Trips and Patenting Activity: Evidence from the Indian Pharmaceutical Industry

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TRIPs AND PATENTING ACTIVITY: EVIDENCE FROM THE INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

This paper studies the impact of the strict patent regime on the patenting activity of Indian pharmaceutical firms and finds that patenting activity of these firms has increased after the signing of TRIPs. The study is conducted for 65 pharmaceutical firms for the period 1991 to 2004 using different parametric and semiparametric count panel data models. Results across different count data models indicate a positive and significant impact of the introduction of stronger patents on patenting activity. Further, the results show a gestation lag of two years between R&D spending and patent applications.

KEYWORDS: PHARMACEUTICALS, PATENTS

JEL CLASSIFICATION: L65, 031

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I. INTRODUCTION

Under the World Trade Organization (WTO) regime, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) is the most comprehensive international treaty on intellectual property rights (IPRs). The aim of TRIPs is to strengthen patent protection worldwide - particularly in developing countries like India that did not provide for strong IPRs for pharmaceuticals and agricultural chemicals - by setting out procedures that governments must provide under their domestic law for the enforcement of IPRs. For the pharmaceutical industry, IPRs are sought to be protected by the patent system that encourages inventors to direct more resources for R&D by providing exclusionary rights for a period of time. Mansfield (1986) in a survey of 100 R&D executives in the U.S. found that 60 percent of the inventions in the pharmaceutical industry and 40 percent in the chemicals industry would not have been developed without patent protection. Levin et al. (1987) in a survey of 130 U.S. industries found that the R&D executives for pharmaceuticals and chemicals industry placed a high emphasis on patents compared to alternative means of protection.

The theoretical literature assumes that broader patents and longer patent terms induce more R&D efforts and hence greater innovative output measured by patent applications (Nordhaus, 1969; Klemperer, 1990 and Gilbert and Shapiro, 1990). However, most of the empirical studies on technological innovation at the firm level have concentrated on developed countries. Studies on the impact of TRIPs for developing countries like India have mostly addressed the issue of welfare losses associated with rising drug prices due to stronger patent protection since higher drug prices would adversely affect net incomes for a large section of the populations in developing
countries. But, there are hardly any empirical studies for developing countries that examine the change in the domestic inventive potential with stronger patent rights. It is true that even though the nature of R&D in India is different from that of developed countries, being adaptive rather than basic R&D, it is not insignificant particularly in research-intensive industries like pharmaceuticals. This paper attempts to fill the gap in the literature on microeconometric studies of technological innovations by analyzing the determinants of patenting activity of pharmaceutical firms in India by using a new dataset for R&D and process patents (product patents for pharmaceuticals were introduced only in January 2005). The paper investigates the hypothesis that a stricter patent regime induces patenting activity after accounting for other determinants of patenting like R&D and technological spillovers to a firm by other firms in the industry.

The paper uses a variety of count data models for longitudinal data and finds that a stricter patent regime has indeed stimulated patenting activity. In particular, the estimation procedure takes into account the unobserved heterogeneity associated with firm-specific characteristics such as R&D productivity of a firm or the motivation of its R&D personnel to innovate. In the patent-R&D relationship, it is not unreasonable to believe that the regressors are correlated with the unobservables such as scientific and managerial abilities and this positive correlation leads to upward-biased estimates necessitating the use of fixed effects models (Cincera, 1997). To begin with, the basic Poisson model is introduced, followed by the negative binomial model, the zero-inflated models and the zero-truncated hurdle models. Finally, we estimate the semiparametric negative binomial model that handles the unobserved heterogeneity without any assumptions about its distribution and takes care of outliers which are likely to be present.
in patent data. Results across all the models confirm that patenting activity has significantly increased with the introduction of stronger patent rights. In the case of India, the greater R&D and patenting activities means welfare losses arising from the higher prices in a stricter patent regime would be lower compared to other developing countries without the know-how for manufacturing drugs since Indian drug manufacturers can use patents for penetrating export markets.

The rest of the paper is organized as follows: Section II gives some historical background regarding patent legislations, TRIPs and the Indian pharmaceutical industry. Section III gives a brief review of previous studies on patent reform. Section IV describes the data sources and section V outlines the methodology used for the econometric study. Section VI outlines the results of the study and section VII concludes.

II. INDIAN PATENT LAWS AND TRIPS REGULATIONS

The pharmaceutical industry in India has been a success story for the development of an indigenous and self-reliant industry. Due to favorable government policies, domestic firms have been able to overcome the dominance of multinational corporations (MNCs) in the pharmaceutical market. This is very different from the scenario prevailing at the time of Independence, when the industry was dominated by MNCs, prevailing drug prices were among the highest in the world and technology for the production of essential drugs was denied to India.

