Competitive entry in the market for branded generic drugs*

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Abstract

In the first part of this paper, I examine the factors driving competitive entry decisions in the Indian generic pharmaceutical industry, where there exist no apparent barriers to entry. Here I find that while larger markets are more likely to see entry, more product varieties launched by the originator might also be able to restrict or defer entry. In the next part, within a subset of markets where there is entry, I examine whether the lead time to competitor's entry confers some advantage upon the originator. When potential endogeneity of lead time is addressed using an instrumental variable approach, I find no evidence of it's link with originator's market share/price. This indicates the possibility for factors other than lead time which explain the competition dynamics, those that might hinge upon marketing strategies of firms.

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1 Introduction

Indian pharmaceutical firms have for long held their position as exporters of low cost generics and within the domestic market as well, generics dominate the sales.[1] Given that there are no regulatory barriers to entry into the domestic generics market, one would expect that within each molecule market there is rapid entry and substantial competition that enable keeping prices low. However, data appears to reveal a different story - of 466 new drug launches in the Indian market between 2007-16, I find that entry of atleast one competitor was noted only in 189 cases.[2] The gap is enormous and leads to question the factors that drive entry and competition within the pharmaceutical market.

In this paper, I first carry out a hazard analysis in monopoly markets that are at risk of competitive entry. While on the one hand I find that market size has a significant effect upon the risk of entry, I also find that as the originator launches more strength and/or pack varieties of the same molecule, they are in some way able to restrict or delay competitive entry. Next, I observe only those markets where there is competitive entry within the sample and see whether the length of delay in competitive entry confers some sustainable long term advantage to the originator firm.

In markets with patent protection or other regulatory exclusivities, the originator firms have a significant lead time to develop a base of brand loyal consumers and therefore, their market shares may be difficult to erode even following competitive entry (Lieberman and Montgomery (1988), Grabowski and Vernon (1992), Frank and Salkever (1997), Porath (2018)). I examine this in the market for generic drugs in India, where there are no such exclusivities. The overall effect in such a market is not immediately obvious. The absence of exclusivities, on the one hand, would imply shorter lead times. While on the other hand, since brands are attached to non-patented drugs

[1]The Indian pharmaceutical industry is one of the largest suppliers of generic medicines to over 200 countries across the world, and accounts for 20% of the world's generics supplies (WHO, 2015). It is also home to the one of the largest number of US Food and Drug Administration (US FDA) approved manufacturing plants outside of the US (there are 262 as per the (DOP, 2017)).

[2]New drugs here refer to those drugs for which a patent never existed in India.

in India, it may be feasible for originator firms to sustain post-entry market shares. Some initial descriptive statistics indicate the presence of lead time driven first mover advantages, however once I account for potential endogeneity of lead time, I find no evidence of sustained market shares or price advantage for the originator.

For the Indian generics market, it appears the market leadership position of the originators may be explained factors other than lead time. With a wide portfolio of leading brands across therapeutic classes alongside the ability to recruit and retain more sophisticated marketing team, these firms have a greater chance at being successful in introducing new products (Slatter, 1977). Moreover, they would likely launch the molecule in high revenue markets such as those in metros and tier-1 cities, and undertake investment towards disseminating knowledge about the therapeutic merits of the new molecule. The first competitor thus, has the opportunity to free ride upon the success and investments of the originator, while catering to the gaps in supply and driving up access in tier 2-3 towns and beyond.

This paper contributes to the existing literature by firstly, providing evidence based on recent data from a branded generics pharmaceutical market, which provides a unique research opportunity by allowing for much variation in lead time values. In addition, the paper examines drivers of entry decisions as well as originator shares/prices and their pattern linked with lead time, which to the best of my knowledge has not been carried out within this context.

2 A Brief Review of Literature

In a recent study, Chaudhuri (2018) notes that monopoly markets exist not only in case of patented drugs in India, but this trend is evident in not-patented molecule markets as well. While some of these not-patented products were biosimilars which face rather stringent regulatory barriers to entry, monopolisation in the case of other small molecules, he contends, may be on account of poor profit prospects in these markets. Previous empirical literature on entry has pointed out that demand entry thresholds are critical

determinants of equilibrium number of firms in markets, where there is otherwise free entry (Bresnahan and Reiss, 1991). Other relevant factors that guide entry decision include similarity with existing portfolio of products (Scott, 1999). In addition, Kyle (2006) examines geographic diffusion of new drugs and finds that firm characteristics (such as domestic or foreign status of firm) have bearing upon entry decisions. Another strand of literature links entry behaviour to strategic entry deterrence, where originator firms may be able to invest heavily in advertising and thereby generate product loyalty (Ellison and Ellison, 2011), product proliferation and price discrimination. On the other hand, in markets where competitive entry does occur, firm's relative success and profitability can hinge upon it's position in the order of entry. The theory of first mover advantages (FMA) and its empirical validation across various industries has been carried out in several prior studies, both in the fields of economics and marketing (Robinson et al. (1994) do a comprehensive overview of relevant studies). In a given market, first mover firms are often able to earn positive economic profits through creation of some asymmetry that enables such a firm to gain a head start over the other players in the market (Lieberman and Montgomery, 1988). This asymmetry may be generated for several reasons including, technological leadership (say, patents), preemption of assets and buyer switching costs.

The empirical evidence documented has, in some cases supported the existence of these advantages and in others, negated them. In the pharmaceutical industry, however, FMA has remained in existence mostly due to the technological leadership of pioneering firms. Reiffen and Ward (2005) show that in the case of generics too, the first follower firm is likely to be able to recoup application related costs and potentially outsell it's competitors for a longer period of time.

FMA can be a cause of concern if demand for the early entrant's product is price inelastic, which can occur if the brand loyal consumer does not switch to other and/or possibly cheaper options. This has been corroborated for the US market by Frank and Salkever (1997), where they show that originator firms increase the prices of their brand name patented drugs and are able to maintain profitability, even after generic entry, due to demand from the brand

loyal and price inelastic consumer base. The longer the lead time ahead of competitive entry, the stronger will be the effects of brand loyalty. This may be since physicians are more likely to respond favourably to promotion of early entering brands that provide novel treatment options, than those that come in later which may be perceived as copies of the first (Bond and Lean, 1997). Such effects are likely to be stronger for drugs used for chronic illness, which require repeat prescriptions.[3] Finally, there is also the possibility that the greater is product proliferation by the early entrant, the longer competitive entry can be deferred until the competitor can develop it's own specific niche (Sutton, 1991).

In a recent study, Porath (2018) examines order of entry effects for patented drugs across 7 different developed country markets and finds that lead time does matter in building up advantages, these however are competed away in the long run with generic competition. Nevertheless, the dynamics should differ in the Indian case, where proliferation of brands is prevalent even at the level of generics.

