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WPS6063

Policy Research Working Paper 6063

Pharmaceutical Patents and Prices

A Preliminary Empirical Assessment Using Data from India

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The World Bank
Development Economics
Research Support Unit
May 2012

Policy Research Working Paper 6063

Abstract

The enforcement of stringent intellectual property rights in the pharmaceutical sector of developing countries generates considerable controversy, due to both the extensive research investment and the public policy importance of this sector. This paper explores the likely effects of enforcing product patents on prices and utilization of drugs in the Central Nervous System market in India. The Central Nervous System segment is the second largest therapeutic category in terms of retail sales in the world and is one of the fastest growing segments in India. Using information on product patents granted by the government and panel data on pharmaceutical prices and utilization from 2003–2008, the paper finds limited evidence of overall price increase following the introduction of product patents. However, there appear to be heterogeneous effects on prices by the type of product patent granted on drugs, implying the need for a careful examination of the product patent portfolio.

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Produced by the Research Support Team

Pharmaceutical Patents and Prices:
A Preliminary Empirical Assessment Using Data from India

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JEL: O31, 034, L24, L43, I18

Keywords: Intellectual Property Rights, Technological Innovation, Patents, Pharmaceutical Industry

* We are extremely grateful to Pete Lanjouw for bequeathing Jenny Lanjouw's background material on India's pharmaceutical industry to us, and to Daniel Lederman for help in obtaining the proprietary data from IMS Health. Thanks to a number of Intellectual property rights lawyers and industry experts, in particular Tahir Amin, Ramesh Adige, Usha Rao, Manoj Kamra, Sudip Chaudhuri, Jayashree Watal for explaining the institutional details of the pharmaceutical market and legal implications of TRIPs reform in India. Funding from the World Bank Research Support Budget, and the World Bank executed Trust Fund on Trade is gratefully acknowledged. The views expressed in this paper are those of the authors and do not necessarily reflect those of the World Bank, its Board of Directors, or the countries they represent.
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I. Introduction

Government policy towards the pharmaceutical sector differs significantly both across countries and within individual countries over time. Such policies potentially affect innovation incentives as well as the utilization of available treatments. While there has been considerable work on policies affecting the pharmaceutical sector in the U.S. and other industrialized countries, relatively little empirical work has been done on developing countries, which is surprising given the profound changes affecting the pharmaceutical market in developing countries in recent years.

One type of policy that has recently been implemented in India, China, and Brazil, and is currently being considered in many African countries, is an increase in patent enforcement. Throughout the 1970s, 1980s, and 1990s in India, for example, patents were issued on the process of manufacturing a product, rather than on the product itself. This meant that a slight modification in the synthesis of a molecule yielded a new patent and thus allowed several firms to produce essentially the same drug, implying that generic firms could essentially reverse-engineer a product by slightly changing the production process. Indeed, copies of global brands like Pfizer's top-selling cholesterol drug Lipitor and Eli Lilly's popular anti-depressant drug Prozac were manufactured and sold in India by generic firms within two years of being introduced in the United States.

The policy controversy over the impact of stronger intellectual property rights (IPRs) in developing countries is stark. A weak IPR regime might benefit developing countries by allowing domestic firms to imitate foreign technologies to enhance access to pharmaceuticals (Fink and Maskus 2004). On the other hand, it would reduce incentives for R&D investments on drugs that could differentially benefit developing countries (Arora, Branstetter and Chatterjee 2008). Perhaps partly because of this latter point, the World Trade Organization (WTO) recently started to require member countries to change their enforcement of patents. The implementation of the Uruguay Round agreement in 1995 entailed the implementation of a system of product patents and legal protection to all Trade-Related Intellectual Property Rights (TRIPs), including pharmaceuticals. As a result, beginning in January of 2005, firms in India (and China and Brazil from 2002 and 1997, respectively) could no longer reverse-engineer patented products.

The debate about the merits of TRIPs implementation has been contentious in the economics literature as well. On the one hand, patent enforcement is likely to lead to higher prices of drugs, which might lower utilization and adversely affect health. Several recent academic papers have echoed these concerns, using theory and empirics to forecast the potential welfare losses affecting current and future consumers, especially in countries like India, through higher drug prices (Dutta 2010, Chaudhuri, Goldberg, and Jia 2006, McCalman 2001, Cockburn and Lanjouw 2001). On the other hand, prices may not rise if most drugs affected by the patent reform have therapeutic substitutes and thus face substantial competition from other products. In addition, the innovator patent holder might be somewhat more efficient at production than generic

imitators, and thus their lower costs might to some extent offset the market power effect.

