TRIPS, Patents, and Drug Prices in India*

Margaret Kyle[1], Bhaven Sampat[2], and Ken Shadlen[3]

[1]MINES ParisTech and CEPR
[2]Columbia and NBER
[3]LSE

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1 Introduction

Before the 1995 Trade Related Intellectual Property Rights (TRIPS) agreement, India did not allow pharmaceutical product patents. TRIPS changed this, requiring India (and many other developing countries) to amend patent laws to grant product patents on drugs. Because patents have the potential to restrict competition and raise prices—in the U.S., for example, patented prices are 3 times the generic prices for the same drugs on average [Duggan et al., 2016]—TRIPS generated concerns among policymakers, academics, and advocacy groups that the new patent regime would hinder access to medicines. Since over half of healthcare spending in India is out-of-pocket, and medicines account for the majority of these expenditures, shifts from generic to monopoly prices could potentially have significant health and financial consequences. Patents in India have broader effects as well, since Indian generic firms have long been the "pharmacy of the developing world."[1]

This paper assesses the impact of TRIPS on generic competition and drug prices in India. It goes beyond previous research not only by using new and updated data on patents, competition, and prices, but also by exploiting the precise institutional details of TRIPS implementation in India. We argue that because of the way TRIPS was implemented in India, a significant competition or price impact was unlikely to be immediate, and indeed may have been realized only relatively recently. Though India started receiving applications in 1995 and granting patents in 2005, it is only recently that most drugs qualify for "primary" patents in India. This reflects two factors: (1) India's decision to make pre-1995 priority patents (those first filed globally before TRIPS) ineligible for patent protection; (2) the long lag between patent priority and drug approval. This is crucial since (across the world) "primary" patents have clearer legal boundaries and more likely to be valid/infringed than "secondary" patents. When we focus on the set of drugs fully under the TRIPS regime (those that are eligible for stronger "primary" patent protection), we find large effects of patents on competition. We argue that the impact of patents on competition and prices estimated for these newer drugs is much more representative of the long-run steady state impact of TRIPS on prices and competition in India than are previous estimates (typically from older drugs with only "secondary" patents), since most new drugs will get primary patents in India going forward.

We proceed as follows. In the next section (Section 2), we provide an overview of previous research on patents and prices/competition, including previous estimates of the effects of patent protection on prices in India, and review the relevant details of TRIPS implementation in India. Section 3 discusses our empirical approach and data collection. Section 4 provides descriptive statistics on our sample, and Section 5 reports our estimates of the effects of patents on competition and prices. Section 7 concludes.

[1] Most famously, Indian generics were the main providers of low-cost treatments that enabled the expansion of HIV-AIDS treatment in the 2000s.

2 Background

2.1 Patents, competition, and prices

2.1.1 In the U.S. and Europe

Most of the research on the effects of patents on competition and prices comes from the U.S. and European markets. For example, a long legacy of survey research suggests patents are much more effective at restricting competition in pharmaceuticals than most other industries [Taylor et al., 1973, Mansfield et al., 1981, Levin et al., 1987, Cohen et al., 2000]. This has several implications. First, patents are more important (relative to other mechanisms) as incentives of innovation in drugs than other industries. But second, patents have a strong impact on drug prices through the restriction on competition. Though the pharmaceutical industry is typically viewed as a "discrete product" industry with one patent per product [Cohen et al., 2000, Levin et al., 1987], in recent decades drug companies increasingly take out not only a "primary" patent on the drug's active ingredient, but also "secondary" patents on formulations and compositions, dosage forms, new uses, etc. "Secondary" patents aim to extend effective patent term, but are in general more vulnerable to invalidity challenges, and easier to invent around. In the U.S. Hemphill and Sampat [2012, 2013, 2011] show that these patents are frequently challenged after issue, and these challenges are often successful. Indeed, in most cases it is the "primary" patent that matters for timing of generic competition; for most important drugs, "secondary" don't bind [Hemphill and Sampat, 2012]. In this sense, even in the U.S., it is mainly "primary" patents that matter for competition and prices, a point we will return to when thinking about the impact of TRIPS in India.

In the U.S. and Europe, most of the research on the impact of patents on competition and prices has been "within-molecule": the analysis concerns pricing before and after a drug experiences generic entry, i.e. after all patents relevant for the drug expire, are invalidated, or are invented around by competitors. In the U.S., there is usually a sharp decline in molecule price, the extent of which is depends on the intensity of generic competition [Reiffen and Ward, 2005, Frank and Salkever, 1997]. A recent estimate from analysts at IMS Health suggests that generic entry in the U.S. between 2002 and 2014 reduced prices by 51 percent in one year after entry (relative to the pre-expiry brand price) overall, and 66 percent for oral medications [IMS Institute for Healthcare Informatics, 2016].[2] The extent of generic entry and the intensity of generic competition vary across European markets, but Germany and the United Kingdom typically have patterns of price declines that are similar to the U.S. [Kyle, 2017].

2.1.2 In developing countries

Since most developing countries did not have product patents on drugs until relatively recently, looking at within-molecule changes in competition and price after patent expiration is limited to a small number of molecule that were protected by now-expired post-TRIPS patents. During the TRIPS debates, concerns about the impact of patents were based not on own country experiences, but instead on generalizations from the U.S./European markets, case study evidence[3], cross-national evidence comparing prices in countries with and without product patents, and general intuition (consistent with economic theory) that patents would restrict competition and raise

[2] After 5 years, the reductions are 67 percent overall and 80 percent for oral drugs.

[3] e.g. from sharp price reductions on anti-retroviral drugs globally after Indian generic companies entered to compete with multinational branded firms [Perez-Casas et al., 2001]

thus prices. In the economics literature, one influential empirical study [Chaudhuri et al., 2006] used demand models to simulate the price impact of product patents on a segment of the antibiotics market (quinolones), and projected potential price increases of 100 to 400 percent.[4] Based on theory and the evidence cited above, health and civil society activists in India and elsewhere feared these sorts of large effects of product patents on competition and prices in India.[5] These fears influenced India's implementation choices, reviewed in Section 2.2 below.

2.1.3 Empirical research on TRIPS in India

Despite these concerns, recent empirical research on the actual effects of TRIPS on drug prices and competition in Indian has not identified significant effects. Duggan et al. [2016] examine prices on about 1000 molecules that were on the Indian market in 2005, when India started granting product patents (see Section 2.2 below). They observe these molecules until 2011, and find about one-third are covered by at least one product patent. Using changes in patent status over time (in this case, the addition of patents to a molecule rather than the expiration of a patent), the authors find small (but statistically significant) effects of patents on the molecule price, on the order of 3 percent overall, and negligible effects on competition. They suggest that the presence (or threat) of price controls, compulsory licensing, and a provision that allowed generics on the market before TRIPS to remain active (Section 11(A)7; more on this below) could explain these surprisingly small effects, or a generally "poorly functioning patent system" (page 133) may be to blame.[6]

Another analysis [Berndt and Cockburn, 2014] looks at 184 molecules introduced in the U.S. in the decade after TRIPS, between 2000 and 2009. The authors find high rates of genericization of these new molecules even after TRIPS. For example, nearly 90 percent of the drugs in their sample have multiple producers in India five years after they were introduced globally, as opposed to zero percent in both Germany and the U.S (where they are presumably under patent protection). These authors too suggest incomplete implementation, noting "[a]t least in principle, new drugs are now eligible for patent protection in the country. But it is unclear how much this de jure change provides de facto protection to new products." Moreover, the authors suggest this lack of effective protection may lead to less rapid launch of drugs in India by branded firms (which the authors also observe in their data) and thereby hurt Indian consumers. The authors point to a specific "loophole" of Indian patent law (called Section 3(d)) as a potential reason why many drugs don't get patent protection in India. As they point out, this controversial provision was used to strike down patents on Novartis's breakthrough cancer drug Gleevec (imatinib mesylate). They conclude that eliminating 3(d), or supplementing patent rights with data exclusivity, may be needed to strengthen Indian protection.

These studies collectively point to aspects of Indian competition law or regulation (compulsory licensing and/or price controls) or features of TRIPS implementation—Section 11(A) or Section 3(d)—as potential explanations for their surprising findings. However, few of the drugs studied

[4] In another simulation study, [Watal, 2000] estimated potential price increases of 26-242 percent (relative to the no-patent counterfactual), depending on demand characteristics.

[5] A related theoretical literature focused on welfare, including effects on innovation. By and large, the theoretical literature predicted a limited impact of product patents in India or developing countries overall on innovation, with the potential exception of neglected tropical diseases without rich country markets. See for example [Fink, 2001, Deardorff, 2011, Subramanian, 2004]. Kyle and McGahan [2012] provides empirical evidence.

[6] The authors also explore the possibility that the profit maximizing monopolist price is simply lower in India than rich countries, so the monopoly-generic gap smaller, but reject it in light of previous evidence from [Chaudhuri et al., 2006] suggesting otherwise.

by previous studies have been subject to price controls, and there has been only one compulsory license issued in India since TRIPS.[7] And the specific implementation explanations are also incomplete, as we next discuss.

2.2 TRIPS Implementation in India

Though TRIPS was enacted in 1995, developing countries negotiated a delay until 2005 to begin granting drug product patents. Reflecting concerns about the impact of drug prices in India, its ability to export cheap generic drugs globally, and perhaps also the strength of its generic industry and civil society groups, India (unlike other developing countries, such as Brazil) took full advantage of this transition period[Sampat and Shadlen, 2015b]. Patent applications were not examined until 2005. All applications filed after 1995 were held in a "mailbox" until this time.

The Indian Patent Act also had a provision, Section 11(A)7, which essentially allows for automatic compulsory licensing of granted patents filed via the mailbox. Specifically, Indian generic firms which had made significant investments in producing and marketing a drug that later received a mailbox patent could continue doing so after 1995 without being vulnerable to infringement proceedings, subject to payment of a "reasonable royalty." As noted, this "grandfather clause" is one of the mechanisms cited by Duggan et al. [2016] as a potential explanation for limited price effects in their analysis.

The most distinctive (and controversial) aspect of Indian TRIPS implementation—and the most controversial—is Section 3(d) of the Patent Act, which aimed to restrict grants of certain "secondary" patents, rendering unpatentable:

> 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 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. [8]

This provision received global attention when the Indian Patent Office (IPO) used it to reject a secondary patent on Gleevec, a rejection that was ultimately appealed to and upheld by the Indian Supreme Court[Sampat et al., 2012].[9] As already noted, 3(d) is the main mechanism cited by Berndt and Cockburn [2014] as a potential explanation for high rates of genericization of Indian molecules in their sample.

Previous studies did not directly test for the role of 11(A)7 or 3(d), and nor will we here. But there are a few points to note. First, as far as we can tell there are no documented cases of 11(A)7 being used.[10] More importantly, 11(A)7 is explicitly transitional and about mailbox drugs only: any estimates driven by this mechanism would have limited relevance for thinking about TRIPS going forward.

[7] These policies could have indirect effects on pricing as [Duggan et al., 2016] note.

[8] It continues: "For the purposes of this clause, 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."

[9] Another unique aspect of Indian implementation was pre-grant opposition, which allowed a broad range of groups (civil society, generic drug companies) to subject arguments against patentability of an invention to the IPO. For example, Gleevec was originally challenged through a pre-grant opposition.

