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Farasat A.S. Bokhari[a] and Weijie Yan[b,c,]

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**Corresponding Author: weijie.yan@esri.ie*

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JEL Classification: L40, L12, I11, L79

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a School of Economics and Centre for Competition Policy, University of East Anglia, UK
b Economic and Social Research Institute, Dublin, Ireland
c Department of Economics, Trinity College Dublin, Ireland

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Farasat A.S. Bokhari [a] and Weijie Yan [b,c,*]

[a] *School of Economics and Centre for Competition Policy, University of East Anglia, UK*

[b] *Economic and Social Research Institute, Ireland*

[c] *Department of Economics, Trinity College Dublin, Ireland*

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*Corresponding Author: Weijie Yan (weijie.yan@esri.ie)

1. INTRODUCTION

Do firms invest in capacity to deter entry and, if so, how can we tell it apart from other unilateral profit maximizing incentives for investment? Further, when are these strategies effective? Firms may invest in capacity to meet an expected increase in future demand, or may invest in product variety to appeal to a larger customer base and to grow. But these can also be preemptive actions to fill the product space and prevent entry. Although there is extensive theoretical research on this topic and when such actions might be credible, empirical evidence is limited. This is because entry deterrence via strategic investments is empirically difficult to isolate from other profit maximizing incentives. Also, the impact of such a strategy is hard to measure due to the lack of an observable counterfactual: did the non-entrant not enter because of a successful deterrence strategy, or because entry was never intended? Our paper contributes to the growing empirical literature on strategic deterrence and its effectiveness using the timing of product line extensions in pharmaceutical markets in the UK.

Some of the earlier theoretical literature has argued that deterrence is not rational or on the equilibrium path, and that investments can be delayed till after entry to drive out competition. Later models, such as those building on commitment mechanisms showed that preemption can be a subgame perfect outcome (Spence, 1977, Dixit, 1979, 1980). In line with this literature, our results show that originators indeed launch additional variants of their drugs preemptively under the threat of entry, and change their launch strategy once entry becomes very likely. Further, this result is mostly driven from medium size markets where motive for deterrence is strongest. We find that these preemptive launches are successful in deterring entry, but in a non-obvious way. Deterrence is successful in medium size markets when the originator covers the horizontally differentiated product space with enough patients for each of its product line extensions. However, this strategy does not work in small or large markets. An alternative (and rarer) strategy is to shift most of the patients to only the new variants of the drug. In small markets this opens up an opportunity for entry and we find that shifting patients to new drugs is correlated with entry. In larger markets however, shifting patients to the new drug is likely to be accompanied with significant marketing efforts that convince patients and doctors of the higher quality of the new variant (i.e., products are vertically differentiated). In these markets entry can be blocked as it is no longer attractive to enter in the original variant, while the originator's new variant may be protected by intellectual property. Accordingly, we find that entry in large markets is deterred when patients are mostly shifted to the newer variants.

A central issue in identifying entry deterring investments is to separate the decisions of incumbents under the threat of entry from entry itself, since in the latter case incumbents may be adjusting to the new market structure (key in Goolsbee and Syverson (2008) and Cookson (2017) who study

incumbent behavior in response to exogenous changes in potential entry). To this end, pharmaceutical markets present an ideal opportunity for testing deterrence versus accommodation. In most western markets, originators are protected against generic competition for a fixed period of time due to a combination of patent laws and data/market exclusivity rules that prevent generic firms from filing entry applications. While the date of actual entry by a generic firm is potentially endogenous, the date of the end of marketing exclusivity is a pre-determined fixed period of time starting from when the initial market authorization was issued to the originator.

An often noted point in the literature is that large markets are more likely to attract generic entry (Scott Morton, 1999, Reiffen and Ward, 2005). This observation, combined with the fixed end of exclusivity period, allows us to compare the product launch rate before and after the end of exclusivity of those originators that eventually loose monopoly but *before* entry takes place. We compare these with the launch rate of originators that do not attract entry but reach the end of data exclusivity just the same. As in Ellison and Ellison (2011) and in Dafny (2005), if entry is not possible, we should not see any difference in investment strategies by originators in the latter group before and after the end of exclusivity. Further, post the end of exclusivity, it is quite possible that originators know if any generic firms have filed applications, and hence if entry is imminent (in the EU, the European Medicines Agency publishes monthly a list of original drugs for which it is reviewing generic applications and hence the originator would be aware of it). If entry is imminent and originators know about it, they would stop investing in deterrence. Thus the end of exclusivity marks a sharp point at which firms' actions would change in the presence of deterrence, but not necessarily if they were accommodating entry.

If strategic deterrence is present, it raises the second issue: when are these strategies effective? There are two related but distinct mechanisms by which entry can be deterred via product launches. First, as discussed in Schmalensee (1978) or Smiley (1988), firms can fill the product space via proliferation. However, as pointed out in Judd (1985), this is not credible because the incumbent can always withdraw a product post entry, and since the competitor knows that, product proliferation would not be a deterrent without a commitment mechanism. In pharmaceuticals, the commitment to not withdraw its products comes via physician detailing efforts (i.e., advertising and sales calls which require significant sunk costs) where a significant portion of the existing patients are moved to the newer formulation or dosage before entry by a competitor. If both the original and the new variants of the drug are covered by the originator such that there are enough patients using both type of drugs, then the product space is covered, and there may not be any room for entry in the Schmalensee sense. Further, withdrawing any variants of their drug post entry would be costly as the originator will need to undertake further detailing to move patients to the remaining variant.

An alternative mechanism is via 'product hopping', where entry can be blocked by switching almost all the patients to the newer formulation, again via physician detailing, and sometimes in conjunction with withdrawing the initial formulation from the market prior to entry. This strategy, was highlighted in the European Commission's pharmaceutical sector inquiry as well as in several antitrust cases in the US (see EC, 2009, Carrier and Shadowen, 2016). To understand how this works, note that in the EU, data exclusivity granted to the original formulation applies simultaneously to any additional strengths or formulations, and hence any product line extensions launched later do not get exclusivity extensions by the drug approval agencies. By contrast, in the US, a new formulation can get three years of exclusivity. Nonetheless, as pointed out in Kyle (2016), new formulations may still be protected against generic entry via secondary patents on the product line extensions. Thus, if through physician detailing efforts patients can be switched to newer formulations or dosages, and via secondary patents entry into new product line extensions can be blocked, then it can still deter entry even in the original formulation due to lack of patients. Such detailing efforts are likely in large markets, but less likely in smaller markets. In the latter case if the originators switch to the newer version, it may be because it is costly to maintain multiple product lines and the newer variant is more profitable. Thus product hopping could lead to accommodation in smaller markets and to deterrence in larger markets.

To carry out this work we use sales data of pharmaceutical products in the UK over the period 1996 to 2016. The data set contains information on sales, drug characteristics, and identity of the originator firm. Importantly, it also includes the date of the first launch in the UK. We define originator as the first firm that sells a drug with a specific molecule within a therapeutic class, where the combination defines a market, and all other firms that enter later in the same class-molecule combination as followers. Additional products by the originator are drugs that have the same molecule and therapeutic classification, but differ in formulation alone, or by formulation, dosage or pack size (we use two different measures). During this period, 430 originators reached the end of market exclusivity, counted as the end of the tenth year since entry, from which we restrict our initial analysis to 263 originators for whom this event was between 2001 and 2011. The latter restriction was imposed so as to be able to observe product launch rates of originators both before and after the end of exclusivity, while the larger data is used to estimate the effectiveness of shifting patients to later launched products on the probability of entry by competitors.

We compare the incumbents product launch rates before and after the end of exclusivity event, as well as before and after the actual entry as described above. Those that experience entry launch significantly more product line extensions before the end of exclusivity compared to those that never experienced entry. For the former group, we find a sharp and significant decline in their launch rate after the end of exclusivity. A typical originator with entry slows their new formulation launch rate by 0.017 per quarter and new formulation/dosage/pack launch rate by 0.140 per quarter after

the end of exclusivity. When we compare these changes to the launch rates of originators that never experienced any entry in the entire period, despite also reaching their end of exclusivity, the conclusions don't change: relative to the group with no entry, the launch rates in the first group slow by 0.017 and 0.126 respectively post the end of exclusivity. In fact, incumbents with no entry do not change their launch strategy after the end of exclusivity and continue to introduce new formulations at a lower rate of .003 per quarter. The decline in launch rate after an actual entry is of similar magnitude but slightly smaller. The relative change in launch rate is more prominent in medium size markets. We conclude from this evidence that entry deterrence via product launches is a strong motive in pharmaceuticals.

We also estimated hazard models at the market level to test if launching additional variants deters entry. Given our earlier finding that originators with eventual entry launch more drugs than those without entry, it is hardly surprising that in any such model, the count of products is positively correlated with probability of entry. We confirmed this to be the case in our estimates as well, and that higher (lagged) sales attract more entry. More importantly however, we focus on the role of shifting patients to the newer drugs. We find that if the originator launches additional variants, and *if* the relative market share of the originator's drugs are evenly spread across its various formulations to fill the product space, then it reduces the risk of entry significantly in medium size markets. This strategy does not deter entry in large size markets. The alternative strategy of product hopping, where most of the patients are shifted to the newer formulations, seems to be effective in deterring entry in large markets, and attracts entry in small markets, though the evidence is somewhat weaker.

In summary then, we find that before the end of exclusivity, incumbents launch at a higher rate than after the end of exclusivity, and that this change is more prominent in medium size markets, where the incentive to engage in deterrence is highest, than in small or large markets. If this was driven purely by demand side fundamentals, then one would expect easier/faster generic entry after the end of exclusivity as well, but it is precisely in the medium size markets that we find that entry is less likely if (i) the incumbent has launched more products and (ii) has covered all variants with significant share of patients. On the other hand, product hopping is rare but creates opportunity for entry in small markets, and deters entry in large markets, possibly due to differences in detailing efforts across these two markets.

Our paper is related to two streams of literature, the first in empirical industrial organization that focuses on entry deterrence strategies such as capacity, product proliferation, advertising, fighting brands, licensing, and pricing and builds on the insights from theoretical models (see Wislon, 1992, for a review of the theory). In the earlier empirical literature, Lieberman (1987) did not find any evidence of investment in capacity to deter entry, but Weiman and Levin (1994) documented in a case study that Southern Bell Telephone dramatically expanded capacity in long-distance and

toll lines as preemptive investment. Particularly, they note that the company expanded it's pole miles from 2,000 to 8,600 and their toll wire coverage from 5,000 to over 55,000 miles, and that the timing of this investment was strategic. More recently, Dafny (2005) uses a monotonicity test to document evidence of investing in capacity to deter entry in an invasive cardiac procedure by the US hospitals. Goolsbee and Syverson (2008) analyze incumbent reaction when Southwest airlines becomes present at both ends of a route, but before flying the specific route itself. They find strong evidence that incumbents lower their fares when faced with the threat of entry, but the reasons for such preemptive actions for deterrence versus accommodation have mixed evidence. Seamans (2012) finds that incumbent cable TV providers responded to the threat of entry by municipal entrants (but not private entrants) by upgrading their cable systems, but conditional on upgrade, they were less likely to offer services that run on those upgrades when compared to incumbents not facing a similar threat. Additionally, they report that the strategy appeared to have worked: of the 400 cases where an incumbent faced potential entry by a public utility and upgraded their system, only nine actually experienced entry. Finally Cookson (2017) provides evidence from the American casino industry and document both the investment in capacity to deter entry, as well as the effectiveness of these investments that reduced the likelihood of entry.

Our paper is also related to a second more specialized literature in pharmaceuticals that considers similar strategies as above (capacity, prices, advertising etc.), but often within the context of intellectual property and market exclusivity rules or other country specific regulations. For instance, Caves et al. (1991) analyzed price and advertising expenditures for 30 drugs that experienced patent expiration in the US between 1976 and 1987, and found no evidence of limit pricing. They also noted that while reduction in advertising expenditures typically starts two years before patent expiration, it is because innovators expect lower returns from advertising once the generic entry takes place rather than to deter entry. Reduction in advertising two years prior to loss of patent is also noted in other studies, including most recently in Castanheira et al. (2019). Similarly, Scott Morton (2000) also finds that pre-patent expiration advertising by the originator does not deter entry by generics. On the other hand, Bergman and Rudholm (2003) find evidence of limit pricing in the Swedish market, where once a branded firm lowers the price, they are committed to that price because regulations in the country prevent it from raising them easily post generic entry.

Inline with the focus of our paper on product-line extensions, Huskamp et al. (2008) maintain that new formulations allow pharmaceutical firms in the US to extend market exclusivity, and instead investigate how new formulations affect a branded firm's advertising strategy. They find that promotions are shifted away from the original formulation and towards the newer formulation well before generic entry takes place. Ellison and Ellison (2011) use the non-monotonicity test and provide some (weak) evidence from the US showing that additional products are launched more in the medium size markets, as would be predicted under a deterrence hypothesis. By contrast,

Danzon and Furukawa (2011) look at the effectiveness of launching additional formulations pre-patent expiration and find that it lowers the probability of generic entry in the US, but not in other countries, including in the UK. While we find a similar result for the number of formulations (like their case, positive but not significant for UK), we find that probability of entry is lowered if originator can successfully shift patients to the newer formulation in medium or large markets.

