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First-Mover Advantages Before and After TRIPS
Evidence from the Indian Pharmaceutical Industry

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Abstract

Scholars argue that the presence of persistent first-mover advantages obviates the need for relatively long-lived patents as incentives for innovations. What then is the impact of the strengthening of patent protection, particularly in developing economies, on non-patent-based first-mover advantages? We investigate this question by estimating the extent of erosion of first-mover advantages in the Indian pharmaceutical industry due to the introduction of a stronger product-patent regime in January 2005. We distinguish between newly created and pre-existing markets, in which the strength of product patent protection differs systematically. Our analyses account for the endogeneity of entry order. We find evidence of erosion—as high as 50-percent—that is robust to alternative estimation strategies and definitions of dependent variables. We extend the Suarez-Lanzolla framework and highlight the role of regulatory factors on the relationship between first-mover advantages and intellectual property rights and discuss managerial and policy implications.

Keywords: First-mover advantage, pharmaceuticals, IPR, India

1 Introduction

What is the impact of 'macro' environmental or institutional factors on first-mover advantages or, more broadly, on order-of-entry effects? What factors enable or disable first-mover advantages in particular industries? These questions have gained considerable importance recently as scholars attempt to reconcile the inconclusive nature of support for the first-mover advantage hypothesis across industries (Suarez and Lanzolla 2007).[1]

In this paper, we focus on the role of intellectual property rights (IPR) regime as the key institutional factor affecting the extent of first mover advantages. We argue that a weak IPR regime facilitates imitation and the creation of non-patent-based first mover advantages. Such advantages may derive, for example, from greater cost-reductions from learning-by-doing for early entrants. They also may derive from early entrants making investments in complementary assets such as marketing and distribution services. By contrast, the strengthening of IPR regime increases the cost of imitation and causes firms to be more cautious in their entry strategies due to the prospect of patent litigation. In a stronger IPR regime, early entrants are therefore more likely to enter at a smaller initial scale of operations, leading to a decline in the extent of non-patent-based first mover advantages arising from mechanisms such as learning-by-doing.

We test these expectations in an empirical study based on the Indian pharmaceutical industry. We estimate the extent of erosion of first-mover advantages due to the introduction of a stronger product-patent regime in January 2005, after India acceded to the World Trade Organization (WTO) mandated Trade-Related Aspects of Intellectual Property (TRIPS) agreement. We focus on the pharmaceutical industry, where prior studies have found evidence for persistent first-mover advantages (e.g., Gorecki 1986). We choose the Indian context for two main reasons. First, India leads the world in the production of generic drugs, wherein firms have historically thrived on free entry and non-patent-based first-mover advantages that are not conferred automatically by the patent law. Second, the patent regime—a particularly relevant institutional factor for the growth of the industry—underwent a significant policy transformation in India, providing us with a quasi-natural experiment to study the impact on first-mover advantages (see, for a detailed case study of the industry, Kapczynski 2009).

We focus primarily on 120 newly created pharmaceutical therapeutic markets in India at the 4-digit level of the Anatomical Therapeutic Chemical (ATC) classification over a period of thirteen years, punctuated by the 2005 patent-regime shift. As Figure 1, panel (a) shows, the average number of producers per market increased steadily from 1.78 in the first month to five producers in the first year,

[1] The FMA hypothesis is supported by, among others, Bond and Lean, 1977; Robinson, 1988; Robinson and Fornell, 1985; and in our particular context, Grabowski and Vernon, 1992 and Dutta, 2006. The FMA hypothesis is not supported by, among others, Golder and Tellis, 1993 and Boulding and Christen, 2003. See, also, Lieberman and Montgomery 1988, 1998; Mitchell, 1989, 1991; Robinson et al., 1994; and Finklestein, 2002.

ten in four years, and 15 in nine years. The figure reflects a relatively short period of a few months, on average, of market exclusivity and highlights the competitive nature of these markets arising from free entry. We also plot the market share of the first-movers in each of these markets. The figure reflects a sharp initial decline in the average market share from 100 percent to 62 percent in the first year. In the long run, however, the average market share of the first-movers hovers at around 40 percent, which suggests that there are large and persistent first-mover advantages in our setting.

We contrast these patterns in the newly pioneered markets with those from the pre-existing markets in our data in January 1999. In the latter set of markets, India's new product-patent regime has relatively less impact because the patents associated with drugs in pre-existing markets are more likely to have expired by 2005, given that the effective length of pharmaceutical patents is ten years (Grabowski and Vernon 2000). Our data begin in 1999, and we cannot disentangle the order of entry among incumbents in pre-existing markets. So, we plot the combined market shares of all incumbents averaged across all pre-existing markets in panel (b) of Figure 1. The figure shows that there were five incumbents, on average, in these pre-existing markets. Despite new entry over time—the average number of firms in these markets doubled in six years—the combined market share of these incumbents declined modestly from 100 to 88 percent after six years, reflecting persistent first-mover advantages.

These trends conceal an empirical puzzle. We compare the extent of first-mover advantages in markets newly created during 1999-2004 and 2005-2011, respectively. Figure 2 shows that the market share of the first-movers in the latter period eroded more quickly than that in the former period. We restrict the analysis to markets in which only one entrant was the first-mover. Hence, the difference between the two trends cannot be explained away by the difference between the average number of first-movers in the two periods. In addition, the difference is underestimated as firms in the later period are on average larger, older, more experienced, and have broader scope. What explains the faster erosion of first-mover advantage since 2005? While plausible reasons include heterogeneity in firm capabilities, market structure, or technological and market evolution, we argue that, controlling for other explanations, it is explained by the shift in the product-patent regime in India beginning in 2005.

Our analyses also account for the endogeneity of entry order resulting from firms choosing their timing of entry into a market. Our results are robust to alternative estimation strategies and choices of the dependent variable. We find evidence of erosion—as high as 50-percent according to some estimates—in newly created markets. We find evidence of erosion, to a lesser extent, in the pre-existing markets. These results have implications for both managerial and policy implications for the generic pharmaceuticals industry in developing countries.

The erosion of first-mover advantages is an important policy question for the global generics manufacturers and for healthcare expenditures in many countries across the world. Abbott et al. (2005) and Scherer (2005) in particular argue that Indian generics manufacturers may lose their first-mover advantage due to the regime shift, as the Italian industry did in 1978 after it implemented similar reforms (see, for a discussion of the Italian experience, Scherer and Weisburst 1995). We estimate the extent of

the problem; in the meantime, regulatory procedures enabling timely entry of generic alternatives continue to be worked out in the Indian courts through cases involving the original innovators of drugs and the Indian generics manufacturers.

We do not attempt to resolve the current debate surrounding the existence of first-mover advantages in the management and marketing literatures or to develop a universal theory that fits all industries. Instead, focusing on a setting in which significant first-mover advantages are known to exist and product patents are important, we ask how exogenous changes in the regulatory environment affect first-mover advantages. Our paper is most similar conceptually to Suarez and Lanzolla (2007) and methodologically to Boulding and Christen (2003) and Dutta (2006). Our study adds to the growing literature on environmental or institutional factors that enable or disable first-mover advantages (e.g., Bhaskarabhatla and Klepper 2014); the interaction between firm capabilities and industry dynamics and its impact on the timing of entry and success (e.g., Franco et al. 2009); and the interaction between firm-level incentives to innovate and the choice of market segment to enter (e.g., de Figueiredo and Silverman 2007).

The next section provides a brief overview of the pharmaceutical industry in India. In Section 3, we review related literature and develop our hypotheses. We describe our estimation strategy in Section 4 and outline the data used in this research in Section 5. We present our results in Section 6 and conclude in Section 7.

2 Industry Background

Several developing countries, such as Brazil and China, have adopted a stronger product- patent regime in recent years in accordance with the WTO-TRIPS agreements. India, through a series of amendments to its patent laws, adopted the new regime in January 2005, reversing a 35-year-old patenting environment that protected only process patents in pharmaceuticals and for only a relatively short duration of five to seven years. The new regime conferring 20 years of protection is intended to create incentives for product innovation and facilitate the early launch of new products in these countries (see, for more details, Chatterjee 2011).

The most severe criticisms of the change and its most direct impact in India has been on firms in the generic-pharmaceuticals industry—the world's leading producer and supplier of generic alternatives to patented medicines (Kapczynski 2009). Until 2005, most firms in the industry benefited from being, either directly or indirectly, nurtured by the state under a protectionist patent regime. Firms in the industry entered freely to reverse-engineer, produce, and sell patented drugs without paying royalties to the original innovators. The extent of investment in R&D in the Indian industry remained less than one percent. Domestic firms entered during the patent life of drugs, improved production processes, and advanced along the learning curve, lowering their marginal costs of production.