In this paper, we explore the effects of introducing product patents for one particular therapeutic segment of the Indian pharmaceutical market - the market for CNS (Central Nervous System) drugs. The CNS market is the second largest therapeutic category in terms of retail sales in the world and is one of the fastest growing segments in India (Goldberg 2006). We use proprietary data on pharmaceutical sales in India[1] from 2003 to 2008, and link these data on when product patents were granted. We differentiate between two types of product patents. As described by Hemphill and Sampat (2010), a product patent claiming the active ingredient is generally the strongest and is likely to prevent any use of the same drug. In contrast, ancillary patents on chemical variants, alternative formulations, delivery systems, and relatively minor aspects of the drug may not exclude generic entry, since a local manufacturer may be able to employ a different, non-infringing mechanism for accomplishing a similar incremental drug innovation.

Our identification strategy exploits the differential timing of product patents across drugs during the 2003 to 2008 time period. Our key identifying assumption is that the timing of the patents is not correlated with other unobserved factors that might affect the price and utilization of the drug. Our findings suggest that the introduction of product patents was associated with a significant increase in the share of total quantity sold by the innovator, especially for patents granted to the drug compound. The share did not increase to 100 percent in most cases because innovator firms could still grant voluntary licenses to generic firms to manufacture and sell their products. We also find an increase in average prices after the introduction of stronger product patents, although there is no detectable significant effect on utilization. The analysis underscores the importance of investigating the type of product patent granted by the government.

The findings contribute to the growing theoretical and empirical work on the effect of patent policies on the pharmaceutical industry. For instance, price responses to generic entry in the markets for generics and brand-name drugs that have lost patent protection in the United States have been studied by Caves et al. (1991), Grabowski and Vernon (1996), Frank and Salkever (1997), Berndt (2002), Wiggins and Maness (2004), Reifan and Ward (2005), Ellison and Ellison (2007), who find that market entry by generics resulted in heterogeneous responses in price based on the segmentation of the pharmaceutical market.

Several studies have also used explicit models of consumer and firm behavior to simulate the welfare losses implied by patent protection in developing countries (Challu (1991), Fink (2000), Maskus and Konan (1994), Nogues (1993), Subramanian (1995), Watal (2000)). The paper most relevant to our study is by Chaudhuri, Goldberg and Jia (2006) who analyzed the effects of patent enforcement for a sub-segment of antibiotics in India using a structural approach to compute own and cross-price elasticities of demand as well as the marginal costs of production. While their findings (and the findings in previous literature) are ultimately limited by the fact that the potential

[1] This data is similar to the data used for the U.S. market in Duggan and Scott Morton (2010).

impact of patents is simulated using estimates of demand characteristics and market structure from other settings, the model yields important welfare predictions that can be tested using the data at hand. The fact that we now have access to data on actual pharmaceutical product patents granted by the Government of India gives us the opportunity to examine empirically the impact of product patents on pharmaceutical prices and utilization. The purpose of this paper is to provoke discussion on some of the preliminary findings from using these data. In forthcoming work we extend the analysis to all therapeutic segments of the Indian pharmaceutical market, and explore in greater detail heterogeneous effects by sub-therapeutic segments and welfare implications using the demand and supply parameters estimated by Chaudhuri, Goldberg, Jia (2006) for the Indian pharmaceutical market.

The rest of the paper is organized as follows. Section II provides background on the evolution of India's pharmaceutical industry and the details of the TRIPs reform. The data and findings are discussed in Section III, and Section IV concludes.

II. Background

A. Evolution of India's Pharmaceutical Industry

The development of the Indian pharmaceutical industry was shaped by the introduction of the Patents Act of 1970. Before the enactment of the Patents Act, the Indian pharmaceutical market was dominated by western multinational corporations that controlled over 75 percent of the market, primarily through imported drugs.[2] Almost all of the pharmaceutical products under patent in India at the time were held by foreign companies and domestic drug prices were among the highest in the world (Chaudhuri 2005).[3] The situation changed substantially with the passage of the 1970 Patents Act. An important feature of the Act was the special provision relating to drugs (as well as agricultural chemicals and food products) that could be patented only for a new method or process of manufacture and not the product itself.[4] This meant that a slight modification in the synthesis of a molecule was patentable and allowed several firms to produce essentially the same product. Furthermore, the Act provided only seven years of process patent protection for pharmaceuticals, about half of the average fifteen years required to develop and test a new drug. The complete elimination of product patent

[2] Many western multinational corporations like Merck, Pfizer, and Bayer entered the Indian market in 1950s not to initiate manufacturing but to distribute and sell imported products. See Chaudhuri (2005) for a historical account of the Indian pharmaceutical industry.

[3] The process of drug manufacturing has two interlinked components: bulk drug production that is production of active ingredients present in the drugs and second, formulation production, that is processing of bulk drugs into finished dosage forms such as tablets, capsules, ointments. India was dependent on imports of a majority of the essential bulk drugs. Manufacturing by western multinational corporations was primarily restricted to processing of imported bulk drugs into formulations and not necessarily the production of bulk drugs itself.

