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

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Abstract

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduced unprecedented convergence in national patent policies. Prior to TRIPS few developing countries granted pharmaceutical product patents, though all but the very poorest are now required to do so. As countries established pharmaceutical patent systems, some have introduced measures designed specifically to address "secondary" patents, which can increase periods of exclusivity. Policies restricting secondary patenting aim to ameliorate the perceived harmful effects of TRIPS. The two most prominent examples of such policies are in India and Brazil. While the Indian and Brazilian policies have received a great deal of attention, cited as both models to emulate and avoid, little is known about their effects on patent examination outcomes. This paper offers the first large-sample empirical analysis of the effects of restrictions on secondary patents. We follow the filing and granting of over 5,000 drug patent applications filed in India, Brazil, and six other developing and developed countries, we code the claims of each application as secondary or primary, and we analyze how national grant rates for these two types of patents differ. In India and Brazil we also undertake detailed examination of the patent prosecution processes to examine the specific roles of these countries' policies. We find that

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.

1 Introduction

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduced unprecedented convergence in national patent policies. Historically, 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].

Pharmaceuticals is an area where the convergence inspired by TRIPS has drawn a great deal of attention. 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 becoming 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 Commission, 2009]. 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 has interpreted its role in the prosecution process to be to limit 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 proposed draft of the Trans-Pacific Partnership (TPP) agreement includes provisions to limit restrictions on secondary patents.[1]

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]. A study examining Indian and Brazilian patent applications on about 150 drugs launched between 1996 and 2004 with at least one U.S. patent, found these provisions were rarely used [Sampat and Shadlen, 2015b]. 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). Moreover, that study was only able to ensure similarity of the Brazil and Indian applications for a small number of cases, making comparing grant rates on secondary patents difficult. Most importantly, by focusing only on India and Brazil there was no baseline against which to assess grant rates for secondary patents.

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 characteristics of which applications that are filed in particular countries, 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.

[1] `http://infojustice.org/archives/32152`

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 some observers suggest 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.[2] 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.

[2]The following four paragraphs draw on our previous work [Sampat and Shadlen, 2015b].

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.[3]

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.[4] 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 [Amin and Kesselheim, 2012]. For all of these reasons, once patents are granted they may be particularly difficult to remove in

[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].

[4]This would be true even if there were exclusivity "bounties" for successful challengers in other jurisdictions, which to our knowledge there is not.

developing countries.

Rather than relying on post-grant litigation to invalidate 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 [2008], prevention is better than 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 [Jaffe and Lerner, 2011, Hemphill and Sampat, 2013]. 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 [Qian, 2007] or global [Kyle and McGahan, 2012] innovation incentives. If this is correct, it would seem that restrictions on *secondary* patents would only have a second-order effect on multinational firms' innovation incentives for new molecules.[5]

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

[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.

> 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) [Sampat and Shadlen, 2015a, Sampat et al., 2012]. The Novartis case galvanized opposition to 3(d) from the pharmaceutical lobby and developed countries, and also vigorous defense of the provision 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 of the Prior Consent system that was 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 of this decision. Although ANVISA lacks the legal authority to reject patents, INPI can only grant patents where ANVISA approves.

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, Basso, 2006].

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.[6]

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 [Correa and Matthews, 2011, UNAIDS, 2011, South Centre, 2011]. 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 2003, soon after introducing pharmaceutical product patents in 2000, more recently adopted new examination guidelines to restrict most forms of secondary patents [Bensadon and Echague, 2014, Witthaus, 2003]. 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.

[6]The authority of ANVISA to make patentability decisions has been challenged in the Brazilian courts. These challenges led to a new workflow as of 2012 where ANVISA evaluates applications first, before sending them to INPI.