Under the new regime, generics manufacturers in India cannot market a generic alternative until the patent associated with a drug has expired, except under a few exemptions that we will discuss momentarily. Regulations concerning whether generics manufacturers can experiment with patented

drugs before they expire, perfect their production processes, and obtain marketing approvals can introduce imitation lags in transitioning from a patented drug to its generic alternative. In a market such as that for new pharmaceuticals introduced in India, delays in months can lead to significant forgone revenues, because market shares fall rapidly over time and with entry order as reflected by Figure 1. To address the delay, the 'Bolar' provision, introduced in the U.S., allows generics firms to obtain necessary regulatory approvals, sometimes *before* drug patents expire.

Developing countries have been extended a few exemptions (or flexibilities) under the TRIPS agreement—including compulsory licensing and 'Bolar' provisions—although their judicial and administrative implementations in India have been uncertain. Developing countries can exercise the compulsory licensing exemption to permit domestic firms to produce patented drugs at modest licensing rates, particularly in cases where such drugs remain unaffordable for most consumers with life-threatening illnesses such as AIDS and cancer. In addition, Kapczynski (2009) notes that India employs several other important flexibilities such as limits on patentable subject matter, expansive procedural opportunities to challenge patents, and restrictions on injunctive remedies. The issue at hand is not merely one of domestic consumer welfare, but of the survival of a group of producers in the Indian generics industry, which supplies affordable medicine to a number of countries around the world.

Notwithstanding these flexibilities, Abbott et al. (2005) raised concerns months after the policy shift about the very survival of the Indian generics industry. Citing Lerner (2002) and Sakakibara and Branstetter (2001) in the editorial of a leading newspaper in India, Abbott et al. wrote: "Its generic manufacturers are too crucial for India, and for the world, to be allowed by a misguided patent law to be wipedout." Scherer (2005) added a month later in another editorial titled "Losing the first mover advantage" that unless the first-mover advantage of its generics manufacturers is protected—either through the implementation of a Bolar-like provision or through compulsory licensing of under-patent drugs before expiry, where appropriate—the Indian generics industry could go the Italian way. Scherer noted that Italy adopted drug product patents in 1978 through a Supreme Court order, which did not increase the number of new drugs developed thereafter in Italy relative to the world trend, but undermined its status as the world's leading generics industry.

The implementation of the TRIPS agreement has been shown to vary across countries (Deere 2009). Sampat (2010) notes that TRIPS implementation is not dichotomous, but additional flexibility exists in India to allow for entry in the pharmaceutical industry, including exploiting the limits placed on incremental patents (also known as evergreening of patents). Consequently, generic entry into new molecule markets in India has not stopped post-TRIPS. However, the uncertainty surrounding the costs and benefits of such entry is being resolved both judicially and administratively. Kapczynski (2009) argues that the ability to implement flexibilities negotiated under TRIPS by developing countries,

including India, is fraught with difficulties due to resource limitations and potential retaliation by the U.S. using other trade regulations.[2]

In August 2009, India clarified and exercised its patent law for the first time in the post-TRIPS era against the original innovator *Bayer* in favor of the Indian manufacturer *Cipla* for the patented anticancer drug *Nexavar* with active ingredient Sorofenib Tosylate. The Indian Supreme Court rejected *Bayer's* argument that marketing approval cannot be given to drugs under patent protection. India also exercised the compulsory licensing exemption for the first time in March 2012 by granting a compulsory license to *Natco* to produce *Bayer's Nexavar* at a six-percent royalty fee on sales. *Bayer*, whose pricing, some estimate, excludes 98-percent of the relevant patient population in India, appealed the order. The Indian Intellectual Property Appellate Board, setup in 2003 to consolidate patent-related disputes, dismissed *Bayer's* plea in September 2012. There have been other instances. *Roche* has sued some Indian companies for infringing on its patents related to the cancer drug *Tarceva* with active ingredient Erlotinib. In addition, the Indian patent office has refused to grant or has revoked some patents by *Novartis* and *Roche*.

In response, the original innovators have begun, in recent years, to adopt innovative business strategies to lower first-mover advantages in addition to those caused by regulatory delays. Until recently, the original innovators of patented drugs abandoned the production of drugs after patents had expired. More recently, however, innovators have continued to sell branded drugs through exclusive marketing channels in developed countries, sometimes at discounted prices. Jackevicius et al. (2012) document *Pfizer's* strategies in the market for cholesterol-lowering statin drugs when its patent on Lipitor expired in 2011: (a) agreements with pharmacy-benefits management companies and insurance companies, where Lipitor is the only alternative; (b) competitive pricing at the pharmacy level and co-payment rates; and (c) direct-to-consumer advertising and home delivery by mail.

The original innovators have also begun to implement new strategies in the developing world to lower first-mover advantages—including lowering the prices of branded drugs through differential pricing, a strategy that *Merck* adopted for its branded drug *Januvia*. Multinational firms (MNCs) have also begun to enter India through the acquisition of leading generics manufacturers, which lowers the degree of competition among the generics and branded drugs and delays generic entry. The original innovators have also made efforts to control the timing of entry of generic alternatives in the U.S. through their newly acquired Indian generics subsidiaries. These regulatory and strategic factors make both our context and study timely and relevant as many countries around the world look to contain the rising costs of healthcare.

3 Literature Review and Hypotheses

[2] The Indian patent examiners face twice the workload of their overburdened counterparts in the U.S. The budget of the Indian patent office adjusted for purchasing parity is half of that for the U.S (Kapczynski 2009).

In the broad literature on first-mover advantages across industries, several studies have attempted to overcome methodological and measurement issues by addressing firm heterogeneity, selection bias, and the operationalization of the dependent variable in explaining the inconclusive nature of support for the first-mover advantage hypothesis. In a recent review of the literature, Suarez and Lanzolla (2007) summarize the emerging empirical regularities:

- First-mover advantage seems to be associated with specific product categories and industry characteristics.
- First-mover advantage tends to be observed mainly in the form of higher market shares.
- The longer the lead time to competitive entry, the higher is the likelihood of achieving first-mover advantage.

The empirical literature on the extent of first-mover advantage differs by industry type (see Robinson et al. 1994). The extant literature set in the pharmaceutical industry has provided strong evidence of first-mover advantages (Bond and Lean 1977; Gorecki 1986; Hurwitz and Caves 1988; Grabowski and Vernon 1992; and Dutta 2006). Similarly, while the usefulness of patent protection also differs by industry type, product patents are considered important in the pharmaceutical industry (Levin et al. 1987; Scherer and Ross 1990; Cohen et al. 2000).

Following the prior literature, we argue that there are persistent first-mover advantages, as measured by indicators of performance such as revenue and survival, in the Indian pharmaceutical industry.

Hypothesis 1. The earlier the timing of entry in a market, the better is the performance in the market.

While the prior literature has focused on explaining whether or not first-mover advantages exist, recent advances in the literature have examined when first-mover advantages are enabled or disabled. In a recent study, Bhaskarabhatla and Klepper (2014) develop a theory based on Klepper and Thompson (2006) and Klepper (2002), in which technological discontinuities can trigger a change in the nature of the relationship between previously independent submarkets and unleash both the incentives for process R&D and the attendant first-mover advantages. They argue that in the laser industry, first-mover advantages were unleashed only after the emergence of a dominant submarket, which supported increasing returns to process R&D in that submarket. Franco et al. (2009) argue that achieving first-mover advantages is conditioned by technological capabilities and show that only the early entrants that exhibited technological leadership derived such advantages in the hard disk drive industry.

This 'new first-mover advantage' literature was triggered by Suarez and Lanzolla (2007), who propose a theoretical framework to account for the role of environmental factors in enabling or disabling first-mover advantage, as well as for the roles played by firm heterogeneity and its interaction with various mechanisms such as technological leadership and learning-by-doing). Suarez and Lanzolla (2007) call for incorporating environmental elements—particularly, the pace of technology evolution

and the pace of market evolution—into theories of first-mover advantages. We build on these studies to incorporate the role of regulatory factors.

Figure 3 describes the theoretical framework we adapted from Suarez and Lanzolla (2007). According to the framework, several factors enable (or disable) first-mover advantages: (a) macro environmental factors; (b) 'isolating mechanisms' such as technological leadership or superior access to resources; and (c) firm capabilities.[3] We investigate the role of the regulatory environment in enabling or disabling first-mover advantages, which, to our knowledge, has not been previously empirically investigated.

Suarez and Lanzolla (2007) propose that when the pace of both technological and market evolution is smooth (to use their terminology), the *enabling* effects of environmental elements on isolating mechanisms, such as technological leadership, will be strongest. In contrast, when the pace of both technology and market evolution is abrupt, the *disabling* effects are the strongest. In the case of traditional drugs, according to Suarez and Lanzolla (2007), the pace of technology evolution is considered to be slow (along with other industries, such as organic and inorganic chemicals). However, the pace of market evolution is abrupt and time-sensitive, as Figures 1 and 2 demonstrate. According to the Suarez-Lanzolla framework, there will be an environmental effect, albeit weak, on the extent of first-mover advantages.

