Strong Medicine: Patent Reform and the Emergence of a Research-Driven Pharmaceutical Industry in India*

Ashish Arora
Lee Branstetter
Chirantan Chatterjee

H. John Heinz III School of Public Policy and Management
Carnegie Mellon University

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Abstract

How do private returns to inventive activity change in developing countries when IPR regimes are substantially strengthened? Our paper investigates this question by looking at the impact of patent reforms in India on India-based pharmaceutical companies. In a fundamental policy shift, India agreed to introduce product patents for pharmaceuticals when it signed the WTO TRIPS treaty in 1995. This policy came into effect through enabling legislation in 2000 and final implementation in 2005. We estimate the impact of this policy shift by using data on a panel of 315 Indian pharmaceutical firms drawn from the years 1990 to 2005. We find evidence of an increase in both R&D investment and measured inventive output that appears to be broadly coincident with patent reform. We also find that the private returns to R&D investment appear to be rising as a consequence of patent reform. Private returns to firms' investments are measured using a hedonic stock market valuation of tangible total assets (A) and intangible inventive assets (K), measured as the stock of R&D spending. The findings indicate an economically and statistically significant increase in private returns to inventive activity. However, this effect appears to be highly concentrated in the most technologically progressive Indian firms.

Key Words: Patent reforms; private returns; intangible assets; market value of innovation; Indian pharmaceuticals.

Ashish Arora
Heinz School of Policy and Management
Carnegie Mellon University
5000 Forbes Avenue
Pittsburgh, PA 15213
ashish@andrew.cmu.edu
and NBER

Lee Branstetter
Heinz School of Policy and Management and
Department of Social and Decision Sciences
Carnegie Mellon University
2504B Hamburg Hall
Pittsburgh, PA 15213
branstet@cmu.edu
and NBER

Chirantan Chatterjee
Heinz School of Policy and Management
Carnegie Mellon University
5000 Forbes Avenue
Pittsburgh, PA 15213
chirantan@cmu.edu

I. Introduction

Can a shift to strong intellectual property rights induce higher levels of inventive effort in developing countries? This question has acquired increased salience in recent years as developing country governments, international agencies, and economists have all struggled to understand the impact of the worldwide movement to stronger IPR on developing countries. The existing evidence on this question appears to be inconclusive, at best.[1]

The Indian pharmaceutical industry provides a particularly interesting context in which to explore this question. From the early 1970s through 2005, India's pharmaceutical industry operated under a legal regime that nearly nullified patent protection for pharmaceutical products. Indian firms were effectively free to sell imitations of patented Western medicines without sanction in their own country (and in other countries that did not enforce product patents for pharmaceuticals). This business model was gravely threatened by the ratification of the TRIPs Agreement in the mid-1990s. This agreement bound all signatory states to enact and enforce patent regimes that offered strong protection to pharmaceutical products.

Indian industry leaders and their advocates in the Indian government asserted that the creation of pharmaceutical product patents in India would force up prices for essential medicines without generating any positive benefit in the form of increased R&D and innovation, either on the part of domestic firms or through multinational firms shifting R&D to India. These concerns led Indian government officials to sharply criticize TRIP. Several recent academic papers have echoed these concerns, using theory and/or empirics to forecast the potential welfare losses affecting current and future consumers, especially in countries like India, through the higher drug prices a stronger patent regime might bring.

[1] Maskus (2000) provides a masterful overview of the critical issues. See also Fink and Maskus (2004) for a focused discussion of the role of intellectual property rights in the development process. Lerner (2002) presents evidence based on a very long, comprehensive set of patent reforms. See Qian (2007) and the references therein for recent studies that address this issue. The literature is quite extensive, and we make no attempt at a comprehensive review.

These papers include Chaudhuri, Goldberg, and Jia (2006), McCalman (2001), and Cockburn and Lanjouw (2001). A common feature of these papers is that they either completely ignore or heavily discount the possibility that stronger patents might actually induce increases in R&D in developing countries.

This may be problematic, because recent Indian data reviewed in this paper point to a striking increase in the R&D intensity of Indian pharmaceutical firms. This appears to be a firm response to market opportunities. The stock market valuation of Indian firms' investment in R&D has increased sharply. More detailed investigation of the data suggests a concentration of the increase in R&D spending in a small group of local firms with especially well developed research capabilities; this also appears to be the same group of firms in which the rising stock market valuation of R&D investment is concentrated. Press accounts, industry analysts, and the statements of Indian pharmaceutical executives all seem to point to a development once widely viewed as improbable – the emergence of a domestic research-driven pharmaceutical industry. The timing of these shifts is so strongly coincident with important changes in India's patent regime that it is hard not to view the shift to stronger patents as having played a causal role in this transition.

We do not claim that the recent rise in innovation is sufficient to outweigh the welfare concerns raised above. Given these developments, however, it seems clear that any attempt to gauge the welfare impact of the patent regime change in India which ignores the impact on innovation is incomplete. In this paper, we seek to document this impact, quantifying its magnitude and its distribution across time and the cross-section of Indian firms. Our findings suggest a number of directions for future research, and these will be discussed in our conclusion.

As we proceed, some words of caution are in order. The Indian pharmaceutical industry remains a small part of the global industry, and its R&D efforts remain a very small part of the global pharmaceutical research enterprise, as has been stressed by Cockburn

(2007). Should the trends documented in the paper continue, even on their current trajectories, it would still be impossible for us to suggest that these trends will change the broad contours of global pharmaceutical activity in the near future. The medium to long-run future, however, could be a very different story.

II. The Evolution of India's IPR Regime

India began its history as an independent nation with relatively strong intellectual property rights for pharmaceutical products. India adopted the British Patents and Design Act of 1911 after independence in 1947 and kept this law in place until 1972. Under this statute, firms could patent all the processes by which a given drug could be manufactured, they could obtain product patents, and patents lasted for 14 years. The relatively strong patent regime allowed multinational drug countries to translate their research strength into high market shares. Foreign drug companies dominated the Indian drug industry throughout the period during which this law was in effect, collectively holding a 68% market share in 1970. It was widely believed, at least in India, that the strong IPR regime effectively prevented the development of an indigenous drug industry (Chaudhuri [2005]).

