Institutional Innovation or Institutional Imitation?

The Impacts of TRIPs on India's Patent Law and Practice

Bhaven N. Sampat*

Assistant Professor

Department of Health Policy and Management

Mailman School of Public Health

Columbia University

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Abstract

The 1995 Trade Related Intellectual Property Rights (TRIPs) agreement led to an upward harmonization of developing country patent standards towards those of the developed world. Among other changes, TRIPs requires that developing countries allow for product patents in pharmaceuticals. Most theoretical and empirical work in economics tends to treat TRIPs as dichotomous---there is widespread perception that TRIPs flipped the patent switch from "off" to "on" in developing countries. But the interpretation, implementation, and operationalization of these laws also matter. Like many international agreements, TRIPs includes room for interpretation, and, in pharmaceuticals, flexibilities. This paper provides empirical data on the impacts of TRIPs in Indian pharmaceuticals. This is an interesting context both because of the unique role of the Indian generics industry in the provision of drugs to the developing world, and because India was active in exploiting TRIPs flexibilities. Most prominently, Indian patent laws limit patents on "incremental" innovations, which dominate drug patenting in the developed world. This *institutional innovation* has been greeted with enthusiasm by some, but concern from others (including the U.S. pharmaceutical industry and USTR). This contrasts sharply with the *institutional imitation* argument: there are also concerns that these standards, however high, are not being implemented in practice, reflecting resource constraints and other pressures toward mimicry at the Indian Patent Office. Proponents of the institutional innovation and imitation views agree that, if nothing else, the welfare impacts of TRIPs in India will be determined by the extent to which India sticks to, or departs from, international patentability standards. In this paper I use novel data on Indian drug applications (and, in some analyses, a matched sample of "twin" applications filed at the European Patent Office, or EPO) to assess the institutional innovation versus institutional imitation hypotheses. I find some correlation of prosecution outcomes across countries, but also that India *is* different---with a much lower grant rate than the EPO. However, the main source of these differences cited in existing policy discussions----Section 3(d) of India's patent law, which limits patents on "incremental" pharmaceutical innovations----has had very little effect on outcomes in India vis-à-vis the control sample.

Introduction and Background

Developing countries historically have had flexibility in how they designed their patent laws. The World Trade Organization's 1995 Trade Related Intellectual Property Rights (TRIPs) agreement appears to have changed this. TRIPs led to an upward harmonization of patent standards towards those of developed world. Perhaps most importantly, prior to this many developing countries prohibited product patent protection in pharmaceuticals. TRIPs forbids excluding entire fields from patentability. Most developing countries were compelled to introduce TRIPs-compliant patent laws a decade ago, by January 1, 2000. Deere (2009) observes that as a result, “[B]y the end of 2007 the IP standards of developing countries were higher than ever before" (1).

TRIPs was widely condemned by development economists (see e.g. Bhagwati, 2004; Stiglitz 2006; Sachs 1999). Most theoretical work suggests that world welfare is optimized when developing countries ignore patent protection (Deardroff 1992; Panagariya 2003). This criticism also reflected historical evidence that most successful instances of development historically occurred in contexts of weak intellectual property rights, with developing countries assimilating and adapting knowledge and technologies from the developed world (Cimoli et al. 2010.) Related to this, a long-standing industrial policy concern in developing countries has been that high standards of patent protection would privilege multinational firms over indigenous ones.

While much of the work on development has focused on acquisition of technological capabilities, another major strand of alarm about TRIPs has emerged from health policymakers, NGOs, and civil society groups concerned with access to medicines. Much of this focus has been on India, reflecting its internationally unique status. Known sometimes, in global health circles, as "the pharmacy of the developing world," India is a major provider of low-cost, generic drugs to developing countries. India also has a large patient population unable to afford drugs at developed country prices. Since patented medications are much more costly than generics, critics of TRIPs have expressed concern that it will lead to substantial price increases for drugs in India and other developing countries.

Others have argued that the introduction of patent protection in India could help shift its drug industry from one that is imitative to an innovative one by incentivizing domestic R&D (see Arora et al 2008 for an empirical examination). Another argument is that patents in developing countries will create incentives for developed country drug firms to conduct research on neglected tropical diseases (see Kyle and McGahan 2009 for an empirical examination). These predictions find support in a fifty-year empirical legacy in economics suggesting patents are extremely important for appropriating returns to R&D in pharmaceuticals, more so than in any other sector (Levin et al 1987).

While there is considerable argument about whether it is for better or worse, most economists believe that TRIPs represents a sharp shift from the

status quo ante. But maybe not so fast. Though most theoretical and empirical work in economics tends to treat TRIPs as dichotomous---there is a widespread perception that TRIPs flipped the patent switch from “off” to “on” in developing countries ---the interpretation, implementation, and operationalization of these laws also matters. Like many international agreements, TRIPs includes room for interpretation and, in pharmaceuticals, flexibilities (Deere 2009).

This paper provides empirical data on the impacts of TRIPs in Indian pharmaceuticals. This is an interesting context both because of the unique role of the Indian generics industry in provision of drugs, and because India was active in exploiting TRIPs flexibilities. On their face, the novel aspects of its patent laws could make the patent scene there very different from that in much of the developed world. As one example, in an editorial written during deliberations about India's post-TRIPS patent law, Abbott et al. (2005) suggested that most drug patents filed in India after TRIPs would not be patentable there if the law incorporated certain patent standards; most of those standards were ultimately incorporated into the law, as I discuss below.

