Determinants for drug launches in pre-TRIPS India: A survival analysis approach

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Abstract:

There is a huge theoretical and empirical literature on the question of what determines the launch of products in markets. This paper analysis a specific case: drug launch in India. Usually drugs are launched in other countries before they are launched in India. Hence, data is available about the possible and actual launch time. We study the delay in launching a drug in India in order to examine the determinants for the launch decision. Survival analyses are used to investigate the delay of new drug launch in India for drugs launched in the German market during 1990-2004. The paper finds that global commercial success of a new drug, first mover advantage, and the threat of imposition of strong IPR system shortens delay. Innovativeness of a new drug, however, has no impact on delay. This has important policy implications that are discussed.

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Introduction:

In the medical sector the introduction of new products on the market is of strong political and social interest. On the one hand, governments try to secure with laws and regulations that new drugs are not introduced on the market before they are sufficiently tested. The Thalidomide tragedy has made us realise that new medical therapies are ambiguous blessings and the absence of adequate safety standards can, fatally, expose human beings to the threats of false claims and unintended consequences of new technologies. Recent studies have highlighted that in the drug market we find usually contestable claims about the appropriateness of a new technology by a profit seeking agent (Gold et al 2001) and call for an appropriate regulatory framework. The need for regulation is compounded by the fact that medicine falls into the category of *credence goods*, whose quality cannot be ascertained merely by consuming it (Nelson 1970).

On the other hand, in general, new drugs imply better treatment of illnesses. It is widely accepted that access to modern medical therapies have immensely contributed to the developmental catch up process of many less developed countries (Kremer 2002). A delay in the introduction of new medical therapy, therefore, can prove to be detrimental to economic development. Especially if a drug is already approved and available in an other country, it is socially preferable to introduce the drug in all countries. Nevertheless, there is sometimes quite a delay in such an introduction. This paper examines the factors that cause this delay for the case of India.

There is an extensive literature on the launch of new products. However, this literature focuses on the launch of products that are new to the world market, usually products that are technological advancements of the prior product. Furthermore, most of this literature is industry-specific.

Many studies on drug launch have revolved around one central question: to what extent do the various regulations on introducing new drugs contribute to this delay? Furthermore, inter-country differences are frequently studied (for a seminal work see Wardell 1973). Wardell examined whether stringency in the US FDA regulation, post-Thalidomide, resulted in a longer delay of the launch of new drugs. Motivated by this study, many other empirical studies were conducted to understand the dynamics of drug launch across countries (Peltzman 1973, Grabowski 1980, Cullen 1983, Parker 1989). A strong point of many of these studies is their use of comprehensive proprietary databases for the cross country launch of new drugs. However, one can identify two

broad limitations of these studies. First, these studies mainly focus on the launch of new drugs in the major pharmaceutical markets of the developed countries, and confine themselves primarily to examining whether stringency in regulation can explain delay. Second, methodologically, most of these studies do not intend to deal with the right censorship problem, which arises from the finite length of their data set. A censorship problem arises because drugs that are first launched in a country during the later years of observation may be diffused in some of the studied countries after the period of observation. As a consequence, it is difficult to judge whether the absence of those drugs in some markets is due to an insufficient period of observation or implies their non launch.

Major pharmaceutical markets in the industrialized countries are largely homogenous in terms of disease profile and institutional arrangement (Cullen 1983: 74). If one roughly categorises diseases into two broad groups, communicable tropical diseases and non-communicable systemic diseases, then developed industrialised countries have a disproportionately high share of non-communicable diseases. Concerning the institutional structure, most of the countries have a very stringent, perhaps uniform, set of norms for new drug approval. They also have a strong product patent system in place. Due to this strong product patent system, only the innovator or its licensee(s) can launch a new innovation in any of these markets.