Product-line extensions in pharmaceuticals often rely on secondary patents, which maybe weaker and draw challenges from potential generic entrants. In the context of market exclusivity rules in the US, Grabowski and Kyle (2007) report that generic firms are increasingly engaging in a 'prospecting' approach, i.e., where even a small probability of a win in a patent litigation can draw many generic challenges (particularly for drugs that have large sales) and shorten the effective market exclusivity period for the branded firms. Hemphill and Sampat (2012) also report a similar increase in patent challenges. However, they also find that weaker and later expiring patens i.e, those associated with product line extensions via firms' 'evergreening' strategy, draw disproportionately more challenges and in fact maintain the historical effective exclusivity period for new molecular entities.

Finally, a closely related literature considers pre-emption by a branded firm into the generic segment either via the launch of an in-house 'pseudo' or branded generic, or via a licensing agreement with a third party to launch an 'authorized generic'. Hollis (2003) and Hollis and Liang (2007) argue that authorized generics diminish incentives for independent entry, particularly in small markets (in the US, the Hatch-Waxman act rewards the first successful generic with a 180-day market exclusivity over other generics). Consistent with that view, the Federal Trade Commission estimated that authorized generics can reduce first generics revenue by 40-52% during the exclusivity period issued to the generic and by 53-62% in the following 30 months (FTC, 2011). Reiffen and Ward (2007) use calibration for the US market to estimate that anticipated entry of a branded generic crowds out 1.7-2.4 independent generic entries regardless of market size. However, they argue that deterring motivation is likely present in small and medium size markets, as it also helps maintain higher prices (manage cannibalization) in the branded segment, while in large markets, their motivation is to capture generic profits rather than deterrence itself. Berndt et al. (2007) claim that despite the increasing rate of authorized generics, the rate of challenges under the provisions of the act is also high, and there is no evidence on the entry deterrence effect of authorized generics. Finally, Appelt (2015) provides more direct evidence from the German pharmaceuticals market that authorized generics have no significant impact on entry of independent generic drugs.

2. Background and Data

Prior to describing our data, we summarize the information related to market entry and the exclusivity period used in our analysis, and leave further details to Appendix A. To bring a new drug

to a European national market, a firm requires market authorization (MA) from either a national authority, such as the Medicines and Healthcare Products Regulatory Agency in the UK or, as of 1995, from the European Medicines Agency. This process starts with the firm filing for a new drug application in case of a new molecular entity, or an abridged application for a generic drug. In the former case, MA is granted after establishing safety and efficacy via three phase clinical trials that take several years to complete, while in the latter case, the applicant references the safety and efficacy data of the originator's drug, and aims to establish therapeutic and bioequivalence to it.

Since a patent life is 20 years from the date of filing, and significant time is lost in drug development, EU provides two routes that allow innovators to extend the exclusive marketing of their products. The first, available since 1993, is the Supplementary Protection Certificate (SPC) which allows originators to extend the patent for up to five years after the expiration of the original patent, or fifteen years from the first market authorization date in the EU, whichever is less. Second, there is an explicit data exclusivity period which was introduced in 1984 at the EU level. Prior to that, drug approval was at the national level and with varying rules, during which a generic firm may not reference the originator's data. In the European community, data exclusivity extended either to six years or ten years from the start of MA, depending on the member state (UK had ten years) and starts from the date of first market authorization registered anywhere in the community. Further, the data exclusivity protects original novel substances, for instance the molecule in the original drug, while subsequent improvements such as new therapeutic indications, dosage strengths, or formulations are not granted any additional protection. Nonetheless, these product line extensions may be protected via secondary patents. In 2005, a new '8+2(+1)' exclusivity period was introduced at the EU level which provided unified rules of exclusivity across all member states – eight years of data exclusivity during which a generic cannot file for an abridged application, plus two additional years of market exclusivity, i.e., the generic may file the abridged application, but not market the drug, and a final one additional year of market exclusivity for new indication(s) if they constitute a significant clinical benefit.

We use the 1996:Q3-2016:Q3 British Pharmaceutical Index (BPI) data series by Intercontinental Marketing Services (IMS) which provides national level sales for all drugs sold in the UK but disaggregated by individual items at the pack level. The BPI contains information in terms of total shipments by nominal sales value and various measures of quantity from wholesalers to retail pharmacies and dispensing doctors, but does not include direct sales from manufacturers to hospitals or to non-pharmacy stores (e.g. grocery stores). Drugs are identified by manufacturer (except for generics), product name, which is either a brand name or its international non-proprietary name in the case of generics, main/active molecule(s), and strength and package size e.g. 20mg 28pills. In our data, the identity of a generic drug's manufacturer is typically not known but other information about the drug is known. For each item, the data lists its associated four-digit

anatomical therapeutic chemical code (ATC4) and a three-digit code for formulation (NFC3), which tells us if a drug is a tablet, a capsule, extended release, ointment or other forms. The data also includes information on if a drug is branded or generic, and the month and year a pack was first launched in the UK. We use the UK launch date as a proxy of actual market authorization, and forty quarters from then as the end of exclusivity. We combine the information on ATC4 with the molecule to define a market, and identify an originator as the manufacturer with the first launch date on any individual pack(s) within the ATC4-molecule combination. Line extensions by the originator are all other drugs that differ by the NFC3 code, dosage, or pack size within the same ATC4-molecule combination and with a later launch date. Entry by a competitor is identified in a similar manner, i.e., when a drug is introduced which is in the same ATC4-molecule combination, but differs by manufacturer (in that respect an entrant could be a generic or a branded competitor with a 'me-too' drug which has the same ATC4-molecule but perhaps a different formulation). Further details about selection criteria and data cleaning are given in Appendix B.

For our analysis we constructed two primary data sets. The first data was constructed so as to observe sales and product launches by originators before and after expiration of their market exclusivity period. Since our data series is for 1996-2016, and market exclusivity lasts for ten years since the initial launch, we selected those originators that would have lost exclusivity between 2001-2011 i.e., working backwards, if their UK launch date was between 1991-2001. This window gives us at least five years of observations if exclusivity ended as early as 2001, and at least five years after the end of exclusivity if it ended as late as 2011. This resulted in a final data set of 263 originators consisting of 58 distinct firms as some firms are originators in multiple classes. The second set consists of all originators with the end of exclusivity anytime between 1996 and 2016. This larger data is used in hazard models to estimate the probability of entry by a competitor and consists of 430 originators as 70 distinct firms at risk of entry. Table 1 provides a summary of entries by originators and competitors by first-digit therapeutic classes and (simplified) formulations.

There is significant variation in entry by therapy classes and formulations. The nervous system class has the highest number of entries by originators as well as by competitors, where of the 70 originators that entered in this class, 42 experienced entry by a competitor. This is followed by molecules treating antiinfectives for systemic use with 65 originators and 14 competitor entrants. Others such as parasitology draw very few originators and competitors. Similarly, among formulations, ointments draw fewest entries while solid form drugs, e.g. tablets, capsules etc. have the highest entry rates.

Table 2 provides summary statistics of all the variables related to the 430 originators and used in the analysis (for the smaller sample of 263 originators, descriptive statistics are very similar and are given in Table B-2 in the appendix). For each originator, we count product line extensions with two

TABLE 1. Risk Sets And Entry Events By ATC and Formulations

Originator's class and formulation		End of Exclusivity Period			
		1996 - 2016		2001 - 2011	
		At risk	Entry	At risk	Entry
A	Alimentary t.& metabolism	32	9	21	8
B	Blood + b.forming organs	26	3	15	1
C	Cardiovascular system	51	23	24	15
D	Dermatologicals	23	4	15	2
G	G.u.system & sex hormones	28	11	20	8
H	Systemic hormones	10	0	6	0
J	Systemic anti-infectives	65	14	33	6
L	Antineoplast+immunomodul	47	14	35	13
M	Musculo-skeletal system	27	10	14	5
N	Nervous system	70	42	48	28
P	Parasitology	4	0	3	0
R	Respiratory system	22	5	14	4
S	Sensory organs	25	2	15	2
Total		430	137	263	92
Solid	Tablets, capsules, extend release, etc.	194	91	121	62
Liquid	Liquids & aerosols	40	6	22	3
Injection	Ampules, vials, pre-filled syringes, etc.	115	23	67	14
Ointment	Ointments, creams, gels & sols	26	2	18	2
Other	All others & multiple formulations	55	15	35	11
Total		430	137	263	92

Notes. The data contains 181 ATC4 classes (132 ATC3, 64 ATC2, and 13 ATC1 classes) and 78 values for NFC3 formulation codes. The latter are collapsed into simplified formulation classifications. See data appendix Table B-1 for details.

main measures. The first is $D1_j$, which provides for the j-th originator a count of the total number of drugs in the same ATC4-molecule that differ by their formulation code NFC3 (this code can take upto 78 unique values). This measure counts product line extensions when there is a change in formulations, for instance from an initial tablet to extend release tablet or to a capsule, but this count ignores smaller changes like dosage or pack size differences for any given formulation. Our second measure is $D2_j$, which provides a count of drugs by the originator within the same ATC4-molecule class at the pack variety level, and differentiates drugs by their NFC3 code as well as by dosage strength or pack sizes. Thus $D2_j \geq D1_j$. Based on formulations, on average an originator has 1.35 drugs in their portfolio with a standard deviation 0.67 and range upto 5, but most of the variation is cross-sectional as indicated by *between* standard deviation, which is 0.58, while the *within* standard deviation is 0.30 ('within' is due to variation over time for a given originator). Based on the second measure, originators launch 3.23 drugs with a standard deviation of 3.40 and a max of 37 different varieties at the pack level.

Since we are also interested in measuring the effect of product proliferation or hopping on entry, i.e., if an originator has not just launched an extension of the ordinal drug, but has successfully

TABLE 2. Originator's Characteristics: Full Sample (430 Originators)

Variable	Description	Mean	Std. Dev.			Min	Max
			overall	between	within		
$D1$	Count based on formulations	1.35	0.67	0.58	0.30	1	5
$D2$	Count based on pack variations	3.23	3.40	3.18	1.33	1	37
$S1$	1/HHI from shares of D1	1.12	0.29	0.23	0.15	1	3.61
$S2$	Share of D1 launched after 5 years	0.05	0.20	0.16	0.10	0	1
Sales (log)	Sales by originator	10.91	4.31	4.05	2.05	0	18.27
†Monopoly	Originator monopolist in other classes	0.92	0.27	0.25	0.13	0	1
†Nearby	Other monopolists in ATC3 class	0.82	0.39	0.34	0.19	0	1
†Chronic	Chronic disease drug	0.71	0.46			0	1
†SPC	Originator enters after 1993	0.74	0.44			0	1
†1Form	Single original formulation	0.94	0.23			0	1
†Solid	Tablets, capsules, extend release, etc.	0.43	0.50			0	1
†Liquid	Liquids & aerosols	0.10	0.30			0	1
†Injection	Ampules, vials, pre-filled syringes, etc.	0.27	0.45			0	1
†Ointment	Ointments, creams, gels & sols	0.07	0.25			0	1
†Other	All others & multiple formulations	0.12	0.33			0	1

Notes. Summary stats from unbalanced panel of 430 originators over 80 quarters with 21,670 observations. For time invariant variables, there is no *within* standard deviation and overall standard deviation is the same as *between*.
† 1/0 Dummy variable, 1 if true.

moved patients to the newer drugs fully or, spread them evenly into all variants, we use relative market shares of originator's products to compute two additional variables. The first is the inverse of the Herfindahl-Hirschman index constructed from market share s_{ij} (by value) of the total I_j drugs sold by the j-th originator, i.e., $S1_j = 1/\sum_{i\in I_j}(s_{ij}^2)$. This measure can be thought of as a count of $D1$, but only if the individual drugs have a significant share of the originator's portfolio. A second measure is the total share of all drug variants launched by the incumbent after five years of original launch, $S2_j = \sum_{i\in\mathcal{N}5_j}(s_{ij})$ where $\mathcal{N}5_j$ is the subset of new drugs $D1_j$ launched by the originator after five years of initial entry. Note that both measures are inclusive of shares of all pack variations within a formulation. The mean value $S1_j$ is 1.12, indicating that not all formulations retain significant market share, while the mean share of drugs launched after five years is only .05 of the originator's portfolio, but sometimes going up to 1.0. Nonetheless, variance in this measure is less than the $S1$ variable, both overall as well as within and between. Further, hopping is relatively rare. For instance if we define an indicator variable as $I(S2 > 0.5)$ (i.e., 1 if share of new drugs greater than 0.5), then only 19 out of 430 originators, or 4.42%, engage in product hopping.

In the analysis that follows, we also use several additional variables about the originator or their initial drug. The variable (log) sales is the sum of sales from all drugs by the originator within the ATC4-molecule class and is recorded for each period (converted to constant 2015 value using the consumer price index for the UK). The mean value is 10.91 with almost twice as much variation

between originators than over time (within). While not shown in this table, we also used the time invariant value of sum of sales over the two years prior to the end of market exclusivity (or two years prior to entry in the handful of cases where entry occurred before end of exclusivity) to classify the originators as belonging to small, medium and large market sizes. The mean and median of log of sum of sales over these two years is 13.19 and 13.88 respectively, and we used the 33rd and 66th percentile values of the distribution, 12.29 and 15.43 respectively, to classify the originators into the three equal sized groups. Other variables include if the originator entered before or after 1993 (when SPC came into effect), type of originator's original formulation, if the originator entered with a single formulation (23 originators entered with more than one formulation), codes of therapeutic class (they are used at two digit level in most of the regression analysis), whether the original drug is for a chronic disease or not, if the originator is a monopolist in any other class, and finally if there are other monopolists in the same ATC3 class as the reference drug. Summary statistics of these variables are also given in Table 2.