In our context, the environmental change we exploit is the strength of patent protection. In theory, patent protection and first-mover advantages both provide an incentive for market pioneering. Consequently, scholars have argued for relatively shorter-lived patents for the original innovators of drugs in the presence of persistent first-mover advantages (e.g., Nordhaus 1969; Scherer 1972; Scherer and Ross 1990). The strengthening of product patent protection in developing countries, however, can produce unintended consequences, particularly for non-patent based mechanisms of survival that firms have developed over time. In the Indian pharmaceutical industry, where there are no local original innovators of drugs, the strengthening of patent protection leads to imitation lags and forgone technological leadership in terms of process improvements and learning-by-doing. In addition, the domestic firms face competition from innovators looking to extend sales from existing drugs in the backdrop of the decline in pharmaceutical R&D productivity. We argue that the introduction of a stronger product patent regime raises the cost of imitation and lowers the extent of learning-by-doing for the Indian manufacturers (e.g., Scherer and Weisburst 1995; Scherer 2005; Abbott et al. 2005). Consequently, we develop the following hypothesis.

Hypothesis 2. The introduction of a stronger product patent regime in India lowers first-mover advantages in the Indian pharmaceutical industry.

[3] See Lippman and Rumelt (1982) for the literature on isolating mechanisms and Teece et al. (1997) for the dynamic capabilities literature.

Deere (2009) documents the differential levels of enforcement of the TRIPS agreement across countries. Even within a country, there is considerable variation in enforcement depending on the particular characteristics of the market. Kapczynski (2009) and Sampat (2010) document the variation in implementation of TRIPS within the Indian context. If the extent of patent protection in the pharmaceutical industry differs by molecule-market within a country, then, building on Hypothesis 2, it is expected that in markets in which patent protection is relatively higher, the extent of erosion after 2005 will be greater. One way to distinguish between molecule-markets in terms of the extent of patent protection is based on their age. In the older, pre-existing markets, the direct impact of the new product patent regime is expected to be limited. Consequently, product patents associated with pre-existing molecule-markets are more likely to have expired by January 2005—when the patent regime shifted—given that the effective patent life of pharmaceuticals is approximately ten years (Grabowski and Vernon 2000). Hence, we develop the following hypothesis.

Hypothesis 3. The extent of erosion of first-mover advantages is higher in newly introduced pharmaceutical than in older, pre-existing markets.

4 Estimation Strategy

We consider the arrival of new drugs in India to be exogenous, as domestic firms do not invest in product R&D to influence their timing of entry, but rely on the principle of 'reverse engineering' (see, also, Dutta 2006). We also consider the shift in policy to a stronger product patent regime in India to be exogenous to the particular industry we study, notwithstanding the flexibility in TRIPS implementation (Kapczynski 2009). We closely follow the prior literature on first-mover advantages in developing our estimation strategy, as described below.

4.1 Estimating First-Mover Advantages

First, we estimate the following equation:

$$\log(Revenue_{ijt}) = \alpha\, Entry\_Order_{ij} + \beta\, Entry\_Order_{ij} * Policy_t + \boldsymbol{\gamma X} + \sum_{j=1}^{120} \theta_j MARKET_j + \sum_{t=1}^{156} \kappa_t MONTH_t + \sum_{l=1}^{120} \sum_{n=1}^{13} \sigma_{l,n} MARKET_l * YEAR_n + \epsilon_{ijt}$$

where $\log(Revenue_{ijt})$ refers to revenue generated by firm i in market j in month t. The key variables of interest are $Entry\_Order_{ij}$ and $Policy_t$, which represent, respectively, the time-invariant rank order of entry of firm i in market j and the shift in product patent regime in India beginning in January 2005 (the measure is set to zero if t is earlier than January 2005 and one otherwise). The vector $\boldsymbol{X}$ includes several variables that control for firm capabilities and market structure: Firm Age in a market in a month; Firm Scope in the industry in a month; Firm Type (MNC or Not); Number of Firms in a market in a month; Number of Substitute Markets for a market in a month; and Number of Presentation Forms (see, for a description of variables, Table A1). The specification also includes market, month, year, and

market-specific year fixed-effects to soak up any other factors that uniquely affect all firms over time or firms in particular markets over time.

The error term in the specification includes firm-specific time-invariant unobservables, where $\epsilon_{ijt} = c_{ij} + u_{ijt}$. Our method of estimation is generalized least squares (GLS) for random-effects regression, and standard errors are clustered at the firm-level. We cannot use firm fixed-effects, as time-invariant variables, including $Entry\_Order$, will drop out of the estimation. However, if c_{ij} are correlated with $\boldsymbol{X}$, then the coefficient estimates of the random-effects regression will be biased. Hence, we employ fixed-effects regression as a robustness check and estimate β although $Entry\_Order$ drops out of the estimation and we cannot estimate α.

In our specification, $\alpha < 0$ would reflect the presence of first-mover advantages, as later entrants with a higher measure of $Entry\_Order$ have lower monthly market revenues. The net effect of entry order after the policy shift is given by $(\alpha + \beta)$, compared to α before. Consequently, $\alpha < 0$ and $\beta > 0$ would reflect lesser forgone revenue due to later entry after the shift in policy and, thus, reflect an erosion of the first-mover advantage.

4.2 Endogeneity of Entry Order

4.2.1 Procedure based on Garen (1984)

The endogeneity of entry order arises from firms choosing when to enter a new market, based on factors such as their prior experience in the market. Unless these factors are controlled for, the coefficient estimate of $Entry\_Order$ will be correlated with the error term, leading to a bias. To address this selection bias, we implement a suitable selection procedure. If the outcome, $Entry\_Order$, is ordered and if the number of such choices is small, an ordered probit model can be used for the first stage of the selection model. However, if $Entry\_Order$ can take on large values (in our case, $Entry\_Order$ has a mean of 18.37, median of 13, standard deviation of 18.57, and ranges from one to 92), then the ordered probit estimation becomes intractable.[4] Dutta (2006) adopts the procedure developed in Garen (1984), which is described in greater detail in Supplementary Note A1 in the Appendix (see, also, Wooldridge 2010, pg. 145).

In the first stage, the endogenous regressor z (in our case $Entry\_Order$) is regressed on observables such as firm type, prior experience in the ATC 3-digit therapeutic area, and fixed-effects for therapeutic areas (corresponding to the ATC 3-digit level) using OLS estimation. We use the ATC 3-digit and not the ATC 4-digit market experience because we are modeling entry into ATC 4-digit markets using related prior experience before entry (see, for the broader literature on related entry, Helfat and Lieberman 2002). In the regression, the part of the variation in z that is correlated with firm

[4] Ordered-probit-based Heckman selection procedure in STATA, oheckman, becomes intractable with more than 30 choices of the endogenous regressor and cannot be used in our context.

and market characteristics prior to entry is captured, and the part of z uncorrelated with these observables is isolated in the regression residuals. The first-stage equation is:

$$z = \beta_0 + \beta_1 MNC + \beta_2 Prior\_ATC\_3\_Experience + \sum_{k=1}^{22} ATC\_3\_Therapeutic\_Area_k + \eta$$

The estimates of the residuals from the first stage, $\hat{\eta}$, are used to estimate the following second-stage equation:

$$y = \alpha_0 + \alpha_1 x + \alpha_2 z + \alpha_3 x^2 + \alpha_4 z^2 + \alpha_5 x \cdot z + \gamma_1 \hat{\eta} + \gamma_2 \hat{\eta} \cdot z + \epsilon,$$

where y is $\log(Revenue)$, x denotes explanatory variable(s), and ϵ is the error term.

4.2.2 Instrumental Variables Approach

As an alternative to Garen (1984), we correct for the endogeneity of entry order using an instrumental variables approach (Wooldridge 2010). We instrument for the entry order z_{ij} of firm i in market j by the average of entry orders of the same firm in all its other markets $\overline{z_{iJ-}}$. We expect entry orders of a firm to be correlated across markets, satisfying the relevance condition $Cov\left(\overline{z_{iJ-}}, z_{ij}\right) \neq 0$, which is supported in our data. But we do not expect a firm's average entry order in all other markets to explain sales in the focal market, satisfying the exogeneity condition $Cov\left(\overline{z_{iJ-}}, u\right) = 0$.