Examining the scenario for FMA within the India's large generics market merits attention for atleast three reasons. First, as mentioned before, there is branding of products even where no patents exist and such branding is used to distinguish one firm's product from that of other company's generics. These are called branded generics, off-patent drugs that carry a trademark and are sold at a premium. Since common practice is that prescriptions are generated by brand name, such branding can lead to creation of brand loyalty which the originator firms can use to 'lock in' prescribers. There is some evidence to suggest that this may indeed be the case since the market concentration is high at the molecule level and this may be due to the artificial differentiation created by firms' marketing strategies (Bhattacharjea and Sindhwani, 2014). FMA might also imply that the originator can sustain high market shares alongside higher prices. Given that the marginal costs of producing a specific formulation (with the same active pharmaceutical ingredient), is low and not

[3]Grabowski and Vernon (1992) suggest that pharmacies may also stock the the same product as patients may continue to demand products that have attributes that they are familiar with (such as, recognisable shape, size, colour).

widely different from one firm to the next and so, any price dispersion could be related with a brand premium (Berndt et al. (1995) and Dutta (2006)). Therefore, branding can help sustain FMA in generic drugs.

Second, a large number of drugs launched in India are combination molecules (i.e., consist of two or more active pharmaceutical ingredients in a single dosage form), which as independent markets also show first mover effects. Prior to 2012, close to 40% of all new drug approvals granted by the nodal regulatory agency were for combination drugs, but with greater regulatory stringency around the issue since then, has brought this figure down.[4]

Third, perils of high prices linked with FMA are particularly grave for the Indian population since, close to 80% of the Indian population does not have access to any kind of health expenditure support (NSSO, 2014). This implies that prescription expenses have to be borne by consumers out-of-pocket. Additionally, there are no mandatory generic substitution laws in place at the moment.

While previously Dutta (2006) shows that order of entry effects are prevalent in the pre-TRIPS Indian pharmaceutical sector, but Bhaskarabhatla and Chatterjee (2012) contend that with TRIPS implementation in India this effect seems to have reduced.[5] However, neither documents the nature of the relationship between lead time and the originator's post-entry shares or prices.

This study not only provides evidence from recent data considering generics-only segment of the pharmaceuticals market which has not be dealt with since Dutta (2006) in the pre-TRIPS context, but comments on the sustainability of these advantages as well as, their pattern linked with longer delay. This is methodologically similar to Porath (2018). The present study takes a step forward and explores the nature of the relationship between lead time and market share/price advantage.

The next section provides data and descriptive statistics. In section 4, I present the hazard model of entry, and subsequently examine the case for

[4]See Wattal et al. (2017)

[5]In 1994, India, along with other World Trade Organisation (WTO) member countries, signed the Trade related intellectual Property Rights (TRIPS) agreement and thereby, sought to recognise product patents.

first mover advantages in section 5. In section 6, I briefly discuss the results and present the conclusion in section 7.

3 Data and Descriptive Statistics

The parent dataset is a product-level monthly sales data from April 2007-November 2016. The data is compiled by AIOCD AWACS, a pharmaceutical market research organization which is a joint venture between All Indian Origin Chemists and Distributors (AIOCD), the largest organization of pharmacy retailers in India, and Trikaal Mediinfotech Pvt Ltd. This dataset is disaggregated to the level of individual pack, and provides information on sales value, quantity sold and product level information such as drug type (tablets, capsules, syrups, etc.), strength of dosage, pack size, whether it is for acute or chronic ailments, etc. This represents 85-90% of the total market. Since this data is collected at the level of stockists, some drugs may not feature in the data if they were not in supply or scantily supplied to limited pharmacies.

For the purpose of this study, a subset of this data containing non-patented molecules launched 2007 onwards is used. Towards making the most representative dataset, the following therapy areas are also excluded due to the complexities involved, such as dermatologicals (this therapy area has numerous formulation types - gels, creams, lotions, soaps, etc - which renders price comparisons quite difficult) and vitamins, minerals and other nutrients (these products are combinations of four or more constituent ingredients). Additionally, hospital solutions, injectables and anti-neoplastics (cancer drugs) are excluded because their point of sale, as well as administration are hospitals, and therefore their market entry behaviour would not be comparable with other products that reach the retail market. Finally, vaccines are also excluded because they usually contain biological elements which are unique and often cannot be exactly compared across manufacturers. At this stage the data represents 466 molecules which are sold across 298 companies. However, this panel is unbalanced since products enter at different points of time and may remain in the market for varying durations.

The summary statistics for this data are provided in table 1 below. It can be noted that the average lead time to entry is 5 quarters (see figure 4 for a distribution of lead time values in the sample), and on the average, not only is the first entrant an old player in the pharmaceutical market, but also has significant experience in the relevant therapy class.

The dataset has information at the product level, i.e., a specific brand with dosage strength (100 mg, 150 mg, etc) and specific pack size (10 tablets, 20 capsules, etc). Therefore, if a brand has two different dosages then each will be listed as a separate product. Similarly, if they have identical dosage but different pack sizes, or if they have same brand but different novel drug delivery system (i.e. extended release, sustained release, or immediate release capsules), then also they will be listed as unique products. Each such product is called a stock keeping unit (SKU). For the price and market share graphs explained below, the unit of analysis is at the brand level for each molecule. This implies that the first entrant is the first brand to enter the molecule market and all of the different SKU's that may have been launched by the first brand are considered as the originator. Note that the first entrant is referred to as the originator, even when there may be no patent linked with the product. Accordingly, the second brand to enter the market and all its different SKUs are identified as the first competitor. This terminology is maintained throughout the paper.

As a next step, the possibility of an escalation mechanism is explored briefly. An escalation mechanism refers to an increase in advertising or R& D by the originator firm to gain market share, but the countervailing effect of this is that it increases fixed costs of entry for firms (Matraves, 1999). In the present data, there are 117 molecules where the originator launched a single SKU in the molecule market, 62 molecules where the originator launched two SKUs, 7 molecules with three SKUs, 4 molecules with four SKUs, one molecule with 5 SKUs, and 2 molecules with 6 SKUs. Since most originator firms have single SKUs or at most 2 SKUs, there does not seem to be any supporting evidence of an escalation mechanism.

The portfolio of products isn't very different for faster vs slower entrants. A glance at the average number of molecules launched by a second mover

Table 1: Summary statistics

	Total
Total Market	
Total number of molecules	466
Number of brands	1978
Number of firms	298
Molecules with atleast one competitive entrant	189
Single ingredient	53
Combination	140

	Mean	Standard Deviation	Minimum	Maximum
Cases of competitive entry				
Lead time (in quarters)	5.05	5.08	0	23
Experience of first entrant in therapy area (in quarters)	8.89	11.51	0	114
Age of first entrant (in quarters)	24.44	27.59	0	114

	Firm type	Mean	Standard Deviation	Minimum	Maximum
Pre entry market size	MNC	644.05	1512.99	0.34	6295.48
	Export	341.14	556.08	0	3324.92
	Local	222.46	371.27	0	1496.92

firm in the same time period reveals that late movers have a basket of 12 molecules, while early movers have 13 molecules. Also note, some of the firms may be originators in some molecule markets while they may be competitive entrants in others. But those originator firms that also are second movers in some markets (150 molecule markets), have a wider portfolio of products.