[4] The Indian Patents Act (1970), which replaced the inherited British colonial law regarding intellectual property rights, specifically excluded pharmaceutical product patents and only admitted process patents for a period of seven years.

protection, the provision that only one process could be patented by an applicant and the shorter protection period of just seven years, all encouraged generic drug development in India. The result was more than three decades of reverse engineering of 'on patent' products, and a flourishing domestic generics market.[5] Most foreign pharmaceutical manufacturers abandoned the Indian market altogether due to the absence of legal mechanisms to protect their patented products and local firms were quick to respond to the favorable provisions created by the 1970 Patents Act.

Over the last forty years the Indian pharmaceutical industry grew rapidly to the point where its annual revenues are currently valued at $21.8 billion and is the third largest in the world in terms of production volume (behind U.S. and Japan). The structure of the industry also evolved. In 1970, the industry was dominated by multinational subsidiaries; by 2001, Indian-owned firms were not just the leading players in the industry, many had also become major exporters (Chaudhuri, Goldberg, and Jia 2006).[6]

India's entry into the World Trade Organization (WTO) in 1994 necessitated significant changes in its patent regime. Under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), member states of the WTO were required to implement minimum levels of intellectual property protection. [7] These include providing for product and process patents in all fields of technology, including pharmaceuticals, with a minimum patent term of 20 years.[8] Although TRIPS came into force on 1 January 1995, developing countries such as India were granted a transition period of five years to implement the provisions of TRIPS. In addition, if a country did not provide product patent protection in any field when TRIPS came into force (such as in the case of agro-chemicals, food and drugs in India), then an additional five years were granted. The provision was designed to give developing countries time to adapt their patent systems and patent offices to the post-TRIPs world. During this 10 year transition period (from 1 January 1995 to 1 January 2005) to implement the new policy, India introduced a

[5] The two stated objectives of the 1970 act were: the development of an indigenous pharmaceuticals industry; and the provision of low-cost access to medicines for Indian consumers. Consistent with these objectives, and with the broader leftward tilt in policy, a number of other measures were introduced–drug price controls, restrictions on capacity expansion, limits on multinational equity shares that kept pharmaceutical prices low, and encouraged the development of the Indian pharmaceutical industry (Chaudhuri, Goldberg, and Jia 2006).

[6] Moreover, Indian companies account for over 70 percent of drugs sold in the country, making India one of the few countries in the world achieving self-sufficiency in drugs, and an important supplier of certain product segments that treat diseases prevalent in less regulated markets of Africa, Asia and Latin America, most notably vaccines and ARVs.

[7] TRIPS aims at establishing strong minimum standards for intellectual property rights. Apart from patents, intellectual property includes copyrights, trademarks, geographical indications, industrial designs, integrated circuits, trade secrets. The protection of IPRs is binding and legally enforceable. TRIPs has three broad components, the first (Parts I and II, Articles 1-40) set out the goals, objectives and standards of IPRs. The second component (Parts III, IV, and V, Articles 41–61) deals with the mechanisms of enforcement of IPRs. The third component (Parts VI and VII, Articles 65–73) focuses on the specific needs of developing countries, such as transitional arrangements, technology transfers and technical cooperation, and institutional arrangements for monitoring and review. The text of TRIPS is available at: www.wto.org.

[8] Least developed countries (LDCs) are not required to implement patents for pharmaceuticals until 2016.

facility (*'mailbox')* to receive and hold patent applications in the field of pharmaceuticals (and agricultural chemicals), which were examined beginning 1 January 2005. Thus, product patent protection in all fields, including pharmaceuticals, began in India from January 1, 2005.[9]

B. Important Provisions Relating to TRIPS Compliance

Due to the absence of product patent protection in pharmaceuticals under the Patent Act of 1970, the Indian generic companies could reverse engineer to produce and market in India any new drug developed abroad. For example, copies of global brands like Pfizer's top-selling cholesterol drug Lipitor (active ingredient-Atrovastatin) and Eli Lilly's popular anti-depressant drug Prozac (active ingredient-Fluoxetine) were manufactured and sold in India by generic producers within two years of being introduced in the United States. The absence of any restriction on the entry of firms resulted in a competitive market structure with low prices. Policymakers anticipated that with the introduction of full product patent protection in pharmaceuticals from 1 January, 2005, as the generic companies are prevented from introducing new drugs, the decrease in competition would result in higher prices and thus lower utilization of pharmaceutical treatments.