In recent years, a number of studies explored the dynamics of drug launch in developing countries (Lanjouw 1999, Lanjouw 2002, Bhaduri and Ray 2006, Ray and Chakravorty 2007). Broadening the sample and incorporating these countries enhances the scope of research in two ways. First, being located in tropical regions, the disease pattern in these countries is quite different (Lanjouw 1999, Lanjouw 2002). The majority of population in these countries suffer from communicable tropical diseases. Demand differences is thus a key verifiable determinant of the diffusion of new drugs in these countries. Secondly, pharmaceutical markets in many of these countries, until very recently, were under weak patent system, which permitted reverse engineering and incremental innovations. New drugs in these countries can, therefore, be launched by any firm present in the market, and not only by the innovating firm (Lanjouw 2002). Issues like competitive pressure to launch, and first mover advantages can also, thus, be incorporated in the analyses of drug launch (Bhaduri and Ray 2006).

Although these studies lead to an interesting set of conjectural hypotheses, there is not much attempt to subject these conjectures to rigorous empirical analyses. This paper

makes an attempt to contribute to this growing literature by analysing the drug launch pattern in India. We use Cox proportional hazard model to understand the determinants of drug launch delay in India for the drugs which have been launched in Germany during 1990-2004. The final year of analysis was chosen to be 2004, as this is the last year under weak intellectual property rights regime in India. In the next section we develop the conceptual framework of our study. Section 3 describes the sample. We give a detailed account of our estimation methods in section 4. In section 5, we draw our hypotheses. Results are describes in section 6, and our main arguments are synthesised in section 7.

2. Background

2.1 Background on product launch

The literature provides a lot of analyses and discussions about the entry of firms in markets. Most of this literature focuses on questions about the social optimum of entry processes, the number of competitors on the market and firm characteristics that influence the entry decision.

In the context of this paper, findings on the firm characteristics that influence the decision to launch a (new) product are of most interest. A fact that is repeatedly found is that the number of competitors increases with the size of the market (see, e.g., Bresnahan and Reiss, 1987, 1990). Hence, the market size is found to have a positive impact on the decision to launch a product.

Furthermore, the literature provides evidence for the fact that firms tend to launch products that are similar to other product that they already offer (Berry 1992 and Scott Morton 1999) or match their firm's characteristics (Kyle 2006). Markets that are geographically near to the headquarters of the firms are also preferred (Kyle 2006).

However, most empirical studies are conducted for one industry only. Hence, little general knowledge is available. Therefore, we will discuss the specific findings for drug launch in the next subsection and use these findings to develop hypotheses about the drug launch in India.

2.2 Empirical findings on drug launch and hypotheses

Impact of regulation

Most of the studies on drug launch have analysed how/whether stringency in regulation leads to delay in launches (Peltzman 1973, Wardell 1973, Grabowski 1980, Cullen 1983, Parker 1989, Danzon et al 2005). The conclusion, however, varies. While studies by Wardell (1973) and Cullen (1983) found that stricter regulation led to drug delay in the USA, Parker (1989) does not find any evidence of delay in drug launch in the USA compared to other countries in his sample. It was also found that average delay declined in the decade of 1980s, compared to 1970s. With more recent data Grabowsky and Wang (2006) find that the US is becoming the country of first launch for a majority of drugs in recent years. Hence, the findings on the impact of regulations are mixed.

The literature on technology transfer, on the other hand, emphasises that stricter patent regulation reduces delay in transfer of new technologies (see, for instance, Mansfield 1994). However, both these sets of literature only visualise the innovating firms or their licensees as the main agents of transfer or diffusion of (drug) technologies. In the absence of a strong patent regulation, however, a new technology can also be introduced in the market by other firms through process engineering and imitation. Suppose there are two groups of firms: multinationals and domestic firms. Further assume that new drug discovery research is carried out only by the former group of firms. The domestic firms do not have the requisite technological capability and, instead, only carry out reverse engineering based minor innovations. When the prospect of a strong patent system appears, multinational firms might postpone its launch decision in the Indian market until such a system is in place to pre-empt competition, with the consequence of prolonging the delay. However, a product may be imitated by the domestic firm when the innovating firm decides to abstain from launching it in the host market. In fact, the domestic firms would attempt to speed up the imitation process and launch new drugs before a strong patent regime comes forth. Hence, the impact of patent regulations on drug launch decisions depends on the mixture of firms present on the market. Without detailed knowledge about this mixture of firms we assume, on average, no impact:

Hypothesis 1: Patent regulations have no impact on the delay of drug launch in the Indian market.