4 Hazard Model of Entry

For entry analysis, I look at the set of molecules that were faced with the risk of competitive entry. I observe entry over intervals, specifically quarters, which could in fact have occurred at any date within the quarter and hence I use a discrete time hazard model. The data is left truncated and right censored. This is because while all molecules under study were launched 2007 onwards, they enter at different points of time hence left truncated, and because in some of these markets entry may have occurred at a later date after my study period ends, hence it is right censored. The approach I use is one to study the probability of competitive entry in a market in the interval t. I carry out a complimentary log-log analysis, which is an alternative to a logit model, but allows for the proportional hazard assumption. Cox's proportional hazard model works on the following framework:

$$S(t_j|\mathbf{x_i}) = S_0(t_j)^{e\{\mathbf{x}b\}}$$

where $S(t_j|\mathbf{x_i})$ is the probability that a given molecule market with covariates $\mathbf{x_i}$ remains as a monopoly upto time t_j and $S_0(t_j)$ is the baseline survival function. This can be expressed in terms of an instantaneous hazard function;

$$[1 - \lambda(t_j|\mathbf{x_i})] = [1 - \lambda_0(t_j)]^{e\{\mathbf{x}b\}}$$

and once transformed, the complimentary log log form looks like the following;

$$log(-log(1 - \lambda(t_j|\mathbf{x_i}))) = \underbrace{log(-log(1 - \lambda_0(t_j)))}_{\alpha_j} + \mathbf{x}b$$

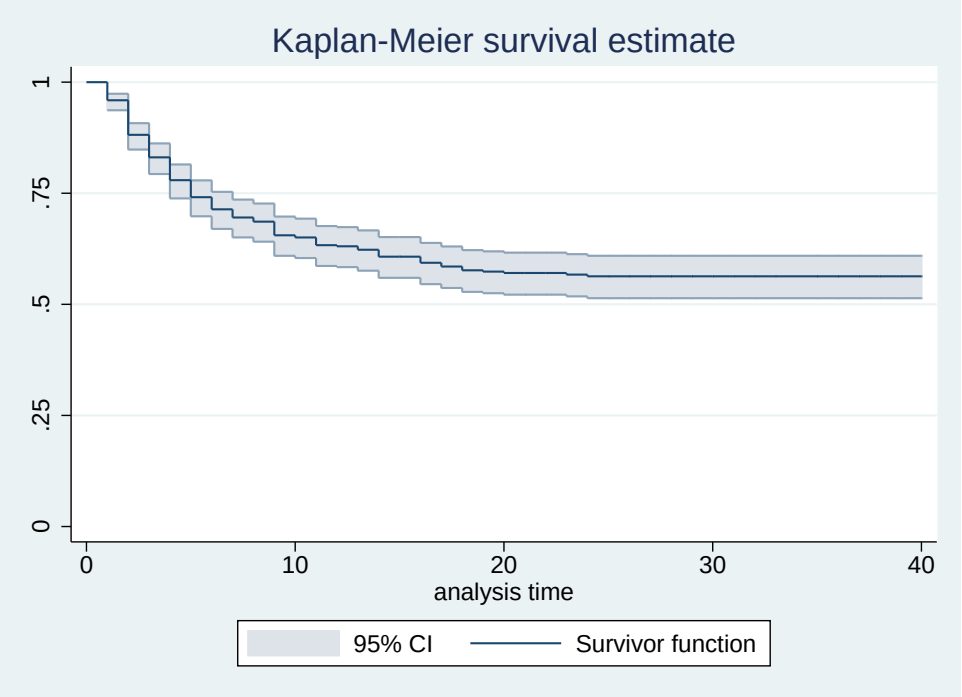

Figure 1: This figure shows the Kaplan-Meier survival estimate for 466 molecule markets at the risk of entry. The analysis time is in quarters since the monopolist's entry. Each step shows markets that have experienced entry at the time and thus dropped from the risk set.

This can be applied to the discrete time case, as is relevant in the present context, since the discrete hazard is the conditional probability that in a given market the originator faces competitive entry in interval j, given that the originator was still a monopolist at the start of the interval. Figure 1 below shows the Kaplan-Meier survival estimate, which plots the probability of survival against time. In the present case, it implies that with passing time the probability of survival decreases but the function becomes horizontal at 56%, since entry is not observed for any other cases.

4.1 Regression results

There are 466 molecule markets that face the risk of competitive entry. I run three different models to test for drivers of entry within each market with covariates such as, average pre-entry market size, whether the molecule is for chronic ailments, whether it is a combination of two or more molecules, age of the originator in the therapy class, age of the originator in the overall market and total product varieties (formulations) by the originator. The results for each of these are shown in table 3. The difference is that I control for calendar and time dummies in column 2, further add drug category and therapy class dummies in column 3. Here the molecules are identified into four drug categories, i.e. inhalants, liquids, solids and others. The average pre-entry market size has a positive and significant effect on the risk of entry in a molecule market, whereas the total number of formulations of the originator during their monopoly period decreases the risk of entry. The variable combination and age of the originator in the therapy class is significant only in the first model and it appears that the risk faced by combination drug markets is lower than that for single drug markets, which seems to make sense since combination drug markets may not be so lucrative as are single molecule markets.

I find that markets with greater sales during the monopoly period, see increased likelihood of competitive entry. Moreover, it can be observed that the molecule markets that see no entry at all are smaller in size compared with markets that face competitive entry (see Table 2). Finally, the more formulation types that the originator has, the lower the likelihood of entry. This seems to indicate that the originators might be able to restrict entry by launching more product types. In the next section, I consider whether the originator firms are infact able to sustain any post-entry advantage in terms of higher market share or prices and whether that stems from the length of delay in entry.

Table 2: Average market size when only monopolist is present

In million(INR)	Mean	Standard Deviation	Minimum	Maximum
Markets with no entry	2.67	11.06	0	359.61
Markets with competitive entry	14.08	36.04	0	865.70

Table 3: Hazard model of entry
Dependent Variable: Probability(Entry=1)

	(1)	(2)	(3)
Average monopoly sales	0.0076**	0.0143***	0.0154***
	(0.0032)	(0.0034)	(0.0036)
Chronic	-0.2145	-0.0955	-0.2433
	(0.2009)	(0.1575)	(0.2259)
Combination drug	-0.4341**	-0.1751	-0.1005
	(0.1786)	(0.1350)	(0.1453)
Age of the first mover in the therapy class	0.0137*	0.0007	-0.0006
	(0.0070)	(0.0056)	(0.0064)
Age of the first mover in the market	-0.0031	0.0011	-0.0009
	(0.0041)	(0.0030)	(0.0030)
Total product varieties - monopoly	-2.7271***	-0.3776***	-0.1998*
	(0.1814)	(0.1252)	(0.1212)
N	7687	5841	5810
Groups	466	466	464
Log Likelihood	-1106.8597	-793.0611	-773.3171
Calendar Dummies	No	Yes	Yes
Time Dummies	No	Yes	Yes
Therapy Dummies	No	No	Yes
Drug Category Dummies	No	No	Yes

Cluster robust standard errors in parentheses

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

5 First Mover Advantage

Following from entry analysis, it is evident that larger markets are more likely to see competitive entry but it seems to suggest that if the originator is able to launch more product varieties of the same molecule, entry may in some way be restricted. So I next consider the determinants of any post-entry market share advantage for the originator firm and see if the lead time that the originator has, strengthens the advantage or any strategy of the originator might possibly strengthen its market position. I first carry out some descriptive analysis of market share and price trends and then provide more formal regression analysis.

