data sources were accessed to complement patent and spc information where necessary.

[22] Strength, drug form and therapeutic field(s) of indication are specified. The drug form classification follows the New Form Code (NFC) Classification established by the *European Pharmaceutical Market Research Association (EphMRA)*, the classification of therapeutic fields in turn rests upon the Anatomical Therapeutic Chemical (ATC) Classification System which was introduced by the *WHO* in 1976.

is significantly larger in the retail segment – approximately three times larger in 2007 – compared to the turnover generated by the hospital channel (Commission, 2008). Thus, for the vast majority of substances in this study (prescription drugs), retail revenues provide nevertheless a sufficiently reliable measure.

The unit of observation is the pharmaceutical retail form, i.e. a medical product in a defined packaging size. A medical product in turn is a substances being available in different strength and routes of administration. The date of a retail form's launch is given as well as a classification of the "type of drug" that is marketed: non-generic, generic, original or patent-protected. The classification system goes by the patent status of the according substance. As soon as its patent expires and generic firms enter, retail forms previously launched by the original drug producer or reimport suppliers, are no longer classified as *patent-protected* but *original*. If no generic companies enter, the classification switches to *non-generic* instead. Retail forms marketed by generic firms[23] are designated as *generic*. Based on the retail form's date of launch and drug classification, those substances which possibly experienced generic entry for the very first time between 2002-2007 can be identified. This in turn provides a first indication of patent or spc expirations. In total, 69 substances were found that potentially experienced a loss of exclusivity.

After matching patent and spc data and restricting the generated exclusivity data set to mono-substances, EP and DE patents, and the geographical focus on Germany[24], pharmaceutical market data and exclusivity data were finally merged using the substance's name as identifier. Given information on the date of patent and spc expirations, 65 substances were found to have experienced a loss of exclusivity between 2002-2007. Exclusivity data provide additional information on patent holders, originators, the date of patent and spc application, the date of first market approval and a list of various trade names the substance was marketed under. Finally, this data set was matched with trademark data based upon the correspondence of product name and trademark.[25] Trademark data has been obtained from the German patent and trademark office (*Deutsche Patent- und Markenamt (DPMA)*) and gives inter alia information about the date of trademark registration and publication, the trademark owner(s) and the trademark's Nice classification[26]. Trademark data shall be used to address product differentiation efforts on parts of early entrants. Data on advertising expenditures in the pharmaceutical industry are very difficult to come by, with the consequence that there is currently a lack of such data. Given the relevance of trademarks for German generic firms and the fact that generic advertising[27] is limited (Scherer, 2000; Morton, 2000), the lack of advertising data is not a severe constraint. Trademark activities should serve as a sufficiently reliable proxy for generic firms' product differentiation efforts.

[23]The reimport business with generic drugs is relatively small but does exist.

[24]The data is confined to market authorizations and spc extensions in Germany.

[25]Moreover, it was verified that trademark owner and producer (or its parent firm) coincide.

[26]The Nice Classification is based on a multilateral treaty – the Nice Agreement Concerning (1957) – and is administered by *WIPO*. It serves as an international classification of goods and services for the purposes of the registration of marks, and currently describes 34 classes of goods and 11 classes of services.

[27]Direct advertising of prescription medications to consumers is forbidden in the European Union.

Many of the 69 substances that experienced generic entry for the very first time between 2002-2007 are also to be found among the 65 substances that either lost patent or spc protection in the according time interval. Through an extensive review of additional data sources[28] exclusivity information was complemented if missing, and validated. Additionally, the consistency of generic entry data and exclusivity data was checked upon. The date of first generic entry, for instance, was compared with the date of patent expiration. If generic entry occurred before patent or spc expiration, further investigations were carried out to find evidence for early entries or patent invalidity cases that would explain entry prior to the official date of patent or spc expiration. In total, 79 substances were identified that experienced a loss of exclusivity between 2002-2007. By the end of 2007, generic entry had occurred in 49 markets out of which 16 had been affected by early entry. In five of these cases early entrants had pursued a branding strategy and had registered trademarks accordingly. The fact that several entry opportunities attract no generic entry is not unusual (Morton, 1999; Hollis, 2003), as generic entrants focus on high revenue markets (Commission, 2008).

Table 1 provides an overview of the 79 entry opportunities arising between 2002-2007. It outlines important characteristics of the markets that were affected by generic entry, early entry and "branded" early entry: pre-entry market size (substances' market size in € Mio., two years prior to loss of exclusivity and evaluated at producer prices), the number of entries (generic retail form launches) until 2007, the number of therapeutic fields substances are used in[29], and the number of drug forms or routes of administration[30] which are available.

	Substances	Pre-Entry Market Size		Entries	Indications (ATC2)		Drug Forms (NFC1)	
	N	Mean	Median	N	Mean	Median	Mean	Median
Generic Entry	49	48.3	33.3	6358	1.14	1	1.75	1
No Early Entry	33	44.7	26.2	3552	1.09	1	1.72	1
Early Entry	16	55.6	39.8	200	1.25	1	1.81	1
With Trademark	6	73.9	49.4	63	1.16	1	1.67	1
No Trademark	10	44.6	39.8	137	1.30	1	1.90	1.5
No Generic Entry	30	0.55	0.22	0	1.06	1	1.30	1
Total	79	32.1	14.7	6558	1.11	1	1.58	1

Table 1: Generic Entry Opportunities (2002-2007)

Very small markets do not experience any generic entry. Early entrants in turn appear to focus on high revenue markets, in particular when trademark-protected retail forms are launched. On average there tend to be more routes of administration for substances that attract generic entry or early entry compared to markets where no entry occurs. Differences with respect to substances' therapeutic applicability are either minor or non-existing.