TRIPS, however, provides opportunities to developing countries to tackle such consequences of product patent protection. For instance, countries are permitted some flexibility in determining what an invention is and in deciding their own standards of patentability.[10] Indeed, the two important instruments available with the Indian government to regulate prices are (i) to use the flexibilities provided under TRIPs and (ii) price controls. For instance, the Patents Amendment Act of 2005 (the TRIPS consistent Indian patent law) limits recourse to ancillary patents on chemical variants, alternative formulations, delivery systems, and relatively minor aspects of the drug unless these incremental innovations demonstrate an increased level of effectiveness (as stated in section 3(d) of the Act).[11] This type of provision finds no parallel in any other

[9] It is important to note that exclusive marketing rights (EMRs) could be obtained during this transition period for a particular application if a product patent had been granted in some other WTO member country and the application has not been rejected in the country as not being an invention. The term EMR means the exclusive marketing rights to sell or distribute the article or substance covered in a patent or patent application in the country. Only four EMRs were ever granted by the Indian patent office. EMR was granted to Novartis for blood anti-cancer medicine, Glivec/Gleevec (beta crystalline form of imatinib mesylate); to Eli Lilly for erectile dysfunction medicine, Cialis (Tadalafil); to Wockhardt for 'Nadifloxacin' under the brand name Nadoxin, and to United Phosphorus for 'fungicide saaf, a combination of carbendazim and mancozeb. Upon acquiring EMR, the applicant has the exclusive right to sell or distribute the product of the invention for a period of five years or till the date of grant or rejection of the patent application, whichever is earlier. No EMR was granted to any CNS drug.

[10] Thus an invention that has been patented under the laws of one country may not be considered patentable in another country.

[11] It is made explicit in the 2005 Act (section 3(d)) that *'The mere discovery of new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.'* will be prohibited to receive product patents.

patent legislation in the world, and was intended as a response to concerns over patents that extend the total duration of protection for a drug beyond the protection offered by the basic patent claiming the active ingredient. [12]

Despite its official patent standards, the Indian Patent Office is in fact granting numerous product patents on incremental innovation that do not meet the efficacy requirement. [13] In recent work, Sampat (2010) argues based on aggregate data on pharmaceutical patent applications and grants in India, that section 3(d) requirements of India's patent law, which limits patents on incremental pharmaceutical innovations, is often ignored, and the standards of patentability, however high, are not implemented in practice.

It is worth noting that some patents are more likely to exclude generic entry than others. As described by Hemphill and Sampat (2010), a product patent claiming the active ingredient – basic patents that cover the drug compound are generally the strongest and will most likely prevent any use of the same drug. In comparison to patents on active ingredient, patents for a particular formulation (or chemical variants) such as a sustained release version of the drug may not exclude generic entry since a local manufacturer may be able to employ a different, non-infringing mechanism for accomplishing the sustained release of the drug.

Some of the other major flexibilities under TRIPS that are available in the Indian patent law are provisions relating to Bolar Exemption[14] and parallel imports[15]. Compulsory licensing and government use authorizations are also options that are permitted under

[12] Developed countries, for example USA, follow very liberal patent standards. Patents are granted not only for new chemical entities (NCEs) involved in the new drugs but secondary patents can also be taken for new formulations, new combinations and new uses of existing NCEs even if these new products provide no clinical benefits (Chaudhuri 2005). Moreover since the secondary patents can be taken later and would be valid even after the expiry of the patents on NCEs, this could extend the patent life beyond 20 years thereby delaying the entry of generics.

[13] The section 3(d) provision has been the most controversial clause of the Indian Patent Act of 2005 and litigation has already ensued over this provision. India's new patent regime provides for both ex ante and ex post opposition procedures that could be based on any patentability criteria that can be challenged, including the lack of novelty, inventive step, utility, non-eligible subject matter, the failure to disclose the source of biological material used for the invention, and inventions which are considered traditional knowledge. On the one hand, this procedure is likely to lengthen the patent prosecution process and make the outcome more unpredictable. On the other hand, Indian generic pharmaceutical manufacturers favored retention of litigation mechanisms in the new Patents Act to prevent ever greening, and thus far generics have strategically used the procedure frequently. Decisions on recent pharmaceutical pre and post grant opposition cases can be found at http://www.i-mak.org/pharma-patent-decisions/.

[14] Under section 107A(a) of the 2005 Patents Act, use of a patent for development and submission of information for regulatory approval will not be considered as an infringement of the patent right. Thus in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics immediately after the expiry of patents.

[15] Under section 107A(b) 2005 Patents Act, importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights. This clause effectively permits parallel imports.

the TRIPS Agreement and that are available in the Indian patent laws, but the implementation of these provisions has not yet taken place.[16]

In addition, price controls administered by the Government of India are usually cited as another channel that could dampen the effect of product patents on prices. The Indian government currently controls the price of only 74 commonly used drugs, representing approximately 8 percent of the pharmaceutical market (Government of India 2010).[17]

III. Data and Findings

To estimate the impact of product patent enforcement on our outcome variables of interest, we begin by merging together data from two sources. The first main source of data was obtained from IMS Health and contains proprietary data on total sales (excluding those to hospitals and long-term care facilities) in India for all CNS products in each quarter from 2003 to 2008. According to IMS, these data covered 85 percent of all pharmaceutical sales in the country during this time period. The data also contains the number of doses (standardized units) of the product that were sold in each quarter. This allows us to calculate the average price per dose in each quarter for each product.[18] Pharmaceutical products are available in multiple presentations, such as dosage forms (capsule, tablet, syrup, etc.), and strength (10 milligrams, 50 milligrams, etc.). In calculating prices, we aggregate sales and quantities for all versions of the same drug in each quarter.[19]