Impact of market size

Besides regulatory framework of drug approval, expected market size is also shown to influence the lag in drug launch. Larger expected market size reduces delay (Cullen

1983), and lower expected prices are shown to reduce the number of new launches and enhance delay due to the problems of external referencing and the possibility of parallel exports (Danzon et al 2005). Hence, we expect:

Hypothesis 2: Larger expected market sizes imply a reduction of the delay in drug launch in India.

However, as has been mentioned above, most of these studies pertained to developed countries having broadly similar disease profile (hence, demand structure for health care) and similar institutional arrangements. Indeed, differences in medical, legal and commercial environments existing in developing countries were believed to have adversely affected the launch of new drugs in these countries (Cullen 1983).

Differences in demand pattern and institutional arrangements in developing countries can help explore a plethora of other issues related to the diffusion of drugs. Concerning demand pattern, broadly, there are two types of diseases, namely, non-communicable diseases and infective diseases (Troullier and Olliaro 2001). Non-communicable diseases, caused by intrinsic malfunctioning of our systems, are mostly non curable and requires prolonged (life long) treatment. Infective diseases, on the other hand, are caused by external pathogens (bacteria and virus due to pollution and bad hygiene). These diseases are generally short lived and completely curable through medicine. Being located in non-tropical regions and due to improved hygiene, communicable infective diseases do not pose any serious health problems in developed countries.[1] Their main health burden remains in the area of various non-communicable systemic diseases. People in the developing countries, on the other hand, suffer more from infective diseases (also known as tropical disease). As an illustration of this different disease profile, one may note that the share of communicable diseases in the total Disability Adjusted Life Years (DALY) for Germany is around 4%, while in India around 45% of total DALY is due to communicable diseases. On the other hand, non-communicable diseases count for around 90% of DALY in Germany. The relevant share for India is around 40%.[2]

[1] This is true, occasional outbreaks of flues notwithstanding. Also, disease like AIDS is a communicable, yet not curable, disease. However, spread of AIDS does not depend on poor hygiene or climatic conditions. In tropical conditions, however, AIDS patients may have higher possibility of getting other kinds of infections. Thus, drugs for AIDS may be needed more in tropical countries, compared to non-tropical countries.

[2] See http://www.who.int/healthinfo/statistics/bodgbddeathdalyestimates.xls for details. Last accessed on 26 August, 2008.

It may, therefore, be plausible that delay will be shorter for drugs which have higher demand. Under a strong patent regime, Danzon et al (2005) argue that the prevalence of high demand in a country raises the opportunity costs of delay by shrinking the discounted value of total patent-monopoly profits to be earned. Their study, however, takes into consideration only countries which have strong patent systems. Monopoly profit is ensured for the innovating firm during the length of the patent protection in these markets. In the absence of a strong product patent system, however, competition between brands becomes feasible even during the life of a patent, adding uncertainty to patent monopoly. The potential of first mover advantage may crucially determine the lag in such cases. The theory of industrial organisation highlights that the first mover advantage would be high when the scope of repeat purchase is high. Note that non-communicable diseases are non-curable in nature. Medicines have been successful only in controlling their adverse effects on the body. On the other hand, most of the communicable diseases are often fully curable by medicine. Greater need for repeat purchases of drugs for non-communicable diseases, arising out of the need for long term treatment, have important consequence for first mover advantage in markets with weak patent protection, such as India.

Bhaduri and Ray (2006), in this context, argue that psychological costs of brand switch-over are higher for drugs for non-communicable diseases compared to the drugs for infective diseases. Non-communicable diseases are also known as life style diseases. In the context of a developing country, demand for these drugs seem to emerge more from the upper socio-economic strata who are comparatively more quality conscious and litigious than people of lower socio-economic strata. The latter group, on the other hand, constitutes the major market for drugs for infective diseases due to their unhygienic living conditions. Due to higher level of quality awareness and the litigious nature of the patients, the physicians of non-communicable diseases would be reluctant to switch brands, solely on grounds of cost efficiency. This adds to the psychological costs of brand switching and strengthens first mover advantage for drugs of non-communicable diseases. As a consequence, delay for drugs for non-communicable diseases can, in fact, be shorter compared to anti-infective drugs (Bhaduri and Ray 2006). Hence, we expect:

Hypothesis 3: Drugs for non-communicable diseases find a large market in India and, therefore, show a shorter delay in drug launch than anti-infective drugs.