At the time of Independence, India inherited the Patents and Designs Act 1911, which provided product patents for all inventions including foreign inventions, for a period of 16 years from the date of application. However, to reduce the dependence on
imports for bulk drugs and formulations and promote the development of a self-reliant indigenous pharmaceutical industry, the government did away with the 1911 Act and introduced the Patents Act 1970 which abolished product patents for pharmaceuticals and reduced the patent term to seven years from the date of filing or five years from the date of sealing, whichever was earlier. It allowed only process patents\(^1\) in the areas of food, pharmaceuticals and agricultural chemicals. The Act also had a provision for invoking compulsory licenses (a license to use a product under reasonable and nondiscriminatory terms) after three years if a price was deemed ‘unreasonable’. The lack of protection for product patents in pharmaceuticals resulted in “reverse-engineering”\(^2\) of drugs that were under patent protection as products in industrialized countries. In fact, Redwood (1994) has calculated that in 1993, 20 percent of the generics marketed by the top 15 Indian pharmaceutical firms were based on brandname drugs that were covered by pharmaceutical product patents in Europe and an additional 37 percent were based on brandname drugs that had gone off-patent somewhere between 1972-93. Meanwhile, it is noteworthy that Indian firms did not seek foreign technical assistance to reverse-engineer the foreign patented drugs. Indian manufacturers were able to imitate the patented drugs by using the information provided in the patent title owing to their well-developed chemical infrastructure and process skills (Fink, 2000).

These measures stimulated technological learning by Indian firms and helped the pharmaceutical industry to develop while at the same time keeping drug prices low. To encourage local players and lower the prices of essential drugs, the government

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\(^1\) Process patents are granted for a novel way of manufacturing a product using a different production process even if that product is covered by product patents elsewhere.

\(^2\) Reverse-engineering is a method of evaluation of a product so as to understand its functional aspects and underlying ideas and then use the technique to develop a similar or identical product.
introduced price controls through the ‘Drug Policy’ in 1979 that brought 347 drugs under price control. The government also promoted indigenous production by exempting the small-scale sector from price control.

However, the liberalization era that began in 1991 also affected the Indian pharmaceutical industry. In 1994, the Government of India introduced the ‘New Drug Policy’ that reversed many features of the 1979 policy and reduced price and production controls, progressively reducing drugs under price control to 73 in 1995 and 39 in 2002. Around the same time, the WTO was set up in 1995 and India signed TRIPs in 1994, generating awareness about the commercialization of IPRs. As a signatory to TRIPs, India is required to meet the minimum standards regarding patents for pharmaceuticals.

Regarding the enforcement of WTO provisions, Article 65.4 of TRIPs provides a transition period till January 1, 2005 for developing countries like India that did not provide for product patents in certain areas of technology like food, chemicals and pharmaceuticals, as on January 1, 1995. However, Article 70.8 requires these developing countries to provide a means for the acceptance of applications for product patents with effect from January 1, 1995 itself with the setting up of the WTO. In addition, under Article 70.9, exclusive marketing rights (EMRs) are to be provided during the transition period for a period of five years from the date of obtaining marketing approval in that country or until a product patent is granted or rejected, whichever is earlier, provided certain conditions are met. Thus, the combined effect of Articles 70.8 and 70.9 through “pipeline protection” and EMRs is to provide the same protection for pharmaceutical and agricultural chemical products as would have been available under product patents right from the date of entry into force of TRIPs or January 1, 1995 (Watal, 2001).
In keeping with its commitments under TRIPs, India introduced the Patents (Amendment) Act 1999, which grants inventors pipeline protection through a ‘mailbox’ system i.e. while applications for product patents are to be accepted immediately after the entry into force of the WTO, the decisions on the patents are to be kept pending till the time product patents are introduced in 2005. Hence, if an inventor has filed an application for an invention in any WTO member country and a patent or EMR has been granted in that country on or after January 1, 1995, the applicant would be eligible to file for patents for pharmaceutical and agricultural chemical products in India and would be granted EMRs in India for a period of five years or until the patent is granted or rejected, whichever is shorter. The amended Patents Act provides for limited compulsory licenses for EMRs. The Patents (Second Amendment) Bill 1999, which was enacted in 2002, has closely followed TRIPs and has paved the way for stronger patent rights in India. Under Section 53(1) of the amended Act, the patent term has been increased to 20 years from the date of filing of the patent application, whether for product or process patents. Under Section 48, patent owners have the exclusive right to prevent others from making, using, selling or importing the invented product or process in India. Under the original 1970 Act, importing was not mentioned as an exclusive right. Section 104A has been added relating to the reversal of the burden of proof in case of infringement suits. A new set of provisions under Section 107A have been added to permit pre-market testing of generics during the patent term to enable them to be marketed immediately upon expiration of the patent (Bolar provisions). This pro-patent shift culminated in India’s accession to the Paris Convention and its subsidiary, the Patent Cooperation Treaty (PCT) in December 1998.
Finally, product patents were introduced for pharmaceuticals and agricultural chemicals with the enactment of the Patents (Third Amendment) Act, 2005 in March 2005 to meet India’s commitments to the WTO regarding the enforcement of product patents. The Act has provisions for granting compulsory licenses to enable export of patented medicines to countries with inadequate or no manufacturing capacity to meet public health emergencies such as HIV-AIDS (in accordance with the Doha Declaration on TRIPs and Public Health 2001). It provides for both pre- and post-grant opposition to a patent grant by streamlining the procedures for opposition and does away with the provisions relating to EMRs. Thus, with this third amendment regarding product patents, India is obliged to provide strong patent protection rights and the pharmaceutical industry is again facing competition from MNCs necessitating greater R&D efforts since Indian firms can no longer survive on the basis of reverse-engineering.

