Early Entry and Trademark Protection – An Empirical Examination of Barriers to Generic Entry

Silvia Appelt*

Munich Graduate School of Economics, University of Munich

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Abstract

Examining the joint impact of early entry and trademark protection, we investigate generic entry deterrence in pharmaceutical markets. Patent holders attempt to mitigate the loss of monopoly power by authorizing generic entry prior to patent expiry. Competition in off-patent markets may be adversely affected, especially if early entrants build brands. Estimating probit, bivariate and trivariate probit models, we show that early entrants' use of trademarks deters generic entry. With an average reduction of the entry probability of 7%, the effect is sizeable but not large enough to impair generic entry in the high-revenue markets which early entrants target.

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*Address: Amalienstr. 17, Room# B202, 80333 Munich, Germany, telephone: +49-89-2180-4698; Mail to: MGSE, Kaulbachstrasse 45, 80539 Munich, Germany; E-mail: *silvia.appelt@lrz.uni-muenchen.de.*

1 Introduction

Patents grant innovators in pharmaceutical markets monopoly rents for a limited period. By authorizing generic entry prior to patent expiry, patent holders may attempt to mitigate the loss of monopoly power. Competition in off-patent markets may be adversely affected, especially if early entrants build brands. This study investigates generic entry deterrence examining the joint impact of early entry and trademark protection. We have assembled a dataset comprising pharmaceutical market, exclusivity and trademark data for the German pharmaceutical market which is the second largest generic drug market in the world. Estimating probit, bivariate and trivariate probit models – where the latter two models account for the endogeneity of the early entry dummy regressors –, we show that early entrants' use of trademarks deters generic entry. With an average reduction of the entry probability of 7%, the effect is sizeable but not large enough to impair generic entry in the high-revenue markets which early entrants target. Pre-entry market size is the main determinant of generic entry.

As blockbuster drugs lose patent protection and drug pipelines have run dry, "Big Pharma" seeks ways to limit profit erosion following generic entry (Economist, 2008). 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 entry occurs frequently in many pharmaceutical markets throughout the world with early entrants often pursuing product differentiation strategies, i.e. they register trademarks and build brands for the generic drugs they launch (branded early entry). Griffith and Webster (2004) and Greenhalgh and Rogers (2006) show trademarks to be positively correlated with firms' market value in several industries. What bearing early entrants' use of trademarks has on subsequent generic entry is an important yet unresolved question that also requires investigation. If market segmentation effects play a role, the effect of early entry likely depends on the anticipated trademark (brand) strategy of the early entrant. 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), and the brand-name drug's goodwill stock (Hurwitz and Caves, 1988; Hudson, 2000) to be important influencing factors of generic entry. Several empirical studies (Hollis, 2003; Reiffen and Ward, 2005a; Berndt *et al.*, 2007a,b) explicitly deal with early entry and its potentially anti-competitive effect on generic entry. Authors arrive at different conclusions about the effects of early entry. Overall, there is no comprehensive empirical evidence based on recent data that would show early entry to have had a delaying or deterring effect on independent generic entry (Berndt *et al.*, 2007a). Given empirical evidence of first-mover-advantages (Caves *et al.*, 1991; Grabowski and Vernon, 1992; Hollis, 2002) and the revealed preference of early entrants for trademark protection, we hypothesize early entry and trademark protection to be complementary barriers to generic entry. 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

[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.

office. We make use of trademark data to address product differentiation efforts of early entrants[2]. 79 substances[3] lost exclusivity between 2002-2007. By the end of 2007, generic firms entered in 49 markets, resulting in a total of 767 market entries[4] by generic firms. Of the 49 markets, 16 were affected by early entry. Early entrants in turn embarked on a trademark strategy in 6 markets. Estimating a probit model, recursive bivariate and recursive trivariate probit model, we show that early entrants' use of trademarks deters generic entry. First mover advantages alone do not explain entry deterrence. Treating early entry or branded early entry as exogenous variables (probit model) could give rise to a selection problem and inconsistent estimates if early entry or branded early entry occurred in markets that are more attractive than given market characteristics suggest. Bivariate and trivariate probit estimates provide no evidence of selection. The effect of branded early entry is significantly negative in all specifications, reducing the probability of generic entry of 7% on average. With an average marginal effect of 12% pre-entry market size is the major determinant of generic entry. The observed entry patterns in high-revenue markets targeted by early entrants suggest that anticipated branded early entry has not impaired generic entry. The number of off-patent substitute active ingredients has a negative impact on entry. Firms' therapeutic and drug form 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. It also outlines empirical results on the economic relevance of trademarks. Main aspects of the generic drug 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 entry is not a new phenomenon in Europe or the USA. Nevertheless, few empirical studies deal with early entry – also known as authorized, branded or pseudo-generic entry – and its potentially anti-competitive effect on generic entry. However, first generic entrants have been shown to have long-lasting advantages 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. Prior studies draw different conclusions about the effect of early entry on independent generic entry. Whereas Hollis (2003) strongly argues that early entry has a deterring effect on independent generic entry and substantial welfare effects, Berndt *et al.* (2007a) and Reiffen and Ward (2005a) take a more moderate

[2]Generic advertising is typically rare (Scherer, 2000; Morton, 2000).

[3]Throughout the paper the term substance is equivalently used for mono-substance, i.e. a substance that contains one active ingredient only. As the allocation of all relevant patents and supplementary protection certificates to mono-substances is not trivial, the analysis is confined to mono-substances for now.

[4]Overall there are 96 generic entrants. As one firm typically enters in more than one market, we observe 767 generic entries in total.

position. Berndt *et al.* (2007a) posit that the effect of early entry on independent generic entry and consumer welfare is likely to be small. Reiffen and Ward (2005a) in turn show that early entry may considerably impair generic entry in small or medium-sized markets only. Overall, however, there is no comprehensive empirical evidence based on recent data that would show early entry to have had a delaying or deterring effect on independent generic entry (Berndt *et al.*, 2007a). Early entrants' use of trademarks as a complementary barrier to generic entry is an untouched subject in the previous literature.

Hollis (2003) explains that patients' unwillingness 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. He 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[5] 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, he 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 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. She 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 USA to introduce authorized generics pre-patent expiry, and explicitly dealing 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 the consumer welfare effects of authorized generic entry in the USA has been provided by Berndt *et al.* (2007a,b), examining its effect on the filing of Abbre-

[5]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.

viated New Drug Approvals (ANDA)[6] with a paragraph IV certification (claim of patent non-infringement or invalidity). 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 market the same version of the drug. These studies look at the change of generic entrants' incentives to enter timely, not necessarily at the decision to enter or not, or related, the extent of generic entry. Berndt *et al.* (2007b) point out, that several factors besides authorized generic entry may limit the profitability of the 180-day exclusivity period.[7] 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 argue that authorized generic entry and its recent increase have not delayed generic entry in the USA.

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 subject of "generic product differentiation" has not been touched yet despite the apparent relevance of trademarks for generic firms (von Graevenitz, 2006), in particular for 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 among 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 and firms' market value in various industry sectors. Given early entrants revealed preference for trademark-protection, a closer look at their trademark activities is warranted. We investigate if early entry and trademark protection are complementary barriers to 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 entry and brands.
Drug expenditures have steadily increased in Germany over the last couple of years. In the German statutory health-insurance system[8] alone drug expenditures amount to €25.6 Bn.[9], 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 medication 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

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

[7] Multiple entrants are awarded 180-day exclusivity given they apply for the same dose at the same day.

[8] The statutory health-insurance plan covers about 85% of the German population.

[9] BPI Pharma-Daten 2008; see also Commission (2008), p. 26.

route of administration. Generic drugs are typically offered at a substantial price discount[10] as a consequence of price competition and lower R&D outlays. No safety and efficacy tests have to be conducted, only the less cost-intensive bioequivalence studies[11]. An increase in generic substitution has been achieved through the *Aut-idem* regulation for prescription drugs which was introduced in 2002. If doctors have not explicitly excluded substitution, a pharmacist generally has to sell one of the three cheapest generic alternatives to the patient. If a more expensive product is sold instead, the pharmacist incurs the difference in price. Since 2004, dispensing fees on prescription drugs[12] consist mainly of a fixed component. The pharmacist receives 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 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 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 important in the generic market segment. Prices on generic drugs are indirectly regulated through reference prices.[13] 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[14], 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 drug of that firm which their insurance has contracted with. Except for rebate contracts, previous regulation seems to have provided few incentives on parts of doctors, pharmacists or patients to switch between identical generic drugs as long as the price difference is minor. 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. However, some generic drugs are 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

[10] Generic price discounts are in the range of 20-80% of the original drug's price (WHO, 1999).

[11] 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.

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

[13] 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.

