The Effects of Restrictions on Secondary Pharmaceutical Patents in Brazil and India

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1 Introduction

The World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduced unprecedented convergence in national patent policies. Prior to the 1990s countries established their frameworks for establishing and protecting intellectual property according to national conditions (Lerner 2000; Maskus 2000). TRIPS, which came into effect in 1995, requires all countries to adopt minimum standards with regards to patents, copyrights, trademarks, and other forms of intellectual property. Not surprisingly, cross-national measures of the strength of intellectual protection have since converged [Morin and Gold, 2014, Park, 2008].

TRIPS led to major changes in pharmaceuticals. Prior to TRIPS few developing countries granted pharmaceutical product patents. TRIPS requires all countries to do so. Since drugs covered by patents are usually more expensive than those without patents and open to multiple suppliers, many observers fear that TRIPS will restrict access to medicines.

While pharmaceutical patenting is now universal, some countries have exploited flexibilities built into the TRIPS agreement to implement different sorts of pharmaceutical patent systems [Deere 2008, Dreyfuss and Rodríguez-Garavito, 2014, Shadlen 2009]. One prominent use of these flexibilities is enactment of policies restricting “secondary” pharmaceutical patents. In contrast to patents on new molecules, secondary patents are on alternative forms of existing molecules, different formulations, dosages, and compositions, and new uses. Secondary patents can extend exclusivity on drugs, delaying the entry of lower cost generic competitors [European...
Policies restricting secondary patenting aim to ameliorate the perceived harmful effects of TRIPS on access to medicines. These policies reflect the sentiment that even if developing countries now have to grant drug patents, they do not have to be as permissive in granting “low quality” patents as developing country patent offices are thought to be, in pharmaceuticals and other fields [Jaffe and Lerner 2011].

The two most prominent examples of such policies are in India and Brazil. Section 3(d) of India’s post-TRIPS patent law states that new forms of old substances are not patentable (unless they show improved efficacy). In Brazil, pharmaceutical patents cannot be granted by the patent office unless the Brazilian health ministry also approves, and the agency responsible for making these decisions (ANVISA) gives prior consent. ANVISA has interpreted its role in the prosecution process to be to prevent the grant of secondary patents.

The Indian and Brazilian approaches toward secondary patents have been championed by civil society groups and non-governmental organizations, and academics, typically cited as models that should be emulated. They have also been criticized by the pharmaceutical industry as exotic attempts to unfairly limit pharmaceutical firms’ ability to obtain patents in these countries, and have earned both India and Brazil regular spots on the USTR’s Special 301 Priority Watch Lists. The leaked draft of the Trans-Pacific Partnership (TPP) agreement includes language (from developed country representatives) to prohibit restrictions on secondary patents.

Despite the attention they have received, there has been no large sample empirical evidence on grant rates for secondary patents, or an analysis of the effects of the Indian and Brazil provisions. Academic analyses of TRIPS implementation typically assume these provisions are restricting patent grants [Duggan et al. 2014, Berndt and Cockburn 2014]. In previous work [Sampat and Shadlen 2015b] examining Indian and Brazilian patent applications on about 150 drugs launched between 1996 and 2004 with at least one U.S. patent, we found these provisions were rarely used. However, that work focused on a small number applications with various special characteristics (including that they tended to be older applications, and they were associated with “successful” drugs already on the market that had U.S. patents). We were only able to ensure similarity of the Brazil and Indian applications for a small number of cases, which made comparing grant rates on secondary patents difficult. Most importantly, by focusing only on India and Brazil we had no baseline against which to assess grant rates for secondary patents.

http://infojustice.org/archives/32152
The analyses in this paper aim to make progress on each of these issues, and to provide a broader comparative perspective on pharmaceutical patenting. To do so, we follow the filing and grant of over 5,000 drug patent applications filed in India, Brazil, and six other diverse jurisdictions: the US, Japan, the European Patent Office, South Africa, Mexico, and Argentina. We code the claims of each application as primary or secondary and examine how national grant rates for these types of patents differ. Since overall grant rates can be influenced by the quality of filings, some of our analyses focus on “twin” applications filed in all jurisdictions. Though aggregate outcomes on granted vs. non-granted applications are revealing, alone they do not provide the full picture of how countries’ efforts to address secondary patents function in practice. We thus we also examine the details of the prosecution processes in India and Brazil to better understand the specific roles of Section 3(d) and ANVISA.

We find that in most countries secondary patents are less likely to be granted than primary patents. More surprisingly, neither India nor Brazil shows greater differences between primary and secondary grant rates than countries without specific measures targeting secondary patents. Both the comparison of grant rates and evidence from the prosecution process suggest that India and Brazil’s restrictions on secondary patents have had little direct effect on patent examination outcomes.

We proceed as follows. In the next section we provide a general overview of the challenges posed by secondary patents in pharmaceuticals. We then discuss our empirical strategy and data sources. Next, we present our empirical results, including on overall filing and grant rates by country, on whether the effects of policies restricting secondary patents are seen in cross-national differences in grant rates for different types of patents, the analysis of “twin” applications, and the detailed analyses of Indian and Brazilian prosecution. We conclude with various explanations for our results and their implications, drawing in part on complementary qualitative interviews with patent examiners and patent office officials, representatives of brand and generic drug companies, attorneys, and health activists in both India and Brazil.

2 Secondary Patents in Pharmaceuticals: Challenges and Responses

Secondary patents have become increasingly important to the pharmaceutical industry. Previous research reveals sharp increases in secondary patenting
in the U.S. and Europe over the past three decades [Kapczynski et al., 2012, Hemphill and Sampat, 2011, Howard, 2007, European Commission, 2009] and there is a belief that many of the pharmaceutical applications filed in developing countries since TRIPS are secondary [Abbott et al., 2005].

Taking out multiple patents on different aspects of a drug in order to cordon off competitors is now standard practice in the pharmaceutical industry. Secondary patents can protect market shares by extending periods of exclusivity beyond the dates in which patent protection would otherwise lapse. Devising patenting strategies to extend periods of protection is described in the pharmaceutical industry trade literature as a key component of product “life cycle management.” Critics of the practice often use the more pejorative “evergreening” to describe it.

Because secondary patents can postpone the entry of low cost generic competitors, and thus potentially reduce access to medicines, governments have implemented policies to address them. In the U.S., rigorous evaluation (more precisely, reevaluation) of secondary pharmaceutical patents on important drugs tends to occur through the courts, after patents are granted. Secondary patents on important drugs disproportionately draw patent challenges and litigation in the U.S. [Hemphill and Sampat, 2012]. Among cases that are litigated to completion challengers of secondary patents typically prevail, though litigation on secondary patents also often ends with a settlement [Hemphill and Sampat, 2013].