III. PREVIOUS STUDIES

Earlier studies on the strengthening of intellectual property protection and innovation efforts show mixed results. While some studies demonstrate only a modest effect of stronger patent protection on innovative activities (Scherer and Weisburst, 1995; Kortum and Lerner, 1998; Sasakibara and Branstetter, 2001 and Moser, 2005), others suggest that stronger patents indeed have a positive effect on patenting and R&D activities (Deolalikar and Evenson, 1989; La Croix and Kawaura, 1996; Hall and Ziedonis, 2001; Kanwar and Evenson, 2003). Scherer and Weisburst (1995) studied how a shift in patent regime in 1982, which introduced product patents for pharmaceutical products in Italy, affected the new drug development efforts of domestic firms. They
found that product patents in Italy did not induce a significant shift from imitating drugs developed elsewhere to developing innovative drugs. Kortum and Lerner (1998) used aggregate data to examine the causes of the rise in U.S. patenting in the mid-1980s. They found that rather than the institutional change, it was the shift in R&D productivity or automation that was responsible for the heightened U.S. innovations. In another related study, Sasakibara and Branstetter (2001) using a log-linear fixed effects model, found no evidence of increase in R&D or patenting due to the patent reforms of 1988 that expanded the scope of patents in Japan.

Deolalikar and Evenson (1989) studied the patenting activity for 50 manufacturing industries in India from 1960-70 and suggested that the weak patent policy of 1970 may have lowered foreign technology purchase and domestic adaptive R&D. La Croix and Kawaura (1996) studied the impact of a new patent law that introduced product patents for pharmaceuticals and chemicals in 1986 in Korea and found that stronger patents induced greater R&D expenditures among the leading domestic firms. A study, which is closely related to this paper, is that of Hall and Ziedonis (2001), who studied the effect of the stronger patent laws on the patenting propensity of the U.S. semiconductor industry. They used the basic Poisson model which is too restrictive for modeling firm-level unobserved heterogeneity and the possibility of outliers that are likely to be present in count data. This paper is an advance on the earlier studies as it uses a variety of parametric and semiparametric count data models that allow for both, flexible conditional mean specification and flexible heterogeneity specification, thereby improving the fit of the estimated models. Further, we also include technology spillovers as a determinant of
patenting at the firm level to get a better picture of the dynamics of the R&D and patent relationship.

In general, stronger patents are likely to encourage the entry of new products by MNCs thereby enhancing competition in the domestic market. It would also induce domestic firms to become more aggressive in filing patents given the opportunity to gain from the commercialization of IPRs. We expect that the net welfare loss from higher drug prices owing to stronger patents would be lower in India due to its R&D potential and competitiveness in the generic drugs market.

IV. DATA SOURCES

The paper undertakes a microeconometric study of the patenting activity of the Indian pharmaceutical industry in the light of policy changes and relates the same to a set of attributes that reflect the technological capability of firms such as research capital and technological spillovers. The study is based on a universe of 321 pharmaceutical companies (National Industrial Classification 2423) listed on the Bombay Stock Exchange and found in the Prowess database of the Centre for Monitoring Indian Economy (CMIE). The Prowess database is akin to the Compustat database for U.S. companies, providing information that incorporated companies are required to disclose in their annual reports. The disclosure norms under the Indian Companies Act 1956 require companies to report heads of expenditure accounting for more than 1 percent of turnover. Since R&D expenditure in a developing country like India is often less than 1 percent of turnover, the management often does not report it. When a company does not report spending on R&D, it is unclear whether it does not undertake any R&D expenditure or
does not report it being less than 1 per cent of sales. For this study, only firms reporting some spending on R&D for the period 1990-91 to 2003-04 (years are financial years) are included. All these firms turned out to be “large” firms according to the Department of Industrial Policy and Promotion definition (i.e fixed assets in plant and machinery excluding land and buildings above Rs 10 million). From these, firms were clubbed together according to the same ownership group to form an entity i.e. the firm, its subsidiaries and mergers and amalgamations to match the data with patents. After deleting the entries with missing observations and those with less than four years of data, the final sample for the study was an unbalanced panel of 65 entities with 675 data points. The data for patent applications was hand-tabulated on the basis of notifications appearing in the various volumes of the official *Gazette of India, Part III, Section 2*.

Summary statistics of the key variables are shown in Table 1. At 1995 prices, the median firm in the sample has a research capital that is the annual R&D expenditure worth Rs 6.77 million but does not file for any patents. A notable feature of the data is the simultaneous presence of a large number of zeros and a heavy upper tail with the maximum number of patents being filed by Ranbaxy Laboratories, the largest pharmaceutical firm in India. The frequency distribution of patent applications reveals a highly skewed distribution with over 75 percent of firms not filing any patents (Figure 1).

Process patents are important for a generic drug manufacturer since they guarantee protection to its unique manufacturing process and also returns on its R&D

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3 The R&D deflator (base year 1995) is constructed as a weighted average of the capital deflator and the wage index for urban non-manual employees obtained from the Government of India’s *Economic Survey 2003-04*. The capital deflator (base year 1995) is taken as the weighted average of the price indices for construction, and plant and machinery provided by the *Monthly Abstract of Statistics* published by the Central Statistical Organization (CSO) for various years where the weights are based on the relative shares of construction and plant and machinery reported in CMIE’s *National Income Accounts, January 2004*. 
investments. Figure 2 shows the number of process patent applications for the sample firms between 1991-2004. It is clear that after the establishment of the WTO in 1995, patent applications have increased. It is likely that this upward swing will continue in the future owing to the harmonization of patent laws across the world that would strengthen the position of Indian pharmaceutical firms in international markets for generic drugs. This is particularly true because a number of blockbuster drugs are approaching patent expiration in the next few years such as: Zithromax (Pfizer) in 2005; Prevacid (Takeda), Zocor (Merck), Pravachol (Bristol Myers Squibb), Zoloft (Pfizer) and Paxil (GlaxoSmithklineBeecham) in 2006; Norvasc (Pfizer) and Risperdal (Johnson & Johnson) in 2007; Effexor (Wyeth) in 2008 and Lipitor (Pfizer) in 2010 (Business Today, February 27, 2005, pp54). Since most developing countries do not have adequate production facilities, TRIPs would result in a wider generic market for Indian firms. Moreover, with the introduction of product patents for pharmaceuticals from 2005 onwards, MNCs have started locating greater R&D activities in India, thereby opening up the opportunity for domestic firms to form alliances through contract research, contract manufacturing and outsourcing.