[14] 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 also often cooperate with generic firms in order to optimize the product life cycle of their drugs.[15]

Early entry, where a generic version of the original drug is marketed through a generic subsidiary or licensee partner pre-patent expiry, occurs on a frequent basis.[16] The data reveals that licensing was the preferred mode to arrange for an early entry between 2002-2007, and that early entrants often pursued trademark activities. The aim 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.[17] 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 early entry is undoubtedly crucial. Early entrants' trademark activities also suggest that generic firms are well aware of the competitive edge that trademarks provide.

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[18] (data exclusivity period).[19] 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, the original drug producer's market exclusivity period is extended for another year (8+2+1-

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

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

[17] 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).

[18] 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.

[19] 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.

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 prior to loss of exclusivity[20] and actual entry (WHO, 1999). Due to the disclosure[21] of generic applications dossiers, generic firms effectively sunk entry costs simultaneously and can only form expectations about competitors' actions.[22]

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 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[23]. The pharmaceutical market data comprise information on drugs[24], medical products and the retail forms that are available. Additionally, they give information on manufacturers, prices, rebates in kind and the turnover and revenues that manufacturers in the German retail market generate. 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 focused on human medication 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 is significantly larger in the retail segment – approximately three times larger in 2007 – compared to the turnover generated by the

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

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

[22] 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..

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

[24] 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.

hospital channel (Commission, 2008). Thus, for the vast majority of substances in this study (prescription drugs), retail revenues provide a sufficiently reliable measure.

The unit of observation is the market entry decision of a generic firm. Given information on the date of generic firms' retail form launches, we can identify those substances which possibly experienced generic entry for the very first time between 2002 and 2007. Thus, we obtain a primary indication for patent or SPC expiration. In total, 69 substances were found that potentially experienced a loss of exclusivity. For a validation of potential patent and SPC expirations, pharmaceutical market data and exclusivity data were merged. The exclusivity data set was generated by matching patent and SPC data from *Insight Health*, with a restriction of the data to mono-substances, EP and DE patents, and to market authorizations and SPC extensions in Germany. Based on information on the date of substances' patent and SPC expirations, 65 substances were found to have lost exclusivity between 2002 and 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 (international) trade names[25] the substance was marketed under. Many of the 69 substances that are identified to have experienced generic entry for the very first time between 2002 and 2007 were also found among the 65 substances that either lost patent or SPC protection in this period. Through an extensive review of additional data sources[26] 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 entry or patent invalidity cases that would explain entry prior to the official date of patent or SPC expiration. Finally, the data were matched with trademark data based upon the correspondence of product names and trademarks.[27] Trademark data is obtained from the German patent and trademark office (*DPMA*). Inter alia it gives information about the date of trademark registration and publication, the trademark owner(s) and the trademark's Nice classification[28]. Trademark data is used to measure product differentiation efforts on parts of early entrants. Data on advertising expenditures in the pharmaceutical industry at product level could not be obtained. Given the relevance of trademarks for German generic firms and the fact that generic advertising[29] is limited (Scherer, 2000; Morton, 2000), the lack of advertising data is not a severe constraint. Trademark activities will serve as a proxy for generic firms' product differentiation efforts instead.

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 six of these cases early entrants had pursued a branding strategy

[25]A comparison of the listed trade names with the product name (as given in the pharmaceutical data set) facilitated another validity check of the pharmaceutical market and exclusivity data match.

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

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

[28]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.

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

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 market entries that occured by 2007, the number of therapeutic fields[30] substances are used in, and the number of available drug forms[31] by 2007. A more detailled overview of generic and early entry patterns is provided in Appendix [A].

Table 1: Generic Entry Opportunities (2002-2007)

	Markets	Pre-Entry Market Size		Entries	Indications		Drug Forms	
	N	Mean	Median	N	Mean	Median	Mean	Median
Generic Entry	49	48.3	33.3	767	1.14	1	3.18	3
No Early Entry	33	44.7	26.2	445	1.09	1	3.21	3
Early Entry	16	55.6	39.8	26	1.25	1	3.13	2.5
With Trademark	6	73.9	49.4	7	1.16	1	3.00	2.5
No Trademark	10	44.6	39.8	19	1.30	1	3.2	2.5
No Generic Entry	30	0.55	0.22	0	1.06	1	1.67	1
Total	79	32.1	14.7	793	1.11	1	2.61	2

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 products 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.

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. According to the approach of Morton (1999), sets of potential entrants are constructed for each substance in order to deal with the problem of partial observability.[32] 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 from the data set, 991 firms remain. A further restriction of entry candidates 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 419.3 (Median: 216.3) retail forms in their portfolio at the time entry opportunities come up. By restricting the set of potential entrants to manufacturing firms (no re-import) with a portfolio of at least 50 retail forms – a soft constraint –, the number of firms is reduced to 198. These 198 firms manufactured 89.4% of all retail forms available on the German market between 1999-2007, of

[30]Therapeutic fields are classified by the ATC System at the second level of aggregation (ATC2).
[31]Routes of administration are classified by the NFC System at the second level of aggregation (NFC2).
[32]Kyle (2007) determines market entry opportunities in a similiar fashion.

which 184 firms were also found to have generic drug portfolios[33]. As active manufacturers with mostly some generic market-orientation, these 198 firms represent potential market entry candidates. Out of these 198 companies the first set of potential entrants is created for each substance by including only those firms that are active at the time exclusivity expires, i.e. they must 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, having marketed a positive number of retail forms in the relevant therapeutic field(s). The last set of potential entrants, is created by limiting the firms in set 2 to those firms that additionally have expertise in manufacturing the route(s) the substance is administered in (positive number of retail forms marketed in the relevant drug form(s)), at the time exclusivity is lost. Sets of potential entrants are assigned to each and every substance, such that three different samples are created and a verification and evaluation of the robustness of results is feasible. Table 2 provides an overview of the three sets of potential entrants[34] and generated data sets.

Table 2: Sets of Potential Entrants

	Data Set 1	Data Set 2	Data Set 3
Definition	Firms with no re-import business, a portfolio of at least 50 retail forms, and active at the time of loss of exclusivity.	Firms in Data Set 1 which are active in the relevant field(s) of indication (ATC2).	Firms in Data Set 2 with expertise in manufacturing the relevant route(s) of administration (NFC1).
Potential Entrants	Total: 220 Mean: 197.4 Median: 198	Total: 203 Mean: 57.6 Median: 56	Total: 200 Mean: 50.8 Median: 52
Generic Entries	Total: 767	Mean: 15.7	Median: 14
Zero-Entries	Total: 14825 Mean: 187.7 Median: 191	Total: 3781 Mean: 47.9 Median: 42	Total: 3243 Mean: 41.05 Median: 38
Sample Size (N)	15592	4548	4010

With an increasing limitation of the total number of potential entrants from data set 1 to data set 3, the average and median number of potential entrants each substance attracts declines. The same logic applies to the number of Zero-Entries and sample size. In total 767 generic firm entries are observed, looking at the 49 markets that eventually attracted generic entry. Substances were affected by 15.7 generic firm entries on average. Appendix [B] gives an overview of generic entries' and zero-entries' distribution(s) over substances.

[33]Since the 96 generic entrants had no generic drug portfolio prior to loss of exclusivity in 10 instances (2 business expansions to the generic drug market, 7 company foundations and 1 acquitision), we do not exclude firms with no generic drug portfolio from the sets of potential entrants.

[34]Whenever firme enter which are not tracked in the set of potential entrants, the total number of potential entrants increase accordingly, cp. data set 1, 2 and 3.

4.2 Empirical Model

Based on the three cross-sectional data sets, the impact of early entry and early entry in interaction with trademarks, will be examined. As first-mover advantages are important in the generic market segment, early entry has been argued to diminish the expected profitability of subsequent generic entry. Thus, early entry is assumed to negatively affect independent generic entry if anticipated by potential entrants. Trademarks, in turn, have been shown to be positively correlated with firms' market value, i.e. they turn out be a measure of brand 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 anticipate correctly that some early entrants will embark on a product differentiation strategy. The two hypotheses to be tested are 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 (brand 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[35] determine expected market profits and, as a result both the likelihood of generic and early entry, it is essential to account and test for the endogeneity of early entry when examining its impact. If early entry is endogenous, its effect is likely to become understated 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 – ignoring any endogeneity issues–, we estimate a probit model (Specification (1)) to examine the effect of early entry (ee_i) on the entry of generic firm j in market i (g_{ij}). For the purpose of identifying a correlation between generic entry and early entry over the error terms and providing evidence for selection, we estimate a recursive bivariate probit model in the second step.[36] In the recursive bivariate probit model early entry is instrumented for, i.e. we simultaneously estimate an early entry equation in addition to the generic entry equation. 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.[37] If markets are highly attractive they will attract both generic and early entrants (see Table 1). If generic firms correctly anticipate early entry they will potentially be discouraged to enter if incentives are being lowered substantially. In this line

[35] If future, therapeutic innovations are expected to change the competitive landscape, entry into a certain market may be less attractive than observed market characteristics suggest. 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 trend projections possibly affect expected profits additionally.