[10] Though it is possible no reasonable royalty ever needed to be paid in equilibrium, i.e. brands just didn't even try to remove infringing generics from the market given the presence of this provision.

Section 3(d) is more complicated. It is meant to target "secondary" patents. At least over the period covered by previous analyses, it was if anything underutilized by a resource-constrained IPO, which granted many secondary patents in spite of it[Sampat and Shadlen, 2015b, 2017].[11] More importantly, even where it did have a role, it did so because of another, more fundamental, aspect of implementation.

In deciding to take full advantage of the transitional period allowed by TRIPS, India also exempted pre-TRIPS patents (technically, those with patent "priority" dates, i.e. first global filing dates, before 1995) from protection. What this means is that only drugs whose primary patent has post-1995 priority can get strong patent protection in India. Others (like Gleevec, whose primary patent has priority date April 3, 1992) could only get "secondary" patents in India, and these too would be vulnerable to 3(d) (and more conventional inventive step) rejections.

From this point of view it is unsurprising that previous studies found limited effects of TRIPS in India, since they were mainly focused on drugs that had weak patent protection because of the 1995 cutoff. But going forward, we would expect more and more drugs to get primary patents, and for these to have significant competition and price effects. We examine these hypotheses below, using newer data than was available to previous researchers, and more post-1995 molecules that are actually fully "treated" by TRIPS in India.

3 Empirical approach

3.1 New molecular entities approved between 1995 and 2017

We began by collecting data from the U.S. Food and Drug Administration (FDA) database on all new molecular entities (NMEs) approved in the U.S. between 1995 and 2017.[12]. This set covers most important global drug approvals over this period. There are 550 distinct molecules (active ingredients) in this set. In addition to the molecule (active ingredient) name, we also recorded information on the year in which the FDA approved the drug (which we use as a proxy for global launch date for the drug) and whether the drug was approved via the FDA's priority review pathway. Drugs that obtained priority review are those that (at the time of application) were expected to represent "significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention"[13]; this is one rough indicator of drug quality.

We collected additional information from FDA labels and the RXNORM data provided by the U.S. National Library of Medicine, including the diseases each drug may treat or prevent; the number of contraindications identified; and the number of drug interactions identified. We use this information as proxies for a drug's quality or usefulness. We also include the number of other drugs with the same mechanism of action, such as "Protein Kinase Inhibitors" or "RNA Replicase Inihibitors." This is a proxy of novelty as well as potential experience manufacturers may have with the production of similar molecules.

To measure the potential demand or market size, we attempt to map each drug, based on its associated diseases, to the causes listed in the Institute for Health Metrics and Evaluation's Global

[11] As an empirical matter, 3(d) is typically always accompanied by more traditional novelty and inventive step rejections. Whether it has much independent force beyond novelty and inventive step is an interesting unresolved question.[Sampat and Shadlen, 2015b, 2017, 2018]

[12] https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files

[13] https://bit.ly/2VEvzo2

Burden of disease data[14]. Out of 550 molecules, we could identify at least one "Level 3" cause for 465, with associated measures of disease burden including prevalence, years of life lost, disability-adjusted life years, and mortality.

3.2 U.S. and Indian patent data

Next we obtained information on all U.S. and Indian patents (and for India, patent applications) on the drugs from IMS Health/IQVIA's Ark Patent Intelligence Database[15]. Ark uses expert patent landscaping to identify patent applications and patents in each of the 130 countries it covers. We verified the accuracy of Ark against previous approaches to manually landscape Indian filings [Sampat and Shadlen, 2015b], finding in almost all cases Ark included the relevant patent filings. We also compared U.S. patent records to that reported in current and historical FDA Orange Book data, again finding that Ark has good coverage.

In addition to listing the patents, we also use Ark data for two other pieces of information crucial for our analysis. First, we collect information on the "priority" date, the date of first global filing, for each granted patent. Second, we collect information on patent type. Ark characterizes each patent (or application) into the following categories/sub-categories based on the "highest level" (strongest) claim in the published claims:

[14] http://www.healthdata.org/gbd/2019

[15] https://www.iqvia.com/solutions/industry-segments/generics/ark-patent-intelligence

Table 1: Patent coding

Category	Subcategory
Molecule	Molecule patent Salts, hydrates and solvates Polymorphic forms Other molecule forms
Process and preparation	Intermediates and preparations thereof Final synthethic stages Complete synthesis Purification methods Fermentation methods Biotechnology
Formulation	General formulation and methods Route specific (injectable, oral, opthalmic, otic, nasal, inhalation, topical, transdermal patch, rectal, vaginal, penile, urinary) Kits and packaging Excipients
Use	New use related to main indication Dosage regimen/administration conditions Drug with device
Combination	Novel combination; Use of combination
Assay	Assay methods Patient suitability
Device	Injection Respiratory Opthalmic Diagnostic Energy dependent Oral admin

We are interested in the "primary" patent, what is typically called the compound patent, or what we have in previous research called the "strict" active ingredient patent [Hemphill and Sampat, 2012]. In the U.S. almost all new molecular entities have one (and typically only one) strict active ingredient patent.[Hemphill and Sampat, 2013]. Other types of patents are generally easier to invent around, and are also viewed by some legal scholars as being more legally vulnerable [Correa et al., 2007] and thus harder to enforce if granted. Based on the description of the categories, the first Ark subcategory ("Molecule patent") corresponds most closely to these strict active ingredient patents. The Appendix also provides empirical validation. To avoid nomenclature confusion, we will refer to the "Molecule Patent" subcategory as *primary patents* in this paper, and all other patent types as *secondary patents*.

In addition to categorizing patents based on their strongest claims, for most patents in their database Ark also conducts what they call a constraint analysis "to determine whether or not the claims in the patent will prevent a generic or biosimilar version of an INN from entering a commercial market whilst enforced."[16][17] These analyses are based not just on patent type, but bring in information on drug labels, clinical trial information, and features of national laws. The analyses categorize patents/applications as constraining ("We don't believe it is possible to launch generic equivalents of all currently marketed dosage forms whilst this patent or any related term extension is in force"), partially constraining ("We believe that this patent protects a portion of the product, whilst the patent is in force, it is possible to develop a generic equivalent but it cannot be marketed for these particular product attributes"), and not constraining ("We believe that this patent does not prevent the development of a generic equivalent of any currently marketed dosage form which can be launched whilst the patent is in force.") We also create a variable *constraining patent* to flag the first category. Though, as expected and as we will show below, in practice this has a high degree of overlap with the *primary patent* indicator.

For each of the 550 molecules we defined the *molecule priority year* as the priority year of the primary patent, based on the U.S. patent data. This will help us determine which drugs were at risk of receiving a strong primary patent in India. We have argued that drugs with molecule priority year after 1995 are the relevant risk set for thinking about strong patent protection in India. Accordingly, we created a *post-1995* indicator variable.

We also collected all Indian patents and applications for these molecules form Ark. We constructed four different measures of Indian patent protection: (1) if there was *any Indian application*; (2) if there was *any Indian patent*; (3) if there was *any Indian primary patent*; and (4) if there was *any Indian constraining patent*.

3.3 Indian market data

To determine Indian price levels and competition, we also searched for these 550 molecules in the IQVIA/IMS MIDAS data, which includes quarterly revenues and units at the package level. Of these 550 drugs, we were able to locate 504 in the MIDAS data for the US. The 46 unmatched cases were generally discontinued products, diagnostic agents, very small sales drugs, or OTC drugs that we would not expect to see in the MIDAS data. Five of these drugs are sold in India, however, and we include these observations. We focus on the March 1, 2019 cross section, which

[16] "INN" is the international nonproprietary name for a drug, i.e. the official generic name

[17] Ark is marketed primarily at firms making launch decisions. They note in their promotional materials "We carry out analysis of the claims of each patent in order to determine if the patent is a true barrier, or could theoretically be worked around."

includes 299 molecules that were launched in India. Each molecule can have different forms (tablet vs. suspension), in and some cases maps to different indications (which we operationalize as ATC codes; see below). After expanding to the the molecule-form-ATC code level of analysis, there are 401 observations.

The Indian market is populated by a large number of domestic producers. While we use the term "generic" to describe their products, it is important to recognize some key differences with "generics" in the U.S. (many of which are produced in India). A generic drug in the U.S. is approved via a regulatory pathway that requires a demonstration of its bioequivalence to a reference drug, usually the originator's version; the generic is sold using its international non-proprietary name (INN), and is generally considered a (near) perfect substitute for other generics and the originator product. For example, the antibiotic azithromycin is sold as Zithromax by Pfizer, its originator, but as azithromycin by 20 generic manufacturers. In India, azithromycin is sold under more than 200 different product names, such as Azee, Azithral, and Zady. These are not necessarily bioequivalent, and consumers may have brand-specific preferences.

While our unit of analysis is a new molecular entity introduced between 1995 and 2017, most of these drugs compete with older products. To account for this, we calculate the number of other drugs in the same ATC3 class, their average age, and their average price per unit in India.

4 Descriptives

4.1 Priority and approval years

Though the majority of our empirical analyses will focus on the 296 molecules launched in India (396 molecule-form-ATC code level observations), here we begin by examining the relationship between molecule priority year and U.S. approval year. Here we focus on the 452 drugs from the full set (of 550) for which IQVIA/IMS reported there being a U.S. "primary" patent.[18]

Figure 1 shows the molecule priority year (again, defined as the priority year of the primary patent on the molecule) on the vertical axis, and U.S. approval year (our proxy for the global launch date) on the horizontal axis. Each bubble is scaled to the number of drugs with a given priority year-approval year. The reference line is at priority year 1995. Clearly, among drugs approved since 1995, most have pre-1995 priority until about 2010.

Figure 2 shows that is not until after 2010 that the majority of drug approvals are consistently post-1995 molecules.

This is notable since previous analyses focused on earlier drugs. Berndt and Cockburn [2014] focus on drugs approved between 2000 and 2010, where only 23 percent of drugs are post-1995 molecules. Duggan et al. [2016] focus on drugs on the Indian market between 2003 and 2012, presumably also with much earlier global approval dates.

As previously argued [Sampat and Shadlen, 2015b] it is only these post-1995 molecules that are at risk of getting strong patent protection in India. (We will examine this hypothesis directly immediately below.) Equally important, Figures 1 and 2 also clearly show that most drugs will be post-1995 molecules going forward, as the long shadow of transition fades.

[18]Consistent with previous research, e.g. Hemphill and Sampat [2012], about 80 percent of NMEs have at least one molecule patent. The remainder rely for protection on secondary patents and/or FDA exclusivities even in the U.S.