However, it must be borne in mind that although patents are considered to be the output of the R&D process, they are not perfect indicators since not all new innovations are patented and the study does not take into account the value of patents. Moreover, the data on patent applications is for process patents only since India did not recognize product patents for pharmaceuticals till 2005. Nevertheless, patents are a readily available measure to gauge the innovation process since detailed patent data are more readily available than R&D data. Therefore, patents constitute a relevant measure of the output
of R&D activities (Griliches, 1990). In the context of developing countries, process patents can be taken as a proxy for innovation since their R&D activity is mainly adaptive in nature. Thus, we take the output of the knowledge production function as the number of process patents filed by Indian pharmaceutical firms in the domestic patent offices since only selected patent applications are filed abroad owing to the higher costs involved.

The basic premise for including technological spillovers as a determinant of patenting is that Indian R&D is mainly adaptive rather than innovative. Technological spillovers are measured as the difference between total industry R&D expenditure for a given year and the firm’s own R&D expenditure for that year. Thus, technological diffusion is restricted to intra-industry technology. Technological spillovers are usually taken as exogenous technology-push factors that can be complementary or competitive depending on positive or negative spillovers (Cincera, 1997). Competitive spillovers have a negative effect on a firm’s propensity to patent if more R&D investment by rivals implies less R&D expenditure by the given firm to win the patent race. On the other hand, complementary or diffusion spillovers are positive since the benefits of R&D are not entirely appropriable and hence benefit other firms (Griliches, 1992; Cincera, 1997).

V. METHODOLOGY

A. Poisson and negative binomial regression models

To explore into the change in patenting activity of pharmaceutical firms with a change in the patent regime, a patent production function is estimated, where the dependent patent variable is explained by research capital and technological spillovers
and their lags. The discrete non-negative nature of the dependent patent variable generates non-linearities that make the usual linear regression models inappropriate. We use different models of the Poisson and the negative binomial (Negbin) family to estimate the patent production function.

The Poisson regression model is the basic count model such that the probability of a count is determined by a Poisson distribution and the mean of the distribution is a function of the independent variables. In the simple Poisson regression model, the dependent patent variable follows a Poisson distribution with parameters $\lambda_i$. Taking the exponential of $(x/\beta)$ ensures that the expected patent count is positive as required for a Poisson distribution. Let $p_i$ represent the number of patent applications filed by firm $i$ at time $t$ where $i = 1, \ldots, N$ indexes firms and $t = 1, \ldots, T$ indexes time periods. The basic Poisson model is

$$\Pr(p_i|x_i) = \frac{\exp(-\lambda_i)\lambda_i^{p_i}}{p_i!}$$

(1)

This model can be extended to a regression setting by allowing for different $\lambda_i$ to vary according to the set of explanatory variables for the patent production function:

$$\lambda_i = \exp(x_i \beta) = \exp(\beta_0 + \sum_{m=0}^2 \beta_k k_{it-m} + \sum_{m=0}^2 \beta_s s_{it-m} + \beta_t + \beta_T T)$$

(2)

where $x_i$ is the set of explanatory variables and $\beta$ is the vector of parameters to be estimated. The determinants of patents are the log of research capital that is the annual R&D spending $k_i$ and its lags up to two years, the log of technological spillovers $s_i$ and its lags up to two years, time trend $t$ and a dummy $TD$ for TRIPs that takes the value 1
for the year 1999 onwards and 0 otherwise, to account for the first amendment to the Indian Patent Act 1970 in line with the provisions of TRIPs.

A restraining property of the Poisson model is the equality between its first two moments which makes the model intrinsically heteroskedastic:

\[ E(p_{it} \mid x_{it}, \beta) = V(p_{it} \mid x_{it}, \beta) = \lambda_{it}. \]  

This equality between the mean and variance is called equidispersion. However, in practice, the counts show “overdispersion” whereby the conditional variance is greater than the mean. In the presence of overdispersion, the estimates of the Poisson regression model are consistent but inefficient (Gourieroux et al., 1984). Another problem with the Poisson model arises from heterogeneity since \( \lambda \) varies across individual firms. Thus, heterogeneity among firms has to be taken into account to avoid overdispersion in the marginal distribution in the count. Finally, even if the mean structure is correct, the standard errors from the Poisson model are biased downward resulting in large \( t \)-values.