4.2.3 Hausman-Taylor Approach

We also employ Hausman-Talor approach to address endogeneity of the timing of entry as well as the position of entry (or the choice of the number of presentation forms upon entry). As Wooldridge (2010, pg. 358) notes, the key feature of these models is the availability of instrumental variables from within the model. Intuitively, Hausman-Taylor approach recognizes that fixed-effects estimator is a type of instrumental variables estimator with $(x_i - \bar{x})$ as an instrument for x_i.

5 Data

Our data are obtained from IMS Health in India, which collects proprietary data on total units and sales (excluding those to hospitals and long-term care facilities). The data include all cardiovascular, anti-coagulant and oral anti-diabetic products on a monthly basis from 1999 to 2011.[5] There are several reasons for our choice of these drugs, the time period, and the context. First, these therapeutic areas represent a substantial part (more than 15 percent) of sales in the Indian pharmaceutical industry. Second, they represent the fastest- growing 'life-style' markets in which new

[5] Our dataset comprises oral anti-diabetic drugs (at the ATC 3-digit level A10B), anti-coagulants (at the ATC 3-digit level B01A) and 22 ATC 3-digit markets for cardiovascular drugs (between C01 to C10 at the ATC 2-digit level). Markets in our specification were defined at a finer level of disaggregation—universally at the ATC-4 digit level. There were 36, 25 and 147 ATC-4 digit level sub-therapeutic markets under the overarching classification of ATC A10B, B01A and C, respectively. Examples of markets in our study include: oral anti-diabetic A10B1 Glibenclamide; anticoagulant B01A2 Ticlopidine; and betablocker C01E1 Atenolol. Our data are not disaggregated at the ATC 5-digit level, which corresponds to true bioequivalence.

drugs are more likely to be introduced. Third, our period of study begins when IMS began collecting monthly data in India in 1999 (as opposed to annually in previous years) and allows for estimating first-mover advantages six years before the policy shift and seven years after.

We observe monthly revenues of each drug by a census of (major) Indian firms for an unusually long period of 156 months. The data are disaggregated at the level of individual dosages (presentation forms) for each drug a firm produces each month, which we aggregate monthly in each market. The data include both single-molecule and combination molecule markets.

Descriptive statistics are shown in Table 1—the two panels correspond to the two subsamples on which we run regressions. The top panel includes all observations of all markets created during 1999-2011. The bottom panel contains all observations for previously existing markets as of January 1999 during 1999-2011. The correlations among variables are shown in Table 2 for both subsamples of newly created and pre-existing markets.

The data contain 206 markets, 272 manufacturers, and 156 months from January 1999 to December 2011. Among them, 120 markets were created after January 1999, allowing us to construct $Entry\_Order$ for each participating firm. For the 86 pre-existing markets, we cannot determine the entry order of incumbents as of January 1999, and they are all assigned a rank of one. All subsequent entrants to the preexisting markets are assigned higher entry-order ranks based on the timing of their entry in each market afterwards.

6 Results

6.1 First-Mover Advantage

We estimate the extent of first-mover advantages for the newly created markets during 1999-2011. The coefficient estimates for newly created markets are obtained based on various estimation strategies: GLS random-effects in specification (1); fixed-effects in (2); Hausman-Taylor estimator in (3); random-effects instrumental variable approach in (4); and the estimator based on Garen (1984) in (5).

The results are shown in Table 3. In specification (1), the coefficient estimate of $Entry\_Order$ is negative and significant, reflecting that there are strong first-mover advantages in the Indian pharmaceutical industry, consistent with Hypothesis 1. A unit increase in the entry order (each later entrant) is associated with a 7.3-percent decline in the monthly revenue in the subsample of new markets created during 1999-2011. We interact $Entry\_Order$ with $Policy$ to test Hypothesis 2. The coefficient estimate of the interacted variable in specification (3) is 0.039, which implies that the net effect of entry order after the policy shift is $-0.076 + 0.039 = -0.037$. It reflects a 3.6-percent decline in monthly revenue after the policy shift and an erosion of first-mover advantages after 2005 by nearly half compared to before, consistent with Hypothesis 2.

It may be argued that the random-effects estimation strategy leads to biased estimates because firm-fixed effects are correlated with a firm's choice of timing of entry, entry scope, and presentation-form scope. As outlined in section 4, we consider four alternative strategies to address such a concern.

First, we run fixed-effects regression, where the interaction term between $Entry\_Order$ and $Policy$ is estimated, although $Entry\_Order$ is not. The coefficient estimate of $Entry\_Order * Policy$, shown in specification (2) of Table 3, is similar in magnitude to that in specification (1) and reflects an erosion of first-mover advantage after the policy shift, consistent with Hypothesis 2.

Next, we employ an intermediate estimation strategy between fixed-effects and random-effects regression, which is the Hausman-Taylor approach. Boulding and Christen (2003) introduce this methodology to the first-mover advantage literature (see, for more details, Verbeek 2012). We treat $Entry\_Order$, $Firm\_Scope$, and $N\_of\_Presentation\_Forms$ as endogenous variables that are likely to be correlated with the firm fixed-effect leading to a bias in estimating the effects of entry order and policy shift. The Hausman-Taylor approach is a 'fixed-effects-type' estimator in which $(x_i - \bar{x})$ is used to instrument for these endogenous variables x_i. The coefficient estimates, shown in specification (3), of $Entry\_Order$ and $Entry\_Order * Policy$ are similar to those in specification (1) in terms of the sign and magnitude.

In specification (4), the results of the random-effects instrumental variables approach are presented. The proposed instrument, the average entry order in other markets of the firm, is correlated with the entry order in a given market with a correlation coefficient of 0.56, making it a relevant instrument. The coefficient estimates remain unchanged from previous estimation strategies and are consistent with Hypothesis 2. We further estimate the selection equation developed in section 4.2. The results are shown in specification (5) of Table 3 for the subsample of all newly created markets during 1999-2011. The coefficient estimate of $Entry\ \_Order$ is larger compared to previous specifications, as specification (5) includes the quadratic term of $Entry\_Order$, which is not present in other specifications. The coefficient estimate of the interaction between $Entry\_Order$ and $Policy$ is positive and significant at the 0.1 level, reflecting lower first-mover advantages under a stronger product patent regime. The coefficient estimate of $N\ of\ Firms$ is now negative, as expected, although not statistically significant. In addition, being an MNC has a positive and significant impact on revenues, and older firms in the market and those with broader scope have relatively higher revenues. Not surprisingly, more presentation forms are also associated with greater revenues.

6.2 Analysis of Pre-existing Markets

We extend these analyses to pre-existing markets and include an additional variable, $Incumbent\_Dummy$, to control for factors that uniquely affect incumbents. The results of the regression are shown in Table 4. The coefficient estimate of $Entry\_Order$ is negative in specifications (1) and (2), reflecting the presence of first-mover advantages even in pre-existing markets. A unit increase in entry order is associated with a 4.3-percent decrease in the monthly revenue, according to specification (1). However, after the policy shift, a unit increase in entry order is associated with a 2.8-percent decline in the monthly revenue, which amounts to a one-third decline in the extent of first-mover advantages post-2005.

The coefficient estimates obtained using other estimation strategies are similar in sign and magnitude to that obtained in specification (1), except for specification (5). However, because of the inclusion of various second-order terms in specification (5), interpreting the coefficient estimates is difficult. Nonetheless, the coefficient estimate of the interaction between $Entry\_Order$ and $Policy$ is positive and significant at the 0.1 level, consistent with our argument. The extent of erosion of first-mover advantages in the pre-existing markets is lowered by a third after the policy shift, compared to a 50-percent decline in the newly created markets. Hence, consistent with Hypothesis 3, the new product patent regime has less impact on pre-existing markets than on newly created markets. The coefficient estimate of $Incumbent\_Dummy$ is positive and significant in all the specifications, reflecting higher revenues for incumbents compared to later entrants, even in pre-existing markets.

6.3 Survival Analyses

We test the robustness of our results with the hazard rate of exit from a market as an alternative dependent variable to monthly revenue. We estimate the hazard rate of exit with parametric assumptions concerning the shape of the baseline hazard. The results with the Weibull distribution assumption are shown in Table 5. The explanatory variables, described in previous sections, have largely the expected signs. Multinationals, firms present in more markets, and those offering more presentation forms have a lower hazard of exit, as reflected by their corresponding coefficient estimates in specifications for both newly created and pre-existing markets.

The coefficient estimate of $Entry\_Order$ in specifications (1) and (2), corresponding newly created and pre-existing markets respectively, are positive and significant at the 0.05 level, reflecting that the later entrants with a higher entry order have a higher hazard of exit from the market. The size of the effect is 4.7-percent $(= exp(0.046) - 1)$ in newly created markets and 2.9-percent in pre-existing markets. The coefficient estimate of the interaction term between $Entry\_Order$ and $Policy$ is negative and significant at the 0.05 level in specification (1), reflecting that after 2005, later entrants have a lower hazard of exit from the market by 1.9 percent, which is consistent with Hypothesis 2. The coefficient estimate of the same interaction term in specification (2) has the expected sign but it is not statistically significant, reflecting that for firms in pre-existing markets, the policy shift has no significant effect on the hazard of exit, which is consistent with Hypothesis 3.