Evidence that the post-TRIPs Indian patent practices reflect *institutional innovation* (developing patent standards and practices catered to her own national interests) would suggest very different implications for the likely impacts of TRIPs (for better or worse) than would an *institutional imitation* story, i.e. that it is basically copying developed-country practices and standards. These issues are important not only in practice, but also in theory. This paper joins a small

empirical literature in law and economics focused on the institutional structure of patent offices and patent systems (Jensen et al 2005; Cockburn et al 2003; Sampat 2010; Lemley and Sampat 2009, 2010; Alcacer, Gittleman, Sampat 2009). That there is even a debate suggests how laws are actually administered may matter a lot, a theme in the old political science literature on implementation (Pressman and Wildavsky 1984) and work in legal realism distinguishing between "laws on the books" and "laws in practice" (Pound 1910). Finally, understanding how TRIPS is being implemented, as well as its impact in practice, is also important for assessing its impacts on innovation, diffusion, and access in developing countries (Arora et al 2008; Kyle and McGahan 2009).

For all these reasons, adjudicating the institutional innovation versus institutional imitation arguments is important. This paper represents a first step in doing so. It follows a large subset of pharmaceutical patent applications filed after TRIPs, and examines the extent to which they were granted, factors affecting whether they were granted, and how Indian patent prosecution outcomes are associated with outcomes at the European Patent Office (EPO). It also traces twin applications through the patent-prosecution process in India and abroad, and estimates difference-in-difference models to assess whether the putatively novel aspects of India's patent laws on the books have a real impact on patent prosecution outcomes.

I proceed as follows. In Section 2, I provide background information on Indian patent law and pharmaceuticals before and after TRIPs, and more detail

on the institutional innovation and institutional imitation hypotheses. Section 3 begins by describing the data collection, and data sources used. Section 4 describes the empirical analyses, and presents results. In Section 5, I conclude.

Patent law and pharmaceuticals in India

Before TRIPs

An important part of the motivation for Indian independence in 1947 was the concern that the British colonial system subordinated the economic interests of Indians to those of the British. This distrust of foreign influence extended to India's patent laws. Its pre-Independence patent laws were modeled on British laws. A committee report authored by Supreme Court Chief Justice Rajagopala Ayyangar is typically viewed as the blueprint for India's post-independence patent policy before TRIPs. The Ayyangar Committee had two concerns. One was that the old law benefited foreigners over Indians: on the eve of independence, Indians accounted for only 10 percent of granted patents in India (Mittal, 1999). Another was that the Indian provision to grant product patents on pharmaceuticals---contrary to many developed and developing countries at the time----was not in its national interest, leading to high drug prices and suppressing local production (Mueller, 2007b).

The Patent Act of 1970, modeled after the recommendations in the Ayyangar report, featured a number of provisions limiting patent strength, including broadening grounds for issuance of compulsory licenses, and a

research exemption. It shortened patent terms from sixteen to fourteen years, and to seven years for drugs, and raised patent renewal fees. It made patent examination more rigorous. Finally, it prohibited product patents in pharmaceuticals, and mandated compulsory licensing after three years of patent grant.

The Act proved influential in pharmaceuticals. In the decades that followed, the pharmaceutical patent landscape in India also changed, with Indian firms becoming much more prominent (Mittall 1999). Many believe it was responsible for the creation of the Indian pharmaceutical industry: Yusuf Hamied, the founder of Cipla, describes these legal changes as “the dawn of the Golden Age” of the indigenous pharmaceutical industry. Following the elimination of pharmaceutical product patents, new Indian firms entered and old firms expanded, competing to reverse-engineer bulk drugs, which they either sold wholesale or developed into formulations. Indian generic firms are particularly important sources of low-cost drugs for other developing countries.

TRIPs

Since the history of the TRIPs negotiations have been chronicled elsewhere (Chadhuri 2005; Mueller 2007b; Drahos 2008; Sell 2003), I will not repeat it here. In pharmaceuticals, the main changes imposed on developing countries such as India were the lengthening of patent terms (to 20 years), and

the elimination of restrictions on product patents in pharmaceuticals (where such restrictions had existed).

In part owing to her large generic pharmaceutical industry and its role in global health, India was among the developing countries most vocally against TRIPs during WTO negotiations. Numerous civil society groups and NGOs in India and abroad opposed it. After they lost this fight, these same groups began to try to shape the actual patent law in India to take advantage of the room for maneuvering under TRIPS (Chaudhuri 2005). Deere (2009) suggests in India and elsewhere, “a second battle began after the TRIPs negotiations ended” (1), focused on implementation.

Implementation proceeded through fits and starts between 2000 and 2005. The legislation went though many amendments, and was tabled and substantially changed several times. Finally, in March 2005, India passed a TRIPs compliant patent law: the Patents (Amendments) Act of 2005. This law exploited a number of TRIPs flexibilities. First, it took advantage of a “mailbox” option, a transitional provision where countries that did not previously have product patent protection were allowed to hold them in waiting, to be considered after January 1, 2005. This provision was designed to give developing countries time to adapt their patent systems and patent offices to the post-TRIPs world. Mailbox applications began being accepted in 1995 (after India signed on to TRIPS), but were not published or examined until after January 2005, when the mailbox was opened.

Another provision, the focus of this paper, is Section 3(d) of India's patent law. Among the provisions championed by civil society groups in India (and NGOs abroad) during the TRIPs debate was restricting drug patents to new molecular entities (Basheer,2008). This was in response to concerns about "evergreening": that incremental patents on existing substances would be used to extend market life and delay generic competition; the allegation was that this practice was common in developed countries. A particular source of this concern was that incremental patents on HIV/AIDS drugs would have negative impacts on public health in India (Gopakumar, 2010).

Until the very last days of the debate, there was uncertainty about what this aspect (and others) of India's TRIPs-compliant patent law would look like. Thus, even in January 2005, a *New York Times* editorial ("India's Choice," January 18, 2005) noted that the legislation was "uncomfortably vague about whether companies could engage in `evergreening,'" further opining, "this practice, a problem in America and elsewhere, extends monopolies and discourages innovation."