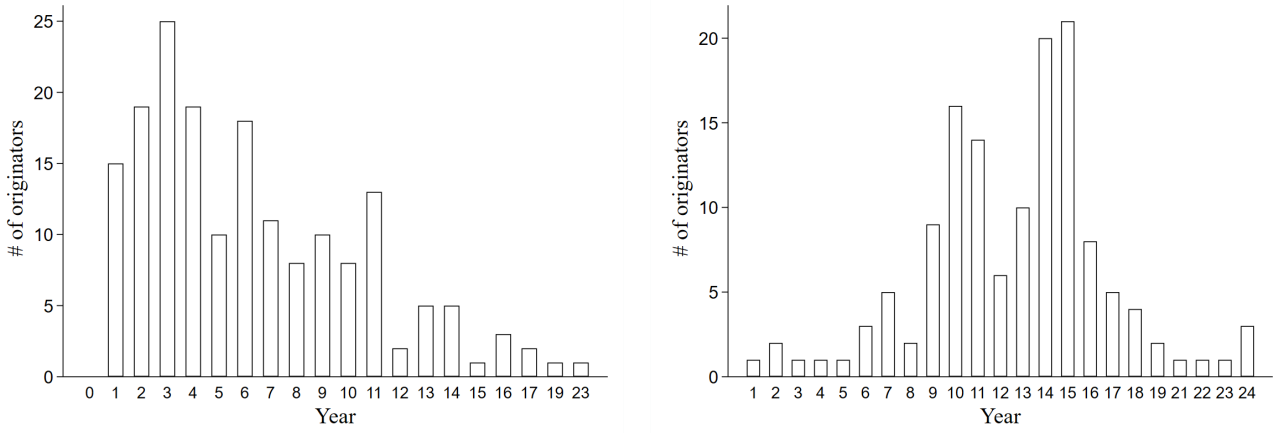

FIGURE 1. Distribution of product launches over time and monopoly durations

Finally, before moving to the analysis, Figure 1 shows the distribution of new formulations launched over time by the originators post the introduction of their original drug, as well as of monopoly duration of the originators that experienced entry. As shown in the left panel, most originators launched additional formulations during the first ten years with an additional spike in the eleventh year, but then further introductions drop off fast after that. By contrast, as shown in the right panel, entry by competitors has two peaks, first in the 10th year and a second one in the 15th year, perhaps due to the SPC extensions discussed earlier. Notably however, entry can in fact also happen before the 10th year, as was the case for 30 originators in the larger data set used in the hazard models. The reasons could be a prior launch elsewhere in the EU or after patent litigation.

3. RESULTS

3.1. **Product launches by the originator.** To identify if originators launch additional products to deter entry, we exploit the variation in product launch rates before and after the end of exclusivity, and *prior to any entry* by a competitor and when the market size has not changed. Using the sample of 263 originators described earlier, we divided the originators in two groups, those that experienced entry during the observational period, and those that do not, where recall that the sample was selected such that we can observe each originator for at least five years before and after the end of exclusivity (EoE) period. The mean value of counts of products, $D1_j$ and $D2_j$ are higher for the group with entries (before entry) than for the group without any entries. For instance, the mean values of $D1_j$ are 1.44 and 1.30 for the two groups respectively, and that of $D2_j$ are 4.77 and 2.57 respectively. Importantly, the two groups also differ by sales value and by the distribution of formulation types. For instance, the mean (log) of sales is 13.68 for the group that experienced entry and 9.48 for those that did not (additional statistics by entry status are given in Table B-3 in the appendix). Figure 2 further plots the value of counts of products ($D1_j$ and $D2_j$) over time and the vertical line marks the EoE period.

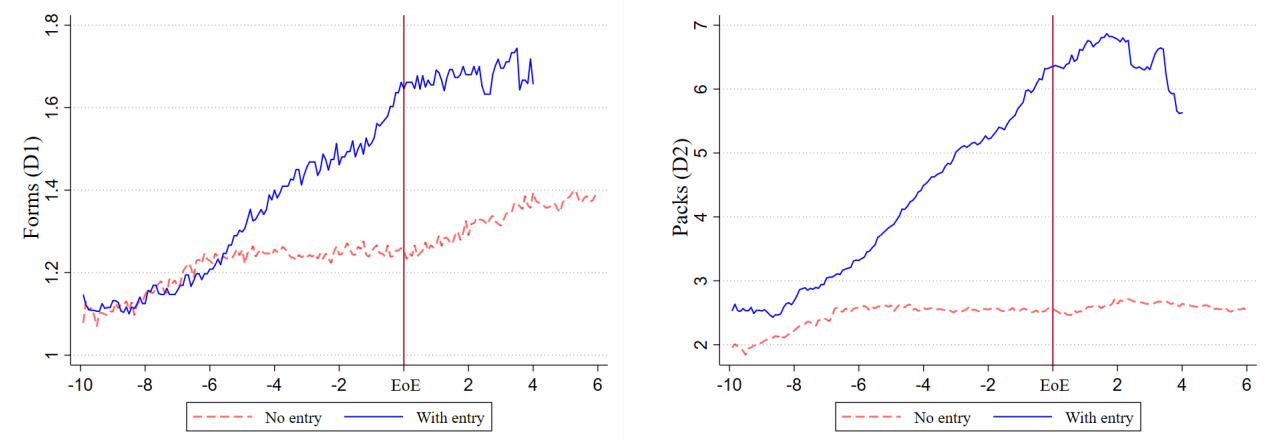

FIGURE 2. Count of products by originators

As the graph indicates, not only is the overall count for the two groups different, the rate of launch, as measured by the slope is higher for the originators that experience eventual entry than those that do not. Further, there is a discernable *change* in the slope for the originators that experienced entry after the EoE compared to those that do not experience any entry. Our identification strategy relies on the fact that originators know the likelihood of entry based on their own sales, therapy class, and formulation. Further, since the potential competitors can file for market authorization of their generic only after the EoE, and it takes time before competitors can obtain the required authorization and enter, originators know if entry is imminent or not based on if any generic entry applications have been filed for their drug. And if indeed entry deterrence is the motivation for

product line extensions, and an application for entry has been filed, then these originators would *change* their product launch rate as it is no longer possible to deter entry, even if entry itself has not yet taken place. Similarly, the group that never experiences any entry would not see entry applications, and hence should continue launching products at the original rate.

To test for the change in slopes summarized in the graph above, we estimated a reduced form equation for the total number of drugs ($D1$ or $D2$) as function of time as,

$$\begin{aligned} D\#_{jt} =& \beta_0 + \beta_1 T_{jt} + \beta_2 E_j + \beta_3 B_{jt} + \beta_4 T_{jt} E_j + \beta_5 T_{jt} B_{jt} + \beta_6 B_{jt} E_j \\ &+ \beta_7 E_j B_{jt} T_{jt} + \beta_8 \ln(\text{Sales})_{j,t-1} + X_{j,t-1}\gamma + \epsilon_{jt}. \end{aligned} \tag{1}$$

In the equation above, T_{jt} is time difference to EoE, and is negative for periods before and positive after EoE, E_j is an indicator variable equal to one if the originator experienced entry or not, and B_j is an indicator variable equal to one before the EoE and zero afterwards. The variable $\ln(\text{Sales})_{j,t-1}$ is one period lagged value of sales, and $X_{j,t-1}$ is vector of other variables listed in Table 2 plus dummy variables for ATC2. Note that some of these variables are time invariant, but those that are not, enter with lagged values. The change in the launch rate from before to after the EoE for the 171 originators that do not experience entry is given by β_5, while a similar change in the launch rate for the 92 originators with eventual entry is given by $\beta_5 + \beta_7$. Our primary interest is in the coefficient β_7 on the three way interaction term as it provides the difference in the change in the launch rate between these two group of originators. Specifically, this coefficient measures the change in slope around the EoE period for the group of originators that experience entry relative to the change in slope around EoE for competitors who did not experience any entry. Table 3 shows selected regression coefficients for different sub-samples, along with robust and clustered standard errors, where clustering is at the originator level. The full set of regression coefficients are given in the appendix in Table C-4.

Columns (1) and (2) show the regression coefficients when the equation is estimated on the sample of 263 originators for $D1$ and $D2$ respectively. The originators that never faced any entry changed their product launch rates by $\beta_5 = 0.000$ or $\beta_5 = 0.013$, and neither are statistically significant under clustered standard errors. However, the coefficients on the triple interaction terms are $\beta_7 = 0.016$ and $\beta_7 = 0.135$ respectively, and both are statistically significant. Thus, a typical originator that faces eventual entry slows their product launch rate after EoE by 0.016 or 0.135 drugs per quarter *more* than those originators that also passed EoE but never faced any entry (for $D1$ and $D2$ respectively). Recall that this slow down in launch rate is before any actual entry takes place.

While the sample is restricted to originators that reach the EoE within the 2001-2011 period, some of the originators in our sample do not have observations both before and after the EoE. For instance, we may observe sales for a given original drug in our data only after 2006, even though the

TABLE 3. Product Launch Rate Of The Originators

	Event: EoE		Event: EoE		Event: EoE		Event: Entry	
	(1 - D1)	(2 - D2)	(3 - D1)	(4 - D2)	(5 - D1)	(6 - D2)	(7 - D1)	(8 - D2)
T	0.003	0.004	0.003	0.004	0.004	-0.005	0.003	0.004
	(0.001)^a	(0.003)	(0.001)^a	(0.003)	(0.001)^b	(0.009)	(0.001)^a	(0.004)
	[0.001]^b	[0.006]	[0.001]^b	[0.007]	[0.002]^b	[0.007]	[0.001]^b	[0.007]
E	0.245	2.764	0.233	2.665	0.188	2.442	0.231	2.187
	(0.041)^a	(0.213)^a	(0.041)^a	(0.213)^a	(0.049)^a	(0.248)^a	(0.030)^a	(0.165)^a
	[0.128]^c	[0.736]^a	[0.131]^c	[0.744]^a	[0.123]	[0.685]^a	[0.104]^b	[0.634]^a
E×T	-0.009	-0.067	-0.009	-0.060	-0.003	-0.039	-0.005	-0.041
	(0.002)^a	(0.012)^a	(0.003)^a	(0.013)^a	(0.004)	(0.022)^c	(0.001)^a	(0.007)^a
	[0.005]^b	[0.025]^a	[0.005]^c	[0.026]^b	[0.006]	[0.031]	[0.003]	[0.016]^b
B	-0.008	0.159	0.001	0.177	-0.023	-0.085	-0.011	0.161
	(0.017)	(0.106)	(0.018)	(0.107)^c	(0.024)	(0.148)	(0.019)	(0.112)
	[0.025]	[0.115]	[0.024]	[0.111]	[0.018]	[0.088]	[0.026]	[0.120]
B×T	0.000	0.013	0.000	0.014	-0.003	0.003	0.001	0.014
	(0.001)	(0.004)^a	(0.001)	(0.005)^a	(0.002)	(0.012)	(0.001)	(0.005)^a
	[0.002]	[0.011]	[0.002]	[0.012]	[0.003]	[0.012]	[0.002]	[0.012]
E×B	-0.081	-0.765	-0.035	-0.728	0.018	-0.295	-0.100	-0.371
	(0.050)	(0.257)^a	(0.053)	(0.267)^a	(0.066)	(0.329)	(0.040)^b	(0.223)^c
	[0.066]	[0.364]^b	[0.066]	[0.340]^b	[0.044]	[0.226]	[0.063]	[0.317]
E×B×T	0.016	0.135	0.017	0.126	0.011	0.133	0.006	0.076
	(0.003)^a	(0.013)^a	(0.003)^a	(0.014)^a	(0.006)^c	(0.028)^a	(0.002)^a	(0.009)^a
	[0.006]^b	[0.035]^a	[0.007]^b	[0.037]^a	[0.008]	[0.039]^a	[0.004]	[0.027]^a
Sales (log)	0.054	0.282	0.055	0.290	0.056	0.307	0.061	0.332
	(0.001)^a	(0.009)^a	(0.001)^a	(0.009)^a	(0.002)^a	(0.012)^a	(0.001)^a	(0.009)^a
	[0.007]^a	[0.057]^a	[0.008]^a	[0.059]^a	[0.009]^a	[0.065]^a	[0.008]^a	[0.057]^a
Observations	13,559	13,559	12,560	12,560	8,052	8,052	15,209	15,209
R-squared	0.414	0.408	0.425	0.418	0.429	0.445	0.408	0.444
‡Cases	92	92	66	66	66	66	92	92
‡Controls	171	171	146	146	146	146	171	171

Notes. Robust errors are in first parentheses, and cluster adjusted standard errors in second square parentheses, with clustering at the originator level. Superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All regressions include other controls and ATC2 dummies. Full set of regression coefficients available in the appendix (see Table C-4). ‡Cases and Controls refers to originators that experienced entry or not, respectively.

drug entered the UK market in 1995 and reached its EoE period in 2005. Thus, we restricted the sample further to 212 originators with observations both before and after the EoE and re-estimated Equation 1. This set consists of 66 originators that faced eventual entry and 146 without any entry. The results for the two measures of count of drugs $D1$ and $D2$ are summarized in Columns (3) and (4) respectively. The coefficients of interest do not change by much either in magnitude or in significance levels. These estimates show that on average an originator with entry slows their new formulation launch rate by 0.017 and new formulation/doage/pack launch rate by 0.140 per quarter after the end of exclusivity ($= \beta_5 + \beta_7$), while relative to the originators with no entry, the rate slows to 0.017 and 0.126 respectively ($= \beta_7$). Incumbents with no entry do not change the launch rate and continue to introduce new formulations at a lower rate of .003 ($= \beta_1 + \beta_5$).