In response to these concerns, the Government of India enacted a fundamentally different law, the Indian Patent Act of 1970, which was implemented in 1972. This law shorted the life of a patent to 5-7 years and allowed a manufacturer to patent only one method of production for a drug. Other producers were free to produce the same product, so long as they used a different production process. This dramatically weakened patent protection – in many cases, it effectively nullified it -- and the market position of the multinational firms.[2] Indian firms could now legally imitate newly introduced drugs without sanction in their own country, so long as they did not use patented processes. By 1980, the market share of the multinationals had fallen to 50%, and it would continue to fall over the

[2] The position of the multinationals was also weakened by the Foreign Exchange Regulation Act of 1973, which limited the permitted level of foreign equity ownership and the scope of business of multinational drug firms. The New Drug Policy of 1978 introduced new restrictions which tended to weaken the position of the multinationals. A series of drug price control acts, begun in the 1970s, further reduced the attractiveness of the Indian market for foreign multinational firms.

next two decades (Chaudhuri [2005]) as these new, weaker patent laws remained in place. Indian firms that had been founded prior to the Patent Act of 1970 grew, and large numbers of new firms entered the market over time.

Indian pharmaceutical production grew rapidly after the implementation of the new patent act, as shown in Table II.1.[3] The table divides production into bulk drugs (the raw ingredients used in pharmaceuticals) and formulations (mixtures of substances ready for human consumption). Both categories grew substantially. Given the weak patent regime, little effort was devoted to drug discovery, but the manufacturing capabilities, reverse engineering skills, and imitative capacity of domestic firms became steadily more advanced. Indian firms were able to produce and sell drugs initially invented in the West within only a few years of their introduction into major markets.[4] Low costs of production increasingly provided Indian firms with a competitive edge outside India, particularly in product categories or markets in which patents were not an issue. By 1988-89, India had become a net exporter of pharmaceutical products, exporting more than 75% of its bulk drug production and about 25% of its production of formulations. Indian firms captured global headlines at the end of the 1990s, when they announced their intention to manufacture and sell combinations of anti-AIDS retroviral drugs for a fraction of the costs being charged by the Western firms that had originally developed these drugs. Even the U.S. Food and Drug Administration attested to the quality of Indian pharmaceutical manufacturing: by 1999, it had certified 193 Indian manufacturing plants as complying with its regulations and standards for production for export to the U.S. market.

[3] The table includes production in foreign affiliates, but much of the growth was coming from indigenous firms.

[4] The penchant for rapid imitation emerged quickly. See Keayla (1998).

Table II.1 Production of Bulk Drugs and Formulations

Year	Bulk	Formulations
1974-75	900	4000
1979-80	2260	11500
1984-85	3650	18270
1989-90	6400	34200
1994-95	15180	79350
1999-2000	37770	158600
2003-2004	77790	276920

Source: Ministry of Chemicals and Fertilisers, Government of India Annual Report Various Issues, Chaudhuri 2005;

Figures in Indian Rupees million – at current prices.

Despite these successes – or perhaps because of them – the intellectual property rules under which the Indian firms operated were about to change again. In 1986, the Uruguay Round of international trade negotiations was launched. They would drag on for nearly a decade. One of the most divisive issues in these negotiations was the demand of the developed countries for developing countries like India to substantially strengthen their patent laws by ratifying the so-called Trade Related Intellectual Property Rights (TRIPs) Agreement that would eventually become part of the WTO charter.

Western countries insisted that India adopt strong patent protection for pharmaceutical products, a demand that appeared to pose a grave threat to the Indian pharmaceutical industry. Product patents would protect a chemical entity, not a manufacturing process. All conceivable manufacturing processes that produced a chemically identical substance would be effectively covered by such a patent regime, making the kind of reverse engineering practiced by Indian firms illegal. Indian industry leaders and their

advocates in government asserted that the creation of effective patent protection for pharmaceutical products in India would force up prices for essential medicines without generating any positive benefit in the form of increased R&D and innovation. Despite strong Indian objections, however, a TRIPs Agreement incorporating relatively strong patents for pharmaceuticals survived the negotiating process. If India wanted to be a part of the newly created World Trade Organization, it would have to ratify the TRIPs Agreement along with the other components of the WTO Charter. Reluctantly, the Indian government did so, signing the TRIPs treaty in late 1994.

When the Indian government took this step, it effectively committed itself to a path of reform that would eventually produce a patent statute consistent with the standards outlined in the new TRIPs Agreement. However, the treaty allowed developing country member states a number of years in which to come into full compliance with the treaty. Indian stretched out its patent reform process for more than a decade, and the domestic debate that raged within India over exactly how to honor its WTO obligations complicated the reform process in some ways. Table II.2 provides a summary of the key steps in this reform process.

Table II.2 Intellectual Property Laws and Indian Pharmaceuticals

Year	IPR events in India	Implications
From Pre'72 to Post '72	British Patents and Design Act, 1911 - Patents Act 1970	• Pre 1972: A product and process patent regime; Life of drug patents 14 years; One could patent all processes for drug manufacturing. • Post 1972: Product patent regime abolished, patent only a method or a process, Life reduced to 5 – 7 years, for a particular drug only one method or process patentable.
1994-1995	Signing of the WTO TRIPs treaty by India as a result of the 1986-1994 Uruguay Round of negotiations	▪ Dec 31st, 1994: The Patents (Amendment) Ordinance allowing filing and handling of product patent applications for pharmaceutical and agricultural chemical products, as well as the granting of exclusive marketing rights, EMRs on those products. The Ordinance became effective on January 1, 1995.

		▪ The Patents Amendment Bill 1995 was introduced.
1996-1997	Transition period	• Indian Patent office keeps receiving product patent applications. ▪ Meanwhile disputes with US and EU at WTO related to violation of product patents. ▪ WTO asks India to complete institutional reform on new IPR laws by April 1999.
1998 – 2001	India signs and ratifies Paris convention and PCT	▪ WTO reviews the TRIPs terms and grants an extension to India beyond 2000 but before January 1st 2005 – the new deadline to implement product patents.
May 2002	Patent Amendment Act Promulgated	• Terms of all patents in force on this day including process patents are extended to 20 years from the grant date.
2002-2003	Period of change, interest groups fight granting of EMRs by IPO, City High Courts put up stay orders.	▪ Examples of disputes: Rejection of EMR for GSK's Rosiglitazone and Hoffman La Roche's HIV drug Squinavir, based on patent application having been filed before 1995. Natco Pharma gets a stay order from Chennai High Court on EMR for Novartis's cancer drug Glivec – the Indian generic producers getting a safe cushion against government enforcement.
Dec 2004 – 1st of Jan' 2005.	Amendments to Patents Act before deadline of Jan 1st 2005 as set by WTO	• Product patent regime in place finally. From 1st of Jan'2005 a firm could also now file for a product patent within India, and be granted the same.
Source: Chaudhuri [2005], Oxford, Analyst Reports, Thomson Scientific, World Wide Web.		