[28] E.g. the esp@cent patent database, the FDA Orangebook, and the PATDPASPC database.

[29] Therapeutic fields are classified by the ATC System at the second level of aggregation (ATC2).

[30] Drug forms are classified by the NFC System at the first level of aggregation (NFC1) which effectively corresponds to the ATC2 System in the level of detail.

We can track firms that decided to enter a market through the observation of generic entries. On the contrary, we remain agnostic about those firms which refrained from entry. For an examination of generic entry decisions, negative entry decisions ("zero-entries") need to be accounted for, as well. Since "zero-entries" cannot be observed, they need to be created artificially instead. According to the approach of Morton (1999), sets of potential entrants are constructed in order to deal with this problem. The pharmaceutical data set provides information on the names of the various firms that supplied the German pharmaceutical market between 1999-2007. After the exclusion of pharmacies in the data set, 991 firms remain. A further restriction of the firms is warranted as one would not expect all 991 firms to decide upon each of the 79 entry opportunities. Generic firms that enter markets have on average 436.54 (Median: 223.06) retail forms in their portfolio at the time entry opportunities come up. By restricting the set of potential entrants to those firms that have a portfolio of at least 50 retail forms – a soft constraint –, the number of firms is reduced to 225. These 225 firms supplied 92% of all retail forms available on the German market between 1999-2007 and 210 firms also had generic drugs in their portfolio. Thus, these 225 firms represent potential market entry candidates. Out of the 225 companies the first set of potential entrants is created by including only those firms that are active at the time exclusivity expires, i.e. they have launched a positive number of retail forms by that time. Set 2 restricts the set of potential entrants further to those firms that are not only active but also prove to be experienced in the therapeutic field(s) the substance is used in. Sets of potential entrants are assigned to each and every substance in turn, such that two different samples are created and a verification and evaluation of the robustness of results is feasible. Table 2 provides an overview of the two sets of potential entrants[31] and the generated samples. With an increasing limitation of the total number of potential entrants from set 1

	Set 1	Set 2
Definition	All firms with a portfolio of at least 50 retail forms, active at the time exclusivity expires.	All firms with a portfolio of at least 50 retail forms, active at the time exclusivity expires, and experienced in the field(s) of indication (ATC2).
Potential Entrants	Total: 241 Mean: 223.33 Median: 224	Total: 224 Mean: 75.03 Median: 74
Entrants	Total: 96 Mean: 15.65 Median: 14	
Generic Entries	Total: 6358 Mean: 129.76 Median: 82	
Early Entries	Total: 200 Mean: 12.5 Median: 11	
"Zero-Entries"	Total: 16876 Mean: 213.62 Median: 218	Total: 5160 Mean: 65.32 Median: 63
Sample Size N	23234	11518

Table 2: Sets of Potential Entrants

to set 2, the number of potential entrants each substance may attract on average and the median declines. The same is true for the number of "zero-entries" and sample size. A total of 96 firms – on average 15.65 firms – enter the 49 markets that eventually attracted generic entry. Substances were affected by 129.76 generic entries (retail form launches) on average.

[31] Whenever firms enter that are not tracked in the set of potential entrants, the number of potential entrants increases accordingly (cp. Set1).

4.2 Empirical Model

Based on cross-sectional data, the impact of early entries and in interaction with trademarks, will be examined. As first-mover advantages are eminent in the generic market segment, early entries are very likely to diminish the expected profitability of entry. Thus, early entry is assumed to deter subsequent, independent generic entry if anticipated by potential entrants. Trademarks, in turn, have been shown to be positively correlated with sales and market share, i.e. they turn out be a means of strengthening market positions. Along these lines of reasoning, trademarks possibly intensify the deterrence effect of early entry on independent generic entry. Again the underlying assumption is that potential generic entrants can anticipate that some early entrants will embark on a product differentiation strategy. The two hypotheses to be tested are briefly summarized below.

H1: Early entry prior to loss of exclusivity, has a significant, negative effect on subsequent, independent generic entry (deterrence effect).

H2: Trademarks significantly intensify the deterrence effect of early entry on subsequent, independent generic entry (signaling effect).

Both generic entry and early entry are dichotomous variables. One observes entry but not the profits the generic firm or early entrant expected to reap upon entry (latent variable), which in turn motivated the firm's entry decision. Given that observed and unobserved factors[32] determine expected market profits and, as a result both the likelihood of generic and early entry, it is essential to account for the endogeneity of early entry when examining its impact. If early entry is endogenous, its effect is likely to become understated due to selection as early entrants possibly focus on the more profitable entry opportunities. The selection effect may counterbalance the presumably negative early entry effect. In the first step, a univariate probit model is estimated that ignores any endogeneity issues. For the purpose of identifying a correlation between generic entry (g_i) and early entry (ee_i) over the error terms and providing evidence for selection, a recursive bivariate probit model is estimated in the second step where early entry is being instrumented for and where generic entry and early entry equations are estimated simultaneously.[33] In the presence of a significantly (positive) correlation between the two equations, early entry is to be considered endogeneous. Generic entry decisions effectively occur simultaneously due to the lengthy entry process, even though early entry and generic entry will occur sequentially.[34] If markets are highly attractive they will attract both generic and early entrants (see Table 1). If generic entrants have correctly anticipated early entry they are potentially discouraged to enter if incentives are being lowered substantially. In this line of reasoning, we include the early entry dummy in the outcome equation and not vice versa.