Given the complexity of patent examination, and since most patent applications are associated with drug development efforts that ultimately fail, granting patents liberally and allowing interested parties to litigate after they learn which patents are important (after drug approval) could be a rational way for resource-constrained patent offices to allocate their efforts [Lemley, 2001]. However, invalidating patents through litigation is expensive and risky. Litigation also has public good characteristics: a challenger solely bears the costs and risks, but if successful the benefits accrue to any generic firm. To address this problem and incentivize patent challenges, the U.S. Hatch-Waxman Act created a bounty, in the form of temporary period of exclusivity to the first generic to successfully overturn a patent through litigation [Hemphill and Sampat, 2012, Hemphill and Sampat, 2012] suggest that these patent challenges help ameliorate the potential negative effects of secondary patents in the U.S.

2 This section draws on Sampat and Shadlen [2015b].
3 There are many costs to this system in the U.S., including various forms of “gaming” by both brand and generic companies. See Hemphill and Sampat [2012].
A litigation-based system for overturning secondary patents may be less likely to work in low-income countries for several reasons. First, the smaller size of markets means the gains to successful litigation are smaller, thus reducing the incentive to challenge patents. Second, the greater resource asymmetries between owners and challengers means it may be more difficult to succeed in litigation. Third, in many developing countries the introduction of pharmaceutical patenting, and the ensuing flood of pharmaceutical patents, may overwhelm the capacities of local legal systems. A final issue is search costs: not knowing how many patents exist on a given drug creates uncertainty, and conducting searches on patent landscapes in developing countries is difficult. For all of these reasons, once patents are granted they may be particularly difficult to remove in developing countries.

Rather than relying on post-grant litigation to weed out low quality patents, countries implementing new patent laws under TRIPS have introduced “pre-emptive” mechanisms, at the point of examination. These policies try to limit the grant of secondary patents in the first place. They reflect a belief that, in the language of Drahos, prevention is desired over treatment.

Most of the policy discussion surrounding secondary patenting in developing countries is focused on access to medicines, not innovation. But there is at least an implicit belief that restrictions on secondary patents in any individual low-income country will not significantly blunt global innovation incentives. This is similar to arguments in the U.S. and other high-income countries that limiting “low-quality” patents won’t hurt innovation, and may even help create incentives for the “right” kind of innovation. While there has not been any direct work on this issue that we know of, it is relevant that most empirical research suggests that developing country patent policies have only a limited effect on either domestic or global innovation incentives, so it is reasonable to conclude that restrictions on secondary patents would only have a second-order effect on multinational

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4 This would be true even if there were exclusivity “bounties” for successful challengers in other jurisdictions, which to our knowledge there is not.
firms’ innovation incentives.

2.1 India

TRIPS was signed in 1995, but its transitional provisions allowed countries until 2005 to begin granting pharmaceutical patents. India took full advantage of this transition period, and held waiting in a “mailbox” applications filed between 1995 and 2005, which would be examined after 2005. In the final amendments to its new TRIPS-compliant patent law, in early 2005, India introduced Section 3(d), explicitly designed to minimize the grant of secondary patents:

The following are not inventions within the meaning of this Act... 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.

Section 3(d) was a surprise to most observers, including the pharmaceutical industry [Sampat and Amin, 2013]. It has since been the source of much controversy. The provision was (unsuccessfully) challenged in the Indian Supreme Court by Novartis, following the Indian Patent Office’s rejection of a secondary patent on a cancer drug Gleevec (imatinib mesylate).

The Novartis case galvanized opposition to 3(d) from the pharmaceutical lobby and developed countries, and also vigorous defense of the provision

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5 It is possible that restrictions on secondary patents may disproportionately hurt domestic innovators in developing countries, since the share of local firms’ innovations that are “incremental” is likely to be greater than the corresponding share for multinationals (see e.g. the Mashelkar Report in India, Shadlen 2011). Our dataset is not suited to answer this question since we focus on PCT-filed applications, which are mainly from multinational firms.

6 We have previously argued [Sampat and Shadlen, 2015a; Sampat et al., 2012] that Gleevec was mainly a victim of timing, not 3(d). The primary patent on Gleevec was not possible to obtain in India since it pre-dated TRIPS, leaving Novartis to rely on a secondary patent more vulnerable to rejection on 3(d) and other grounds.
from civil society and health activists. Section 3(d) is also regularly targeted by PhRMA and the USTR in the annual Special 301 process.

2.2 Brazil

While India’s patent law establishes a (rebuttable) presumption that secondary inventions are not patentable, Brazil’s patent law makes no such specific provisions. Rather, secondary targets become targeted via a shared examination system. Brazil introduced pharmaceutical patents in 1997, and in 2001 the new patent law was reformed to state that “The concession of patents for pharmaceutical products and processes depends on the prior consent of the National Agency for Sanitary Vigilance [ANVISA]” (Article 229-C). That is, pharmaceutical patent applications must be approved not only by the Brazilian patent office, the National Institute for Industrial Property (INPI), but also by the Ministry of Health’s surveillance agency (ANVISA).

Under the workflow in place for most of the period we study, if INPI determines that the patent should not be granted, then it is rejected and the process ends. However, if INPI determines that the patent should be granted, the application is then passed to ANVISA. In such cases, ANVISA examines the application and INPI’s technical report, often requesting additional material from the patent office and the applicants. If ANVISA issues its consent, INPI then grants the patent. If ANVISA decides that the patent should not be granted, it notifies INPI (and the applicant) of this decision. Although ANVISA lacks the legal authority to reject patents, INPI can only grant patents where ANVISA has given its prior consent.

At the time that the Prior Consent system was launched, there was considerable confusion about what exactly it would mean to involve health authorities in this way. ANVISA decided to use its authority to try to limit the grant of secondary patents. The health agency created its own intellectual property division, and developed its own examination guidelines, more restrictive than INPI’s, specifically targeting secondary patents [Shadlen 2012, 2011].

Like 3(d) in India, Prior Consent has also been controversial internationally, attacked by the pharmaceutical industry and embraced by health activists and civil society. In ways, Prior Consent is similar to “second set of eyes” reviews of business method (U.S. Patent Class 705) patents in the U.S., where there have also been concerns about patent quality. One reason it is controversial in Brazil and internationally is that it involves an agency other than an intellectual property office in making patentability determinations.\footnote{The authority of ANVISA to make patentability decisions was challenged in the Brazil-}
2.3 . . . and beyond

Part of the opposition to these provisions reflects concern about international emulation. Indeed, these two countries’ measures, especially India’s Section 3(d), are commonly cited as models for other developing countries (UNDP, Correa 2007, other cites). Other countries have specific restrictions on secondary patents as well [Deere 2008, Dreyfuss and Rodríguez-Garavito 2014, Musungu and Oh 2005]. For example, Argentina, which declared second medical uses non-patentable in 2001, soon after introducing pharmaceutical product patents in 2000, more recently adopted new examination guidelines to restrict most forms of secondary patents (Withaus; REFS.). Paraguay and Egypt, like Brazil, involve their health ministries in patent examination [Shadlen 2012]. The Philippines has 3(d) like provisions, and they have been recommended by legal scholars to Caribbean nations [Abbott et al. 2009]. In May 2015 the Israeli patent office enacted guidelines to restrict certain secondary patents.