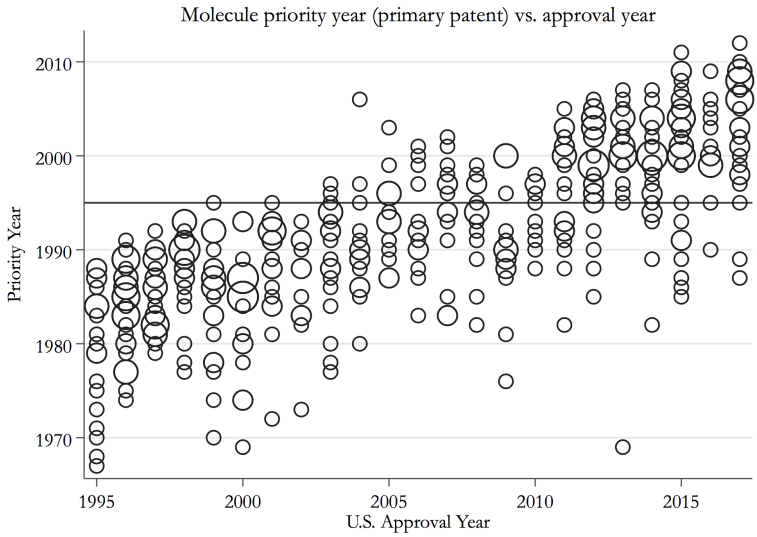

Figure 1

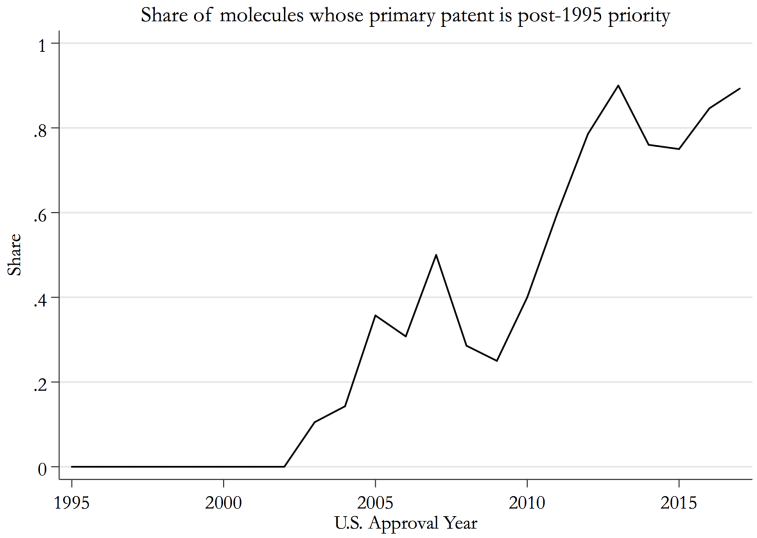

Figure 2

4.2 Indian patenting by priority year

For the full set of 452 drugs with primary patents in U.S. (i.e. as in the previous section, before restricting to those actually launched in India) we can directly test the hypothesis that the 1995 cutoff matters for primary patent protection in India.[19] For expository convenience, we focus on the 390 drugs with priority years from 1980 to 2005, i.e. 15 years before the cutoff and 10 years after it. Panel 1 of Figure 3 shows the share of these 390 drugs with an Indian application, an Indian patent, and/or Indian primary patent by priority year. In addition to primary patents, we

[19] In several specifications below we will use the 1995 cutoff as an instrumental variable for probability of patent protection in India. The results here may be thought of as visual evidence for the first stage.

also plot data for the second measure of patent strength, constraining patents, though results are similar. Panel 2 shows the same information but conditional on an Indian application.

Panel 1 shows there is a very slight and continuous increase in overall application and patenting by priority year. By the end of the period, almost all drugs have an Indian application, and most get at least one Indian patent. Patents that are categorized as "primary" in our dataset are rare before 1995; in principle, there should be zero, if patent examiners perfectly applied the law and analysts correctly characterized the patents. But for post-95 priority drugs nearly all drugs not only have a patent, but a primary patent. Similar results are seen in Panel 2, focusing on the subset of drugs with at least one Indian application.

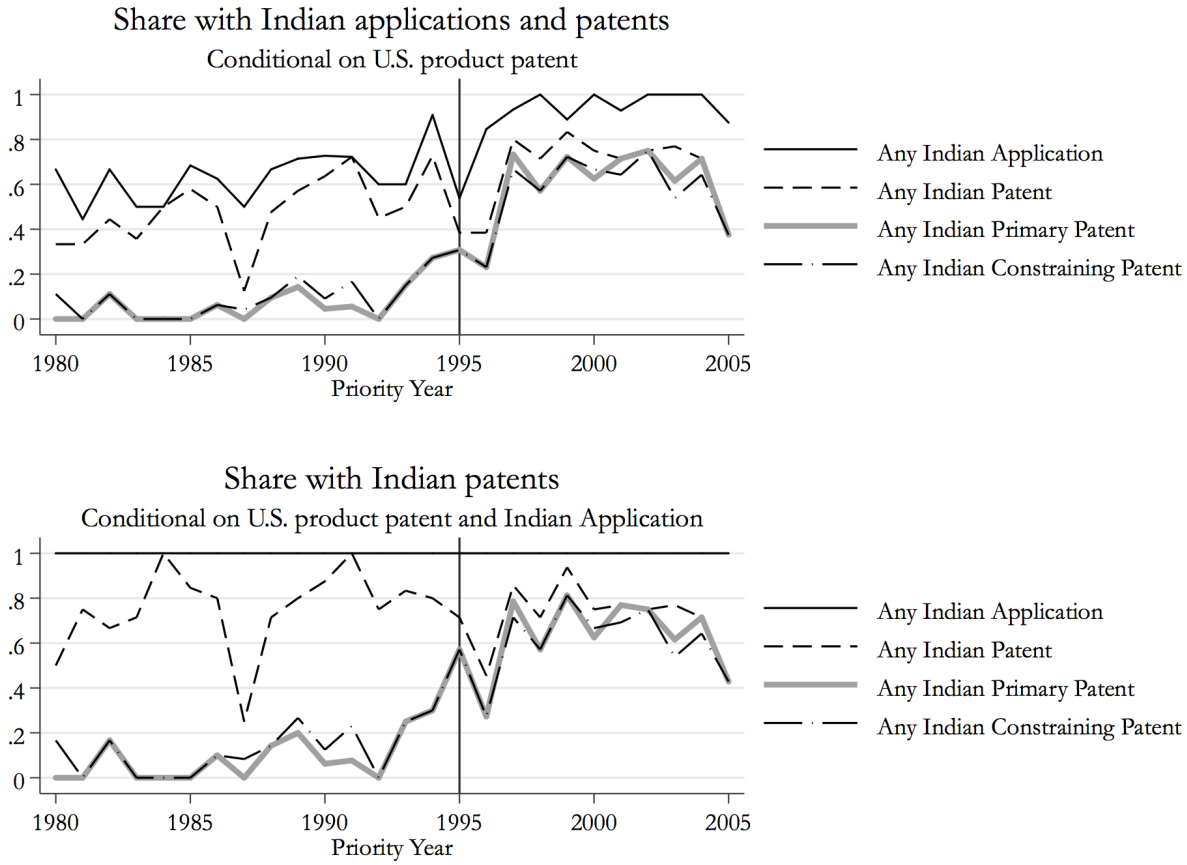

Figure 3

In the empirical analyses below, focused on the drugs launched in India, we will examine the impact of *any patent* and *primary patent* directly, and in some specifications instrument for *primary patent* using the post-1995 indicator.

4.3 Drugs launched in India

There were 299 molecules launched in India (from the 452 molecules with U.S. approval years 1995-2010 that had a primary patent in the U.S.). This yields 396 molecule-form-class observations

(which we will refer to simply as "drugs"). For each drug, we determined the Indian *price per unit* in 2018 rupees, the *relative price* compared to the US, whether there was *any generic* producer in India, and the *number of producers* in India, our main measures of prices and competition respectively. We also collect information on the Indian launch year, which we use to construct a variable *years since local launch*. We include information on the ATC (Anatomical Therapeutic Chemical) class of the code, which we aggregate to the 1-digit level as a broad measure of drug class.

Table 1 shows summary statistics:

Table 2: Summary statistics

Variable	Mean	Std. Dev.	Min.	Max.	N
Any generic entrant	0.9	0.3	0	1	401
N producers	11.81	19.49	1	177	401
Price per SU in local currency	1273.16	5565.66	0.27	61910.39	380
Price relative to US	0.11	0.25	0	2.17	153
Any Indian Application	0.66	0.47	0	1	401
Any Indian Patent	0.51	0.5	0	1	401
Any Indian Product Patent	0.12	0.33	0	1	401
Any Indian Constraining Patent	0.14	0.35	0	1	401
Post 1995 molecule (1=yes)	0.15	0.35	0	1	401
FDA Priority	0.36	0.48	0	1	401
Years since local launch	12.77	6.3	0.33	39.41	401
Number of molecules in ATC3-form	35.14	80.78	1	792	401
Average age of competing molecules in ATC3-form	13.15	4.32	2.3	31.75	396
No older drugs in class	0.05	0.21	0	1	401
Average price of non-NMEs in ATC3-form	399.76	1072.67	0.32	7881.84	382
N drugs with same MOA	44.16	134.73	1	1867	379
N contraindications	3.31	4.24	1	37	337
N drug interactions	897.33	461.41	1	1885	376
N associated diseases	3.23	2.92	1	18	378

About 90 percent have some generic entry, and on average there about 12 producers (including the originator, if the originator chooses to enter). About two-thirds have an Indian application, and 51 percent an Indian patent. Thus for about 80 percent of the drugs where firms sought an Indian patent, they got at least one. However, only 12 percent have a primary (product) patent, similar to the share (15 percent) that are post-1995 molecules. About 36 percent were priority review drugs, our main indicator of drug quality.

As controls, we introduce variables related to a drug's competitive environment and some of its characteristics. While 5% of the drugs in our sample have no older competitors in the same class (the novel treatments for hepatitis C, for example), the average number of competing drugs in the same ATC3 is about 35, similar to the number of drugs with the same mechanism of action. The average price of these older drugs is around 400 rupees, about 1/3 of that for the NMEs in our sample. Our sample drugs are used for treating or preventing about 3 diseases. The average price relative to the U.S. is 11%, although the median is closer to 4%.

In our main analyses, we focus on the log number of producers and log prices, reflecting the

skewed distribution, and take logs of the explanatory variables as well.[20]

5 Regression results

5.1 Competition

We began with OLS regressions relating competition to Indian patent status for the 401 drugs. Although the dependent variables (a dummy variable for the existence of any generic or a count of the number of producers) are discrete, we prefer to use a simple linear model due to our relatively small sample size and because addressing endogeneity is easier than in a non-linear model.

The first column of Table 3 shows that overall drugs with Indian patents are about 9 percentage points less likely to have generic competition than other drugs in the same ATC class, vintage (U.S. approval year), years since Indian launch, and "quality" (proxied by the priority review indicator).[21] However, Column 3 shows that drugs with primary patents have a 27 percentage point lower likelihood of generic entry. Column 5 shows similar results for "constraining" patents, which is not surprising since most primary patents are constraining and vice versa. Including additional drug characteristics (Columns 2, 4 and 6) yields similar results.

Table 4 shows the same information but for the number of producers in India, a measure of the extent of competition. Patents overall have a positive (and insignificant) relationship with competition, but primary patents and constraining patents have strong negative effects.

So far, the results are consistent with the idea that not all patents are equally important: most patents don't matter for competition, but primary patents do. This, rather than 3(d), likely explains why analyses such as [Berndt and Cockburn, 2014] found significant competition in India even 5-15 years after TRIPS was signed. Because of the 1995 cutoff, most drugs had patents—but not primary patents—in India over this period (as shown in Figure 3). However, only primary patents effectively exclude competition.

We used the post-1995 indicator to instrument for whether the drug is protected by a primary (or constraining) patent in India. Figure 3 already showed there is a strong relationship between post-1995 priority and the probability of getting a primary patent in India. Not surprisingly, we also see this in the first-stage regressions, i.e. a much larger likelihood of primary patents post-1995 in Table 5 below.