6.4 Additional Robustness Analyses

One plausible reason for the erosion of first-mover advantage is the potential existence of second-mover advantages for MNCs after 2005. In theory, firms can choose to enter later with a higher quality, vertically differentiated product and gain second-mover advantages (Dutta et al. 1995, Hoppe and Lehmann-Grube 2001). If the pharmaceuticals produced by MNCs are perceived to be of a higher quality, then their later entry into markets after 2005 patent reforms increases the extent of MNC second-mover advantages, which we may interpret as the erosion of first-mover advantages for the domestic firms. We test this alternative explanation by excluding MNCs from the sample and re-estimating the regressions. The results, shown in Table A2, confirm our hypotheses 1, 2, and 3 even

when MNCs are excluded from the sample. Hence, our results are not driven by the presence of any second-mover advantages for the MNCs.

Our results remain broadly unchanged at the level of individual therapeutic areas reflecting robustness to alternative market definitions. We report results by restricting the sample to each of the two large ATC 3-digit therapeutic areas—oral anti-diabetics, and statins—and the results remain qualitatively similar (see Table A3). In unreported regressions, we found our results to be robust to the inclusion of marketing expenses for a subgroup of 52 firms that reported financial data in the Center for Monitoring Indian Economy database.

Notwithstanding our extensive robustness checks, it may be argued that an omitted variable correlated with the policy shift drives our results. In such a case, the omitted variable that one proposes must explain not only the erosion of first-mover advantages after 2005, but also the differential erosion of first-mover and survival advantages in newly created and pre-existing markets after 2005. Naturally, any proposed omitted variable must not be collinear with firm-specific, time-specific, market-specific, or market-specific time-varying factors as we control for them in our regressions along with other observables.

6.5 Future Extensions

Our identification strategy relies on comparing pre- and post-treatment effects. Subsequent research can exploit molecule-level variation in the enforcement of patents to estimate the differential erosion of non-patent-based first-mover advantages in the Indian pharmaceutical industry and elsewhere. In particular, subsequent research can exploit the variation in the intensity of patenting across pharmaceutical markets induced by regulations such as price controls (markets in our dataset are not subject to price controls). Subsequent research can also exploit alternative 'medicines', in which patenting is rare, as a control group. We, however, do not have access to such data.

Our operationalization of the treatment effect was binary—zero until December 2004 and one beginning January 2005. Although our empirical approach treats all entry post-2005 as "treated" by patents, the change in 2005 did not retroactively grant patent protection. Therefore, our operationalization of the policy change is imperfect. An alternative measurement strategy is to use a time-varying international index of patent protection to better reflect the underlying heterogeneity in treatment effect over time. However, Park's (2008) compilation of the patent index is quinquennial and extends only until 2005. Naturally, our results are robust to using Park's index for 2000 and 2005, which are 2.27 and 3.76 respectively, instead of the binary variable measuring the adoption of TRIPS in India. An additional alternative measure of the strength of patent protection in India is the intensity of patent litigation in India relative to the world. The Indian Intellectual Property Appellate Board (IPAB) was created in September 2003 to consolidate cases of litigation concerning patents and trademarks. The number of cases decided at the IPAB increased by our count from 86 in 2005 to 242 in 2011. These trends are consistent with a general strengthening of the patent regime in India. Our analyses control for such other channels of strengthening patent protection through time dummies and still yield robust

evidence of erosion of first-mover advantages. Nonetheless, it may be possible that other TRIPS-related changes would affect first-mover advantages, such as those related to trademarks.

While the prior literature suggests that consumers perceive differences between branded and generic versions of a drug, or that physicians bias decision-making in terms of drug purchases, such effects are likely to be secondary in the Indian context, and we do not expect them to undermine the evidence we presented for several reasons. The erosion of first-mover advantages of pharmaceutical firms in India is not expected to be driven by differences in reputation relative to multinationals because Indian firms have built strong reputations over the years, not only in India but also around the world. We also control for the MNC effect in all our regressions. In addition, Indian generics are also branded, and branding alone may not explain the post-2005 erosion of first-mover advantages, notwithstanding our controls for firm-fixed effects. Physicians' prescribing habits may have been influenced by the strategies of the original innovators. We do not have data to investigate this aspect since such data are not collected at the molecule-level in India. However, we do include market-year fixed-effects in our estimations that should absorb such changes to a large extent.

Finally, we do not have data on the cost structure of firms in the Indian pharmaceutical industry to estimate the impact of TRIPS-induced imitation lags on the rate of decline of production costs due to learning-by-doing as a mechanism that leads to the erosion of first-mover advantages. An examination of the relative importance of alternative isolating mechanisms pre- and post-TRIPS remains beyond the scope of this study.

7 Conclusion

We investigate the impact of the strengthening of patent protection in India on the extent of non-patent-based first-mover advantages present in its pharmaceutical industry, which is predominantly composed of generic manufacturers. We document persistent first-mover advantages and find robust evidence of their erosion due to the strengthening of the patent regime in India in 2005, consistent with our hypotheses. The extent of erosion is greater in newly pioneered markets than in pre-existing markets in which patents are expected to be less effective after 2005. Our results are robust to selection bias, alternative dependent variables, market definitions, estimation strategies and additional robustness analyses.

We incorporate the technology-management and industrial-organization perspectives into the first-mover advantage literature by highlighting the role of product patent protection. We focus on the dynamic dimension of the first-mover advantages by estimating them in newly created markets over a period of several years and also the change in the extent of first-mover advantages in narrowly defined markets due to regulatory changes. Our study is, to our knowledge, among the first to empirically address the 'macro' gap in the first-mover advantage literature, as described by Suarez and Lanzolla (2007).

The Indian generics industry has been undergoing a transformation towards product R&D and obtaining patents. The investment in R&D has gone up from two percent in the early 1990s to nearly

seven percent in recent years. India has also been producing a large number of well-trained science and engineering graduates. Scherer (2005) hopes that such comparative advantages India possesses today, relative to Italy in 1978, may mitigate the unintended consequences of the strengthening of the product patent regime in India, although R&D operations of domestic Indian firms still remain relatively small to develop new products.

Several other developing countries, such as China and Brazil, have begun to adopt similar intellectual-property-protection policies (Goldberg 2010). Kyle and McGahan (2009) argue that, since TRIPS, investments in pharmaceutical R&D have not increased in developing and less-developed countries, and they contemplate whether there are better alternatives to patents as incentives for innovation. Qian (2007) arrives at similar conclusions concerning the extent of domestic innovation in a cross-country study of the adoption of pharmaceutical patent protection during 1978-2002. Our study highlights the unintended consequences of product patenting after TRIPS in a setting where there is little history of patenting (at least as far as pharmaceutical products are concerned). We provide a cautionary note to the domestic generic manufacturers and the policy makers to think about how they can mitigate the erosion of first-mover advantages.

Our work has exploited the adoption of TRIPS in India; a future study can extend the work to include the adoption of TRIPS in various developing countries, include developed countries and non-adopters as control samples and estimate the extent of erosion of first-mover advantages for the domestic firms using a differences-in-differences estimation strategy. A future study can also exploit cross-national data to explain the differential timing of entry of a given firm in a given molecule-market across countries and the corresponding differences in the extent of order-of-entry effects.