3 Data and Empirical Approach

3.1 PCT applications

The majority of global pharmaceutical patent applications on important drugs are filed in developing countries through the Patent Cooperation Treaty (PCT), which allows for single applications to be deposited in multiple jurisdictions after undergoing preliminary analysis by an International Searching Authority. Accordingly, our analysis focuses on “national stage” applications in each country that emanate from PCT applications.

Using the World Intellectual Property Organization’s Patent Statistics database, we identified all PCT applications that were filed (at any receiving office) between 2000 and 2002 that had at least one International Patent Classification of A61K or C07D, the main classes associated with drugs. From these, only consider applications that were filed, either as original filings or as national entry stages through the PCT, in the US, the European Patent Office (EPO) and Japan. Applying these criteria leaves us with 15,815 applications.

ian courts as well. These challenges led (paradoxically) to a new workflow as of 2012 where ANVISA evaluates applications first, before sending them to INPI.

In the case of non-PCT member Argentina, we use the equivalents of the PCT filings; see below.
We focus on the years 2000 to 2002 both to allow a long window to observe outcomes (many of the countries in our sample have long pendency, as we discuss below). Another benefit of focusing on this time period is that the Indian and Brazil national stage applications from PCT applications filed during these years would have been submitted before Section 3(d) was introduced or ANVISA’s secondary patent restrictions were fully implemented, limiting the effect of selective filing on our results. Since many of our analyses involve searching patent by patent, to keep the analyses manageable we further restricted the set to those filed between January and July, leaving 8,600 applications.

Patent classifications are known to be noisy. Scanning this set revealed it contained many applications that were not actually for pharmaceuticals (e.g. they included agricultural chemicals, cosmetics), and some on biologic drugs. To solve these problems, we determined the Thomson Reuters Chemical Patent Index code for each application. These CPI codes are based on expert coding of the applications. Each application can have many CPI codes. We restricted the set of patent applications to those with at least one “B” (Pharmaceutical) Code, dropping 826 applications. Among the remaining applications, we also determined which were likely biotechnology-related (those with any codes B04-E, F, G or D05-H). We also dropped these applications (about a third of the total) since our focus here is on small molecule drugs. This resulted in a final set of 5,193 pharmaceutical (non-biotechnology) applications.

In many of our analyses, we examine matched “twin” applications, i.e. the same PCT applications that go national in all of the countries. While the specific claims filed in individual jurisdictions vary slightly, by and large they are substantively similar, if not always “identical” twins. (Appendix 1 shows the title and first independent claim in both the US and India for a random sample of the PCT applications from our dataset that had national stage filings in both the US and India.)

All of our analyses focus on national stage filings. This means that some “national” filings are not included in our grant rate calculations. An example may be useful. If a US applicant filed an application at the U.S. Patent and Trademark Office (USPTO) then went national in five other countries via the PCT (claiming priority to the original US application), but pursued the original US application in the US independently, the five other applications would be in our sample of national stage applications, and count in our grant rate calculations, but the original US application would not. By contrast, if the U.S. applicant filed a provisional application in the US, using that as priority for a PCT, then went national in the US and five other countries via
the PCT (abandoning the US provisional application) the US and five other national stage applications would count in our grant rate calculations. The reason for counting the US application in the second case but not the first is that we are more confident that linked “national stage” filings are similar to one another (in terms of timing, content, and informational available to the patent office at time of filing) than we would be if we compared the priority filings to national stage applications.

3.2 Coding the applications

To start, we need to know which of the PCT applications (and by extension, the national stage filings that result) include primary claims or only secondary claims. We had a pharmaceutical patent attorney code each of the applications, using a coding guide adapted from Hemphill and Sampat [2012]. (Appendix 2 reproduces the first pages of the coding guide.)

About 10 percent of the applications contained only process claims. Of the remainder, 38 percent were coded as including a novel active ingredient claim (an “A1” claim, using the terminology in the coding guide), and 49 percent as including any compound claims (an “A” claim, including novel active ingredients but also polymorphs and other crystalline forms, enantiomers and other isomers, and salts, metabolites, pre-metabolites, derivatives, and intermediates).

In our main analyses, we drop the pure process applications, and classify a PCT application as secondary if it did not include a novel active ingredient claim. Comparing the expert codings to other measures of patent application importance (each collected from WIPO and/or DWPI), we find that the primary patent applications categorized this way were more highly cited (31 versus 21 forward citations; p<.01), filed in more countries (9.3 versus 8.7; p<.01; and had more claims 29 vs. 24; p<.01). We also replicate our main results using an alternate measure of whether a patent is primary or secondary in Appendix 4.

9In practice, almost all PCT applications filed at the EPO “go national” in the EPO through the PCT. About a quarter of PCT applications filed through the US go national in the US via the PCT. (Typically, they are based on a provisional priority application in the U.S. which is then abandoned.) The analogous figure is 55 percent for Japan.

10All of the main results are robust to a narrower category of secondary patents, those without any product claims (whether or not the product claims are to novel active ingredients).
3.3 Empirical approach

We are interested in whether restrictions on secondary patents in India and Brazil generate differences in patent prosecution outcomes. Seeing differences between grant rates for primary and secondary patents in India and Brazil would be insufficient to make this case, since it is possible that these differences would be present even without the specific policies targeting secondary patents. The reason why is that secondary patents are vulnerable even using conventional patentability criteria: almost by definition they are less likely to be novel or inventive than primary patents [Hemphill and Sampat, 2012, 2013]. A comparison of grant rates for secondary patents across countries may also mislead, since there are other reasons that grant rates may vary across countries, such as the speed by which patent offices examine applications and the efforts that applicants make on account of the economic importance of particular markets. Accordingly, we will compare differences in primary and secondary grant rates across countries. This is similar to a difference-in-difference framework: countries without specific restrictions on secondary patents are the “control” group, and grant rates on primary patents are the baseline grant rate unaffected (in theory, at least) by any policies targeting secondary patents[^11].