We imposed one final restriction on the sample, where we required that all observations for an originator be within five years of the EoE. This was so that product launches that are too far before or after the EoE do not contribute to the measurement of change in slopes, as these product launches could be for other reasons as well. Doing so does not reduce the number of originators in the sample any further, only the periods over which they are followed which leads to a drop in observations from 12,560 to 8,052. The results from estimating on this sample are given in Columns (5) and (6). The magnitude of the coefficient on the triple interaction term is slightly smaller in magnitude for $D1$ relative to the first case (.011 vs .017), but is essentially the same in the equation for $D2$ (0.133 vs 0.126).

To check which originators launch more products prior to the EoE and change their launch strategy after the EoE, we re-estimated the last sample by sub-groups, small, medium and large as previously described. Results by sub-groups are given in Table C-5 in the appendix. The number of originators in each of these sub-groups is small, and subject to issues of statistical significance. Nonetheless, two coefficients standout. First, β_6 which measures the level of products launched before the EoE by those that experience entry relative to their counter part, is positive and significant in the medium size group and not the other two groups. Second, the relative magnitude of the coefficient on the three way interaction term β_7 across regressions for the small, medium, and large indicate that it is primarily the medium size group where launch strategy changes the most post the EoE, and β_7 in medium size is statistically different from the other two market sizes. However, the evidence is slightly weak as the three way interaction term for the medium size group is not statistically significant for $D1$ with clustered standard errors (it is significant for robust standard errors).

Returning to the main sample, we also estimated how much the product launch rate changes from before to after the actual entry for those who experienced entry. We compared these to any change in product launch rates around the EoE for those who never experienced entry (for the latter group we obviously cannot construct a period before and after entry). Thus, we re-estimated Equation 1

on the initial sample, but replaced the event EoE with the entry date by a competitor for the first group of originators. Results are given in columns (7) and (8) in Table 3. The change in the product launch rate around entry is much smaller than the previous cases. In fact, the coefficient on the triple interaction term drops from 0.016 to 0.006 for D_1 (and is not statistically significant with clustered standard errors), while for $D2$ it drops from 0.135 to 0.076 (and is still significant). Thus, the product launch rates change by almost twice as much (2.67 and 1.78) with the EoE period than with actual entry.

Monotonicity test. Prior to estimating the effect of product launch by originators on the probability of entry, we also implemented a test based on a monotonicity argument proposed in Ellison and Ellison (2011, initially proposed in 2000 in the working paper) and in Dafny (2005). The general idea is that firms' investments may be monotonically related to profitability/size of the market, but the relation may not be monotone when there are strategic considerations. For instance, a firm may introduce more product varieties to match closely consumer tastes in larger markets than in smaller markets. Thus, absent any strategic considerations, there might be a monotonically increasing relationship between the size of the market and the number of products launched by the originator. But size/profitability may also be correlated with the risk of entry, and the incumbent may change their investment if they can deter entry. In small markets, high entry costs relative to profits may mean that entry is blocked, while in large markets deterrence may not be feasible, and hence originators may not take any deterring action in either case. On the other hand, in medium size markets there may be incentives to over-invest in product launches thus breaking the monotone increasing relation. To this end we estimated the specification suggested in Ellison and Ellison (2011), given by

$$D\#_j = \beta_0 + \beta_1 \ln(\text{Sales})_j + \beta_2(\ln(\text{Sales})_j - \overline{\ln(\text{Sales})})^2 + X_j\gamma + \epsilon_j. \tag{2}$$

In the equation above, $D\#_j$ is one of the two measures of count of products launched by the originator, and the term $(\ln(\text{Sales})_j - \overline{\ln(\text{Sales})})^2$ captures the deviation in sales of the jth originator relative to the mean value of sales for all originators. We use cross-sectional observations where values for all variables are computed using the average value from two years prior to the EoE (and in the handful of cases where entry took place before the EoE, we used average values from two years prior to entry or by dropping those observations). A negative and significant value of β_2 would indicate a break from the monotonic relationship where originators in medium size markets (or closer to the mean) launch more products than those in small or large markets.

We estimated the model using $D1$ and $D2$ measures of count of products on both the smaller and the larger sample of originators, as well as on a different variant where size of the market measured as log of sales was replaced by the likelihood of entry using a simple probit model of entry. Results from these six cases are given in the appendix in Table C-6, but based on this test, we did not find

any evidence consistent with entry deterrence based on these tests. In fact the coefficient β_2 turns out to be positive and significant in most cases, as would be the case if the underlying relation is very steep or convex. The convexity can be seen in Figure 3, in which case the test is not applicable, and hence we do not discuss it further.

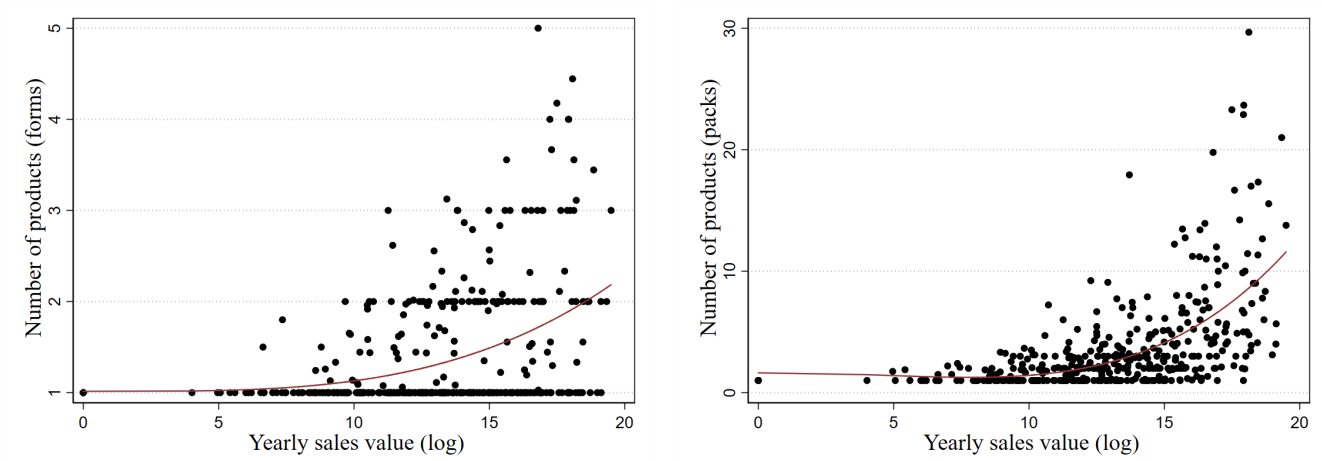

FIGURE 3. Count of products and market size

3.2. **Probability of Entry.** We use hazard rate models to assess the impact of product line extensions on the probability of entry. One way to proceed is to model the entry decision by a potential entrant, where they enter the market at a point in time when the future discounted profit from entry becomes greater than zero, and the hazard is set as a function of entrant's characteristics interacted with the market characteristics (see Reinganum, 1989, Bokhari, 2009). However, our interest is not if a generic manufacturer with given characteristics enters a specific market, but rather if an incumbent's actions, particularly, moving patients to the newer formulations, reduces the probability of entry in their market by any generic manufacturer. To that end, we use hazard models to assess the impact of how well these additional drugs have diffused in the patient population, on the probability of entry by a competitor in the therapy-molecule class of the originator. Thus, let $\lambda_j(\tau)$ be a continuous time hazard that incumbent j experiences entry at time τ and is given by the proportional form $\lambda_j(\tau) = \lambda_0(\tau)exp(Z_j(\tau)'\beta)$ where $\lambda_0(\tau)$ is the baseline hazard and $Z_j(\tau)$ are the time varying covariates of the originator. We can generate a discrete time hazard from this by grouping time τ along the quarterly intervals $[0, \tau_1), [\tau_1, \tau_2), \ldots, [\tau_{t-1}, \tau_t), \ldots, [\tau_l, \infty)$ so that λ_{jt}, the probability that originator j experiences entry in quarter t conditional on no entry until the previous quarter, is given by

$$\begin{aligned} \lambda_{jt} &= \Pr[\tau_{t-1} \leq T_j < \tau_t | T_j \geq \tau_{t-1}] \\ &= 1 - exp\{-exp(Z'_{jt}\beta + \alpha_t)\}. \end{aligned} \tag{3}$$

In the equation above, α_t is the natural log of the baseline hazard within an interval $[\tau_{t-1}, \tau_t)$ and is given by $\ln \int_{\tau_{t-1}}^{\tau_t} \lambda_0(s)ds$ (see Cameron and Trivedi, 2005). The vector Z consists of variables D, S, X and their interactions, where D is one of the variables in $\{D1, D2\}$, and S is measure of the extent to which patients use these additional drugs, i.e., one of the variables in $\{S1, S2\}$. The variable X is a vector and includes size of the market (dummy variables M and L for medium and large) as well as other product or originator characteristics listed in Table 2. Specifically,

$$Z'_{jt}\beta = \beta_1 D_{jt} + \beta_2 S_{jt} + \beta_3 M_j + \beta_4 L_j + \beta_5 S_{jt} M_j + \beta_6 S_{jt} L_j + \beta_7 \ln(\text{Sales})_{j,t-1} + X_{j,t-1}. \quad (4)$$

Figure 4 illustrates the survival probability over time as a monopolist and is grouped by market

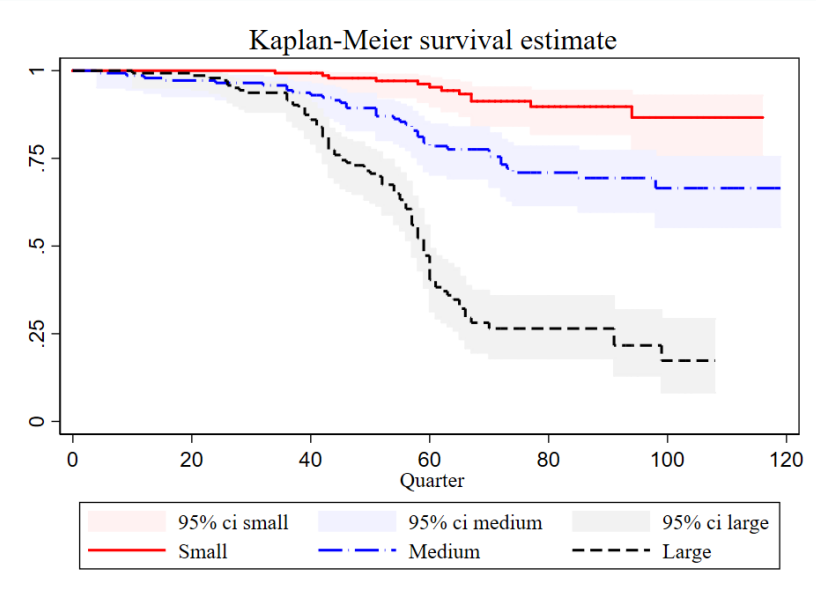

FIGURE 4. Survival by market size.

size. Recall that we defined small, medium or large based on sales value over the two years prior to the EoE, or two years before entry for the 30 originators that experienced entry prior to the EoE. The Kaplan-Meier curves show that entry probability differs by market size. Unsurprisingly, probability of entry is lowest when market size is small, as an entrant can expect lower profits post entry in these markets. Entry probability is higher when market size is large, and entries are more concentrated between the 10th and 15th year since the launch of the original drug. Entry probability for medium size market is located between the other two market sizes.

We already know both from Figure 2 as well as from the results reported in Table 3 that firms that experience entry launch more products than those that do not (for the latter case, note that the coefficients on dummy variable E in all columns for $D1$ and $D2$ are positive and significant). Consequently, a hazard model as described above with $D1$ or $D2$ on the right hand side will capture this positive correlation, but cannot be interpreted as causal, nor does it shed any extra light over what we already know. Instead our primary interest is in the impact of $S1$ and $S2$ and their

interaction with categorical variables for market size (medium and large) on the probability of entry after controlling for $D1$ (or $D2$) and other variables. The hazard model given in (3) was estimated under four different specifications which differ by variables controlled for in the model, the observations used, or the time period used to compute the value of $D1, D2, S1, S2$ and ln(sales).

Selected regression coefficients and clustered standard errors for the variables of interest are shown in Table 4, and the coefficients of other variables are available upon request. Columns (1)-(4) show estimates when $S = S1$, and columns (5)-(8) provide estimates when $S = S2$ for each of the four specifications respectively. Note that the hazard models for $S2$ have fewer observations since this variable measures the relative share of originators drugs that were introduced after five years, and hence observations for the first five years are omitted. Columns (1) and (5) are estimated on the baseline sample of 430 originators, include the duration dummies, and the variables listed in the table, but do not control for other product/originator characteristics listed in Table 2, nor do they include any of the ATC2 dummy variables. By contrast, columns (2) and (6) includes all these additional variables as controls. An alternative set of regressions that control for $D2$ instead of $D1$ give similar results, and are available in the appendix in Table C-7.