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

[37] With patent holders' permission early entrants may launch products any time prior to loss of exclusivity.

of reasoning, we include the early entry dummy in the generic entry equation and not vice versa. A trademark dummy is finally interacted with the early entry dummy (ee_tm_i) and added to the probit and recursive bivariate probit models' first generic entry specification in order (Specification (2)) to estimate the impact of trademarks on the particular size of the early entry effect. The value of the *Branded Early Entry* dummy equals one whenever early entrants have registered trademarks for product name(s). Potential endogeneity issues with respect to early entrants' trademark activities are abstracted from in both the probit and recursive bivariate probit model. In a recursive trivariate probit model we finally attempt to account and test for the endogeneity of both early entry and branded early entry.

Factors such as pre-entry market size, monopoly duration and the number of off-patent substitute active ingredients obviously affect the likelihood of generic entry, and need to be controlled for (co-variates $\mathbf{X}$[38]). As firm characteristics – in particular the experience in a therapeutic field or with a particular drug form – have also been shown to strongly influence generic entry decisions (Morton, 1999), potential entrants' therapeutic field experience and drug form experience will be accounted for as well (capability $\mathbf{C_{ij}}$). Generic entry decisions are likely not to be independent on firm-level, thus observations are clustered over firms and heteroscedasticity-robust standard errors are adjusted accordingly. The probit model with the two specifications to be estimated is the following[39]:

$$\begin{aligned} g_{ij} &= 1[g_{ij}^* > 0] \quad where \quad g_{ij}^* = \mathbf{X\boldsymbol{\beta_{11}}} + \mathbf{C_{ij}\boldsymbol{\alpha_1}} + \delta_1 ee_i + \epsilon_{ij} \qquad (1) \\ g_{ij} &= 1[g_{ij}^* > 0] \quad where \quad g_{ij}^* = \mathbf{X\boldsymbol{\beta_{21}}} + \mathbf{C_{ij}\boldsymbol{\alpha_2}} + \delta_2 ee_i + \gamma_2 ee\_tm_i + \epsilon_{ij} \qquad (2) \end{aligned}$$

In contrast to the probit model, the recursive bivariate probit model allows for the possibility that unobserved determinants of generic entry and early entry are correlated. The error terms ϵ_{ij} and μ_i are assumed to be distributed bivariate normal, with $E(\epsilon_{ij}) = E(\mu_i) = 0$, $Var(\epsilon_{ij}) = Var(\mu_i) = 1$ and $Cov(\epsilon_{ij}, \mu_i) = \rho$. Early entry is now being instrumented for and generic entry (g_{ij}) and early entry (ee_i) equations are estimated simultaneously with standard errors being again clustered and heteroscedasticity-robust. In order to allow for identification, we add four variables (identifiers $\mathbf{I}$) to the early entry equation which explain early entry and have no direct impact on markets' attractiveness and thus generic entry decisions: *Patent holder*, *Revenue Share*, *Revenue Pipeline* and *Revenue Loss*. Econometricians (Heckman, 1978; Wilde, 2000) argue that exclusion restrictions are not required in simultaneous equation systems with endogenous dummy regressors to achieve identification given there is at least one exogenous regressor that shows sufficient variation. Yet, we attempted to find variables which promise to provide valid exclusion restrictions on theoretical grounds.[40] The bivariate probit model's specifications to be estimated are outlined below:

$$\begin{aligned} g_{ij} &= 1[g_{ij}^* > 0] \quad where \quad g_{ij}^* = \mathbf{X\boldsymbol{\beta_{11}}} + \mathbf{C_{ij}\boldsymbol{\alpha_1}} + \delta_1 ee_i + \epsilon_{ij} \qquad (1) \\ ee_i &= 1[ee_i^* > 0] \quad where \quad ee_i^* = \mathbf{X\boldsymbol{\beta_{12}}} + \mathbf{I\boldsymbol{\tau_{12}}} + \mu_i \\ g_{ij} &= 1[g_{ij}^* > 0] \quad where \quad g_{ij}^* = \mathbf{X\boldsymbol{\beta_{21}}} + \mathbf{C_{ij}\boldsymbol{\alpha_2}} + \delta_2 ee_i + \gamma_2 ee\_tm_i + \epsilon_{ij} \qquad (2) \\ ee_i &= 1[ee_i^* > 0] \quad where \quad ee_i^* = \mathbf{X\boldsymbol{\beta_{22}}} + \mathbf{I\boldsymbol{\tau_{22}}} + \mu_i \end{aligned}$$

[38]The matrix $\mathbf{X}$ also includes therapeutic field, drug form and year dummies.

[39]The parameters α, β, δ and γ are indexed by the specification and number of equation estimated (if appearing in more than one equation). Variables and error terms are not indexed to keep notations short.

[40]A test of over-identifying-restrictions is not feasible given the dichotomy of both generic and early entry.

The recursive trivariate probit model's structure is similar. Whereas the recursive bivariate probit model has two equations, the recursive trivariate probit model incorporates three equations (g_{ij}, ee_i, ee_tm_i) and allows for the possibility that unobserved determinants of generic entry, early entry and branded early entry are correlated. The error terms ϵ_{ij}, μ_i and ν_i are assumed to be distributed trivariate normal, with $E(\epsilon_{ij}) = E(\mu_i) = E(\nu_i) = 0$, $Var(\epsilon_{ij}) = Var(\mu_i) = Var(\nu_i) = 1$, $Cov(\epsilon_{ij}, \mu_i) = \rho_{12}$, $Cov(\epsilon_{ij}, \nu_i) = \rho_{13}$ and $Cov(\mu_i, \nu_i) = \rho_{23}$. Given the simultaneity of early entry and branded early entry[41] we use the same instruments in the early entry and branded early entry equation, i.e. we do assume that we achieve identification through sufficient variation in exogenous regressors. The recursive trivariate probit model to be estimated for Specification (2) is the following:

$$\begin{array}{rcll} g_{ij} & = & 1[g_{ij}^* > 0] & where \quad g_{ij}^* = \mathbf{X}\boldsymbol{\beta_{21}} + \mathbf{C_{ij}}\boldsymbol{\alpha_2} + \delta_2 ee_i + \gamma_2 ee\_tm_i + \epsilon_{ij} \\ ee_i & = & 1[ee_i^* > 0] & where \quad ee_i^* = \mathbf{X}\boldsymbol{\beta_{22}} + \mathbf{I}\boldsymbol{\tau_{22}} + \mu_i \\ ee\_tm_i & = & 1[ee\_tm_i^* > 0] & where \quad ee\_tm_i^* = \mathbf{X}\boldsymbol{\beta_{23}} + \mathbf{I}\boldsymbol{\tau_{23}} + \nu_i \end{array} \quad (2)$$

The dependent variable of interest – *Generic Entry* – is defined as market entry of an independent generic firm after substances' loss of exclusivity and is coded as 0-1 dummy. If a generic subsidiary or licensee partner of the original drug producer entered a market prior to loss of exclusivity (early entry), the according *Early Entry* dummy regressor takes on the value one. If early entrants launch products 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* is 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. Previous studies have 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 add *Monopoly Duration* as variable to generic entry and early entry equations, measuring the number of years from the original drug producer's first market approval to loss of exclusivity. *Substitutes* – the number of off-patent substitute active ingredients – is included as another covariate in generic entry and early 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[42]. As a proxy for potential entrants' therapeutic experience we use the number of retail forms the firm has launched prior to loss of exclusivity in the therapeutic field(s) the substances is used in. Similarly, we use the number of retail forms the firm 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 equations.

As an 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 licensees thereof. If original drug producers hold the relevant patent(s) they

[41] One may observe branded early entry only if early entry occurred.

[42] 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.

can directly decide upon early entry arrangements, i.e. they have the decision power and transaction costs are lower.[43] Thus, one would expect *Patent holder* to have a positive effect on early entry. The attractiveness of a market, however, does not seem to be impaired by the fact that original drug producers possess or license the relevant patent(s) protecting the compound in question. Early entries are likely to be motivated by original drug producers' financial need. For this reason, we include the variables *Revenue Share*, *Revenue Pipeline* and *Revenues Losses* as instruments in the early entry equation. *Revenue Share* indicates the substances' share in original drug producers' total annual revenues in the year of loss of exclusivity. The larger the substance's share in original drug producers' total annual revenues, the larger the chances that early entry occurs. *Revenue Pipeline* measures the total annual market revenue with patent-protected substances original drug producers' generate in the year substances' exclusivity expires. We expect *Revenue Pipeline* to have a negative effect on the likelihood of early entry. *Revenues Losses* lastly sums up other revenue losses original drug producers face due to losses of exclusivity in the time period 2002-2007. Early entries are assumed to be less likely when original drug producers revenue losses in the given time period are smaller. Again, we argue that original drug producers' 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. Therapeutic field (ATC1 Classification)[44], drug form (NFC1 Classification)[45], and year dummies are finally included in all generic entry and early entry equations to account for field, drug form and year fixed effects.[46] A summary of definitions is provided in table 3 below. The distribution of variables differs in the three data sets given that the number of Zero-Entries is lower in second and third data set. The fraction of generic entries, early entries and brand early entries increases from data set 1 to data set 3 respectively. One should note, that the mean and median therapeutic field and drug form experiences increase with a restriction to therapeutic and drug form experienced firms from data set 1 to data set 3.[47] An overview of the according summary statistics is presented in the Appendices [C1]–[C3]. Additional variables such as the size of the original drug producers' retail form portfolio or the number of re-import suppliers in the market two years prior to loss of exclusivity proved insignificant, and so only a parsimonious set of variables is presented here.