From a policy evaluation perspective, it would be ideal to have other countries with similar patent systems (and other characteristics) to India and Brazil, absent their policies targeting secondary patents. Or, a sharp policy change in India and Brazil with a clear pre- and post- period. In practice, the other countries are a diverse set, so we think of them more as a comparison group than a control. They include three developed jurisdictions: the US, EPO, and Japan. And also three developing countries: South Africa, Mexico and Argentina. This variety is as much a feature as a bug, since it allows us to compare secondary patenting in India and Brazil to prosecution outcomes from a number of diverse contexts, about which little is known.

What are the important dimensions on which the comparison countries vary? The U.S. is often alleged to have a lax patent system [Lemley and Sampat, 2008] and also allows for continuation applications (in pharmaceuticals and other fields) which can complicate grant rate calculations[^12]. The Japanese Patent Office (JPO) and European Patent Office (EPO) have deferred examination systems, though of different lengths.

[^11]: This is not a conventional difference-in-difference analysis since there is no time dimension.
[^12]: In our empirical analyses, we calculate U.S. grant rates accounting for outcomes on any continuation applications.
EPO patents must be validated (via payment of various translation and publication fees) in countries that are members of the European Patent Convention after EPO grant. There is also diversity among the developing countries. As mentioned, Argentina restricts patents on new uses. Unlike the other countries in our set, Argentina is not a member of the PCT. South Africa has a registration system, essentially allowing all patents that are filed as long as fees are paid. Mexico is thought to have a pro-drug patent policy, shaped by pressures from the U.S. and the transnational pharmaceutical industry [Shadlen 2009].

Since comparing outcomes can be a noisy signal of policy effectiveness, especially without a obvious control sample to represent the counterfactual, we also collected data to gain insights on how specific policies designed to address applications for secondary patents were working. Specifically, in India and Brazil we collected detailed records on each of the national applications to examine exactly what role 3(d) and ANVISA had in the patent prosecution process. Appendix 3 provides details.

Beyond India and Brazil, the most difficult part of the empirical analysis was obtaining national stage grant data in each of the countries, since outcomes data are not maintained in any standard form or any individual database. This too is discussed in Appendix 3.

3.4 Other variables

Beyond application characteristics and country characteristics, another variable that may affect filing and grant rates is applicant effort.

Accordingly, we also collected information on “family size”, based on the number of countries in which a national application was filed. We collected this from the Derwent World Patents Index. Family size is a commonly used measure of invention importance, on the theory that inventions that are more important to firms will be filed more broadly [Lanjouw et al. 1998]. On average, applications in our sample were filed in nine countries.

For applications granted at the USPTO, we also collected information from the U.S. Maintenance Fee register to whether they were renewed (as of October 2015) or allowed to lapse. Among those applications resulting in issued US patents, about half (48 percent) have been maintained to date.
4 Results

4.1 Filing Rates

Recall that by construction, each of the applications was filed in the US, EPO, and Japan (either originally or as a national stage application). What about the developing countries? About 42 percent of the PCTs in our sample had national stage applications in Mexico, 35 percent in Brazil, 26 percent in South Africa, and 24 percent in India. In Argentina there were national applications linked to 19 percent of the applications in our sample.

Though the majority of applications in our sample are not filed in developing countries, Figure 1 shows that in every country, the probability of filing is higher for more “important” inventions, as measured by family size. The relationship is on one hand mechanical: applications filed in many countries are more likely to be filed in any given country. But it also suggests that there is little tendency to avoid particular countries for inventions where firms seek global protection. One exception is Argentina: though filing rates increase with family size, the share of applications filed in Argentina is only about 60 percent even at the very top of the distribution.

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13 Applications in the first decile of family size were filed in 3.8 countries on average; applications in the top decile were filed in 20 countries on average.

14 This is most likely a function of Argentina not being in the PCT, so applicants cannot take advantage of extended grace periods in deciding whether to file nationally. Applications filed in Argentina need to be received by the Argentine patent office within twelve months of the priority date.
Among other reasons, filing propensities are interesting since they can tell us about potential selection. Are countries where there are more restrictions on secondary patenting less likely to receive secondary applications? Figure 2 shows that in all countries, secondary filings are less likely than primary filings. However, this difference is actually smaller in India and Brazil (7 percentage points in both) than it is in any of the other countries. This is consistent with our earlier argument that decisions to file in India were made before 3(d) was implemented or anticipated, and the decisions to file in Brazil were made before ANVISA’s role in patent examination and its policy of restricting secondary applications was known.
4.2 Grant Rates: Overall

Next we examine grant rates for pharmaceutical patents in each country, conditional on filing. We count a PCT as “granted” in a country if any national stage application is granted there, including though continuations or divisionals.

Figure 3 shows that the US grant rate is 62 percent, the EP grant rate 51 percent, but the JPO rate is much lower, at 30 percent. Mexico grants 53 percent. South Africa has a grant rate of 100 percent, since it does not examine applications. Argentina, which does not receive as many applications as other countries, also grants many fewer conditional on filing, only about 13 percent.\footnote{Note that applications that are not granted are not necessarily rejected. This category includes applications that were withdrawn, or abandoned during examination. In some countries, it is difficult to distinguish between applications rejected on the merits versus those not granted for other reasons [Lemley and Sampat 2008]. Non-granted applications also include those that are pending, typically a small number given the timing of filings in our sample.}

What about India and Brazil? Despite recent criticism of India as a...
patent unfriendly country, the grant rate is not an outlier. The Indian grant rate is about 10 percentage points higher than the Japanese rate, but 10 percentage points lower than the EPO. By contrast, Brazil has the lowest grant rate in the sample, only 6 percent.

Grant rates are the result of several variables including the types of applications filed in a country, patent laws and guidelines, how laws and guidelines are enforced, and patent office processing speed. The level of applicant effort in pursuing an application also matters: some inventions are more important to firms than others.

Figure 3: Grants Rates By Country

One window on effort is family size: what do grant rates look like for applications that were filed more broadly? Figure 4 shows that in all countries, grant rates increase with family size. (The exception is South Africa, which grants everything.) In the US and EPO, more than 80 percent of applications in the top decile of the family size distribution are granted, and in Japan about 60 percent. The comparable figures for Brazil and India are 18 percent and 70 percent. In both Brazil and India, the likelihood of getting a patent increases for patents that are filed more broadly. But in India the likelihood is similar to that in developed countries at the top of the distribution. In Brazil it remains quite low even for these applications.
Filing rates represent the importance of applications to firms, but not necessarily patent “quality”. Figure 5 shows the share of applications filed in a country that are granted, as a function of how many of the other jurisdictions grant. This chart suggests international harmonization: as more and more other countries grant an application, the probability that any given country will do so increases. In most countries the share is almost one at the top of the distribution: with the exception of Brazil, few countries fail to grant applications that are granted by all other countries in our sample.
Figure 5: Grant Rates By Country and Number of Other Countries Granting
Of the 3,477 applications with U.S. filings, 38 percent were not granted, 32 percent were granted but not maintained, and 29 percent have been renewed to date. Figure 6 shows grant rates by these categories. In each of the countries, the grant rate is sharply higher for patents granted and maintained in the U.S. As it is reasonable to expect applicants to continue pursuing applications where the U.S. equivalents are not just granted but maintained, we interpret this as an indication of grant rates corresponding to some degree with effort on the part of applicants. However, while the Indian rate for patents granted and maintained in the U.S. is 65 percent (similar to Japan and Mexico) the Brazilian grant rate for these “important” patents remains less than 20 percent. We explore the latter in more detail when discussing detailed Brazilian outcomes, below.