The evolution of the reform process suggests that the years since 1990 can be divided into three parts. In the years 1990-1994, there was considerable uncertainty regarding the outcome of the Uruguay Round negotiating process. Only by 1994 was it clear that the Indian government would sign the TRIPs Agreement. We therefore consider this to be a period in which knowledgeable industry observers and the stock market would likely heavily discount the probability of substantial change in the Indian IPR regime for pharmaceuticals.

That changed significantly in the period from 1995 through 1999. The Indian government began accepting and processing applications for product patents and exclusive

marketing rights. However, national legislation was required to provide a legal basis for these product patent applications. While a patent amendment was introduced in 1995, it was not enacted for another 10 years. Disputes continued, both within India and between India and its trading partners, regarding the exact contents and timing of this legislation. Patent reform was now inevitable, but the exact nature of that reform was still not completely clear to market participants. This suggests a different sort of discount factor being applied by the market.

At the end of the 1990s, India requested and was granted an extension by the WTO for additional time to complete its institutional reform process. The WTO gave Indian until Jan. 1, 2005 to complete the process. We believe that, in this final period, the "end game" was increasingly evident to all market participants and observers. This view is supported by conversations with industry practitioners and a reading of the contemporary business press. The final amendment legally authorizing product patents was passed just before the deadline, and came into force in 2005.

If our reading of the policy reform process is correct, then we should be able to identify discrete shifts in market behavior corresponding to the three subperiods outlined above. That is a central goal of this paper. Working with a panel of 315 Indian pharmaceutical firms from 1990 to 2005, we aim to test empirically the effects of fundamental patent reform on the private returns to R & D. Although there were as many as 5,877 drug manufacturing units in India toward the end of our sample period, only a bit more than 300 firms were publicly traded on the stock exchanges. These larger firms dominate the Indian industry, cumulatively accounting for more than 90% of the market, and we have data at the firm level on most of them[5]. For these larger firms from the more organized part of the industry, the significant shift in the Indian patent system toward greater protection of product innovation may induce important changes in firm strategy. It is

[5] This was shared to us in a conversation by Mr D G Shah, the Secretary General of the Indian Pharmaceutical Alliance, the leading industry body for domestic drug firms in India.

possible that many of these firms will seek to create new drugs, adopting a business model more like that of established pharmaceutical firms in the West. To the extent that this is the case, financial markets in India are likely to respond by changing the valuation of firms' R&D investments. Our paper seeks to quantify the extent to which this has occurred.

III. Measuring the (Private) Returns to R&D Using Market Value

Both private firms and governments have a keen interest in measuring the economic returns to innovative activities. This is especially true if one can place the measurements in context with policy changes, thereby quantifying the effects of changes in innovation policy on the economy. To measure the impact of changes in IPR regimes on innovation investments, many researchers have sought to quantify the correlation between total factor productivity or profit growth of a firm and measures of innovation investment (Mairesse and Mohnen [1995]). This popular approach is subject to a number of potential pitfalls (Hall [1998]). In the pharmaceutical industry, the drug development process is subject to long, variable lags. Often ten years or more can elapse between the initial conception of a new drug and its introduction into the market place at a scale sufficient to move the profits or revenues of the firm. Given that the shift to a stronger patent regime began in India only in the mid-1990s, we may be hard pressed to find any evidence of an increase in innovative output by the mid-2000s if we rely on revenue-based or profit-based measures. In addition, a long tradition of scholarship in IO has criticized accounting based measures of profits as being poorly reflective of economic concepts of profitability or market power (Fisher and McGowan [1983]).

These considerations have led many researchers to turn to measures of innovative output based on stock market data. The literature in this area implicitly or explicitly assumes that the stock market values the firm as a bundle of tangible and intangible assets (Griliches [1981] and others). Thus the market value V of a firm is a function of the set of assets that it is comprised of and looks thus:

$$V(A_1, A_2, ...) = f(A_1, A_2, ...) \quad \text{---------- (1)}$$

If we assume that the firm is comprised of a single asset A, with constant returns to scale and linear homogeneity of the profit function, then the market value V of a firm is a multiple of the book value of the asset A, with the multiplier equaling Tobin's Q.

Since the true functional form of (1) is unknown, the econometric literature has tended to work with simple ad-hoc approximations like linear or Cobb-Douglas (linear in logs) equations. Rather than attempt to justify these simple approximations theoretically, some researchers simply regard them as a first order approximation to the true underlying functional form of *f* (Hall [1998]). Following in this tradition, we define the market value $V_{i,t}$ of a firm i at a time t, with two kinds of assets, $A_{i,t}$ and $K_{i,t}$. The tangible assets $A_{i,t}$ are measured by the book value of total assets of the firm[6] and the intangible assets $K_{i,t}$, used as proxy for knowledge capital, are measured by stocks of R & D expenditure of a firm. The aim in such a setting is to capture the shadow value of $K_{i,t}$, the intangibles, over the tangible assets $A_{i,t}$ through the effect of $K_{i,t} / A_{i,t}$ on the market value of the firm. This effect is captured through the coefficient in the estimating equation, β. We can interpret the above as follows: the additive combination of both the tangible and intangible assets assigns the firm a value, expectations of which lead a firm's investors to price firm *i* at time *t* at $V_{i,t}$. The basic market value equation of the firm thus assumes the form:

$$V_{i,t}=q_t(A_{i,t}+\beta_t * K_{i,t})^{\sigma} \quad \text{---------- (2)}$$

where σ measures returns to scale and q is shadow value of the measured market value of the firm (as a combination of its tangibles and intangibles) over its real market value, which in the long run should equal 1[7]. We can also impose the assumption that σ will be equal to 1, which seems like a reasonable assumption, at least in the long run. Taking natural logs on

[6] The construction of variables is outlined in subsequent sections and the appendix in the paper.