The CNS market is the second largest therapeutic category in the world in terms of retail sales and is one of the fastest growing. Figure 2 shows the quarterly trend in mean price and total quantity of all drugs within the CNS therapeutic category in our sample. Within this market, the largest segment of sales are for anti-depressants, antipsychotics, anti-epileptics, sleep disorders, attention deficit disorders, and Alzheimer's disease (see Table 1). Many of the new products developed by pharmaceutical companies these days are life quality enhancing drugs such as anti-depressants and are likely to be affected by product patents. Although, this segment accounted for about 7% of the total retail

[16] Compulsory Licensing refers to "use without authorization of the patent holder", and includes use by third parties and use by the government in situations of national or extreme emergency, and public non-commercial use. No compulsory licenses have yet been issued in India under the amended Patents Act (personal communication with Patent officer in the Delhi Patent office).

[17] The details of the procedures for price fixation can be found in the official government website: http://www.nppaindia.nic.in/index1.html, under the link "Drug Price Control Order 1995".

[18] Note that the prices we use in our estimation are not the posted prices at the drugstore but the revenues of each drug divided by units sold from invoice data.

[19] These data are available from the retail pharmacy audits undertaken by IMS Health, the best known market research firm for pharmaceuticals. The audit provides detailed product-level estimates of quarterly sales, dozes, launch dates, brand name, active pharmaceutical ingredient, therapeutic categorization on all pharmaceutical products sold in India. The coverage of the audit is extensive, reaching a representative panel of thousands of retail chemists in across cities and towns in India. The data collected, which provide the only real source of disaggregate information on the Indian pharmaceutical market, are used by both the government of India in formulating pricing policy and other decisions, and the Indian pharmaceutical industry in determining pricing and marketing strategies (Goldberg 2008).

pharmaceutical sales in India and ranked # 5 in 2008, it is arguably less important than anti-infectives from a public health perspective (Goldberg 2010). Nevertheless, it represents a useful starting point to investigate the impact of the newly introduced product patent regime on the pharmaceutical industry in India.

The data contains 2,425 CNS products across 21 sub-therapeutic categories in the Indian CNS market. For simplicity, we focus on single ingredient products (products containing one active molecule) where there is only one innovator, and this causes our sample to go down by approximately 28 percent. We further drop 35 products that have zero number of doses sold throughout our six-year study period. When duplicate products appear (i.e. same product in different sub-therapeutic categories), we combine all sales for a product and keep the observation with the highest sales value. As a result, we are eventually left with 1,693 single ingredient products containing 160 molecules with total sales, total number of doses and average price per dose for 24 quarters from 2003-2008.

The second main source of data was obtained from the Patent office of the Government of India and contains data on CNS pharmaceutical product patents granted from January 1, 2005 to December 31, 2008. We were able to obtain detailed data on the application number, year the patent application was filed, date of patent grant, patent number, molecule, disease, and the innovator company for this category of drugs.[20] Unfortunately, the classification of granted product patent type was not provided to us initially by the Government. However, we worked with an examiner of drug patent applications in India to code each granted product patent according to whether it contained an active ingredient claim. Surprisingly, 90 percent of the granted product patents in the CNS therapeutic segment turned out to not claim the active ingredient, lending support to observations by Chaudhuri (2005), and Sampat (2010) who note the high rate of "low quality" patents being filed and granted in India.

From a total of 150 product patents, 42 percent of the patents are for combination drugs (drugs made of two or more active ingredients) that we exclude from the current analysis. In instances where multiple secondary product patents are granted (such as product patents for a new salt, a new formulation, or a new derivative of a drug), we consider the earliest granted secondary product patent to a molecule, causing us to be left with 39 unique single ingredient product patents, though we later explore the sensitivity of the main results using the number of granted patents as an additional explanatory variable.

Figure1 shows the percentage of molecules in the CNS category of drugs that were granted product patents in each year. There were 0 product patents granted in 2005 (the first year of the reform). By the end of 2006, 5 percent of the molecules (8 out of 160) had received a product patent, rising to 16 percent in 2007 and 24 percent (39 out of 160) by the end of 2008.

[20] We are in the process of collecting detailed data on product patents granted in other therapeutic segments to extend the analysis to the entire pharmaceutical market in India.

The molecule information for each patent is necessary for matching the patent's molecule with the corresponding commercial drug data from IMS. Interestingly, there are four (out of 39) product patents, for which while the corresponding sales data exists in IMS, the innovator is not present in IMS. For example, Eli Lilly was granted a product patent for its schizophrenia drug Zyprexa (active ingredient Olanzapine) in August 2007. While Olanzapine is manufactured in India by various generic firms (e.g. Cipla, Lupin Labs, Torrent Pharma) as indicated in the IMS data, the innovator Eli Lilly, is not one of the manufacturers in India. One possible explanation could be the existence of an agreement between the innovator and a generic manufacturer such as license deals, or joint ventures. Our interviews with industry executives reveal that comprehensive information on these deals is not publicly available.