The final law, passed after March 2005, included harsher restrictions on incremental innovations (though not as harsh as an outright ban on non-NME patents) than the version referred to in the *Times* editorial. Specifically, Section 3(d) of the act limits patentable subject matter as follows:

> 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. 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.

This provision was a surprise to many observers, including the *Indian Business Standard*, which editorialized in March 2005 that these provisions were "'better put together than seemed possible a month or two ago.'' On the other hand, these late-added provisions almost immediately became a source of concern to developed-country pharmaceutical firms. In its official statement on the passage of the patent law in 1995, the pharmaceutical trade group PhRMA notes:

> PhRMA members welcome the passage today of India's Patents Third Amendment Bill, 2005. This legislation is a milestone for the Government of India, re-establishing patent protection for pharmaceutical products in India. With the passage of this legislation, India has taken an important step toward complying with its obligations under the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). *However, America's research-based pharmaceutical industry does remain concerned about a number of late amendments to the bill that may bring India into conflict with its minimum international obligations* (Emphasis added.)

The main "late amendment" causing concern was 3(d). This concern is perhaps understandable, given the heavy reliance on follow-on patents for market life in the U.S. (Hemphill and Sampat 2010) and Europe (EC Commission Report 2010).

Concerns about 3(d) rose to prominence in 2006, when the Swiss pharmaceutical firm Novartis filed a lawsuit challenging the constitutionality of 3(d), and whether it was TRIPS compliant. (The Madras High Court ruled that 3(d) was constitutional, and that it lacks the jurisdiction to decide on TRIPs-compliance.) By then, the concern surrounding this institutional innovation was more vociferous. Paul Herrling, head of corporate research at Novartis, noted that with 3(d) India's new patent laws "provide no patent protection for companies developing innovative drug products, because they do not allow the patenting of incremental improvements, which is often the way that science advances" (Owens 2007).

At least on its face, India's TRIPs implementation made its patent laws very different from those in the developed world. This is the *institutional innovation* point of view. As discussed above, not everyone greeted this innovation favorably. For example, Roger Bate of the American Enterprise Institute (AEI) highlights "certain peculiar provisions" in the Indian patent law (Bate 2007). The U.S.-India Business Council, in a report on Section 3(d), notes:

> [D]espite the increasing harmonization of intellectual property norms, India stands alone as the only country in the world to exclude the full range of incremental pharmaceutical innovations from patent eligibility" (US India Business Council 2009, 2).

A recent analyst report notes "the 2005 fell short of complete westernization of India's IPR laws" ("Understanding India's New Patent Laws," 2009, 28). Specific concerns raised in the report include that "the IPO [Indian Patent Office] ...

has considerable freedom to deny applications for new molecules" (28). It concludes that the pharmaceutical industry that pushed for TRIPs may have been "overly optimistic" in predicting it would actually matter, noting the Indian pharmaceutical patent scene remains "hazardous" (28). And the 2010 U.S. Trade Representative Country Report on India, in justifying keeping India on a Special 301 list for concerns about intellectual property, highlights 3(d): "The United States continues to urge India to improve its IPR regime by providing stronger protection for patents. One concern in this regard is a provision in India's Patent Law that prohibits patents on certain chemical forms absent a showing of increased efficacy. While the full import of this provision remains unclear, it appears to limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery" (USTR 2010)[1].

While these observations are generally opposed to India's idiosyncratic laws, Mueller (2007a), reflecting on public health implications of TRIPS, suggests India's safeguards "could ensure that only truly innovative advances will be patented" and, elsewhere, that its "innovative patents framework … will determine whether and how national patent systems can truly accommodate domestic economic conditions and cultural norms while still satisfying international baseline standards" (Mueller 2007b). Basheer (2005) suggests that

[1] It is no doubt also a source of concern that other developing countries are considering following India's lead in adopting 3(d) type provisions.

given the strong imprint of the Ayyangar legacy on the IPO, it is likely to interpret the flexibilities in a way to limit patent grants.

The recent push by multinational drug firms for “TRIPs---plus” provisions in India's patent laws (e.g., relatively long data exclusivity periods) may be seen as a response to these institutional innovations that make patenting in India difficult for them.

The institutional innovation view contrasts sharply with the *institutional imitation* argument. Thus there are also concerns that these *de jure* standards, however high, are not being implemented in practice. One issue is a large backlog of applications created by the surge of post-TRIPS filing, as well as a lack of adequate resources to hire examiners or support thorough examination (Kapczynski 2009.; Mueller 2007b; Austria Wirtschaftsservice 2008). While these issues are prominent even in the U.S. (Lemley and Sampat 2010), they are more likely to bind in India. As in developed countries, these conditions make more likely the granting of “low quality” patents, those that don't meet a nation's standards of patentability. A recent Thomson-Reuters report notes “significant questions about the quality of what is coming out of the Indian IP Office” (Thomson Reuters 2009).

Journalists have alleged that, despite its official patent standards, the IPO is in fact granting numerous patents on incremental innovation that do not meet the 3(d) requirements. Some observers argue that , based on aggregate data on

patent applications and grants in India, the grant rate in pharmaceuticals is over 90 percent (Wild 2008; Unnikrishanan and Narayan 2008).

The presence of pre- and post-grant opposition could ameliorate low quality examination by bringing third-party information into patent prosecution. But this has been hindered by lack of readily accessible information on patent filings and grants (Jishnu, 2008). Until very recently, India's official database of patents and applications was nearly impossible to search. And even the current (much improved) database does not include full specifications for applications, and thus is of limited use for pre-grant oppositions.