Tables 6-7 show the results of instrumenting for patent status. The coefficients are larger in magnitude for all patent measures and remain largest in magnitude for primary and/or constraining patents, continuing to suggest strong negative effects of strong patents on competition. Specifically, the IV estimates suggest 50-90 percentage point less generic entry with strong patent protection.

5.2 Price

Note that our analysis is a cross-sectional comparison of drugs with and without patents. While we think this makes sense when considering competition (with appropriate controls for market size, etc.), it is more problematic for price. For example, drugs differ in the duration of their dosing

[20] Since prices in some cases are fractions of rupees, the log price is sometimes negative. For a few drugs (3) the reported price is zero, and the log is undefined.

[21] In future work we will also look separately at drugs with rejected Indian applications and those with no Indian applications at all. For now we collapse these categories.

Table 3: Regression of Any generic entrant

	(1) Any generic entrant	(2) Any generic entrant	(3) Any generic entrant	(4) Any generic entrant	(5) Any generic entrant	(6) Any generic entrant
Any Indian Patent	-0.0867*	-0.0704*				
	(-2.79)	(-2.28)				
Any Indian Product Patent			-0.266*	-0.230*		
			(-5.40)	(-4.69)		
Any Indian Constraining Patent					-0.282*	-0.241*
					(-6.07)	(-5.11)
Years since local launch	0.00689+	0.00986*	0.00626+	0.00910*	0.00414	0.00728+
	(1.78)	(2.46)	(1.67)	(2.32)	(1.11)	(1.86)
FDA Priority	-0.0202	-0.0222	-0.0326	-0.0334	-0.0260	-0.0278
	(-0.53)	(-0.59)	(-0.88)	(-0.90)	(-0.71)	(-0.76)
Log N molecules in ATC3	-0.00815	-0.00452	-0.00574	-0.00367	-0.00270	-0.00184
	(-0.48)	(-0.26)	(-0.35)	(-0.22)	(-0.17)	(-0.11)
Average age of competing molecules in ATC3-form	0.000608	-0.000349	-0.0000690	-0.000886	-0.00144	-0.00200
	(0.14)	(-0.08)	(-0.02)	(-0.21)	(-0.35)	(-0.48)
No older drugs in class	-0.419*	-0.426*	-0.382*	-0.400*	-0.422*	-0.437*
	(-3.75)	(-3.80)	(-3.52)	(-3.67)	(-3.94)	(-4.02)
Log average price of non-NMEs in ATC3-form	-0.0333*	-0.0282+	-0.0254+	-0.0229	-0.0312*	-0.0284*
	(-2.32)	(-1.91)	(-1.81)	(-1.58)	(-2.26)	(-1.99)
Log N drugs with same MOA		-0.00112		0.000726		0.000440
		(-0.09)		(0.06)		(0.04)
Log N contraindications		-0.0430		-0.0376		-0.0362
		(-1.51)		(-1.36)		(-1.32)
Log N drug interactions		-0.0197		-0.0177		-0.0159
		(-1.14)		(-1.06)		(-0.95)
Log N associated diseases		-0.00847		-0.0101		-0.0131
		(-0.25)		(-0.31)		(-0.40)
Missing MOA		0.425*		0.413*		0.397*
		(3.26)		(3.26)		(3.15)
Missing contraindications		-0.221*		-0.191*		-0.166*
		(-3.64)		(-3.21)		(-2.78)
Missing drug interactions		0.0660		0.0465		0.0496
		(0.48)		(0.35)		(0.37)
Missing diseases		-0.292*		-0.262*		-0.267*
		(-2.20)		(-2.02)		(-2.07)
Constant	0.995*	1.136*	0.992*	1.122*	1.072*	1.184*
	(7.18)	(6.19)	(7.38)	(6.27)	(8.01)	(6.64)
R-sqr	0.317	0.369	0.357	0.399	0.370	0.406
Obs	396	396	396	396	396	396

Includes fixed effects for ATC1, U.S. approval year, and form

+ p<0.10, * p<0.05

Table 4: Regression of Log N producers

	(1) Log N producers	(2) Log N producers	(3) Log N producers	(4) Log N producers	(5) Log N producers	(6) Log N producers
Any Indian Patent	0.191	0.213				
	(1.41)	(1.58)				
Any Indian Product Patent			-0.528*	-0.430*		
			(-2.40)	(-1.97)		
Any Indian Constraining Patent					-0.665*	-0.526*
					(-3.19)	(-2.50)
Years since local launch	0.0733*	0.0674*	0.0737*	0.0664*	0.0686*	0.0623*
	(4.35)	(3.85)	(4.40)	(3.81)	(4.10)	(3.55)
FDA Priority	-0.0281	0.0500	-0.0539	0.0324	-0.0430	0.0412
	(-0.17)	(0.30)	(-0.32)	(0.20)	(-0.26)	(0.25)
Log N molecules in ATC3	0.0927	0.0633	0.110	0.0791	0.120	0.0842
	(1.26)	(0.84)	(1.51)	(1.06)	(1.65)	(1.13)
Average age of competing molecules in ATC3-form	0.0337+	0.0351+	0.0319+	0.0346+	0.0283	0.0320+
	(1.79)	(1.89)	(1.70)	(1.86)	(1.51)	(1.72)
No older drugs in class	-0.505	-0.445	-0.488	-0.430	-0.575	-0.504
	(-1.04)	(-0.91)	(-1.01)	(-0.88)	(-1.20)	(-1.04)
Log average price of non-NMEs in ATC3-form	-0.0371	-0.0293	-0.0171	-0.0114	-0.0273	-0.0214
	(-0.59)	(-0.46)	(-0.27)	(-0.18)	(-0.44)	(-0.33)
Log N drugs with same MOA		0.0452		0.0435		0.0431
		(0.84)		(0.81)		(0.81)
Log N contraindications		-0.203		-0.225+		-0.222+
		(-1.63)		(-1.82)		(-1.81)
Log N drug interactions		-0.123		-0.119		-0.114
		(-1.64)		(-1.59)		(-1.53)
Log N associated diseases		0.420*		0.418*		0.411*
		(2.85)		(2.84)		(2.80)
Missing MOA		0.752		0.559		0.510
		(1.33)		(0.99)		(0.91)
Missing contraindications		-0.906*		-0.848*		-0.785*
		(-3.42)		(-3.19)		(-2.93)
Missing drug interactions		-0.163		-0.275		-0.279
		(-0.27)		(-0.46)		(-0.47)
Missing diseases		0.112		0.212		0.212
		(0.19)		(0.37)		(0.37)
Constant	-0.128	0.587	-0.0701	0.663	0.124	0.800
	(-0.21)	(0.73)	(-0.12)	(0.83)	(0.21)	(1.00)
R-sqr	0.312	0.364	0.320	0.367	0.329	0.371
Obs	396	396	396	396	396	396

Includes fixed effects for ATC1, U.S. approval year, and form

+ p<0.10, * p<0.05

Table 5: First stage

	(1) Any Indian Product Patent	(2) Any Indian Product Patent	(3) Any Indian Constraining Patent	(4) Any Indian Constraining Patent
Post 1995 molecule (1=yes)	0.483*	0.488*	0.428*	0.418*
	(8.42)	(8.26)	(6.90)	(6.64)
Years since local launch	0.00350	0.00341	-0.00449	-0.00491
	(0.92)	(0.84)	(-1.09)	(-1.13)
FDA Priority	-0.0407	-0.0379	-0.0152	-0.0140
	(-1.09)	(-1.00)	(-0.38)	(-0.35)
Log N molecules in ATC3	0.0206	0.0157	0.0303+	0.0226
	(1.26)	(0.92)	(1.71)	(1.24)
Average age of competing molecules in ATC3-form	0.00348	0.00352	-0.00196	-0.00181
	(0.81)	(0.82)	(-0.42)	(-0.39)
No older drugs in class	0.185+	0.152	0.0252	-0.0134
	(1.70)	(1.36)	(0.21)	(-0.11)
Log average price of non-NMEs in ATC3-form	0.0280*	0.0230	0.00644	-0.000501
	(2.00)	(1.56)	(0.42)	(-0.03)
Log N drugs with same MOA		0.0135		0.0107
		(1.09)		(0.81)
Log N contraindications		0.00125		0.00648
		(0.04)		(0.21)
Log N drug interactions		-0.0163		-0.00560
		(-0.93)		(-0.30)
Log N associated diseases		-0.0237		-0.0334
		(-0.70)		(-0.93)
Missing MOA		-0.0595		-0.136
		(-0.46)		(-0.98)
Missing contraindications		0.102+		0.202*
		(1.68)		(3.12)
Missing drug interactions		-0.253+		-0.219
		(-1.84)		(-1.49)
Missing diseases		0.0962		0.0755
		(0.72)		(0.53)
Constant	-0.200	-0.0603	0.110	0.207
	(-1.45)	(-0.33)	(0.74)	(1.06)
R-sqr	0.468	0.485	0.446	0.476
Obs	396	396	396	396

Includes fixed effects for ATC1, U.S. approval year, and form.

+ p<0.10, * p<0.05

Table 6: IV regression of Any generic entrant

	(1) Any generic entrant	(2) Any generic entrant	(3) Any generic entrant	(4) Any generic entrant
Any Indian Product Patent	-0.818* (-6.39)	-0.755* (-6.02)		
Any Indian Constraining Patent			-0.923* (-6.05)	-0.879* (-5.63)
Years since local launch	0.00578 (1.43)	0.00759+ (1.82)	-0.00122 (-0.27)	0.000703 (0.15)
FDA Priority	-0.0590 (-1.45)	-0.0572 (-1.45)	-0.0397 (-0.93)	-0.0410 (-0.97)
Log N molecules in ATC3	0.00565 (0.32)	0.00490 (0.27)	0.0167 (0.87)	0.0130 (0.67)
Average age of competing molecules in ATC3-form	-0.00174 (-0.38)	-0.00190 (-0.43)	-0.00640 (-1.29)	-0.00615 (-1.27)
No older drugs in class	-0.333* (-2.83)	-0.358* (-3.08)	-0.462* (-3.72)	-0.485* (-3.90)
Log average price of non-NMEs in ATC3-form	-0.00694 (-0.44)	-0.00698 (-0.44)	-0.0239 (-1.49)	-0.0248 (-1.52)
Log N drugs with same MOA		0.00253 (0.20)		0.00178 (0.13)
Log N contraindications		-0.0403 (-1.37)		-0.0355 (-1.13)
Log N drug interactions		-0.0129 (-0.73)		-0.00559 (-0.29)
Log N associated diseases		-0.0133 (-0.38)		-0.0249 (-0.66)
Missing MOA		0.305* (2.25)		0.231 (1.56)
Missing contraindications		-0.122+ (-1.88)		-0.0208 (-0.27)
Missing drug interactions		-0.0333 (-0.23)		-0.0349 (-0.23)
Missing diseases		-0.172 (-1.24)		-0.179 (-1.20)
Constant	1.018* (6.99)	1.139* (6.00)	1.283* (7.94)	1.367* (6.58)
R-sqr	0.118	0.190	0.015	0.074
Obs	396	396	396	396

Includes fixed effects for ATC1, U.S. approval year and form. Instrumenting for patent status using Post-95 indicator.

