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Product Patents In Developing Countries:  
Evidence From India**

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# THE MARKET IMPACTS OF PHARMACEUTICAL PRODUCT PATENTS IN DEVELOPING COUNTRIES: EVIDENCE FROM INDIA\*

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## Abstract

In 2005, as the result of a World Trade Organization mandate, India began to implement product patents for pharmaceuticals that were compliant with the 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS). We combine pharmaceutical product sales data for India with a newly gathered dataset of molecule-linked patents issued by the Indian patent office. Exploiting variation in the timing of patent decisions, we estimate that a molecule receiving a patent experienced an average price increase of just 3-6 percent with larger increases for more recently developed molecules and for those produced by just one firm when the patent system began. Our results also show little impact on quantities sold or on the number of pharmaceutical firms operating in the market.

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## 1. Introduction

Intellectual property (IP) protection for pharmaceuticals in the developing world is a heavily discussed issue. The debate has only grown more contentious as many formerly poor countries have experienced rapid economic growth and now represent potentially profitable markets for foreign pharmaceutical firms. Partly because of the growing importance of developing countries as consumers for many products, in 1994 all members of the World Trade Organization were required to adopt the Trade Related Intellectual Property Standards (TRIPS). TRIPS established uniform IP standards including a product patent system for pharmaceuticals. Many developing countries were given ten years to implement a TRIPS-compliant regime and have only recently created these systems. As a result, little is known about the actual effects that these policies have in a developing country. In this paper, we aim to partially fill this gap in the literature by examining the effects of the 2005 implementation of a product patent system in India on pharmaceutical prices, quantities sold, and market structure.

Patent protection for pharmaceutical products represents an economic tradeoff. Economic theory suggests that providing firms with monopoly rights via patents will result in price increases and an inefficiently low number of pharmaceuticals sold today. In exchange for this inefficiency, these patents are intended to provide the necessary incentives for the development of products in the future (Nordhaus, 1969; Kyle and McGahan, 2012; Berndt and Cockburn, 2014). In accordance with this view of a potential inefficiency, Chaudhuri, Goldberg, and Jia (2006) estimated that implementing a strong Indian product patent system (i.e. one that removed domestic firms currently manufacturing the product) would raise prices by 100 to 400 percent in a sub-segment of the antibiotic sector and thereby reduce welfare. Alarmed by predictions such as these, activists and policymakers decried TRIPS. Abbot, Kapczynski, and Srinivasan (2005) said, “[i]t is likely that prices of essential drugs will go up significantly once patents are granted.” Similarly, Saha (2004) said “[w]hile the benefits of strong IP protection for developing countries are a matter of debate and nearly always in the distant future, such protection invariably entails substantial real and immediate costs.”

These predictions and protestations generally represent fears about the outcome of a “textbook” product patent system, i.e. one in which foreign innovating firms are granted monopoly rights while domestic infringing firms are pushed out of the market. Perhaps as a result of the concerns highlighted above, the actual Indian system was far from the textbook

example. As Sampat (2010) describes, “there is a widespread perception that TRIPS flipped the patent switch from ‘off’ to ‘on’ in developing countries . . . (but) like many international agreements, TRIPS includes room for interpretation and, in pharmaceuticals, flexibilities.”

In India these flexibilities included regulatory measures such as compulsory licensing (i.e. the ability to force patent holders to grant a license to domestic firms under certain conditions), formal price controls, and the right for domestic firms producing newly patented molecules to pay a royalty and continue their commercial activities. Some commentators complained these policies countered the very purpose of the reform. Dugger (2001) said “Indian companies will probably be able to go on making and selling copycat drugs even after 2005.” On the other hand, even the regulatory flexibilities included in TRIPS did not mollify all of its critics. Chatterjee (2005) said that “[d]espite several last-minute amendments, the new law will make it far more difficult for poor people across the developing world to access vital drugs, especially new ones, at affordable prices.”

In practice, during our sample period, the Indian government only sparingly used the available regulatory tools. However, previous theoretical and empirical work has shown that regulators need not actually exert their power to affect market outcomes. Given the threat of onerous regulations, firms have been shown to preemptively modify their behavior (Glazer and McMillan, 1992; Efrle and McMillan, 1990; Ellison and Wolfram, 2004). Therefore, the mere existence of the additional regulatory tools discussed above could constrain excessive price increases even without their explicit use. Perhaps as evidence of this, the maker of Sovaldi recently announced that it would sell its controversial Hepatitis C cure Sovaldi for \$900 in India (Silverman, 2014). This medication is currently under consideration for a patent and the list price in the United States is \$84,000.

In addition to the regulatory flexibilities in TRIPS, there may also simply be differences between the *de jure* and *de facto* operation of product patents in developing economies. This would not be unique to this product market. There is a broad literature demonstrating substantial differences between the operation of government institutions in the developed and developing world. Many studies have found that formal rules in the developing world are often subverted in ways that are not typical to other settings (e.g. Bertrand et al., 2007; Fisman and Wei, 2004). If this were the case with patent regulations, then TRIPS may actually have few market effects.

Given the variety of factors potentially influencing the market effects of TRIPS, the net effect is ultimately an open empirical question. In this paper, we use a newly gathered dataset of

product patents matched to a comprehensive set of longitudinal sales data on single molecule products sold in the Indian market in the years preceding and for several years after the introduction of the patent system. Our analysis sample includes more than 6,000 products containing approximately 1,000 molecules with strictly positive sales in the first quarter of 2005. Given data constraints we cannot systematically link patents to specific products in our sales data, and we therefore consider patenting activity at the molecule level based on an exhaustive keyword search of granted patents. Because our data include single molecule products, our linkage between patents and molecules is relatively direct. Approximately one-third of the molecules in our sample are covered by at least one product patent by the end of 2011.

We aggregate our outcome variables to the molecule-quarter level and focus primarily on the (log of) average price per daily dose, the (log of the) number of daily doses, and the number and relative concentration of firms selling the molecule. Our identification strategy exploits variation across molecules in the timing of patent grants. As we discuss below, certain features of the Indian patent system make the timing and outcome of patent decisions uncertain to applying firms and the broader market. For example, the reform provided the Indian patent office with a good deal of latitude regarding what innovations qualify as patentable and therefore firms were likely unable to easily predict whether their applications (or those of their competitors) would be successful. Our baseline specification controls for molecule fixed effects and quarter by year fixed effects and we account for the possibility that molecules receiving a patent during our study period may be on different trends than those that are never patented.

We find a statistically significant but economically modest price increase for molecules receiving a patent. Our point estimate suggests a price increase of only about 3 percent after a patent is granted and we can rule out average price increases of more than 5.3 percent. To provide some context for this magnitude, patented products are on average about three times more expensive than generic versions in the U.S. (Alazarki, 2011).

We test our key identifying assumption – that the timing of a patent is orthogonal to unobserved determinants of pharmaceutical prices and our other outcome variables of interest – by investigating how these outcomes evolve in the quarters leading up to the one in which a patent first takes effect. Figure 1 displays the evolution of the average price (relative to baseline) for the eight quarters before and after a patent is granted from an event study version of our baseline specification. Prior to the grant of a patent there is little change in prices, however following a patent grant there is a small, immediate, and persistent price increase.

We also exploit variation based on the age of the molecule. The legislation treated molecules with their first patent outside of India before 1995 differently from more recent molecules. This institutional feature should result in these more recent molecules having stronger patent protection. Figure 2 contains estimates from an event study specification for samples based on whether the molecule was first sold in India before or after 1995 (which serves as a proxy for the first date of patent outside of India). Consistent with patents for older molecules being weaker, we find that the post-patent price increase is driven by more recent molecules.<sup>1</sup>

One concern with estimating specifications on the full sample is that it includes a heterogeneous set of molecules and potentially some measurement error in the matching of patents to specific products. To obtain a more comparable set of molecules for which patents are likely to be more important and well matched to products, we next focus on molecules first approved for sale in the United States between 1996 and 2004. These drugs likely had more potential for a large welfare effects in the Indian market. In this smaller sample we have data on patent grants, denials, and pending applications. Comparing patented drugs to those whose patents were still pending, we find a statistically significant ( $p$ -value  $< 0.05$ ) price increase of approximately 6 percentage points and can rule out an increase of greater than 15 percent.

Given the juxtaposition between the concern that TRIPS would cause large price increases and our relatively small estimates, we next consider the potential mechanisms underlying our modest price effects. We note that the presence of substitute goods should moderate the pricing power of firms receiving patent protection. One of the regulatory flexibilities included in the Indian patent reform is that firms making a newly patented product prior to a patent being granted must be allowed to pay a reasonable royalty and continue selling the good. This should greatly limit the effect of patents for these molecules. Accordingly, we find that our price effects are primarily driven by products containing molecules that are sold by only one firm. We estimate that these products had an average price increase of approximately 20 percent following a patent. These single firm molecules are perhaps more similar to newly developed products that will receive patent protection in the future and therefore might serve as a reasonable estimate of the future effects of the Indian patent reform. However, these future price increases would be still be relatively small compared to the estimates of the patent premium in developed economies such as the U.S.

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<sup>1</sup> In contemporaneous work, Kyle and Qian (2014) also exploit this difference in the priority year to estimate the effect of TRIPS on the patent premium across a number of developing countries. They also find relatively modest price increases across these developing countries.

We next examine quantity changes following these price increases. While the demand curves for pharmaceutical products are presumably downward-sloping, it is not immediately clear that our modest price increases should result in market wide quantity reductions. Given that originating firms can potentially claim a greater share of the profits following a patent, and patent protection may provide an entry barrier, these firms may now make large fixed costs investments to promote their products (such as advertising). Previous work has found that firms may attempt to strategically deter entrants through reductions in advertising when entry barriers are weakened (Ellison and Ellison, 2011). Our point estimates suggest a modest decline in the quantity sold, though these estimates are statistically insignificant.

We also consider the effect of patents on market structure. More specifically, we estimate that the molecule level sales concentration – as measured by the Hefindahl-Hirschman index – increased following the grant of a patent. The magnitude of the estimate suggests that while sales became more concentrated after a patent was granted, incumbent firms did not exit to a significant extent. Consistent with this, the average number of firms with strictly positive sales for molecules that receive a patent was virtually unchanged during the latter part of our study period, actually rising slightly from 14.6 firms in the first quarter of 2006 (when virtually none of them yet had a patent) to 14.7 firms in the first quarter of 2011.

Our results demonstrate that the implementation of product patents for India did not cause either the large increases in pharmaceutical prices or the dramatic consolidation of the market that some predicted prior to its enactment. This is likely at least partly a result of the provisions in TRIPS intended to limit the impact on access to pharmaceuticals combined with the difficulties of implementing and enforcing a new patent system in a developing economy.

The lack of large profit increases from patents is important for understanding firm behavior. Previous research has found little change in innovation targeting the developing world or in the rate of new drug launches in India as a result of TRIPS (Kyle and McGahan, 2012). Similar to this previous work, an analysis of our data provides little evidence to suggest that the pace of new molecule introduction accelerated as a result of India's adopting a TRIPS-compliant patent system. This could result from innovative efforts not responding to changes in expected profits, but previous evidence from profit shocks in the developed world suggest otherwise (Acemoglu and Linn, 2004; Finkelstein, 2004; Dranove, Garthwaite, and Hermosilla, 2014). Our results strongly suggest that the lack of an innovation response stems from at best small changes

in expected profits. As a result, the small post-patent price increases we estimate should not be thought of as a purely positive outcome.

This paper proceeds as follows. In section 2 we describe the TRIPS patent reform and we then describe our data in section 3. The fourth section describes the Indian pharmaceutical market before and after the TRIPS reform and section 5 contains our estimates of the effects of the reform on a variety of outcomes. The final section concludes and discusses some implications for future intellectual property reforms in the developing world.

## 2. Patent Reform in the Developing World

Under the 1994 Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), member states of the WTO were required to implement minimum levels of intellectual property protection that far exceeded those in India's 1970 Patents Act. Among other features, TRIPS required WTO member nations to provide product and process patents in all fields of technology, including pharmaceuticals, with a minimum patent term of 20 years. Although TRIPS became effective on January 1, 1995, developing countries were granted a transition period of five years to implement the agreement. Countries such as India that did not provide product patent protection in any field when TRIPS came into force were granted an additional five years. TRIPS provided a large shock to the global patent system with nearly 95 percent of countries having product patent systems by 2005 (LaCroix and Liu, 2008).

While the Indian patent system was not established until 2005, beginning in 1995, India was required to introduce a "mailbox" facility that would receive and hold patent applications. As the mailbox was filled, the government did not provide a running tally of the number of submissions or a description of their contents.<sup>2</sup> Therefore, pharmaceutical firms around the world did not know the number or types of applications submitted for consideration.<sup>3</sup>

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<sup>2</sup> 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 another WTO member country and is awaiting a patent decision in India. EMR provides the exclusive rights to sell or distribute the article or substance covered in a patent or patent application in the country for a period of five year or the date of grant or rejection of the patent application, whichever is earlier. 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.

<sup>3</sup> On January 1, 2005 this mailbox was officially "opened," marking the start of modern product patent system for pharmaceuticals in India. In addition to reviewing the applications, the patent office began publishing single page summaries of the applications and by June 2006 approximately 75 percent of the nearly 9,000 applications had been summarized. The majority of these summaries were published in March 2005 (Mueller, 2006).



Absent other policy interventions, product patents should result in higher prices and an inefficiently low quantity sold for existing products. This inefficiency could have particularly large costs in the developing world because changes to the domestic manufacturing industry in more prosperous developing economies can spill over to other even less developed settings. For example, domestic manufacturers in India currently provide a large portion of the treatments for the AIDS-infected population of sub-Saharan Africa (Ahmed and Sharma, 2012). If many firms were to stop manufacturing newly patented pharmaceutical products after a patent expansion, this could have far reaching effects on public health across the developing world.

While most of the attention to patent reforms focuses on the negative effects of price increases, over a longer time horizon these higher prices are not necessarily inefficient. Monopoly pricing power could provide the appropriate incentives for existing or potentially new innovators to make the large fixed cost investments required to develop (or simply begin selling) new socially beneficial products. Lacking an ability to recoup their investment, many international firms avoid developing markets – especially for their most valuable products. Perhaps more concerning, these firms might also shift their research and development efforts away from treatments for conditions that are more prevalent in countries lacking adequate intellectual property protection. This could create an inefficiently small set of treatments available at any price for individuals residing in these areas.

This dynamic effect on product development from changes in expected profits is not limited to patents. For example, Finkelstein (2004) found that policies that increased the use of vaccines resulted in more clinical trials for these products. However, she finds little change in patenting activity, which suggests that these trials are not the result of advances in basic science. Similarly, Dranove, Garthwaite, and Hermsillo (2014) found that the expansion of Medicare Part D increased clinical trial activity but that most of the new products targeted diseases that already had many existing treatments. Both of these studies suggest that investments in therapeutically innovative products are not particularly sensitive to policy-induced demand shocks. This may limit some of the welfare benefits of new patent systems.