[7] In effect this q is actually an estimate of the log of average Tobin's Q, where our LHS measures market value of a firm, our RHS measures replacement cost of assets, as we explain in our appendix.

both sides, the market value equation reduces to:

$$\ln \frac{V_{i,t}}{A_{i,t}} = \ln q_t + \ln(1 + \beta_t * (K_{i,t}/A_{i,t}) + \varepsilon_{i,t} \quad \text{---------- (3)}$$

We should note here that without assuming $\sigma = 1$, Equation (2) on would effectively look like this:

$$\ln V_{i,t} = \ln q_t + \sigma_t \ln A_{i,t} + \sigma_t \ln(1 + \beta_t (K_{i,t}/A_{i,t})) + \varepsilon_{i,t} \quad \text{---------- (4)}$$

For the purposes of our empirical investigation, we use equation (3) as our primary guiding specification. Preliminary regressions (using (4)) suggested a value of σ quite close to 1. The left hand side of (3) is Tobin's Q for firm *i* at time *t*. The right – hand side of the equation is approximated for the term within the logarithm as $\ln(1+x) \approx x$ for small values of x or here K/As. This approximation works reasonably well for K/A levels in the range of 15% and below, and that means the approximation works well for nearly all the observed values of K/A in our data. Thus the estimating equation would assume the form:

$$\ln Q_{i,t} = \ln q_t + \beta_t * (K_{i,t}/A_{i,t}) + \varepsilon_{i,t} \quad \text{---------- (5)}$$

And this is the equation that we actually run[8]. As a robustness check, we relax the assumption of $\sigma = 1$ and generate a reduced form approximation for (4) :

$$\ln V_{i,t} = \ln q_t + \sigma_t \ln A_{i,t} + \sigma_t \beta_t * (K_{i,t}/A_{i,t})) + \varepsilon_{i,t} \quad \text{---------- (6)}$$

Subtracting $A_{i,t}$ from both sides of (6) we get:

$$\ln Q_{i,t} = \ln q_t + (\sigma_t - 1) * \ln A_{i,t} + \sigma_t \beta_t * (K_{i,t}/A_{i,t})) + \varepsilon_{i,t} \quad \text{---------- (7)}$$

We use pooled ordinary least squares to estimate equation (7) including a full set of year dummies for our estimations and introducing firm specific fixed-effects in the pooled regressions. As a further robustness check, we dispense with the log linear approximation

[8] We also test for higher order terms of K/As and note that they are of no significance for the square of R & D / Assets term, the coefficient estimates which would be square of β ranging between -1.03 to -10.16.

and employ non-linear least squares to estimate (3) above. Our non-linear estimation results include time dummies and first-differences to account for firm specific unobserved heterogeneity.

Shifts over time in the market valuation of R&D

A key motivation for the paper is to investigate the time trends in the shadow β. This should capture the effects of a changing IPR regime on the private returns to R & D undertaken by a firm. For our basic estimating equation (5) β stands for the semi-elasticity of Q with respect to changes in K/As, or:

$$\beta_t = \frac{\partial(\ln Q_{i,t})}{\partial(\frac{K_{i,t}}{A_{i,t}})} \text{----------} (8)$$

If the markets are efficient[9] and investors are assumed to be rational, one can expect that stronger patents will give the firm with a higher K/A ratio better valuations in a stricter appropriability environment. While that might not be universally true (quality of research will matter as well as quantity), we modify our estimating equation to allow us to test for such a shift. We introduced period effects in our specification and interact them with our measure of R&D. We break our period of analysis into three phases, noting the period 1990 – 1994 as a categorical variable DA, 1995-1999 as categorical variable DB and 2000-2005 as categorical variable DC. The basic estimating equation (5) with interactions of these dummies and the K/As then becomes:

[9] We assume that Indian stock markets are "efficient." A full description of the functioning of Indian equity markets is beyond the scope of this paper. We note, however, that foreign investment in Indian bourses has surged in recent years, presumably reflecting the confidence of sophisticated foreign institutional investors in this market.

$$\ln Q_{i,t} = \ln q_t + \beta_0 * (K_{i,t}/A_{i,t}) * DA + \beta_1 * (K_{i,t}/A_{i,t}) * DB + ...$$

$$\beta_2 * (K_{i,t}/A_{i,t}) * DC + \varepsilon_{i,t} \quad ----------(9)$$

Using the interaction terms, we check for the movements of β over our three periods. In all our regressions we also use controls of log of sales and mean of overall industry Q for the Indian industry,[10] computing Q for the overall industry in the same way that we construct it for individual pharmaceutical firms.

IV. Data

For the purposes of our research, we have created a unique dataset matching firm-level accounting information with inventive output data and additional controls. The details are outlined below:

Firm Data

Our primary dataset comes from the *Prowess* database of the Centre for Monitoring of Indian Economy, which gives a ready-made industry classification of the firms. The *Prowess* database is similar to *Compustat* database for U.S. companies, providing information that incorporated companies are required to disclose in their annual reports. Our study is conducted using a panel of 315 drugs and pharmaceutical firms (National Industrial Classification 2423) from 1990 to 2005. For these firms, the dataset also provides us annual data from 1990 to 2005 on market capitalization of the firms listed on the Bombay Stock Exchange (BSE). This gives us the market value of the common stock of a firm; we also collect data on preferred stock for these firms. To capture the debt component of a firm's market value, we collect data on borrowings and current liabilities; all of this comes from the CMIE dataset. We also collect data on the total assets of firms as a measure of the tangible assets component of a firm's valuation. Our firm data also includes information on

[10] A note on how we measure Tobin's Q is included in the appendix and in construction of variables.

ownership groups, R & D expenditures, exports, sales, profits and age of the firm as measured from their year of incorporation. We have cross-checked some of our data against equivalent firm financial data from annual reports of firms and from the electronic data source, EDIFAR, of the Securities and Exchange Board of India, Government of India. The CMIE data appear to be broadly reliable. However, we do see extreme values of key variables, including measures of firm assets and R&D, and sharp movements in other variables that are difficult to reconcile with rational markets and nontrivial adjustment costs. We have engaged in some efforts to clean the data and remove suspicious outliers. These steps are discussed further in a data appendix available upon request.