[32]If future, therapeutic innovations are expected to change the competitive landscape, entry into a certain market may be less attractive than it currently – given observed market characteristics – seems. On the contrary, long-term clinical studies may reveal that a substance is particularly effective in a (different) field, and entry is more attractive. Demographic trends possibly determine expected profits also.

[33]Evans and Schwab (1995) adopt this empirical approach in a seminal paper among the first.

[34]With the permission of the original drug producer early entrants can start to launch retail forms any time before exclusivity is lost.

A trademark dummy is finally interacted with the early entry dummy (ee_tm_i) and additionally included in the bivariate probit model's generic entry equation in order to estimate the impact of trademarks on the size of the early entry effect. The value of the "branded early entry" dummy equals one when early entrants have registered trademarks for the product names of the retail forms they launch up front. Potential endogeneity issues with respect to early entrants' trademark activities are abstracted from at this point in order to simplify the empirical model. In a trivariate probit model we will attempt to account for the endogeneity of both early entry and early entrants' trademarking. Preliminary results for data set 2 can be found in Appendix [C].[35] We estimate both the univariate probit and bivariate probit model sequentially including the branded early entry dummy in the generic entry equation in order to ascertain differences in the estimates for the two data sets at hand.

Several factors such as pre-entry market size, monopoly duration or the number of off-patent substitute active ingredients affect the likelihood of generic entry and need to be controlled for (co-variates $\mathbf{X_1}$). As the main drive of generic entry (Morton, 1999; Saha *et al.*, 2006), pre-entry market size is also added to the early entry equation (covariate $\mathbf{x_2}$) when estimating the bivariate probit model in the second step. In order to allow for identification, we include two further variables (identifiers $\mathbf{I}$) in the early entry equation which in turn explain early entry but have no direct impact on generic entry decision. Econometricians (Heckman, 1978; Wilde, 2000) point out that exclusion restrictions are not necessarily required in simultaneous equation systems with endogeneous dummy regressors to achieve identification given there is at least one exogenous regressor that shows sufficient variation (full rank regressor matrix). Nevertheless, we have attempted and found two variables that on theoretical grounds promise to provide valid exclusion restrictions.[36] As one instrument we use the dummy variable *Patent holder* which is assigned a value of one when original drug producers are the holders of the patent that protects the compound and not only licensees thereof. If original drug producers own the relevant patent(s) they can directly decide upon early entry arrangements, i.e. they have the power of decision and transaction costs are lower. The attractiveness of a market however, does not seem to be directly impacted by the fact that original drug producers possess the relevant patent(s) protecting a compound. In the 16 markets that have been affected by early entry, only two original drug producers were licensees in fact. Early entries might also be motivated by the financial need of the original drug producer. For this reason, we include the variable *Revenues Pipeline* as a second instrument in the early entry equation. The variable measures the total annual market revenue with patent-protected substances original drug producers' achieve in the year the

[35] We do not comment on those results in detail now given the preliminary status of the trivariate probit estimations. The maximum likelihood estimation involves the integration of trivariate joint normal probabilities which is achieved either through numerical integration or simulation. Severe convergence problems are typical. In any case, one should note that even in the parsimonious trivariate probit model we were able to estimate using data set 2, the overall effect of early end brand early entry is negative. The variable *Trademark Activity* – the number of DPMA trademarks the most active Early Entrant has registered by 2006 – serves as identifier in the branded early entry equation.

[36] A test of over-identifying-restrictions is not feasible at this point given the non-continuous nature of both generic and early entry.

exclusivity of substances expires. Early entries are assumed to be less likely when original drug producers are finally well-off. Again, we argue that original drug producer's financial need has no direct impact on generic entry decisions. It influences generic entry indirectly only in that it affects the likelihood of early entry which in turn impacts generic entry. As generic entry or early entry decisions are not independent on a firm-level, observations are clustered over firms and heteroscedasticity-robust standard errors are adjusted accordingly. To allow for the possibility that unobserved determinants of generic entry and early entry are correlated, the error terms ϵ_i and μ_i are assumed to be distributed bivariate normal, with $E(\epsilon_i) = E(\mu_i) = 0$, $Var(\epsilon_i) = Var(\mu_i) = 1$ and $Cov(\epsilon_i, \mu_i) = \rho$. The bivariate probit model to be estimated is the following, which in contrast to the univariate probit model incorporates the early entry equation additionally:

$$\begin{aligned} g_i &= 1[g_i^* > 0] \quad where \quad g_i^* = \mathbf{X_1}\boldsymbol{\beta_1} + \delta ee_i + \gamma ee\_tm_i + \epsilon_i \\ ee_i &= 1[ee_i^* > 0] \quad where \quad ee_i^* = \mathbf{x_2}\boldsymbol{\beta_2} + \mathbf{I}\boldsymbol{\tau} + \mu_i \end{aligned}$$