When considering the tradeoff between these static and dynamic inefficiencies from pharmaceutical patents in the developing world, more attention is generally paid to the potential for monopoly prices further decreasing access to critical existing treatments. In truth, the presence of both sources of inefficiency is relatively clear in theory but the magnitude of these

countervailing effects remains an open empirical question.<sup>4</sup> As a result of relatively little prior experience with patent systems in developing countries, studies estimating the static inefficiency of systems such as TRIPS have been primarily prospective in nature and have predicted price increases and welfare losses (Chaudhuri, Goldberg, and Jia 2006). These papers have provided valuable evidence regarding the potential effect of a western style patent system in these countries. However, as is discussed in Goldberg (2010), there are many features of developing a product patent system in a setting such as India that might limit the price effects predicted by theory. Our paper follows up on this point and provides some of the first evidence regarding the actual magnitude of these effects in a large developing country.

For many reasons, one would not necessarily expect the effect of a patent system in a developing country such as India to mimic the effect in the U.S. or in other industrialized countries. As Sampat (2010) discusses, actually creating a patent system for an existing market in a developing country requires many “flexibilities” that don’t exist in developed markets or in the many theoretical models of patents.<sup>5</sup> Given worries about potentially negative effects of expanded intellectual property protections, TRIPS included relatively broad powers to influence prices. Bond and Saggi (2012) present theoretical evidence as to how these different policies can work as complements.

Under TRIPS, countries were allowed to protect the existing investments made by generic manufacturers. As a result, if a generic firm in India made a significant investment in products containing a newly patented molecule before 2005 and continues to manufacture the molecule on the date of the patent being granted, it cannot be forced to halt production. Instead, the firm can continue its commercial activity and pay a “reasonable royalty” to the patent holding firm (Hason and Shimotake, 2006). This was particularly important in the Indian market. Of the nearly 9,000 patent applications, approximately 7,500 were submitted by foreign owned multinational corporations. Over 2,300 applications came from the United States and Pfizer submitted the most applications for any firm with over 300 (Narendranath, 2005). Given that these foreign firms represented only 30 percent of the Indian market in 2005, there were fears that the patent law would significantly damage India’s growing generic drug industry.

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<sup>4</sup> Though it should be noted that some dispute the theoretical benefits with respect to dynamic efficiency, e.g. Boldrin and Levine (2002). Gallini (2002) provides a nice overview of the argument that in situations where innovation is sequential, strong patents could inhibit innovation. Kremer and Williams (2010) argue that innovation can be promoted through means other than intellectual property rights.

<sup>5</sup> These flexibilities can serve to reduce the effective breadth or length of a patent. Gilbert and Shapiro (1990) develop a model in which they explore the effects of patent breadth and length.

Countries were also given the right of compulsory licensing, which allowed governments to force a patent holding company to allow generic competitors to produce a protected molecule if the price of the patented product was found to be unaffordable for most of the nation. In March 2012, India first exercised this right by requiring Bayer to allow Natco to manufacture and sell Nexavar – a drug for advanced liver and kidney cancer. In exchange, Natco must pay Bayer a six percent royalty and sell a generic version of Nexavar for approximately \$176 a month instead of the \$5,600 a month charged by Bayer (Bajaj and Pollack, 2012). Beyond compulsory licensing, the reform also allowed for explicit price controls. By 2013, India had only used this measure on 74 drugs (Government of India, 2010). In that year, India expanded this to cover nearly 350 drugs (Chowdhury, 2013). In 2014, the use of price controls grew and at that point approximately 6 percent of total sales in the country were affected by price controls (Mclain, 2014).

Under TRIPS, countries were also granted flexibility in determining the standards for what constitutes an invention that is deserving of patent protection.<sup>6</sup> India defined patentability standards in Section 3(d) of the Patents Amendment Act of 2005. This section limits the patentability of chemical entities existing and patented outside of India as of January 1, 1995 to *inventions* (e.g. alternative formulations or delivery systems) that demonstrate significant increased therapeutic efficacy. Mere *discoveries*, such as the fact that an existing molecule can be used to treat a new condition, do not meet the standard for a newly patentable product.<sup>7</sup> Section 3(d) was an attempt to halt “evergreening”, i.e. minor changes to existing drugs to extend the life of existing patents (Mueller, 2006).

The Section 3(d) standard of a “significant” increase in efficacy requires patent officials to judge both a product’s actual efficacy increase and whether this change was large enough to be deemed significant.<sup>8</sup> Lacking specific criteria in the law, the Indian Patent Office retains a great

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<sup>6</sup> Countries also retain the ability to institute price controls. However, as of 2010 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). 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.”

<sup>7</sup> Section 3(d) provides the following description of what is not considered an invention for the purposes of patent protection: “*the mere discovery of a 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 of 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. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy*”

<sup>8</sup> For example, advantageous properties such as “improved bio-availability; better stability; improved flow properties; and lower hygroscopicity,” while important for being able to develop new delivery mechanisms are not deemed to have changed the therapeutic effectiveness of the molecule and therefore they are not considered improvements in efficacy under Section 3(d) (Chaudhuri, 2010).

deal of latitude and discretion in the approving of patents that are not for a purely new chemical entity (Mueller, 2006). In our results below, we will separate molecules based on their vintage to determine if this feature of TRIPS had a meaningful influence on the effect of patents.

The combination of the unknown timing of the mailbox review process and the unclear patentability requirements created uncertainty about which pharmaceuticals would be granted a patent, and when these grants would occur. For example, despite the opening of the mailbox on January, 1 2005, the first pharmaceutical patent product was not granted for more than a year later for Roche's Hepatitis C drug Pegasys (Greene, 2007). Recent litigation concerning Pegasys and other molecules demonstrates further uncertainty regarding the likelihood of patents being granted and/or upheld in the face of post-grant oppositions. In November 2012, Pegasys gained the unique distinction of being the first pharmaceutical product patent to lose a post-grant opposition hearing before the Intellectual Property Appellate Board (Ahmed, 2012).

In another highly publicized controversy, the Swiss pharmaceutical company Novartis has challenged the patent denial for its anti-cancer medication Glivec—a modification of an older compound first patented in the United States in 1993 (Kurzius, 2013). Novartis claims its invention makes it 30 percent easier for the body to absorb the original compound and points out that Glivec received patent protection in over 40 countries. However, India ruled that the product was simply an incremental innovation with no improvement in efficacy and denied patent protection. In April 2013, the Indian Supreme Court rejected Novartis' claims for patent protection (Harris and Thomas, 2013). Several other foreign firms including Gilead Sciences and Roche are fighting similarly unfavorable patent decisions for drugs aimed at treating HIV and cancer (Ahmed and Sharma, 2012).

Uncertainty over patent decisions was not limited to whether the Indian Patent Office would be too rigid in its interpretations. Many molecules that seemingly did not exceed the stringent 3(d) requirement received patents. Based on aggregate data on pharmaceutical patent applications and grants in India, Sampat (2010) argued that the standards of patentability, however high, are often ignored and not implemented in practice. Similarly, Chaudhuri et al. (2010) conducted a title search of patent applications and found a large number that had indications of only changes in the delivery mechanism – which was not intended to be a patentable innovation under the inventiveness criteria of Section 3(d).

The unpredictable nature of the timing and likelihood of a patent grant made it difficult, if not impossible, for firms and consumers to adjust their behavior prior to a determination by

the Indian Patent Office. This has important implications for our identification assumption that the granting of a patent represents a plausibly exogenous shock to customers and producers. And given our longitudinal sales data, which we describe in more detail below, we can control for pre-existing differences in levels or trends for prices and other outcome variables of interest.

Previous work on the effect of TRIPS on prices and quantities sold predicted potentially large effects on prices and quantities. Chaudhuri, Goldberg, and Jia (2006) estimate the welfare consequences of patent protection by predicting changes in prices and quantities in the fluoroquinolones sub-segment of the antibiotic sector. Given the lack of evidence regarding the effect of patents in developing countries, these authors implicitly assume the existence of a patent system in India that is comparable to the United States, i.e. a system that provides monopoly status to innovating firms. The counterfactual exercises in this earlier work primarily involve removing one or more of the non-innovating domestic firms from the market. Our analysis below suggests a much smaller effect from India's reform on the number of firms and on average prices.

As discussed above, the change in prices and quantities sold resulting from patents is primarily a question of static efficiency. However, policymakers and economists are also concerned about the dynamic efficiency in the form of research and development (R&D) by pharmaceutical firms. Consistent with this, many firms argue that the lack of adequate patent protection in developing countries has dampened research into diseases that are more prevalent in these countries. Research into the historical provision of intellectual property finds a connection between firm investments in innovation and patent policy (Moser, 2005).

However, the implementation of TRIPS has produced far more mixed evidence concerning the dynamic effects – particularly in the developing world. Arora, Branstetter, and Chatterjee (2008) found an increase in patenting activity in India after 2005 and Borrell (2005) found that product patent systems caused a swifter introduction of HIV/AIDS treatments in developing countries with relatively equal income distributions. However, Lanjouw and Cockburn (2001) found little effect of TRIPS on the development of products targeting diseases prevalent in developing countries. The authors posit this is likely the result of insufficient time for firms to respond. In a later and more definitive study, Kyle and McGahan (2012) estimated the dynamic efficiency of the TRIPS reform and find little change in R&D expenditures for “neglected diseases” such as malaria and river blindness that have a higher prevalence in poorer countries. This lack of a change in R&D activity could be a result of insufficiently profitable

markets for these products in developing countries even after reform. However, it could also be the result of a poorly functioning patent system that does little to change the static efficiency and provide the incentives necessary for innovation.

### **3. Pharmaceutical Sales and Patent Data**

The main data for this project come from two primary sources. Sales data on the Indian market were obtained from IMS Health, Inc. the premier source of pharmaceutical sales data in the world. Comparable data for the U.S. has been used to explore the effect of policy interventions such as Medicare Part D on pharmaceutical prices and utilization (Duggan and Scott Morton, 2010). Our patent data were obtained through a partnership with Origin IP Solutions, an Indian IP search firm.

#### *3.1 Pharmaceutical Sales Data*

Our retail sales data were obtained from the IMS MIDAS dataset (hereafter IMS).<sup>9</sup> IMS collects Indian retail pharmaceutical sales data through the Stockist Secondary Audit—a sample of approximately 5,100 Indian stockists that covers between 80 and 85 percent of the pharmaceutical market. We obtained quarterly data on all single molecule pharmaceutical products sold in a retail setting from the first quarter of 2003 through the second quarter of 2012.<sup>10</sup> In the first quarter of 2003, there are approximately 6,300 products containing roughly 850 molecules that have positive sales. This increases to approximately 10,000 products in the first quarter of 2006 and nearly 12,000 products in the last quarter of 2011. This change comes both from an increase in the number of molecules and the number of products per molecule. In 2003 there were nearly 7.4 products per molecule while in 2012 this number increased to just over 9 products per molecule.

Appendix Figure 1 contains the percentage of molecules in the IMS data with positive sales by quarter. In general, the number of molecules with positive sales in the market increased smoothly over time. However, between the last quarter of 2003 and the first quarter of 2004 there is a nearly 10 percentage point increase in the number of products with non-zero sales. This is by far the largest increase over the sample period. This appears to be a function of the creation

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<sup>9</sup> IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

<sup>10</sup> IMS also collects data on sales at hospitals. According to IMS data, in the average quarter these sales only amount to a small fraction of the market.

of the IMS data and not an actual reflection of the Indian market. Therefore in our empirical results we exclude data before this discontinuous jump in products and create a sample that starts when 90 percent of products have positive sales, i.e. the second quarter of 2004.<sup>11</sup> In addition, since we are not explicitly modeling the effect of patents on the entry of new products, we limit the sample to molecules that had positive sales one year prior to the issuing of the first patent, i.e. the first quarter of 2005. It is worth noting, however, that an examination of our data reveals that the rate of new molecule introduction in the Indian market did not increase after 2005 (see Appendix Figure 1).<sup>12</sup>

While we do not have data for products containing combinations of molecules, the single molecule products in our sample comprise over half of the sales in the Indian market throughout the time period of our sample.<sup>13</sup> Our sample contains manufacturer-product-level data for each quarter on the quantity sold and average price paid. The prices in these data are calculated by IMS and they represent that average price per standard unit.<sup>14</sup> IMS also provides data on the main and sub therapeutic category for the product. Many molecules are sold by a very large number of firms and under many different product names. For example in 2006, Atorvastatin (Lipitor) was sold by 67 firms. Additionally, many molecules fall into multiple sub-therapeutic categories, with IMS tracking the sales for each use. In constructing our sample we drop observations that are diagnostic agents (and thus not drugs) or that cannot be assigned to a therapeutic category, with these two categories accounting for just 1.8 percent of sales in the first quarter of 2005.

The IMS data also contains information on the first date when the product was sold in the Indian market. Given that the Indian patent law was intended to only provide patents for new innovations after 1995, we use this product launch data to split our sample of molecules based on

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<sup>11</sup> We also do not include data for the first two quarters of 2012 in our analyses because the sales data for that period are incomplete (we acquired the pharmaceutical sales data in the Fall of 2012).

<sup>12</sup> We define molecule introduction as the first quarter with strictly positive sales in our data. Appendix Figure 1 shows a fairly smooth increase in the number of molecules with positive sales. This is broadly consistent with Kyle and McGahan (2012) and others cited above. Of course, one could argue that all of our data is actually post-reform, as the TRIPS changes were made in 1995, though evidence from Lanjow and Cockburn (2001) suggests little effect during this earlier period as well.

<sup>13</sup> From 2003 – 2011 the share of all Indian pharmaceutical sales accounted for by single molecule projects decreases from approximately 58 percent to 53 percent.

<sup>14</sup> A standard unit is defined by IMS as “[t]he number of standard ‘dose’ units sold. It is determined by taking the number of counting units sold divided by the standard unit factor which is the smallest common dose of a product form as defined by IMS HEALTH. For example, for oral solid forms the standard unit factor is one tablet or capsule whereas for syrup forms the standard unit factor is one teaspoon (5 ml) and injectable forms it is one ampoule or vial. Standard units should be used when the packs or products being compared are different in form” (IMS 2013).

the first time a product containing that molecule was sold in the Indian market. In our final sample, approximately 60 percent of the molecules were first sold in India after 1995.