5.1 Price and market share trends

For the purpose of analysis in this section, the prices are calculated using the following methodology:

1. For solids, the quantity for a combination SKU consisting of 2 or more ingredients was computed as:

$$q_s = (\sum_{i=1}^{k}(d_{is})) * packsize_s$$

where d_{is} is the dosage strength of each ingredient i of each SKU s and $k = 1$ for a non-combination, single ingredient product. Therefore, if a combination product has k constituent ingredients, their respective strengths are added up and then multiplied by packsize (number of tablets/capsules).

2. For liquids or creams or gels, where the dosage was in weight by volume (w/v)or weight by weight (w/w), the following conversion is used:

1% w/w implies $(1/100) * 1000 = 10(mg) * packsize(mg)$
1% w/v implies $(1/100) * 1000 = 10(mg) * packsize(ml)$

3. Final quantity was calculated by multiplying the quantity with sales units (quantity sold), to arrive at the milligrams sold.

4. Final price was arrived at by dividing sales value by the aforementioned final quantity.

Next, to compute normalised prices for the originator and the competitor, consider price ratios relative to the originator's price pre-competitive entry. This is explained as follows:

- Price ratio for originator:

  [price at time t/ price at pre-competitive entry]

- Price ratio for first competitor:

  [price of the first competitor at time t/ price of originator at pre-competitive entry]

It should be noted that continuous prices are not available for all drugs at all points of time. This is due to the following two reasons:

- Since the data reflects drugs that were launched at different times between 2007-16, the number of molecules decreases for increasing values of t.
- In addition, there may be instances where the drug may not have made any sales in a given month or may not have been distributed altogether.

Next, figure 2 depicts the case for prices averaged at each point t for each molecule, both for the originator and the competitor. Here t is measured as the number of months elapsed since the entry of the first competitor, and not calendar months[6]. This reflects that the average price remains consistently higher for the originator firm even close to 60 months after competitive entry.

Figure 3 shows average market share pattern for low, medium and high values of lead time. In the instance where the first competitor enters within 12 months of originator's entry, the originator seems to be able to maintain

[6]Note that competitive entry takes place at t=0.

a higher market share all throughout. But if the first competitor enters any time between 1-4 years post originator's entry, the market share of the originator narrows down over time. For the case where the leadtime is high, i.e., more than 4 years, we see that competitive entry in one product leads the originator to eventually phase out from the market. Alternatively, if very high value of lead times indicates relative lack of demand in the relevant market, it may not entice immediate entry. At later stages, the competitor might find an edge by launching a different formulation (say a different dosage form/strength).

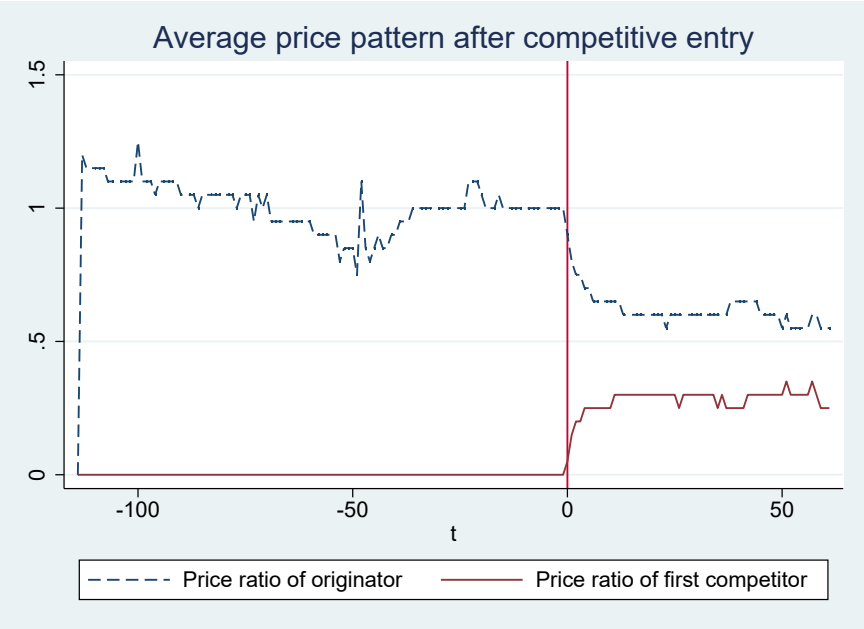

Figure 2: This figure shows post-entry trends in average prices for the originator and the competitor. Each price is normalised to the originator's pre-competitive entry price. The x-axis measures the number of months elapsed since competitive entry.

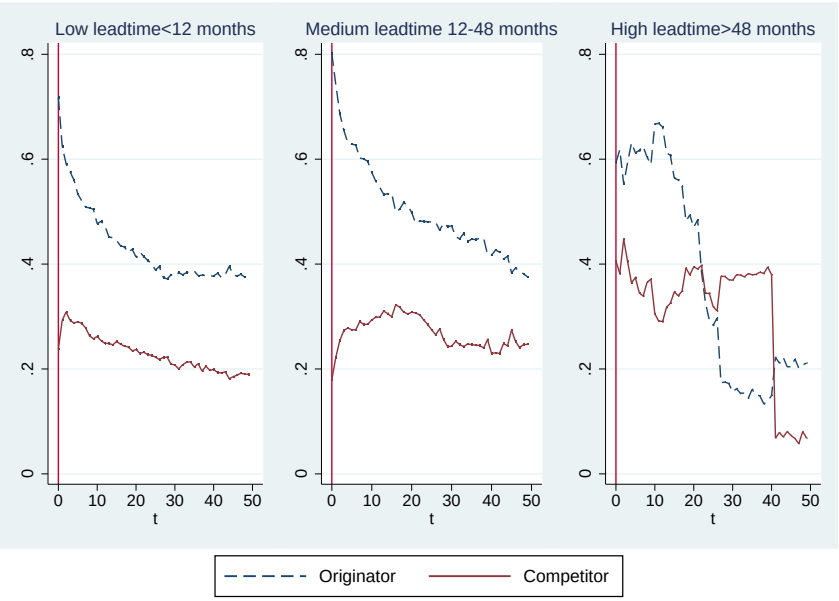

Figure 3: This shows pattern in average market share of both the originator and competitor by three broad values of lead time. The sample is divided into three groups of molecule markets with: (a) lead time of less than a year, (b) lead time between 12 to 48 months, and (c) high lead time of more than 48 months.

5.2 Empirical Methodology

The subsequent attempt is to unpack the determinants of FMA. This is done by running a panel estimation of market share of the originator upon factors such as lead time, and other covariates listed in Table 4 below.