Columns (1,2,5, and 6). Starting with these four columns (1,2,5 and 6), the probability of entry increases in log sales in all four cases as expected. However, the dummy variables for size of the market, medium or large, are either positive and significant, or if negative (as in column 5) then it is not significant. The coefficient for the variable S can be interpreted as value of $S1$ or $S2$ in small markets. This coefficient is positive and significant in all four columns except in column (2) when it is not significant for $S1$ when additional controls are included in the specification. The positive coefficient implies that probability of entry increases in small markets when originators have more drugs that are well diffused among the patient population.

Importantly however, the interaction terms with the dummy for medium and large size markets are negative and significant in all but one case (the negative coefficient on the interaction between $S1$ and large is not significant in column (2) when other controls are included in the hazard model). The negative coefficients on these interaction terms imply that the probability of entry does not increase in medium and large markets as much as in the base case of small markets. Whether the probability actually decreases or not depends on the magnitude of these negative coefficients relative to the positive magnitude of the coefficient on S for small sized markets. In fact the probability decreases in all cases for both the medium and large markets, but we postpone that discussion until we discuss marginal effects.

Columns (3 and 7). We next removed the 30 originators that experienced entry before the EoE period and retained all other variables in the specifications in columns (2) and (5). Since in this case there is no entry event in the first ten years for any originator, it also requires dropping all

TABLE 4. Discrete Time Hazard Models For S1 And S2 (Controlling For D1)

	S=S1				S=S2			
	(1-A)	(2-B)	(3-C)	(4-D)	(5-A)	(6-B)	(7-C)	(8-D)
S	1.337^b	0.731	1.332	1.840	2.379^a	2.692^a	2.833^a	3.259^a
	(0.671)	(0.874)	(1.077)	(1.836)	(0.826)	(0.818)	(1.017)	(1.043)
Medium	3.253^a	4.479^a	5.163^a	6.299^b	-0.060	0.506	0.286	0.348
	(1.156)	(1.436)	(1.757)	(2.451)	(0.361)	(0.545)	(0.659)	(0.766)
Large	2.168^b	2.242^c	2.378	3.294	0.488	1.602^b	1.080	1.011
	(0.944)	(1.268)	(1.591)	(2.280)	(0.532)	(0.780)	(1.029)	(1.145)
Medium× S	-3.159^a	-3.931^a	-4.790^a	-5.873^a	-3.187^b	-3.587^a	-3.675^b	-3.888^b
	(0.990)	(1.230)	(1.476)	(2.067)	(1.277)	(1.271)	(1.442)	(1.717)
Large× S	-1.816^b	-1.366	-1.798	-2.942^c	-3.457^a	-3.658^a	-4.029^a	-6.029^a
	(0.749)	(1.008)	(1.171)	(1.785)	(1.069)	(1.271)	(1.429)	(1.476)
Sales (log)	0.274^a	0.244^b	0.359^b	0.465^a	0.261^a	0.185^c	0.331^b	0.436^a
	(0.077)	(0.105)	(0.146)	(0.139)	(0.081)	(0.097)	(0.146)	(0.138)
D1		0.362^b	0.307	0.364		0.200	0.135	0.027
		(0.161)	(0.192)	(0.241)		(0.136)	(0.167)	(0.194)
			Marginal effects: $\partial\lambda/\partial S$ (×100)					
Small	0.402^b	0.242	0.660	0.911	0.807^b	1.016^a	1.399^b	1.604^b
	(0.203)	(0.284)	(0.525)	(0.852)	(0.407)	(0.391)	(0.691)	(0.734)
Medium	-1.281^b	-2.456^a	-3.489^a	-4.072^a	-0.563	-0.692	-0.851	-0.635
	(0.545)	(0.766)	(1.211)	(1.346)	(0.676)	(0.827)	(1.227)	(1.572)
Large	-0.967	-1.445	-1.934	-4.563	-2.484	-2.575	-4.977	-11.482^b
	(0.600)	(1.54)	(2.853)	(3.207)	(1.557)	(2.791)	(4.604)	(4.714)
Includes X_j?	No	Yes	Yes	Yes	No	Yes	Yes	Yes
Originators	430	386	312	312	410	364	312	312
Entry events	137	137	104	104	131	131	104	104
Observations	13,456	12,063	5,961	5,961	11,848	10,444	5,961	5,961
Log likelihood	-664	-606	-412	-413	-623	-563	-415	-415

Notes. Clustered standard errors are in parenthesis and superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All models include duration dummies and ATC2 dummies included in all but columns (1) and (5). Table C-7 provides similar estimates but controlling for $D2$ instead of $D1$.

observations for these years in the hazard model as non-entry is predicted perfectly. This reduces the sample size considerably from ∼12k and ∼10.4k to ∼5.9k. The results are given in columns (3) and (7) for $S1$ and $S2$ respectively. Compared to the previous case, all coefficients retain their sign, and most increase in magnitude with some exceptions. Also the coefficient for $D1$ is no longer significant. Overall however we see a similar pattern for the interaction terms indicating as before that the probability of entry does not increase with S as fast in medium or large markets as in small markets (and in fact once again, it actually decreases with S in these markets).

Columns (4 and 8). Our final, and preferred, specification uses the same sample as in the previous case, but now measures the value of $S = \{S1, S2\}$, $D1$ and ln(sales) not as one period lagged values, but instead are time invariant values equal to their average value two years prior to the EoE. Note that this could not be done in the first two specifications as those also included observations from the first ten years when originators were considered at risk. Results from this change are given in columns (4) and (8) and are very similar to those reported earlier. The main difference is that coefficients generally increase in magnitude, but particularly for the interaction terms.

Marginal Effects. Because of the interaction terms, the marginal effect of a variable may not have the same sign as that of the coefficient on the interaction term. If we rewrite (3) as $\lambda_{jt} = 1 - exp\{-exp(I_{jt})\}$, where $I_{jt} = Z'_{jt}\beta + \alpha_t$, then the marginal effect with respect to S, $\partial\lambda_{jt}/\partial S_{jt}$, is given by $(1 - \lambda_{jt})(\beta_2 + M_j\beta_5 + L_j\beta_6)$, where the sign of the marginal depends on the sum of the coefficients $(\beta_2 + \beta_5)$ or $(\beta_2 + \beta_6)$ is medium and large markets respectively. The marginal effect can be computed at either the mean of the sample or for each data point separately, and the standard error can be computed using the delta method. A difficulty in the first case is that there is a very large number of dummy variables in our specifications. These include not only the duration dummies, but also for ATC2 classes and most of the other variables listed in Table 2, and hence either the predicted probability or the marginal at the mean can be difficult to interpret. Thus instead we provide the mean marginal effects with respect to $S1$ or $S2$ in the lower part of Table 4. The marginal effect with respect to $S1$ or $S2$ is negative in all cases for medium and large markets and positive in small markets. Particularly, the marginal effect for $S1$ in medium size markets is negative and significant in all specifications, indicating that entry is less likely in these markets if originator has more products and patients are spread more evenly across all of the originator's products. On the other hand, the marginal effect for $S2$ is negative and significant in large markets for only the last specification, and remains positive and significant for the small markets. In turn it implies that perhaps product hopping, where most patients are switched over to the newer drug, is successful in preventing entry in only large markets, while in smaller markets there may be other demand driven reasons for switching to newer formulations. Regardless, the evidence of its effectiveness in large markets is not robust to specifications, as the marginal effect is not significant in the initial three cases (though the interaction terms are significant).

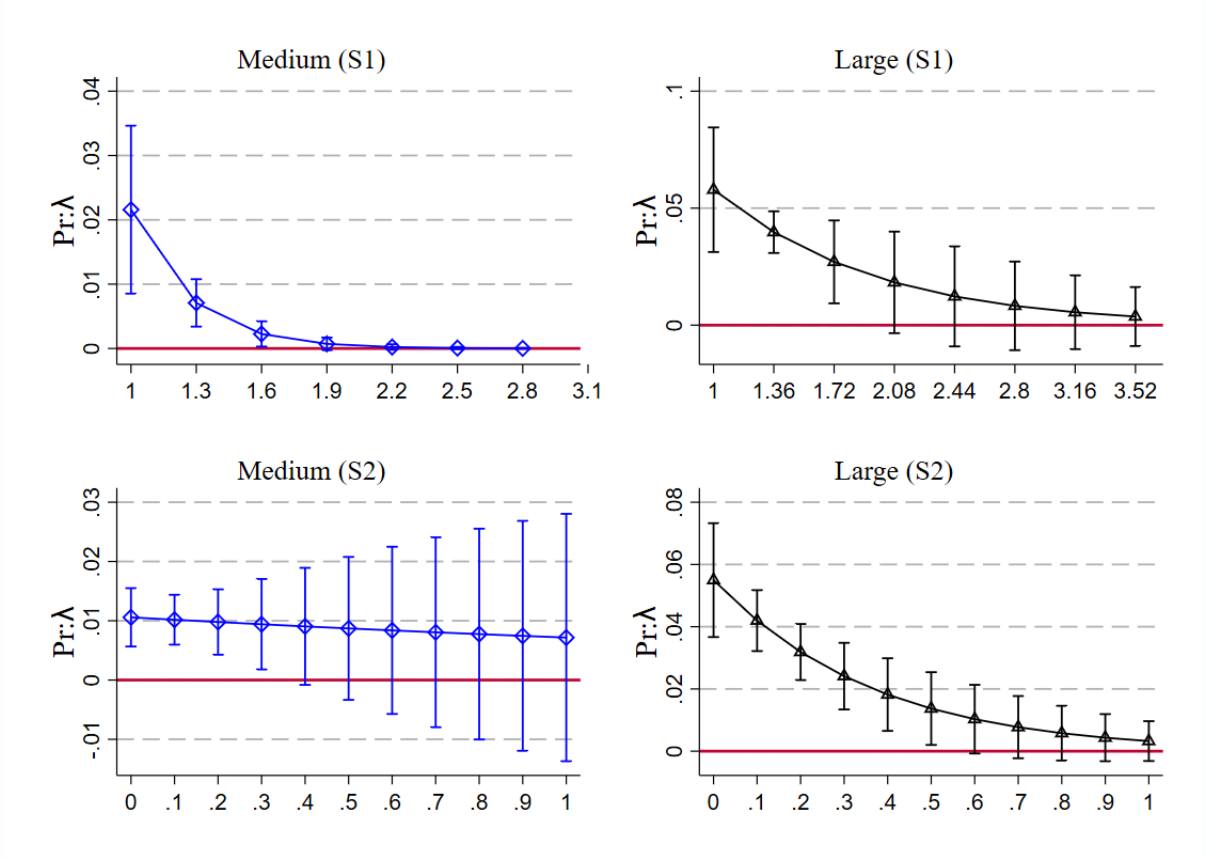

FIGURE 5. Predicted entry probability

Figure 5 additionally plots the mean of the predicted values of λ against values of $S1$ and $S2$ in medium and large size markets. The slope of the plotted line is equal to the marginal effect, $\partial\lambda/\partial S_j$. To be clear, we computed λ based on the coefficients from the last specification for each data point, and where $S1$ and $S2$ are varied over the specified range in the graph, but other variables are held at their observed value. The error bars are equal to the 95% confidence interval. The slopes are negative over the plotted range but as in the case for mean marginal effects, not always significantly different from zero.

3.3. **Discussion.** Entry is deterred in medium size markets with higher values of $S1$, i.e., if the originator has more products and patients are evenly spread across these additional variants. This is in line with entry deterrence motives in medium size markets, as well as our earlier result that the slow down in the launch rate after EoE among those that experience entry relative to those that don't, is largest in medium size markets. However, the alternative measure $S2$, associated with hopping, deters entry only in large markets, but puzzlingly is also positively correlated with entry in small markets.

Note that product hopping is relatively rare. Of the 430 originators in our sample, the variable $S2 > 0.5$ for only 19 cases spread as 6, 8 and 5 in small, medium and large markets. And of these

cases, entry occurred 3, 2 and 1 times in small, medium, and large markets for a total of 6/19 (32%) cases. By contrast, in the 411 cases when $S2 \leq 0.5$, entry took place 131 times (131/411 = 32%), but this time most of the entry was in large markets. See Table 5 below.

TABLE 5. Entry Conditional On Product Hopping

	$S2 \leq 0.5$			$S2 > 0.5$		
	Originator	Entry	Percent	Originator	Entry	Percent
Small	138	9	7%	6	3	50%
Medium	135	35	26%	8	2	25%
Large	138	87	63%	5	1	20%
Total	411	131	32%	19	6	32%

We conjecture that positive and negative correlations with product hopping in small and large markets respectively, is because hopping takes place when an originator cannot maintain multiple product lines. Further, in small markets, they move to the newer variant of the drug without necessarily engaging in significant detailing effort. In turn, this creates an entry opportunity for others. In larger markets, it is more likely that the originator undertakes significant detailing efforts and convinces patients and their physicians that the newer variant is of superior quality. As mentioned earlier, product line extensions do not get additional data or marketing exclusivity by the drug approval authorities in the EU. Thus the EoE for these additional products is the same as that for the original drug, but they may still be protected due to any additional patents. If so, this makes it difficult for competitors to launch generic versions of these newer drugs, and if the originator has successfully moved patients to the newer drug, then entry becomes difficult.

Thus while we cannot check detailing efforts, we additionally verified if indeed entry into the newer versions launched by the originator is less common.