### *3.2 Indian Patent Data*

While IMS data contain detailed information on prices, quantities, and the distribution of sales across firms, there is no systematic information on Indian patent coverage accompanying these data or that is readily available from another source. Given this lack of an available patent data source that can be systematically linked to our molecule-quarter level sales data, we contracted with Origin IP Solutions, LLC (hereafter Origin) an intellectual property firm located in Bangalore, India to compile a dataset of all granted patents linked to the molecules in the IMS sales data. Implementing a methodology developed by Origin, the firm's patent attorneys and employees conducted broad and exhaustive keyword searches in the Indian Patent Database using inputs such as the molecule name, other names of the molecule, the International Union of Pure and Applied Chemistry (IUPAC) name, technological classification, and therapeutic indications.<sup>15</sup> Given these data are based on a keyword search of granted patents, it is possible that this method inaccurately links some patents to molecules where the product is listed in the patent grant but is not actual the patented product. To address this potential measurement error issue, we perform the two sets of sensitivity analyses on subsets of molecules discussed below.

Patents were first granted in India in 2006 and then there was a relatively smooth increase in the percentage of molecules covered by at least one patent. In our sample, approximately one third of the molecules are covered by a patent before the end of our study period. Figure 3 depicts quarterly revenues in the Indian pharmaceutical market by the single molecule patent status. Prior to 2006, there were no sales for patented molecules. In subsequent years, the revenues for drugs covered by pharmaceutical patents swiftly increased. By 2009, there were more sales for products containing molecules covered by a patent than for all other products combined. Before that date, increased patented sales were primarily matched by lost sales from the unpatented molecule category. However, following that date the sales of non-patented molecules stabilized and actually increased but the sales of patented drugs increased more rapidly.

A limitation of our patent data is that they do not contain the systematic information on originating firms that would be necessary for us to reliably connect the patent data to specific

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<sup>15</sup> A large number of the patents uncovered in this keyword search were for combinations of molecules. Given we only have single molecule product retail sales data, Origin separated out those patents which pertained to products containing only a single molecule.



products and firms in the IMS data. One reason for this is that firms are able to license their patents and intellectual property to other firms to manufacture and sell the patented product. As a result, the foreign firm receiving a patent in India is very often not one of the firms listed by IMS as a manufacturer in the Indian retail market. There is no source of data that systematically catalogues these commercial relationships. Therefore, we link the patent data to the sales data at the molecule rather than at the molecule-product or molecule-firm level. The most practical implication of this data limitation is that we cannot estimate the increased sales an *originating firm* gains after receiving patent protection. As a proxy for this, we estimate changes in molecule level sales concentration. If sales are shifted to the *originating firms* after a patent grant, then the sales for products containing the newly patented molecule should become more concentrated.

Another limitation of our data is that we do not have precise information about the strength of each patent. Hemphill and Sampat (2010) argue that a product patent claiming the active ingredient—basic patents that cover only the drug compound—are generally the strongest and will most likely prevent any sale of the same molecule by new entrants. These patents are most similar to the original patents granted for compounds in the United States. In contrast, patents for a particular formulation (or chemical variants) such as a sustained release version of the drug may not meaningfully 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. In long standing product patent markets this is less of a concern because the firms holding incremental innovation patents often hold the original patent on the base molecule.

If a large number of the single molecule patents granted by India are of the relatively weak variety discussed above, our coefficients may underestimate the true effect of strong patents in India. Similarly, if there is some degree of measurement error in our patent variable for the full sample that results from the keyword search process, we may also underestimate the actual effect of TRIPS on the Indian market. Therefore, we supplement our main estimates in two ways. First, we split our sample based on whether a product containing that molecule was sold in India prior to 1995.<sup>16</sup> Absent innovations that create a significant increase in therapeutic efficacy, these molecules should not qualify for product patents in India and the product patents that exist for

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<sup>16</sup> While the restriction on patenting in the TRIPS law was based on the priority year (i.e. the first year of patenting in any setting), we use the year of first sale in India as an upper bound of this date. If the priority year were actually earlier, then we would classify patents as strong when in fact they were weaker than would appear. This would create a downward bias in our estimates. We are able to reliably identify the priority year for a sub-sample of the molecules in our data. We present results in an online Appendix from this subsample of molecules.

these molecules should be substantially weaker than those for newer products.<sup>17</sup> In our analysis below, we examine differences in the effects of patent grants based on whether the product was sold in India prior to 1995. Given the structure of the Indian patent law, we would expect to find larger effects for products first sold after 1995.

We also recognize that innovations approved for sale outside of India (i.e. in the United States or Western Europe) after the signing of TRIPS may have a greater potential for affecting welfare than products that were not marketed in these countries. Large price increases for these products may be more likely to attract the attention of regulators, and as a result firms may be more hesitant to exercise the pricing power conferred by a patent. Sampat, Shadlin and Amin (2012) gathered data on the patent applications submitted in India for molecules that were approved for sale in the United States between 1996 and 2004.<sup>18</sup> We supplement our main analyses with specifications that focus on these molecules.

In total, the authors identify 220 Indian patent applications associated with 70 of the 159 drugs that were approved in the United States over this time period.<sup>19</sup> In these data there are 75 granted patents for 44 distinct ingredients and 79 pending applications for 44 distinct ingredients. There is some overlap between these categories, which results in 44 drugs with a patent and 21 drugs that have a patent pending but have not yet been granted a patent. Not all of these products, however, are in our single molecule retail sales data. Ultimately, from these data on molecules approved in the United States from 1996 through 2004, we identify 27 distinct molecules with at least one granted Indian product patent and 19 molecules with a pending Indian patent decision (and no other granted patents) that are included in our retail sales sample. Analyses with these molecules have the advantage of estimating our effects of interest with a more comparable analysis sample but the disadvantage of less precision.

Appendix Figure 3 contains the distribution of patents over time within this sample of molecules. Even among this relatively small sample, there is significant variation in the timing of

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<sup>17</sup> Appendix Figure 2 contains the percentage of molecules with a patent based on the product launch date. Despite the intention of the Indian patent law, the variation in the timing of patent grants is remarkably similar across these two groups of products.

<sup>18</sup> Details on these patent data were provided in supplementary materials to this article. They are available at: <http://www.sciencemag.org/content/suppl/2012/07/03/science.1224892.DC1>.

<sup>19</sup> The authors gathered information as of March 2012 on whether these patents were granted, denied, withdrawn, or the decision is still pending. Of the 220 applications, 75 were granted, 36 were withdrawn, 27 were rejected and 82 were still pending. Each drug can, and often does, receive multiple patents. Comparing these patent data to the aggregate data provided by Origiin we note that 80 percent of these patents were included in the Origiin data. To provide a comprehensive list of patents, the patent sample used for our final analysis is a combination of our patent data and the data identified in Sampat, Shadlin and Amin (2012).

patent grants. There are no patents granted until the first quarter of 2007 and then the percentage of molecules with at least one patent smoothly increases until it peaks at approximately 60 percent in the second quarter of 2010. It is important to note that since these are more recently developed products, they appear to systematically enter the Indian market at later dates than the full sample. Given that the first patent in this sample is not issued until a year after the first patent in the main sample, we limit this sample to products with positive sales in the first quarter of 2006. This creates a generally comparable sample to the main estimates.

#### **4. The Indian Pharmaceutical Market before and after TRIPS Reform**

Despite its large population, the Indian pharmaceutical market remains relatively small in terms of global sales. In 2012, IMS estimated that sales in the Indian market were approximately \$14.3 billion (less than \$12 per capita). By comparison, in 2012 sales in the United States market were approximately \$322 billion (more than \$1,000 per capita). From 2007 to 2011 the Indian market grew at an annual rate of 15.3 percent compared to only 3.7 percent growth in the United States. Future growth for both markets is expected to be roughly consistent with these trends (IMS, 2012). This rapid growth in India compared to growth in more developed markets is one reason that, despite its relatively small size, foreign firms have become increasingly interested in obtaining stronger intellectual property protections there.

India's modern pharmaceutical industry was primarily shaped by the Patents Act of 1970. Prior to this, the Indian pharmaceutical market was dominated by western multinational corporations that controlled over 75 percent of the market, primarily through imported drugs. 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).

An important feature of the 1970 Patents Act was the special provision relating to pharmaceuticals that allowed patent protection only for a new method or process of manufacture and not for the product itself.<sup>20</sup> This granted patent protection to slight modifications in the synthesis of a molecule and essentially allowed several firms to legally produce and sell the same product in the Indian market. Even this limited patent protection was provided for only seven years for pharmaceuticals. Following these changes, most foreign pharmaceutical manufacturers

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<sup>20</sup> 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.

exited the Indian market altogether. Over the next three decades, a market that had been primarily composed of foreign multi-national companies transformed into one in which thousands of Indian-owned firms were responsible for 70 percent of pharmaceutical manufacturing in India (Chaudhuri, 2005).

This robust domestic manufacturing industry for pharmaceuticals stems, in part, from the 1970 Patents Act effectively encouraging the reverse engineering of internationally patented products. For example, according to the date of first sales in our IMS data, 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 first manufactured and sold in India by generic producers within two years of being introduced in the United States. Perhaps in an attempt to protect intellectual property, many international firms often entirely abstain from participating in India's domestic market with their most valuable products.

Given the historic lack of a product patent system and the relatively developed domestic pharmaceutical manufacturing sector, the Indian pharmaceutical market prior to patent reform bore few similarities with the more traditional markets of the United States or Western Europe. Perhaps the most immediate difference is the sheer number of Indian firms that were manufacturing products containing the same molecules. Panel A of Table 1 contains a breakdown of molecules by the number of firms producing single molecule products containing that compound during the first quarter of 2006. The average molecule has 8.6 firms selling a single molecule product, 68 percent of molecules have more than one firm, and 39 percent of molecules have 5 or more firms manufacturing single molecule products with the molecule. Column (2) contains the number of firms weighted by the value of sales. This shows an even more disperse industry with 90 percent of (sales-weighted) molecules being produced by 5 or more firms.

This pattern is similar for the highest grossing products. Panel A of Table 2 contains the average number of firms selling single molecule products in the first quarter of 2006 by the total molecule sales. In the United States the highest grossing drugs are generally produced by a single firm holding the patent. However, the 68 molecules with 2006 sales greater than \$10 million have an average of 55 firms with non-zero sales. The 82 molecules with sales between \$5 and \$9.99 million have an average of 21 firms selling single molecule products. As would generally be consistent in a market with free entry to production, the average number of firms producing a molecule is monotonically increasing in the annual revenue of the molecule.

To more clearly see the distinction between the global and Indian markets, consider the descriptive statistics for the top 15 selling drugs for each market in 2006 contained in Tables 3A and 3B. Several facts are immediately apparent. First, the sheer size of the global market relative to India's is clear. Despite India containing more than one-sixth of the world population, pharmaceutical sales across the globe range from 100 to 2,200 times the value in the Indian market among products sold in both markets. Second, there is very little overlap in terms of the highest grossing drugs in each of the two markets – only 1 of the top 15 highest grossing drugs in the world are among the top 15 grossing drugs in the Indian market. Third, the top selling drugs in the world are covered by patents and therefore sold by only one or at most two firms. In the Indian market there is an average of 23 firms making each of the 15 products with the highest global sales, and an average of 89 firms making each of the top 15 drugs with the highest sales in India. Interestingly, only 7 of the 15 firms holding the patent for the highest grossing products in the world is reported in the IMS data as selling these drugs in the Indian market. Even for those firms, their share of drug sales in India does not exceed 50 percent.

## **5. The Effect of Product Patents in the Indian Pharmaceutical Market**

The characteristics of the Indian pharmaceutical market summarized above suggest it was a setting in which introducing a product patent system could generate very large changes. In this section, we explore the effect of increased patent protection on average prices, total quantity, and other outcome variables of interest.

### *5.1. Average Prices*

If the large price increases that some predicted following the adoption of TRIPS were realized, they should be evident in the aggregate data. Figure 4 contains the 25<sup>th</sup>, 50<sup>th</sup>, and 75<sup>th</sup> percentile of prices (per daily dose) in the Indian market from 2003-2012. Over this time period prices are smoothly rising.<sup>21</sup> These aggregate data suggest that any change in prices following a patent is on average likely small, though changes in the composition of molecules sold over time could obscure important changes. We more formally investigate the effect of patent grants on

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<sup>21</sup> There is one noticeable drop across the entire price distribution in 2008. This appears to be the result of a change in the excise tax treatment of pharmaceuticals that was expected to decrease prices by 5 to 7 percent (PharmaTimes, 2008). Appendix Figure 4 contains the median log price by whether a molecule ever receives a patent in our sample. Products containing molecules that eventually receive patent protection had lower prices per standard unit than those that are never patented but the two groups follow a very similar increasing trend over our sample period. Additionally, both sets of molecules experience the same dip in 2008.

our outcome variables of interest using our longitudinal sales data and estimating specifications of the following type:

$$Y_{mt} = \alpha_m + \delta_t + \lambda \cdot t \cdot I\{EverPatent\}_m + \beta \cdot I\{HasPatent\}_{mt} + \varepsilon_{mt} \quad (1)$$

In this equation,  $m$  indexes molecules and  $t$  indexes quarters. We include a full set of molecule fixed effects ( $\alpha_m$ ) to control for the substantial heterogeneity across products with respect to both average prices and quantities. We additionally control for a full set of year\*quarter ( $\delta_t$ ) fixed effects and a separate time trend for molecules that receive a single molecule patent at some point in our sample. The variable  $I\{HasPatent\}$  is an indicator variable that equals one during the quarters in which the molecule is covered by at least one single molecule patent and is otherwise zero.<sup>22</sup> Across our specifications we condition inclusion in the sample on there being at least one firm making the molecule.<sup>23</sup>

Panel A of Table 4 contains the estimates for specifications in which the log of average price per unit is the outcome variable of interest. Column (1) contains the estimates from the full sample of molecules and indicates that single molecule patents raise average molecule-level prices per unit by approximately 2.7 percent. This estimate is statistically significant (p-value < 0.05) and the upper bound of the 95 percent confidence interval rules out patent-related price increases of greater than 5.3 percent.

Our primary identifying assumption is that the timing of patents being granted was orthogonal to other events that might also have affected the market outcomes of newly patented products. We include both molecules that received a patent and those that did not receive a patent during our study period – and allow those molecules eventually receiving a patent to follow a different linear time trend. We therefore exploit the differential timing of the patent grants by the Indian patent office to estimate  $\beta$ , our primary parameter of interest. We test the validity of this assumption by estimating the following event-study specification:

$$Y_{mt} = \varphi_m + \sigma_t + \sum_{k=-8}^8 \mu_k I\{k \text{ quarters since patent}\}_{mt} + \nu_{mt}. \quad (2)$$

in which  $I\{k \text{ quarters since patent}\}_{mt}$  is an indicator variable for the number of quarters before and after a patent is granted. The results from this specification shed light on whether there are

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<sup>22</sup> This variable equals 1 during the first quarter the molecule is covered by a single patent. If the molecule receives additional patents in subsequent quarters, this variable remains as a simple indicator variable.