The goal of our empirical analysis is to examine the impact of enforcing product patents on prices and utilization of drugs in the Indian CNS market over time. Since different molecules received stronger patent protection at different times, this differential timing is used to isolate the impact of the reform. The identification strategy exploits the variation in the timing of the introduction of product patents across the 35 affected molecules to identify the effect.

The basic model we estimate is as follows:

$$Y_{jt} = \alpha + \beta_1 Patent_{jt} + \beta_2 Patent_{jt} * Type_{jt} + \gamma_j + \theta_t + Z_{jt} + e_{jt}$$

where the outcome variable is the log price of molecule *j* at quarter *t*. Since prices are likely to change proportionally rather than by a fixed dollar amount, it is sensible to transform the variable using logs. Furthermore, pharmaceutical prices are highly skewed to the right, and the log transformation produces a distribution that is much less sensitive to outliers (Duggan and Scott Morton, 2006). The γ_j*'s* represent a full set of molecule fixed effects that control for unobserved time invariant differences across drugs. The θ_t*'s* represent a full set of quarter*year fixed effects to control for any time varying aggregate factors affecting the price or utilization of pharmaceutical products. The standard errors are clustered at the molecule level to account for serial correlation in the error term. $Patent_{jt}$ is an indicator variable for whether molecule *j* received a product patent in quarter *t*. $Type_{jt}$ is an indicator variable that takes the value 1 if the product patent is on the active ingredient (the strongest type of product patent) and is zero otherwise. The interaction $Patent_{jt}*Type_{jt}$ allows us to investigate heterogeneous effects of the patent on pharmaceutical prices. Z_{jt} includes a vector of controls such as whether the molecule is under price control or not.

To the extent that product patent enforcement results in the withdrawal of generics from the market, we should expect to find a negative effect on the number of products sold that contain the patented molecule. Similarly, the withdrawal of generics from the market is likely to result in an increase in the fraction of total quantity sold to the innovator. We are also interested in the effect on utilization. On the one hand as prices rise we may expect to find lower utilization. On the other hand, the innovator may spend more on advertising, which could serve to increase utilization. In addition, the

innovator might be somewhat more efficient at production, and these lower production costs (resulting in lower prices than would otherwise occur) might to some extent offset the market power effect. Thus, both the sign and magnitude of the effect on utilization are theoretically ambiguous. Additional outcome variables such as (i) the total number of products containing molecule *j* that are sold at time *t*, and (ii) the fraction of total quantity sold to the innovator of molecule *j* at time *t*, and (iii) the utilization (total quantity) of molecule *j* at time *t*, allows us to investigate the mechanism underlying the price change.

Results from price regressions in Table 2 are of interest in two respects. First, inclusion of time and molecule fixed effects is critical to avoid spurious conclusions. This is visible from comparison of columns 1 and 3 where addition of the relevant indicator variables not only improves the regression's fit but also illustrates that what might be interpreted as a significant and large effect of product patents on pharmaceutical price (almost a doubling as per column 1) are due largely to changes over time that affected all molecules and, to a lesser extent, molecule-specific factors. Once relevant controls are included, the point estimate for patent becomes positive, but significant only at the 10 percent level, suggesting that post reform patenting had a weak effect on average pharmaceutical prices. At the same time, the coefficient on the interaction of the patent variable with the type of patent, points towards a large, positive and significant impact on drug price. Product patents claiming the active ingredient, as opposed to a secondary patent (on a new formulation, or a new derivative of a molecule) have a positive and significant effect on drug price, raising it on average by 12 percent.

Table 3 shows the results from estimating equation 1 for additional outcome variables. In columns 1-2, the dependent variable is the total number of products containing molecule *j* that were sold at time *t*. We find that the introduction of product patent did not generate any significant effect on the number of products containing that molecule. In contrast, product patents claiming the active ingredient led to a significant decline in the number of products sold. The point estimate is -2.4 and is significant at the 5% level, implying that the patent on the base molecule, indeed, led to the withdrawal of, on average, two generics from the market. Nevertheless, in columns 3-4, we do not find any corresponding significant effect of product patent enforcement (or type of product patent) on utilization as measured by the log of standardized units (total number of doses sold).

Interestingly, in columns 5-6, we find that the product patent on the active ingredient led to a significant increase in the fraction of total quantity sold by the innovator of almost 40 percent. One possible explanation for why the share sold to the innovator did not increase to 100 percent in all cases could be the existence of an agreement between the innovator and a generic firm such as license deals or joint ventures to produce and market the drug. Our interviews with industry executives reveal that comprehensive information on such deals is not publicly available.