Knowledge Capital data

We collect information on knowledge capital from CMIE and validate it from various public and commercial sources. Knowledge capita is proxied by the R & D expenditure of the firms from the CMIE dataset. This is selectively cross-checked against information from annual reports for the firms, and R & D stocks are constructed from R&D expenditure flows at various literature specified depreciation rates. The disclosure norms under the Indian Companies Act 1956 require companies to categories of expenditure accounting for more than 1% of turnover. Since R & D expenditure in pharmaceutical firms in India are often less than 1%, firms do not report it, even though positive R&D expenditure takes place. We observe in our data gaps in the R&D series, which may reflect reporting series in which R&D expenditure dropped below 1% of sales. Keeping this in mind, we constructed an imputed R & D stock variable with R & D flows being imputed on a firm by firm case basis when these gaps appear. Unlike in the U.S., Indian firms are allowed to treat part of their R&D expenditures as an expense and capitalize the rest. This means that R&D data reported by Indian firms are not equivalent to what would be reported by U.S. firms under the FASB reporting conventions for R&D, which treat all R&D expenditures as an expense. We combine R&D expenditures recorded in the firm current

account (expenses) and the capital account in a given year, and report this combination as our best measure of R&D investment. Given the unresolved debate in the literature concerning the rate at which knowledge stocks depreciation, alternative estimates of our knowledge stocks were created with depreciation rates of 15%, 20%, 25%, 30%, and 35%. Further details of data construction are discussed in an appendix that can be obtained from the authors upon request.

Unfortunately, the Indian statistical authorities do not seem to publish either an R&D labor price index or an R&D capital goods price index. It is possible that these two components of R&D spending have followed different price trends in recent years. Conversations with industry observers suggested a pronounced escalation in salaries for Indian research personnel in this industry. We attempted to deal with this by depreciating R & D expenditure on the current account (reporting current year salaries) more in comparison to R & D expenditure on capital account (no salary related research expenses). A combination of 15% - 30% and 20%-40%[11] were the respective depreciation rates used on the two kinds of R & D expenditure and details on that are included in the data appendix. Finally, we subject the same treatment to imputed R & D expenditure to construct imputed R & D stocks at the various depreciation rates. We report here coefficients of K/As with 15%, 25% and the 15%-30% combination of depreciation rates for stocks computed using both treated and untreated R & D expenditure. We also collect other inventive assets data proxying for K with counts and stocks of Drug Master Files and Abbreviated New Drug Applications (ANDAs) for our set of firms from the Food and Drug Administration of the

[11] CEO of Glenmark Pharmaceuticals Ltd, one of India's upcoming drug firms, Mr Glen Saldanha confirmed our expectation about firm salaries for R & D scientists going up in Indian pharmaceuticals in the last ten years. Professor Narayanswamy from IIM Bangalore, India shared his insights on how to use firm accounting data on R & D stating that in most cases firms report salaries on their current account and report other R & D related expenditure on their capital account. Thus given higher salaries, a higher depreciation rate was applied on the current account entries for R & D expenditure. Rik Santanu Sen, a doctoral student in finance at Stern School of Business, New York University who has worked previously as an industry analyst with ICICI Bank, India finds such a usage of depreciation rates in measuring R & D expenditure for Indian firms sensible.

United States. For our set of firms we also used stocks of domestic patents starting from 1995, collected from the Indian Patent Office, and stocks of U.S. patents, beginning in 1990, as alternative measures of K. Regression results with these alternative measures yielded results qualitatively similar to the ones obtained with R&D stocks, reported in this draft. Details about other Ks are specified in the appendix.

Other Data

The Food and Drug Administration of the United States provides us ten year approval data on manufacturing standards of pharmaceutical firms in India, Japan Korea and Taiwan. This information is used to create a subset of the industry. We also use log of sales as a control in our analysis. The CMIE dataset also provides us information to construct overall Tobin's Q in the Indian industry from 1990 to 2005. We use that as an additional control in our regressions. Finally, we stratify our samples[12] based on data from firm websites and annual reports, governmental reports of industrial R & D and analyst reports. Using these data, we are able to classify our firms into subsets that could be expected, ex ante, to respond differentially to the changes in India's pharmaceutical patent regime. We estimate our key regressions for these subsets and note some interesting patterns in the results.

V. Construction of variables

For our 315 firms, Tobin's Q, is constructed as follows:

a. Tobin's Q of a firm = market value of a firm / replacement cost of its assets.

b. Market value of a firm = market value of its equity + market value of its debt.

c. Market value of firm equity = Market value of its common and preferred stock.

- Market value of common stock = Outstanding shares * closing price (both at BSE, year-end)

[12] The various sample stratification strategies have been outlined in the appendix. The industry was stratified into subsets of firms engaging in US patenting, firms identified by analysts as good investment options, firms approved by FDA and modern firms. Results for shadow of K/A were investigated for these broad sub-samples.

- Market value of preferred stock = Preferred capital provided by the CMIE data (Sarkar and Sarkar [2005]).

d. Market value of firm debt = It's borrowings with current liabilities and provisions.

e. Replacement Costs of a firm's assets = Total assets of a firm in a year, with misc. expenditure and intangible assets, both subtracted from it.

This method for measuring Tobin's Q is also applied to the overall industry dataset and an *Industry Q* is used as an additional control. The dependent variable used was *logarithms of Tobin's Q* for firms in our dataset. Apart from Industry Q, we also used *log of sales* as another control in the regressions. When returns to scale is not assumed to be 1, *log of assets*, is used as one of the independent variables, assets being measured as described in point (e) above. Our *K/As* consisted of two components. The numerator K consists of one our various measures of R & D stocks, as discussed above, and the denominator A is the replacement costs of a firm's assets measured with figures on total assets (misc. expenditure and intangible assets like advertising expenditure reported by firms on this head subtracted). Table V.1 and Table V.2 outline the variables and descriptive statistics. Note that Table V.2 provides summary statistics for our cleaned data set, from which extreme values have been removed.