TABLE 6. Entry Type by Competitors

	Incumbent	Initial Entrant		All Entrants	
137 molecules					
Original formulations	148	117	(81%)	121	(74%)
New formulations	85	27	(19%)	42	(26%)
Total	233	144	(100%)	163	(100%)

Starting with the 137 (=131+6) originators that experienced entry, we classified their 233 $D1$ formulations launched before entry into two groups, 148 original, and 85 follow-on formulations. We then checked the formulation type of the drugs launched by competitors within the first year of their entry, and whether these drugs matched the originators' original formulation, or the originators' follow-on formulations. Results are summarized in Table 6, and show that in 81% of the cases,

entry was in the originators' original drug formulation and 19% was for the newer follow-on formulations, i.e., competitors initially enter original formulations more often than new formulations by the originators. If we do not restrict to generic drugs that entered within the first year of any generic entry, the percentages change to 74% and 26% respectively.

3.4. **Robustness and limitations.** While we have already included several robustness checks in the paper, our main results are also robust to several alternative specifications that we did not discuss. For instance, our results hold up if we change the level of aggregation from quarterly to monthly observations, include or drop some of the control variables, or use different level of ATC classifications. In the hazard models we also experimented with changing the S2 variable to share of drugs introduced after three or seven years (instead of five) or to an indicator variable if the share of the newer drugs was greater than or equal to 0.5, 0.6 or 0.7 with fairly similar results with varying degree of statistical significance. We have not included these to keep the length of the paper manageable.

There are two main limitations of our work. First, launch of a product line extension is most likely a worldwide, or at least a Europe-wide decision, rather than just based on entry prospects by a competitor in the UK market. We have relied on the fact that trade within Europe is easier, and the launch of an additional product by the originator, or an entry event by a competitor is a Europe-wide phenomena. But firms can choose to launch products in limited national markets. While UK is an important market, and most firms would launch here as well if they were entering or introducing a new variant in other parts of Europe (or other parts of the world), future work should attempt to overcome this difficulty. Second, we do not have access to detailing (marketing) data by originators. This is a choice variable, and some of our explanations rely on differences in marketing efforts by market size. We do not actually observe if, for instance, detailing is less in small markets compared to large markets around the time of product line extension. Ideally this variable should be included in the analysis.

4. CONCLUSIONS

There is a long standing interest in entry deterrence in the theoretical literature, but there are relatively few empirical studies, primarily due to difficulties in identifying deterrence from other unilateral actions. Our paper adds to that sparse but growing empirical literature. Using data from the UK pharmaceuticals, we tested for changes in product line extension rate by originators over time, but before any entry takes place. The threat of entry changes after the end of exclusivity, where some originators may find out that entry is imminent in the near future, and hence may change their rate of product line extensions. Taking advantage of this, we use a difference-in-difference design on the rate of product launches and compare it to the originators that never experience

entry but also reach the end of exclusivity. An identifying assumption we make is that originators know the likelihood of entry based on their past sales/size of the market, therapy class, formulation and other characteristics of their original drug, and may also observe if a competitor has filed for generic entry with the EMA or other national authorities.

We find that for firms that eventually experience entry, there is a sharp decline in their product launch rate after the end of exclusivity, and before any entry. This drop in rate is significant even when we compare it to originators with no entry who also experience the end of exclusivity period for their drugs. The effect is larger in medium size markets. We conclude from this that entry deterrence is a strong motive for launching product line extensions in the pharmaceuticals. We also find that product line extension is a successful strategy to deter entry in medium sized markets if the originators can spread their patient base over the old and newer formulations. Since such a move requires expensive physician detailing, it probably makes it credible that the originator will not necessarily withdraw after an entry takes place. This does not appear to act as a deterrent in large or small markets. An alternative strategy, called 'product hopping' is to shift almost all the patients to the newer formulation prior to any generic entry. However the evidence on its success is not very robust across different specifications but appears to deter entry in large markets.

APPENDIX A. LEGAL PROTECTION IN THE EU AND UK

Market authorizations and patents provide legal protection for the originator to exempt it from generic competition for a period of time. Since 1965, all pharmaceutical products need market authorization (MA) prior to launch, to ensure safety and effectiveness based on the Council Directive 65/65/EEC (and Medicines Act 1968 in the UK). In order to get MA, all applicants (originators) normally have to provide information from pre-clinical test and human clinical trials. However, given the understanding that replication of such data can be expensive, generic entrants are exempt from such requirement and can refer to the originators' data when applying for market authorization of their generic versions of the same molecule - as long as they can provide that their generic version is bio-equivalent to the originator.

Furthermore, the intellectual property right, based on Article 39.3 of the TRIPS Agreement, protects the data supplied by the originators against 'unfair commercial use'. It implies that in some countries such data should not to be used to authorize generic versions. Test and clinical trial data were protected as trade secret until 1987 in the European community, when the 87/21/EEC Directive (and the 65/65/EEC Directive amendment) was introduced. This amendment protects the originator's data for a pre-determined period, during which generic entrants cannot refer to such data to get market authorization. This data exclusivity period varies from 6 or 10 years across European countries. In the UK, data exclusivity consists of 10 years, referring to the official report of the Parliament in 30th June 1987 (Cook et al., 1991). The period of data exclusivity starts from the date of first market authorisation registered anywhere in the European community. Although this data exclusivity runs in parallel and irrespective of patent production, it often extends the monopoly position of the originator beyond the patent expiration, as ten or more years can elapse between the filling of primary patent and the launch date (Cook et al., 1991, Kyle, 2016). Moreover, data exclusivity only protects novel substance (molecules), while subsequent improvements to a drug, such as new therapeutic indications, dosage strength, or formulations, are not granted for an additional period of protection.[1]

Pharmaceutical companies can get licence either from national authorization in each member states of EU or the centralized agency, European Medicines Agency (EMA), since 1995 when it was created. The difference between the centralized and decentralized licensing regime is that drugs can be sold in all member states if they are licensed from EMA, while they can only be sold in a specific country if they get licence from the local agency. In addition, under the mutual recognition process, preceding countries that received MA applications do not have to start their own review but can refer to the decision by the first agency that approves the drug (Kyle, 2016). In the UK, Medicines and Healthcare products Regulatory Agency (MHRA) is currently the agency that is responsible for medicine market authorization. Moreover, National Institute for Health and Care Excellence (NICE) also assesses drug's cost effectiveness and issues recommendations for the National Health Service (NHS) in England.

One notable change in the EU market authorization system is the harmonization of the '8+2+1' formula introduced in 2001/83/EC Directive and amended by the follow-on Directive 2004/27/EC and Regulation 726/2004/EC. Market authorization applications made from November 2005 and onwards will follow this new rule. Under this new system, all member states of EU will have harmonised 8 years of data exclusivity from the first authorisation date in the EU, followed by 2 years of 'market exclusivity'. This 10-year protection can be extended by one additional year if

[1] The Queen v The Licensing Authority established by the Medicines Act 1968 (acting by The Medicines Control Agency), ex parte Generics (UK) Ltd, The Wellcome Foundation Ltd and Glaxo Operations UK Ltd and Others. Case C-368/96. European Court Reports 1998 I-07967.

a 'significant new indication' or 'significant clinical benefit over existing therapies' is granted for this relevant medical product. Although generic entrants cannot market their versions during data exclusivity and market exclusivity period (and possibly the additional year), they can make use of originator's pre-clinical and human clinical trial data after the first 8 years of data exclusivity. Comparing the old and new systems in the UK, the overall protection period for the originator remains 10 years. However, generics may apply for MA two years in advance under the new system. Although MA cannot be issued before the expiration of market exclusivity, the new system may reduce the gap between the expiration of market exclusivity and the launch of generic products, as they can start preparations for launch two years earlier (Kyle, 2016). Moreover, as the old system, the new system does not consider additional strengths, formulations, administration routes, presentations, and variations and extensions as new sources for another market authorization other than the initial one.

Running in parallel with the market authorization system is patent protection. In the EU, patent life lasts normally for 20 years since filing during which the originator has an exclusive right to prevent generics from marketing their products. However, the effective patent protection period for drugs marketed after MA is generally short, as it may take a long time for firms to get enough data for MA. In order to compensate for the loss of patent protection and to protect innovation in the pharmaceutical market, Supplementary Protection Certificate (SPC) was introduced in 1992 in the EU.[2] SPC offers same protection as the basic patent (*sui generis*) and it extends patent life of medicines up to 5 years since patent expiration or 15 years since market authorization, whichever is less. Moreover, as noted in Kyle (2016), the EU regulators tend to prevent the linkage between patent and exclusivity. It means that regulators may review generics even if the originator may still have some valid patents. Since investing around a secondary patent is easier than a primary product patent, generics may enter earlier.

One side effect of this de-linkage is that patent information is difficult to link to drugs in the UK/EU other than in the US. Although both regulatory data protection and patent aim at protecting the innovation of the originator, the interaction between MA and patent (and SPC) is complex, as distinct laws govern them. One medical product can have several patents, while only one MA will be granted. Therefore, how to implement patent production to the entire product depends on specific conditions, which vary across different cases. Since we do not obtain patent information for our products, we rely on MA information and firms' launch date as recorded in IMS to determine when a molecule (or market) is open for generics to entry.

APPENDIX B. DATA CONSTRUCTION

As mentioned in the main text, our source is sales data from the British Pharmaceutical Index (BPI) series by Intercontinental Marketing Services (IMS) for the period 1996:Q3-2016:Q3. This appendix describes various data cleaning steps.

B.1. **Zero sales and counts of drugs.** For each item, IMS only reports values of positive sales (quantity and value) at monthly interval and are based on shipments from wholesalers to retailers. If a particular item was not shipped within a given month, it would not appear as a line item in the data. Since we count how many products an originator has in each period based on it being present in the data, zero sales within a given month can lead to erroneously under-counting of products

[2]Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products entered into force in 1993. It has been replaced by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

lines. On the other hand, products may be formally or effectively withdrawn by setting sales to zero. To resolve this problem, we (1) aggregate the data to quarters and (2) check if an individual item ever has a positive sale in any of the future periods. If there is a positive sale in the future, the item is not considered withdrawn from the market. Instead we set its sales value equal to zero for all intermediate periods until it makes a positive sale, and the originators product count is not decreased. If however there are no future sales, then the product is considered withdrawn from the market and the count of originators product lines are adjusted accordingly from that point onwards.

B.2. **Mergers and acquisitions.** Merger and acquisition activities during the period are handled by IMS by retroactively reassigning the sales and associated products to the end-of-period corporation that owns them as if they owned it for the entire period. Thus, if two firms merged during the observed period they appear to be a single firm from the start. Generally, a similar rule applies to product line acquisitions, however here we found some inconsistencies in the data. Further, the full 1996-2016 data series was obtained from IMS in three parts, and so the above rule was applied to each data cut separately which lead to further inaccuracies about ownership. We corrected for these by tracking the name of a manufacturer listed against a propriety name for each branded drug that we used in our sample (described below). If the name of the manufacturer changed, we assigned it for the entire period to the last owner in the series. In some cases IMS makes this task easier by appending an abbreviation of manufacturer's name to a proprietary product name when the ownership changes. Clearly the method does not apply to generics, as they are listed only by non-proprietary names and the name of a generic manufacturer is typically not listed in the data. However this should not matter since the analysis is centered around originators and whether they experience any generic entry or not (identity of the generic firm is not important in our analysis).

B.3. **Formulations.** We used the three digit New Form Code (NFC3) system introduced by EphMRA (version 2016) to distinguish between formulations and to construct our measure $D1_j$, i.e., count of drugs by the originator that differ by the value of this code. It takes upto 78 different values in our sample. We also constructed simplified version from these codes (based on first or second and given in Table B-1) to include in our analysis and follow aggregation similar to that used in the literature (see Scott Morton, 1999).

TABLE B-1. Formulations

Formulation	Description	NFC Code combinations
Solid	Oral solid (ordinary or long acting) as tablet, coated tablet, or a capsule	NFC1 $\in \{A, B\}$ and NFC2 $\in \{A, B, C\}$
Liquid	Liquid & ressured aerosols	NFC2 $\in \{G, H\}$
Injection	Ampoules, pre-filled syringe, vials, infusions and cartridges/pens	NFC2 $\in \{M, N, P, Q, R\}$
Ointment	Ointments, creams and gels and sols	NFC2 $\in \{S, T, V\}$
Other	All others (i.e., powers /granules, suppositories, medicated dressings and other special forms) or if the originator had multiple original formulations	NFC2 $\in \{E, L, W, Y\}$

Notes. Other NFC codes do not appear in the final version of the data sets we used so are not listed here.

B.4. **Data Samples.** Several drugs were eliminated from the analysis. These included multi-molecule drugs like vitamins and vaccines (J07), as well as those with single 1-digit ATC categories of hospital solutions (K), diagnostic agents (T) and various (V). For such drugs it is not clear

what constitutes as a market, i.e., if the competitors are other drugs with exact same molecule combinations or any drugs with individual molecules. Additionally, we only focus on Prescription only Medicines (PoM), which count for about 75% of single molecule medicines. Over-the-Counter (OTC) drugs are excluded as they could also be sold in supermarkets, whose sales information is not included in IMS data. From this set, we restricted the analysis to only those originator (branded) drugs that lost exclusivity between 1996 and 2016 (measured as the tenth year from the UK launch date noted in the IMS data). This criteria initially identified 508 originators. However in some of these cases, a generic version of the drug was pre-dating entry into UK by the originator in the same ATC4-molecule class. This may be due a merger or product acquisition, re-registration with MHRA in the UK, or other errors in the date and we eliminated these cases. This lead to 450 originators. Of these, an additional 11 originators were eliminated because competitors entered before our data series begins in 1996 and two more were discarded because they show zero sales until a competitor enters giving us a sample size of 437 originators. Finally seven more were eliminated as they had less than five total observations in the 20 year data span. This gave us our final full sample of 430 originators of which 137 experienced entry. This data is described in the main text (descriptive statistics are given in Table 2) and used in hazard analysis. A smaller sub-sample was constructed for studying originators product launches before and after the end of exclusivity, where the period for the end of exclusivity was restricted to be between 2001-2011. This gave 263 originators of whom 92 experienced by the end of our series. The descriptive statistics are given below in Table B-2 and the mean values of these variables by entry status are given in Table B-3.