The Negbin model is more general than the Poisson model as it allows for heterogeneity in the mean function and thus relaxes the variance restriction. While the expected value of the Negbin distribution is the same as the Poisson distribution, the conditional variance is different:

\[ V(p_{it} \mid x_{it}) = \lambda_{it} + \alpha g(\lambda_{it}) \]  

where \( \alpha \) is the unknown dispersion parameter and the conditional variance of \( p_{it} \) increases as \( \alpha \) increases. The function \( g(\lambda_{it}) \) is a known function, \( g(\lambda_{it}) = \lambda_{it}^2 \) or \( g(\lambda_{it}) = \lambda \). When the conditional variance is quadratic in the mean, it results in the
Negbin model or the NB2 model of Cameron and Trivedi (1998).

\[ \frac{V(p_{it}|x_{it})}{E(p_{it}|x_{it})} = 1 + \alpha E(p_{it}|x_{it}) \]  \hspace{1cm} (5)

The Negbin model is obtained as a mixture model of the Poisson and gamma distributions. Moreover, according to the Two-Cross Theorem of Shaked, the Negbin model can also handle the large number of zeros in our dataset (see Cameron and Trivedi, 1998).

To account for the problem of unobserved heterogeneity, let us consider a count panel data model with conditional mean given by

\[ E(p_{it}|x_{i1}, \ldots, x_{it}, \eta_i) = \exp(x_{it} \beta) \eta_i + u_{it} \] \hspace{1cm} (6)

where \( u_{it} \) is the random error term and \( \eta_i \) is the unobserved firm-specific effect which enters multiplicatively in the conditional mean function. Equation (6) defines a regression model given by

\[ \lambda_{it} = \mu_i \nu_i + u_{it} \] \hspace{1cm} (7)

where \( \mu_i = \exp(\beta x_{it}) \) and \( \nu_i = \exp(\eta_i) \) is a permanent scaling factor for the individual specific mean and is i.i.d. distributed with density \( g(\nu|x_i \alpha) \). In the case of parametric models, this is assumed to be a gamma distribution function. The firm-specific effect assumed to be invariant over time could be a fixed or a random effect.

**B. Zero-inflated models**

The problem of excess zeroes arises when the data shows a higher relative frequency of zeroes, or some other integer (Lambert, 1992; Greene, 1994; Gurmu and Trivedi, 1996; Mullahy, 1997a). In fact, the presence of excess zeros is itself an
implication of unobserved heterogeneity. Zero counts reflect corner solutions from an economic viewpoint and non-linearities from an empirical viewpoint. As such, the usual Poisson and Negbin model will yield inconsistent estimates of the parameters if it does not allow for the additional non-linearity generated by an excess of corner solutions (Gurmu and Trivedi, 1996).

While the Negbin model improves the underprediction of zeros in the Poisson model by changing the conditional variance but not the conditional mean, the zero-modified count models explicitly model the number of predicted zeros by changing the mean structure to allow the zeros to be generated by two distinct processes. This is done by assuming that a different process generates zeros than the positive counts. This possibility increases the conditional variance and the probability of zero counts. The zero-inflated count data model is a form of hurdle model, where the hurdle is set at zero to account for the “excess zeros” or “zero inflation” problem. The zero-inflated model assumes that the population consists of two types of firms, one that gives a Poisson count including zero and the other that always gives a zero count. Thus, the firms in the latter group have an outcome of 0 with probability 1. Therefore, the distribution has two parameters: the mean $\lambda$ and the proportion of the firms that are of the second type, $\psi$. In the zero-inflated Poisson (ZIP) and zero-inflated negative binomial (ZINB) models, $\psi$ is determined by a logit or probit model:

$$\psi_{it} = F(z_i, \beta)$$

(8)

where $F$ is either the normal or the logistic cumulative density function.

For both the ZIP and ZINB models, Greene (1994) shows that the conditional mean and variance of the model are changed by reducing the expected count by $\lambda \psi$:
Thus, the observed probabilities are a mixture of the probabilities for the two groups. Since $0 \leq \psi \leq 1$, the expected value is less than $\lambda$, i.e., the mean structure in zero-inflated models differs from the mean structure in the Poisson and Negbin models.

For the ZIP model, variance exceeds the mean for $\psi \neq 0$:

$$V(p_{a} | x_{a}, z_{a}) = \lambda_{a}(1-\psi_{a})(1 + \lambda_{a}\psi_{a})$$

(10)

For the ZINB model, the dispersion $\alpha$ is greater than the Negbin model for $\psi \neq 0$:

$$V(p_{a} | x_{a}, z_{a}) = \lambda_{a}(1-\psi_{a})[1 + \lambda_{a}(\psi_{a} + \alpha)]$$

(11)

### C. Hurdle models

Hurdle models are modified count models where the two processes generating the positive and zero counts are different. Zero-truncated models include observations in the sample only after the first count occurs since there may be observations in the dataset that record zero patents in some but not all periods. A probability distribution governs the binary outcome of obtaining a zero or a positive count and if the realization is positive, the hurdle is crossed. Thus, a truncated-at-zero count data model can be used for the conditional distribution of the positive outcomes obtained by rescaling the probabilities of strictly positive outcomes. In the case of zero-truncated Poisson (ZTP) or zero-truncated negative binomial (ZTNB) models, the possibility of counts less than 1 are omitted resulting in the following density function:

$$\text{Pr}(p | \theta, p \geq 1) = \frac{f(p | \theta)}{1 - F(0 | \theta)} \quad \text{for} \quad p_{i} = 1, 2, 3...$$

(12)
where $f(p|\theta)$ is the Poisson or binomial density function and $F(p|\theta) = \Pr(P \leq p)$ is the cumulative distribution function of the count variable $p$. Since the likelihood function is separable with respect to the parameters to be estimated, the log likelihood is the sum of the log likelihoods of the binary outcome and the truncated-at-zero models. By excluding the zero counts, the variance is less than that of the untruncated probability distributions. However, in the presence of truncation, the mean structure changes with overdispersion and this results in inconsistent estimates of the parameters (Grogger and Carson, 1991).