Our model predicts differential effects of patent enforcement on the drugs that are under price control. Out of 160 molecules in the CNS category, only nine are under

government price controls. However, out of the nine that are under price control, only one molecule was subjected to a product patent implying that, at least within this therapeutic segment, the likely effect of price controls on curbing price increases is negligible.

IV. Conclusion

This paper explores the effects of product patent protection on drug prices and utilization using data on one particular therapeutic segment relating to central nervous system treatments in the Indian pharmaceuticals market. The study highlights the importance of the distinction between different types of product patents and their differential impact on average prices and total utilization of drugs. The analysis finds a statistically significant effect of a sub-class of product patents. In particular, product patents that were granted on the active ingredient instead of incremental innovations of a drug, led to a significant increase in drug prices, and an increase in the fraction of total quantity sold to the innovator with a corresponding withdrawal of generics from the pharmaceutical market in India. The purpose of this paper is to provoke discussion on some of the early estimates emerging from preliminary analysis using this data. In forthcoming work we plan to extend the analysis to all therapeutic segments of the Indian pharmaceutical market, and explore in greater detail heterogeneous effects by sub-therapeutic segments, welfare implications of stringent patent protection using demand and supply parameters estimated earlier in the literature, and whether there are any substitution effects between patents and price controls as alternative policy approaches.

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Figure 1: Percentage of CNS Molecules Granted a Product Patent