Another way for firms to estimate the potential market size is to consider the success of a drug in countries in which it is already introduced. Assuming that prescription pattern in major pharmaceutical markets would have demonstration effect in markets of developing countries, a negative relationship between commercial success of a new drug in major markets and its launch in country like India may be hypothesised without much difficulty. Besides such demand side factors, commercial success in other countries might also encourage the domestic firms in the follower country to speed up their R&D and process engineering by raising their profit expectations. As a result, imitation may become faster, increasing the possibility of a faster launch in the domestic market. On the other hand, when a new drug is not commercially successful in leading countries, domestic firms may adopt a cautious strategy for imitation leading to a longer delay, ceteris paribus. Sax (1982), however, does not find evidence of any shorter delay for drugs that are commercially successful, when compared with the delay associated with commercially unimportant ones in Israel. Nevertheless, we hypothesize:

Hypothesis 4: The delay in drug launch in India decreases with the commercial success of the drug elsewhere.

Impact of the innovativeness of drugs

The importance of a new drug therapy also seems to shape the dynamics of drug launch. Quite often, commercial success of a drug has been taken as a proxy for its therapeutic importance. Commercially significant drugs diffuse faster, especially to non-leading countries like Israel, compared to 'all new drugs' (Sax 1989). However, all commercially significant drugs may not necessarily bring about major therapeutic advancements. However, most of the studies seem to overlook this distinction between the commercial significance of a drug and the therapeutic advancement it brings about. Grabowski and Wang (2006), for instance, argue that the drugs that are 'present in all G7 countries are also the drugs of 'high quality', or 'commercially successful' or 'both'. Roy and Chakraborty (2007) make a pioneering attempt to distinguish between these two characteristics of drugs: commercial success and therapeutic advancement. Drawing upon the categorisation of therapeutic advancement made by the United States Food and Drug Administration (USFDA), this study shows that the share of 'advanced therapy' was not significantly different from the share of 'non-advanced therapy' for 77 new drugs (out of 297 new drugs launched in the USA), which were launched in India during 1995-2003. This finding, perhaps, implies that innovativeness of a drug has got little to

do with its launch in India. However, for a more meaningful conclusion it would be necessary to study the launch pattern of commercially successful drugs and of innovative drugs separately. The literature suggests:

Hypothesis 5: The delay in drug launch in India does not depend on the innovativeness of the drug.

2.4 Summary of background

In a nutshell, the studies on drug launch have identified stringency in regulation, market size and opportunity costs as major determinants of the delay in drug launch in major pharmaceutical markets of industrialised countries. However, few studies have attempted to understand the diffusion of new drugs in developing countries. These countries have different disease profile and a different institutional structure compared to developed countries. To elaborate, there is more prevalence of tropical communicable diseases as opposed to a high prevalence of non-communicable diseases in the industrialised countries. These two segments have different first mover advantages. Furthermore, these countries often have weak patent protection, giving protection only to processes and not product innovations, so that competition is possible even during the patent protection period. Many of these aspects have remained unexplored in the literature. We investigate some of these aspects by analysing launches of drugs, present in the German market, in India.

3. Method and data

3.1 Sample

Our analysis concerns the period 1990-2004. Although data was available for later years, we decided to take December 2004 as the end point because this marks the end of the era of weak patent protection in India. Note that India amended its patent legislation in 2005 to comply with the Trade Related Intellectual Property Rights (TRIPS).

We have a sample of 634 drugs that were launched in Germany during this period. Among these, 201 drugs have been launched in the Indian market during the same period. We had to consult two corporate data bases (Rote Liste and Dimdi Pharmasearch) to obtain the comprehensive list of all drugs launched in Germany during that period. It has to be taken into account that one molecule may be sold in different dosage forms. The Dimdi dataset contains the dates of first launch of all these individual entries. Among all these entries, we took the earliest entry pertaining each molecule,

since later entries merely give the range of product differentiation for a particular therapy (drug). However, both datasets share a common shortcoming: they only record information about those drugs that are currently present in the market. This implies that we cannot obtain any information about drugs which have been withdrawn from the market, even if they were launched after 1990.[3] In addition, if a drug is re-introduced after some time, these datasets would only give us the date of re-introduction[4].