### 4.3 Grant Rates: Secondary Applications

Next, we examined grant rates by application type. Figure 7 shows grant rates for secondary applications and primary applications. Despite the absence of formal policies or guidelines to restrict secondary patents, in the US, EPO, and Japan grant rates are lower for secondary patents than oth-
ers, with the largest difference (about 24 percentage points) in the US. In India, grant rates for secondary patents are actually slightly higher than for primary patents. But the differences are small, as in Brazil. This suggests that Section 3(d) and Prior Consent have little differential impact, a point we will explore in more detail below.

Figure 7: Grant Rates By Country and Whether Application is Secondary (1=Secondary; 0=Primary)

We also examined grant rates for secondary applications as a function of the number of other countries that grant them (Figure 8). In India, the vast majority of secondary applications granted by the seven other countries in our sample are granted, and the same is true of Brazil. If we focus on secondary applications granted by six of the eight countries in our set (excluding the influence of any individual outlier country), India grants about 80 percent of secondary applications, and Brazil about 20 percent.
4.4 Grant Rates: Twin Applications

One of the issues complicating cross-country comparison of grant rates is that some applications are not filed in all countries. It is possible, for example, that Brazil gets many more low-quality applications than Mexico, or vice versa. To ameliorate the influence of differential filing patterns on our results, we separately examined the 322 “twin” applications (of which about half are secondary) that were filed in all eight countries. By “twin” applications we mean national stage filings emanating from the same PCT application [Webster et al., 2007, Jensen et al., 2005, Sampat and Amin, 2013, Sampat and Shadlen, 2015b].

Figures 9 and 10 show results for primary and secondary twins respectively. In general, the results are consistent with what we have already seen. For secondary patents, India’s grant rate is the median across the countries in our set, similar to Mexico and Japan, but lower than the EPO or US. Brazil has the lowest grant rate. And in neither India nor Brazil is there a striking difference between primary and secondary grant rates. In the “twins” analyses the differential grant rate between primary and secondary applications
is highest in the US (26 percentage points), followed by Japan (12 percentage points), then the EPO (7 percentage points). Taking stock, in none of the analyses so far is there evidence that India or Brazil have differentially lower grant rates for secondary patents. This is in contrast to what we see for many of the countries without explicit restrictions on secondary patents, including the US, EPO, and Japan.

Figure 9: Grant Rates By Country, Primary Twins
Focusing on applications that “go national” in all three of the US, JPO, and EPO using the PCT may introduce some selection. We also examined the 516 applications filed in each of the developing countries that examine patents (i.e. excluding South Africa), regardless of whether they filed in the U.S., EPO, and Japan as PCT national stages or, instead, as national applications that were the bases for PCT filings in other countries.
Figure 11: Grant Rates By Country, Primary Four-Way Twins
Figure 12: Grant Rates By Country, Secondary Four-Way Twins

The results are similar, with Argentina as the only developing country with large differences in primary and secondary grant rates (Figures 11 and 12). Taken together, these grant-rate comparisons suggest that the restrictions on secondary patenting are not having a major effect on outcomes for secondary patents. We examine this more directly in the next section, where we examine detailed prosecution outcomes in India and Brazil.\footnote{We also examined differences in grant rates in a regression framework, which allowed us to control for application year. The basic story is similar to what we see from the charts, so we do not report the regression results here. We are currently collecting additional information on application characteristics that may vary within-country and within-PCT applications, including number of claims in the national filing, the timing of request for examination, and whether the applicant is foreign or domestic.}
4.5 Detailed Outcomes in India and Brazil

Beyond collecting the national stage applications, in India and Brazil we also collected detailed information on the prosecution of each application in our sample. As Appendix 3 details, for the 1269 PCT applications with Indian filings we collected information from all examination reports on whether 3(d) was cited as a ground, or the only ground, for rejecting a patent. For the 1822 Brazilian filings we collected information on the outcome of the application at the Brazilian Patent Office (INPI), and on what role ANVISA had in the examination process.

Figure 13 shows detailed outcomes in India. The grant rate is about 40 percent, as in Figure 4 above. A small number of applications (less than 4 percent) remain pending in India. About a quarter were withdrawn before examination: their prosecution could not directly have been affected by 3(d). Of the 357 applications that were rejected, the vast majority (259/357) were rejected without any mention of 3(d), typically on conventional patentability grounds (novelty, inventive step, etc.) Only 98 of the applications (8 percent of the total) include any 3(d) rejections. However, most of these are also include rejections on other (more conventional) patentability grounds. Only
four applications were rejected on 3(d) grounds alone.\footnote{Because some individual PCT applications spawn multiple national applications, including divisionals, the 1269 PCT applications in our sample with Indian filings yield 1382 distinct Indian applications.}

What about Brazil? There we examined whether applications were granted, pending, rejected, or withdrawn prior to the conclusion of examination (“Arquivado”) at INPI. While all granted applications would have been approved by ANVISA, none of the rejected (INR) or Arquivado (ARQ) applications would have been examined by ANVISA.\footnote{Pending applications are complicated by the introduction of a new workflow in 2012, whereby pharmaceutical patent applications go to ANVISA before INPI examines them. This means that pending applications may be at ANVISA awaiting initial examination, or at INPI awaiting examination after having been returned by ANVISA.} Applications that involved ANVISA and that ended up either rejected or arquivado are classified as Prior Consent Reject (PCR). In a few instances, which we call “frozen” (FRZ), ANVISA denied the application but INPI has not rejected them.\footnote{The applications we classify as frozen “FRZ” are pending, formally, but they could only be granted if ANVISA’s ruling is overturned through litigation or dual examination system itself is dismantled.}

Figure 14 shows the results. As already discussed, about 6 percent of Brazilian applications were granted. Many more remain pending in Brazil (about 10 percent) than in India, reflecting Brazil’s long backlog. The modal outcome in Brazil is withdrawal before the completion of examination (ARQ). Among applications that were rejected, the vast majority were rejected by the patent office itself (INR). Arquivado or rejected applications involving ANVISA (PCR) account for less than 2 percent of the applications overall, and only 9 percent (31 of 339) of rejected applications. Similar to India, the controversial provision restriction on secondary patents in Brazil has little direct effect on prosecution outcomes.