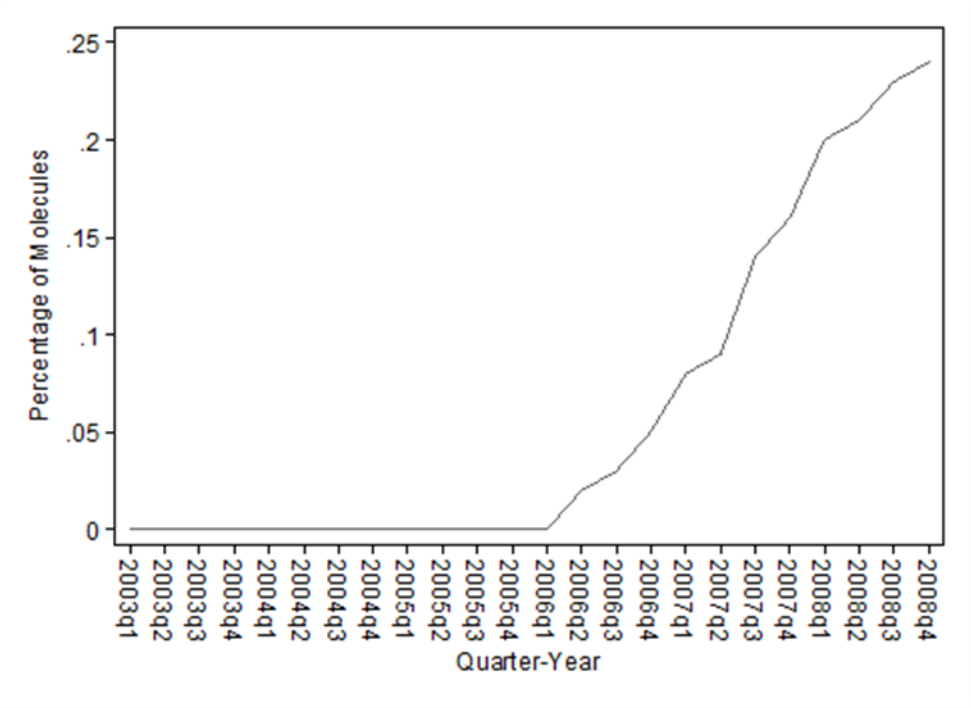


Figure 2: Broad Trends in Price and Utilization of CNS Drugs over time

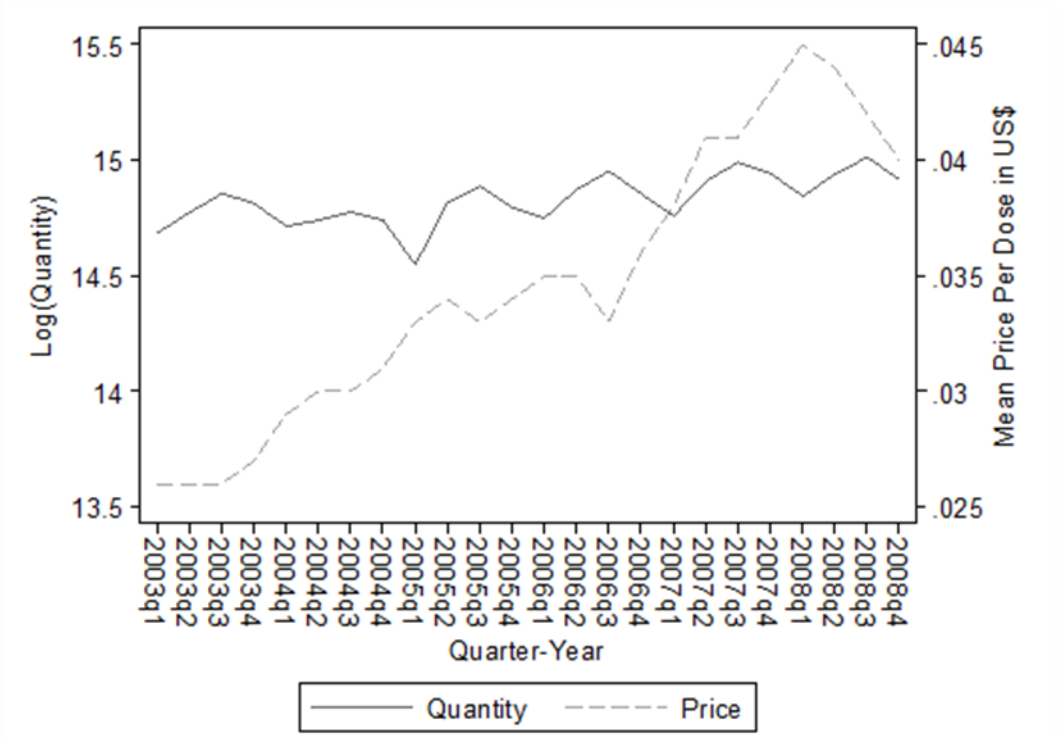


Table 1: Shares of Major Therapeutic Segments in Retail Sales

	share of retail sales (%) in 2003				
Main Therapeutic Category	Rank	Share (%)	Sub Therapeutic Category (within CNS)	Rank	Share (%)
ALIMENTARY TRACT & METABOLISM	1	0.25	ANTI-EPILEPTICS	1	0.23
ANTI-INFECTIVES	2	0.2	NON-NARCOTIC ANALGESICS	2	0.19
RESPIRATORY SYSTEM	3	0.11	TRANQUILLISERS	3	0.16
CARDIOVASCULAR SYSTEM	4	0.10	ANTIDEPRESSANT & MOOD STABILIZERS	4	0.13
CENTRAL NERVOUS SYSTEM (CNS)	5	0.07	ANTIPSYCHOTICS	5	0.06
MUSCULO-SKELETAL	6	0.07	ANTIVERTIGO PRODUCTS	6	0.04
DERMATOLOGICALS	7	0.05	ANTI-PARKINSON	7	0.03
GENITO-URINARY	8	0.04	PSYCHOLEPT-PSYCHOANALEPT	8	0.03
BLOOD & BLOOD FORMING AGENTS	9	0.04	HYPNOTICS & SEDATIVES	9	0.03
SENSORY ORGANS	10	0.02	ANTI-MIGRAINE	10	0.02
PARASITOLOGY	11	0.01	ANAESTHETICS	11	0.02
SYSTEMIC HORMONAL PRODUCTS	12	0.01	ANTI-ALZHEIMER PRODUCTS	12	0.01
DIAGNOSTIC AGENTS	13	0.00	ANTI-SMOKING PRODUCTS	13	0.01

Source: Authors' calculation using IMS Data

Table 2: Effect of Product Patents on Prices of CNS Drugs

	Log Drug Price			
	(1)	(2)	(3)	(4)
patent	0.32	0.109	0.0726	0.035
	[0.145]*	[0.0782]	[0.0385]	[0.0321]
patent*type				0.123
				[0.054]*
constant	-2.027	-2.113	-3.045	-3.045
	[0.200]*	[0.240]*	[0.0729]*	[0.0729]*
Quarter*Year FE	No	Yes	Yes	Yes
Molecule FE	No	No	Yes	Yes
Observations	704	704	704	704
R-squared	0.003	0.009	0.95	0.95

Robust standard errors in brackets, clustered by molecule

* significant at 5%; ** significant at 1%

Table 3: Effect of Product Patents on Number of Products, Fraction sold to the Innovator and Total Quantity of CNS Drugs

	Number of Products		Log(Total Quantity)		Fraction sold to the innovator	
	(1)	(2)	(3)	(4)	(5)	(6)
patent	0.239	0.319	-0.0974	-0.123	0.0244	0.0112
	[0.628]	[0.648]	[0.442]	[0.449]	[0.0334]	[0.0366]
patent*type		-2.419**		0.783		0.397**
		[0.914]		[0.488]		[0.0296]
Constant	-2.392**	-2.403**	0.535	0.539	0.0319	0.0336
	[0.711]	[0.713]	[0.301]	[0.302]	[0.0343]	[0.0343]
Quarter*Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Molecule FE	Yes	Yes	Yes	Yes	Yes	Yes
Observations	840	840	840	840	840	840
R-squared	0.886	0.886	0.832	0.833	0.806	0.815

Robust standard errors in brackets, clustered by molecule

* significant at 5%; ** significant at 1%