Table V.1. Description of Variables

Variable Name	Description
Q	Tobin's Q of firm measured as described in the text
ln Q	log of Tobin's Q
A	Total Assets measured as described in the text
ln a	log of Total Assets in a year in Rs crore
Sales	Sales of firm in a year in Rs Crore
ln sales	log of Sales of a firm in a year
Industry Q	Mean of Tobin's Q of entire industry in CMIE database
K/A (untreated, 15%)	Ratio of Un-treated R & D expenditure stocks at 15% depreciation and Total Assets
K/A (untreated, 25%)	Ratio of Un-treated R & D expenditure stocks at 25% depreciation and Total Assets
K/A (untreated, 15%-30%)	Ratio of Un-treated R & D expenditure stocks at 15%-30% combination of depreciation and Total Assets
K/A (treated, 15%)	Ratio of Treated R & D expenditure stocks at 15% depreciation and Total Assets
K/A (treated, 25%)	Ratio of Treated R & D expenditure stocks at 25% depreciation and Total Assets
K/A (treated, 15%-30%)	Ratio of Treated R & D expenditure stocks at 15%-30% combination of

	depreciation and Total Assets

Table V.2. Descriptive Statistics

Variable	*Obs*	*Mean*	*Std. Dev.*	*Min*	*Max*
Q	2790	1.27	1.14	0.00	9.33
Log of Q	2789	-0.03	0.75	-5.46	2.23
Total Assets (10 million INR)	2793	85.12	185.86	0.00	2323.96
Log of Total Assets	2790	3.28	1.52	-4.61	7.75
Sales (10 million INR)	2793	82.74	167.86	0.00	2362.50
Log of Sales	2688	3.07	1.97	-4.61	7.77
Industry Q	5119	1.18	0.36	0.00	1.66
Un-Treated R & D					
R&D Stocks at 15% depreciation / Total Assets	2790	0.02	0.04	0.00	0.32
R&D Stocks at 25% depreciation / Total Assets	2790	0.02	0.03	0.00	0.27
R&D Stocks, 15%-30% combination of depreciation rates / Total Assets	2790	0.02	0.03	0.00	0.28
Treated R & D					
R&D Stocks at 15% depreciation / Total Assets	2790	0.02	0.04	0.00	0.33
R&D Stocks at 25% depreciation / Total Assets	2790	0.02	0.03	0.00	0.29
R&D Stocks, 15%-30% depreciation / Total Assets	2790	0.02	0.03	0.00	0.32

VI. Results and Discussions

In this section we summarize our results. We begin with a review of shifts over time in firm R&D spending and inventive output, before shifting to our main focus on changes in the market valuation of firm R&D spending.

When we focus on data from our 315 listed Indian pharmaceutical firms, we observe a sharp rise in R&D spending that appears to be related to Indian patent reform. We see an initial increase in the 1990s that appears to be broadly coincident with the ratification of the TRIPs Agreement. However, R&D intensity began to grow quite rapidly after 2000, when Indian applied for and received an extension to complete its institutional reform process. In the run-up to the final legislative act that (re)introduced product patents for pharmaceuticals, R&D intensity rose to unprecedented heights. The striking increase at the end of the sample

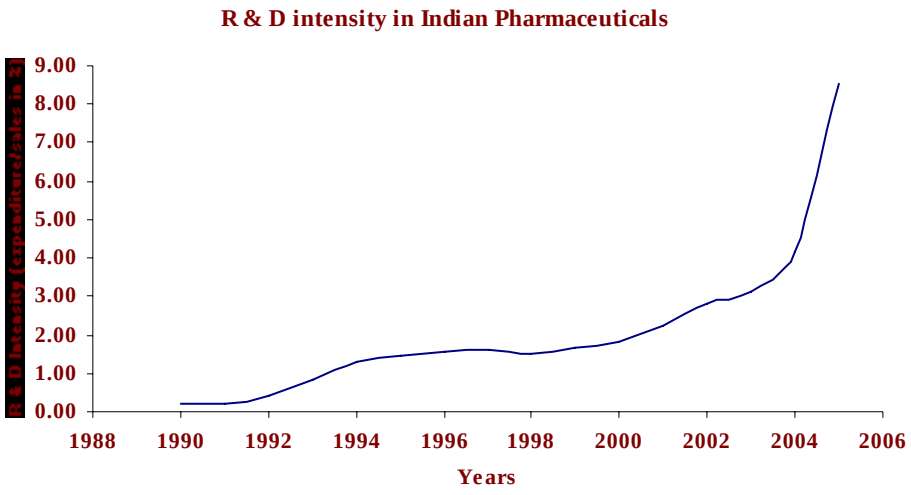
appears to be driven not only by an increase in R&D expenditure but also by exits and sales declines on the part of some of the least R&D intensive firms. Figure 1 and Table VI.1 both suggest a connection between TRIPS-mandated patent regime changes and the shift to a much greater degree of R&D intensity. Numerous articles in the Indian trade press support the idea of a causal relationship between the patent regime change and the rise in R&D intensity.

Table VI.1 R&D Intensity

R & D	Year	R & D/Sales (%)
9	1990	0.23
162	1995	1.45
419	2000	1.80
553	2001	2.22
832	2002	2.79
1,059	2003	3.12
1,568	2004	4.19
2,171	2005	8.51

R&D expenditures are given in 10 million INR

Figure VI.1 R&D Intensity in Indian Pharmaceuticals



There has also been a sharp increase in domestic patent applications, U.S. patent grants, and other innovation indicators that appears to be related to patent reform. Table

VI.2 illustrates trends in Indian firms' domestic pharmaceutical product patent applications, U.S. pharmaceutical patent grants, and certifications for generic production. The latter reflects, to some extent, the results of focused process R&D. All indicators are trending up sharply, in a manner completely consistent with the rise in R&D spending (and market perceptions of the profitability of that spending) we noted in the previous paragraph.

These trends suggest that at least some firms in the Indian pharmaceutical industry are shifting their business model to something far more research-driven than what has been pursued in the recent past. The timing of these shifts, as well as the financial press commentary and the public statements of industry practitioners surrounding these shifts, are all consistent with the view that patent regime change was an important factor driving this transition.