3 Data and Empirical Approach

3.1 PCT applications

The majority of global pharmaceutical patent applications on important drugs are filed through the Patent Cooperation Treaty (PCT), which allows for single applications to be deposited in multiple jurisdictions after underdoing preliminary analysis by an International Searching Authority. Accordingly, our analysis focuses on "national stage" applications in each country that emanate from PCT applications.[7]

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.[8] Applying these criteria leaves us with 15, 815 applications.

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

[7] In the case of non-PCT member Argentina, we use the equivalents of the "national stage" filings, as we explain in more detail below.

[8] In the US, about a quarter of the applications filed at the patent office then "go national" in the US via the PCT. These are typically based on provisional priority applications that get abandoned. In Japan roughly half of the applications filed at the JPO also have national-stage PCT entries at the JPO. The case of Europe is more complicated. Often applicants initially file at national patent offices, e.g. Germany or UK, and then, when the applications are converted into PCT applications, they have EPO "national stage" designations. Even when applicants' initial filings are directly at the EPO, these too typically return to the EPO as "national stage" filings, so-called "Euro-PCT" applications.

drugs. To solve these problems, we consulted 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 applications.

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.

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.)

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 8 percent of the applications contained only process claims. We drop these, since our focus is on product patenting. Of the remaining 4765 applications, 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).

We 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; $p<.01$). In the Appendices, we also examine robustness of our main results to using an alternate measure of whether a patent is primary or secondary, using expert codings from DWPI.

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.[9]

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, Jaffe and Lerner, 2011] and also allows for continuation applications (in pharmaceuticals and other fields) which can complicate grant rate calculations.[10] The Japanese Patent Office (JPO) and European Patent Office (EPO) have deferred examination systems, though of different lengths. 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, 2012].

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

[9] This is not a conventional difference-in-difference analysis since there is no time dimension.

[10] In our empirical analyses, we calculate U.S. grant rates accounting for outcomes on any continuation applications.

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 (47 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 43 percent of the PCTs in our sample had national stage applications in Mexico, 36 percent in Brazil, 26 percent in South Africa, and 24 percent in India. In Argentina there were national applications linked to 20 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.[11] 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.[12]

[11] 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.

[12] 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. Applica-

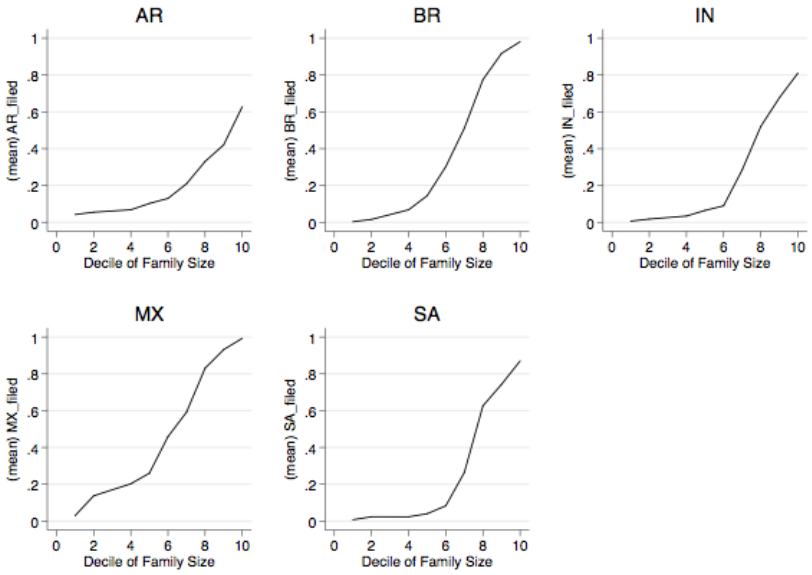

Figure 1: Filing Rates By Country and Family Size

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 Argentina or Mexico, and similar to that in South Africa (which essentially grants all patent applications). 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.

tions filed in Argentina need to be received by the Argentine patent office within twelve months of the priority date. That is, at the time that applicants are deciding whether to convert their national applications into PCT applications (to then, up to thirty months later, decide which countries to file), they have to decide if they wish to file in Argentina.