<sup>23</sup> We find no evidence that patent introduction affects the probability that a molecule has zero sales. Also, our results are qualitatively similar if we include these observations. For example, in our quantity specifications, if we set quantity to 1 (and thus the log of quantity to 0), our point estimates are very similar.

differential trends in the quarters leading up to patent introduction and how any post patent effects evolve over time.

Figure 1 contains the estimates from this event-study specification with a dependent variable equal to the log of the average price per unit. These estimates provide strong support for product patents causing an immediate and statistically significant increase in drug prices that is ultimately relatively small in magnitude. Prior to a patent grant, the estimated coefficients are nearly indistinguishable from zero and stable. However, in the quarter after a patent is granted there is a sudden and persistent jump in the average price. These estimates demonstrate that the post-patent price increase peaks at approximately 4 percent, with an upper bound to the confidence interval of approximately 9 percent.

Beyond differential trends, there could be a concern that molecules never receiving a single molecule patent, which compose a portion of the comparison group in any period for our main sample, would be affected differentially by other secular events in the marketplace. To address this potential concern, we supplement our main estimates with those from a sample that only includes molecules that eventually receive a single molecule patent during our sample period, and therefore in this sample we only exploit variation in the timing of the patent effective dates. This is a far more demanding test of the data since many of the patents are granted in a relatively small number of quarters and this sample contains a far smaller set of molecules (336 versus 1,012 in the full sample). Column (2) contains the estimated change in average prices for the sample containing only molecules that receive patent protection at some point. The point estimate for our parameter of interest declines by approximately one-third (to 0.017) and is no longer statistically significant, thus suggesting at most a small effect on average prices in this smaller sample.

Given the large number of patents in our dataset, there is undoubtedly some heterogeneity in the strength of the patent and the relative importance of the product in the Indian market. Lacking a systematic means of classifying the expected strength of patents, we next make two attempts based on the age of patented molecules and whether the product was approved for sale in the United States after the signing of TRIPS.

We first examine differences based on the vintage of the molecule. As discussed above, the product patent system in India was intended to provide intellectual property protection for new innovations as of January 1, 1995. The only way for molecules invented before that point to receive a patent would be through improved therapeutic efficacy rather than simply a new use for

an existing molecule. However, as documented in Chaudhuri et al. (2010), many patents have been granted for “innovations” that are meant to be explicitly not patentable in India. It is likely that if these patents were legally challenged they would not be upheld. Given this fact, patents granted for products that existed before 1995 are on average likely to be weaker than for products containing newer molecules.

Figure 2 contains the event study estimates for two samples of molecules based on whether the molecule was first available in India before or after 1995. As discussed above, we use this date of first sale as an upper bound estimate of the priority year, i.e. a molecule would not likely be sold in the Indian market before it was patented somewhere in the world. Prior to the issuing of a patent, both sets of molecules follow a generally similar flat trend. However, after a patent is issued there is an immediate jump in the prices for molecules first sold after 1995. Consistent with our hypothesis that patents are weaker for older drugs, there was no noticeable change in the prices resulting from the patents for molecules first sold prior to 1995. To investigate the statistical significance of these differences, we estimate the following triple difference specification based on the date of first sale:

$$Y_m = \alpha_m + \delta_t + \lambda \cdot t \cdot I\{EverPatent\}_m + \delta_t \cdot I\{Post95Launch\}_m + \eta_1 \cdot I\{HasPatent\}_m + \eta_2 \cdot I\{HasPatent\}_m \cdot I\{Post95Launch\}_m + \varepsilon_m. \quad (3)$$

in which  $I\{Post95Launch\}_m$  is an indicator variable equal to one if there was no product sold in the Indian market containing molecule  $m$  prior to 1995 and all other variables are defined as in equation (1). The coefficient of interest is  $\eta_2$  which represents the change in the dependent variable (e.g. log of average price, log of quantity, or sales concentration) after a patent for molecules released after 1995 compared to patented molecules released before that date.

Columns (3) and (4) of Table 4 contain the estimates from equation (3) for the full sample of products and for the sample of only patented molecules, respectively. The estimated effect for  $\eta_2$  for the full sample is similar in magnitude to the estimate in column (1) but is not statistically significant. The estimate for  $\eta_2$  using the sample of only patented molecules shows a statistically significant 4.9 percent average price increase – relative to the effect for pre-1995



molecules - following a patent.<sup>24</sup> The upper bound of the 95 percent confidence interval rules out an increase greater than 9.3 percent. In addition, the point estimate of -0.014 for  $\eta_1$  suggests little impact on prices for pre-1995 molecules.

One potential concern with our division of molecules based on the year of first sale in India is that this event, almost by definition, occurred after the molecule's priority year, i.e. the date that determines patentability under the reform. To the extent this is true, it would bias against our finding a difference in the preceding analyses as it would incorrectly label some pre-1995 molecules as post-1995 (and thus the post-1995 effect would be biased down). To explore this issue further, we supplement our main results with those based on the molecule priority year.

We were able to reliably match the priority year for approximately one-third of the products in our single molecule sample. Appendix Figure 6 contains the event-study coefficients for this sub-sample of molecules based on whether the priority year is before or after 1995. These estimates show a qualitatively similar pattern to the sample using the first year of sale in Figure 2. While the pattern of estimates is similar, the magnitude in the post-1995 priority year sample is generally larger than in the post-1995 first year of sale sample in Figure 2. However, given the relatively small number of molecules that we identify with a post-1995 priority year, these estimates are quite imprecise. Column (1) of Appendix Table 1 contains the estimates for a DD specification for the full sample of molecules for which we have a priority year. Column (2) further restricts to molecules from this set that receive a patent at some point during our study period. The estimates from these two specifications show a statistically significant price increase of approximately 4 percent.

The large difference in the post-patent event study coefficients by priority year in Appendix Figure 6 suggests a larger effect for molecules with a post-1995 priority year. To examine the magnitude and statistical significance of these differences, we estimate a specification of equation (3) based on the priority year rather than the first sales year. For comparison purposes, columns (3) and (4) of Appendix Table 1 contain estimates for equation (3) based on the first year of sale for the sample of molecules with a reliably matched priority year. Columns (5) and (6) contain DDD estimates based on the priority year being before or after 1995. While the estimated coefficients are statistically insignificant, they are generally similar in magnitude to the estimates based on the year of first sale. In addition, even though these estimates are

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<sup>24</sup> If we instead interact the  $I(HasPatent)$  variable with a pre-1995 indicator, so that the main effect estimate represents the average price for the newer molecules, the point estimate of 0.035 is statistically significant with a p-value of 0.069.

imprecise, they rule out post-patent price increases of more than 23 percent for molecules with a post-1995 priority year relative to those with a pre-1995 priority year. While these are somewhat larger than the estimated price increases using the first year of sale, they are still substantially less than what would be predicted for a textbook product patent system. Taken together, the priority year estimates show that the year of first sale is a reasonable proxy for differences in patent strength based on molecule vintage.

To further address concerns regarding heterogeneity in the strength of patents or the importance of the patented molecules in the Indian market, we next examine the subset of patent applications identified in Sampat, Shadlin and Amin (2012). These data include molecules that were approved for sale in the United States between 1996 and 2004. These products are (a) patented by foreign firms and (b) more likely to represent the types of products that will qualify for strong patents in the coming years. As discussed above, this sample contains molecules which receive patents, those that were denied patents, and those whose patent decision is still pending. We construct two samples of molecules with alternative comparison groups: (1) those that have received patents and those that have had no patent decisions to date, and (2) those that have received patents and those that have had their applications denied.

Columns (1) and (2) of Table 5 contain the estimates for the effect on log price in the sample of molecules previously approved for sale in the United States. The first column contains the estimates for a sample containing molecules that were either granted a patent or still had a patent decision pending. The point estimate of 0.061 suggests an approximately 6 percent that is statistically significant at a p-value of 0.05. There could be a concern that the molecules in this sample that are still waiting for their first patent decision could be quite different from those that have received patents. For example, they likely applied for their patents at later dates. To address this concern, Column (2) contains estimates from a sample composed of molecules that received patents and those that had their patent denied (primarily as a function of section 3(d) of the Indian patent law). For the sample with a smaller comparison group composed of molecules with rejected patent applications the estimate is quite similar in magnitude and precision.

Even among this group of molecules with recently approved patents, there is likely to be some variation in the expected strength of the patent. Using data provided by the authors of Sampat, Shadlin and Amin (2012), we re-estimate this specification with indicator variables for whether a molecule was covered by a strong patent for the active ingredient. Hemphill and Sampat (2010) suggest that these strict strong patents should have a larger effect on price than

the active ingredient patents. However, it should be noted that these patents are relatively rare. Less than 20 percent of the molecules in this sample had a strict patent.

Column (3) of Table 5 contains the estimated effect on log prices from active ingredient patents among the sample of recently approved molecules that have received patents or have patents pending. The estimated coefficient on the strict patent indicator variables is positive but is not statistically significant from zero. This is also true in the sample in which the comparison group is composed of molecules with denied patent applications.

Taken together, our estimates demonstrate that the implementation of a modern product patent system in India caused a statistically significant but economically modest increase in prices for newly patented molecules. Across all of our estimates, we can rule out increases of greater than 20 percent for the average molecule – and note that this occurs for just a small subset of products. This effect is much smaller than the decrease in average prices in the United States following the expiration of a patent – which is often 70 percent or more. It is also much smaller than the pre-TRIPS estimates of a strong product patent system in India.

An open question is why do we find a smaller price increase than was expected prior to the reform? There are many potential reasons why this may have occurred. First, it is possible that demand in the Indian market is such that even the profit maximizing price for a monopolist is only slightly higher than the market price prior to 2005. However, the earlier work of Chaudhuri, Goldberg and Jia (2006) suggests that, for at least one sub-sector of the Indian market, the profit maximizing price is at least twice as high as the pre-patent price. This suggests that the lack of demand is likely not driving our modest price effects.

Another potential mediating factor is the presence of substitute products. Even in the case of strong intellectual property rights, close substitutes would mediate price effects. We now consider the role of two types of substitute products in explaining our results. First we consider therapeutic substitutes for patented molecules, which are products that contain other molecules intended to treat the same condition. IMS data contains a three digit anatomical therapeutic classification (ATC) code for each product. This pharmaceutical subgroup (of which there are nearly 300 distinct values in our data) is fairly narrowly defined and provides a reasonable approximation of a substitute product.

We examine the role of therapeutic substitutes by estimating specifications of equation (1), in which we allow the effect of the patent to vary by whether the molecule has two or fewer therapeutic substitutes. Approximately one-fourth of molecules fit into this category. Columns

(1) and (2) of Table 6 contains the estimates from this specification. The sample for this analysis includes only molecules released after 1995 – those molecules exhibit a post-patent price increase in the analysis above. Our estimates indicate that there is not a statistically significant difference in the price effect based on the number of products that are therapeutic substitutes.

We next consider the role of products that are direct substitutes, i.e. those that contain the same molecule as the patented product. In addition to being a more direct substitute than those discussed above, the Indian patent law requires non-patent holding firms selling the molecule to be allowed to continue selling after paying a “reasonable” royalty. While the definition of reasonable is obviously up for interpretation, it should be noted that in the Nexavar compulsory licensing case, Natco is only required to pay Bayer a 6 percent royalty (Bajaj and Pollack, 2012). As a result of this flexibility granted to the Indian government under TRIPS, single molecule products not receiving a patent serve as a strong substitute for the patented product and the size of the royalty limits the pricing power of patent holding firms.

Columns (3) and (4) of Table 6 contains estimates from specifications of equation (1) that allow the effect of a patent to vary by whether the molecule was sold by a monopolist in the first quarter of 2005. The sample for this analysis includes only molecules released after 1995 – those molecules exhibit a post-patent price increase. The statistically significant point estimates of approximately 0.17 in both specifications for the effect of a patent on molecules with just one producer suggest a nearly 20 percent price increase from a patent grant. The estimate for the main effect is small in magnitude and statistically insignificant, suggesting that the average price effects that we estimate for the full sample are driven by molecules with just one producer. While firms that were the sole producers of a molecule prior to their receipt of a patent might have had some pricing power, they still presumably faced the threat of entry. This may have caused them to implement some version of a limit pricing strategy in order to deter entry (Milgrom and Roberts, 1982). Similar deterrence using prices was documented in the airline industry by Goolsbee and Syverson (2008). Armed with a patent as a stronger barrier to entry, these firms apparently decided to increase prices.

Figure 5 contains the event study coefficients based on whether a molecule is produced by a monopolist. Prior to the granting of the patent, prices for molecules are trending similarly regardless of the number of firms. However, in the quarter after a patent is granted there is a sudden and substantial increase in prices for molecules that were produced by only one firm. There was little change in average prices for all other molecules.

These results suggest that the modest price effect we find is actually the combination of a relatively large effect for molecules produced by a single firm and small effects for other molecules. This demonstrates both the importance of market structure and the role of the statutory flexibilities in TRIPS for moderating firm behaviour.

There are two important points to consider about these estimates. First, the market structure for these single-firm molecules is similar to what we might expect for innovations that enter the global market in the future. These new products will apply for patents in India prior to being globally available and therefore will not have pre-existing generic competition within the same molecule. Therefore, the estimates in Table 6 for single-firm molecules may presage a growing effect of the TRIPS-induced patent policy in the future.

Second, molecules produced by a single firm had lower average sales than those produced by more than one firm (\$100,800 per quarter versus \$1,280,000). Thus, for the majority of molecules and the vast majority of sales-weighted molecules, our estimates indicate that patents had very little effect on prices. This demonstrates that the static inefficiencies created by product patents in India were quite small, but that there may be dynamic efficiency gains because firms can see the price increases for monopoly molecules as evidence of the potential for future profits from newly patented innovations in this market.

## *5.2. Number of Firms and the Concentration of Sales*

Our estimates suggest that patents caused a modest increase in average pharmaceutical prices. In this setting, there are multiple mechanisms that could drive this change. Perhaps the most direct is a decrease in the number of producers due to the increased exit rate of incumbent firms or a lower entry rate of new firms. In addition, firms granted intellectual property rights can extract payments from other firms making the products. Therefore, the change in prices can occur without any actual difference in observed market structure. As evidence of the existence of this phenomenon, we note that some of the firms receiving patents for molecules never appear in the retail sales data.

We begin by examining changes in market structure that are observable in the aggregate data. Table 2 contains the distribution of the number of firms producing each molecule in 2006 and 2011. Interestingly, there is little change during this period despite the introduction of hundreds of single molecule patents. Consider the sales weighted percentages in columns (2) and (4). In both 2006 and 2011, 90 percent of the sales weighted molecules were for products made

by five or more firms. More than 60 percent of the sales weighted molecules were for products made by 20 or more firms in both years.