The dependent variable of interest – *generic entry* – is defined as the introduction of a retail form by an independent generic firm after the substance's loss of exclusivity and is coded as 0-1 dummy.[37] If a retail form is launched prior to loss of exclusivity by an early entrant, the according *Early Entry* dummy takes on the value one. If early entrants launch retail forms under a new tradename for which a trademark has been registered for, the *Branded Early Entry* dummy is additionally coded as one. The variable *Pre-Entry Market Size* appearing in both the generic entry and early entry equation is in turn defined as the logged annual revenue in a given market two calendar years prior to loss of exclusivity, which are evaluated at producer prices and given in € Mio. We use a lagged variable to account for the fact that entry decisions are made earlier in time and to avoid endogeneity issues that may arise as original drug producers typically change their advertising behaviors in the year prior to loss of exclusivity (Grabowski and Vernon, 1992). The number of off-patent substitute active ingredients (*Substitutes*) is included as another covariate in generic entry equations where one would expect a negative correlation with entry. Whenever an off-patent substance falls into the same ATC2 group(s) a particular substance is listed in, it is counted as a substitute[38]. Previous studies have also shown that the effective duration of monopoly has a negative effect on generic entry, mainly arguing that original drug producers' goodwill stocks are larger (Hurwitz and Caves, 1988; Hudson, 2000). We include *monopoly duration* as variable in generic entry equations, which measures the time from the original drug producer's first market approval to loss of exclusivity. We also add the variable *Entry Opportunities* to generic entry equations. As more entry opportunities in a given year allow generic entrants to be more selective, we expect a negative effect. As firm characteristics – in particular the experience in a therapeutic field or with a particular drug form – have been demonstrated to influence generic entry decisions (Morton, 1999), *therapeutic field experience* and *drug form experience* variables are added into the generic entry equation. As a proxy for therapeutic

[37] In addition to filing separate applications for each and every drug form and strength, producers have to decide upon packaging sizes. Each retail form – a substance in a particular form, strength and packaging size – has a unique pharmaceutical identification number and represents the unit of observation.

[38] Of course, substances in the same ATC2 class are not necessarily perfect substitutes. Nevertheless, this variable should at least proxy for the degree of competition in a certain therapeutic field.

experience we use the number of retail forms the potential entrant has launched prior to loss of exclusivity in the therapeutic field(s) the substances is used in. Similarily, we use the number of retail forms the potential entrant has marketed, which use the same route(s) of administration as the particular substance, as a proxy for drug form experience. To account for possible non-linear effects of experience the square of each variable is also included in the generic entry equation. The above-mentioned prescription-dummy is added as the identifier to the early entry equation. Therapeutic field (ATC1 Classification), drug form (NFC1 Classification), and year dummies are finally included in both the generic entry and early entry equations to account for field, drug form and year fixed effects. A summary of all definitions is provided in table 3 below.

Variable Name	Definition
Generic Entry	0-1 dummy variable,=1 if retail form was launched by independent generic firm after the substance's loss of exclusivity.
Early Entry	0-1 dummy variable,=1 if early entry occured prior substance's loss of exclusivity.
Branded Early Entry	0-1 dummy variable,=1 if early entry occured prior substance's loss of exclusivity, with the early entrant's retail form(s) being trademark-protected.
Pre-Entry Market Size (log)	Annual market revenue two calendar years prior to loss of exclusivity, in € Mio., evaluated at producer prices and log taken.
Substitutes	Number of off-patent substitute active ingredients – substances in the same ATC2 class – at the time exclusivity expires.
Monopoly Duration	Number of years from original drug's first market approval to loss of exclusivity.
Entry Opportunities	Number of entry opportunities in the year the exclusivity of a given substance expires.
Therap. Field Experience	Number of retail forms a potential entrant has launched in those therapeutic field(s) the substance exposed to loss of exclusivity is used in (ATC2 Classification).
Therap. Field Experience^2	Square of Therapeutical Field Experience .
Drug Form Experience	Number of retail forms a potential entrant has marketed, which use the same route(s) of administration as the substance exposed to loss of exclusivity (NFC2 Classification).
Drug Form Experience^2	Square of Drug Form Experience.
Patent holder	0-1 dummy variable,=1 if original drug producer holds the patent(s) protecting the compound in question, and not a marketing license only.
Revenue Pipeline (log)	Original drug producers' total annual market revenue with patent-protected substances in the year exclusivity is lost, in € Mio., evaluated at producer prices and log taken.
Field Dummies	0-1 dummy variable,=1 if substance is used in Therapeutical Field (ATC1 Classification: 17 classes/dummies).
Drug Form Dummies	0-1 dummy variable,=1 if substance is administered in particular drug form (NFC1 classification: 18 classes/dummies).
Year Dummies	0-1 dummy variable,=1 if loss of exclusivity occured in given year (2002-2007).

Table 3: Definition of Variables

The distribution of variables differs in the two data sets given that the number of "zero-entries" is lower in the second data set. An overview of summary statistics is presented in Appendix [A]. The fraction of generic entries, early entries and brand earlier entries in the data increases from set 1 to set 2 respectively. The mean (log) pre-entry market size taken over all 79 substances amounts to 15.74. In data set 1 the mean (log) pre-entry market size – now taken over all 23234 observations – is larger because entry is concentrated in high-revenue markets such that more weight is put on these markets. With a reduction in the number of "zero-entries" in data set 2, the mean (log) pre-entry market size increases again. A similar pattern can be observed for the according median statistics. Substances in the

data set have on average 50.25 substitutes and a monopoly duration of 12.06 years[39]. Again, the variables' distributions differ in the two data sets due to a different sample composition. One should note, that the mean and median field and drug form experiences increase with a restriction to therapeutically experienced firms from data set 1 to data set 2. The same is true for the average therapeutic and average drug form experience that potential entrants have at the time substances' exclusivity expires when one compares the 241 firms in data set 1 with the 224 firms in data set 2.