+ p<0.10, * p<0.05

Table 7: IV regression of Log N producers

	(1) Log N producers	(2) Log N producers	(3) Log N producers	(4) Log N producers
Any Indian Product Patent	-1.966*	-1.888*		
	(-3.79)	(-3.68)		
Any Indian Constraining Patent			-2.220*	-2.200*
			(-3.76)	(-3.60)
Years since local launch	0.0725*	0.0622*	0.0556*	0.0450*
	(4.41)	(3.65)	(3.21)	(2.44)
FDA Priority	-0.123	-0.0339	-0.0763	0.00688
	(-0.74)	(-0.21)	(-0.46)	(0.04)
Log N molecules in ATC3	0.140+	0.103	0.167*	0.123
	(1.94)	(1.41)	(2.24)	(1.63)
Average age of competing molecules in ATC3-form	0.0275	0.0318+	0.0163	0.0211
	(1.49)	(1.76)	(0.85)	(1.12)
No older drugs in class	-0.362	-0.313	-0.671	-0.630
	(-0.76)	(-0.66)	(-1.40)	(-1.30)
Log average price of non-NMEs in ATC3-form	0.0311	0.0327	-0.00976	-0.0118
	(0.49)	(0.51)	(-0.16)	(-0.18)
Log N drugs with same MOA		0.0485		0.0466
		(0.93)		(0.88)
Log N contraindications		-0.232+		-0.220+
		(-1.93)		(-1.80)
Log N drug interactions		-0.105		-0.0869
		(-1.45)		(-1.16)
Log N associated diseases		0.409*		0.380*
		(2.86)		(2.60)
Missing MOA		0.261		0.0754
		(0.47)		(0.13)
Missing contraindications		-0.656*		-0.403
		(-2.47)		(-1.36)
Missing drug interactions		-0.497		-0.501
		(-0.85)		(-0.84)
Missing diseases		0.460		0.444
		(0.81)		(0.77)
Constant	-0.00346	0.709	0.635	1.279
	(-0.01)	(0.91)	(1.01)	(1.58)
R-sqr	0.234	0.281	0.218	0.251
Obs	396	396	396	396

Includes fixed effects for ATC1, U.S. approval year and form. Instrumenting for patent status using Post-95 indicator.

+ p<0.10, * p<0.05

or the course of treatment; a cardiovascular treatment taken daily for years may have a low price per unit compared to a Hepatitis-C treatment administered over several weeks. Patents may affect the prices of both, but that effect is likely to be swamped by other factors. Even within a group of relatively close substitutes, a drug that requires one capsule per day might have a higher price than a competing product taken twice per day. While using defined daily doses (DDDs) provided by the World Health Organization partially addresses this issue, restricting our analysis to products for which we have DDDs reduces our sample by almost half.

Table 8 shows an OLS regression with log price as a dependent variable. Column 1 shows that consistent with [Duggan et al., 2016], patents have a small and statistically significant relationship with prices. Primary and constraining patents have a larger positive effect, although the inclusion of additional drug characteristics reduces the point estimate. Drugs with primary patents have about 10-35% percent higher prices than drugs in the same class, vintage, local launch year, and quality that don't have such patents.

As an alternative to the within-molecule, within-country analysis of patents on price that is typical of research using U.S. or European data but that would limit us to a small sample of drugs in India, we compare the relative prices of drugs with and without patents in India to their US equivalents that are still on patent. This is an indirect way of approximating a drug fixed effect, though it requires us to assume that the competitive environment these drugs face is otherwise similar (or sufficiently controlled for by other explanatory variables).

The results of an OLS regression of relative price are presented in Table 9 below. The estimates are noisy and statistically insignificant (the sample size is also lower), but suggest that relative Indian prices of drugs with patents are 36-49% higher than those without patents.

Of course, the mechanism for the effect of patents on price is through competition. We present results from an OLS regression of price on competition, rather than patents, in Table 10. The relationship between price and competition is notoriously endogenous, so we instrument for competition using the post-1995 indicator described above, with the results in Table 11. In both the OLS and the IV specifications, we find that competition is associated with lower prices when we exclude controls for drug characteristics, and the IV results are larger in magnitude. The addition of drug characteristics reduces the magnitude of the coefficient slightly, but does not fundamentally alter the results.

Tables 12-13 present the corresponding OLS and IV results using the relative India-U.S. price. Again, we have noisy estimates that are of the expected sign: increased competition is associated with lower relative prices in India.

6 Robustness and discussion

We explored the robustness of these results in several ways. First, we include different measures of disease burden. Two candidate measures are years of life lost due a cause (YLL) and the prevalence of a disease. A drug can be mapped to multiple diseases, but we only have its total sales. We therefore also experiment with using the average of the burden measures across all diseases to which a drug is mapped; the maximum; and the sum. While the coefficients on these different measures vary, the coefficients on the patent variables of interest are generally similar. Tables A1-A4 contain the results of this exercise.

The price measure used in the specifications described above is a weighted average (by revenues) of the price per unit across all presentations within a form for a molecule. That is, a drug

Table 8: OLS regression of Log price

	(1) Log price	(2) Log price	(3) Log price	(4) Log price	(5) Log price	(6) Log price
Any Indian Patent	0.0542	0.00950				
	(0.52)	(0.09)				
Any Indian Product Patent			0.354*	0.301+		
			(2.12)	(1.79)		
Any Indian Constraining Patent					0.248	0.170
					(1.55)	(1.03)
Years since local launch	-0.0806*	-0.0834*	-0.0800*	-0.0825*	-0.0782*	-0.0816*
	(-6.31)	(-6.20)	(-6.31)	(-6.16)	(-6.11)	(-6.02)
FDA Priority	0.338*	0.355*	0.351*	0.366*	0.341*	0.357*
	(2.62)	(2.75)	(2.73)	(2.85)	(2.64)	(2.77)
Log N molecules in ATC3	-0.0194	0.00830	-0.0256	0.00360	-0.0255	0.00471
	(-0.35)	(0.14)	(-0.47)	(0.06)	(-0.46)	(0.08)
Average age of competing molecules in ATC3-form	0.00689	0.00510	0.00802	0.00563	0.00902	0.00628
	(0.46)	(0.34)	(0.54)	(0.38)	(0.61)	(0.42)
No older drugs in class	2.826*	2.750*	2.789*	2.721*	2.847*	2.766*
	(6.70)	(6.38)	(6.65)	(6.34)	(6.77)	(6.43)
Log average price of non-NMEs in ATC3-form	0.422*	0.423*	0.413*	0.416*	0.422*	0.424*
	(8.60)	(8.29)	(8.44)	(8.18)	(8.63)	(8.33)
Log N drugs with same MOA		-0.0444		-0.0458		-0.0451
		(-1.07)		(-1.11)		(-1.10)
Log N contraindications		0.176+		0.176+		0.173+
		(1.79)		(1.81)		(1.78)
Log N drug interactions		-0.103+		-0.105+		-0.105+
		(-1.77)		(-1.81)		(-1.80)
Log N associated diseases		0.000973		0.00328		0.00443
		(0.01)		(0.03)		(0.04)
Missing MOA		-0.304		-0.240		-0.261
		(-0.70)		(-0.56)		(-0.60)
Missing contraindications		0.348+		0.299		0.303
		(1.69)		(1.44)		(1.44)
Missing drug interactions		-1.154*		-1.103*		-1.126*
		(-2.50)		(-2.40)		(-2.44)
Missing diseases		-0.194		-0.247		-0.217
		(-0.44)		(-0.56)		(-0.49)
Constant	2.139*	2.751*	2.132*	2.737*	2.062*	2.696*
	(4.63)	(4.44)	(4.65)	(4.44)	(4.45)	(4.35)
R-sqr	0.896	0.902	0.898	0.903	0.897	0.902
Obs	375	375	375	375	375	375

Includes fixed effects for ATC1, U.S. approval year, and form

+ p<0.10, * p<0.05

Table 9: OLS regression of Log of India/US price

	(1)	(2)	(3)	(4)	(5)	(6)
	Log of India/US price	Log of India/US price	Log of India/US price	Log of India/US price	Log of India/US price	Log of India/US price
Any Indian Patent	0.586*	0.560*				
	(2.33)	(2.28)				
Any Indian Product Patent			0.843*	0.658*		
			(3.05)	(2.34)		
Any Indian Constraining Patent					0.878*	0.662*
					(3.15)	(2.31)
Years since local launch	0.0284	0.0297	0.0314	0.0347	0.0422	0.0415
	(1.04)	(1.03)	(1.17)	(1.20)	(1.55)	(1.41)
FDA Priority	0.104	0.108	0.108	0.119	0.0624	0.0675
	(0.33)	(0.34)	(0.35)	(0.37)	(0.20)	(0.21)
Log N molecules in ATC3	0.240+	0.266+	0.213	0.244	0.192	0.234
	(1.72)	(1.75)	(1.55)	(1.60)	(1.39)	(1.53)
Average age of competing molecules in ATC3-form	-0.0174	-0.0249	-0.0122	-0.0233	-0.0103	-0.0210
	(-0.48)	(-0.68)	(-0.35)	(-0.64)	(-0.29)	(-0.58)
No older drugs in class	0.656	0.270	0.511	0.132	0.627	0.253
	(0.70)	(0.29)	(0.55)	(0.14)	(0.68)	(0.27)
Log average price of non-NMEs in ATC3-form	-0.0538	-0.134	-0.0593	-0.123	-0.0454	-0.109
	(-0.48)	(-1.17)	(-0.54)	(-1.08)	(-0.42)	(-0.96)
Log N drugs with same MOA		0.0396		0.0594		0.0589
		(0.42)		(0.63)		(0.62)
Log N contraindications		0.418+		0.416+		0.400
		(1.69)		(1.68)		(1.62)
Log N drug interactions		-0.170		-0.179		-0.168
		(-1.31)		(-1.38)		(-1.29)
Log N associated diseases		-0.511		-0.524		-0.491
		(-1.55)		(-1.59)		(-1.48)
Missing MOA		-1.417		-1.142		-1.115
		(-1.60)		(-1.27)		(-1.24)
Missing contraindications		0.972*		0.851*		0.806+
		(2.29)		(2.00)		(1.88)
Missing drug interactions		-1.324		-1.352		-1.356
		(-1.32)		(-1.35)		(-1.35)
Missing diseases		1.326		0.995		1.098
		(1.54)		(1.15)		(1.28)
Constant	-4.328*	-2.725+	-4.331*	-2.712+	-4.562*	-3.016+
	(-3.66)	(-1.73)	(-3.74)	(-1.73)	(-3.93)	(-1.90)
R-sqr	0.634	0.691	0.647	0.692	0.649	0.692
Obs	150	150	150	150	150	150

Includes fixed effects for ATC1, U.S. approval year, and form

+ p<0.10, * p<0.05

Table 10: OLS egression of Log of price

	(1) Log price	(2) Log price	(3) Log price	(4) Log price
Any generic entrant	-0.600*	-0.516*		
	(-3.24)	(-2.69)		
Log N producers			-0.104*	-0.0908*
			(-2.49)	(-2.13)
Years since local launch	-0.0773*	-0.0794*	-0.0731*	-0.0775*
	(-6.14)	(-5.94)	(-5.63)	(-5.69)
FDA Priority	0.325*	0.342*	0.340*	0.362*
	(2.55)	(2.68)	(2.66)	(2.83)
Log N molecules in ATC3	-0.0239	0.00497	-0.00725	0.0146
	(-0.44)	(0.09)	(-0.13)	(0.25)
Average age of competing molecules in ATC3-form	0.00966	0.00689	0.0119	0.00950
	(0.66)	(0.47)	(0.80)	(0.64)
No older drugs in class	2.687*	2.618*	2.781*	2.711*
	(6.44)	(6.11)	(6.65)	(6.33)
Log average price of non-NMEs in ATC3-form	0.407*	0.412*	0.418*	0.421*
	(8.39)	(8.15)	(8.60)	(8.30)
Log N drugs with same MOA		-0.0475		-0.0401
		(-1.16)		(-0.98)
Log N contraindications		0.154		0.161+
		(1.59)		(1.65)
Log N drug interactions		-0.109+		-0.113+
		(-1.89)		(-1.95)
Log N associated diseases		0.00404		0.0370
		(0.04)		(0.32)
Missing MOA		-0.0987		-0.255
		(-0.23)		(-0.59)
Missing contraindications		0.234		0.273
		(1.12)		(1.32)
Missing drug interactions		-1.086*		-1.170*
		(-2.38)		(-2.56)
Missing diseases		-0.323		-0.177
		(-0.74)		(-0.41)
Constant	2.702*	3.272*	2.153*	2.811*
	(5.56)	(5.10)	(4.70)	(4.57)
R-sqr	0.900	0.904	0.898	0.903
Obs	375	375	375	375

Includes fixed effects for ATC1, U.S. approval year, and form.