Table VI.2 Rising Measures of Innovative Output

Year	US Patent Counts	Indian Patent Counts	ANDAs
1990	6	0	0
1991	0	0	4
1992	2	0	2
1993	2	0	2
1994	2	0	0
1995	7	1	0
1996	4	9	0
1997	18	33	1
1998	34	59	6
1999	31	40	5
2000	38	50	8
2001	42	56	12
2002	44	71	12
2003	50	86	12
2004	62	374	26
2005	35	605	20
2006	45	552	50
2007	63	689	72

This view is reinforced by our study of shifts over time in the market valuation of firms' knowledge capital assets. We use the specification in equation (9) above to estimate the time effects on the shadow values of knowledge capital for the full firm-level data set

as well as various subsets of these firms. Our period dummies 1990-1994, 1995-1999 and 2000-2005 were interacted with the knowledge capital measures (the K/As) and the coefficients for the interaction terms are reported below in Table VI.3.

Table VI.3 Period trends in β - in industry subsets and overall sample

Pooled OLS	**Entire Industry**	**Only Modern Firms**	**Analyst Firms**	**FDA Firms**	**Other Firms**
1990-1994	1.360	0.182	-1.673	-3.830	2.048
	(0.95)	(0.12)	(0.84)	(1.38)	(0.96)
1995-1999	1.990	2.074	2.704	2.681	1.765
	(3.19)**	(2.95)**	(2.62)**	(1.62)	(2.21)*
2000-2005	2.569	3.301	4.567	5.103	1.706
	(6.41)**	(6.94)**	(6.02)**	(5.55)**	(3.58)**
Log of sales	0.010	0.163	0.231	0.158	-0.005
	(0.95)	(9.16)**	(5.68)**	(3.80)**	(0.42)
Industry Q	0.219	0.274	0.239	0.208	0.212
	(4.95)**	(5.50)**	(2.75)**	(2.22)*	(3.93)**
Constant	-0.254	-0.711	-0.932	-0.739	-0.235
	(4.03)**	(8.65)**	(5.12)**	(4.05)**	(3.10)**
P-value of Wald Tests of Equality	0.5047	0.0390	0.0061	0.0041	0.9861
Observations	2686	1330	426	399	2236
Number of Firms	315	143	41	42	268
R Squared	0.11	0.25	0.41	0.37	0.09
Regressions Using Imputed R&D Data					
1990-1994	1.210	0.048	-1.738	-4.822	1.884
	(0.94)	(0.03)	(0.91)	(1.79)	(1.08)
1995-1999	1.764	1.704	1.999	1.351	1.707
	(2.96)**	(2.57)*	(1.95)	(0.88)	(2.26)*
2000-2005	2.249	2.899	3.90	4.634	1.575
	(5.95)**	(6.36)**	(5.33)**	(5.03)**	(3.49)**
Log of sales	0.010	0.165	0.239	0.160	-0.005
	(0.98)	(9.23)**	(5.82)**	(3.80)**	(0.42)
Industry Q	0.218	0.273	0.237	0.215	0.210
	(4.89)**	(5.45)**	(2.69)**	(2.27)*	(3.87)**
Constant	-0.253	-0.715	-0.959	-0.746	-0.233
	(4.01)**	(8.66)**	(5.20)**	(4.05)**	(3.07)**
P-value of Wald Tests of Equality	0.5677	0.0368	0.0087	0.0009	0.9742
Observations	2686	1330	426	399	2236
Number of Firms	315	143	41	42	268
R Squared	0.11	0.25	0.40	0.37	0.09

We find a tendency for β to rise in the complete sample of 315 listed firms, but this is not statistically significant at conventional levels. However, when we focus on the most technologically progressive firms in the industry, we find statistically significant increases in β, despite the smaller sample size induced by our focus on this subset. The size of the coefficients, and their significance levels, increase in a manner consistent with the direction and increasing certainty of fundamental patent reform in India. These results obtain regardless of whether or not we impute missing R&D data, as described in the previous section.

We employ a number of different measures to identify the relatively technologically progressive firms, including the judgments of security analysts (Analyst Firms), certification by the U.S. Food and Drug Administration (FDA Firms), and possession of formal R&D centers, divisions, or alliances (Modern Firms). Our results are robust to these alternative definitions. In contrast, when we focus on firms in the industry that are outside this technologically progressive subset (Other Firms), there is no evidence of an increase in β. The market appears to be rewarding increases in R&D investment in that subset of firms that is *ex ante* most capable of making a shift from a business model built on the piracy of foreign intellectual property to one that depends heavily on the domestic creation of new products. Interestingly, these quantitative findings are consistent with the published judgments of financial analysts and industry observers. Financial press commentary reflects a clear belief that the patent regime change is an important driving factor in this transition.

These results are robust to a number of robustness checks. We have used alternative, narrower definitions of tangible assets that exclude land. We have dropped industry Q. We have added data on investment in advertising as an alternative measure of knowledge capital. Our qualitative results are unchanged.

Table VI.4 Estimates of Market Valuation of R&D using Varying Depreciation Rates
β with constant returns to scale

σ = 1	**Un-Treated R & D**			**Treated R & D**		
Pooled OLS						
	D = 15%	***d = 25%***	***D = 15%-30%***	***d = 15%***	***d = 25%***	***d = 15%-30%***
R&D Stock/Asset (K/A)	**2.467**	**2.622**	**2.674**	**2.173**	**2.363**	**2.421**
	(6.36)**	**(5.82)****	**(6.05)****	**(5.91)****	**(5.46)****	**(5.71)****
Log of sales	**0.010**	**0.008**	**0.008**	**0.010**	**0.008**	**0.008**
	(0.95)	**(0.79)**	**(0.73)**	**(0.97)**	**(0.80)**	**(0.75)**
Industry Q	**0.216**	**0.217**	**0.217**	**0.213**	**0.214**	**0.215**
	(4.89)**	**(4.92)****	**(4.93)****	**(4.82)****	**(4.84)****	**(4.85)****
Constant	**-0.251**	**-0.254**	**-0.253**	**-0.250**	**-0.252**	**-0.251**
	(3.99)**	**(4.03)****	**(4.02)****	**(3.95)****	**(3.99)****	**(3.98)****
Observations in OLS	**2686**	**2686**	**2686**	**2686**	**2686**	**2686**
No of Firms	**315**	**315**	**315**	**315**	**315**	**315**
R Squared in OLS	**0.11**	**0.11**	**0.11**	**0.11**	**0.11**	**0.11**
Non-Linear Least Squares						
R&D Stock/Assets (K/A)	**2.002**	**1.863**	**1.847**	**1.901**	**1.806**	**1.789**
	(2.42)*	**(2.27)***	**(2.26)***	**(2.33)***	**(2.20)***	**(2.19)***
Observations in NLLS	**2372**	**2372**	**2372**	**2372**	**2372**	**2372**
R Squared in NLLS	**0.13**	**0.13**	**0.13**	**0.13**	**0.13**	**0.13**