We now estimate the effect of receiving a patent on the number of firms and the molecule level sales concentration as measured by the HHI. Panel A of Table 7 contains the estimates for a dependent variable equal to the number of firms in a quarter that are selling single molecule products containing that molecule. The first column contains the estimates from our most basic specification of equation (1) discussed above. While the coefficient of -0.39 on the indicator variable for having single molecule patent is negative, it is not statistically significant (p-value = 0.145). Given the standard error of 0.32, we can rule out an average reduction of more than 0.93 firms at the 95 percent level. Note that prior to TRIPS, each molecule had an average of approximately 15 firms manufacturing products, so there was scope for large average changes along this dimension.<sup>25</sup>

We next examine changes in the molecule level sales concentration as measured by the Herfindahl–Hirschman Index (HHI) of sales in dollars for each molecule in each quarter. If patents cause sales to shift toward the firm with the patent though do not cause firms to exit the market, then this may be reflected in an increased HHI. Column (5) in Panel B of Table 7 contains the estimates for the full sample of molecules and shows that the molecule level HHI (measured on a 0 through 1 scale) increases by a statistically significant (p-value < 0.05) 0.014 after the first single molecule patent was granted. Column (6) contains the estimates for the more limited sample of molecules that are eventually patented. This coefficient is roughly the same in magnitude to the main estimate and has a p-value of 0.066.

Figure 6 contains the estimated coefficients from an event-study specification with molecule HHI as the dependent variable. Prior to the granting of a patent, the HHI is relatively smooth, negative but generally close to zero. However, after the granting of the patent there is an immediate jump and then a consistent upward trend in the estimated coefficients – though it is not until approximately a year and a half after the patent that the estimated coefficients are statistically different from zero. At this point the effect of the patent is a 0.02 increase HHI.

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<sup>25</sup> One concern might be that there is churn in the market – including exits of incumbent firms - around the time a patent is granted and our effects for the number of firms are masking these changes. Therefore, we estimated a specification with the molecule-firm-quarter as the unit of observation and define a dependent variable equal to 1 if a firm exits the market for that molecule. In these specifications, we find no evidence for an increase in firm exit probabilities following a patent grant.

We find similar evidence of the small but statistically significant effect using the triple difference identification strategy. Figure 7 contains the event-study estimates based on whether a product containing the molecule was first sold in India prior to 1995. Prior to a patent being issued, the estimated coefficients for the sample of molecules sold after 1995 are trending smoothly and relatively close to zero. However, after a patent is issued there is a sudden jump in the estimated coefficients that then trends upwards over time. A similar pattern is not seen for the sample containing the older molecules, consistent with our hypothesis that patents for more recent drugs are stronger. Columns (7) and (8) of Table 7 contain triple difference estimates from equation (3) for the full sample of molecules and a sample only containing patented molecules, respectively. The estimated coefficient for the sample containing only patented molecules shows a statistically significant ( $p$ -value  $< 0.10$ ) 0.022 increase in the molecule level HHI.

To provide some context for the magnitude of this change in concentration, we look to the horizontal merger guidelines provided by the United States Department of Justice (DOJ). In the first quarter of 2006, the average molecule that eventually received a patent had an HHI of 0.534. If each molecule were a market, then the average market would be considered highly concentrated. According to the United States Department of Justice (DOJ) horizontal merger guidelines, our estimates of an HHI increase between 0.01 and 0.02 in the HHI would “potentially raise significant competitive concerns and often warrant scrutiny” while an increase of greater than 0.02 would be “presumed to be likely to enhance market power.” Therefore, our estimate of an increase in the years after a patent is granted is a statistically significant and economically meaningful increase in sales concentration that would likely give the originating firm additional pricing power. This could explain at least part of the mechanism underlying the price increase in Table 4. However, it is also important to note that this estimated change in market concentration is far smaller than what would occur if all sales went to just one firm as a result of the patent.

Returning to our estimates using the sample of products recently approved for sale in the United States, we find much larger effects on HHI. Column (6) of Table 8 contains the estimates for a sample containing molecules that were either granted a patent or still had a patent decision pending. The estimated effect is similar in magnitude to the DDD estimate in Table 7, but is not statistically different from zero.

Taken together, our estimates show that the introduction of a large number of product patents did not transform the market structure in terms of the number of firms or the

distribution of sales. These regression estimates are quite consistent with the aggregate data, which suggest little change in the average number of firms producing each molecule during a period with hundreds of new patents issued. Many years after the creation of the patent system, there was also no meaningful change in the raw number of firms participating in the Indian pharmaceutical market. This suggests that previous predictions of the effects of the TRIPS patent reform that assume, either explicitly or implicitly, that it would cause a marked change in the number of firms in the market have likely overstated the immediate effects of TRIPS on access to pharmaceuticals and on consumer welfare in India.

In addition to the removal of infringing firms, the TRIPS reform was intended to promote the introduction of new products to the Indian market. Appendix Figure 1 contains the share of molecules that appear in our data during our study period with positive sales entering the Indian market. We see no marked increase in the rate of new molecule introduction after the creation of a product patent system. This lack of a large increase in the number of new molecule introductions in the Indian market matches the existing work by Kyle and McGahan (2012). The lack of a substantial price increase after patent introduction demonstrated above may partially explain the absence of a large change in the rate of new molecule introduction.

### *5.3. Quantities Sold*

We next examine the effect of patents on the quantity of drugs sold. While the price effects described above are relatively modest, the structure of the Indian retail market means that even without a substantial price increase, it is possible that decreased sales could result from differential access across firms to local distribution networks. As a result of the large number of domestic firms manufacturing similar products, the Indian retail pharmaceutical market is relatively fragmented. Pharmaceutical firms supply products to carrying and forwarding agents. These agents then supply stockists, who then in turn provide inventory to retail pharmacies that sell products to customers. In 2008 there were approximately 65,000 stockists working with 550,000 retail pharmacies (Langer and Kelkar, 2008).<sup>26</sup> Given these facts, removing domestic

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<sup>26</sup> Goldberg (2010) details this fragmentation when discussing the preference among Indian consumers for products containing the same molecule produced by domestic manufacturers over those produced by foreign multinational firms. They posit that this preference across seemingly homogenous products stems in part from domestic firms having better access to specific retail settings across India and potentially investing more in local marketing efforts. After all, the ability of a consumer to purchase a product at any price is a function of that product being in stock at the point of purchase.



firms with differential access to retail channels could decrease the quantity sold through a channel other than price increases.

Columns (5) and (6) of Table 4 contains the results for specifications in which the dependent variable is equal to the log of the number of standard daily doses. In both samples, we estimate a small, negative, and statistically insignificant decrease in the quantity sold following a patent grant. For example, in the full sample the estimate suggests a 5.5 percent decrease, but has a p-value of 0.129. Figure 8 contains the event study specifications. These coefficients show little change in the quantity sold in the quarters before or after a patent was granted.

Figure 9 contains the event study coefficients for samples split by the vintage of the molecules. While neither sample provides strong evidence of a sales decline, the sample of post-1995 molecules does have a large change in the time period shortly after the granting of a patent. Columns (7) and (8) of Table 4 contain the estimates from equation (3) with the dependent variable as the (log of) quantity sold. Neither estimate is statistically significant but both are in the expected (negative) direction given the post-patent price increase.

The estimated effect of patents on the quantity sold for the sample of molecules approved in the United States between 1996 and 2004 is substantially greater than the estimate from the main sample. The specifications summarized in columns (1) and (2) of Table 8 show that following the granting of a patent, there was an approximately 27 percent decrease in the quantity of standard doses sold. This estimate is statistically significant with a p-value less than 0.05, though the wide confidence interval is compatible with a large range of effect sizes. Appendix Figure 5 contains the estimates from an event study specification. This shows that the large quantity decline appears to be driven by a strong negative pre-trend in the quantity sold for drugs that receive patents compared to those that still have their patents pending. This pre-trend stands in stark contrast to the relatively flat and stable pattern for the main sample in Figure 8.

Overall, there appears to be relatively little average change in quantity resulting from the creation of an Indian product patent system. However, for a sample of products that are recently approved by the U.S. Food and Drug Administration, there appears to be a large sales decline.

## 6. Conclusion

In 2005, India enacted a fundamental change to its patent system for pharmaceutical products. Since then, India has granted hundreds of patents to both domestic and multinational

firms. This represents one of the first attempts to apply an entirely new patent system to an existing market of this size and scope. Prior to the new patent system, there were many products being sold containing molecules that were patented outside of India but were domestically manufactured and sold by a large number of firms. These conditions appeared ripe for large changes from a product patent system.

While there were significant fears across a variety of constituencies that this new system would cause dramatic price increases and further limit access to pharmaceuticals in India, we find little evidence of large changes. Looking at both aggregate statistics and longitudinal data, we find that the product patents did not decrease the number of firms making molecules but we do see a statistically significant shift in the molecule-level sales concentration. This is consistent with patents benefiting originating firms. We also find that the new product patents increased prices, but the magnitude of the change was ultimately quite small. Overall, we find little change in the quantity sold as a result of these price increases. However, when we focus on a subset of products that were recently patented outside of India by foreign firms we do see substantial decreases in the quantity sold. This is consistent with an important role for retail distribution networks established by domestic firms as discussed in Goldberg (2010). Over time, foreign originating firms could invest in these networks, limiting any effects on quantity.

Previous work regarding the effect of these patents in India predicted large price increases, quantity decreases, and losses in consumer welfare. A fair question arises as to the source of the difference between our estimates and these earlier predictions. Certainly, the actual rules of the new patent system play an important role. As described by Sampat (2010), the reality of implementing TRIPS was more complicated than simply creating a new version of United States Patent and Trademark Office or the European Patent Office. For example, molecules that were patented outside of India prior to 1995 were meant to be excluded from this system unless they were part of a new invention. This appears to have limited the strength of many of the newly issued patents which apply to products before this date but likely have little effect on market outcomes. Examining our estimates, we find essentially no effect from patents issued for molecules that were first sold in the Indian market before 1995. However, when we concentrate our estimates on more recent molecules, we find price effects that are larger but can still rule out price increases larger than 10 percent. Even when we limit our focus to a subset of products recently patented in foreign markets, the upper bound of our confidence interval rules out average price increases larger than 20 percent, which is much lower than previous estimates. One

possible explanation is that demand in the Indian market cannot support profit maximizing prices at higher levels. However, Chaudhuri, Goldberg, and Jia (2006) show that very large prices after an effective product patent would be profit maximizing for originating firms within the fluoroquinolones sub-segment.

This suggests that the difference between our estimates and earlier work might not be solely the result of the demand structure but instead stem from other regulatory features included within TRIPS. For example, the Indian government retains the ability to institute direct price controls and to force originating firms with prices that are deemed to be unaffordable for the Indian population to license their technology to a generic competitor. While these features of TRIPS have been sparingly used, their specter hangs over the pricing decisions of originating firms and may limit their ability to raise prices by as much as predicted in previous work.<sup>27</sup>

Our relatively small estimated effects could be seen as both good and bad news for the Indian market. At least in the short-term, they suggest relatively few static inefficiencies resulting from an increase in intellectual property protection. This takes on additional significance when one considers that India is also one of the largest exporters of pharmaceuticals – particularly to the developing world. In 2010, India exported approximately \$17.2 billion worth of pharmaceuticals (Kallummal and Bugalya, 2012).<sup>28</sup> Many of these exports were critical in supplying certain product segments that treat diseases prevalent in markets of Africa, Asia and Latin America—most notably vaccines and antiretroviral drugs for treating HIV (Greene, 2007). The non-profit organization Doctors without Borders estimates that 80 percent of the AIDS medications it distributes are manufactured in India (Ahmed and Sharma, 2012). This role of the domestic Indian pharmaceutical manufacturers in providing affordable pharmaceuticals for impoverished countries was an additional concern for the potentially far reaching effects of the TRIPS reform. For example, in 2001 CIPLA announced it would provide Anti-Retro Viral (ARV) drugs for the treatment of AIDS for one dollar a day in sub-Saharan Africa. Previously, these products had been sold for between ten and fifteen thousand dollars a year (Doshi, 2004).

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<sup>27</sup> Previous work has examined how firms may change their behavior to avoid the imposition of regulations. Glazer and McMillan (1992) develop a model where firms set prices below the profit maximizing point to avoid the attention of regulators. Efrle and McMillan (1990) show that oil firms did not pass along the full costs of the 1979 oil shock and that this was particularly true for large firms such as Exxon and for salient products such as home heating oil. Of interest to our setting, Ellison and Wolfram (2004) show that pharmaceutical firms in the United States restrained price increases during a debate about health care reform that may have negatively affected their profits.

<sup>28</sup> Unfortunately our IMS data does not contain any information on the quantity or value of India's export market.

If a large number of firms are forced to exit the market, or there is a marked price increase from the TRIPS reform, this could cause health concerns well outside of India's borders.

However, this suggests that there may only be a small increase in expected profits for pharmaceutical firms in India, which should limit the increase in incentives to create new products for this market. This might explain why research to date has not detected a marked shift in innovation towards conditions that are more prevalent in the developing world. And consistent with this, our data (summarized in Appendix Figure 1) provide little evidence to suggest that there was an increase in the rate at which new molecules were introduced in India after the move to a new patent system.