The list thus obtained had to be pruned further by omitting homoeopathic drugs and plant medicines, to make it comparable with the list we use for Indian drugs. The source for drugs launched in India is the proprietary corporate database Pharmabiz (www.pharmabiz.com). This list matches with the list of drugs mentioned on the webpage of the Central Drug Standard Control Organisation (CDSCO), Government of India[5]. It may also be noted that, like the German data, Indian data is also available on individual products (dosage forms) for each molecule. Again, we have only considered the first entries for each molecule to make our two datasets comparable.

3.2 Independent variables

In order to test the Hypotheses 1 to 5 we define for each of them an empirical variable that reflects the respective independent variable (some descriptive statistics are given in Table 3 and 4 in the appendix).

Patent regulations [TRIPS]

India became a signatory to the World Trade Organisation in 1995 with the commitment to introduce a strong product patent system in line with Trade Related Intellectual Property Rights (TRIPS) in the year 2005. Thus, in the year 1995 it became common knowledge that India will adopt a strong patent regime in the year 2005. It may be reiterated that strong TRIPS compatible patent system prohibits reverse engineering activities. We, introduce a dummy variable (TRIPS) taking the value '1' for drugs which are launched in the global market (represented by launch in Germany) since 1995, and '0' for drugs launched in pre-1995 period.

[3] Such a situation may arise if a drug cannot qualify the requisite standards of quality and safety in the phase of post-marketing surveillance. Many so called blockbuster drugs have also often fallen prey, leading to their withdrawal or suspension from the market. Nimesulide, Celecoxib, Refocoxib are some of the examples.

[4] Please note that this problem is not present in the proprietary corporate database called AMIS (full name required). However, financial resources at our disposal did not permit us to exploit this data source to the fullest possible extent.

[5] This list is, however, available only from 1999.

Expected market size [MARKET]

We use market share variable in two ways: (1) as a covariate, attempting to explain the physical time delay in terms of market share of a drug. (2) We use the opportunity costs dimension of market share and reconstruct the 'analysis time' or 'onset of risk' as a function of cumulative opportunity costs (product of time and market share, see Section 3.3).[6] .

The true market share for a drug which is yet to be launched is non-existent. As a proxy we take the market share of the therapeutic category to which the prospective new drug belongs. ICRA (2005, pp. 5-6) categorises all diseases into 14 therapeutic groups and provides market share for each of them. Each drug in our data set, therefore, gets the value depending on which one of the 14 therapeutic categories it belongs to. We use this information only for India.

Therapeutic category [TYPE]

Following Bhaduri and Ray (2006) and the above arguments, we categorise all drugs into two broad therapeutic categories, namely, infectious diseases (ID) and non-communicable diseases (ND). Chronic diseases have been merged with ND on the assumption that they, unlike infectious diseases, are not completely curable through medication. As argued above, infectious diseases are caused by external pathogens, often as a result of contaminated food, drinks or bad sanitation. Non-communicable diseases, on the other hand, are not caused by external pathogens but by malfunctioning of the internal human system.

Our dataset provides the therapeutic category of each drug. We grouped them into two groups with the help of drug information available on the websites and the various issues of Indian Drug Review. We use a dummy variable TYPE, which takes the value '1' if a drug is for the treatment of ND, and '0' if it is to treat any ID.

Global commercial success [GLOBAL]

Global commercial success can be measured by the annual global sales of a drug. In particular, a drug is considered globally successful, unequivocally, if it gets the status of a blockbuster drug. A drug becomes a blockbuster drug if its global sales turnover

[6] Conceivably, temporal ordering of 'failure time' would be more different when 'onset of risk' is measured in terms of a joint function of time and market share than when 'onset of risk' is measured only in terms of physical time.

reaches US$ 1 bn per annum (Landau et al 1999). However, the FDA does not collect this information. Proprietary databases which claim to maintain such data are also prohibitively expensive. Therefore, we use the US sales reports of prescription drugs and the pharmacy magazine Drugtopics (www.drugtopics.com), which carried a list of top 200 branded drugs in various years[7]. We also reviewed the company reports of some of the leading innovating firms. Finally we find that 52 such blockbuster drugs are present in our list of drugs in Germany. The variable GLOBAL is a dummy variable that takes the value '1' for blockbuster drugs, and '0' otherwise.