We see similar results if we focus only on secondary applications, or India-Brazil twins, omitted here for brevity.

As we discussed earlier, grant rates reflect effort in addition to quality. We also explored the US outcome for Brazilian applications that were abandoned (Arquivado). Of these, 41 percent were not granted in the U.S., and another 42 percent were granted but not maintained. This suggests that in the face of the long backlog, firms gave up in Brazil on many applications that were not granted abroad or were granted but later deemed to be not worth maintaining even in the U.S.
5 Discussion and Conclusion

Despite policies targeting secondary patents, the grant rates in India and Brazil for secondary patents are not different from grant rates for primary patents. This is in contrast to many patent offices without explicit restrictions on secondary patents, including the USPTO, JPO, and EPO. Indeed the difference between primary and secondary grant rates is largest in developed countries. This is interesting since policies restricting secondary patents were themselves responses to concerns that mimicking the lax patent standards in developed countries would lead to the grant of too many low quality patents.

One reason why we don’t see much of a difference in grant rates in India and Brazil emerges from the focused analyses of the patent prosecution process in these countries, which show that neither Section 3(d) nor ANVISA has had a direct role in prosecution outcomes in many cases.

One could interpret these results as evidence of ineffective implementation of the instruments to reduce secondary patenting. As we have suggested previously, there may be gaps between laws on the books and laws in practice [Sampat and Amin 2013, Sampat and Shadlen 2015b]. An important
line of research attributes such gaps to enforcement [Levitsky and Murillo 2009]. In the case of pharmaceutical patent examination, the technical and specialized nature of the field can impede enforcement by making it difficult for politicians to monitor and control the actions of patent offices [Drahos 2010, 2008].

The explanations for why Section 3(d) and ANVISA are having minimal direct roles are different in the two countries, however, as are the implications for subsequent research.

In India, the low utilization of 3(d) is consistent with standard accounts of under-enforcement. The fact that patent examiners are tied into global patent examination networks (through training and through access to prosecution materials), and face severe resource constraints, may limit the extent to which they employ 3(d) [Kapczynski 2009, Sampat and Amin 2013]. As a result, notwithstanding the attention that Section 3(d) has earned, the grant rates for secondary patents in India are comparable to those in developed countries, especially for more important applications and patents.

Our research—particularly the fact that nearly all rejections citing Section 3(d) also gave other grounds for denying the patent—also suggests that the actual scope for independent 3(d) rejections may be quite limited. To the extent that 3(d) is similar to more conventional patentability criteria, such as inventive step, then the limited use of 3(d) per se is not surprising. That said, there may be an important “fringe” of pharmaceutical applications, particularly regarding claims for formulations and compositions that could satisfy novelty and inventiveness requirements, where 3(d) could have independent force. Trying to identify the effects of 3(d) on particular types of applications and claims is a topic of our ongoing research.

The situation seems to be different in the case of Brazil. There, Prior Consent plays a minor role too, but this is largely because most of the work is done by INPI itself. A key feature of the Brazilian system is the large backlog of unexamined applications. Applicants simply tire of waiting, or move on to the next technology (e.g. after a molecule fails in human trials). As a result, few of the applications in our dataset were ever reviewed by ANVISA, for they were either rejected by INPI (under the old workflow) or withdrawn (arquivado) before examination was completed. Brazil’s dual examination system is not simultaneous but rather sequential, and examination rarely reached the second stage of the sequence. Thus ANVISA had little direct effect because it was rarely involved in examination. While, in theory, the backlog may itself be a function of the dual examination arrangements, it is present in all fields (not just pharmaceuticals) and the amount of time that applications stay at ANVISA is short.
Overall, the data suggest that Brazil’s patent system is more effective in limiting secondary patents than India’s, but the way it does so is not through Prior Consent but INPI itself. Here it is important to keep in mind that, despite the low grant rate, INPI’s rejection rate is not particularly high. Again, as discussed above, Brazil’s low patent rate is a function of the exceptionally long backlog and pendency rate. Yet this arrangement is widely regarded as unsustainable; not only does it generate intense opposition, but taking roughly twelve to fourteen years to examine patents is also counter-productive on account of the guarantee of 10 years of protection in the case of grants. Thus, while the backlog may filter out many applications, in the case of applicants that persist and, finally, get their patents, the system effectively increases patent terms. Indeed, a high priority among actors in Brazil (about the only thing that everyone seems to agree on) is to reduce the pendency rate. But if and when Brazil eventually addresses this aspect of the patent system and begins processing applications more quickly, then the way the country approaches applications for secondary patents will become more important.

Before concluding, we note the possibility that the overall grant rates used in this paper may be too blunt to capture the effects of 3(d) and Prior Consent. These instruments may play more important roles for more important inventions, for example. With such a low overall rates of use we are skeptical, but plan to explore heterogeneity more in subsequent research. Both 3(d) and ANVISA may also have important roles in narrowing the scope of granted patents, if not leading to rejections outright. This has been suggested in previous work\(^{20}\), and one we intend to explore by examining claim changes in detail for a subset of the application in our dataset.

Beyond India and Brazil, this paper presents what we believe to be the first cross-national comparison of pharmaceutical patent rates that includes numerous developing countries. There is interesting variation across countries that warrants further exploration. (For example: is the relatively low grant rate in Japan related to its deferred examination policy? Is the lack of filing in Argentina due to its non-membership in the PCT? How effective are Argentinian restrictions on new use patents? What role do continuations play in shaping U.S. grant rates? Do long backlogs effectively function as deferred examination systems?) But there is also convergence in outcomes for the more important applications: in all countries (except South Africa) national grant rates increase with application family size, and with the number of other countries granting.

\(^{20}\)See e.g. Silva 2006.
Exploring these dynamics, too, is the focus of ongoing research.

6 References

References


Appendix 1: A Sample of Twin Applications

Titles (to 80 characters) and first independent claim (to 160 characters) for US and Indian national stage applications emanating from 10 randomly chosen PCT Applications.