Table 4: Variables and definitions

Lead time	Time that the originator has before the first competitor enters the mth market
Chronic	whether the molecule m is used for chronic ailments
Experience in therapy class	Age of originator since the first molecule launched by the originator in the therapeutic class of the molecule m at the time of launch of molecule m
Age	Total age of molecule m at time t
Total formulations	The number of different formulations across all manufacturers for the mth molecule market
Scope of firm	The number of different therapy areas the originator firm of molecule m is active in at a given time t
Scope_chronic	is the interaction term between scope of the firm and chronic, given that the molecule is for chronic disease how the scope of the originator firm impacts its market share
Formulations by originator	Number of different types of formulations (tablets, capsules, syrups, etc.) that have been launched by the originator

With reference to choosing the precise functional form for empirical specification, I use economic rationale in selection of a log linear functional form which has also been carried out by Bhaskarabhatla and Chatterjee (2012) and Dutta (2006).

$$lnY_{mt} = \beta_0 + \beta_1 X_m + \beta_2 W_m + \beta_3 Z_{mt} + \epsilon_{mt}$$

where

Y_{mt} is the market share of the originator in the mth molecule market at time t

X_m is the key variable of interest, i.e., lead time of the originator before the first competitor enters the mth molecule market

W_m contains all the control variables for the mth molecule market, such as chronic, experience of the originator firms in the therapeutic class of the molecules at entry date,

Z_{mt} contains control variables that vary across both molecules and time including, scope of the originator firm, total number of competitors, number of formulations launched by the originator, age of the molecule.

The regression technique will use random effects estimator since lead time, the key explanatory variable, is time invariant, and would be otherwise absorbed in the intercept should a fixed effect model be used. It is expected that longer lead time to entry should confer greater market share advantage to the originator. This would follow if there are no apparent barriers to entry in the market for generic drugs, thereby leading to a strategic entry decision by the competitor, that would depend upon factors such as, firm specialisation in product type or therapeutic class, firm size. However, later entrants may be still be able to maintain relative profitability by operating

in markets geographically distinct from that of the originator, however I do not have geographically segregated data to explore this possibility.

It is expected that experience of the originator in the relevant therapy class will make it a specialist in the area and would more likely be selected for its range of products by pharmacists and /or physicians. More formulations (either by having multiple dosages or formulation types - tablet, syrup, creams, etc.) by an originator firm is also an indication of launching the product in a wider range of the market by catering to varied patient needs and making competitive entry harder. Moreover, older firms are likely to have had a head start in building their reputation across the market than relatively new firms, and therefore firm's scope would also positively effect market shares. Finally, the originator's market shares may be lowered with the increasing age of the molecule (product life cycle effect) and by increasing competition.

Both, the number of originator firm's own formulations and the total number of competitors in the molecule market are computed by taking the inverse of the Hirschman-Herfindahl index (HHI)- which is the sum of the squares of the market shares. Doing so, instead of simple counts, allows one to see the effective number of competitors, as those formulations that have greater hold over the market are stronger competitors relative to those with insignificant market shares.

Before proceeding towards the estimation results, there remains another possibility that needs to be accounted for, that is the endogeneity of lead time which would then require instruments to address this issue. In the absence of marketing exclusivities-led barriers to entry, entry timing may be driven by expected market size. This expected market size could be proxied from two sources, one would be the market revenue generated by the originator in the period preceding competitive entry and the other is disease prevalence. For the former, an average of the originator's market revenue in it's monopoly period is used.[7] Disease prevalence is built into the present dataset using the

[7]The expected market size was computed in multiple ways, such as lagged one period prior to entry and average values of four periods lagged. However, given the unbalanced nature of the panel, most robust estimates are obtained when the average over the entire monopoly period is taken.

data collected from Institute of Health Metrics and Evaluation (IHME) for the year 2016 which is the latest year available. Using the narrowest possible therapy or class definition available for each molecule in AIOCD AWACS dataset, this was matched with the prevalence statistic provided by IHME. IHME defines 'prevalence' as the total number of cases of a given disease in a specified population at a designated time. It is differentiated from 'incidence', which refers to the total number of new cases in the population at a given time. Accordingly, the following section presents the results from OLS as well as two stage least squares estimation that addresses the endogeneity problem.

5.3 Regression results

Market share advantage: For the regression analysis, the data is aggregated quarterly so as to deal with any issues of no sales made by an SKU in a given month (as was pointed out in the previous section). It should be mentioned at this point, that expected (average) market size is often contested as a valid instrument given that market size could be correlated with the number of entrants in the market, which in turn is captured among the independent variables of the structural equation. However, the present estimation defines expected market size as the average market sales of the originator in the period of monopoly and while it affects the likelihood of entry, it should not be correlated with the total number of entrants.

Table 5-6 show the results for market share estimations.[8] The results in table 5 include the OLS specification, along with that for one instrument, i.e., disease prevalence, and two instruments i.e., both, disease prevalence and average market size. The OLS results show that lead time has a positive and significant effect on market share of the originator, however when the potential endogenous nature of lead time is accounted for, the effect of lead time is not significant in one instrument case and the first stage F test fails, implying that disease prevalence alone may not be a strong instrument. In

[8]These results are for a stable sample across various specifications and/or methodologies.

the two instrument case, lead time has a positive and significant effect on the originator's market share, but in the first stage it can be seen that disease prevalence remains insignificant but average market size has a very small but positive and significant effect on lead time.

This positive relationship is also evident from figure 5 below, where low lead time refers to less than 5 quarters (one year), medium is upto 16 quarters (4 years), and high is more than 16 quarters. While entry analysis shows that average pre-entry market size increases the risk of entry, there could be a counter effect as well. If the originator has a strong market position and the competitor isn't strong enough, the former may be able to defer entry. Should this be the case, the number of entrants could be correlated with the instrument, a concern flagged earlier in the paper as well. In order to address any potential bias that this might cause, a different set of instruments are used for this addressing the endogenous nature of lead time.

I consider a firm's existing product portfolio as an important indicator of its future launches. Local, but export-oriented, or multinational (MNC) pharmaceutical firms are more likely to launch important products that have large potential, similar to their international portfolio. However, local firms that are not exporting may have smaller scale of operations and therefore could launch relatively less important products. The scale of operations are evident from the statistics from table 1, where pre-entry market size is largest for MNC firms, followed by export-oriented and then lowest for local firms. In this instance, lead time should be shorter for exporting firms or MNCs as they can expect other competitors to enter rather quickly to cater to the large demand for the product. The AIOCD data allows me to identify originator firms as Indian or MNC, and I further classify Indian firms as export-oriented versus local, based on whether the firm has atleast one WHO-GMP certified manufacturing plant which is a necessary minimum requirement to export.[9] This information is available from the central drug

[9]The World Health Organisation (WHO) has established detailed guidelines for good manufacturing practice (GMP) known as the WHO GMP for quality assurance of pharmaceutical products. Though many importing countries have their own protocol based on WHO GMP, but in order to export anywhere in the world this is the minimum requirement.