[43] In the 16 markets affected by early entry, only two original drug producers were licensees.

[44] Substances' therapeutic applicability does not change, i.e. increase, after loss of exclusivity.

[45] Substances' total number of routes of administration increases after loss of exclusivity in 5 instances. Both original drug producers and generic firms introduce between one to two new drug forms (same strengths). Given that original products are named identically, we conclude that in the three given cases no second generation, patent-protected products were launched and exclusively supplied. We consider the complete spectrum of substances' drug forms being available by 2007, when constructing drug form (NFC1) dummies. Empirical results do not change when using a more restrictive definition, i.e. when we account for drug forms available prior to loss of exclusivity only.

[46] Parasitology and sense organs as therapeutic fields, ophthalmologic or lung administration as drug forms, and the year 2002 as year of loss of exclusivity, form the reference group.

[47] Firms in data set 3 resemble generic entrants most, looking at the size of retail form portfolios as well as the average therapeutic and drug form experiences prior to loss of exclusivity.

Table 3: Definition of Variables

Variable Name	Definition
Generic Entry	0-1 dummy variable,=1 if generic firm entered market after substance's loss of exclusivity.
Early Entry	0-1 dummy variable,=1 if early entry occured prior to 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 product(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.
Monopoly Duration	Number of years from original drug's first market approval to loss of exclusivity.
Substitutes	Number of off-patent substitute active ingredients – listed in the same ATC2 class(es) – at the time exclusivity expires.
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).
Field Experience^2	Square of *Field Experience*.
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).
Form Experience^2	Square of *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 Share	Substances' share in original drug producers' total annual revenues in the year exclusivity is lost (revenues measured in €Mio. and evaluated at producer prices).
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.
Revenue Losses (log)	Sum of other revenue losses (pre-entry market sizes) original drug producers face due to losses of exclusivity in 2002-2007.
Therap. Field	0-1 dummy variable,=1 if substance has been used in Therapeutical Field by 2007 (ATC1 Classification: 13 dummies).
Drug Form	0-1 dummy variable,=1 if substance has been administered in particular drug form by 2007 (NFC1 classification: 10 dummies).
Year Expiry	0-1 dummy variable,=1 if loss of exclusivity occured in a given year (6 year dummies).

5 Results

In the first instance we estimate a probit model – ignoring any selection problems that may exist – and examine the impact of early entries and trademarks on independent generic entry. We estimate two probit specifications for each of the three data sets at hand. An overview of the estimated coefficients is given in table 4 below. Overall, estimates are very similar, even though sample size drops notably from data set 1 to data set 3. Probit estimates indicate that early entry has a significantly negative effect on generic entry (Spec.1). However, as soon as the *Branded Early Entry* dummy is included in the generic entry equation (Spec.2), the effect of *Early Entry* becomes insignificant. The coefficient of *Branded Early Entry* is significantly negative and in absolute terms larger than the coefficient of *Early Entry* in Spec.1. This result suggests that the presumed deterrence effect of early entry is to be attributed to early entrants with a trademark and product differentiation strategy. First mover advantages alone do not explain deterrence (*H1*), and trademarks appear not to intensify (*H2*) but to facilitate the deterrence effect of early entry. Moreover, we find that generic entry decisions are strongly driven by substances' pre-entry market size. The number of off-patent substitutes in turn has a significant, negative impact on generic entry. Both therapeutic and drug form experiences have a significantly positive (linear[48]) effect on generic entry. The coefficients of *Field Experience* and *Form Experience* become smaller from data set 1 to data set 3, though. By restricting the sets of potential entrants to firms experienced in the relevant therapeutic fields and the manufacture of relevant drug forms, firm experience seems to have less explanatory power. A striking result is the significantly positive effect of *Monopoly Duration*. One explanation is that monopoly duration is not necessarily a good proxy for the goodwill original drug producers accumulated over the years but another market value correlate.[49] Legally enforced generic subsitution mechanisms do neutralize original drug producers' reputation advantage. As a consequence, generic firms will benefit first and foremost if medications are well-established. Therapeutic field, drug form and year effects are significant in all specifications.

Strictly speaking, if early entry (or branded early entry) is endogenous, a probit model will be misspecified, potentially underestimating the early entry effect(s). In order to account and test for the potential endogeneity of *Early Entry* we estimate a recursive bivariate probit model in the second step. The results of the recursive bivariate probit regressions are presented in the Appendices [D1]–[D3]. Alike the probit regressions, we subsequently add the *Branded Early Entry* dummy regressor to the generic entry equations (Spec.2) and estimate the two specifications for each of the three data sets at hand. *Early Entry* – the variable possibly affected by selection – is now instrumented for by the variables *Patent holder*, *Revenue Share*, *Revenue Pipeline* and *Revenue Losses*. Apart from the dummy variable *Patent holder*, the instruments have the expected sign, and they are all significant. The correlation coefficient ρ is insignificant in all bivariate probit regressions at a minimum significance level of 5%. Moreover, as soon as the *Branded Early Entry* is added to the generic entry equations (Spec.2) the significance of both *Early Entry* and ρ[50] deteriorates mostly. Hence, we find no evidence for a selection problem which was assumed to lead to an understatement of

[48]The linearity of the experience effects is likely driven by the small unit of measurement (retail forms).

[49]Results are robust to the exclusion of *Monopoly Duration* from generic entry and early entry equations.

[50]Compare the probability level at which the Null Hypothesis can be rejected (Wald Test of $\rho = 0$).

the early entry effect whenever selection is not accounted for. The coefficients of *Monopoly Duration*, *Substitutes*, *Field Experience* and *Form Experience* as shown in the generic entry equations practically remain the same. Only the coefficients of *Pre-Entry Market Size* increase slightly in comparison to the probit estimates. Yet, the sign of all coefficients and their statistical significance is generally robust to the variation in the choice of econometric model. Therapeutic field, drug form and year effects are statistically significant. To be on the safe side, we account and test for the endogeneity of both *Early Entry* and *Branded Early Entry*, estimating a recursive trivariate model[51] in the third and last step. The results of the recursive trivariate probit regressions are similar, i.e. we find no statistically significant correlation between the early entry and generic entry (ρ_{12}) or branded early entry and generic entry (ρ_{13}) equations, and thus no evidence for selection. The correlation between the early entry and branded early entry (ρ_{23}) equations is almost perfect (by definition) and significant. Appendix [E] presents the estimates from the data 3 regression.[52]

In summary, bivariate and trivariate probit estimates suggest that there is no selection problem associated with the occurrence of early or branded early entry. As a consequence, probit regressions provide consistent estimates of the effect of early entries and trademarks on generic entry. Table 5 below presents the marginal effects obtained from the probit regressions (Spec.2) which will allow for a more accurate assessment of the *Branded Early Entry* effect and its economic importance. In the light of empirical evidence affirming the positive influence of therapeutic and drug form experience on generic entry decisions, we confine the interpretation of marginal effects to the results obtained for data set 3. Data set 3 comprises firms with the relevant therapeutic and drug form experiences as potential entry candidates, thus giving the most realistic picture of actual occurrences. The marginal effect of *Branded Early Entry* amounts to -0.0153, implying that the probability of generic entry is reduced by about 1.5% at the mean. The average marginal effect in turn amounts to -0.0706, i.e. the probability of generic entry is reduced by about 7% on average. Given a mean entry probability of roundabout 19%, the joint effect of early entry and trademark protection on generic entry is sizeable. However, with a marginal effect of 3.3% and an average marginal effect of 12% the main determinant of generic entry is *Pre-entry Market Size*: a 1% increase in *Pre-entry Market Size* leads to a 12% increase in the likelihood of generic entry on average. Results also show that the entry probability increases by 0.1%/0.06% on average with one retail form more potential entrants have marketed in the relevant therapeutic field(s)/drug form(s) prior to substances' loss of exclusivity. On the contrary, an increase in the number of off-patent substances by one reduces the entry probability by about 0.2% on average. In summary, *Branded Early Entry* has a sizeable, negative effect on independent generic entry. Considering the dominance of *Pre-entry Market Size* effect and the entry pattern[53] in the targeted high-revenue markets, we posit, however, that the effect of anticipated *Branded Early Entry* has not been large enough to sustainably impair generic entry.