5 Results

In the first instance we have estimated a univariate probit model to examine the impact of early entry and trademarks on independent generic entry, completely ignoring potential endogeneity or selection problems that may exist. Results indicate that pre-entry market size influences generic entry decisions strongly. The number of off-patent substitutes of a substance has a significantly negative impact on entry, albeit small. The number of entry opportunities in the year a substances' exclusivity expires, has a negative effect on generic entry which proves that generic firms selectively decide upon entry. Both therapeutic and drug form experiences have a significantly positive impact on generic entry which seems to marginally decrease at a very small rate. Therapeutic field, drug form and year effects are significant in all specifications. These estimates overall confirm the results obtained in previous empirical studies on generic entry. A somewhat striking result is the significantly positive effect of monopoly duration on both generic an early entry. One explanation is that monopoly duration is not necessarily a good proxy for the goodwill original drug producers have accumulated over the years but another indicator of the value of a market. If a market is more valuable, original drug producers' incentives to retain a monopoly position, through spc extensions for instance, will certainly be higher.[40] Moreover, probit estimates indicate that early entry has a significantly negative effect on generic entry, where the size of the effect decreases as the trademark interaction term (*Branded Early Entry*) is included in the model. The effect even becomes insignificant in the data set 2 regressions. If early entry is endogenous, and the selection problem is empirically not being dealt with, the early entry effect will be substantially weakened, which may explain why the effect turns insignificant at one point as the branded early entry dummy is added to the generic entry equation. *Branded Early Entry* generally has a significantly, negative effect on generic entry which is in absolute terms larger than the *Early Entry* effect. The effect of experience on generic entry decisions is smaller in data set 2. This sample is based upon potential entrants being experienced in the therapeutic fields suggesting that experience has less explanatory power. The estimates for data set 1 and data set 2 are overall similar, even though sample size has dropped by more than 50%. An overview of the probit estimates is given in table 4 below.

If early entry is endogenous, a probit model is strictly speaking misspecified and a recursive bivariate probit model that deals with sample selection is to be adopted instead.

[39]Grabowski and Kyle (2007) find similar average market exclusivity periods for that time interval.

[40]This finding warrants further data consistency checks and investigations. Patent attorneys currently review the allocation of patents and spcs to substances to confirm data quality.

	Data Set 1		Data Set 2	
Independent Variables	*Generic Entry*		*Generic Entry*	
Early Entry (0/1)	-0.307462***	-0.168553**	-0.110789*	0.023641
	(0.061615)	(0.054427)	(0.057831)	(0.053713)
Branded Early Entry (0/1)	–	-0.424429***	–	-0.400634***
		(0.079079)		(0.071901)
Pre-Entry Market Size	0.711012***	0.675100***	0.758461***	0.709444***
	(0.040148)	(0.045528)	(0.034700)	(0.038501)
Subsitutes	-0.002574*	-0.003012*	-0.002755*	-0.002928*
	(0.001524)	(0.001540)	(0.001514)	(0.001522)
Monopoly Duration	0.141807***	0.147210***	0.129846***	0.133207***
	(0.015144)	(0.015514)	(0.013531)	(0.013887)
Entry Opportunities	-0.155673***	-0.161712***	-0.157854***	-0.162762***
	(0.012099)	(0.012594)	(0.009999)	(0.010213)
Field Experience	0.019970***	0.020280***	0.007240**	0.007365**
	(0.002732)	(0.002771)	(0.002448)	(0.002478)
Field Experience^2	-0.000054***	-0.000055***	-0.000009	-0.000009
	(0.000009)	(0.000009)	(0.000008)	(0.000009)
Form Experience	0.004959***	0.005004***	0.002798***	0.002848***
	(0.000649)	(0.000655)	(0.000589)	(0.000591)
Form Experience^2	-0.000003***	-0.000003***	-0.000002***	-0.000002***
	(0.000001)	(0.000001)	(0.000001)	(0.000001)
Field Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Form Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Year Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-12.2462***	-12.9360***	-10.6943***	-11.1804***
N	23234		11518	
Prob > chi2	0.0000	0.0000	0.0000	0.0000

* p<0.05, ** p<0.01, *** p<0.001

Notes: An observation in the regression is the decision of a generic firm to launch a retail form after substances' loss of exclusivity (generic entry). Heteroskedasticity-robust and clustered standard errors in parentheses.