+ p<0.10, * p<0.05

Table 11: IV regression of Log of price

	(1) Log price	(2) Log price	(3) Log price	(4) Log price
Any generic entrant	-0.984*	-1.046*		
	(-2.15)	(-2.13)		
Log N producers			-0.401*	-0.416*
			(-1.99)	(-1.97)
Years since local launch	-0.0754*	-0.0754*	-0.0523*	-0.0567*
	(-6.37)	(-5.90)	(-2.78)	(-3.00)
FDA Priority	0.317*	0.330*	0.348*	0.391*
	(2.68)	(2.80)	(2.74)	(3.05)
Log N molecules in ATC3	-0.0279	0.00117	0.0221	0.0360
	(-0.55)	(0.02)	(0.38)	(0.61)
Average age of competing molecules in ATC3-form	0.0114	0.00869	0.0259	0.0251
	(0.83)	(0.64)	(1.49)	(1.41)
No older drugs in class	2.600*	2.482*	2.662*	2.568*
	(6.54)	(6.04)	(6.32)	(5.93)
Log average price of non-NMEs in ATC3-form	0.397*	0.401*	0.406*	0.411*
	(8.60)	(8.44)	(8.32)	(8.14)
Log N drugs with same MOA		-0.0504		-0.0242
		(-1.34)		(-0.58)
Log N contraindications		0.133		0.110
		(1.47)		(1.08)
Log N drug interactions		-0.114*		-0.148*
		(-2.15)		(-2.41)
Log N associated diseases		0.00729		0.166
		(0.07)		(1.18)
Missing MOA		0.118		-0.0580
		(0.27)		(-0.13)
Missing contraindications		0.115		0.00189
		(0.53)		(0.01)
Missing drug interactions		-1.014*		-1.223*
		(-2.39)		(-2.70)
Missing diseases		-0.455		-0.119
		(-1.09)		(-0.28)
Constant	3.056*	3.803*	2.170*	3.015*
	(5.12)	(5.09)	(4.79)	(4.85)
R-sqr	0.898	0.902	0.882	0.885
Obs	375	375	375	375

Includes fixed effects for ATC1, U.S. approval year, and form. Instrumenting for competition using Post-95 indicator.
+ p<0.10, * p<0.05

Table 12: OLS regression of Log of India/US price

	(1) Log of India/US price	(2) Log of India/US price	(3) Log of India/US price	(4) Log of India/US price
Any generic entrant	-0.998*	-0.859*		
	(-3.11)	(-2.40)		
Log N producers			-0.245*	-0.220+
			(-2.16)	(-1.96)
Years since local launch	0.0389	0.0453	0.0293	0.0369
	(1.44)	(1.53)	(1.07)	(1.25)
FDA Priority	0.0167	0.0777	0.135	0.145
	(0.05)	(0.24)	(0.43)	(0.44)
Log N molecules in ATC3	0.225	0.272+	0.191	0.227
	(1.64)	(1.79)	(1.35)	(1.46)
Average age of competing molecules in ATC3-form	-0.0117	-0.0271	0.00707	-0.00436
	(-0.33)	(-0.75)	(0.19)	(-0.12)
No older drugs in class	0.230	-0.132	0.703	0.319
	(0.25)	(-0.14)	(0.75)	(0.33)
Log average price of non-NMEs in ATC3-form	-0.100	-0.143	-0.0357	-0.0989
	(-0.90)	(-1.25)	(-0.32)	(-0.86)
Log N drugs with same MOA		-0.00127		0.0679
		(-0.01)		(0.71)
Log N contraindications		0.327		0.369
		(1.32)		(1.48)
Log N drug interactions		-0.184		-0.192
		(-1.41)		(-1.46)
Log N associated diseases		-0.611+		-0.620+
		(-1.86)		(-1.87)
Missing MOA		-0.903		-1.293
		(-0.99)		(-1.44)
Missing contraindications		0.614		0.841+
		(1.37)		(1.95)
Missing drug interactions		-1.231		-1.544
		(-1.22)		(-1.53)
Missing diseases		0.592		1.094
		(0.66)		(1.26)
Constant	-3.069*	-1.315	-4.292*	-2.520
	(-2.53)	(-0.80)	(-3.62)	(-1.59)
R-sqr	0.648	0.693	0.631	0.687
Obs	150	150	150	150

Includes fixed effects for ATC1, U.S. approval year, and form.

+ p<0.10, * p<0.05

Table 13: IV regression of Log of India/US price

	(1) Log of India/US price	(2) Log of India/US price	(3) Log of India/US price	(4) Log of India/US price
Any generic entrant	-0.411	-0.538		
	(-0.65)	(-0.86)		
Log N producers			-0.140	-0.185
			(-0.65)	(-0.85)
Years since local launch	0.0300	0.0390	0.0269	0.0356
	(1.26)	(1.53)	(1.19)	(1.48)
FDA Priority	0.0852	0.102	0.134	0.144
	(0.32)	(0.40)	(0.52)	(0.57)
Log N molecules in ATC3	0.236*	0.272*	0.214+	0.234+
	(2.09)	(2.30)	(1.74)	(1.84)
Average age of competing molecules in ATC3-form	-0.0136	-0.0249	-0.00242	-0.00701
	(-0.47)	(-0.87)	(-0.07)	(-0.21)
No older drugs in class	0.477	0.0270	0.680	0.315
	(0.60)	(0.03)	(0.89)	(0.43)
Log average price of non-NMEs in ATC3-form	-0.0609	-0.129	-0.0347	-0.0999
	(-0.62)	(-1.39)	(-0.38)	(-1.12)
Log N drugs with same MOA		0.0180		0.0651
		(0.22)		(0.86)
Log N contraindications		0.350+		0.372+
		(1.78)		(1.92)
Log N drug interactions		-0.181+		-0.190+
		(-1.78)		(-1.84)
Log N associated diseases		-0.601*		-0.614*
		(-2.35)		(-2.37)
Missing MOA		-1.118		-1.322+
		(-1.39)		(-1.85)
Missing contraindications		0.745+		0.861*
		(1.79)		(2.44)
Missing drug interactions		-1.333+		-1.537*
		(-1.66)		(-1.96)
Missing diseases		0.841		1.120
		(1.02)		(1.63)
Constant	-3.728*	-1.767	-4.247*	-2.520*
	(-3.15)	(-1.18)	(-4.40)	(-2.05)
R-sqr	0.636	0.690	0.627	0.687
Obs	150	150	150	150

Includes fixed effects for ATC1, U.S. approval year, and form. Instrumenting for competition using Post-95 indicator.

+ p<0.10, * p<0.05

with a 10mg tablet and 20mg tablet enters as one drug-oral solid observation. Alternatives include allowing each presentation to enter separately; creating a measure of price per mg or other unit of strength; or creating a measure based on defined daily doses. While we favor the last, we have fewer observations and therefore noisier estimates. Otherwise, results do not vary systematically depending on the measure chosen.

The noise in any price measure raises a concern that patents are correlated with some omitted variable, so that coefficients of patents on price reflect unobserved quality, costs of production, etc. To explore this, we estimated a regression of U.S. prices on Indian patents and the same controls. The estimated price coefficients vary in sign across specifications and are never significant, which is somewhat reassuring.

Finally, we re-ran the same regressions using other cross-sections, such as from quarters in 2015 and 2018. The number of NMEs and the patent status of NMEs change, but results are broadly similar.

We noted in the introduction that several empirical studies of TRIPS and drug prices in India have found only small effects. While we demonstrate that primary patents do have a statistically significant and economically important effect on competition, our results on price are generally noisy and sometimes counterintuitive. In particular, we do not find that competition is associated with significantly lower prices after instrumenting for competition using eligibility for post-TRIPS primary patents.

As discussed above, a cross-sectional analysis of price that compares drugs with and without patents in India may be too noisy to yield informative results. A within-molecule analysis of prices before and after patent expiration is preferred. Table X below shows the change in the number of local producers and price for the 40 products whose primary patent expired in India before the start of 2019. ADD THIS TABLE.

It nevertheless remains possible that the effect of patents on prices, through restricting competition, is more limited in India than in markets such as the US. Most Indian consumers of pharmaceuticals pay out of pocket, without insurance; they are likely to be far more price sensitive than the average American consumer, even aside from per capita income differences. The monopolist's optimal price for a patented drug may be quite low, though the producer does expect higher unit sales with a patent to block competition. Pressure on multinational firms, including large pharmaceutical manufacturers, to demonstrate corporate social responsibility may lead them to set lower prices on patented products in developing countries like India as well.

Price competition between branded versions of an off-patent drug in India may also be less intense than competition between generics in the US, where insurers and pharmacists have strong incentives to steer demand to the cheapest generic. Table 13 below compares the results of a simple OLS regression of the log price on the number of local producers for drugs with at least 2 producers, for India and the US. An additional seller in the US is associated with a much steeper decline in price than in India. This is suggestive evidence that competition plays out differently in the Indian market, but merits more rigorous analysis in future.