[51]The maximum likelihood estimation involves the integration of trivariate joint normal probabilities either through numerical integration or simulation. Severe convergence problems are typical. In order to achieve convergence we had to exclude all dummies from the early entry and branded early entry equations.

[52]The results for data set 1 and data set 2 are similar and can be obtained from the author upon request.

[53]The smallest market (€17.1 Mio.) attracts 9, the largest market (€187 Mio.) 41 generic firms.

Table 4: Generic Entry: Probit – Coefficients

	Data Set 1 (N=15592)		Data Set 2 (N=4548)		Data Set 3 (N=4010)	
	Generic Entry		*Generic Entry*		*Generic Entry*	
Independent Variables	*Spec.1*	*Spec.2*	*Spec.1*	*Spec.2*	*Spec.1*	*Spec.2*
Early Entry (0/1)	-0.1307**	0.0051	-0.1368*	0.0086	-0.1267*	0.0469
	(0.050)	(0.053)	(0.063)	(0.065)	(0.064)	(0.067)
Branded Early Entry (0/1)		-0.3479***		-0.3866***		-0.4586***
		(0.072)		(0.087)		(0.090)
Pre-Entry Market Size (log)	0.5615***	0.6032***	0.6355***	0.6699***	0.6530***	0.6973***
	(0.045)	(0.051)	(0.049)	(0.053)	(0.050)	(0.055)
Monopoly Duration	0.0464***	0.0384**	0.0600***	0.0526***	0.0541***	0.0446**
	(0.012)	(0.012)	(0.014)	(0.014)	(0.015)	(0.015)
Substitutes	-0.0042**	-0.0045**	-0.0082***	-0.0085***	-0.0087***	-0.0092***
	(0.001)	(0.001)	(0.002)	(0.002)	(0.002)	(0.002)
Field Experience	0.0207***	0.0210***	0.0075**	0.0076**	0.0064*	0.0066**
	(0.002)	(0.002)	(0.002)	(0.002)	(0.002)	(0.003)
Field Experience^2	-0.0001***	-0.0001***	-1.1e-05	-1.2e-05	-8.62e-06	-9.05e-06
	(1.1e-05)	(1.1e-05)	(8.38e-06)	(8.50e-06)	(8.53e-06)	(8.65e-06)
Form Experience	0.0051***	0.0052***	0.0038***	0.0038***	0.0037***	0.0037***
	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)	(0.001)
Form Experience^2	-2.21e-06***	-2.24e-06***	-1.09e-06	-1.13e-06	-9.96e-07	-1.04e-06
	(4.97e-07)	(5.01e-07)	(6.80e-07)	(6.80e-07)	(6.82e-07)	(6.82e-07)
Therap. Field (0/1)	*yes*	*yes*	*yes*	*yes*	*yes*	*yes*
Drug Form (0/1)	*yes*	*yes*	*yes*	*yes*	*yes*	*yes*
Year Expiry (0/1)	*yes*	*yes*	*yes*	*yes*	*yes*	*yes*
Const.	-10.8859***	-11.3282***	-11.1560***	-11.5209***	-11.0474***	-11.4994***
Prob > chi2	0.000	0.000	0.000	0.000	0.000	0.000
Log-Likelihood	-1682.32	-1676.73	-1289.70	-1285.16	-1241.86	-1235.74

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

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

Table 5: Generic Entry: Probit (Spec.2) – Marginal Effects

	Data Set 1 (N=15592) *Generic Entry*		Data Set 2 (N=4548) *Generic Entry*		Data Set 3 (N=4010) *Generic Entry*	
Independent Variables	*Marg.Effect*	*Average Marg.Effect*	*Marg.Effect*	*Average Marg.Effect*	*Marg.Effect*	*Average Marg.Effect*
Early Entry (0/1)	1.08e-05	0.0003	0.0003	0.0013	0.0023	0.0081
	(1.1e-04)	(0.003)	(0.002)	(0.010)	(0.004)	(0.012)
Branded Early Entry (0/1)	-0.0005*	-0.0175***	-0.0107***	-0.0550***	-0.0153***	-0.0706***
	(1.9e-04)	(0.004)	(0.003)	(0.012)	(0.004)	(0.013)
Pre-Entry Market Size (log)	0.0013**	0.0343***	0.0260***	0.1056***	0.0337***	0.1201***
	(4.25e-04)	(0.004)	(0.005)	(0.010)	(0.006)	(0.011)
Monopoly Duration	0.0001*	0.0022**	0.0020**	0.0083***	0.0022**	0.0077**
	(3.53e-05)	(0.001)	(0.001)	(0.002)	(0.001)	(0.003)
Subsitutes	-9.47e-06*	-0.0003**	-0.0003***	-0.0013***	-0.0004***	-0.0016***
	(4.02e-06)	(7.56e-05)	(7.96e-05)	(2.45e-04)	(9.98e-05)	(2.72e-04)
Field Experience	4.41e-05**	0.0012***	0.0003**	0.0012**	0.0003**	0.0011**
	(1.53e-05)	(1.45e-04)	(9.29e-05)	(3.62e-04)	(1.2e-04)	(4.1e-04)
Field Experience^2	-1.24e-07**	-3.36e-06***	-4.45e-07	-1.86e-06	-4.38e-07	-1.56e-06
	(4.75e-08)	(6.65e-07)	(3.19e-07)	(1.30e-06)	(4.10e-07)	(1.46e-06)
Form Experience	1.1e-05**	0.0003***	0.0001***	0.0006***	0.0002***	0.0006***
	(3.79e-06)	(3.96e-05)	(3.65e-05)	(1.2e-04)	(4.39e-05)	(1.3e-04)
Form Experience^2	-4.70e-09**	-1.27e-07***	-4.40e-08	-1.79e-07*	-5.03e-08	-1.79e-07
	(1.70e-09)	(2.73e-08)	(2.62e-08)	(8.81e-08)	(3.27e-08)	(9.58e-08)

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

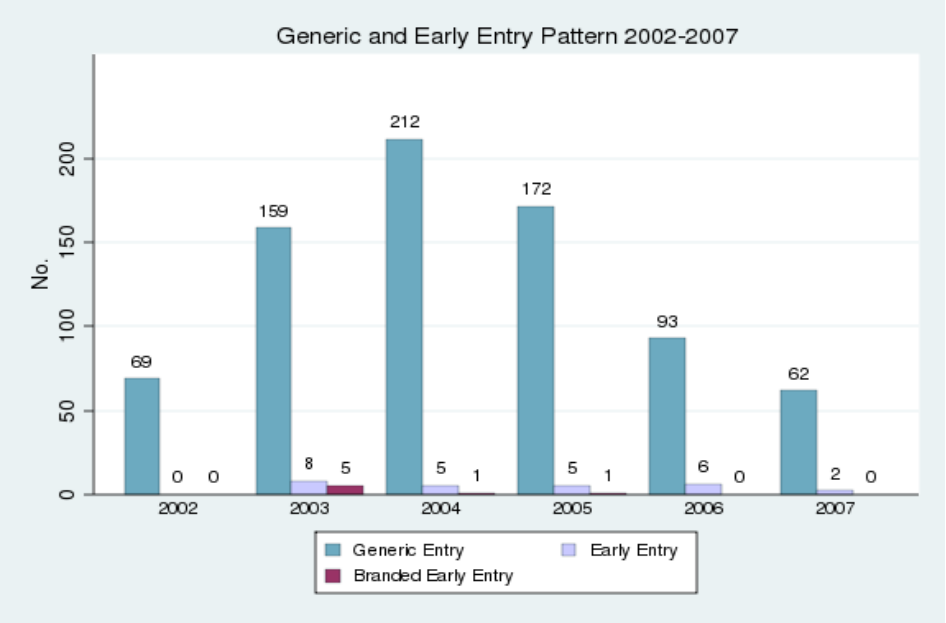
Notes: At the mean, *Pre-entry Market Size*, *Monopoly Duration* and *Substitutes* amount to 16.0 (or €36.7 Mio.), 11.92 and 57.5 respectively. *Field experience* and *Form experience* amount to 24.1 and 148.1 on average.