Table 4: Generic Entry: Univariate Probit – Coefficients

In such a model early entry – the variable possibly affected by selection – is instrumented for. We use the variables *Patent holder* and *Revenues Pipeline* as instruments because they should not be directly correlated with generic entry decisions, as we have argued above. Yet, they should explain early entry decision sufficiently well. We have run a univariate probit estimation regressing *Early Entry* (inter alia) on the two instrumental variables to provide evidence for their relevance. The coefficients are statistically significant and have the expected sign. The according results are presented in Appendix [B]. Alike the univariate probit regressions, *Branded Early Entry* is sequentially added to the generic entry equation in the bivariate probit regressions. Tables 5 and 6 below present the according results obtained for data set 1 and data set 2 regressions. The sign of the correlation coefficient ρ is significantly positive in all specifications and the size of the correlation between the generic entry and early entry equation has the same order of magnitude in data set 1 and data set 2. The result suggests that once early entry and early entrants trademark activities have been accounted for, unobserved factors that have a positively influence early entry increase the likelihood of generic entry as well. Hence, we have obtained evidence for selection, i.e. the endogeneity of early entry which presumably leads to an understatement of the early entry effect when not accounted for. In fact, the size of the *Early Entry* coefficients increase substantially in any of the bivariate probit specifications in comparison to the probit estimates.[41] The early entry effect now seems to dominate the branded early entry effect which is also significantly negative. The instruments are statistically significant and have the expected sign. The coefficients of *Substitutes*, *Monopoly Duration*, *Entry Opportunities* and the therapeutic and drug form experience variables practically remain the same. Only the coefficients of *Pre-Entry Market Size* increase in comparison to the probit estimates. Yet, the sign of all coefficients and their statistical significance is generally, robust to the variation in the model's specification. Therapeutic field, drug form and year effects are statistically significant in all instances.

In the light of empirical evidence affirming the positive influence of experience on generic entry decisions, data set 2 does reflect the status quo better than data set 1. As a consequence we assign more importance to the estimates that we have been obtained using data set 2, and base our interpretation on those results accordingly. We have computed marginal and average marginal effects for the univariate probit model to provide a first impression of the economic impact that early entry and trademarks have on generic entry. Given the presence of selection issues, the presented marginal effects are, however, to be interpreted cautiously and taken at best as a lower bound. The average marginal effect of early entry is insignificant in data set 2 (amounting to -2% in dataset 1) in contrast to the average marginal effect of branded early entry which is estimated to be -7.6%. Given that generic entry is predicted to occur with a probability of roundabout 40%, the overall effect of early entry and trademarks on generic entry is sizeable. The main drive of generic entry is, however, pre-entry market size. With an average marginal effect of 13%, this factor appears to counterbalance early entry and trademark deterrence effects most of the time, at least in this best case scenario.

[41] Marginal and average marginal effects will be computed and compared to provide a definite answer and describe the various effects in more detail.

	Data Set 1			
Independent Variables	*Generic Entry*	*Early Entry*	*Generic Entry*	*Early Entry*
Early Entry (0/1)	-1.209974***		-1.086019***	
	(0.108560)		(0.105939)	
Branded Early Entry (0/1)	–		-0.348240***	
			(0.064805)	
Pre-Entry Market Size (log)	0.805626***	0.887039***	0.845786***	0.884244***
	(0.040436)	(0.085481)	(0.045409)	(0.014894)
Subsitutes	-0.002901*	–	-0.003317*	–
	(0.001415)		(0.001429)	
Monopoly Duration	0.125753***	–	0.130767***	–
	(0.014195)		(0.014415)	
Entry Opportunities	-0.141461***	–	-0.147390***	–
	(0.011126)		(0.011531)	
Field Experience	0.018654***		0.018978***	
	(0.002478)		(0.002507)	
Field Experience^2	-0.000050***		-0.000051***	
	(0.000008)		(0.000008)	
Form Experience	0.004387***		0.004441***	
	(0.000563)		(0.000568)	
Form Experience^2	-0.000003***		-0.000003***	
	(0.000006)		(0.000006)	
Patent holder (0/1)		0.477513***		0.495978***
		(0.056865)		(0.005542)
Revenues Pipeline (log)		-0.034298***		-0.033963***
		(0.003047)		(0.003048)
Field Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Form Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Year Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-13.7554***	-17.5638***	-13.5903***	-17.6557***
ρ	0.618979		0.698284	
LR-Test ($\rho = 0$)	0.0000		0.0000	
N	23234			
Prob > chi2	0.0000		0.0000	

* p<0.05, ** p<0.01, *** p<0.001

Notes: An observation in the regression is the decision of a generic firm to launch a retail form after substances' loss of exclusivity (generic entry). The dependent variable is a binary variable that is 1 if generic entry occurs. In columns (2) and (4) early entry is treated as endogenous and instrumented by the variables *Patent holder* and *Revenues Pipeline*. Heteroskedasticity-robust and clustered standard errors in parentheses.

Table 5: Generic Entry: Bivariate Probit – Coefficients (I/II)

	Data Set 2			
Independent Variables	*Generic Entry*	*Early Entry*	*Generic Entry*	*Early Entry*
Early Entry (0/1)	-1.086754***		-0.954119***	
	(0.115998)		(0.124423)	
Branded Early Entry (0/1)	–		-0.267754***	
			(0.062260)	
Pre-Entry Market Size (log)	0.789532***	0.946628***	0.810404***	0.943400***
	(0.038933)	(0.029118)	(0.041977)	(0.029217)
Subsitutes	-0.002722*	–	-0.002862*	–
	(0.001306)		(0.001328)	
Monopoly Duration	0.115999***	–	0.119332***	–
	(0.012690)		(0.012962)	
Entry Opportunities	-0.152133***	–	-0.156224***	–
	(0.009859)		(0.010101)	
Field Experience	0.007036**		0.007177**	
	(0.002259)		(0.002294)	
Field Experience^2	-0.000008		-0.000009	
	(0.000008)		(0.000009)	
Form Experience	0.002371***		0.002439***	
	(0.000533)		(0.000541)	
Form Experience^2	-0.000002***		-0.000002***	
	(0.000000)		(0.000000)	
Patent holder (0/1)		0.308771**		0.329923**
		(0.095961)		(0.097388)
Revenues Pipeline (log)		-0.051407***		-0.051215***
		(0.004833)		(0.004824)
Field Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Form Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Year Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-12.7098***	-18.7296***	-12.9909***	-18.6930***
ρ	0.649296		0.622864	
LR-Test ($\rho = 0$)	0.0000		0.0000	
N	11518			
Prob > chi2	0.0000		0.0000	

* p<0.05, ** p<0.01, *** p<0.001

Notes: An observation in the regression is the decision of a generic firm to launch a retail form after substances' loss of exclusivity (generic entry). The dependent variable is a binary variable that is 1 if generic entry occurs. In columns (2) and (4) early entry is treated as endogenous and instrumented by the variables *Patent holder* and *Revenues Pipeline*. Heteroskedasticity-robust and clustered standard errors in parentheses.