Table 5: First Mover Advantage- Market Shares

		1-Instrument		2-Instruments	
Dependent Variable: Log(market share)	OLS	First Stage	Second Stage	First Stage	Second Stage
Lead Time	0.0558***		-0.1512		0.3675*
	(0.0164)		(0.4107)		(0.2148)
Chronic	0.1210	1.2614***	-0.1366	0.8252**	0.5363
	(0.3751)	(0.3782)	(0.6431)	(0.3823)	(0.4926)
Combination	0.0172	0.6822***	0.1877	-0.2097	0.1344
	(0.1501)	(0.1726)	(0.4352)	(0.1942)	(0.3466)
Age	-0.0470***	0.3114***	-0.0450***	0.3146***	-0.0626***
	(0.0122)	(0.0283)	(0.0137)	(0.0311)	(0.0145)
Age squared	0.0005*	-0.0037***	0.0005*	-0.0036***	0.0008**
	(0.0003)	(0.0009)	(0.0003)	(0.0009)	(0.0003)
Scope of firm	0.0174	-0.0168	0.0073	-0.0863**	0.0389
	(0.0612)	(0.0428)	(0.0735)	(0.0434)	(0.0757)
Scope_chronic	-0.0081	-0.2116***	-0.0004	-0.0567	-0.0566
	(0.0612)	(0.0581)	(0.0689)	(0.0597)	(0.0771)
Experience in therapy class	0.0060	-0.0959***	-0.0141	-0.0935***	0.0348
	(0.0063)	(0.0118)	(0.0413)	(0.0126)	(0.0268)
Total formulations - HHI	-0.0990***	-0.3012***	-0.0995***	-0.2897***	-0.0785***
	(0.0123)	(0.0231)	(0.0133)	(0.0227)	(0.0118)
Formulations by originator - HHI	0.6776**	0.3040**	0.7132*	0.2752**	0.7722
	(0.3205)	(0.1218)	(0.4108)	(0.1219)	(0.5188)
Disease prevalence		0.0007		-0.0006	
		(0.0013)		(0.0014)	
Average market size				0.0009***	
				(0.0002)	
Constant	-1.5402**	1.9939***	-0.3707	2.9967***	-3.8338**
	(0.6059)	(0.3794)	(2.4495)	(0.4327)	(1.7733)
$\chi^2(1)$			0.0000		0.4950
F_instr		0.2817		9.5922	
Rsquared				0.2368	.
Rsquared_with		0.2398	.		
N	3378	3378	3378	3014	3014
groups	189		189		170

Standard errors in parentheses

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table 6: First Mover Advantage- Firm type

Dependent Variable:Log(market share)	OLS	First Stage	Second Stage
Lead Time	0.0558***		-0.2065
	(0.0164)		(0.4862)
Chronic	0.1210	0.9269**	-0.0718
	(0.3751)	(0.3633)	(0.5704)
Combination	0.0172	0.6362***	0.2094
	(0.1501)	(0.1690)	(0.4085)
Age	-0.0470***	0.2974***	-0.0374*
	(0.0122)	(0.0281)	(0.0203)
Age squared	0.0005*	-0.0034***	0.0004
	(0.0003)	(0.0008)	(0.0004)
Scope of firm	0.0174	0.0880**	0.0015
	(0.0612)	(0.0445)	(0.0696)
Scope_chronic	-0.0081	-0.1638***	-0.0068
	(0.0612)	(0.0562)	(0.0616)
Experience in therapy class	0.0060	-0.1004***	-0.0201
	(0.0063)	(0.0123)	(0.0489)
Total formulations - HHI	-0.0990***	-0.3035***	-0.1107***
	(0.0123)	(0.0231)	(0.0237)
Formulations by originator - HHI	0.6776**	0.2384**	0.6075*
	(0.3205)	(0.1165)	(0.3385)
Type=EXPORT		-1.4814***	
		(0.2375)	
Type=MNC		-0.6215**	
		(0.3162)	
Constant	-1.5402**	2.8928***	0.0756
	(0.6059)	(0.3673)	(3.0841)
$\chi^2(1)$			0.0080
F_instr		20.9864	
Rsquared_with		0.2479	.
N	3378	3378	3378
groups	189		189

Standard errors in parentheses

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

regulator's website. A similar classification has been used by Boswell-Dean (2019) to identify quality of products in the Indian pharmaceutical market, where she suggests that export-oriented firms or MNCs are likely to signal high quality since they have an international reputation to maintain as well.

Based on the foregoing, I use the classification as instruments for lead time with local firms as the reference category. The results for this specification are shown in table 6. The first stage estimates suggest that where originators are exporting firms or MNCs, they may see shorter lead times relative to local firms. However, the second stage estimates still reflect no statistically significant results for lead time. The second stage results for other covariates are more or less the same, competition still has a negative effect on originator's long term market share. Evidence for product life cycle effect is also visible, as the age variable has a negative and significant effect on market share. Finally, the formulations by originator also picks up a weak significance in the second stage indicating that increased product varieties increases the originator's market share.

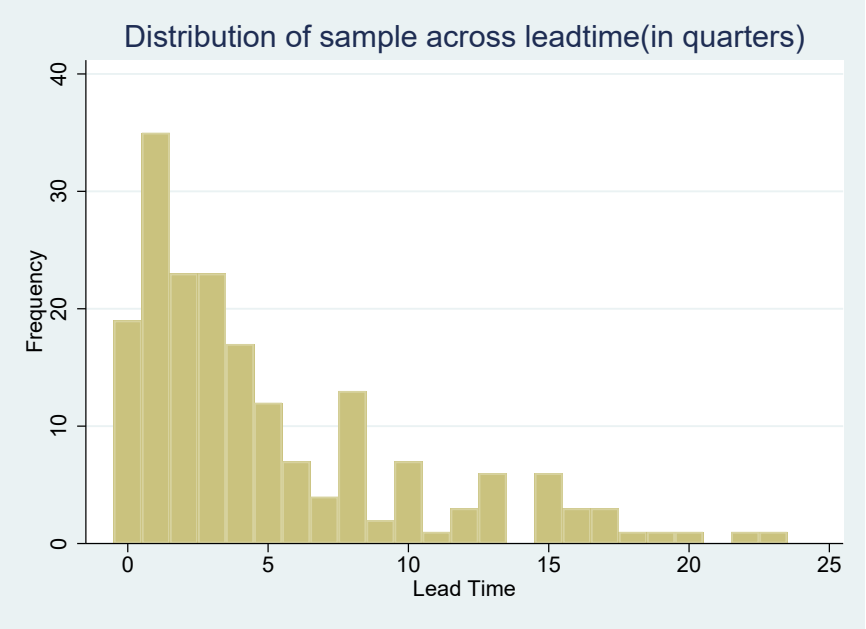

Figure 4: This is a histogram depicting frequency of lead time values across the entire sample of 189 molecules that experience competitive entry. The x-axis measures the lead time in quarters.