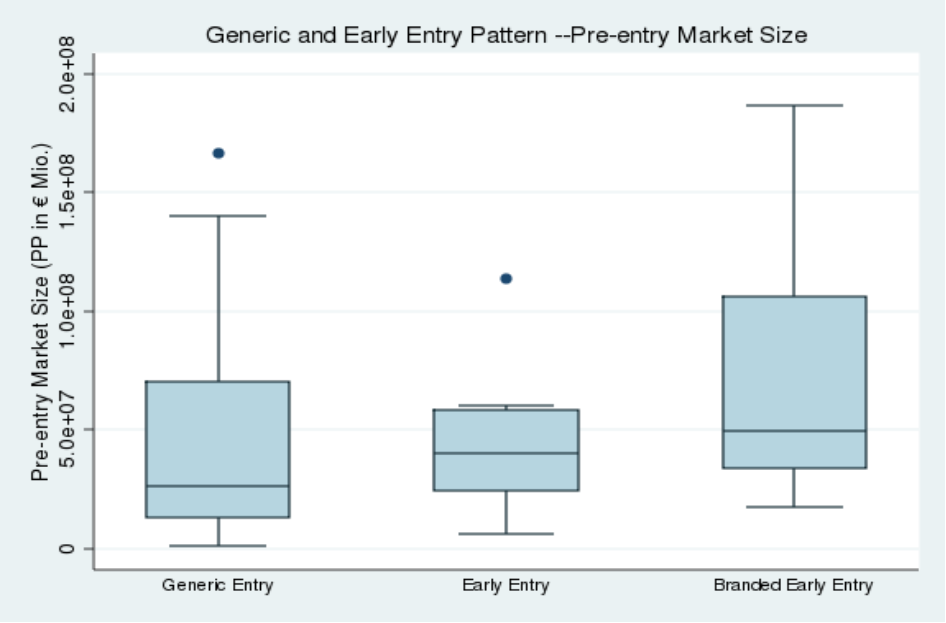
6 Conclusion

We establish evidence that the presumed deterrence effect of early entry is to be attributed to early entrants with a trademark strategy (branded early entry). The average deterrence effect is sizeable but dominated by the effect of pre-entry market size. The generic entry pattern in the high-revenue markets targeted by early entrants suggest that anticipated branded early entry has not undermined generic competition. Some authors argue that anticipated early entry – also known as authorized, branded or pseudo-generic entry – has an anti-competitive, deterring effect on generic entry. First-mover advantages are said to be important and non-transitory in the generic market segment, such that anticipated early entry will lower subsequent generic entrants' incentives to enter substantially. Trademarks, in turn, have been shown to be positively correlated with firms' market value in various industries, i.e. thy enhance market positions. Given early entrants' revealed preference for trademark-protection, we test for generic entry deterrence examining the joint, presumably complementary effect of early entry and trademark protection. Based on a unique pharmaceutical data set, exclusivity and trademark data, we have investigated generic entry decisions in the German pharmaceutical market within the time period 2002-2007. Estimating a probit model, recursive bivariate and recursive trivariate probit model, we test for both entry deterrence and the potential endogeneity of early entry dummy regressors. Treating early entry or branded early entry as exogenous variables (probit model) could give rise to a selection problem and inconsistent estimates if early entry or branded early entry occurred in markets that are more attractive than given market characteristics suggest. Bivariate and trivariate probit estimates suggest that there is no selection problem associated with the occurrence of early or branded early entry, such that probit estimates are consistent. We find that first-mover advantages alone do not cause deterrence, and that trademark protection does not intensify but facilitate the deterrence effect of early entry. The effect of branded early entry is significantly negative in all specifications, reducing the probability of generic entry by 7% on average. With an average marginal effect of 12% pre-entry market size is the main determinant of generic entry. Previous studies alike, we show that the number of off-patent substitute active ingredients has a negative impact on entry, and that firms' therapeutic and drug form experience influence generic entry decisions positively. The positive effect of monopoly duration indicates that legally enforced generic subsitution mechanisms neutralize original drug producers' reputation advantage, with the consequence that generic firms benefit if a medication is well-established. Given the main finding of this study that branded early entry has a negative but apparently not momentous effect on generic entry, associated welfare effects are presumably small. Further research is warranted to clarify what effects early entries and trademark protection have on the extent of generic entry, generic prices, generic drug prescriptions or the assortment of retail forms in off-patent markets. These are important areas of research which we intend to examine in the future.

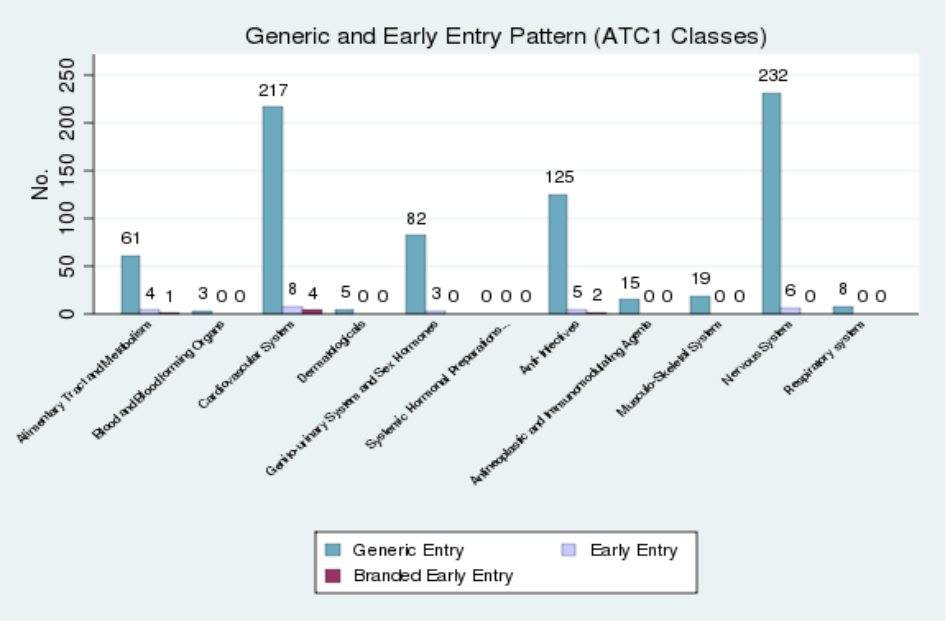
Appendix

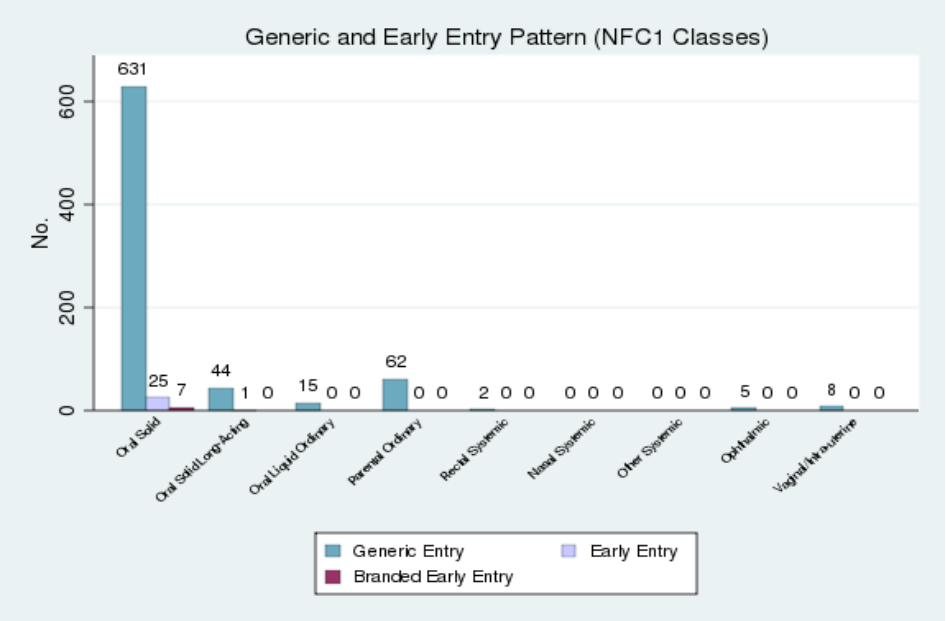
[A] Generic and Early Entry Patterns





[A] Generic and Early Entry Patterns (cont.)