Table 6: Generic Entry: Bivariate Probit – Coefficients (II/II)

6 Conclusion

Based on a unique pharmaceutical data set, exclusivity and trademark data, we have examined generic entry decisions in Germany within the time period 2002-2007. Estimates show that experience in therapeutic fields and drug form experience influence generic entry positively, whereas the number of off-patent substitute active ingredients and entry opportunities have a negative impact on the likelihood that generic retail forms are being launched. Moreover, we find evidence for selection resulting in an understatement – even insignificance – of the early entry effect when endogeneity issues are not accounted for. In the majority of entry models that we have estimated, we nevertheless observe a significantly negative effect of early entry on generic entry, which appears to be intensified by trademarks. Thus we can confirm our hypotheses that anticipated early entry and early entrants' use of trademarks lowers potential generic entrants' incentives to launch retail forms. Further research is warranted to clarify if early entry also causes some firms to completely refrain from entry into certain markets. Such an analysis will instead focus on the extent of generic entry that substances experience. The effects of early entry and trademarks on generic prices and market shares are another important area which we intend to examine in the future.

Appendix

[A] Summary Statistics

Variable Name	*Data Set*	Mean	Median	Min.	Max.	Sd.	N
Generic Entry	*1*	0.27	0	0	1	0.45	23234
	2	0.55	1	0	1	0.50	11518
Early Entry	*1*	0.26	0	0	1	0.44	23234
	2	0.32	0	0	1	0.47	11518
Branded Early Entry	*1*	0.10	0	0	1	0.31	23234
	2	0.13	0	0	1	0.34	11518
Pre-Entry Market Size (log)		15.74	16.50	0	19.05	3.35	79
	1	16.23	17.01	0	19.05	3.07	23234
	2	16.81	17.38	0	19.05	2.59	11518
Substitutes		50.25	41	9	205	38.48	79
	1	49.27	41	9	205	35.73	23234
	2	51.37	43	9	205	33.43	11518
Monopoly Duration		12.06	12.5	5	20	3.25	79
	1	11.92	12.5	5	20	3.15	23234
	2	11.78	12.5	5	20	3.08	11518
Entry Opportunities		14.87	14	4	19	3.63	79
	1	14.64	14	4	19	3.71	23234
	2	14.87	14	4	19	3.63	11518
Field Experience	*1*	9.07	2.70	0	163.06	16.98	241
	1	15.73	0	0	374	35.73	23234
	2	19.49	11.58	0	238.48	25.80	224
	2	31.72	15	0	374	44.91	11518
Form Experience	*1*	72.64	23.22	0	711.92	127.70	241
	1	133.88	30	0	1823	227.71	23234
	2	86.04	35.46	0	718.49	133.92	224
	2	244.77	134	0	1823	278.09	11518
Patent holder		0.84	1	0	1	0.37	79
	1	0.85	1	0	1	0.36	23234
	2	0.86	1	0	1	0.35	11518
Revenues Pipeline (log)		15.18	19.46	0	21.85	7.67	79
	1	15.39	19.49	0	21.85	7.46	23234
	2	15.34	19.46	0	21.85	7.51	11518

[B] Univariate Probit – Coefficients

	Data Set 1		Data Set 2	
Independent Variables	*Early Entry*	*Branded Early Entry*	*Early Entry*	*Branded Early Entry*
Pre-Entry Market Size	0.854296***	0.936846***	0.939351***	0.932765***
	(0.014196)	(0.017011)	(0.024318)	(0.023843)
Patent holder (0/1)	0.701472***	–	0.509611***	–
	(0.029422)		(0.046261)	
Revenues Pipeline (log)	-0.040950***	-0.027625***	-0.050637***	-0.026064***
	(0.001732)	(0.001738)	(0.002555)	(0.002213)
Trademark Activity	–	0.001276***	–	0.001266***
		(0.000025)		(0.000033)
Field Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Form Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Year Effects (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-17.5619***	-18.4033***	-19.1060***	-18.3103***
N	23234		11518	
Prob > chi2	0.0000	0.0000	0.0000	0.0000

* p<0.05, ** p<0.01, *** p<0.001

Notes: Heteroskedasticity-robust and clustered standard errors in parentheses.