TABLE B-2. Originator's Characteristics: Sub sample (263 Originators)

Variable	Description	Mean	Std. Dev.			Min	Max
			overall	between	within		
$D1$	Count based on formulations	1.34	0.67	0.59	0.31	1	5
$D2$	Count based on pack variations	3.21	3.56	3.31	1.38	1	37
$S1$	1/HHI from shares of D1	1.12	0.28	0.23	0.15	1	3.61
$S2$	Share of D1 launched after 5 years	0.03	0.15	0.12	0.10	0	1
Sales (log)	Sales by originator	10.69	4.46	4.16	2.20	0	18.27
†Monopoly	Originator monopolist in other classes	0.91	0.28	0.27	0.14	0	1
†Nearby	Other monopolists in ATC3 class	0.80	0.40	0.36	0.18	0	1
†Chronic	Chronic disease drug	0.71	0.45			0	1
†SPC	Originator enters after 1993	0.87	0.34			0	1
†1Form	Single original formulation	0.93	0.25			0	1
†Solid	Tablets, capsules, extend release, etc.	0.45	0.50			0	1
†Liquid	Liquids & aerosols	0.09	0.29			0	1
†Injection	Ampules, vials, pre-filled syringes, etc.	0.26	0.44			0	1
†Ointment	Ointments, creams, gels & sols	0.08	0.27			0	1
†Other	All others & multiple formulations	0.13	0.33			0	1

Notes. Summary stats from unbalanced panel of 263 originators over 40 quarters with 13,559 observations. For time invariant variables, there is no *within* standard deviation and overall standard deviation is the same as *between*.
†1/0 Dummy variable, 1 if true.

TABLE B-3. Summary statistics by Entry Status

		Entry		No entry		Diff in	P-value
		Mean	sd	Mean	sd	Mean	(2sided)
$D1$	Count based on formulations	1.44	0.79	1.30	0.61	0.13	0.00
$D2$	Count based on pack variations	4.77	4.27	2.57	3.00	2.19	0.00
$S1$	1/HHI from shares of D1	1.13	0.29	1.12	0.28	0.01	0.23
$S2$	Share of D1 launched after 5 years	0.03	0.16	0.03	0.15	0.00	0.39
Sales (log)	Sales by originator	13.68	3.16	9.48	4.33	4.21	0.00
†Monopoly	Originator monopolist in other classes	0.93	0.25	0.91	0.29	0.03	0.00
†Nearby	Other monopolists in ATC3 class	0.88	0.32	0.77	0.42	0.11	0.00
†Chronic	Chronic disease drug	0.84	0.37	0.66	0.48	0.18	0.00
†SPC	Originator enters after 1993	0.86	0.35	0.87	0.33	-0.01	0.06
†1Form	Single original formulation	0.94	0.24	0.93	0.26	0.01	0.01
†Solid	Tablets, capsules, extend release, etc.	0.68	0.47	0.35	0.48	0.33	0.00
†Liquid	Liquids & aerosols	0.04	0.21	0.11	0.31	-0.06	0.00
†Injection	Ampules, vials, pre-filled syringes, etc.	0.15	0.36	0.30	0.46	-0.15	0.00
†Ointment	Ointments, creams, gels & sols	0.01	0.11	0.11	0.31	-0.09	0.00
†Other	All others & multiple formulations	0.11	0.31	0.13	0.34	-0.03	0.00
Originators		92		171			
Observations		3,919		9,640			

Notes. Summary stats from unbalanced panel of 263 originators over 40 quarters with 13,559 observations.
†1/0 Dummy variable, 1 if true.

APPENDIX C. ADDITIONAL REGRESSION COEFFICIENTS

TABLE C-4. Product launch rate of the originators (full version)

	Event: EoE		Event: EoE		Event: EoE		Event: Entry	
	(1 - D1)	(2 - D2)	(3 - D1)	(4 - D2)	(5 - D1)	(6 - D2)	(7 - D1)	(8 - D2)
T	0.003	0.004	0.003	0.004	0.004	-0.005	0.003	0.004
	(0.001)^a	(0.003)	(0.001)^a	(0.003)	(0.001)^b	(0.009)	(0.001)^a	(0.004)
	[0.001]^b	[0.006]	[0.001]^b	[0.007]	[0.002]^b	[0.007]	[0.001]^b	[0.007]
E	0.245	2.764	0.233	2.665	0.188	2.442	0.231	2.187
	(0.041)^a	(0.213)^a	(0.041)^a	(0.213)^a	(0.049)^a	(0.248)^a	(0.030)^a	(0.165)^a
	[0.128]^c	[0.736]^a	[0.131]^c	[0.744]^a	[0.123]	[0.685]^a	[0.104]^b	[0.634]^a
E×T	-0.009	-0.067	-0.009	-0.060	-0.003	-0.039	-0.005	-0.041
	(0.002)^a	(0.012)^a	(0.003)^a	(0.013)^a	(0.004)	(0.022)^c	(0.001)^a	(0.007)^a
	[0.005]^b	[0.025]^a	[0.005]^c	[0.026]^b	[0.006]	[0.031]	[0.003]	[0.016]^b
B	-0.008	0.159	0.001	0.177	-0.023	-0.085	-0.011	0.161
	(0.017)	(0.106)	(0.018)	(0.107)^c	(0.024)	(0.148)	(0.019)	(0.112)
	[0.025]	[0.115]	[0.024]	[0.111]	[0.018]	[0.088]	[0.026]	[0.120]
B×T	0.000	0.013	0.000	0.014	-0.003	0.003	0.001	0.014
	(0.001)	(0.004)^a	(0.001)	(0.005)^a	(0.002)	(0.012)	(0.001)	(0.005)^a
	[0.002]	[0.011]	[0.002]	[0.012]	[0.003]	[0.012]	[0.002]	[0.012]
E×B	-0.081	-0.765	-0.035	-0.728	0.018	-0.295	-0.100	-0.371
	(0.050)	(0.257)^a	(0.053)	(0.267)^a	(0.066)	(0.329)	(0.040)^b	(0.223)^c
	[0.066]	[0.364]^b	[0.066]	[0.340]^b	[0.044]	[0.226]	[0.063]	[0.317]
E×B×T	0.016	0.135	0.017	0.126	0.011	0.133	0.006	0.076
	(0.003)^a	(0.013)^a	(0.003)^a	(0.014)^a	(0.006)^c	(0.028)^a	(0.002)^a	(0.009)^a
	[0.006]^b	[0.035]^a	[0.007]^b	[0.037]^a	[0.008]	[0.039]^a	[0.004]	[0.027]^a
Sales (log)	0.054	0.282	0.055	0.290	0.056	0.307	0.061	0.332
	(0.001)^a	(0.009)^a	(0.001)^a	(0.009)^a	(0.002)^a	(0.012)^a	(0.001)^a	(0.009)^a
	[0.007]^a	[0.057]^a	[0.008]^a	[0.059]^a	[0.009]^a	[0.065]^a	[0.008]^a	[0.057]^a
†Solid	-0.218	-1.354	-0.253	-1.575	-0.235	-1.718	-0.041	-0.532
	(0.032)^a	(0.256)^a	(0.035)^a	(0.284)^a	(0.047)^a	(0.394)^a	(0.032)	(0.227)^b
	[0.229]	[1.908]	[0.254]	[2.131]	[0.283]	[2.448]	[0.230]	[1.692]
Observations	13,559	13,559	12,560	12,560	8,052	8,052	15,209	15,209
R-squared	0.414	0.408	0.425	0.418	0.429	0.445	0.408	0.444
‡Cases	92	92	66	66	66	66	92	92
‡Controls	171	171	146	146	146	146	171	171

Notes. This table is an extended version of regression coefficients shown in Table 3 in the main text. Robust errors are in first parentheses, and cluster adjusted standard errors in second square parentheses, with clustering at the originator level. Superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All regressions include ATC 2-digit dummies. †1/0 Dummy variable, 1 if true. ‡Cases and Controls refers to originators that experienced eventual entry or not not respectively.

TABLE C-4. Product launch rate of the originators (full version)

	Event: EoE		Event: EoE		Event: EoE		Event: Entry	
	(1 - D1)	(2 - D2)	(3 - D1)	(4 - D2)	(5 - D1)	(6 - D2)	(7 - D1)	(8 - D2)
†Liquid	0.022	-2.176	0.002	-2.450	-0.080	-3.266	0.113	-1.739
	(0.045)	(0.324)^a	(0.049)	(0.367)^a	(0.065)	(0.527)^a	(0.044)^a	(0.299)^a
	[0.305]	[2.382]	[0.344]	[2.709]	[0.383]	[3.229]	[0.306]	[2.199]
†Injection	0.245	-0.253	0.223	-0.381	0.210	-0.631	0.374	0.440
	(0.031)^a	(0.229)	(0.034)^a	(0.255)	(0.045)^a	(0.355)^c	(0.031)^a	(0.210)^b
	[0.210]	[1.690]	[0.232]	[1.889]	[0.260]	[2.178]	[0.220]^c	[1.551]
†Ointment	0.105	-0.340	0.132	-0.225	0.133	-0.270	0.286	0.719
	(0.035)^a	(0.247)	(0.043)^a	(0.318)	(0.057)^b	(0.447)	(0.039)^a	(0.259)^a
	[0.229]	[1.771]	[0.287]	[2.292]	[0.322]	[2.688]	[0.251]	[1.817]
†1Form	-0.484	-0.833	-0.473	-0.727	-0.469	-0.971	-0.726	-2.512
	(0.039)^a	(0.275)^a	(0.042)^a	(0.306)^b	(0.056)^a	(0.423)^b	(0.039)^a	(0.266)^a
	[0.253]^c	[1.946]	[0.279]^c	[2.191]	[0.312]	[2.546]	[0.263]^a	[1.908]
†Chronic	0.231	-0.115	0.243	0.016	0.262	0.024	0.179	-0.376
	(0.016)^a	(0.074)	(0.017)^a	(0.079)	(0.023)^a	(0.107)	(0.017)^a	(0.074)^a
	[0.098]^b	[0.505]	[0.105]^b	[0.547]	[0.126]^b	[0.638]	[0.119]	[0.537]
†SPC	-0.204	-0.870	-0.221	-1.059	-0.281	-1.319	-0.291	-1.393
	(0.020)^a	(0.108)^a	(0.021)^a	(0.113)^a	(0.025)^a	(0.139)^a	(0.019)^a	(0.100)^a
	[0.121]^c	[0.662]	[0.128]^c	[0.692]	[0.142]^b	[0.780]^c	[0.144]^b	[0.748]^c
†Monopoly	-0.105	-0.257	-0.107	-0.344	-0.115	0.284	-0.202	-0.562
	(0.013)^a	(0.077)^a	(0.015)^a	(0.093)^a	(0.018)^a	(0.130)^b	(0.015)^a	(0.077)^a
	[0.053]^c	[0.400]	[0.064]^c	[0.503]	[0.081]	[0.727]	[0.059]^a	[0.372]
†Nearby	0.076	0.383	0.083	0.404	0.062	0.346	0.103	0.410
	(0.017)^a	(0.100)^a	(0.019)^a	(0.110)^a	(0.027)^b	(0.160)^b	(0.016)^a	(0.087)^a
	[0.087]	[0.440]	[0.095]	[0.481]	[0.135]	[0.675]	[0.092]	[0.437]
Constant	1.299	2.953	1.288	2.524	1.398	2.829	1.589	4.718
	(0.048)^a	(0.242)^a	(0.055)^a	(0.280)^a	(0.069)^a	(0.375)^a	(0.052)^a	(0.273)^a
	[0.262]^a	[1.272]^b	[0.275]^a	[1.410]^c	[0.354]^a	[1.952]	[0.321]^a	[1.609]^a
Observations	13,559	13,559	12,560	12,560	8,052	8,052	15,209	15,209
R-squared	0.414	0.408	0.425	0.418	0.429	0.445	0.408	0.444
‡Cases	92	92	66	66	66	66	92	92
‡Controls	171	171	146	146	146	146	171	171

Notes. This table is an extended version of regression coefficients shown in Table 3 in the main text. Robust errors are in first parentheses, and cluster adjusted standard errors in second square parentheses, with clustering at the originator level. Superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All regressions include ATC 2-digit dummies. †1/0 Dummy variable, 1 if true. ‡Cases and Controls refers to originators that experienced eventual entry or not not respectively.