[B] Allocation of Generic Entries and Zero-Entries to Substances

Substances	Generic Entry	Early Entry	Generic Entries	Data Set 1			Data Set 2			Data Set 3		
				Zero-Entries	Pot.Entrants Generic	Pot.Entrants Total	Zero-Entries	Pot.Entrants Generic	Pot.Entrants Total	Zero-Entries	Pot.Entrants Generic	Pot.Entrants Total
Acamprosate	No	No	0	197	183	197	36	36	36	30	30	30
Adapalene	No	No	0	198	184	198	39	39	39	21	21	21
Alfuzosine	Yes	Yes	14	184	184	198	40	54	54	38	52	52
Amisulpride	Yes	No	13	183	182	196	68	81	81	66	79	79
Amlodipine	Yes	No	32	167	185	199	37	69	69	30	62	62
Amorol ne	No	No	0	197	183	197	52	52	52	50	50	50
Apraclonidine	No	No	0	198	184	198	38	38	38	38	38	38
Azithromycin	Yes	No	17	181	184	198	76	91	93	76	91	93
Benazepril	Yes	No	8	189	183	197	55	62	63	55	62	63
Cabergoline	Yes	No	8	190	184	198	62	69	70	45	52	53
Calcipotriol	Yes	No	3	195	184	198	19	22	22	17	20	20
Carmustine	No	No	0	198	184	198	37	37	37	33	33	33
Carvedilole	Yes	No	26	172	184	198	44	70	70	43	69	69
Ce xime	Yes	Yes	9	186	181	195	86	93	95	85	92	94
Cefpodoxime	Yes	No	10	187	183	197	81	89	91	73	82	83
Ceftazidime	Yes	No	6	192	184	198	84	88	90	34	38	40
Ceftibuten	No	No	0	198	184	198	93	91	93	85	84	85
Ceftriaxone	Yes	No	10	187	184	197	79	87	89	31	39	41
Cilazapril	No	No	0	197	183	197	63	62	63	63	62	63
Citalopram	Yes	No	31	166	184	197	37	67	68	36	66	67
Clarithromycin	Yes	No	19	179	184	198	73	90	92	73	90	92
Croconazole	No	No	0	197	183	197	52	52	52	50	50	50
Didanosine	No	No	0	198	184	198	40	39	40	34	33	34
Ebastine	No	No	0	197	183	197	42	42	42	39	39	39
Epoetin alfa	Yes	No	3	194	183	197	40	43	43	11	14	14
Fexofenadine	No	No	0	197	183	197	42	42	42	39	39	39
Filgrastim	No	No	0	198	184	198	15	15	15	14	14	14
Finasteride	Yes	Yes	20	177	183	197	51	70	71	37	56	57
Fleroxacin	No	No	0	198	184	198	92	90	92	83	82	83
Fluconazole	Yes	No	19	176	182	195	11	29	30	11	29	30
Flumazenil	Yes	No	5	193	184	198	35	40	40	13	18	18
Formoterol	Yes	No	8	189	183	197	44	52	52	32	40	40
Fosinopril	Yes	No	3	194	183	197	60	62	63	60	62	63
Gabapentin	Yes	Yes	24	172	183	196	19	43	43	17	41	41
Ganciclovir	No	No	0	198	184	198	63	62	63	62	61	62
Glimepirid	Yes	Yes	22	175	183	197	38	60	60	35	57	57
Granisetron	Yes	Yes	3	194	183	197	33	35	36	31	33	34
Itraconazole	Yes	Yes	13	182	181	195	13	25	26	13	25	26
Lacidipine	No	No	0	198	184	198	69	69	69	62	62	62
Lamotrigine	Yes	Yes	29	168	183	197	48	76	77	46	74	75

[B] Allocation of Generic Entries and Zero-Entries to Substances (cont.)

Substances	Generic Entry	Early Entry	Generic Entries	Data Set 1 Zero-Entries	Data Set 1 Pot.Entrants Generic	Data Set 1 Pot.Entrants Total	Data Set 2 Zero-Entries	Data Set 2 Pot.Entrants Generic	Data Set 2 Pot.Entrants Total	Data Set 3 Zero-Entries	Data Set 3 Pot.Entrants Generic	Data Set 3 Pot.Entrants Total
Lansoprazole	Yes	No	14	185	185	199	72	85	86	69	82	83
Leuprorelin	Yes	No	2	196	184	198	47	49	49	10	12	12
Lovastatin	Yes	Yes	16	177	180	193	39	53	55	33	48	49
Meloxicam	Yes	No	11	186	183	197	70	79	81	69	78	80
Miglitol	No	No	0	195	181	195	56	56	56	53	53	53
Miltefosine	No	No	0	198	184	198	42	41	42	16	15	16
Mirtazapine	Yes	Yes	27	171	184	198	44	70	71	44	70	71
Molgramostim	No	No	0	198	184	198	15	15	15	14	14	14
Moxonidine	Yes	Yes	15	180	181	195	31	46	46	27	42	42
Nadi oxacin	No	No	0	198	184	198	39	39	39	21	21	21
Nafarelin	No	No	0	197	183	197	13	13	13	4	4	4
Nefazodone	No	No	0	198	184	198	70	69	70	68	67	68
Olanzapine	Yes	No	7	191	184	198	76	83	83	74	81	81
Ondansetron	Yes	No	22	182	190	204	24	45	46	22	43	44
Oxycodone	Yes	No	4	195	185	199	99	102	103	92	95	96
Paclitaxel	Yes	No	13	189	188	202	28	41	41	23	36	36
Pamidron acid	Yes	No	8	189	184	197	14	21	22	6	14	14
Pergolide	Yes	No	9	187	182	196	37	45	46	37	45	46
Perindopril	No	No	0	194	181	194	61	60	61	61	60	61
Pravastatin	Yes	Yes	24	171	181	195	36	58	60	31	54	55
Prednicarbate	Yes	No	2	192	181	194	41	43	43	41	43	43
Quinagolide	No	No	0	198	184	198	41	41	41	25	25	25
Quinapril	Yes	No	9	187	182	196	53	61	62	53	61	62
Ramipril	Yes	Yes	23	174	183	197	40	62	63	40	62	63
Risperidone	Yes	No	29	169	184	198	57	86	86	54	83	83
Sertaconazole	No	No	0	198	184	198	52	52	52	50	50	50
Sertraline	Yes	No	26	173	185	199	44	69	70	43	68	69
Sevo urane	No	No	0	198	184	198	41	41	41	4	4	4
Simvastatin	Yes	Yes	41	162	190	203	27	66	68	23	63	64
Sumatriptan	Yes	Yes	20	178	184	198	82	101	102	74	93	94
Tamsulosin	Yes	No	28	171	185	199	28	56	56	26	54	54
Temozolomide	No	No	0	198	184	198	37	37	37	18	18	18
Terazosin	Yes	No	20	175	182	195	47	67	67	46	66	66
Terbina ne	Yes	Yes	22	174	182	196	41	62	63	37	59	59
Torasemide	Yes	No	20	177	183	197	43	62	63	42	61	62
Toremifene	No	No	0	194	181	194	44	44	44	41	41	41
Trandolapril	No	No	0	198	184	198	67	66	67	67	66	67
Tropisetron	No	No	0	198	184	198	38	37	38	36	35	36
Zidovudine	No	No	0	198	184	198	39	38	39	38	37	38

Note: The columns referred to as \Generic" indicate the number of potential entrants with a generic drug portfolio.

[C-1] Summary Statistics Data Set1

Variable Name	Mean	Median	Min.	Max.	Sd.	N
Generic Entry	0.05	0	0	1	–	15592
Early Entry	0.20	0	0	1	–	15592
Branded Early Entry	0.08	0	0	1	–	15592
Pre-Entry Market Size	32.1	14.7	0	187	41.0	15592
Pre-Entry Market Size (log)	15.74	16.51	0	19.05	3.35	15592
Monopoly Duration	12.06	12.5	5	20	3.23	15592
Substitutes	50.27	41	9	205	38.25	15592
Field Experience	6.58	0	0	374	20.91	15592
Form Experience	56.87	13	0	1679	125.86	15592
Patent holder	0.84	1	0	1	–	15592
Revenue Share	0.09	0.01	0	1	0.23	15592
Revenues Pipeline	377	282	0	3120	542	15592
Revenues Pipeline (log)	15.42	19.46	0	21.86	7.44	15592
Revenue Losses	93.5	86.9	0	282	87.1	15592
Revenue Losses (log)	14.05	18.27	0	19.46	7.70	15592

[C-2] Summary Statistics Data Set2

Variable Name	Mean	Median	Min.	Max.	Sd.	N
Generic Entry	0.17	0	0	1	–	4548
Early Entry	0.22	0	0	1	–	4548
Branded Early Entry	0.08	0	0	1	–	4548
Pre-Entry Market Size	36.1	17.1	0	187	43.6	4548
Pre-Entry Market Size (log)	15.97	16.66	0	19.05	3.20	4548
Monopoly Duration	12.11	12.5	5	20	3.23	4548
Substitutes	57.43	45	9	205	38.33	4548
Field Experience	22.57	10	0	374	33.73	4548
Form Experience	134.80	56	0	1679	196.71	4548
Patent holder	0.83	1	0	1	–	4548
Revenue Share	0.10	0.01	0	1	0.22	4548
Revenues Pipeline	365	240	0	3120	561	4548
Revenues Pipeline (log)	14.87	19.30	0	21.86	7.87	4548
Revenue Losses	90.5	88.1	0	282	83.8	4548
Revenue Losses (log)	13.80	18.29	0	19.46	7.88	4548

[C-3] Summary Statistics Data Set3

Variable Name	Mean	Median	Min.	Max.	Sd.	N
Generic Entry	0.19	0	0	1	–	4010
Early Entry	0.23	0	0	1	–	4010
Branded Early Entry	0.09	0	0	1	–	4010
Pre-Entry Market Size	36.7	20.1	0	187	43.7	4010
Pre-Entry Market Size (log)	16.00	16.82	0	19.05	3.26	4010
Monopoly Duration	11.92	12.5	5	20	3.06	4010
Substitutes	57.46	45	9	205	39.33	4010
Field Experience	24.05	11	0	374	34.88	4010
Form Experience	148.10	66	0	1679	204.44	4010
Patent holder	0.83	1	0	1	–	4010
Revenue Share	0.10	0.02	0	1	0.23	4010
Revenues Pipeline	377	240	0	3120	587	4010
Revenues Pipeline (log)	14.76	19.30	0	21.86	7.95	4010
Revenue Losses	91.8	88.1	0	282	84.9	4010
Revenue Losses (log)	13.60	18.29	0	19.46	8.05	4010