The resource constraints facing examiners make it more likely that they would mimic the actions and practices of developed-country patent offices. Deere (2009) notes that actual TRIPs implementation occurs by patent offices. Drahos (2008) points to the growing role of developed-country offices in providing technical assistance to developing-country counterparts, including training examiners and consulting for developing-country offices. As the U.S. Congress is currently considering the most significant patent reform in over a half-century—in response to concerns about patent quality--some see this as peculiar. Drahos (2008) argues “developing country patent offices have been integrated into a system of international patent administration in which the grant of low---quality patents by the patent offices is a daily occurrence.” (5)[2] Kapczynski (2009) also emphasizes the role that U.S. and European patent offices provide in training

[2] Gandhi, when asked (during World War Two) what he thought of western civilization, famously responded ``I think it would be a good idea.'' Drahos apparently feels the same way about western patent examination.

Indian examiners, and that patent office guidelines for implementing the new patent laws are sometimes copied from U.S. and European sources. Thus one source of institutional isomorphism is diffusion of standards and norms via technical communities.

Scholars have also suggested a more direct reason why there may be imitation in India (Mueller 2007b; Kapczynski 2009). A large share of post-TRIPs applications, especially those filed by multinationals, is via the Patent Cooperation Treaty (PCT). The PCT is a unified system for patent filing, commonly used by multinational firms seeking patent protection in more than one country. Under the PCT, applicants are provided with prior art searches and patentability opinions by an international search authority, generally a developed-country patent office. These then accompany the individual national stage applications in other states.

Several scholars have raised the concern that developing-country patent offices, including India's, rubber-stamp PCT decisions rather than subjecting them to national patent standards (Drahos 2008; Kapczynski 2009; Mueller 2007b).[3] There is more general concern that the IPO simply follows the lead of developed country patent offices whenever possible. A recent study of the Indian patent system by the Austrian government (!) observes that the relatively small and resource-poor IPO could not be processing the post-TRIPS surge of applications at the rate they are "unless they simply follow research reports of the

[3] Drahos notes, "Developing countries that enter the PCT system generally do so with few resources to carry out substantive examination ... developing-country examiners largely follow the decision of the relevant major patent office" (186-7).

USPO, EPO, and JPO (and the weight of bribery)" (Austria Wirtschaftsservice 2008).

This paper does not take a view on the welfare impacts of 3(d). Instead, it starts from the one thing that proponents of the institutional innovation and imitation views agree about: that the impacts of TRIPs in India will be determined by the extent to which India sticks to, or departs from, international patentability standards. In the remainder of this paper, I use new data on Indian applications and grants post-TRIPs to examine these issues.

Data

I began by collecting information on pharmaceutical patent applications filed after TRIPs in the Indian Patent Office's (IPO's) database of published patent applications. I restricted focus to two international patent classes commonly used to characterize drugs: A61K ("Human Necessities; Medical or Veterinary Science; Hygiene Preparations for Medical, Dental, or Toilet Purposes") and C07D ("Heterocyclic Compounds").[4] This yields 23,960 applications filed between 1995 and 2010.

To allow a post-application window of at least five years for each application, I further restricted the dataset to the 5,078 applications filed before July 1, 2005, i.e. after TRIPs was passed but before India's TRIPs-compliant

[4] To verify that this is a reasonable characterization of pharmaceutical patents, I collected information on IPCs of all patents listed on the FDA's Orange Book. 71 percent of these patents are classified in A61K and 9 percent in C07D. The next most common IPC, A61F, accounts for 4 percent of patents.

patent law was introduced. In considering the impact of 3(d) on Indian patent prosecution this restriction has another advantage. Since it was unclear until 2005 exactly how India's patent law would look, these filings are likely to have been exogenous with respect to 3(d).[5]

I collected information from the IPO's Application Status database on the status of these applications, as of July 1, 2010. Specifically, I determined whether the application was granted, pending, or rejected/withdrawn by this date. As in the U.S., it is conceptually difficult to distinguish between rejections and withdrawals, since withdrawals can be in response to (or in anticipation of) examiner rejections of all or some of the claims in an application (Lemley and Sampat 2008). Accordingly I collapse the two categories, referring to them simply as "rejected" applications for the purposes of the analyses below.

I also collected other front-page bibliographic data from these applications, including the nationality of the first-named inventor. It is useful to examine, in passing, home country bias, a theme in the literature on international patent prosecution (Jensen et al. 2005). In addition, I collected information on whether the application was filed in India via the PCT, and if so, the PCT application number.

The primary goal of this paper is to assess whether 3(d) applications are treated differently in India, both from other applications and (in difference-in-difference type models) relative to identical twin applications filed elsewhere.

[5] This is in principle testable, by looking at what PCT applications were filed as national phase applications in India, and whether applications with 3(d) terms were less likely to be filed there than in other jurisdictions.

That identifying 3(d) applications is extremely difficult complicates this task. After all, this is the job of patent examiners who spend (in theory) hours on each application, and entire court cases (like the Novartis case) have been devoted to this issue.

Unfortunately (for econometric reasons at least) there is no “incremental innovation” patent classification. In the spirit of analyses examining the effects of software patents—another context where class-based algorithms fare poorly (Bessen and Hunt)—I instead rely on parsing patent claims for expert generated keywords to distinguish 3(d) applications from others. Specifically, with the assistance of a patent attorney who specializes in 3(d) cases in India, I identified a set of terms that, when they appear in claims, are likely to trigger 3(d) concerns.

The main applications raising Section 3(d) concerns are those focusing primarily on salts of an already patented compound, or a new formulation of an existing product using different pharmaceutical excipients. In order to identify patents claiming only salts of existing compounds, we conducted keyword searches against a selection of salts commonly used for formulation purposes (succinate, mesylate, fumurate, and tartrate). Similarly, we carried out keyword searches against the most common excipients used by companies when filing for subsequent patents for a formulation or new formulation of an existing compound (polyvinylpyrrolidone, polyethylene glycol, hydroxyethylmethyl cellulose,

magnesium stearate, sorbitan esters or sorbitan fatty acid esters, copolymers).[6] We also searched for patents containing the terms "pharmaceutical composition." This term is typically used in claims language to claim a combination of existing substances, including known compounds with salts and excipients. Patent applications with any of these terms were flagged as 3(d) applications.[7]

To test the sensitivity of the algorithm, I also ran it against at set of 40 applications known to be rejected on 3(d) grounds. Of these, it correctly identified 90 percent (36/40) as 3(d) applications. By contrast, only 15 percent of Indian drug applications overall are flagged as 3(d) applications using this algorithm, as discussed below.