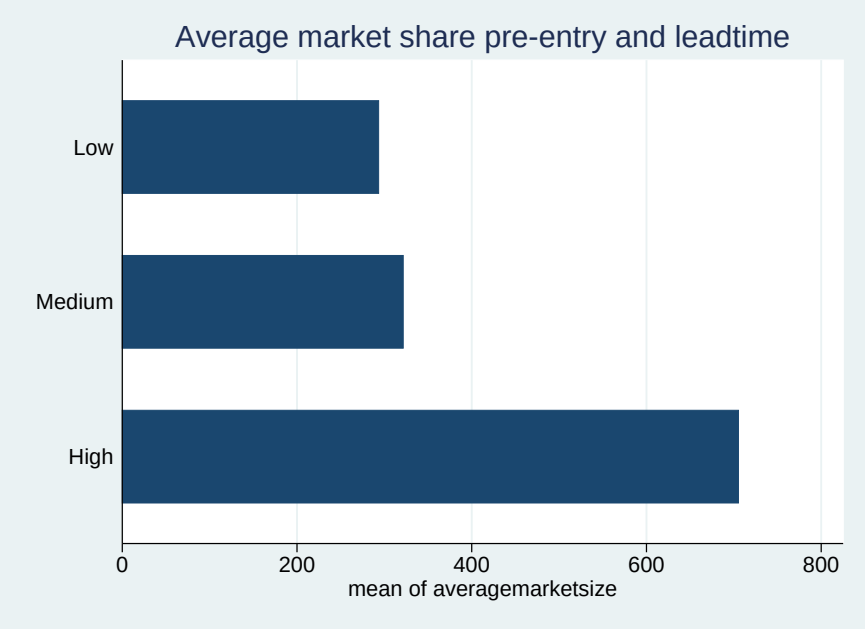

Figure 5: This shows the relation between average pre-entry market size and lead time for 189 molecule markets. For this three groups of lead time values are taken: (a) low - less than 5 quarters, (b) medium - upto 16 quarters, (c) high - more than 16 quarters.

Price advantage: The next set of estimations (tables 7-8) are generated with log of price as a dependent variable. Price is defined as the ratio of the price of the originator of molecule m at time t to the originator's price before competitive entry. The results for this specification are presented in table 7 with OLS results along with those for two instruments, i.e. average market size and disease prevalence. Here the OLS and second stage results show a negative and insignificant effect of lead time on the log of originator's price. Table 8 explores the case when dummies for firm types (export oriented, MNC or local) are used as instruments for lead time. Here the first stage results reveal that where the originators are exporting firms the price ratio is lower than that for local firms. The statistical effect of MNCs upon lead time goes away in this sample. The second stage results remain unchanged. Therefore, lead time effects on log of originator's price remain inconclusive.

The difference in the sample size relative to the market share regressions,

is that there are ten molecules for which originator's pre-entry price is not available, possibly due to no sales in the last period prior to entry.

Moreover, the sample size variation across different instruments is on account of those which have no average pre entry market size data because they have zero lead time, i.e. simultaneous entry. The results remain unchanged if I re-estimate results of table 8 with the common sample.

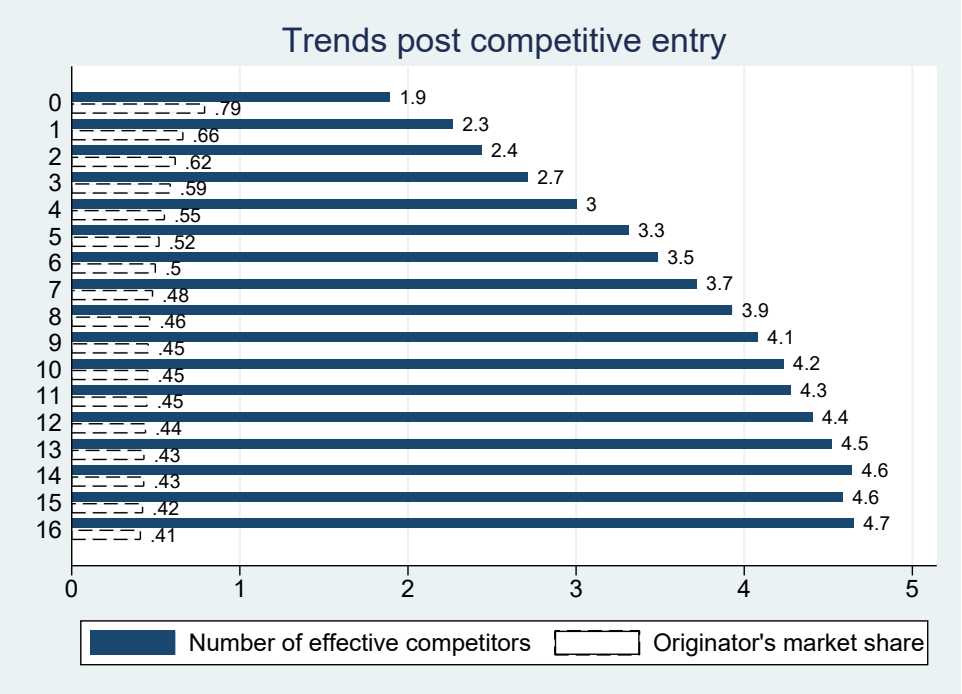

Figure 6: This figure shows average trends in effective competition and originator's market share for all 189 molecules. The y-axis shows time since competitive entry upto 16 quarters. At different points of time post entry, the first bar depicts the effective number of competitors the second bar shows the average market share of the originator.

Table 7: First Mover Advantage- Price

Dependent Variable: Log(price ratio)	OLS	First Stage	Second Stage
Lead Time	-0.0158**		-0.0872
	(0.0077)		(0.0665)
Chronic	0.109	0.917**	0.0951
	(0.108)	(0.399)	(0.117)
Combination	-0.055	-0.411**	-0.0941
	(0.117)	(0.200)	(0.125)
Age	0.0044	0.312***	0.0055
	(0.00371)	(0.0326)	(0.0038)
Age squared	0.0000	-0.0035***	0.0000
	(0.0000)	(0.0009)	(0.0000)
Scope of firm	-0.0031	-0.108**	-0.0060
	(0.0090)	(0.0464)	(0.0098)
Scope_chronic	-0.0016	-0.0724	-0.0023
	(0.0109)	(0.0622)	(0.0112)
Experience in therapy class	-0.0034*	-0.103***	-0.0108
	(0.0019)	(0.0143)	(0.0081)
Total formulations - HHI	-0.0055	-0.269***	-0.0064
	(0.0042)	(0.0248)	(0.00401)
Formulations by originator - HHI	-0.100	0.0354	-0.112
	(0.0621)	(0.126)	(0.0699)
Disease prevalence		0.0020	
		(0.0015)	
Average market size		0.0006***	
		(0.0002)	
Constant	0.288	3.798***	0.834*
	(0.182)	(0.465)	(0.494)
$\chi^2(1)$			0.297
F_instr		4.095	
Rsquared_with		0.241	.
N	2790	2790	2790
Groups	160		160

Robust standard errors in parentheses

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

Table 8: First Mover Advantage- Price -Firm type

Dependent Variable: Log(price ratio)	OLS	First Stage	Second Stage
Lead Time	-0.0176*		-0.224
	(0.0094)		(0.345)
Chronic	0.150	1.022***	-0.0085
	(0.122)	(0.392)	(0.339)
Combination	-0.0798	0.575***	0.0531
	(0.142)	(0.180)	(0.306)
Age	0.0063	0.314***	0.0083
	(0.0055)	(0.0295)	(0.0065)
Age squared	-0.0000	-0.0037***	-0.0000
	(0.0001)	(0.0009)	(0.0001)
Scope of firm	-0.0054	0.0173	-0.0104
	(0.0102)	(0.0483)	(0.0138)
Scope_chronic	-0.0107	-0.175***	-0.0115
	(0.0216)	(0.0601)	(0.0222)
Experience in therapy class	-0.0027	-0.0982***	-0.0238
	(0.0028)	(0.0136)	(0.0370)
Total formulations - HHI	-0.0028	-0.305***	-0.0047
	(0.0055)	(0.0265)	(0.0060)
Formulations by originator - HHI	0.0217	0.127	0.00814
	(0.120)	(0.121)	(0.133)
Type=EXPORT		-1.015***	
		(0.251)	
Type=MNC		-0.333	
		(0.329)	
Constant	0.164	3.116***	1.438
	(0.185)	(0.387)	(2.185)
$\chi^2(1)$			0.757
F_instr		9.270	
Rsquared_with		0.248	.
N	3130	3130	3130
Groups	178		178