One potential issue here is that primary patents are not randomly assigned: perhaps better drugs are more likely to seek and get primary patents. Our intuition is that this is not a major concern. Most NMEs launched in India will try to get a primary patent, and most primary patents are granted. And if anything in India all patents on more valuable drugs are given more scrutiny because of pre-grant opposition.[22]

[22]For example, the primary patent (per our categorization) on the Hepatitis C drug sofosbuvir was initially rejected

Table 14: Regression of log price on competition in the U.S. and India

	(1) U.S.	(2) U.S.	(3) India	(4) India
Log N producers	-1.018*	-1.019*	-0.0875+	-0.0840
	(-6.25)	(-5.91)	(-1.72)	(-1.61)
Years since local launch	-0.00466	0.00245	-0.0718*	-0.0663*
	(-0.12)	(0.06)	(-4.37)	(-3.77)
FDA Priority	0.422	0.408	0.188	0.209
	(1.62)	(1.53)	(1.38)	(1.51)
Log N molecules in ATC3	-0.0744	-0.121	0.0345	0.0707
	(-0.54)	(-0.85)	(0.57)	(1.13)
Average age of competing molecules in ATC3-form	0.0134	0.000506	0.0384*	0.0306+
	(0.59)	(0.02)	(2.53)	(1.96)
No older drugs in class	0	0	2.866*	2.669*
	(.)	(.)	(6.13)	(5.40)
Log average price of non-NMEs in ATC3-form	0.440*	0.455*	0.462*	0.443*
	(6.85)	(6.99)	(8.80)	(8.03)
N drugs with same MOA		0.000703		-0.0548
		(0.01)		(-1.23)
N contraindications		0.236		0.186+
		(1.35)		(1.82)
N drug interactions		0.294*		-0.123+
		(2.11)		(-1.95)
N associated diseases		0.294		-0.0279
		(1.48)		(-0.23)
Missing MOA		0.0751		-0.0112
		(0.07)		(-0.02)
Missing contraindications		0.520		-0.131
		(0.64)		(-0.53)
Missing drug interactions		1.061		-0.758
		(1.03)		(-1.58)
Missing diseases		0.834		-0.126
		(0.57)		(-0.20)
Constant	0.634	-1.855	1.556*	2.204*
	(0.53)	(-1.22)	(3.03)	(3.17)
R-sqr	0.808	0.821	0.905	0.910
Obs	219	219	294	294

Includes fixed effects for ATC1, U.S. approval year, and form

7 Conclusion

We provide several new facts about Indian drug patenting since TRIPS:

1. Most drugs approved globally since 1995 have a "primary" patent that has priority date before 1995, meaning they were not eligible for strong patent protection in India despite the new patent laws

2. This changes for drugs approved in 2010 and after: since then the majority are post-1995 molecules, and by the end of our sample (2017) nearly all are

3. Focusing on India, while most drugs introduced after TRIPS have a Indian patent, it is only those with priority date after 1995 where we see "primary" patenting

4. Consistent with previous research, we find only negligible effects of patents overall on prices and competition in Indian pharmaceuticals

5. However, when we focus on drugs with "primary" patents in India (which again, by now include almost all new drug approvals) competition effects are large, statistically significant, and in the expected direction. Price results are noisier.

These results were in some ways anticipated, if not highlighted, by previous research. For example, Berndt and Cockburn [2014] observed in a footnote that their results "may change in the future as the proportion of new drugs that are "grandfathered out" of eligibility for patent protection by virtue of being invented too early falls." And in some analyses Duggan et al. [2016] look at pre versus post 1995 molecules, but focus on launch dates not priority dates, finding stronger but still small effects for drugs launched in India after 1995. Duggan et al. [2016] also attempt to look at primary vs. secondary patents in their appendix, but their sample includes very few drugs with primary patents for reasons we have discussed already. While these previous results were accurate for the samples they studied, they reflected the long transition and are not relevant for thinking about the impact of patents in TRIPS going forward. And we believe that the specific mechanisms invoked to explain the previous results (compulsory licensing, price controls, Section 11(A)7, Section 3(d), etc.) are of second order importance, at least relative to the 1995 cutoff date.[23]

We are currently examining the robustness of our results to aggregating at different levels (molecule vs. molecule form class level),and to using another plausible cutoff dates[24]. We will also include additional controls and measures of drug quality (e.g. for acute vs. chronic drugs; Indian market size; U.S. sales). It is possible that these factors are correlated with both prices/competition and getting primary patents.[25] In future work we will distinguish between molecules where there

by the Indian Patent Office after a pre-grant opposition by civil society groups. This was later overturned. See Sampat and Shadlen [2015a].

[23]Though as we have noted it is possible that 3(d) interacted with the cutoff data for drugs like Gleevec, which we are currently examining for our sample of drugs.

[24]Article 2 of TRIPS requires countries to comply with the Paris Convention. Though India was not a member of the Convention until 1998, it had to recognize Paris Convention rules and thus apply a month priority rule as of Jan 1, 1995. Under some interpretations this would mean any patents with priority of 1994 or later were patentable in India, so 1994 would be the relevant cutoff date.

[25]If the post-1995 instrument is working as we believe it is, i.e. approximates a random shock to primary patent propensity, these controls are less important.

was an Indian application that was rejected versus those with no Indian application in the "no patent" category.

Nonetheless, in ways these results are unsurprising: strong drug patents restrict competition. To the extent these results hold up they have several implications. First, previous research focusing on 3(d) and other TRIPS flexiblities may have missed the main reason for high competition and limited price increases: the long effect of the pre-1995 priority rule on the ability to get strong product patents in India.

But this was a transient aspect of implementation. The flip side is that the effects of this choice are now starting to wear off, and almost all new drugs introduced globally will have post-1995 primary patents and (if our results are right) have much less competition in India than other drugs in class. If 3(d) is implemented as intended (to restrict secondary patents) it may limit the duration of the patent monopoly (by limiting "evergreening"), but for 10-12 years Indian consumers will face the potential for higher prices[Sampat and Shadlen, 2015b, 2018]. To the extent this is problematic, India may need to explore other approaches to enhance competition or lower prices. Though the Indian patent policy and access to medicine discussion has been dominated by discussions of 3(d), including our own work, increasingly this may miss the forest for the trees.

There are potential global implications as well. Recent reports suggest that in some countries, compulsory licensing has been important to securing access to low-cost medicines [FM't Hoen et al., 2018]. Though this is the subject of ongoing research, our conjecture is that compulsory licensing has been possible mainly in cases where drugs did not have primary patents in India, and Indian generics were able to supply globally. Going forward, this may not be so, because two compulsory licenses (one in the target country and one in India) would be required in cases where there is an Indian primary patent. This is obviously harder to make happen: recall that thus far India has issued only one compulsory license since TRIPS, and that was for the domestic market.

The focus of this paper has been on TRIPS implementation and prices and access, i.e. static efficiency. But there is another side to the equation: the effects of patents on innovation and launch incentives. It is possible that once the transitional period fades and primary patent protection is more common, we will start to see dynamic effects of TRIPS in India and globally as well[Kyle and McGahan, 2012].[26]. These effects would need to be factored into any net welfare calculation, in India or globally, and are the subject of ongoing research.

Beyond the practical importance of these issues, our analyses suggests that all patents are not created equal: the distinctions between primary and secondary patents are crucial for empirical analysis of effects not just in the U.S. [Hemphill and Sampat, 2012, 2013, 2011] but also globally. And national patent law changes are not binary: the precise timing and details of implementation matter.

[26]Though the theory literature is skeptical that there are large dynamic effects of drug patent protection in developing countries: see e.g. [Subramanian, 2004, Deardorff, 2011]

8 Appendix

Table 15: IV regression of Any generic entrant

	(1) Any generic entrant	(2) Any generic entrant	(3) Any generic entrant	(4) Any generic entrant	(5) Any generic entrant	(6) Any generic entrant
Log mean of prevalence	-0.00577					
	(-0.88)					
Log max of prevalence		-0.00490				
		(-0.77)				
Log sum of prevalence			-0.00376			
			(-0.67)			
Log mean of YLL				-0.000427		
				(-0.03)		
Log max of YLL					0.00151	
					(0.11)	
Log sum of YLL						0.00464
						(1.13)
Any Indian Constraining Patent	-0.896*	-0.899*	-0.899*	-0.719*	-0.722*	-0.922*
	(-5.20)	(-5.20)	(-5.22)	(-5.15)	(-5.21)	(-5.17)
Years since local launch	0.00174	0.00176	0.00179	0.00147	0.00145	0.000561
	(0.34)	(0.34)	(0.35)	(0.28)	(0.27)	(0.11)
FDA Priority	-0.0485	-0.0479	-0.0476	-0.0453	-0.0453	-0.0482
	(-1.10)	(-1.09)	(-1.08)	(-1.07)	(-1.07)	(-1.08)
Log N molecules in ATC3	0.0261	0.0262	0.0261	0.0254	0.0258	0.0270
	(1.21)	(1.22)	(1.21)	(1.20)	(1.22)	(1.24)
Average age of competing molecules in ATC3-form	-0.00450	-0.00448	-0.00460	-0.00234	-0.00233	-0.00451
	(-0.89)	(-0.89)	(-0.91)	(-0.48)	(-0.48)	(-0.88)
No older drugs in class	-0.436*	-0.436*	-0.435*	-0.362*	-0.360*	-0.447*
	(-3.11)	(-3.11)	(-3.10)	(-2.67)	(-2.65)	(-3.14)
Log average price of non-NMEs in ATC3-form	-0.0127	-0.0129	-0.0127	-0.000769	-0.000422	-0.0139
	(-0.70)	(-0.70)	(-0.69)	(-0.04)	(-0.02)	(-0.75)
Log N drugs with same MOA	0.00112	0.000818	0.000963	-0.00524	-0.00516	-0.000335
	(0.08)	(0.06)	(0.07)	(-0.39)	(-0.39)	(-0.02)
Log N contraindications	-0.0310	-0.0317	-0.0322	-0.0457	-0.0456	-0.0331
	(-0.95)	(-0.97)	(-0.99)	(-1.43)	(-1.43)	(-1.01)
Log N drug interactions	-0.00288	-0.00269	-0.00239	-0.00224	-0.00204	-0.00447
	(-0.14)	(-0.13)	(-0.12)	(-0.10)	(-0.09)	(-0.22)
Log N associated diseases	-0.0465	-0.0439	-0.0442	-0.0402	-0.0411	-0.0560
	(-1.20)	(-1.13)	(-1.13)	(-1.07)	(-1.08)	(-1.39)
Missing MOA	0.241	0.241	0.242	0.536*	0.537*	0.250
	(1.46)	(1.46)	(1.46)	(2.89)	(2.89)	(1.49)
Missing contraindications	-0.0204	-0.0215	-0.0215	-0.227*	-0.227*	-0.0141
	(-0.25)	(-0.27)	(-0.27)	(-2.97)	(-2.96)	(-0.17)
Missing drug interactions	-0.0832	-0.0860	-0.0852	0.0385	0.0479	-0.0763
	(-0.48)	(-0.49)	(-0.49)	(0.11)	(0.13)	(-0.43)
Missing diseases	-0.0191	-0.0173	-0.0158	-0.216	-0.217	-0.0492
	(-0.09)	(-0.08)	(-0.08)	(-1.05)	(-1.05)	(-0.24)
Constant	1.364*	1.347*	1.342*	1.203*	1.173*	1.234*
	(5.70)	(5.71)	(5.62)	(3.80)	(3.71)	(5.52)
R-sqr	0.082	0.078	0.078	0.290	0.288	0.054
Obs	367	367	367	319	319	367

Includes fixed effects for ATC1, U.S. approval year and form. Instrumenting for patent status using Post-95 indicator.