**D. Semiparametric mixture model**

Patents can be viewed as the number of successful R&D ventures out of a large number of unobserved projects undertaken by a firm. In parametric estimation models, the parameters estimated by a patent production function give an idea about the nature of the returns to scale for R&D expenditures and other factors while the random firm-specific effects are assumed to capture unobserved heterogeneity affecting R&D productivity. Specifically, in pharmaceutical patenting, the nature of corporate R&D is an important factor determining the research productivity of different firms due to differences in firms’ incentives and decision-making procedures (Henderson and Cockburn, 1994). The distribution of the firm-specific effects is assumed to follow a gamma distribution when the count variable follows a negative binomial distribution. But, if this distributional assumption is incorrect, it will lead to inconsistent parameter estimates (Wang et al., 1998 and Guo and Trivedi, 2002).

The long upper tail for the count variable reflects the presence of “outliers” that cannot be modeled by assuming a known distributional form of the unobserved
heterogeneity. Thus, the parametric models become unsuitable since the long upper tail makes it difficult to specify the conditional mean function resulting in a poor goodness-of-fit due to the fact that most parametric distributions assign negligible probabilities to huge numbers (Guo and Trivedi, 2002). The appropriate model that addresses this issue is called the semiparametric or the flexible parametric form model (see Cameron and Trivedi, 1998). The mixture model assumes that the Poisson mean is random and the distribution of this mean is called a mixing distribution (Wang et al., 1998). Assuming a continuous parametric form of the mixing distribution yields a parametric mixture model (Hausman et al., 1984). The semiparametric mixture models relax the assumption of a specific parametric form for the mixing distribution of the mean (Heckman and Singer, 1984). According to Lindsay (1983), finite discrete mixing distributions can successfully account for unobserved heterogeneity without strong assumptions about its parametric distribution. Since, the semiparametric mixture model does not impose restrictions on the mixing distribution, it is more suited to modeling “extreme or asymmetric” departures from the basic Poisson model (Alfò and Trovato, 2004).

According to Guo and Trivedi (2002), the realized improvements in the statistical fit of semiparametric models are guaranteed only if the baseline model is itself sufficiently flexible like that of the Negbin family. Hence, we estimate the semiparametric negative binomial (SPNB) model by dropping the assumption of gamma distribution for the unobserved heterogeneity. From equation (4.7), \( \nu_i \) is the random intercept for cluster \( i \) which represents the time invariant unobserved heterogeneity or within-firm correlation. Here, the conditional mean remains the same as in Negbin but the distribution of the unobserved heterogeneity becomes more general so that the
marginal density of $p$, conditional on the deterministic parameters $\lambda$ and $\alpha$ but unconditional on the random parameter $\nu$, is obtained by integrating out $\nu$:

$$h(p|\lambda, \alpha) = \int f(p|\lambda, \nu) g(\nu|\alpha) d\nu$$

(13)

where $g(\nu|\alpha)$ is the mixing distribution and $\alpha$ is the unknown parameter of the mixing distribution. In this model, each firm is assumed to belong to one of $K$ distinct groups with the prior unconditional probability $\pi_k$ such that $\sum_{k=1}^{K} \pi_k = 1$. The group membership is unobservable, otherwise it would result in the basic Poisson model.

E. Interpretation of estimated coefficients

The partial derivative of $E(p|x)$ with respect to $x_i$ is given by:

$$\frac{\partial E(p_u|x_u)}{\partial x_k} = \frac{\partial \exp(x_u\beta)}{\partial x_k} \frac{\partial x_k}{\partial x_k} = \exp(x_u\beta) \beta_k = E(p_u|x_u) \beta_k$$

(14)

Thus, the greater the value of $E(p_u|x_u)$, the larger is the rate of change in $E(p_u|x_u)$. The partial response depends on $\exp(x_u\beta)$ which is likely to vary across firms. It is clear that $\beta_k$ measures the relative change in $E(p_u|x_u)$ due to a unit change in $x_k$ and since $x_i$ is in logs, $\beta_i$ has an elasticity interpretation.

VI. EMPIRICAL FINDINGS

The patent production function or the knowledge production function relates the number of patent applications filed by a firm in a given year to its research capital and technological spillovers within the industry, together with their lags up to two years. The
lags are chosen according to the Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC). Since it takes time for R&D and technological spillovers to be reflected in new patent applications, it is important to analyze their timing. A priori, one would expect the effect of the TRIPs dummy to be positive since stronger patent protection and a longer patent term would induce firms to file more patents.

Table 2 presents the estimation results of the patent production function for alternative count panel data models. It is clear that the results are quite sensitive to the estimation model used. To begin with, we test whether the estimated coefficients are the same for the efficient random effects estimator and the consistent fixed effects estimator. A Hausman test of random versus fixed effects rejects the random effects model in favour of the fixed effects model, so we estimate the fixed effects models for columns (1) to (6). Although the fixed effects models may handle unobserved heterogeneity, they may not be flexible enough in the presence of large patent counts, necessitating the estimation of the SPNB model. For the ZIP, ZINB, ZTP and ZTNB models, the binary equation is estimated with a logit model. The SPNB model is estimated with the logit canonical link using adaptive quadrature. An important caveat is that since only a small number of individual coefficients are significant at the five or 10 percent level of significance, we compare the sum of elasticities for the explanatory variables.