Unfortunately, full-text claims information is not reliably available for each of the 5,078 Indian applications. Accordingly, in most of the analyses I focus on those in the subset that were filed in India through the PCT: 2,965, or about 58 percent of the applications. Multinationals file the vast majority of their applications in India via the PCT (see below) so this is the subsample of policy interest for the institutional innovation or imitation arguments.

For these applications, I collected application data for the corresponding PCT applications from the World Intellectual Property Organization (WIPO) *Patent Scope* database. Specifically, I downloaded the full text of the claims for

[6] In sensitivity analyses, we are currently considering a broader set of keywords, including a longer list of salts, and their acid forms. We are also hoping to gain access to the Indian generic pharmaceutical association's proprietary database of issued patents with 3(d) concerns.

[7] In developing this algorithm, we aimed to identify keywords that would generate few false positives, so that the "3(d)" applications we flag really are 3(d) triggers. One cost of this is more false negatives, however. We are currently experimenting with other variants of the algorithm, and will examine robustness of results to them.

each of these 2,965 applications, and parsed these for the 3(d) keywords discussed above.

The WIPO database includes information on all international applications emanating from a given application. This allows for construction of a "family size" measure: the number of countries in which a national phase application (resulting from a given PCT application) is filed. This is similar to "family size" measures using priority data, which are commonly used as proxies for patent value (Putnam et al. 1998).

The WIPO data also allows for leveraging information about the outcomes of prosecution of the same patents in other jurisdictions. I focus on what happens to the same applications in the European Patent Office (EPO).[8] Of the 2,965 applications, I was able to collect PCT information for 2920. (The remaining five appear to have had errors in transcribing the PCT data.) Of these, nearly all were also filed at the EPO (2,920, or 96 percent). For these, I collected EPO outcome data as of June 2010: whether an EPO application granted, pending, or rejected/withdrawn. These can be used to examine associations between EPO and IPO outcomes, and also in difference-in-difference analyses where the "twin" applications are subjected to a treatment--3(d)-in one jurisdiction (India) but not another (EPO).

[8] I chose the European Patent Office rather than the USPTO, since a PCT application can spawn numerous continuation and divisional applications in the U.S.; the relationship between PCT and national phase applications in the EPO is more likely to be one-to-one. Nonetheless, in future analyses I plan to incorporate the USPTO and Japanese Patent Office outcome data, already collected.

Descriptive Analyses

Though most of the analyses will focus on the PCT applications, I begin with an overview of the entire sample of 5,078 applications filed between 1995 and 2005. Table One shows that 37 percent of these result in patents by 2010, while 31 percent were rejected and another 31 percent remain pending at the IPO. Among applications that have resulted in final disposition (those that are not pending), the grant rate for pharmaceuticals is about 55 percent.

By comparison, the analogous figure for applications in classes A61K and C07D filed in the U.S. in January 2001 (as of April 2006, or slightly more than five years after filing) is 67 percent, using the data described in Lemley and Sampat (2008), which provides some suggestion that the IPO may be more stingy in granting than the USTPO, at least.

I have only limited other information on the full set of applications, aside from an indicator of whether the application has a PCT application and whether the first inventor is an Indian national. Table Two shows that the Indian applications that emanate from PCT applications have the same grant likelihood as non-PCT Indian applications (about 37 percent). But those with PCT applications are more likely to be pending at the IPO (36 percent versus 26 percent) and less likely to have been rejected (27 percent versus 37 percent).

Table Three shows cross-tabulations of whether an application has an Indian inventor and whether it was filed via the PCT. About 10 percent of the applications with Indian inventors have PCT applications, compared to 78

percent of foreign applications. To put it another way, 95 percent of the PCT applications filed in India have no Indian inventors, compared to 37 percent of non-PCT applications. This suggests that the analyses of PCT applications (below) may not generalize to indigenous Indian inventors: it provides a clearer picture of how foreigners' drug patent applications fare at the Indian patent office.[9]

This is also seen in Table Four, which shows the top 20 firms associated with the PCT applications. While there are 1,031 distinct firms associated with the PCT applications, the top 20 account for nearly 30 percent of the applications. They are dominated by multinational pharmaceutical firms, not surprisingly.

I calculated the EPO status for the applications as of June 2010. Table Five shows a cross-tabulation of the EPO status versus the Indian status, for all PCT applications in the sample. The prominence of the on-diagonal elements suggests some correlation in outcomes across the EPO and IPO. Thus, of applications granted by the EPO, 48 percent are granted in India. Similarly, for those rejected by the EPO, the most likely outcome in India is rejection, which happens about half the time. However, pending applications at the EPO are equally likely to be pending or granted by the IPO. I examine this association more formally in the econometric analyses reported in the next section.

[9] In unreported models, I also examined whether, for the full set of applications, Indian inventors had higher grant rates than foreigners at the Indian patent office. Depending on the specification, Indian applicants had either statistically indistinguishable grant rates or significantly lower grant rates. These specifications, necessarily parsimonious due to limited data on non-PCT applications, show little evidence of "home country bias" at the IPO (Jensen et al 2005)

Econometric Analyses

Baseline models

In this section I estimate linear probability models and multinomial logit models, to examine more formally the impact of 3(d) and associations between IPO and EPO outcomes, for the subset of applications filed via the PCT in India. In a first set of models, I relate application characteristics, including whether an application has 3(d) terms, to whether it was granted in India. I estimate these linear probability models across the entire sample, and across the subset that received final disposition, i.e. are granted or rejected rather than pending. I also estimate multinomial logit models that examine the impact of the covariates on each of the three outcomes.