Innovativeness of drugs [INV]

The US Food and Drug Administration (FDA) specifies their opinion on innovativeness of a new drug by marking drugs with high therapeutic advancement as 'Priority drugs (P)' and drugs with insignificant therapeutic advancement as 'Standard (S)'.[8] We used the CDER website to locate these drugs. Data from 1999 was available in http://www.fda.gov/cder/rdmt/. For the pre-1999 period, data were available in the Reports to the Nation and in http://www.fda.gov/cder/archives/default.htm#Archival. We could go up to 1997, and found that 48 of all priority drugs noted by the CDER (USA) to be present in the German market for the period 1997-2004.[9]

We note that out of the 48 drugs that brought about major therapeutic advancements only 6 could attain the status of blockbuster drugs during our sample period. On the other hand, 20 out of 26 blockbuster drugs launched in the German market since 1997 did not bring about any major therapeutic advancement.

Interestingly, most of the studies do not distinguish between commercially important drugs and drugs that bring about significant therapeutic advancement in analysing delay. Grabowski and Wang (2006), for instance, define a NCE of "high quality or commercially important NCE or both" if it has been launched in all G7 countries. The data presented above, however, give us ample reason to believe that there can be little association between commercial success of a new drug and its innovativeness. We, therefore, chose to examine these two effects separately.

The variable INV is a dummy variable taking value '1' for 'priority drugs' and '0' otherwise.

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[7] We thank CDER for this suggestion.

[8] See also Ray and Chakravorty (2007).

[9] Data prior to that year are not comprehensively available, as reported by the CDER.

3.3 Estimation method

We measure delay by the number of months elapsed between launch of a drug in Germany and its subsequent launch in India. In few cases, drugs have been launched in India before their launch in Germany. The variable in those cases takes negative values. Note that in the absence of exact dates of launch for many drugs we have used the first day of the month as the representative date.

We use two approaches to understand the dynamics of drug launch in India. First, a Cox hazard model is used.[10] However, 41 drugs have been launched in India before their launch in Germany. The Cox proportional hazard model would ignore all observations for which the launch date in India precedes the launch date in Germany, once we set the 'entry time' for an observation to be its launch date in Germany. The determinants of launch of these 41 drugs would remain unknown in such a set up. To understand the determinants of drug launch for all drugs, including these 41 drugs, we use a least square regression including all 201 drugs that are present in both markets.

As we know, survival analysis is primarily concerned with analysing 'time' (known as 'analysis time') to the 'occurrence of events' (or 'deaths' or 'failures'). In this paper, time is calculated in months and an event refers to the launch of a new drug in India *after* its launch in Germany. In survival analysis, 'analysis time' signifies the 'onset' of risk for a subject. This risk ends with the 'death' (or failure) of the subject under consideration. In our paper 'death' ('failure') implies the launch of a drug in India. Cox proportional hazard models explain every such 'occurrence of event' with the help of a set of covariates (x).

A typical Cox proportional hazard model is represented as: $h(t) = h_0(t) \exp(b_0 + x_j b_j)$,

where $h_0(t)$ is the base line hazard function. Unlike a parametric hazard model, which relies on a definite functional form of the hazard function [h(t)], the Cox model leaves h(t) unspecified.

4. Results and discussion

Hypotheses 1 to 5 provide us with the following predictions:

- TRIPS (Hypothesis 1): no impact on delay of drug launch
- MARKET (Hypothesis 2): negative impact on delay of drug launch
- TYPE (Hypothesis 3): negative impact on delay of drug launch
- GLOBAL (Hypothesis 4): negative impact on delay of drug launch
- INV (Hypothesis 5): no impact on delay of drug launch

[10] Note that Cox proportional models are non-parametric in nature.