Robust standard errors in parentheses

* $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$

6 Discussion

So what does this lack of supporting evidence suggest? There is definitely a delay in competitive entry of more than a year for 40% of the molecules in the sample considered, and yet it appears as if there is no link with sustained first mover advantages. To answer this, let's look at the potential causes for entry delay in the first place. The delay in competitive entry is likely to be on account of causes that are regulatory as well as economic in nature.[10] For one, competitors who file for regulatory approval to launch a new drug within four years of the first approval received by the originator, may face regulatory uncertainty. At the moment, there are no published timelines for approval of new drug applications received by the regulator, moreover there may be requirements for additional data that could add to the delay in launch.[11] While this may be more random in nature, there are economic reasons too for entry delay.

Even with a leadtime of as much as 2 years, the effective number of competitors increases from 2-3 within 2 years of competitive entry. Figure 6 above, shows average post-entry trends in number of effective competitors and originator's market share. Over the entire sample, there are effectively 2-3 competitors on the market after four quarters, and this number grows to 4. While the time in the graph is only upto 16 quarters, the trend remains largely unchanged for later values. Interestingly, the average share of the originator is close to 40% even 16 quarters after competitive entry. This seems to allow for the possibility that the market expansion brought in by competitors may be from segmentation of the market.

Any single firm is unlikely to be able to supply the drug in the entire country. Originator firms might focus on releasing the products nationally, but in larger cities where the revenue stream will be greater. This is because bulk of the middle class population with greater disposable incomes, reside in metros and tier-1 cities. Some competitor firms might likely fill the gaps and drive up access in lower income markets, tier-2 markets and beyond. In

[10] This identification is based on anecdotal evidence from interactions with industry experts.

[11] This has been documented in Wattal et al. (2017)

this tiered marketing strategy, it is possible for the competitor not to bother about entering very early on.[12] Follower firms could focus on a geographic territory where they are comparatively strong or market where they have strong distribution networks. A more detailed study of this aspect requires data into marketing and/or distribution costs of firms to evaluate whether they differ across originator or competitor firms, or sub-national segregation of sales data to examine regional competition.

7 Conclusion

In this paper, I first investigate the factors relevant to competitive entry decisions in 466 new drugs launched in the Indian branded generics pharmaceutical market. Subsequently, I analyse a subset of 189 molecule markets where entry does in fact take place, while focusing on the role of lead time upon the market share or price advantage for the originator. I account for potential endogeneity of lead time using different sets of instruments, such as indicators of potential market size and the originator's scale of operations.

The hazard model estimates presented in the first part of this paper indicate that larger markets are more likely to see competitive entry, but entry could potentially be restricted or delayed if the originator launches more varieties of the same molecule. Next, the OLS estimates for first mover advantage show that longer delay in competitive entry confers market share advantage to the originator. However, when potential endogeneity of lead time is accounted for in the IV estimations, the results are inconclusive. There is some shred of doubt on employing the use of average pre-entry market size as an instrument, but alternate instruments also show no significant effect of lead time. Further, there seems no statistically significant evidence linking prices with lead time in the IV estimations. This indicates the possibility for factors other than lead time which explain the competition dynamics, those that might hinge upon marketing strategies of firms.

[12]Refer to appendix A for a detailed discussion of the marketing strategy in the Indian pharmaceutical sector.

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A Market entry strategies in India's generic pharmaceutical industry

Much of the sales in the Indian pharmaceutical industry comes from the branded generics segment.[13] In the absence of exclusivity for any player in this segment, the business operating model is very different from what one might possibly see in other geographies. This implies that if firms want to successfully enter into any molecule or therapy market, they need to be able to set up a robust distribution channel and a strong field force dedicated to reaching out to general practitioners and specialists. Accordingly, each firm has one of the four ways to succeed in the market (IQVIA, 2018).

1. Brand building- Some major MNCs may have few mega brands which drive their success. Even new launches are tied to the success of the existing brands.

2. Therapy Leaders- Top firms draw their revenue from limited therapy areas (their speciality) even if they have presence in multiple therapy areas. They may be focussed on reaching out into a wider geographical area in order to maximize sales.

3. Access Drivers – They attempt at depth coverage instead of only breadth, thereby implying that their field force will cover tier 2 towns and beyond.

4. Speciality Players – They focus on new launches in chronic disease segment and collaborative ventures are common. Their field force may be limited to the specialists based in metros and tier-1 cities.

If a firm is an absolutely new entrant into the Indian market it would likely attempt to model 3 (i.e. supply to the untapped markets) or enter into speciality business which face fewer competitors. India faces a dual burden of disease, i.e. there is a pre-existing high burden of communicable diseases

[13]PWC (2010) indicates that around 90% of total sales come from this segment.

such as diarrhoea, lower respiratory infections, tuberculosis, etc., there is simultaneously a sharp rise in non-communicable conditions such as heart disease, stroke and diabetes.[14] This renders it unlikely that firms will focus on any one type of disease area (data reflects that most originator firms operate in atleast 8 therapy areas and could go upto 14 therapy areas) and their strategy for marketing mass therapies differs tremendously from speciality therapies. Mass therapies are driven by general practitioners and at times may also include a large portfolio of over the counter drugs, whereas speciality therapies require limited outreach to specialists in tertiary care centres and beyond.

The originator firm, if it is therapy leader or speciality player, would likely tap into metros and tier-1 city markets where it can make most profits with large hospitals and/or speciality hospitals, leaving the second entrant to approach the relatively under-served tier 2 or tier 3 cities.

Each originator has been on the therapy market for long but has also provided a range of products in the given market. The average originator firm has 453 molecules on the market. But if only single ingredient products are considered there are on an average 275 molecules per firm. This indicates that firms would have large marketing and distribution networks in place. If this is segregated by firm type, a local firm on average of 97 molecules on the market, but only 55 of these are single ingredient products. The fewer molecules reflect smaller scale of operations. MNCs usually have a limited portfolio of drugs because they may not have have pre-existing distribution networks and operate more actively in speciality segments. Most originator MNCs have less than 200 molecules on the market. The export-oriented local firms have the largest scale of operations as they have an average of 488 molecules on the market, and if one only looks at single ingredient molecules the average is 296 molecules.

[14] As of 2016, communicable diseases contribute to 32.7% of total disability adjusted life years in India, whereas 55.4% comes from non-communicable diseases.(Indian Council of Medical Research et al., 2017)