Table Six shows descriptive statistics on the variables used in these analyses. About 15 percent of the applications have 3(d) keywords in their claims, 61 percent are in A61K (rather than C07D), and 4 percent have Indian inventors.

Table Seven shows results from a linear probability model relating the application characteristics to whether it was granted. Model 7.1 shows result across the whole sample. There is some evidence of correlated outcomes: applications that were rejected by the EPO have a 30 percentage point lower likelihood of being granted by the IPO than pending EPO applications (the left-out category) and applications granted by the EPO have a 6-percentage-point higher likelihood of a grant by the IPO. Surprisingly, more “important” applications are

less likely to be granted by the IPO. And applications with 3(d) keywords are slightly *more* likely to be granted by the IPO than other applications, though that effect is not statistically different from zero at conventional levels.

Model 7.2 shows results for similar models, estimated over applications that were either granted or rejected by the IPO. The Indian grant likelihood is statistically identical for granted EPO applications and pending EPO applications (the left out category). But rejected EPO applications are much less likely to be granted by the EPO: a 48-percentage-point difference. In this model too, family size has a negative effect on the likelihood of grant, and 3(d) applications have a slightly (but statistically insignificant) higher grant rate in India.

Next, I use a multinomial logit model to examine the effects of covariates on the three outcomes at the IPO (patented, rejected, pending) more flexibly. The base category is rejected applications. Table Eight shows results, with coefficients converted to relative risk ratios to ease interpretation. (Relative risk ratios indicate the impact of a one-unit change of an independent variable on the ratio of the probability of the two choices.) Model 8.1 shows that applications rejected by the EPO are much less likely to be granted rather than rejected by the IPO. None of the other variables have a statistically significant impact at conventional levels. Notably, 3(d) applications continue to have higher, albeit still statistically insignificant, grant likelihood in India.

Model 8.2 shows results for pending applications. Again 3(d) does not seem to matter for whether an application is pending rather than rejected in India.

Those with Indian inventors are significantly more likely to be pending, however, perhaps reflecting their relative lack of experience in PCT filings. And while granted applications at the EPO are as likely to be pending at the IPO as rejected (the coefficient on this variable is less than one but statistically insignificant), applications rejected by the EPO are much less likely to be pending at the IPO than to be rejected.

To summarize: The most consistent result across these models is that rejected applications at the EPO are much less likely to be granted by the IPO, both because they are more likely to be rejected and to be pending. This provides some evidence of institutional imitation, though hardly a smoking gun[10]. However, the main criticisms of the IPO (from those concerned about institutional imitation) aren't about rejections, but correlated grants. The data show, however, that EPO grants aren't strong predictors of IPO grants in most of the models, though they do have a small and statistically significant effect on the likelihood an application is granted (rather than being rejected or pending) in the first specification.

At the same time, there is scant evidence that the institutional innovation, 3(d), has had much of an effect in India. In almost all of the models 3(d) applications were *more* likely to be granted than others, though in none of the models is the difference large or statistically significant.

[10] In future research it may be possible to get traction on the innovation issue by looking at the timing of EPO versus IPO actions. Specifically, we can examine how the hazard of grant (or rejection) in India is affected by grant or rejection at the EPO.

Difference-in-difference models

A reasonable reaction to the results thus far is that they don't accurately test the hypothesis that 3(d) matters, since that is necessarily a comparative institutional claim. Specifically, incremental innovations are differentially less likely to obtain patents in India than in other countries, irrespective of how the grant rate on these relates to the grant rate for other pharmaceutical patents. This could be especially true if "other" patents include significant noise, i.e. aren't necessarily more innovative than the patents with the 3(d) keywords we identified.

As a different lens on this, I also estimated difference-in-difference type models. These models more formally leverage the unique "twin" nature of the dataset, which provides a natural matched sample for the Indian applications.

A few words on data structure. Each observation is a PCT application filed in both the EPO and IPO. The observations comprise each of the 2,803 applications from the analysis above, and their corresponding EPO application, for a total of 5,606 observations. The dependent variable is the status of an application (at the IPO for Indian applications, at the EPO for the twins). Regressors include indicators for whether the application is an Indian application, whether it has 3(d) claims, or whether it is a 3(d) application filed in India.

Table Nine shows results. The estimates from the full sample, in Model 9.1, show Indian applications have a 14 percentage-point lower grant probability than their twins. And 3(d) applications are less likely to be granted than others in

the EPO, with an 8 percentage-point lower likelihood of being patented. Even though EPO has no 3(d) subject matter restrictions, applications with 3(d) keywords are treated differently there, a point I will return to. But the difference-in-differences is positive and statistically significant. As a result, 3(d) applications in India have a slightly higher likelihood of grant than other Indian applications: about 3 percentage-points lower (=.11-.08; p.<01), consistent with the results above. Model 9.2 shows that results from models across applications with final disposition are very similar.

Table Ten shows results from analogous multinominal logit models. Here again, the base category includes rejected applications. Model 10.1 shows that Indian applications have a lower grant rate, as do 3(d) applications. But the difference-in-difference interaction term is positive and statistically significant. That is, 3(d) applications have a differentially higher likelihood of being granted (rather than rejected) in India than abroad, as compared to other applications. Model 10.2, where the dependent variable indicates if an application is pending, shows that there is no such difference-in-difference in the impact of 3(d) applications on pendency (relative to rejection). However, Indian applications are much more likely to be pending than are EPO applications.

Conclusions

Given the importance of patents for innovation and diffusion in pharmaceuticals, and the importance of new drugs for global health, assessing

the impacts of TRIPs is an important health and innovation policy issue. India is a useful place to start. Its unique role as provider of low-cost drugs to much of the developing world means the impacts of patents in India have broader implications. Moreover, other developing countries are taking cues from India in implementing TRIPs (Kapczynski 2009).