We divide this section into two subsections. In the first section we report the results of our cross section regression analysis taking only those drugs which have been launched in both countries. In the second section we present the results of the survival analysis in which we have to exclude drugs with a negative delay, meaning that they are launched in India before Germany.[11]

4.1 Regression analysis

Due to heteroscedasticity we take robust estimations. Our model is statistically significant at 1% levels. The results are presented in Table 1. The dependent variable T_LAG is explained by GLOBAL and TRIPS. The coefficient for GLOBAL is negative and significant at the 5% level, showing that the time lag for blockbuster drugs is significantly shorter than for other drugs. Hence, Hypothesis 4 is confirmed: The success of a drug in other market seems to be used by companies as a proxy for the market size of this drug in the Indian market.

In Section 2.3 we found that two different arguments can be put forward with respect to the influence of patent regulations on the delay of drug launch: India joining TRIPS might have motivated small Indian companies to introduce drugs on the market faster and might have motivated international companies to delay the introduction of drugs on the Indian market. We decided that both mechanisms might have the same importance and expected no impact, on average (Hypothesis 1). According to the regression results, TRIPS seems to be the most important explanatory variable with the level of significance being 1%. The coefficient for TRIPS is negative. The delay has decreased after the announcement of stronger patent laws. This implies that the mechanism that is based on the reaction of Indian companies plays a much stronger role. Either Indian companies introduce most drugs to the Indian market or they reacted much stronger to the change in regulations.

Table 1 (Model 1): OLS estimation (Dependent variable: T_LAG)

Independent variables	Model 1
GLOBAL	-12.987**

[11] We are not sure whether this is indeed the case, or the negative lag is because some drugs were withdrawn from the German market before their current launch. As we have mentioned earlier, our dataset would capture the most recent launch in such cases.

	(-2.2)
MARKET	-1.026 (-1.21)
TYPE	7.338 (0.85)
TRIPS	-31.047*** (-4.4)
Constant	59.141*** (4.57)
F Statistics	6.48***
No. of Observation	199

Note: *** - significant at 1% level, **- significant at 5% level, *- significant at 10% level

Both MARKET and TYPE appear with insignificant coefficients, implying that we find no evidence for Hypotheses 2 and 3. The market shares expectations that are based on the market shares of the drug groups or drug types in India seem not to influence the delay of drug launch.

4.2 Survival analysis

Note that our physical time lag is calculated in months, with every launch assumed to take place on the first day of a month. As a result we cannot capture the day to day variation within a month, so that we have many tied failures. For 158 failures we have 84 failure times implying around 2 failures per failure time. We analyse two models: one without considering the innovativeness of drugs (Model 2a) and one in which the variable INV is included (Model 2b). In the latter case, the number of observations is reduced. The variable INV is available only for drugs launched since 1997. Therefore, we discarded all those drugs that were launched in Germany before 1997. As a consequence, the variable TRIPS has the same value for all remaining drugs and is excluded from the analysis. A total of 302 observations remained. The reduced number of observations is the reason for not conducting a regression analysis including variable INV. The results of the survival analysis are presented in Table 2.

Table 2 (Model 2): Survival analysis: (Analysis time: T_LAG)

Covariates	Model 2a Hazard Ratios	Model 2b Hazard Ratios
GLOBAL	5.002*** (8.00)	4.446*** (5.15)
MARKET	1.026 (1.42)	1.006 (1.75)
TYPE	1.29 (1.36)	1.75* (1.75)
TRIPS	2.239*** (4.37)	
INV		1.458 (1.09)
Chi square	74.08***	29.03***
No. of Observation	589	301

Note: *** - significant at 1% level, **- significant at 5% level, *- significant at 10% level

The analysis of the first Cox model leads to statistically significant coefficients for GLOBAL and TRIPS. Again, we find that blockbuster drugs and drugs that appear in the market after stronger patent laws had been announced in India are launched faster in the Indian market. In addition, the survival analysis provides having hazard ratios. For the variable GLOBAL we find a hazard ratio of about 5. Hence, the delays of drug launch are 5 times as large for drugs that are no blockbuster compared to blockbuster drugs. The success of a drug in other markets speeds up the launch in India tremendously. For the variable TRIPS we find a hazard ratio of about 2.2. Hence, it took approximately 2.2 times as long to introduce a drug before the patent law changes have been announced in 1995 than after this announcement.