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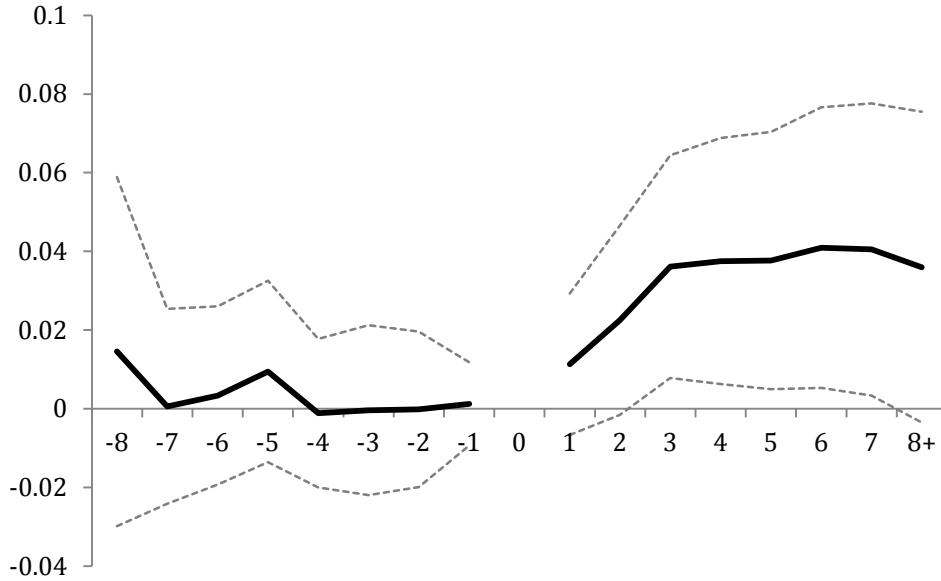
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**Figure 1**

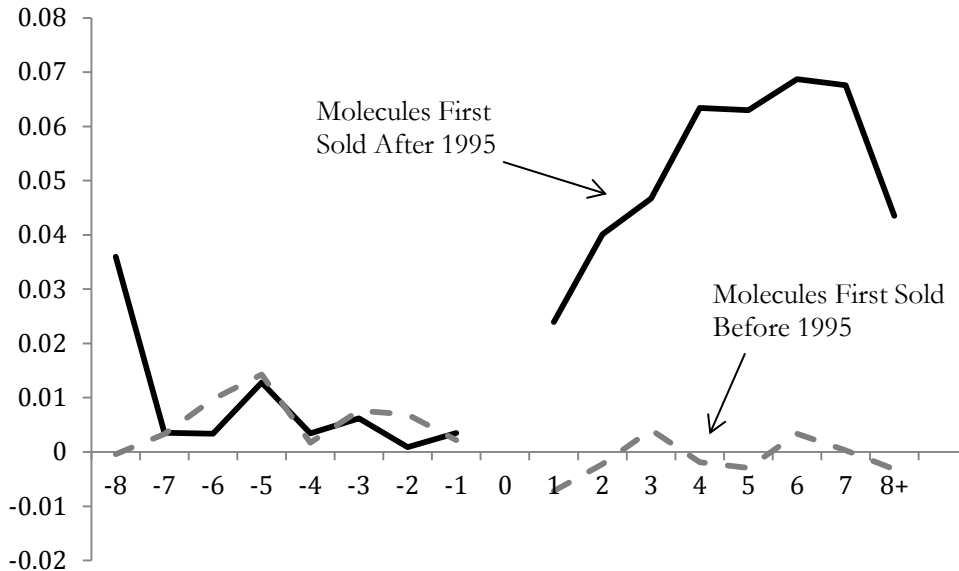
Event Study Estimates for the Log of the Average Price Before and After a Patent is Granted



The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects. The dotted line represents the 95 percent confidence intervals with standard errors that allow for arbitrary correlation between observations within the same molecule. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved.

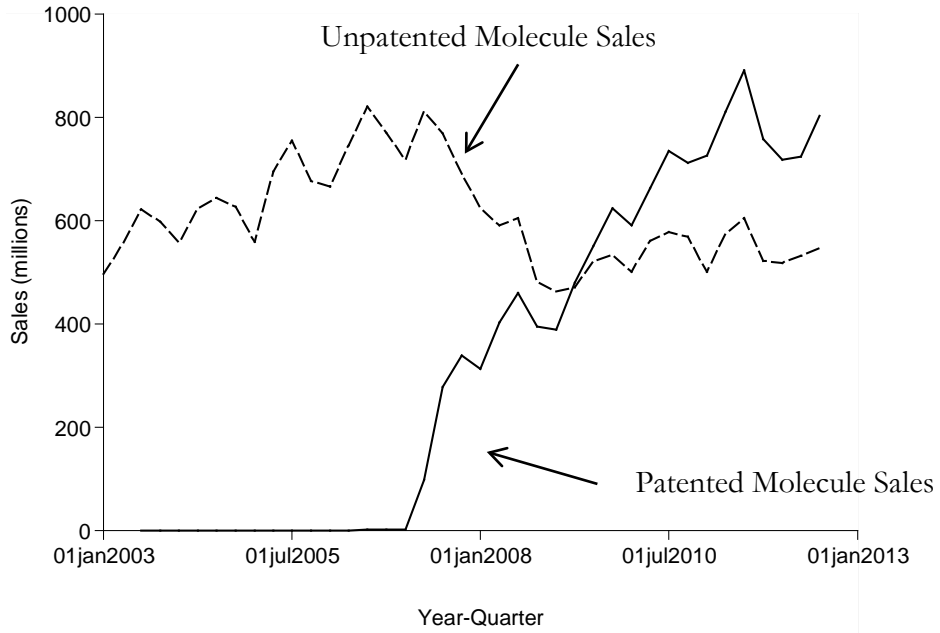
**Figure 2**

Event Study Estimates for the Log of the Average Price Before and After a Patent is Granted by Molecule Vintage



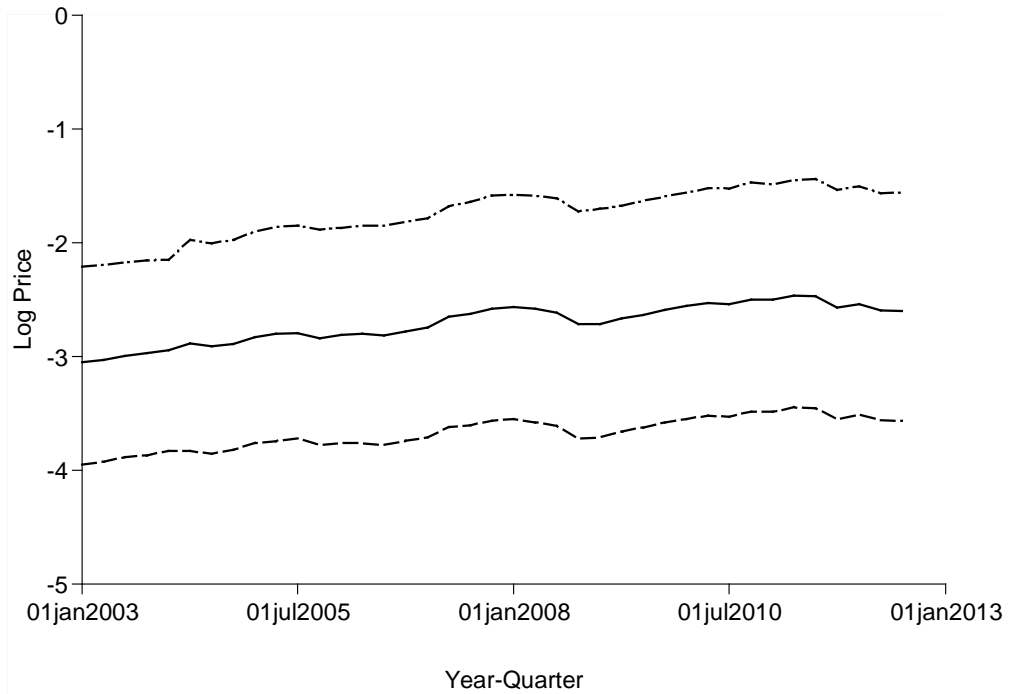
The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects for molecules that are first sold in the Indian market after 1995. The dashed line represents the estimates from a similar model for a sample of products first sold in the Indian market before 1995. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved.

**Figure 3**  
Molecule Sales by Patent Status



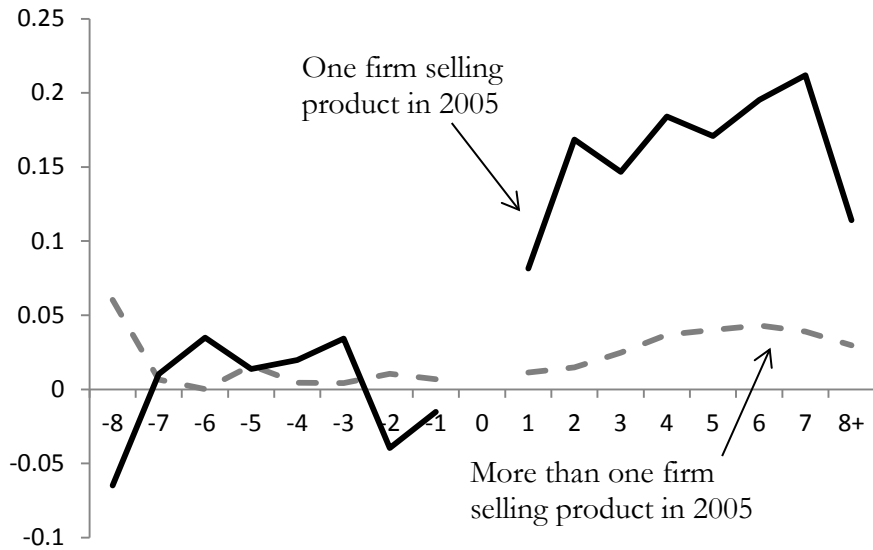
Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Figure 4**  
Indian Pharmaceutical Prices over Time,  
75<sup>th</sup>, 50<sup>th</sup> and 25<sup>th</sup> Percentile



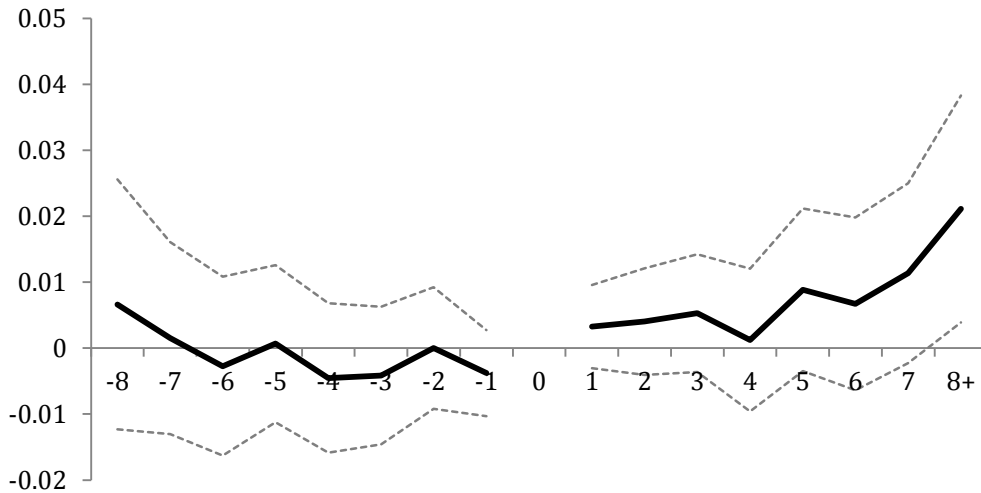
Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Figure 5**  
 Event Study Estimates for the Log of the Average Price  
 Before and After a Patent is Granted by Number of Firms in 2005



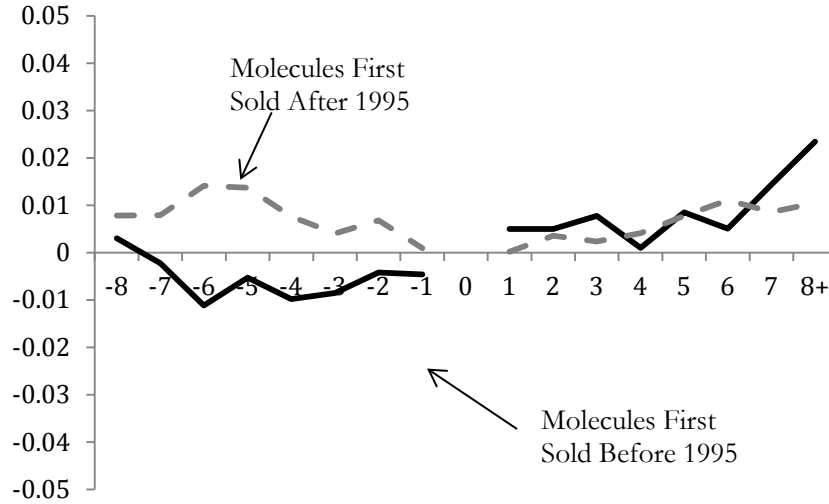
The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects for molecules that are produced by a single firm during the first quarter of 2005. The dashed line represents the estimates from a similar model for a sample of products first produced by more than one firm in 2005. For both specifications the sample includes only those molecule first sold after 1995. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved.

**Figure 6**  
 Event Study Estimates for the Molecule HHI Before and After a Patent is Granted



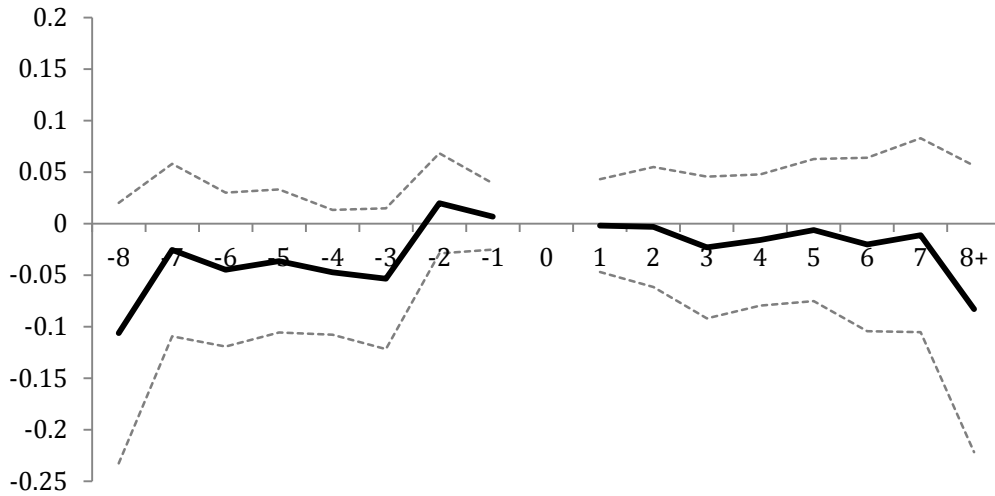
The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects. The dotted line represents the 95 percent confidence intervals with standard errors that allow for arbitrary correlation between observations within the same molecule. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved.