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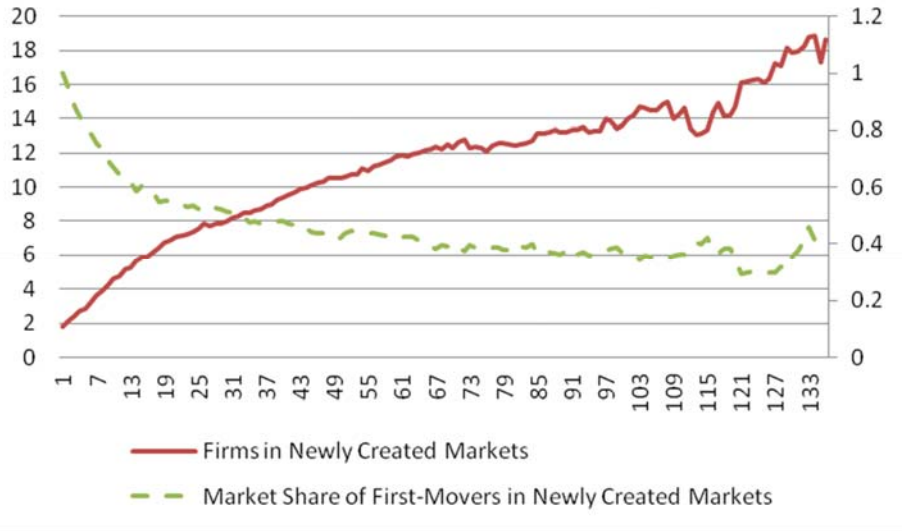
Figures and Tables

Figure 1: Persistent first-mover advantages

Panel (a). Newly Created Markets during 1999-2011



Panel (b). Pre-existing Markets on January 1999

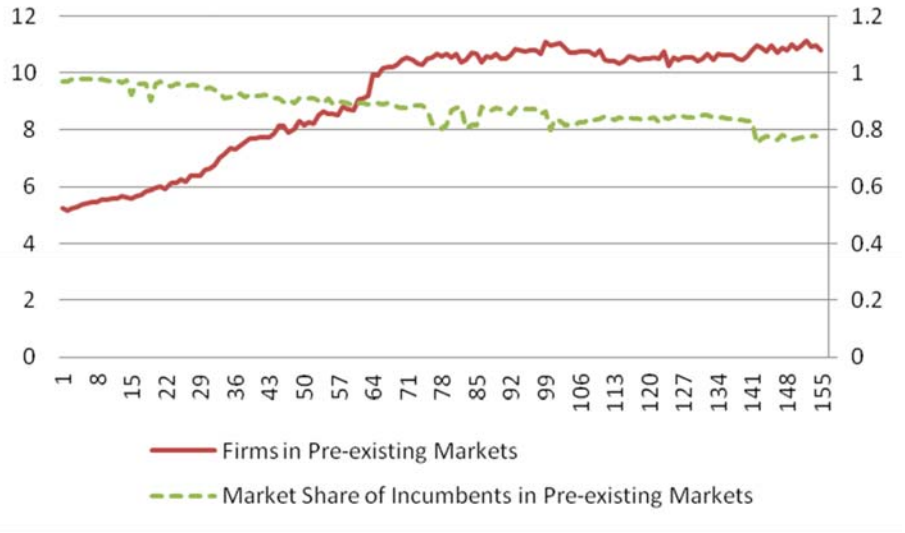


FIGURE 1 NOTES: We plot the average number of producers across markets of the same age (measured in months, starting from the first month of production) on the left Y-axis and the market share of "first-movers" on the right Y-axis. The X-axis measures the number of months, starting from the creation of the market. Panel (a) contains the trends for newly created markets during 1999-2011 and Panel (b) for pre-existing markets.

Figure 2: First-mover advantages during 1999-2004 and 2005-2009

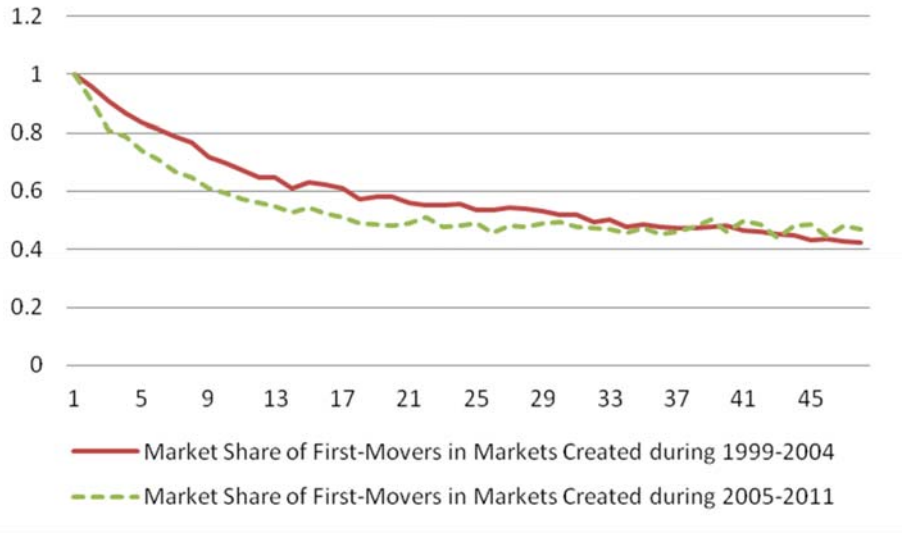


FIGURE 2 NOTES: We plot the average market share of "first-movers" in markets created during 1999-2004 and 2005-2011 on the y-axis for the first 48 months since the launch of each market in India as measured on the x-axis. The figure reflects a lower level of first-mover advantages in the latter period. We restrict the analysis to markets in which only one entrant was the first-mover. Hence, the difference in the two trends cannot be explained away by the difference in the average number of first-movers in the two periods.

Figure 3: Theoretical Framework for First-Mover Advantages

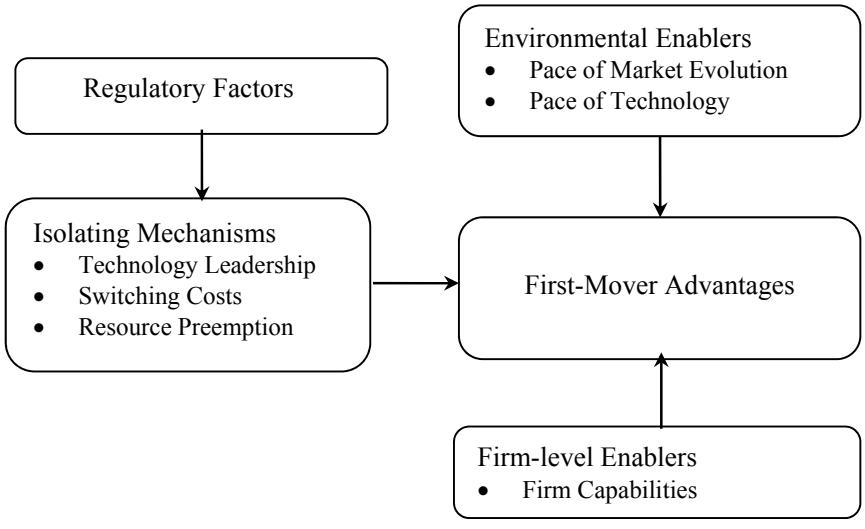


FIGURE 3 NOTES: The figure, an extension of the theoretical framework in Suarez and Lanzolla (2007), highlights the role of regulatory factors in shaping technological leadership and determining the extent of first-mover advantages.

Table 1. Descriptive Statistics

Variable	N	Mean	Std. Dev.	Min	Max
	All Observations of Newly Created Markets during 1999-2011				
log (Monthly Revenue)	104764	-3.24	2.26	-13.63	2.57
Order of Entry	104764	15.95	15.97	1	92
MNC	104764	0.08	0.27	0	1
Firm Age in Market	104764	39.16	29.43	1	155
N of Substitute Molecules	104764	18.44	9.08	1	31
N of firms in Market	104764	25.20	17.23	1	65
Firm Scope	104764	34.21	21.57	1	84
N of Presentation Forms	104764	2.01	1.09	1	10
	All Observations of Preexisting Markets during 1999-2011				
log (Monthly Revenue)	113579	-3.56	2.61	-16.12	2.23
Order of Entry	113579	14.81	18.36	1	88
MNC	113579	0.09	0.29	0	1
Firm Age in Market	113579	55.81	40.21	1	156
N of Substitute Molecules	113579	14.09	9.12	1	31
N of firms in Market	113579	24.04	17.82	1	63
Firm Scope	113579	23.84	20.39	1	84
N of Presentation Forms	113579	2.39	1.54	1	11
Incumbent Dummy	113579	0.43	0.49	0	1

TABLE 1 NOTES: The table contains four panels corresponding to subsamples on which we run regressions.

Table 2. Pairwise Correlations

Variable Name	#	1	2	3	4	5	6	7	8
		All Observations of Newly Created Markets during 1999-2011							
log (Monthly Revenue)	1	1.00							
Order of Entry	2	-0.19	1.00						
MNC	3	0.09	0.06	1.00					
Firm Age in Market	4	0.22	-0.13	-0.05	1.00				
N of Substitute Molecules	5	0.03	0.14	0.02	0.12	1.00			
N of firms in Market	6	0.10	0.70	-0.03	0.23	0.21	1.00		
Firm Scope	7	0.30	-0.32	-0.11	0.25	0.02	-0.17	1.00	
N of Presentation Forms	8	0.35	0.00	0.04	0.20	0.01	0.23	0.11	1.00
		All Observations of Pre-existing Markets during 1999-2011							
log (Monthly Revenue)	1	1.00							
Order of Entry	2	-0.29	1.00						
MNC	3	0.16	-0.04	1.00					
Firm Age in Market	4	0.17	-0.23	-0.01	1.00				
N of Substitute Molecules	5	-0.08	0.26	-0.08	0.19	1.00			
N of firms in Market	6	-0.04	0.62	-0.10	0.14	0.33	1.00		
Firm Scope	7	0.25	-0.12	-0.13	0.32	0.09	-0.04	1.00	
N of Presentation Forms	8	0.37	-0.16	0.06	0.19	-0.21	0.06	0.21	1.00
Incumbent_Dummy	9	0.32	-0.65	0.10	0.28	-0.26	-0.25	0.02	0.20

TABLE 2 NOTES: The table contains correlation coefficients.