<table>
<thead>
<tr>
<th>PCT Number</th>
<th>US Title</th>
<th>India Title</th>
<th>US First Claim</th>
<th>India First Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCT/EP2002/08119</td>
<td>BIOSIMILAR INITIATIVES</td>
<td>BIOSIMILAR INITIATIVES</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, AND THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
</tr>
<tr>
<td>PCT/EP2002/084084</td>
<td>NOVEL PHARMACEUTICALS</td>
<td>NOVEL PHARMACEUTICALS</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
</tr>
<tr>
<td>PCT/EP2002/086327</td>
<td>TOPICAL APPLICATION OF ISOTONAL SOLUTIONS</td>
<td>TOPICAL APPLICATION OF ISOTONAL SOLUTIONS</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
</tr>
<tr>
<td>PCT/EP2002/087883</td>
<td>BIS-PYDROXALINE COMPOUNDS</td>
<td>BIS-PYDROXALINE COMPOUNDS</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
<td>COMPOSITION OF THE POLYMERIC FORMULA (I) IN WHICH R1 IS A POLYPEPTIDE OR A PEPTIDE, OR R2 IS A POLYPEPTIDE OR A PEPTIDE AND THE POLYPEPTIDE OR THE PEPTIDE, OR THE POLYPEPTIDE OR THE PEPTIDE, IS IDENTIFIED OR IDENTIFIES, REPRESENT A POLYPEPTIDE OR A PEPTIDE</td>
</tr>
<tr>
<td>PCT/EP2002/088322</td>
<td>NOVEL THERAPEUTIC METHOD</td>
<td>NOVEL THERAPEUTIC METHOD</td>
<td>USE OF A THERAPEUTIC AGENT IN COMBINATION WITH AN ANTIETHERAPIC AGENT FOR THE TREATMENT OF A DISEASE</td>
<td>USE OF A THERAPEUTIC AGENT IN COMBINATION WITH AN ANTIETHERAPIC AGENT FOR THE TREATMENT OF A DISEASE</td>
</tr>
</tbody>
</table>

Appendix 2: Coding Guide

A coding guide was provided to the two coder to categorize the 5,193 PCT applications. It is adapted from a guide designed by Scott Hemphill that was used to code US patent grants [Hemphill and Sampat, 2011]. Below, we excerpt the first page of the coding guide.

General: We want to code the information in the published application (the WO document). To do so, click through the link provided for each application, which will take you to the Google transcription of the application. (This is useful since Google typically does translation for us, and the layout is pretty clean.) If you need the actual PDF file, you can access it through the PatentScope and/or Espacenet links provided in the Google patent file. We anticipate you will use information in the independent and dependent
claims for the coding, supplemented by information in the title, abstract, description as needed. If you use any information beyond this please indicate this in the notes field.

Coding: Our main goal is to code applications by type. There are five broad categories of claims. A patent can, and often does, include more than one category of claims:

- A: active ingredient (see specific descriptions of A1-A4 below)
- B: formulation or composition
- C: method of use
- D: other, but related to the drug
- E: biologic

For each patent, indicate all categories that apply to a patent. For active ingredient claims, we want to distinguish the four subcategories:

- A1: active ingredient.
- A2: is for polymorphs or other crystal forms.
- A3: is for enantiomers or other isomers.
- A4: salt, metabolite, or intermediate. Also pre-metabolites and derivatives

9 Appendix 3: Identifying National Stage Application Numbers and Outcomes

9.1 The EPO, JPO, and US

We obtained EPO, JPO, and US national stage numbers from the WIPO Statistical Database, the same source we used to construct the basic dataset. We also obtained outcomes data from PATSTAT. For a random sample of 100 applications, we verified these sources provided essentially identical grant rate information as was determinable from the EP Register, the JPO Website, and USPTO Public PAIR. The U.S. grant rate calculated from PATSTAT is based on all grants from a given priority, so includes grants to all “child” applications (continuations) which we also verified against PAIR.
9.2 India

We obtained national stage applications in India from PatentScope, and Indian outcomes from the IPO Website. We considered an Indian application to be withdrawn if the status on the IPO website is Withdrawn without stated reason, or withdrawn under 11(B)4. Section 11(B)4 withdrawals are those where no request for examination was made. Given the time elapsed since filing, we assume that applications Not Yet Published were withdrawn before examination. We also grouped a small number Section 9(1) abandonments as withdrawals: these are cases where a complete specification was not filed.

We consider applications as Rejected if they were abandoned under Section 21(1). Section 21(1) abandonments are typically those where there was a failure to respond to objections in a FER within the time limits prescribed. Our logic here is that these applications were abandoned because of the examiner’s objections. It is also possible, of course, that the lack of response was for other reasons (e.g., the firm went out of business, the technology no longer interesting to the firm, or problems with the application were discovered at another patent office. Accordingly our analysis overstates rejection rates. Refusals through Controller decisions (including those indicated as Section 15 and 16 rejections) were also classified as rejections. Refusals through Controller Decisions result when a controller is unsatisfied with an applicants response to the FER and/or the Controller refuses an application where there is a pre-grant opposition. As discussed more below, we focus on these 218 Rejected cases when we examine how 3(d) is affecting rejection rates.

We considered any application that was Awaiting Examination or Under Examination as Pending. The majority of those we call pending (26/36) are Awaiting Examination. Given that RFE must be filed by now we could have also grouped these with withdrawn applications. Doing so would not affect calculation of grant rate or our assessment of the role 3(d).

How might 3(d) affect whether or not an application is granted? In the process described above, 3(d) could directly lead to rejections in three main ways: (1) The examiner raises 3(d) in an FER, resulting in abandonment of the application, or (2) The controller raises 3(d) on reviewing arguments from response to FER, generating a rejection, or (3) A pre-grant opposition raises 3(d) objections, which are upheld in a Controller Report rejecting the application. Importantly, withdrawals of applications before RFEs are filed cannot be directly due to 3(d), since there are no examination documents prior to RFEs.
To examine the direct role of 3(d) in rejections, we collected information from FER and Controller Reports for applications that have rejections on the merits on the role of 3(d). This set includes all non-granted applications, except those withdrawn before a request for examination was made. For each of these “Rejected” applications we determined if 3(d) was listed as a reason for rejection, and, if so, if this was the only grounds for rejection.

9.3 Brazil

We obtained Brazilian national stage application numbers from the Derwent World Patents Index (and verified against information from PATSTAT). We obtained Brazilian outcomes by searching the INPI website. We dropped a small number of applications where PCT information on the national website did not match the original PCT number.