The elasticities of patents with respect to R&D expenditure in earlier studies for the U.S. were estimated to be 0.43 and 0.38 for the conditional Poisson and conditional Negbin models, respectively (Hausman et al., 1984) and 0.38 and 0.33 for the conditional Negbin model using different samples (Hall et al., 1986). In general, the lag structure is not well defined because of the high within-firm correlation of R&D. Most of the
previous studies (Pakes and Griliches, 1984; Hausman et al., 1984; Hall et al., 1986; Blundell et al., 2002) find a “U-shaped” lag distribution where the bulk of the R&D elasticity is contributed by the first and last year. The literature has attributed such a lag distribution to a possible lag-truncation bias due to the neglect of pre-sample R&D investment. In this study, the research elasticity of patents varies according to the different models ranging from 0.47 for ZTP to 1.82 for SPNB. The SPNB model suggests increasing returns to scale for R&D. It seems firms engaged in R&D get higher returns from their research efforts in developing countries like India than in developed countries. Since a large majority of the firms do not invest in R&D in developing countries, the firms that do undertake R&D activities get high returns from successful R&D. Further, the estimates do not show the contemporaneous relationship between patents and R&D as in earlier studies for developed countries. Only the second lag for R&D is significant in the models estimated, indicating that there is a gestation lag between R&D investments and filing of patents in developing countries even in technology-intensive sectors like pharmaceuticals.

Similarly, the results for technological spillovers not only show positive elasticities but also evidence of increasing returns to scale. This is in contrast to the findings by Crépon and Duguet (1997) who found the elasticity of spillovers to be negative, -0.2. However, the results confirm the findings by Cincera (1997) of a positive elasticity for the spillover variable who found the elasticity to be 1.5 for the conditional Poisson model. Since the nature of Indian R&D is adaptive and pharmaceutical firms imitate the drugs produced by MNCs to produce their own generic versions of the drug, a part of the positive technological spillovers may also reflect greater diffusion of new
technology from the Indian affiliates of MNCs to domestic firms. In general, strong IPRs induce higher inflow of foreign direct investment (FDI) into the host country and it may well be the case that the patent reform initiated by the government of India has raised affiliate R&D spending. Since R&D expenditures by MNC affiliates are mostly concentrated on the adaptation of parent technology to local needs, it is likely that some of their technology gets disseminated in the process.

The estimated coefficient for the time trend shows a negative sign for all the models, which is the same as the finding by Hausman et al. (1984). Everything else being constant, had the regulatory reforms not been introduced, then patent filings would have continued to show the non-positive trend. But TRIPs generated awareness about the IPRs and Indian firms realized the gains to be had from the commercial exploitation of patents.

The parameter estimates for the dummy for TRIPs are positive and significant across the different regression models. Moreover, the LR test for the Poisson and Negbin models for parameter instability shows significant chi-square statistics, indicating a structural break after 1999. The results support the hypothesis that stronger patent laws induce greater patenting activity. This implies that technology-intensive industries like pharmaceuticals require patent protection to undertake risky R&D ventures to enable them to recoup their costs.

Finally, Figure 3 compares the models in columns (1) to (4) by showing the deviations of the predicted probabilities from the observed probabilities for patent counts. It is clear that the Poisson model underpredicts the zeros compared to the other models. The Poisson model rarely has a good fit because of overdispersion and the fact that it only accounts for the observed heterogeneity but not the unobserved heterogeneity
among firms. The Negbin model remedies this situation by adding a dispersion parameter $\alpha$ to allow for more flexibility in the variance structure. Since the models of the Poisson and binomial family are nested, we carried out LR tests for overdispersion and found significant evidence of overdispersion. Thus, binomial family is preferred over Poisson family for all the nested models. Overall, model comparison on the basis of log-likelihood, AIC and BIC shows that the SPNB model is the model with the best fit. This is as expected since the SPNB model does not assume a distributional form for the unobserved heterogeneity and also accounts for large patent counts.

VII. CONCLUSION

This paper has employed different parametric and semiparametric count data models to study the change in process patent applications in an environment of rapidly changing IPR legislations for an original sample of 65 Indian pharmaceutical firms. The main determinants of the patent production function include R&D and technological spillovers and their lags as well as a dummy for TRIPs indicating a structural break after 1999. In order to deal with econometric problems such as unobserved heterogeneity and large patent counts, we find that the more flexible semiparametric mixture model provides a better fit than other models. The results of the econometric exercise indicate that research capital and technological spillovers are important inputs in the patent production function. The findings suggest that there are gestation lags between R&D and patent applications and patenting occurs at a later stage of the R&D sequence in developing countries like India. As regards technological spillovers, the positive elasticity for total spillovers indicates that the social returns of knowledge outweigh the private ones.
The study finds that a stricter patent regime has indeed stimulated patenting activity in the Indian pharmaceutical industry. The harmonization of patent laws worldwide, coupled with the recent patent expirations of a number of blockbuster drugs has opened a window of opportunity for Indian pharmaceutical manufacturers known for their skill at producing generic versions of off-patent drugs at low costs. Thus, even in developing countries, IPRs are increasingly being recognized for their commercial value and are emerging as valuable assets to be protected and exploited.