Table 3: Estimates of the erosion of first-mover advantage in pioneering markets

D.V.= log(Monthly Revenue)	(1) RE	(2) FE	(3) HT	(4) REIV	(5) GAREN
Entry_Order	-0.076**		-0.076**	-0.077**	-0.127**
	[0.0092]		[0.0085]	[0.0047]	[0.0461]
Entry_Order*Policy	0.039**	0.038**	0.038**	0.039**	0.023**
	[0.0076]	[0.0077]	[0.0013]	[0.0013]	[0.0086]
MNC	0.226	0.045	0.099*	0.211**	0.929*
	[0.4857]	[0.5364]	[0.0399]	[0.0382]	[0.4014]
Firm_Age_Market	0.007	0.008*	0.006	0.007**	0.027**
	[0.0044]	[0.0033]	[0.0044]	[0.0024]	[0.0069]
N_of_Substitute_Molecules	0.020**	0.020**	0.020**	0.019*	0.031
	[0.0067]	[0.0067]	[0.0075]	[0.0076]	[0.0243]
N_of_Firms	0.024**	0.025**	0.024**	0.025**	-0.019
	[0.0040]	[0.0039]	[0.0023]	[0.0023]	[0.0135]
Firm_Scope	0.035**	0.036**	0.036**	0.034**	0.047**
	[0.0058]	[0.0066]	[0.0007]	[0.0007]	[0.0130]
N_of_Presentation_Forms	0.222**	0.198**	0.201**	0.214**	0.976**
	[0.0435]	[0.0423]	[0.0081]	[0.0081]	[0.1272]
Entry_Order_Sq					0.003**
					[0.0007]
Residuals					-0.043
					[0.0440]
Residual*Entry_Order					-0.002**
					[0.0007]
Firm_Age_Market_Sq					-0.000**
					[0.0000]
N_of_Substitute_Molecules_Sq					0.000
					[0.0005]
N_of_Firms_Sq					0.000
					[0.0003]
Firm_Scope_Sq					-0.000*
					[0.0001]
Presentation_Forms_Sq					-0.051**
					[0.0129]
MNC*Entry_order					-0.004
					[0.0117]
Firm_Age_Market*Entry_Order					0.000
					[0.0002]
Substitute_Molecules*Entry_Order					0.000
					[0.0004]
N_of_Firms*Entry_Order					0.001*
					[0.0005]
Firm_Scope*Entry_Order					0.001**
					[0.0002]

N_of_Presentation_Forms* Entry_Order					0.000
					[0.0021]
Constant	-6.732**	-7.965**	-6.696**	-6.630**	-8.643**
	[0.6493]	[0.3683]	[1.0772]	[1.0430]	[1.0872]
Observations	104,764	104,764	104,764	103,622	104,764
N of Firm-Markets	1,950	1,950	1,950	1,924	
Market FE	YES	YES	YES	YES	YES
Month FE	YES	YES	YES	YES	YES
Year FE	YES	YES	YES	YES	YES
Market*Year FE	YES	YES	YES	YES	YES
N_of_Clusters	172	172			172
R2_Overall	0.333	0.0674			
R2_Between	0.373	0.034			
R2_Within	0.285	0.286			
R2_Adjusted					0.448
Chi2			41549	42337	

Firm-clustered standard errors in brackets; ** p<0.01, * <0.05, + p<0.1

TABLE 3 NOTES: Method of estimation is GLS with random-effects (RE) in Specification (1); fixed-effects (FE) in (2); Hausman-Taylor estimator (HT) in (3); random-effects instrumental variables estimator (REIV) in (4); and selection à la Garen (1984) in specification (5). The dependent variable is $\log(Revenue)$. All specifications draw from the subsample of newly created markets during 1999-2011, which excludes observations of markets created during or before January 1999. A number of coefficient estimates of the second-order approximation variables included in the selection model are (5), not unusually, close to zero in magnitude. Market, month, year, and market-specific year fixed-effects are included and standard errors are clustered at the firm-level for specifications (1), (2), and (5). All estimations are performed using routines in STATA version 12.

Table 4: Estimates of the erosion of first-mover advantage in pre-existing markets

D.V.= log(Monthly Revenue)	(1) RE	(2) FE	(3) HT	(4) REIV	(5) GAREN
Entry_Order	-0.044**		-0.044**	-0.041**	-0.06
	[0.0075]		[0.0105]	[0.0044]	[0.0422]
Entry_Order*Policy	0.015**	0.014**	0.015**	0.015**	0.008+
	[0.0039]	[0.0039]	[0.0007]	[0.0007]	[0.0049]
Incumbent_Dummy	0.985**		1.024**	1.065**	1.084**
	[0.2332]		[0.3417]	[0.1419]	[0.2410]
MNC	0.767**	0.594*	0.627**	0.765**	1.777**
	[0.2252]	[0.2959]	[0.0619]	[0.0598]	[0.2743]
Firm_Age_Market	0.004	-0.018**	0.003	0.004+	0.018**
	[0.0037]	[0.0047]	[0.0046]	[0.0019]	[0.0055]
N_of_Substitute_Molecules	0.006	0.006	0.006	0.003	0.007
	[0.0060]	[0.0060]	[0.0069]	[0.0070]	[0.0190]
N_of_Firms	-0.014**	-0.012**	-0.013**	-0.011**	-0.167**
	[0.0034]	[0.0033]	[0.0028]	[0.0029]	[0.0156]
Firm_Scope	0.025**	0.025**	0.025**	0.024**	0.067**
	[0.0053]	[0.0054]	[0.0005]	[0.0005]	[0.0122]
N_of_Presentation_Forms	0.178**	0.164**	0.166**	0.167**	0.977**
	[0.0284]	[0.0283]	[0.0052]	[0.0053]	[0.1036]
Additional Selection Variables					YES
Constant	-4.743**	-5.100**	-4.806**	-4.526**	-5.239**
	[0.6031]	[0.1772]	[0.8543]	[0.3723]	[1.0376]
Observations	113,579	113,579	113,579	109,539	113,579
N of Firm-Markets	1,538	1,538	1,538	1,470	
Market FE	YES	YES	YES	YES	YES
Month FE	YES	YES	YES	YES	YES
Year FE	YES	YES	YES	YES	YES
Market*Year FE	YES	YES	YES	YES	YES
N_of_Clusters	230	230			230
R2_Overall	0.332	0.0187			
R2_Between	0.37	0.00945			
R2_Within	0.215	0.215			
R2_Adjusted					0.463
Chi2			30902	31900	

Firm-clustered standard errors in brackets; ** p<0.01, * <0.05, + p<0.1

TABLE 4 NOTES: Specifications use a subsample of observations of all pre-existing markets (as of January 1999) during 1999-2011. Incumbent_Dummy is an additional variable included in specifications (1) through (5). Other second-order approximation terms in specification (5) are those present in specification (5) of Table 3. See notes for Table 3 for additional details.

Table 5: Estimates of order of entry effects on firm survival

D.V.=Hazard Rate of Exit	(1) Newly Created Markets	(2) Pre-Existing Markets
Entry_Order	0.046**	0.029*
	[0.0144]	[0.0118]
Entry_Order*Policy	-0.027*	-0.011
	[0.0117]	[0.0108]
MNC	-0.339	-0.045
	[0.2366]	[0.1916]
Firm_Age_Market	-0.004	0.000
	[0.0045]	[0.0032]
N_of_Substitute_Molecules	-0.009*	-0.017**
	[0.0042]	[0.0050]
N_of_Firms	-0.036**	-0.029**
	[0.0082]	[0.0058]
Firm_Scope	-0.018**	-0.005
	[0.0050]	[0.0049]
N_of_Presentation_Forms	-0.346**	-0.287**
	[0.0659]	[0.0683]
Incumbent_Dummy		-0.346*
		[0.1525]
Constant	-5.461**	-4.863**
	[0.4544]	[0.4685]
ln_p	0.408**	0.208*
	[0.0980]	[0.1017]
Observations	104,764	113,579
N of Subjects	1950	1538
N of Failures	530	700
N of Clusters	172	230
Chi2	66.52	58.38

Firm-clustered standard errors in brackets; ** p<0.01, * <0.05, + p<0.1

TABLE 6 NOTES: See notes for Table 3. The method of estimation is maximum likelihood for a hazard model with Weibull distribution. Specification (1) includes a subsample of observations for markets newly created during 1999-2011, and specification (2) includes a subsample of observations for all pre-existing markets (as of January 1999) during 1999-2011. See Table 3 for additional notes.