TABLE C-5. Product launch rate of the originators by size

	Event: EoE (Small)		Event: EoE (Medium)		Event: EoE (Large)	
	(1 - D1)	(2 - D2)	(3 - D1)	(4 - D2)	(5 - D1)	(6 - D2)
T	-0.000	-0.009	0.006	0.007	0.002	-0.051
	(0.001)	(0.004)^a	(0.002)^a	(0.006)	(0.003)	(0.022)^b
	[0.002]	[0.005]^c	[0.003]^b	[0.007]	[0.006]	[0.029]^c
E	-0.024	0.778	-0.102	0.425	-0.143	-1.115
	(0.029)	(0.130)^a	(0.059)^c	(0.215)^b	(0.059)^b	(0.487)^b
	[0.062]	[0.328]^b	[0.148]	[0.614]	[0.166]	[2.051]
E×T	0.005	0.004	-0.007	-0.023	0.002	0.053
	(0.003)^c	(0.011)	(0.005)	(0.016)	(0.005)	(0.032)^c
	[0.005]	[0.015]	[0.007]	[0.026]	[0.008]	[0.043]
B	-0.021	-0.033	-0.034	-0.093	-0.063	-0.762
	(0.020)	(0.056)	(0.028)	(0.106)	(0.045)	(0.324)^b
	[0.024]	[0.062]	[0.026]	[0.092]	[0.052]	[0.504]
B×T	-0.002	-0.002	-0.008	-0.029	0.008	0.108
	(0.002)	(0.005)	(0.002)^a	(0.010)^a	(0.004)^c	(0.026)^a
	[0.003]	[0.009]	[0.004]^c	[0.015]^c	[0.011]	[0.047]^b
E×B	0.081	-0.093	0.178	0.325	0.020	0.314
	(0.051)	(0.187)	(0.083)^b	(0.290)	(0.075)	(0.449)
	[0.058]	[0.234]	[0.062]^a	[0.174]^c	[0.073]	[0.568]
E×B×T	-0.005	0.022	0.021	0.075	-0.002	0.008
	(0.004)	(0.015)	(0.007)^a	(0.024)^a	(0.007)	(0.039)
	[0.005]	[0.026]	[0.016]	[0.041]^c	[0.013]	[0.059]
Sales (log)	0.022	0.062	0.035	0.120	0.068	0.345
	(0.002)^a	(0.007)^a	(0.003)^a	(0.010)^a	(0.006)^a	(0.028)^a
	[0.008]^a	[0.021]^a	[0.013]^a	[0.046]^b	[0.023]^a	[0.118]^a
†Solid	0.112	1.468	0.138	0.716	-0.518	-6.274
	(0.028)^a	(0.083)^a	(0.032)^a	(0.155)^a	(0.053)^a	(0.631)^a
	[0.088]	[0.384]^a	[0.167]	[0.732]	[0.249]^b	[3.719]^c
†Liquid	-0.317	0.199	1.006	1.879	-0.711	-5.321
Observations	2,431	2,431	3,013	3,013	2,608	2,608
R-squared	0.491	0.619	0.608	0.724	0.734	0.733
‡Cases	5	5	15	15	46	46
‡Controls	60	60	61	61	25	25

Notes. This table provides estimates by 'Small', 'Medium' and 'Large' for the sample used in Columns (5) and (6) in Table 3 in the main text. Robust errors are in first parentheses, and cluster adjusted standard errors in second square parentheses, with clustering at the originator level. Superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All regressions include ATC 2-digit dummies. †1/0 Dummy variable, 1 if true. ‡Cases and Controls refers to originators that experienced eventual entry or not not respectively.

TABLE C-5. Product launch rate of the originators by size

	Event: EoE (Small)		Event: EoE (Medium)		Event: EoE (Large)	
	(1 - D1)	(2 - D2)	(3 - D1)	(4 - D2)	(5 - D1)	(6 - D2)
	(0.057)^a	(0.136)	(0.063)^a	(0.240)^a	(0.144)^a	(0.748)^a
	[0.276]	[0.500]	[0.340]^a	[1.226]	[0.790]	[4.139]
†Injection	0.203	1.184	0.395	1.810	-0.333	-6.015
	(0.031)^a	(0.075)^a	(0.054)^a	(0.216)^a	(0.082)^a	(0.690)^a
	[0.096]^b	[0.312]^a	[0.256]	[1.024]^c	[0.367]	[3.951]
†Ointment	0.095	-0.037	0.666	1.245	-0.654	-19.975
	(0.049)^c	(0.139)	(0.060)^a	(0.206)^a	(0.137)^a	(1.098)^a
	[0.155]	[0.557]	[0.231]^a	[0.906]	[0.577]	[6.031]^a
†1Form	-0.523	-0.837	-0.939	-0.539	-0.086	-1.786
	(0.054)^a	(0.134)^a	(0.049)^a	(0.183)^a	(0.139)	(0.762)^b
	[0.210]^b	[0.696]	[0.246]^a	[0.862]	[0.722]	[4.020]
†Chronic	0.110	1.073	0.412	-0.175	1.762	1.309
	(0.027)^a	(0.087)^a	(0.030)^a	(0.087)^b	(0.044)^a	(0.318)^a
	[0.095]	[0.427]^b	[0.160]^b	[0.509]	[0.156]^a	[1.726]
†SPC	-0.640	-0.756	-0.018	0.238	-0.234	-3.840
	(0.031)^a	(0.060)^a	(0.027)	(0.102)^b	(0.028)^a	(0.319)^a
	[0.195]^a	[0.212]^a	[0.151]	[0.564]	[0.107]^b	[1.538]^b
†Monopoly	0.043	0.107	-0.154	0.079	-0.274	-0.448
	(0.013)^a	(0.047)^b	(0.030)^a	(0.129)	(0.060)^a	(0.176)^b
	[0.061]	[0.178]	[0.123]	[0.574]	[0.112]^b	[0.645]
†Nearby	0.051	0.271	-0.099	-0.626	-0.327	-3.955
	(0.011)^a	(0.048)^a	(0.023)^a	(0.115)^a	(0.049)^a	(0.384)^a
	[0.036]	[0.151]^c	[0.112]	[0.537]	[0.115]^a	[1.542]^b
Constant	1.857	1.115	3.478	4.133	0.357	19.119
	(0.068)^a	(0.171)^a	(0.079)^a	(0.271)^a	(0.207)^c	(0.993)^a
	[0.314]^a	[0.819]	[0.356]^a	[1.178]^a	[0.971]	[4.676]^a
Observations	2,431	2,431	3,013	3,013	2,608	2,608
R-squared	0.491	0.619	0.608	0.724	0.734	0.733
‡Cases	5	5	15	15	46	46
‡Controls	60	60	61	61	25	25

Notes. This table provides estimates by 'Small', 'Medium' and 'Large' for the sample used in Columns (5) and (6) in Table 3 in the main text. Robust errors are in first parentheses, and cluster adjusted standard errors in second square parentheses, with clustering at the originator level. Superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All regressions include ATC 2-digit dummies. †1/0 Dummy variable, 1 if true. ‡Cases and Controls refers to originators that experienced eventual entry or not not respectively.

TABLE C-6. Non-monotonicity tests, full model

	Size (Sub sample)		Size (full sample)		‡Entry risk (full sample)		
	(1 - D1)	(2 - D2)	(3 - D1)	(4 - D2)	(5 - D1)	(6 - D2)	$(P(E)_j = 1)$
$\ln(\text{Sales})_j$	0.102^a	0.700^a	0.092^a	0.652^a			0.09
	(0.013)	(0.075)	(0.011)	(0.056)			(0.428)
$(\ln(\text{Sales})_j - \overline{\ln(\text{Sales})})^2$	0.009^a	0.064^a	0.007^a	0.054^a			
	(0.002)	(0.010)	(0.001)	(0.007)			
$P(E)_j$					1.11^a	5.823^a	
					(0.25)	(1.319)	
$(P(E)_j - \overline{P(E)})^2$					-0.211	3.499	
					(0.595)	(2.999)	
†SPC	-0.246^b	-1.899^a	-0.241^a	-1.221^a	-0.081	-0.214	-0.844^a
	(0.122)	(0.687)	(0.072)	(0.370)	(0.1)	(0.572)	(0.272)
†Nearby	0.310^b	1.266	0.222^b	1.005^c	0.215^b	0.882^c	0.236
	(0.137)	(0.771)	(0.103)	(0.532)	(0.1)	(0.498)	(0.506)
†Monopoly	-0.055	0.735	-0.071	0.706	-0.072	0.634	-0.167
	(0.184)	(1.037)	(0.136)	(0.699)	(0.109)	(0.518)	(1.42)
†Chronic	0.240^b	-0.293	0.160^c	-0.285	0.113	-0.395	0.401
	(0.122)	(0.684)	(0.087)	(0.451)	(0.111)	(0.473)	(0.379)
†Solid	-0.008	0.082	0.129	0.581	0.076	0.34	0.327
	(0.175)	(0.986)	(0.121)	(0.625)	(0.16)	(0.958)	(0.579)
†Liquid	0.058	-1.402	0.439^b	0.327	0.451^b	0.254	-0.468
	(0.290)	(1.634)	(0.201)	(1.036)	(0.226)	(1.349)	(2.11)
†Injection	0.432^b	1.059	0.381^a	1.093	0.345^b	0.844	0.001
	(0.193)	(1.083)	(0.132)	(0.681)	(0.164)	(0.927)	(0.648)
†Ointment	0.300	1.522	0.357	0.847	0.547^b	1.933	-7.139
	(0.355)	(1.996)	(0.242)	(1.245)	(0.254)	(1.433)	(6.192)
†1Form	-0.583^b	-2.883^b	-0.838^a	-2.823^a	-0.869^a	-3.089^c	-0.103
	(0.232)	(1.302)	(0.176)	(0.909)	(0.249)	(1.441)	(0.886)
Constant	0.267	-2.436	0.581	-3.013	1.405^a	2.983	-3.239
	(0.600)	(3.377)	(0.506)	(2.607)	(0.367)	(2.102)	(4.186)
$(\ln(\text{Sales})_j)^2$							0.011
							(0.015)
Observations	263	263	430	430	430	430	430

All regressions include dummies for ATC2 class. Superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. †1/0 Dummy variable, 1 if true. ‡ This is a two-step model where in step 1, probability of entry for the j-th originator is computed via a probit (results shown in the last column), and in step 2, size of the market is replaced with the probability. Standard errors for the two-step model are computed using bootstraps with 500 replications.

TABLE C-7. Discrete time hazard models for S1 and S2 (Controlling for D2)

	S=S1				S=S2			
	(1-A)	(2-B)	(3-C)	(4-D)	(5-A)	(6-B)	(7-C)	(8-D)
S	1.337^{b}	1.038	1.628	2.587	2.379^{a}	2.593^{a}	2.719^{a}	3.182^{a}
	(0.671)	(0.829)	(1.034)	(1.724)	(0.826)	(0.832)	(1.049)	(1.057)
Medium	3.253^{a}	4.320^{a}	5.036^{a}	6.471^{a}	-0.060	0.563	0.378	0.407
	(1.156)	(1.379)	(1.710)	(2.418)	(0.361)	(0.543)	(0.669)	(0.774)
Large	2.168^{b}	2.149^{c}	2.357	3.599	0.488	1.607^{b}	1.095	1.043
	(0.944)	(1.219)	(1.555)	(2.277)	(0.532)	(0.769)	(1.008)	(1.146)
Medium×S	-3.159^{a}	-3.741^{a}	-4.620^{a}	-6.001^{a}	-3.187^{b}	-3.396^{a}	-3.576^{b}	-3.888^{b}
	(0.990)	(1.179)	(1.435)	(2.017)	(1.277)	(1.244)	(1.440)	(1.698)
Large×S	-1.816^{b}	-1.243	-1.772	-3.182^{c}	-3.457^{a}	-3.511^{a}	-3.890^{a}	-5.943^{a}
	(0.749)	(0.949)	(1.140)	(1.755)	(1.069)	(1.316)	(1.483)	(1.472)
Sales (log)	0.274^{a}	0.234^{b}	0.351^{b}	0.465^{a}	0.261^{a}	0.172^{c}	0.309^{b}	0.414^{a}
	(0.077)	(0.104)	(0.146)	(0.142)	(0.081)	(0.093)	(0.141)	(0.140)
D2		0.049^{c}	0.044	0.029		0.045^{c}	0.043	0.023
		(0.026)	(0.031)	(0.032)		(0.025)	(0.029)	(0.029)
			Marginal effects: $\partial\lambda/\partial S$ (×100)					
Small	0.402^{b}	0.345	0.807	1.282	0.807^{b}	0.979^{b}	1.342^{c}	1.566^{b}
	(0.203)	(0.275)	(0.523)	(0.807)	(0.407)	(0.397)	(0.702)	(0.733)
Medium	-1.281^{b}	-2.077^{a}	-3.026^{a}	-3.451^{a}	-0.563	-0.621	-0.868	-0.714
	(0.545)	(0.693)	(1.118)	(1.211)	(0.676)	(0.792)	(1.200)	(1.532)
Large	-0.967	-0.465	-0.597	-2.464	-2.484	-2.440	-4.860	-11.427^{b}
	(0.600)	(1.167)	(2.245)	(2.278)	(1.557)	(2.902)	(4.715)	(4.53)
Includes X_j?	No	Yes	Yes	Yes	No	Yes	Yes	Yes
Originators	430	386	312	312	410	364	312	312
Entry events	137	137	104	104	131	131	104	104
Observations	13,456	12,063	5,961	5,961	11,848	10,444	5,961	5,961
Log likelihood	-664	-607	-412	-414	-623	-562	-414	-414

Notes. Clustered standard errors are in parenthesis and superscripts a, b, c indicate significance at 1%, 5% and 10%, respectively. All models include duration dummies and ATC2 dummies included in all but columns (1) and (5). Table 4 in the main text gives coefficients when controlling for $D1$.

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