The comparative grant data provide some evidence of correlation in grant outcomes, though hardly dispositive evidence of institutional imitation. Interestingly, the correlation appears to be strongest for rejections, whereas most of the concern about institutional innovation is focused on grants. That is, applications rejected by the EPO are much more likely to be rejected by India. The same is not true for grants. In future work, it may be possible to test more directly for institutional innovation by bringing information on the timing of EPO and IPO decisions, i.e. relating the hazard of IPO rejection or grant to rejections or grants that the EPO.

Despite much discussion about the novelty and international uniqueness of India's patent laws, in practice I find the 3(d) provision has little effect on patent prosecution. This may not be surprising to legal scholars who emphasize the differences between laws on the book and laws and practice (Pound 1910), or economists who have been careful to distinguish between institutional environments and institutional arrangements (North 1990).[11] (Interestingly, 3(d)

[11] While North draws this distinction to emphasize that strong property rights in theory may not translate to strong property rights in practice (e.g., if there is lack of enforcement), in India it appears that weak intellectual property rights on the books may be accompanied by strong ones in practice.

applications do have different outcomes from other applications abroad. More on that below.) The results do suggest that the pharmaceutical industry and USTR may be overly concerned about 3(d). They may also suggest that Indian policymakers aren't concerned enough, if its patent office is not enforcing its patent laws. This result is also consistent with journalistic reports that 3(d) is not being employed by examiners practice (Jishnu 2008).

An important caveat to this, however, is that 3(d) could matter for the most economically important applications. That is, even if the IPO ignores section 3(d) routinely, it could be that really important inventions tend to draw pre-grant (or post-grant) oppositions, and 3(d) is invoked in these. Though there've been an extremely small number of oppositions thus far, work by Basheer (2008) suggests most of these raised 3(d) concerns. In future work, I hope to examine oppositions as another dependent variable, and/or to separately consider the effect of 3(d) on more and less important pharmaceutical innovations.

Perhaps the most surprising result of this paper is that while 3(d) keywords don't matter in India, they do matter at the EPO. One possibility is that despite all of the rhetoric surrounding it, 3(d) is not so revolutionary after all. While 3(d) is a subject matter test, in other countries, so-called "incremental" innovations may be more difficult to obtain (than NCEs, for example) for

obviousness/inventive step reasons.[12] If this were true, developing countries aiming to limit grants on "incremental" innovations, but also wishing to avoid political ire, might consider implementing these as patentability standards (e.g., high obviousness bars) rather than subject matter restrictions.

That said, I have not taken a position in this paper on the welfare impacts of TRIPs in India (or developing countries more generally) or on the wisdom/folly of limiting patents on "incremental" innovations. These are complicated questions, beyond the scope of this paper. From the perspective that developed country patent standards would promote innovation, access, or diffusion in the developing world, institutional imitation would be desirable. However, those who believe that imitation of western standards would be bad--e.g., have little impact on pharmaceutical innovation but raise prices and restrict access--also tend to argue that TRIPs must be fought back, and encourage institutional innovation. From either point of view, a better understanding of whether innovation or imitation is occurring in practice is important for assessing the costs and benefits of TRIPs.

[12] At least one legal commentator has pointed this out: http://www.thinkipstrategy.com/ipthinktank/157/what-do-ksr-and-novartis-indian-glivec-troubles-have-in-common/

Table 1: Outcomes of 1995-2005 filed applications

	Frequency	Percent
Granted	1,900	37.42
Pending	1,602	31.55
Rejected/Withdrawn	1,576	31.04
Total	5,078	100.00

Table 2: Outcomes of 1995-2005 filed PCT and non-PCT applications

	No PCT	PCT	Total
Granted	799	1,101	1,900
Row Percentage	42.05	57.95	100.00
Col Percentage	37.81	37.13	37.42
Pending	539	1,063	1,602
Row Percentage	33.65	66.35	100.00
Col Percentage	25.52	35.85	31.55
Rejected/Withdrawn	775	801	1,576
Row Percentage	49.18	50.82	100.00
Col Percentage	36.68	27.02	31.04
Total	2,113	2,965	5,078
Row Percentage	41.61	58.39	100.00

Col Percentage	100.00	100.00	100.00

Table 3: PCT vs. Indian Inventor

	Foreign Inventor	Indian Inventor	Total
No PCT	781	1,332	2,113
Row Percentage	36.96	63.04	100.00
Col Percentage	21.75	89.58	41.61
PCT	2.810	155	2.965
Row Percentage	94.77	5.23	100.00
Col Percentage	78.25	10.42	58.39
Total	3,591	1,487	5,078
Row Percentage	70.72	29.28	100.00
Col Percentage	100.00	100.100	100.00

Table 4: Top 25 assignees on PCT applications filed in India, 1995-2005

Firm	Frequency	Percent	Cum. Percent
ASTRAZENECA AB [SE]	110	3.77	3.77
COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH [IN]	68	2.33	6.10
BOEHRINGER INGELHEIM PHARMA GMBH & CO.	56	1.92	8.01
PFIZER PRODUCTS INC. [US]	56	1.92	9.93
BRISTOL-MYERS SQUIBB COMPANY [US]	55	1.88	11.82
THE PROCTER & GAMBLE COMPANY [US]	46	1.58	13.39
RANBAXY LABORATORIES LIMITED [IN]	42	1.44	14.83
UNILEVER PLC [GB]	42	1.44	16.27
F. HOFFMANN-LA ROCHE AG [CH]	37	1.27	17.53
SCHERING AKTIENGESELLSCHAFT [DE]	35	1.20	18.73
JANSSEN PHARMACEUTICA N.V. [BE]	33	1.13	19.86
SMITHKLINE BEECHAM CORPORATION [US]	32	1.10	20.96
GLAXO GROUP LIMITED [GB]	31	1.06	22.02
NOVARTIS AG [CH]	30	1.03	23.05
PHARMACIA CORPORATION [US]	28	0.96	24.01
TEVA PHARMACEUTICAL INDUSTRIES LTD. [IL]	28	0.96	24.97