Supplementary Material

Table A1. Description of Variables

Variable	Description
Log(Monthly Revenue)	The variable measures the log of the aggregate monthly revenue a firm earns in an ATC 4-digit market in a given month across all presentation forms (dosage forms).
Entry_Order	Entry order is set to one for the group of entrants entering during the first month of the market in India. The group of firms entering in the next time period is assigned two, and so on. A higher entry order refers to later entry.
Policy	The policy variable is a dummy variable set to zero for all months during 1999-2004 (inclusive) and one afterwards.
Incumbent_Dummy	The variable measures all incumbents present in the market on January 1999. The variable is set to one if a firm was present in the industry on January 1999 and zero otherwise.
MNC	This dummy variable indicates whether a firm is a multinational corporation or not. A measure of one represents MNC and zero otherwise.
Firm_Age_Market	The variable measures the age of a firm in an ATC 4-digit market in a given month
N of Substitute Molecules	The variable measures the number of other molecules present in the ATC 3-digit level that can be considered substitutes in a given month
N of Firms	The variable measures the number of firms in an ATC 4-digit market in a given month
Firm Scope	The variable measures the number of other ATC 4-digit markets a firm is present in a given month
N of Presentation Forms	The variable measures the number of presentation forms a firm offers in a given month in a given ATC 4-digit market

Table A2: First-mover advantage before and after TRIPS after excluding MNCs

D.V.=log(Monthly Revenue)	(1) Newly Created Markets	(2) Pre-Existing Markets
Entry_Order	-0.076**	-0.043**
	[0.0093]	[0.0077]
Entry_Order*Policy	0.038**	0.018**
	[0.0073]	[0.0038]
Firm_Age_Market	0.012**	0.009**
	[0.0041]	[0.0035]
N_of_Substitute_Molecules	0.020**	0.006
	[0.0071]	[0.0061]
N_of_Firms	0.024**	-0.013**
	[0.0041]	[0.0035]
Firm_Scope	0.036**	0.025**
	[0.0061]	[0.0056]
N_of_Presentation_Forms	0.195**	0.181**
	[0.0424]	[0.0314]
Incumbent_Dummy		0.732**
		[0.2392]
Constant	-7.262**	-5.092**
	[0.4776]	[0.5741]
Observations	96,745	103,085
N of Firm-Markets	1,766	1,388
Market FE	YES	YES
Month FE	YES	YES
Year FE	YES	YES
Market*Year FE	YES	YES
N_of_Clusters	152	209
R2_Overall	0.375	0.348
R2_Between	0.414	0.398
R2_Within	0.295	0.224

Firm-clustered standard errors in brackets; ** p<0.01, * <0.05, + p<0.1

TABLE A2 NOTES: The method of estimation is maximum likelihood for random-effects GLS. The subsamples are drawn from the overall sample of newly created as well as pre-existing markets by excluding the observations of MNCs. See Table 3 for additional notes.

Table A3: First-mover advantage before and after TRIPS in therapeutic markets

	ORALANTIDIABETICS		STATINS	
	(1)	(2)	(3)	(4)
D.V.= log(Monthly Revenue)	New	Preexisting	New	Preexisting
Entry_Order	-0.098**	-0.013	-0.056**	-0.109
	[0.0183]	[0.0171]	[0.0134]	[0.1488]
Entry_Order*Policy	0.050**	0.006	0.027**	0.025
	[0.0109]	[0.0066]	[0.0091]	[0.0424]
Incumbent_Dummy		1.855**		0.993
		[0.4392]		[1.2409]
MNC	0.137	1.226*	0.387	3.847**
	[0.3854]	[0.5010]	[0.5857]	[1.2666]
Firm_Age_Market	-0.004	0.013	-0.008	-0.015
	[0.0116]	[0.0084]	[0.0071]	[0.0402]
N_of_Substitute_Molecules	-0.144*	-0.317**	-0.554**	-0.313
	[0.0600]	[0.0876]	[0.0857]	[0.5078]
N_of_Firms	0.022**	-0.011+	0.049**	-0.094+
	[0.0055]	[0.0060]	[0.0088]	[0.0537]
Firm_Scope	0.041**	0.026**	0.054**	0.028
	[0.0075]	[0.0066]	[0.0087]	[0.0183]
N_of_Presentation_Forms	0.022	0.141*	0.298**	0.446
	[0.0315]	[0.0587]	[0.0987]	[0.3082]
Observations	30,044	27,573	17,953	3,350
N of Firm-Markets	504	347	341	52
Market FE	YES	YES	YES	YES
Month FE	YES	YES	YES	YES
Year FE	YES	YES	YES	YES
Market*Year FE	YES	YES	YES	YES
N_of_Clusters	100	125	110	43
R2_Overall	0.347	0.368	0.369	0.41
R2_Between	0.362	0.395	0.379	0.559
R2_Within	0.33	0.198	0.27	0.209

Firm-clustered standard errors in brackets; ** p<0.01, * <0.05, + p<0.1

TABLE A3 NOTES: The method of estimation is maximum likelihood for random-effects GLS. The subsamples are drawn from the overall sample of newly created as well as pre-existing markets for two large therapeutic areas—Oral Anti-diabetics (ATC A10B) and Statins (ATC C10A). See Table 3 for additional notes.

Supplementary Note A1: Selection Model by Garen (1984), based on Dutta (2006)

Suppose that y, the dependent variable, depends on x and choice z, which can take values from $1, \dots n$. This leads to a system of equations:

$$y_{1j} = a_1 + b_1 x_{1j} + \epsilon_{1j} \; for \; z = 1$$
$$y_{2j} = a_2 + b_2 x_{2j} + \epsilon_{2j} \; for \; z = 2$$
$$\vdots$$
$$y_{nj} = a_n + b_n x_{nj} + \epsilon_{nj} \; for \; z = n$$

where ϵ_{zn} represent unobserved heterogeneity for each choice of z. The second-order approximation of the above system of equations is

$$y = \alpha_0 + \alpha_1 x + \alpha_2 z + \alpha_3 x^2 + \alpha_4 z^2 + \alpha_5 x \cdot z + \epsilon + \phi \cdot z$$

Assume that $\epsilon_i \sim N(0, \sigma_\epsilon^2)$ and $\phi_i \sim N\left(0, \sigma_\phi^2\right)$ and $Cov(\epsilon, \phi) = \sigma_{\epsilon,\phi}$. The error component, $\epsilon + \phi \cdot z$, depends on z. Suppose that z depends on observables w such that

$$z_{jm} = \beta_0 + \beta_1 w_{jm} + \eta_{jm}$$

The conditional mean of the outcome variable is as follows:

$$\begin{aligned} E[y/\, x, z] &= \alpha_0 + \alpha_1 x + \alpha_2 z + \alpha_3 x^2 + \alpha_4 z^2 + \alpha_5 x \cdot z + E[\epsilon + \phi \cdot z/\, x, z] \\ &= \alpha_0 + \alpha_1 x + \alpha_2 z + \alpha_3 x^2 + \alpha_4 z^2 + \alpha_5 x \cdot z + E[\epsilon + \phi \cdot z/\, z = \beta_0 + \beta_1 w + \eta] \\ &= \alpha_0 + \alpha_1 x + \alpha_2 z + \alpha_3 x^2 + \alpha_4 z^2 + \alpha_5 x \cdot z + E[\epsilon + \phi \cdot z/\, \eta = z - \beta_0 - \beta_1 w] \end{aligned}$$

Garen (1984) shows,

$$E[\epsilon + \phi \cdot z/\, \eta = z - \beta_0 - \beta_1 w] = \frac{Cov(\epsilon, \eta)}{Var(\eta)} \cdot \eta + \frac{Cov(\phi, \eta)}{Var(\eta)} \cdot \eta \cdot z$$

The error term must be mean zero for unbiased estimation, but given that $Cov(\epsilon, \eta) \neq 0$ and $Cov(\phi, \eta) \neq 0$, we correct for endogeneity between the observables in both equations by estimating the following:

$$y = \alpha_0 + \alpha_1 x + \alpha_2 z + \alpha_3 x^2 + \alpha_4 z^2 + \alpha_5 x \cdot z + \gamma_1 \eta + \gamma_2 \eta \cdot z$$

Residuals from the OLS estimation of z_{jm}, $\hat{\eta}$ provide consistent estimates of η above, which is what we use in the main text.