+ p<0.10, * p<0.05

Table 16: IV regression of Log N producers

	(1) Log N producers	(2) Log N producers	(3) Log N producers	(4) Log N producers	(5) Log N producers	(6) Log N producers
Log mean of prevalence	0.0326					
	(1.22)					
Log max of prevalence		0.0328				
		(1.27)				
Log sum of prevalence			0.0303			
			(1.32)			
Log mean of YLL				0.107+		
				(1.89)		
Log max of YLL					0.114*	
					(2.09)	
Log sum of YLL						0.00640
						(0.39)
Any Indian Constraining Patent	-2.537*	-2.533*	-2.551*	-1.803*	-1.791*	-2.462*
	(-3.62)	(-3.61)	(-3.64)	(-3.25)	(-3.26)	(-3.47)
Years since local launch	0.0298	0.0294	0.0288	0.0508*	0.0506*	0.0301
	(1.43)	(1.41)	(1.38)	(2.42)	(2.41)	(1.43)
FDA Priority	0.0167	0.0150	0.0141	-0.129	-0.129	0.00277
	(0.09)	(0.08)	(0.08)	(-0.77)	(-0.77)	(0.02)
Log N molecules in ATC3	0.175*	0.174*	0.175*	0.193*	0.192*	0.175*
	(2.00)	(1.99)	(2.00)	(2.29)	(2.30)	(2.02)
Average age of competing molecules in ATC3-form	0.0298	0.0294	0.0299	0.0296	0.0303	0.0318
	(1.46)	(1.43)	(1.46)	(1.54)	(1.58)	(1.56)
No older drugs in class	-0.268	-0.270	-0.282	0.245	0.274	-0.273
	(-0.47)	(-0.47)	(-0.49)	(0.46)	(0.51)	(-0.48)
Log average price of non-NMEs in ATC3-form	0.0362	0.0371	0.0353	0.110	0.114	0.0356
	(0.49)	(0.50)	(0.47)	(1.46)	(1.52)	(0.48)
Log N drugs with same MOA	0.0303	0.0311	0.0288	0.0158	0.0147	0.0361
	(0.53)	(0.55)	(0.50)	(0.30)	(0.28)	(0.64)
Log N contraindications	-0.262*	-0.262*	-0.262*	-0.229+	-0.229+	-0.237+
	(-1.98)	(-1.98)	(-1.99)	(-1.80)	(-1.81)	(-1.82)
Log N drug interactions	-0.0762	-0.0771	-0.0793	0.00728	0.00800	-0.0811
	(-0.94)	(-0.95)	(-0.98)	(0.08)	(0.09)	(-1.00)
Log N associated diseases	0.408*	0.391*	0.390*	0.475*	0.442*	0.394*
	(2.59)	(2.48)	(2.47)	(3.19)	(2.93)	(2.45)
Missing MOA	0.0476	0.0483	0.0513	0.988	1.002	0.0237
	(0.07)	(0.07)	(0.08)	(1.34)	(1.36)	(0.04)
Missing contraindications	-0.392	-0.386	-0.387	-0.779*	-0.778*	-0.370
	(-1.19)	(-1.18)	(-1.18)	(-2.56)	(-2.57)	(-1.12)
Missing drug interactions	-0.331	-0.320	-0.332	1.615	1.665	-0.271
	(-0.47)	(-0.45)	(-0.47)	(1.14)	(1.18)	(-0.38)
Missing diseases	0.900	0.882	0.859	0.235	0.170	0.901
	(1.08)	(1.05)	(1.02)	(0.29)	(0.21)	(1.08)
Constant	0.525	0.551	0.499	-1.764	-1.913	0.926
	(0.54)	(0.58)	(0.51)	(-1.40)	(-1.53)	(1.04)
R-sqr	0.190	0.191	0.188	0.367	0.370	0.200
Obs	367	367	367	319	319	367

Includes fixed effects for ATC1, U.S. approval year and form. Instrumenting for patent status using Post-95 indicator.

+ p<0.10, * p<0.05

Table 17: IV regression of Log price

	(1) Log price	(2) Log price	(3) Log price	(4) Log price	(5) Log price	(6) Log price
Log mean of prevalence	0.0401*					
	(2.20)					
Log max of prevalence		0.0399*				
		(2.26)				
Log sum of prevalence			0.0404*			
			(2.55)			
Log mean of YLL				-0.0615		
				(-1.56)		
Log max of YLL					-0.0548	
					(-1.44)	
Log sum of YLL						0.00601
						(0.55)
Any Indian Constraining Patent	0.633	0.640	0.609	0.332	0.310	0.701
	(1.42)	(1.43)	(1.38)	(0.84)	(0.79)	(1.52)
Years since local launch	-0.0868*	-0.0873*	-0.0881*	-0.0958*	-0.0959*	-0.0875*
	(-6.44)	(-6.48)	(-6.57)	(-6.34)	(-6.34)	(-6.30)
FDA Priority	0.294*	0.292*	0.291*	0.273*	0.273*	0.279*
	(2.51)	(2.50)	(2.50)	(2.28)	(2.28)	(2.36)
Log N molecules in ATC3	0.0170	0.0159	0.0173	0.00403	0.00616	0.0188
	(0.30)	(0.28)	(0.31)	(0.07)	(0.10)	(0.33)
Average age of competing molecules in ATC3-form	0.0183	0.0176	0.0178	0.0287*	0.0285*	0.0216
	(1.32)	(1.27)	(1.29)	(2.01)	(1.99)	(1.54)
No older drugs in class	2.655*	2.656*	2.624*	2.412*	2.410*	2.649*
	(6.04)	(6.04)	(5.99)	(5.36)	(5.35)	(5.92)
Log average price of non-NMEs in ATC3-form	0.472*	0.473*	0.470*	0.440*	0.439*	0.472*
	(9.42)	(9.44)	(9.41)	(8.02)	(8.00)	(9.30)
Log N drugs with same MOA	-0.0700+	-0.0689+	-0.0724*	-0.0519	-0.0508	-0.0614+
	(-1.90)	(-1.87)	(-1.97)	(-1.39)	(-1.36)	(-1.66)
Log N contraindications	0.136	0.136	0.134	0.171+	0.172+	0.170+
	(1.54)	(1.55)	(1.53)	(1.85)	(1.86)	(1.93)
Log N drug interactions	-0.0808	-0.0821	-0.0859	-0.194*	-0.193*	-0.0825
	(-1.54)	(-1.56)	(-1.64)	(-2.96)	(-2.96)	(-1.55)
Log N associated diseases	0.0381	0.0159	0.0119	0.0796	0.0941	0.0292
	(0.37)	(0.15)	(0.11)	(0.74)	(0.87)	(0.27)
Missing MOA	-0.202	-0.202	-0.196	-0.843	-0.845	-0.214
	(-0.47)	(-0.47)	(-0.46)	(-1.64)	(-1.64)	(-0.49)
Missing contraindications	0.0483	0.0565	0.0566	0.477*	0.479*	0.0698
	(0.21)	(0.25)	(0.25)	(2.12)	(2.13)	(0.30)
Missing drug interactions	-1.474*	-1.458*	-1.479*	-3.825*	-3.804*	-1.419*
	(-3.23)	(-3.19)	(-3.25)	(-3.86)	(-3.84)	(-3.07)
Missing diseases	0.155	0.131	0.0969	0.614	0.647	0.166
	(0.29)	(0.25)	(0.18)	(1.09)	(1.14)	(0.31)
Constant	1.553*	1.595*	1.484*	3.873*	3.794*	2.041*
	(2.42)	(2.53)	(2.33)	(4.37)	(4.29)	(3.44)
R-sqr	0.913	0.913	0.914	0.917	0.917	0.911
Obs	346	346	346	300	300	346

Includes fixed effects for ATC1, U.S. approval year and form. Instrumenting for patent status using Post-95 indicator.

+ p<0.10, * p<0.05

Table 18: IV regression of Log of India/US price

	(1) Log of India/US price	(2) Log of India/US price	(3) Log of India/US price	(4) Log of India/US price	(5) Log of India/US price	(6) Log of India/US price
Log mean of prevalence	0.0433					
	(1.37)					
Log max of prevalence		0.0422				
		(1.35)				
Log sum of prevalence			0.0261			
			(0.97)			
Log mean of YLL				0.0435		
				(0.51)		
Log max of YLL					0.0560	
					(0.67)	
Log sum of YLL						-0.0193
						(-0.63)
Any Indian Constraining Patent	0.668	0.698	0.723	-0.0811	-0.0845	0.885
	(1.01)	(1.05)	(1.08)	(-0.12)	(-0.13)	(1.22)
Years since local launch	0.0443+	0.0445+	0.0442+	-0.00828	-0.00914	0.0537+
	(1.71)	(1.72)	(1.71)	(-0.23)	(-0.25)	(1.80)
FDA Priority	-0.0423	-0.0475	-0.0363	0.351	0.343	-0.0328
	(-0.15)	(-0.17)	(-0.13)	(1.17)	(1.14)	(-0.12)
Log N molecules in ATC3	0.185	0.184	0.179	0.176	0.177	0.155
	(1.38)	(1.37)	(1.33)	(1.24)	(1.24)	(1.13)
Average age of competing molecules in ATC3-form	0.000395	0.000421	0.00314	-0.0236	-0.0241	0.00529
	(0.01)	(0.01)	(0.10)	(-0.68)	(-0.70)	(0.17)
No older drugs in class	0.495	0.512	0.511	-0.0837	-0.0710	0.511
	(0.63)	(0.65)	(0.65)	(-0.10)	(-0.09)	(0.64)
Log average price of non-NMEs in ATC3-form	-0.00498	-0.00104	-0.00313	-0.108	-0.109	0.0170
	(-0.05)	(-0.01)	(-0.03)	(-0.88)	(-0.90)	(0.15)
Log N drugs with same MOA	0.0575	0.0561	0.0640	0.102	0.100	0.0856
	(0.76)	(0.74)	(0.84)	(1.37)	(1.35)	(1.13)
Log N contraindications	0.285	0.286	0.297	0.463*	0.468*	0.339+
	(1.39)	(1.40)	(1.45)	(2.32)	(2.35)	(1.68)
Log N drug interactions	-0.143	-0.139	-0.136	-0.454*	-0.455*	-0.111
	(-1.35)	(-1.32)	(-1.28)	(-3.41)	(-3.44)	(-1.03)
Log N associated diseases	-0.437	-0.452+	-0.454+	-0.562+	-0.574*	-0.414
	(-1.60)	(-1.66)	(-1.67)	(-1.95)	(-1.98)	(-1.47)
Missing MOA	-1.296	-1.316	-1.404	-1.480	-1.504	-1.204
	(-1.43)	(-1.46)	(-1.56)	(-0.95)	(-0.96)	(-1.21)
Missing contraindications	0.646+	0.649+	0.661+	1.153*	1.161*	0.649+
	(1.69)	(1.70)	(1.73)	(2.84)	(2.86)	(1.66)
Missing drug interactions	-1.436	-1.405	-1.429	-6.449*	-6.392*	-1.249
	(-1.55)	(-1.52)	(-1.54)	(-3.24)	(-3.21)	(-1.33)
Missing diseases	1.309	1.284	1.340	1.837	1.822	1.468
	(1.37)	(1.34)	(1.39)	(1.64)	(1.63)	(1.56)
Constant	-4.244*	-4.272*	-4.159*	-0.931	-1.102	-3.706*
	(-2.87)	(-2.87)	(-2.80)	(-0.51)	(-0.59)	(-2.61)
R-sqr	0.708	0.708	0.706	0.742	0.742	0.704
Obs	139	139	139	122	122	139

Includes fixed effects for ATC1, U.S. approval year and form. Instrumenting for patent status using Post-95 indicator.

+ p<0.10, * p<0.05

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