AVENTIS PHARMA S.A. [FR]	25	0.86	25.82
SMITHKLINE BEECHAM P.L.C. [GB]	25	0.86	26.68
COLGATE-PALMOLIVE COMPANY [US]	24	0.82	27.50
PHARMACIA & UPJOHN COMPANY [US]	24	0.82	28.32

Table 5: Application Status, IPO vs. EPO

	Granted (EPO)	Pending (EPO)	Rejected (EPO)	Total
Granted (IPO)	669	280	91	1,040
Row Percent	64.33	26.92	8.75	100.00
Col Percent	47.96	42.55	12.13	37.10
Pending (IPO)	433	274	297	1,004
Row Percent	43.13	27.29	29.58	100.00
Col Percent	31.04	41.64	39.60	35.82
Rejected/Withdrawn (IPO)	293	104	362	759
Row Percent	38.60	13.70	47.69	100.00
Col Percent	21.00	15.81	48.27	27.08
Total	1.395	658	750	2,803
Row Percent	49.77	23.47	26.76	100.00
Col Percent	100.00	100.00	100.00	100.00

Table 6: Descriptive Statistics

	Observation	Mean	Std. Dev.
Does the Application Have 3(d) Keywords? (1=yes)	2,803	0.158	0.365
Log (Family Size)	2,803	2.338	0.426
Is the application in IPC A61K? (1=yes)	2,803	0.615	0.487
Is the first inventor Indian? (1=yes)	2,803	0.039	0.194
Is the application pending at the EPO?	2,803	0.235	0.424
Was the application granted by the EPO?	2,803	0.498	0.500
Was the application rejected by the EPO?	2,803	0.268	0.442

Table 7: Linear Probability Model Relating Application Characteristics to Whether Granted

	7.1 **Dependent Variable: Was the Application Granted?** ***Full Sample***	**7.2** **Dependent Variable: Was the Application Granted?** ***Granted and Rejected Applications Only***
3(d) Claims?	0.027	0.039
	(1.10)	(1.34)
Log Family Size	-0.044	-0.058
	(1.96)*	(2.17)*
A61K?	-0.011	0.015
	(0.59)	(0.70)
Indian Inventor?	0.010	0.035
	(0.21)	(0.47)
Granted by EPO	0.058	0.018
	(2.35)*	(0.64)
Rejected by EPO	-0.304	-0.483
	(12.92)**	(15.43)**
Constant	0.529	0.809
	(8.93)**	(11.51)**
Observations	2803	1799

* significant at 5%; ** significant at 1%; robust standard errors in parentheses; all models include application year fixed effects; the left-out category for EPO status is pending applications

Table 8: Relative-Risk Ratios from Multinomial Logit Model

(Base category: Was the Application Rejected?)

	8.1 ***Dependent Variable: Was the Application Granted?***	**8.2** ***Dependent Variable: Is the Application Pending?***
3(d) Claims?	0.168	0.0641
	(0.149)	(0.146)
Log Family Size	-0.218	-0.00255
	(0.134)	(0.130)
A61K?	0.132	0.314***
	(0.110)	(0.109)
Indian Inventor?	0.525	0.653**
	(0.328)	(0.303)
Granted by EPO	0.116	-0.160
	(0.143)	(0.146)
Rejected by EPO	-2.213***	-0.913***
	(0.168)	(0.145)
Constant	0.311	-2.087***
	(0.445)	(0.590)
Observations	2,803	2,803

*** p<0.01, ** p<0.05, * p<0.1; robust standard errors in parentheses; all models include application year fixed effects; the left-out category for EPO status is pending applications

Table 9: Linear Probability Model of Whether Granted

	9.1 **Dependent Variable: Was the Application Granted?** ***Full Sample***	**9.2** **Dependent Variable: Was the Application Granted?** ***Granted and Rejected Applications Only***
Indian Application?	-0.144	-0.088
	(11.29)**	(6.35)**
3(d) Claims?	-0.083	-0.066
	(3.27)**	(2.13)*
Indian Application*3(d) Claims	0.110	0.104
	(3.70)**	(3.00)**
Log Family Size	0.031	0.038
	(1.71)	(1.66)
A61K	-0.060	-0.032
	(3.92)**	(1.72)
Indian Inventor?	-0.002	-0.056
	(0.04)	(1.17)
Constant	0.474	0.593
	(10.22)**	(10.28)**
Observations	5606	3944

* significant at 5%; ** significant at 1%; robust standard errors in parentheses, clustered on applications; all models include application year fixed effects

Table 10: Relative-Risk Ratios from Multinomial Logit Model

(Base category: Was the Application Rejected?)

	10.1 **Dependent Variable: Was the Application Granted?**	**10.2** ***Dependent Variable: Is the Application Pending?***
Indian Application?	-0.370***	0.457***
	(0.0720)	(0.0811)
3(d) Claims?	-0.286**	0.117
	(0.127)	(0.143)
Indian Application*3(d) Claims	0.447**	-0.0402
	(0.183)	(0.197)
Log Family Size	0.171**	0.0805
	(0.0842)	(0.0931)
A61K	-0.134*	0.236***
	(0.0704)	(0.0795)
Indian Inventor?	-0.215	-0.384**
	(0.181)	(0.193)
Constant	18.68***	18.45***
	(1.502)	(0.428)
Observations	5,606	5,606

*** p<0.01, ** p<0.05, * p<0.1; robust standard errors in parentheses, clustered on applications; all models include application year fixed effects

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