[D-1] Generic Entry: Bivariate Probit (Coefficients)

	Data Set 1 (N=15592)			
	Generic Entry	*Early Entry*	*Generic Entry*	*Early Entry*
Independent Variables	*Spec.1*		*Spec.2*	
Early Entry (0/1)	-0.1513		0.1384	
	(0.116)		(0.137)	
Branded Early Entry (0/1)			-0.3768***	
			(0.075)	
Pre-Entry Market Size (log)	0.5653***	0.8155***	0.5831***	0.8150***
	(0.051)	(0.004)	(0.054)	(0.004)
Monopoly Duration	0.0458***	0.0319***	0.0419**	0.0307***
	(0.012)	(0.001)	(0.012)	(0.001)
Subsitutes	-0.0043*	-0.0149***	-0.0039**	-0.0149***
	(0.001)	(8.67e-05)	(0.001)	(8.63e-05)
Field Experience	0.0208***		0.0210***	
	(0.002)		(0.002)	
Field Experience^2	-5.83e-05***		-5.87e-05***	
	(1.1e-05)		(1.1e-05)	
Form Experience	0.0051***		0.0052***	
	(0.001)		(0.001)	
Form Experience^2	-2.21e-06***		-2.24e-06***	
	(4.97e-07)		(5.00e-07)	
Patent holder (0/1)		-1.2118***		-1.2033***
		(0.014)		(0.014)
Revenue Share		1.4093***		1.4120***
		(0.031)		(0.033)
Revenue Pipeline (log)		-0.1012***		-0.1007***
		(0.001)		(0.001)
Revenue Losses (log)		0.3469***		0.3468***
		(0.001)		(0.001)
Therap. Field (0/1)	*yes*	*yes*	*yes*	*yes*
Drug Form (0/1)	*yes*	*yes*	*yes*	*yes*
Year Expiry (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-10.9458***	-21.1865***	-11.0042***	-21.1781***
Prob > chi2	0.0000		0.0000	
Log-Likelihood	-4856.29		-4850.34	
ρ	0.0169		-0.1009	
Wald Test ($\rho = 0$)	0.8437		0.3249	

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

Notes: An observation in the regression is the decision of a generic firm to enter a market after substances' loss of exclusivity (generic entry). In columns (2) and (4) early entry is treated as endogenous and instrumented by. Heteroskedasticity-robust and clustered standard errors in parentheses.

[D-2] Generic Entry: Bivariate Probit (Coefficients)

	Data Set 2 (N=4548)			
	Generic Entry	*Early Entry*	*Generic Entry*	*Early Entry*
Independent Variables	*Spec.1*		*Spec.2*	
Early Entry (0/1)	-0.3665*		-0.0910	
	(0.154)		(0.170)	
Branded Early Entry (0/1)			-0.3625***	
			(0.087)	
Pre-Entry Market Size (log)	0.6804***	0.7416***	0.6862***	0.7419***
	(0.061)	(0.023)	(0.063)	(0.023)
Monopoly Duration	0.0584***	0.0822***	0.0523***	0.0792***
	(0.014)	(0.014)	(0.014)	(0.013)
Subsitutes	-0.0093***	-0.0165***	-0.0090***	-0.0165***
	(0.002)	(0.001)	(0.002)	(0.001)
Field Experience	0.0075**		0.0076**	
	(0.002)		(0.002)	
Field Experience^2	-1.15e-05		-1.16e-05	
	(8.44e-06)		(8.52e-06)	
Form Experience	0.0038***		0.0038***	
	(0.001)		(0.001)	
Form Experience^2	-1.08e-06		-1.13e-06	
	(6.76e-07)		(6.78e-07)	
Patent holder (0/1)		-1.0110***		-0.9875***
		(0.068)		(0.065)
Revenue Share		1.6216***		1.5877***
		(0.161)		(0.161)
Revenue Pipeline (log)		-0.0997***		-0.0995***
		(0.006)		(0.007)
Revenue Losses (log)		0.3153***		0.3150***
		(0.009)		(0.009)
Therap. Field (0/1)	*yes*	*yes*	*yes*	*yes*
Drug Form (0/1)	*yes*	*yes*	*yes*	*yes*
Year Expiry (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-11.8756***	-19.7039***	-11.7905***	-19.6831***
Prob > chi2	0.0000		0.0000	
Log-Likelihood	-2236.16		-2232.57	
ρ	0.1866		0.0735	
Wald Test ($\rho = 0$)	0.0841		0.5191	

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

Notes: An observation in the regression is the decision of a generic firm to enter a market after substances' loss of exclusivity (generic entry). In columns (2) and (4) early entry is treated as endogenous and instrumented by. Heteroskedasticity-robust and clustered standard errors in parentheses.

[D-3] Generic Entry: Bivariate Probit (Coefficients)

	Data Set 3 (N=4010)			
	Generic Entry	*Early Entry*	*Generic Entry*	*Early Entry*
Independent Variables	*Spec.1*		*Spec.2*	
Early Entry (0/1)	-0.3362*		-0.0027	
	(0.147)		(0.159)	
Branded Early Entry (0/1)			-0.4465***	
			(0.089)	
Pre-Entry Market Size (log)	0.6964***	0.7432***	0.7059***	0.7428***
	(0.061)	(0.023)	(0.063)	(0.022)
Monopoly Duration	0.0532***	0.1088***	0.0446**	0.1054***
	(0.015)	(0.015)	(0.015)	(0.015)
Subsitutes	-0.0098***	-0.0169***	-0.0094***	-0.0169***
	(0.002)	(0.001)	(0.002)	(0.001)
Field Experience	0.0066**		0.0066**	
	(0.003)		(0.003)	
Field Experience^2	-9.09e-06		-9.14e-06	
	(8.58e-06)		(8.66e-06)	
Form Experience	0.0036***		0.0037***	
	(0.001)		(0.001)	
Form Experience^2	-9.83e-07		-1.04e-06	
	(6.80e-07)		(6.82e-07)	
Patent holder (0/1)		-1.1268***		-1.0990***
		(0.067)		(0.064)
Revenue Share		1.8722***		1.8374***
		(0.168)		(0.167)
Revenue Pipeline (log)		-0.0992***		-0.0988***
		(0.006)		(0.006)
Revenue Losses (log)		0.3239***		0.3237***
		(0.009)		(0.009)
Therap. Field (0/1)	*yes*	*yes*	*yes*	*yes*
Drug Form (0/1)	*yes*	*yes*	*yes*	*yes*
Year Expiry (0/1)	*yes*	*yes*	*yes*	*yes*
Const.	-11.7679***	-20.1961***	-11.6480***	-20.1723***
Prob > chi2	0.0000		0.0000	
Log-Likelihood	-2115.51		-2110.29	
ρ	0.1718		0.0369	
Wald Test ($\rho = 0$)	0.0959		0.7308	

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

Notes: An observation in the regression is the decision of a generic firm to enter a market after substances' loss of exclusivity (generic entry). In columns (2) and (4) early entry is treated as endogenous and instrumented by. Heteroskedasticity-robust and clustered standard errors in parentheses.

[E] Generic Entry: Trivariate Probit (Coefficients)

	Data Set 3 (N=4010)		
Independent Variables	*Generic Entry*	*Early Entry*	*Branded Early Entry*
Early Entry (0/1)	-0.044		
	(0.086)		
Branded Early Entry (0/1)	-0.5429***		
	(0.100)		
Pre-Entry Market Size (log)	0.6957***	0.4038***	0.4082***
	(0.047)	(0.019)	(0.027)
Monopoly Duration	0.0361**	0.0923***	0.2984***
	(0.014)	(0.009)	(0.015)
Subsitutes	-0.0065***	0.0003	-0.0105***
	(0.001)	(4.0e-04)	(0.001)
Field Experience	0.0045*		
	(0.002)		
Field Experience^2	-2.41e-06		
	(7.74e-06)		
Form Experience	0.0038***		
	(0.001)		
Form Experience^2	-9.95e-07		
	(6.79e-07)		
Patent holder (0/1)		-0.6767***	-3.1629***
		(0.046)	(0.101)
Revenue Share (0/1)		4.9029***	20.4820***
		(0.180)	(0.816)
Revenue Pipeline (log)		0.0313***	0.3570***
		(0.004)	(0.021)
Revenue Losses (log)		0.3654***	1.7072***
		(0.010)	(0.072)
Therap. Field (0/1)	*yes*		
Drug Form (0/1)	*yes*		
Year Expiry (0/1)	*yes*		

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