**Figure 7**  
 Event Study Estimates for the Molecule HHI  
 Before and After a Patent is Granted by Molecule Vintage



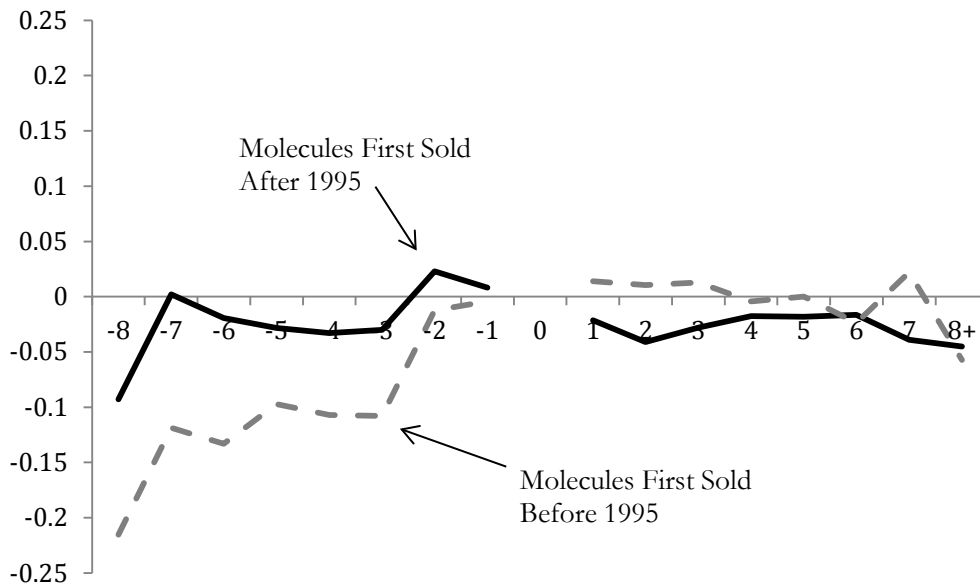
The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects for molecules that are first sold in the Indian market after 1995. The dashed line represents the estimates from a similar model for a sample of products first sold in the Indian market before 1995. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Figure 8**  
 Event Study Estimates for the Log of the  
 Quantity Sold Before and After a Patent is Granted



The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects. The dotted line represents the 95 percent confidence intervals with standard errors that allow for arbitrary correlation between observations within the same molecule. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Figure 9**  
 Event Study Estimates for the Log of the Quantity Sold  
 Before and After a Patent is Granted by Molecule Vintage



The solid line represents the estimated coefficients for indicator variables for the number of quarters before or after a molecule is first granted a patent from an OLS specification including molecule and quarter of the year fixed effects for molecules that are first sold in the Indian market after 1995. The dashed line represents the estimates from a similar model for a sample of products first sold in the Indian market before 1995. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Table 1**  
**Distribution of Molecules in the Indian Market by Number of Manufactures, 2006 and 2011**

Number of Manufacturers	Panel A: 2006		Panel B: 2011	
	Percent of Molecules	Percent of Sales Weighted Molecules	Percent of Molecules	Percent of Sales Weighted Molecules
1	32.1%	2.4%	30.1%	2.3%
2	11.5%	1.9%	13.2%	2.0%
3	10.3%	2.7%	9.9%	2.6%
4	7.4%	3.3%	7.4%	3.0%
5-9	15.9%	10.8%	14.7%	8.1%
10-19	11.8%	17.0%	12.8%	17.9%
20-29	4.4%	10.7%	5.2%	13.9%
30-39	1.4%	6.2%	2.5%	9.8%
40-49	2.1%	12.1%	1.1%	7.1%
50-74	1.9%	17.4%	1.7%	15.4%
75-99	0.8%	6.4%	0.7%	9.7%
100+	0.5%	9.3%	0.6%	8.2%

Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Table 2**  
**Distribution of Firm Molecule Concentration by Molecule Sales Level**

Molecule sales	Panel A: 2006		Panel B: 2011	
	# of molecules	Average firms per molecule	# of molecules	Average firms per molecule
<\$100k	344	1.5	352	1.6
\$100-\$249k	136	2.9	135	2.3
\$250-\$499k	145	4.1	142	3.0
\$500k-\$999k	119	4.8	141	3.9
\$1.00mill-\$2.49mill	157	7.6	178	6.6
\$2.50mill-\$4.99mill	110	12.7	128	11.0
\$5.00mill-\$9.99mill	82	20.9	118	16.2
\$10million-plus	68	55.3	132	40.1

Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Table 3a**  
**Top 15 Highest Grossing Drugs in Global Market, 2006**

Rank	Active Ingredient	Total Global Sales 2006 (\$000)	Total Indian Sales, 2006 (\$000)	Number of Manufacturers (India, 2006)
<b>Panel A: Top 15 Grossing Drugs in the Global Market</b>				
1	Atorvastatin	14,385,000	48,000	67
2	Fluticasone/Salmeterol	6,129,000	6,200	12
3	Clopidogrel	6,057,000	14,202	37
4	Esomeprazole	5,182,000	6,600	21
5	Amlodipine	4,866,000	32,000	58
6	Infliximab	4,428,000	0	0
7	Etanercept	4,379,000	0	0
8	Olanzapine	4,363,600	6,500	27
9	Valsartan	4,223,000	2,100	4
10	Risperidone	4,183,000	2,200	21
11	Darbepoetin alfa	4,121,000	0	0
12	Rituximab	3,861,000	0	0
13	Venlafaxine	3,722,100	1,600	11
14	Pantoprazole	3,621,000	33,400	76
15	Montelukast	3,579,000	6,500	11

Indian Sales data sourced from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved. Global sales data are sourced from *MedAd News*.

**Table 3b**  
**Top 15 Highest Grossing Drugs in Indian Market, 2006**

	Active Ingredient	Total Indian Sales, 2006 (\$000)	Number of Manufacturers (India, 2006)
1	Ciprofloxacin	69,200	145
2	Cefixime	68,300	73
3	Ceftriaxone	66,200	67
4	Ofloxacin	56,700	132
5	Amoxicillin	49,900	122
6	Atorvastatin	48,300	67
7	Diclofenac	44,800	114
8	Ranitidine	43,300	69
9	Cefalexin	40,800	59
10	Paracetamol	39,900	112
11	Azithromycin	37,900	59
12	Cefotaxime	36,900	48
13	Cefpodoxime Proxetil	36,800	49
14	Cefadroxil	35,400	91
15	Nimesulide	33,600	125

Indian Sales data sourced from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated.

Table 4								
Effect of Indian Patent Reform on Prices and Quantity Sold								
	Panel A: Log Price				Panel B: Log Quantity			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
<i>Ever Patent * QuarterTrend</i>	-0.001 (0.002) [0.500]		-0.001 (0.002) [0.455]		0.008 (0.005) [0.064]		0.009 (0.0044) [0.044]	
<i>Has Patent</i>	0.027 (0.013) [0.033]	0.017 (0.013) [0.194]	0.01 (0.024) [0.685]	-0.014 (0.012) [0.246]	-0.055 (0.036) [0.129]	-0.036 (0.035) [0.334]	0.008 (0.07) [0.909]	-0.006 (0.034) [0.858]
<i>Has Patent * Post95</i>			0.029 (0.036) [0.418]	0.049 (0.022) [0.031]			-0.109 (0.112) [0.332]	-0.048 (0.062) [0.439]
<b># of Observations</b>	29,845	10,295	29,845	10,295	29,853	10,295	29,853	10,295
<b># of Molecules</b>	1,012	336	1,012	336	1,012	336	1,012	336
<b>R-squared</b>	0.984	0.981	0.9835	0.9822	0.938	0.952	0.9385	0.9524
<b>Only single patent molecules</b>	No	Yes	No	Yes	No	Yes	No	Yes
<b>Mean of Dep. Var.</b>	-1.987	-2.178	-1.987	-2.178	13.07	15.07	13.07	15.07

Entries in the table represent the estimated coefficients from an OLS regression including molecule and quarter of the year fixed effects. Standard errors are reported in parentheses and allow for arbitrary correlation between observations at the molecule level. P-values are reported in brackets. The estimates in columns (2), (4), and (6) are for a sample containing only molecules that receive a single molecule patent are some point during the sample period. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved



<b>Table 5</b>				
<b>Effect of Indian Patent Reform on Log Prices</b>				
<b>Sample of FDA Approved Products</b>				
	(1)	(2)	(3)	(4)
<i>Ever Patent*QuarterTrend</i>	0.003 (0.005) [0.559]	0.004 (0.006) [0.541]	0.003 (0.005) [0.559]	0.004 (0.006) [0.542]
<i>Has Patent</i>	0.061 (0.029) [0.045]	0.062 (0.030) [0.047]	0.059 (0.030) [0.058]	0.06 (0.031) [0.061]
<i>Has Strict Patent</i>			0.025 (0.059) [0.671]	0.025 (0.059) [0.670]
<b># of Observations</b>	1,236	994	1,236	994
<b># of Molecules</b>	46	37	46	37
<b>R-squared</b>	0.991	0.987	0.9908	0.898
<b>Mean of Dep. Var.</b>	-1.45	-1.54	-1.45	-1.54
<b>Include Rejected Patents</b>	No	Yes	No	Yes
<b>Include Pending Patents</b>	Yes	No	Yes	No

Entries in the table represent the estimated coefficients from an OLS regression including molecule and quarter of the year fixed effects. Standard errors are reported in parentheses and allow for arbitrary correlation between observations at the molecule level. P-values are reported in brackets. The estimates in columns (1), (3), (5), and (7) are for a sample containing only molecules that have received a patent or have a pending patent application as of 2012. The estimates in columns (2), (4), (6), and (8) are for a sample containing only molecules that have received a patent or had a patent application rejected. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

<b>Table 6</b>				
<b>Effect of Indian Patent Reform on Prices by Presence of Substitute Products</b>				
	(1)	(2)	(3)	(4)
<i>Ever Patent * QuarterTrend</i>	-0.002 (0.002) [0.318]		-0.002 (0.002) [0.309]	
<i>Has Patent</i>	0.046 (0.028) [0.10]	0.027 (0.027) [0.322]	0.027 (0.021) [0.214]	0.009 (0.021) [0.672]
<i>Has Patent * Two or Fewer Therapeutic Substitutes</i>	0.027 (0.065) [0.672]	0.03 (0.064) [0.639]		
<i>Has Patent * Only Firm 2005</i>			0.168 (0.099) [0.091]	0.165 (0.099) [0.098]
<b># of Observations</b>	18,908	6,304	18,908	6,304
<b># of Molecules</b>	651	205	651	205
<b>R-squared</b>	0.9816	0.9759	0.9817	0.9762
<b>Only single patent molecules</b>	No	Yes	No	Yes
<b>Mean of Dep. Var.</b>	-1.987	-2.178	-1.987	-2.178

Entries in the table represent the estimated coefficients from an OLS regression including molecule and quarter of the year fixed effects. Standard errors are reported in parentheses and allow for arbitrary correlation between observations at the molecule level. P-values are reported in brackets. The estimates in columns (1) and (2) allow the effect of a patent to vary by whether the molecule is produced by a single firm during the first quarter of 2005. The estimates in columns (3) and (4) allow the effect of the patent to vary by whether the molecule has 2 or fewer therapeutic substitutes during the first quarter of 2005. The estimates in columns (5) and (6) include interactions for both the number of firms and therapeutic substitutes. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

Table 7								
Effect of Indian Patent Reform on the Number of Firms and Sales Concentration								
	Panel A: # Firms				Panel B: HHI			
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
<i>Ever Patent * QuarterTrend</i>	0.070 (0.027) [0.009]		0.069 (0.0269) [0.010]		-0.0001 (0.0006) [0.856]		-0.0002 (0.0006) [0.752]	
<i>Has Patent</i>	-0.39 (0.267) [0.145]	-0.216 (0.273) [0.430]	-0.872 (0.699) [0.212]	-0.193 (0.454) [0.671]	0.014 (0.007) [0.036]	0.013 (0.007) [0.066]	0.001 (0.0106) [0.924]	-0.0003 (0.0065) [0.962]
<i>Has Patent * Post95</i>			0.789 (0.893) [0.377]	-0.051 (0.574) [0.929]			0.0218 (0.0152) [0.151]	0.0216 (0.0124) [0.080]
<b># of Observations</b>	29,853	10,295	29,853	10,295	29,853	10,295	29,853	10,295
<b># of Molecules</b>	1,012	336	1,012	336	1,012	336	1,012	336
<b>R-squared</b>	0.961	0.959	0.961	0.959	0.8867	0.8893	0.8875	0.8940
<b>Only single patent molecules</b>	No	Yes	No	Yes	No	Yes	No	Yes
<b>Mean of Dep. Var.</b>	8.185	15.2	8.18	15.2	0.69	0.512	0.649	0.512

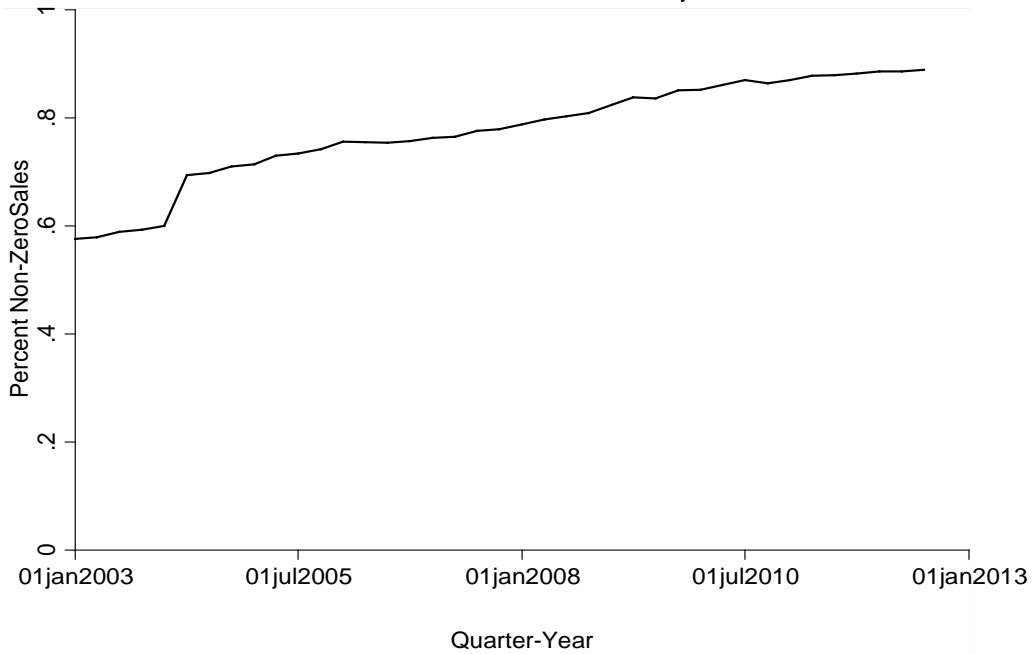
Entries in the table represent the estimated coefficients from an OLS regression including molecule and quarter of the year fixed effects. Standard errors are reported in parentheses and allow for arbitrary correlation between observations at the molecule level. P-values are reported in brackets. The estimates in columns (2), (4), and (6) are for a sample containing only molecules that receive a single molecule patent are some point during the sample period. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Table 8**  
**Effect of Indian Patent Reform on Market Outcomes**  
**US Patent Sample**