[C] Trivariate Probit – Coefficients

	Data Set 2		
Independent Variables	*Generic Entry*	*Early Entry*	*Branded Early Entry*
Early Entry (0/1)	0.1533682		
	(0.081132)		
Branded Early Entry (0/1)	-1.22986***		
	(0.131862)		
Pre-Entry Market Size (log)	0.618334***	0.428798***	0.802948***
	(0.029361)	(0.017828)	(0.036065)
Subsitutes	-0.006259***		
	(0.001072)		
Monopoly Duration	0.049105***		
	(0.011773)		
Entry Opportunities	-0.093987***		
	(0.008235)		
Field Experience	0.005705**		
	(0.001687)		
Field Experience^2	-0.000003		
	(0.000006)		
Form Experience	0.002622***		
	(0.000452)		
Form Experience^2	-0.000002***		
	(0.000000)		
Patent holder (0/1)		0.310630***	
		(0.042925)	
Trademark Activity			0.000200**
			(0.000064)
Field Effects (0/1)	*yes*		
Const.	-9.0729***	-8.1731***	-15.4391***
$\rho 12$ / $\rho 13$ / $\rho 23$	0.201933**	0.343551***	0.932148***
LR-Test ($\rho 12 = \rho 13 = \rho 23 = 0$)		0.0000	
N		11518	
Prob > chi2		0.0000	

* p<0.05, ** p<0.01, *** p<0.001

Notes: Heteroskedasticity-robust and clustered standard errors in parentheses.

References

Accenture (2005). "Die Bedeutung der Generikaindustrie für die Gesundheitsversorgung in Deutschland."

Berndt ER, Mortimer R, Bhattacharjya A, Parece A, Tuttle E (2007a). "Authorized Generic Drugs, Price Competition, and Consumers' Welfare." *Health Affairs*, **26**(3), 790–799.

Berndt ER, Mortimer R, Parece A (2007b). "Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence." Working Paper.

Caves RE, Whinston MD, Hurwitz M, Pakes A, Temin P (1991). "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry." *Brookings Papers on Economic Activity. Microeconomics*, **1991**, 1–66.

Commission E (2008). "Pharmaceutical Sector Inquiry – Preliminary Report."

Danzon PM, Chao LW (2000). "Does Regulation Drive out Competition in Pharmaceutical Markets?" *Journal of Law and Economics*, **43**, 311–357.

Evans WN, Schwab RM (1995). "Finishing High School and Starting College: Do Catholic Schools Make a Difference?" *The Quarterly Journal of Economics*, **110**(4), 941–974.

Grabowski HG, Kyle M (2007). "Generic Competition and Market Exclusivity in Pharmaceuticals." *Managerial and Decision Economics*, **28**, 491–502.

Grabowski HG, Vernon JM (1992). "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act." *Journal of Law and Economics*, **35**, 331–350.

Greenhalgh C, Rogers M (2006). "Trade Marks and Market Value in UK Firms." Melbourne Institute Working Paper No. 4/06.

Griffith W, Webster E (2004). "Trends in the Value of Intellectual Property in Australia." Working Paper No. 18/04.

Heckman JJ (1978). "Dummy Endogenous Variables in Simultaneous Equation System." *Econometrica*, **46**, 931–959.

Hollis A (2002). "The Importance of Being First: Evidence from Canadian Generic Pharmaceuticals." *Health Economics*, **11**, 723–734.

Hollis A (2003). "The Anti-Competitive Effects of Brand-Controlled "Pseudo-Generics" in the Canadian Pharmaceutical Market." *Canadian Public Policy / Analyse de Politiques*, **29**, 21–32.

Hudson J (2000). "Generic Take-up in the Pharmaceutical Market following Patent Expiry - A Multi-Country Study." *International Review of Law and Economics*, **20**, 205–221.

Hurwitz MA, Caves RE (1988). "Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals." *Journal of Law and Economics*, **31**, 299–320.

Moreno-Torres I, Puig-Junoy J, Borrell-Arque JR (2007). "Generic Entry into a Regulated Pharmaceutical Market." Working Paper.

Morton FMS (1999). "Entry Decisions in the Generic Pharmaceutical Industry." *The RAND Journal of Economics*, **30**, 421–440.

Morton FMS (2000). "Barriers to Entry, Brand Advertising, and Generic Entry in the U.S. Pharmaceutical Industry." *International Journal of Industrial Organization*, **18**, 1085–1104.

Morton FMS (2002). "Horizontal Integration between Brand and Generic Firms in the Pharmaceutical Industry." *Journal of Economics and Management Strategy*, **11**, 135–168.

Raasch AC (2007). *Der Patentauslauf von Pharmazeutika als Herausforderung beim Management des Produktlebenszyklus*. DUV.

Reiffen D, Ward ME (2005a). "Branded Generics as a Strategy to Limit Cannibalization of Pharmaceutical Markets." *Managerial and Decision Economics*, **28**, 251–265.

Reiffen D, Ward ME (2005b). "Generic Drug Industry Dynamics." *Review of Economics and Statistics*, **87**, 37–49.

Saha A, Grabowski H, Birnbaum H, Greenberg P, Bizan O (2006). "Generic Competition in the U.S. Pharmaceutical Industry." *International Journal of the Economics of Business*, **13**, 15–38.

Scherer F (2000). *The Pharmaceutical Industry*. Handbook of Health Economics, I. Elsevier. Culyer, A.J., Newhouse, J.P. (Eds.), Amsterdam.

von Graevenitz G (2006). "Which Reputations Does a Brand Owner Need? Evidence from Trade Mark Opposition." Working Paper, University of Munich.

WHO (1999). "Globalization and Access to Drugs."

WHO (2005). "The WHO/United Nations – Pre-qualification Project."

Wilde J (2000). "Identification of Multiple Equation Probit Models with Endogenous Dummy Regressors." *Economics Letters*, **69**, 309–312.