The results of the study have significant policy implications for strengthening patent protection in other developing countries that are at a stage of technological development comparable to India. Finally, the Indian pharmaceutical industry is in a state of transition and the effect of stronger IPRs laws on patenting activity for product patents is a potential area for future research since product patents have been introduced only from January 2005.

REFERENCES


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<th>Mean</th>
<th>Std Dev</th>
<th>Min</th>
<th>1st Q</th>
<th>Median</th>
<th>3rd Q</th>
<th>Max</th>
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<td>0</td>
<td>0</td>
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<td>Research capital</td>
<td>36.24</td>
<td>109.0</td>
<td>0.09</td>
<td>1.88</td>
<td>6.77</td>
<td>27.26</td>
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<td>Technological spillover</td>
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<td>(Rs mn, 1995 prices)</td>
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<td>Dummy for TRIPs</td>
<td>0.79</td>
<td>(N = 534)</td>
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TABLE 2: PARAMETER ESTIMATES FOR THE PATENT PRODUCTION FUNCTION

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<tr>
<th>Variables</th>
<th>(1) Poisson</th>
<th>(2) Negbin</th>
<th>(3) ZIP</th>
<th>(4) ZINB</th>
<th>(5) ZTP(a)</th>
<th>(6) ZTNB(b)</th>
<th>(7) SPNB</th>
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<tr>
<td>(k_t)</td>
<td>0.231</td>
<td>0.198</td>
<td>0.272</td>
<td>0.279</td>
<td>0.273</td>
<td>0.243</td>
<td>0.418</td>
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<td></td>
<td>(0.206)</td>
<td>(0.165)</td>
<td>(0.212)</td>
<td>(0.176)</td>
<td>(0.215)</td>
<td>(0.195)</td>
<td>(0.262)</td>
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<td>(k_{t-1})</td>
<td>0.001</td>
<td>-0.024</td>
<td>-0.014</td>
<td>0.042</td>
<td>-0.024</td>
<td>-0.032</td>
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<td></td>
<td>(0.157)</td>
<td>(0.176)</td>
<td>(0.163)</td>
<td>(0.203)</td>
<td>(0.164)</td>
<td>(0.212)</td>
<td>(0.302)</td>
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<tr>
<td>(k_{t-2})</td>
<td>0.297**</td>
<td>0.555***</td>
<td>0.242*</td>
<td>0.511***</td>
<td>0.224*</td>
<td>0.284</td>
<td>1.478***</td>
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<td></td>
<td>(0.131)</td>
<td>(0.156)</td>
<td>(0.131)</td>
<td>(0.191)</td>
<td>(0.133)</td>
<td>(0.195)</td>
<td>(0.290)</td>
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<td>Sum of (k)</td>
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<td>0.729***</td>
<td>0.500*</td>
<td>0.832***</td>
<td>0.473*</td>
<td>0.495</td>
<td>1.822***</td>
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<td></td>
<td>(0.268)</td>
<td>(0.278)</td>
<td>(0.263)</td>
<td>(0.310)</td>
<td>(0.269)</td>
<td>(0.335)</td>
<td>(0.153)</td>
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<td>(s_t)</td>
<td>2.581**</td>
<td>4.322**</td>
<td>1.409</td>
<td>2.465</td>
<td>1.209</td>
<td>1.061</td>
<td>10.202***</td>
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<td>(1.007)</td>
<td>(1.804)</td>
<td>(1.077)</td>
<td>(1.592)</td>
<td>(1.116)</td>
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<td>(s_{t-1})</td>
<td>-0.583</td>
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<td>(1.085)</td>
<td>(1.927)</td>
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<td>(s_{t-2})</td>
<td>2.853***</td>
<td>-0.051</td>
<td>3.408***</td>
<td>-1.370</td>
<td>3.445***</td>
<td>1.772</td>
<td>-1.625**</td>
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<td>(0.986)</td>
<td>(0.945)</td>
<td>(0.939)</td>
<td>(1.626)</td>
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<td>Sum of (s)</td>
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<td>3.577*</td>
<td>4.388**</td>
<td>0.914*</td>
<td>4.206**</td>
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<td>(1.937)</td>
<td>(2.136)</td>
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<td>(t)</td>
<td>-1.045*</td>
<td>-0.723</td>
<td>-0.995*</td>
<td>-0.200***</td>
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<td></td>
<td>(0.550)</td>
<td>(0.594)</td>
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<td>(0.644)</td>
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<td>(TD)</td>
<td>2.000***</td>
<td>1.378**</td>
<td>1.706***</td>
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<td>1.662***</td>
<td>1.284*</td>
<td>1.797***</td>
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<td>Overdisper- sion test(b)</td>
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<td>225.20</td>
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<td>LR test(c)</td>
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<td>AIC</td>
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**NOTE.** - Robust standard errors are given in parentheses and P-values in square brackets.

***, **, * denote that the coefficients are statistically different from zero at the 1-, 5- and 10-percent levels, respectively.

\(a\) The log-likelihood values for the ZTP and ZTNB models include the log-likelihood of the logit model.

\(b\) The overdispersion test is a likelihood ratio test, under the null that \(\alpha = 0\), for nested models comparing the given column to the column on its left.

\(c\) The LR test for structural stability tests the null hypothesis that the coefficients of the model do not vary between the two subsets of the data before and after 1999.
FIGURE 1.- Frequency distribution of patent applications
FIGURE 1.- Process patent applications for sample firms, 1991-2004
FIGURE 3.- Deviations from observed probabilities