 # Dependent Variable: log Q of firms and excluding upper tail and lower tail outliers.
Time Dummies, Controls & Firm fixed Effects in Pooled OLS
No controls in NLLS but with time dummies and first differences
Absolute value of t statistics in parentheses; * significant at 5%; ** significant at 1%

Table VI.4 tests the robustness of our estimates of average β, altering the assumed depreciation rates and the functional form of the value equation. From Table VI.4, we see that as the depreciation rates used to measure the K/As are increased from 15% to 25%, we are discounting past R&D more heavily, and the measured valuation of the knowledge stock rises. However, the key coefficient does not change much. When we allow this coefficient to vary over time, we see changes within subsamples that are quite similar to those reported in Table VI.3. If one thinks that patent reform shifted the focus of R&D, making the potentially more process-oriented expenditures of the early 1990s less relevant, than one can make the argument that a higher discount rate than the traditional 15% may be appropriate. Changing the assumed depreciation rate, however, does not appear to change the basic tenor

of our results. In other results, not shown, we estimated β using a non-linear least squares specification, and we relaxed the assumption that **σ=1.** This alternative specification did not lead to qualitative changes in the nature of our results, nor did it affect the estimated pattern of changes over time in β for different subsets of firms. The basic finding of a statistically and economically significant increase in the market valuation of R&D for technologically progressive Indian firms as the patent system was reformed appears to be robust.

At this point, we must concede that we do not yet fully understand this transition process, though we have convinced ourselves (and, hopefully, the reader) that it exists. The fact that domestic patent reform in India could induce such a transformation appears to fly in the face of conventional wisdom, as articulated in the received literature on the impact of stronger IPR on invention in developing countries. In principle, Indian firms already had the option of developing new compounds, patenting them in much larger markets, and licensing the compounds or selling drugs directly in the West. In an influential analysis of the effect of international patent harmonization on innovation, Grossman and Lai (2004) drove home this basic point – once the larger Western economies are governed by effective patent systems, all inventors in a global trading economy have significant incentives to develop new products, patent them in the major markets with strong patent protection, and sell them in those larger markets. The accession of smaller markets to this strong patent bloc does not increase the total addressable market very much. Despite India's large geographic size and enormous population, its international purchasing power remains quite small relative to the U.S. or Japan, where strong pharmaceutical patents have been in place for many years.

If the changed patent regime in India did have an effect, it must be that by closing off the possibility of imitation, it increased the payoff to research. In other words, imitation and research must be strategic substitutes (Milgrom and Roberts, 1990). This strategic substitutability may arise in various ways, and trying to model alternative mechanisms which could be distinguished from one another with the data at our disposal is the focus of

ongoing research that will take us beyond the scope of the current paper. If we could explain not only *how* patent reform impacted research activity by Indian pharmaceutical firms, but *why* this impact was so significant, then we may be able to contribute significantly to the debate on when and under what circumstances transition to stronger intellectual property rights can stimulate domestic innovative activity.

The final point to make in this section is, perhaps, an obvious one. India's size, its vast potential human resources, and the possession of a common language with the United States raise some interesting possibilities for India's future role in the global pharmaceutical industry. For decades, India's weak patent regime and its open hostility to foreign multinationals made it an unattractive place to do business. While open questions remain about the willingness of Indian courts to enforce judgments under the new law that are favorable to multinationals, the patent regime has been transformed and the former legislative barriers to multinational activity have been removed. Multinational pharmaceutical companies are aggressively pursuing the possibility of moving some elements of their research, manufacturing, and clinical trials operations to India, where enormous potential cost savings could be realized. Today, India remains a very small part of the global industry, and the rise in inventive activity discussed in this paper remains a vanishingly small fraction of total global investment in pharmaceutical R&D. However, to a far greater extent than is true for nearly all countries, India clearly has the potential to become, in time, a much larger part of the industry and of its inventive effort.

VII. Conclusions and Next Steps

This paper reviews recent changes in the patent laws affecting the Indian pharmaceutical industry. We document significant strengthening of these laws over the 1990-2005 period, and we discuss important discrete steps in the reform process. We go on to present data illustrating a sharp rise in measured Indian drug firm R&D spending and various measures of inventive outputs. While we do not attempt formal statistical tests, we observe that the patterns in these data are quite consistent with the idea that at least some

Indian firms have shifted to more R&D-intensive business models in the wake of patent reform.

This hypothesis receives strong support from our attempts to estimate the changing private returns to R&D spending in India, as inferred from the stock market valuation of R&D stocks. While we find evidence of a large shift in this valuation for a broad sample of 315 Indian drug producers, the estimated market shadow values of R&D are not significantly different from one another. However, when we break our cross-section down into subsamples that could be reasonably expected, *ex ante*, to respond differentially to changes in patent law, some very interesting patterns emerge. Technologically progressive Indian firms have seen the market valuation of their R&D investment rise over time. The increase is economically and statistically significant and follows a pattern that is easy to reconcile with the unfolding of patent reform. The relative laggards in the Indian pharmaceutical industry have not seen any increase in the markets valuation of their R&D spending. In results not shown, we find these basic patterns robust to variations in the assumed rate of knowledge depreciation and to variations in assumptions about the functional form of the basic estimating equation.

These robust findings present a challenge to conventional theoretical analyses of developing country patent reform. Influential recent work by Grossman and Lai (2004) presents a compelling argument that Indian patent reform should have very little impact on incentives for innovation, because the largest global markets are already protected by strong patent law. The existence of the U.S. and Japanese markets as a potential export target should have been sufficient incentive to induce Indian firms capable of switching to a more innovation-driven business model to do so. Understanding why this was not the case – understanding why conventional theoretical analysis appears to fail in the case of India – is the focus of ongoing research.

India's size and potential to contribute to global pharmaceutical industry lend some weight to the phenomena discussed in this paper. India remains a small part of the global industry and its contribution to worldwide R&D efforts also remains small. But, to a far greater extent than is true for most countries, India clearly has the potential to become much more important. Trying to understand the future trajectory of development of the pharmaceutical industry in India is also the focus of ongoing research.

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