	Log Quantity		# Firms		HHI	
	(1)	(2)	(3)	(4)	(5)	(6)
<i>Ever Patent*Quarter Trend</i>	-0.029 (0.024) [0.213]	-0.038 (0.029) [0.204]	0.052 (0.111) [0.642]	-0.152 (0.215) [0.483]	0.006 (0.004) [0.101]	0.008 (0.006) [0.185]
<i>Has Patent</i>	-0.279 (0.137) [0.048]	-0.298 (0.145) [0.048]	-0.936 (0.746) [0.216]	-0.969 (0.764) [0.213]	0.026 (0.026) [0.332]	0.03 (0.028) [0.289]
<b># of Observations</b>	1,236	994	1,242	999	1,242	999
<b># of Molecules</b>	46	37	46	37	46	37
<b>R-squared</b>	0.909	0.898	0.956	0.954	0.814	0.8110
<b>Mean of Dep. Var.</b>	14.19	14.41	10.95	13.98	0.456	0.424
<b>Include Rejected Patents</b>	No	Yes	No	Yes	No	Yes
<b>Include Pending Patents</b>	Yes	No	Yes	No	Yes	No

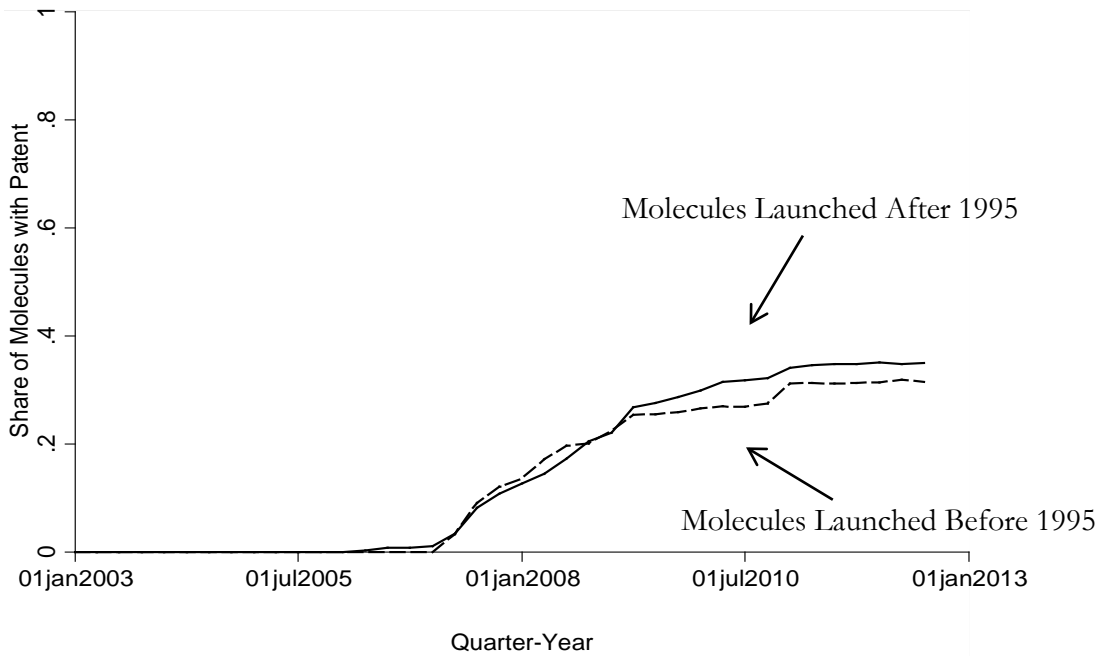
Entries in the table represent the estimated coefficients from an OLS regression including molecule and quarter of the year fixed effects. Standard errors are reported in parentheses and allow for arbitrary correlation between observations at the molecule level. P-values are reported in brackets. Products included in the sample contain molecules identified in Sampat, Shadlin and Amin (2012) as having approved for sale in the United States between 1996 and 2004 and applying for patent protection in India. The estimates in columns (1), (3), (5), and (7) are for a sample of molecules with either granted patents or pending applications. Columns (2), (4), (6) and (8) are for a sample of products with either granted or rejected patents. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Appendix Figure 1**  
Molecules with Non-Zero Sales by Date



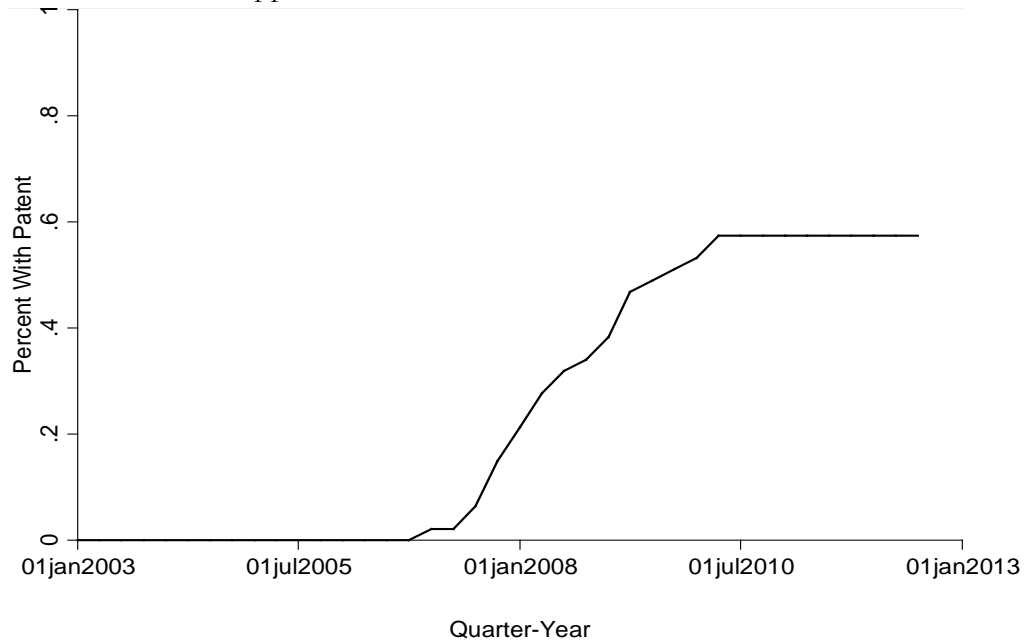
Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Appendix Figure 2**  
Percent of Molecules with Patents by Molecule Vintage



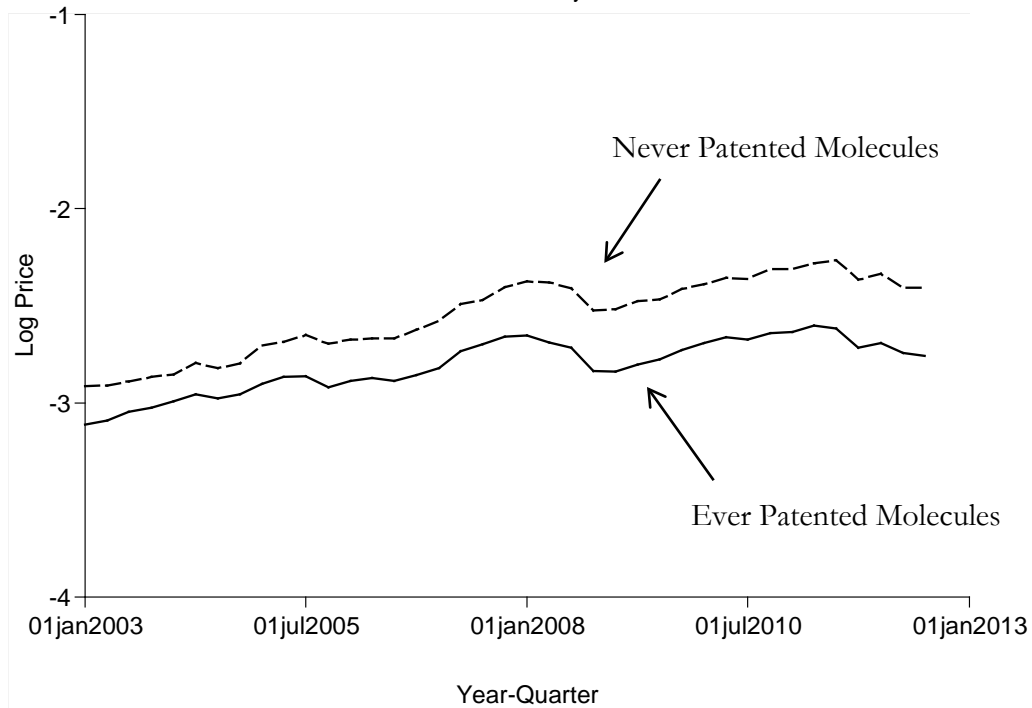
Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Appendix Figure 3**  
Percentage of Molecules with Patents  
Molecules Approved for Sale in the United States from 1996-2004



Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

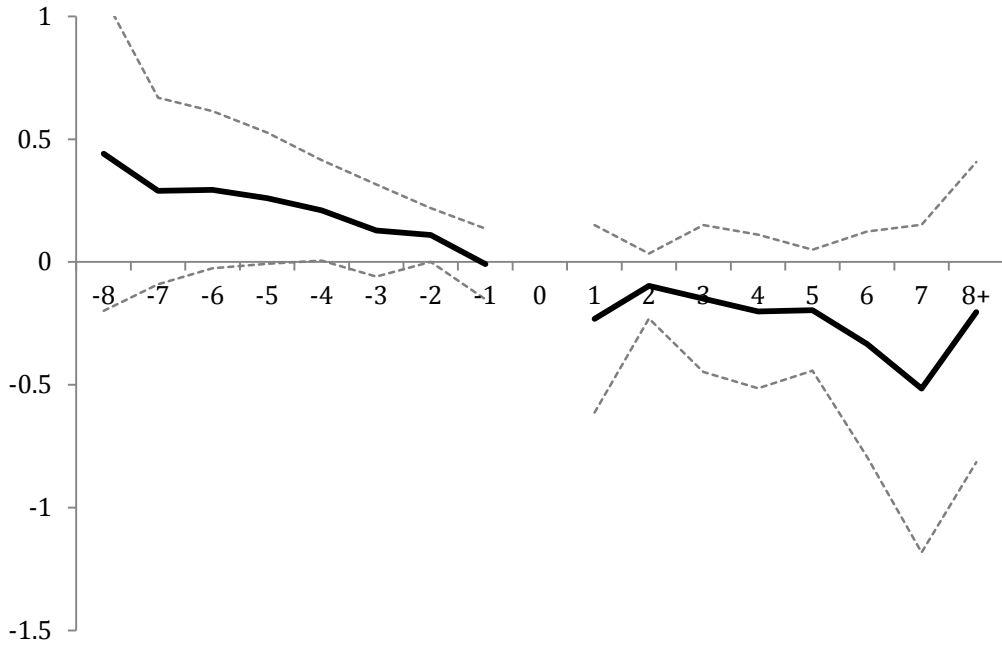
**Appendix Figure 4**  
Median Pharmaceutical Prices by Ever Patented Status



Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Appendix Figure 5**

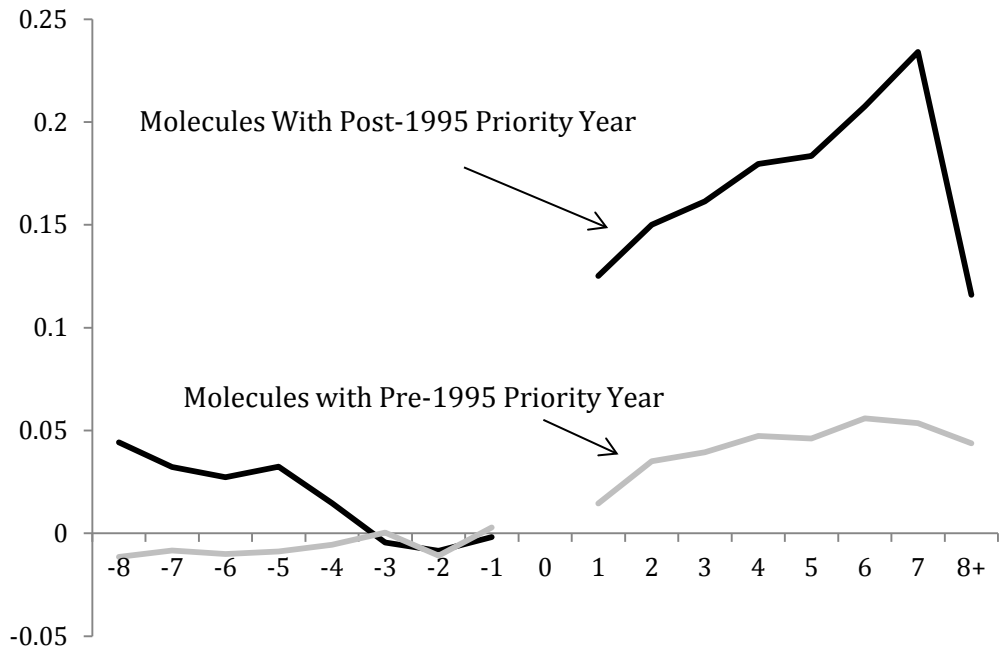
Event Study Estimates for the Log of the Quantity Sold Before and After a Patent is Granted



Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

**Appendix Figure 6**

Event Study Estimates for the Log Price Before and After a Patent is Granted by the Molecules Priority Year



Data Source: IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved

ONLINE APPENDIX – NOT FOR PUBLICATION

<b>Appendix Table 1</b>						
<b>Effect of Indian Patent Reform on Average Prices</b>						
Molecules with Identified Priority Date						
	(1)	(2)	(3)	(4)	(5)	(6)
<i>Has Patent * QuarterTrend</i>	0.0002 (0.002) [0.918]		0.0005 (0.002) [0.826]		0.0003 (0.002) [0.905]	
<i>Has Patent</i>	0.046 (0.017) [0.007]	0.041 (0.018) [0.027]	-0.012 (0.041) [0.766]	0.007 (0.014) [0.624]	0.039 (0.018) [0.032]	0.034 (0.017) [0.055]
<i>Has Patent * Post95 First Sale Date</i>			0.077 (0.054) [0.155]	0.043 (0.027) [0.117]		
<i>Has Patent * Post95 Priority Year</i>					0.059 (0.113) [0.53]	0.059 (0.084) [0.481]
<b># of Observations</b>	10,040	5,672	10,040	5,672	10,040	5,672
<b># of Molecules</b>	331	184	331	184	331	184
<b>R-squared</b>	0.9863	0.9807	0.9864	0.9807	0.9864	0.9809
<b>Only Patented molecules</b>	No	Yes	No	Yes	No	Yes
<b>Mean of Dep. Var.</b>	-1.65	-1.96	-1.65	-1.96	-1.65	-1.96

Entries in the table represent the estimated coefficients from an OLS regression including molecule and quarter of the year fixed effects. Standard errors are reported in parentheses and allow for arbitrary correlation between observations at the molecule level. P-values are reported in brackets. The entire sample is composed of molecules that have a reliably matched priority year. The estimates in columns (2), (4), and (6) are for a sample containing only molecules that receive a single molecule patent at some point during the sample period. These estimates are based on data from IMS AG MIDAS™, 2003-2011, IMS Health Incorporated. All Rights Reserved