Again we find no significant results for the variable MARKET. Our results do not support Hypothesis 2. In the case of TYPE the results are mixed. For Model 2a we do not find significant results. In the case of Model 2b the coefficient for variable TYPE is, at least on the 10% level, significantly larger than 1. This means that we find, at least, a very weak confirmation of Hypothesis 3. Drugs for non-communicable diseases are launched in India with a slightly larger delay. According to Model 2b, this delay is around 1.75 times as large as for infectious diseases.

The coefficient for INV is insignificant, confirming Hypothesis 5, which states that the innovativeness of drugs should have no impact on the delay.

7. Discussion and Conclusions

All our analyses reveal that the global commercial success of a drug shortens the delay in launch. According to our survival analyses, blockbuster drugs have an approximately 5 time higher probability to be launched at each time. In contrast, innovativeness of a drug does not influence its delay of launch in India. Indeed, our data reveals that out of 22 blockbuster drugs launched in India since 1997, 18 do not bring about any major therapeutic gains. Moreover, while only 40% of drugs which brought about major therapeutic advancement were launched in India, for the blockbuster drugs, the respective share is 85%. It thus appear that launch in India is often highly influenced by the prospect of commercial success and not by the prospect of major therapeutic gains.

Another very clear result that is obtained in all analyses is that drugs introduced in the global market since 1995 have a significantly shorter delay compared to its predecessor drugs. Although we failed to obtain the names of firms associated with every launch of new drugs in India, it may be conjectured, on the basis of the discussion in section 5, that most of the drugs are launched in India by domestic firms, who successfully sped up their effort to innovate non-infringing processes for new drugs during the final years of the process-oriented patent regime (1995-2004).

Market share does not seem to influence launch of new drugs in India. We find some evidence that drugs for systemic diseases are faster launched on the Indian market tha drugs for infective diseases. This result is indeed interesting when one compares the figures for Disability Adjusted Life Years (DALY) given by the World Health Organisation (WHO) for India and Germany quoted in section 2. India has an almost equal share of DALY figures for infective communicable diseases and non-communicable diseases. In Germany, however, 90% of DALY is due to non-communicable diseases leaving only 4% for communicable infectious diseases. Hence, drugs for communicable infectious diseases have a comparably larger market in India, which might motivate firms to launch these drugs faster.

Surprisingly, the impact of the type of drug on the delay of drug launch in India is rather weak and not consistently found. Furthermore, out of 199 drugs launched in the Indian market during 1990-2004, 125 drugs belong to non-communicable diseases, and 74 drugs are for infectious diseases. The relevant figures for the German market are 369 and 261 respectively. Thus, while a little more than 33% of the drugs for non-communicable diseases present in the German market have been launched in India, the similar share for the drugs for infective communicable diseases is only around 28%.

Furthermore, while the ratio of drugs for communicable diseases to total drugs in the German market is around 44%, in India the comparable share is 37%. This contrasts the share of the DALY for the two kinds of diseases. Furthermore, even out of 41 drugs whose launch dates in India precede their launch dates in Germany, 25 belong to systemic diseases and 16 belong to infective diseases!

Two important policy implications follow. First, effective regulation should be in place to ensure that new drugs for infective communicable diseases are not delayed because of their low first mover advantages. This is important because infective diseases are caused by poor hygiene making people belonging to lower socio-economic strata the biggest sufferer. Second, effective information dissemination policies should be in place to encourage launch of drugs that bring about major therapeutic advancement, irrespective of their global commercial success, to ensure better access to new medical therapies by Indian people.

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Appendix:

Table 3: Correlation coefficients (all observations)

	T_LAG	DDT_LAG	GLOBAL	MARKET	TYPE	TRIPS
T_LAG	1					
DDT_LAG	0.71	1				
GLOBAL	-0.179	-0.148	1			
MARKET	-0.074	0.478	-0.055	1		
TYPE	-0.082	-0.241	0.049	-0.421	1	
TRIPS	-0.616	-0.466	-0.003	-0.03	0.144	1

Table 4: Correlation coefficients (observations for drugs launched in Germany from 1997)

	T_LAG	DDT_LAG	GLOBAL	TYPE	INV
T_LAG	1				
DDT_LAG	0.76	1			
GLOBAL	-0.091	-0.069	1		
TYPE	-0.1	-0.245	0.074	1	
INV	-0.116	-0.064	-0.07	-0.093	1