Coding outcomes in Brazil is also complicated because of the nature of Brazil’s pharmaceutical patent system. As discussed in the text, Brazil has a shared examination system, with pharmaceutical patent applications examined by both the National Institute for Industrial Property (INPI) and the Ministry of Health’s health surveillance agency (ANVISA). According to the Brazilian patent law (reformed in 2001), pharmaceutical patents can only be granted if both INPI and ANVISA approve. In the first step of this system, INPI receives and examines a patent application. If INPI determines that the patent should not be granted, then it is rejected and the process ends. However, if INPI determines that the patent should be granted, the application is then passed to ANVISA. In such cases ANVISA examines the application and INPI’s technical report, often requesting additional material from the patent office and the applicants. If ANVISA issues its consent INPI then grants the patent, and if ANVISA decides that the patent should not be granted it notifies INPI (and the applicant) of this decision. Though ANVISA lacks the legal authority to reject patents, INPI can only grant patents where ANVISA has given its Prior Consent. As of May 2012 the workflow was inverted, such that INPI sends all pharmaceutical patent applications to ANVISA, where they are given an initial review and then returned to INPI for subsequent examination.

To track outcomes, and to see ANVISA’s role in outcomes, we searched all applications at both INPI and ANVISA. The INPI website provides data on each transaction that occurs during the course of examination. We also consulted two ANVISA documents that indicate the actions that the health agency has taken on each application it has received under the old workflow (through May 2012) and the new workflow (since May 2012). Using data
from these two sources we determined whether Brazilian patent applications were granted, pending, or rejected, and ANVISA’s role.

Granted patents (GRA) were approved by INPI, given “anuencia” by ANVISA, and then granted by INPI. Applications with non-grant final determinations may be rejected or “arquivado.” For applications rejected by INPI, we determined whether the application was rejected by INPI alone, in which case it would not have been forwarded to ANVISA, or whether ANVISA was involved. Applications rejected solely by INPI are recorded as INPI Rejected (INR). Arquivado (ARQ) refers to applications that were classified as archivado by INPI, ordinarily on account of applicants not responding to INPI communication or not paying fees. Neither INPI Rejected nor Arquivado involves ANVISA directly. Prior Consent Reject (PCR) refers to applications with final determinations of either reject or archivado that, at some point in the process, were received by ANVISA. This includes applications initially approved by the INPI and sent to ANVISA, but where ANVISA did not consent to a grant and the INPI subsequently rejected the application. This also includes applications initially approved by the INPI and sent to ANVISA, but where in the course of ANVISA examining the application became arquivado at INPI. And it includes applications where ANVISA finished its examination and denied consent, but rather than being rejected by INPI ended up arquivado. In each instance we code these as PC (Prior Consent) Reject: if an application was received by ANVISA and ended with a non-grant final determination (reject or arquivado), we code this as PC Reject. Pending (PEN) applications lack final determination. This includes “frozen” (FRZ) applications where ANVISA denied anuencia but INPI held without rejecting, and have not been arquivado.

9.4 Mexico

As in Brazil, we obtained national stage application numbers from DWPI, and verified against PATSTAT. We dropped a small number of applications where PCT information on the national website did not match the original PCT number.

In Mexico, the patent office website (IMPI/SIGA) does not report examination outcomes, but rather the specific gazette in which the application is published. All of the applications are published in the “applications” gazette. If an application is also published in the “patents” gazette then we know it is granted. If an application is also published in the “free use” gazette, then we know that it has a non-granted final status, either abandoned, withdrawn, or rejected (it is not possible to distinguish). If an application is not pub-
lished in the either the “patents” or “free use” gazette, i.e. it is only in the “applications” gazette, we classify it as pending. These steps allowed us to classify applications in Mexico in one of three categories: GRA (granted), RWA (rejected, withdrawn, abandoned), PEN (pending). In the analyses in this paper we focus only on whether the applications are granted.

9.5 Argentina

For Argentina, we used information from PATSTAT on all national filings. (Recall that Argentina is not a PCT country, so there are no “national stage” filings.)

We obtained from the Argentinian patent office (INPI) a dataset of all patent applications filed in Argentina from 2000-2005, with bibliographic and priority details, as well as information on final status. We then matched these against the Argentinian application numbers in PATSTAT to determine which of the applications in our sample were filed in Argentina. For Argentina (as Mexico), we have three outcomes: granted, non-granted with final disposal (rejected, withdrawn, abandoned), and pending, though in practice we focus only on whether the application is granted.

9.6 South Africa

For South Africa, we used DWPI and PATSTAT for national stage applications. Since South Africa has a registration system (no formal patent examination) searching for outcomes was not necessary: we assume any applications filed there are granted. On searching a sample we did identify a small number of applications whose status was “lapsed,” but on inspection these lapsed after issue (for non-payment of fees).

10 Appendix 4: Robustness Using DWPI Based Measures of Whether a Patent Application is “Secondary”

Our analyses rely on expert coding of applications. While this has the advantage of allowing for nuanced coding, a disadvantage is that the codings have a subjective component, and the methodology not easily replicated.

In this Appendix, we present results based on another approach to coding, using the “Novelty” information for each application from the Derwent World Patents Index, which is based on what, based on DWPI coders’ reading, the
“inventor alleges distinguishes the current invention from existing technology in the field.”

After inspecting patents coded by a former US pharmaceutical patent examiner (based on US patents for drugs that had first generic entry in US between 2000 and 2011; Hemphill and Sampat 2012) to DWPI entries for these same patents, we determined that most “primary” patents (novel active ingredients) had DWPI novelty statements that:

1. Include a chemical formula or the word “formula”

2. Include the words “is new”, but

3. Do not begin with the words “use” “derivative” “treatment” or “composition.”

With this simple algorithm, applied to this set of patents, 71 percent of active ingredient patents (based on the expert coding) are correctly categorized as such, and 82 percent of secondary patents (based on the expert coding) are correctly categorized as such.

We also examined how this would work in other samples, including a set of 1000 patents on the Orange Book which was also coded as to novel AI or not (Hemphill and Sampat 2011). In this set 85 percent of secondary patents are categorized as such by this algorithm, and 66 percent of primary are. Overall, 80 percent of the patents are correctly categorized using this approach.

When we apply this “secondary” coding based on DWPI to our sample of PCT applications, we find that 61.8 percent of the applications are secondary, as compared to 62.2 based on expert coding used in the main analyses. The DWPI coding and expert coding agree 77 percent of the time. Of those our coder called secondary, the DWPI coding suggests 81 percent were secondary. Of those our coder called primary, our codings based on DWPI categorize 70 percent as primary. This indicates substantial agreement between the expert coding and coding based on DWPI categories.

To assess how our results would change if we used DWPI coding instead, we replicate overall grant rates for primary/secondary and those for twins only using DWPI coding instead. The results (below) are broadly similar to those in the main text:
Figure 15: Grant Rates By Country and Whether Application is Secondary (1=Secondary; 0=Primary) Based on DWPI Coding
Figure 16: Grant Rates By Country, Primary Twins Based on DWPI Coding
Figure 17: Grant Rates By Country, Secondary Twins Based on DWPI Coding