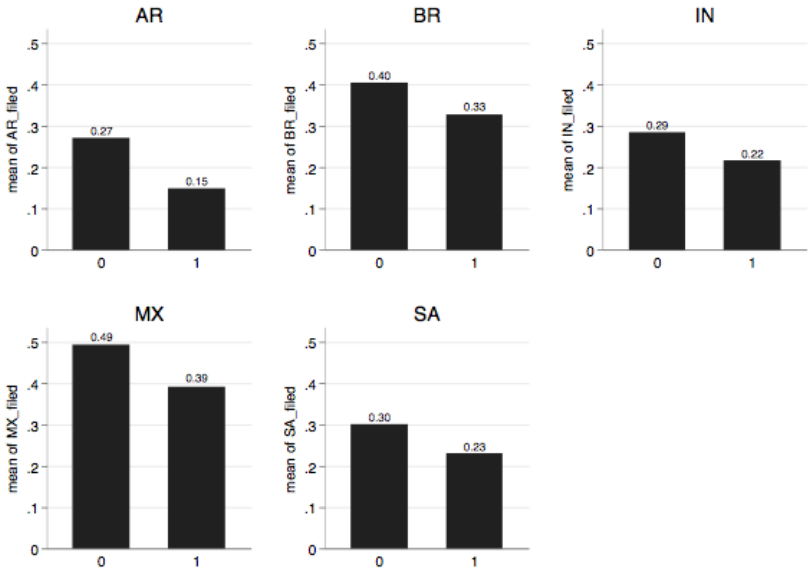

Figure 2: Filing Rates By Country and Secondary (1=Secondary; 0=Primary)

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 61 percent, the EP grant rate 51 percent, but the JPO rate is much lower, at 29 percent. Mexico grants 53 percent. South Africa has a grant rate of 93 percent. Since South Africa does not examine applications the only applications not granted there are those withdrawn during the examination process due to failure to pay issue fees, and (a very small number) applications still pending. Argentina, which does not receive as many applications as other countries, also grants many fewer conditional on filing, only about 12 percent.[13]

[13]Note that applications that are not granted are not necesssarily rejected. This category includes applications that were withdrawn, or abandoned during examination. 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 12 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 5 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.

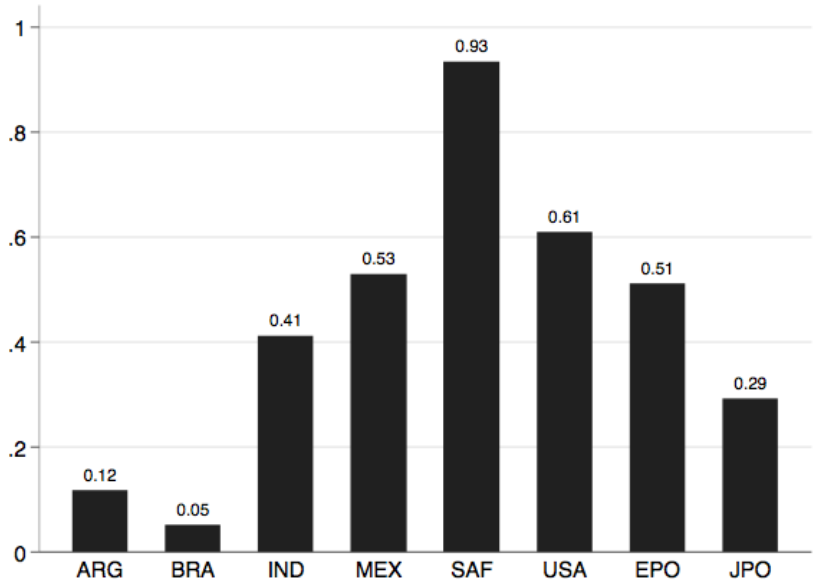

Figure 3: Grants Rates By Country

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. 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.

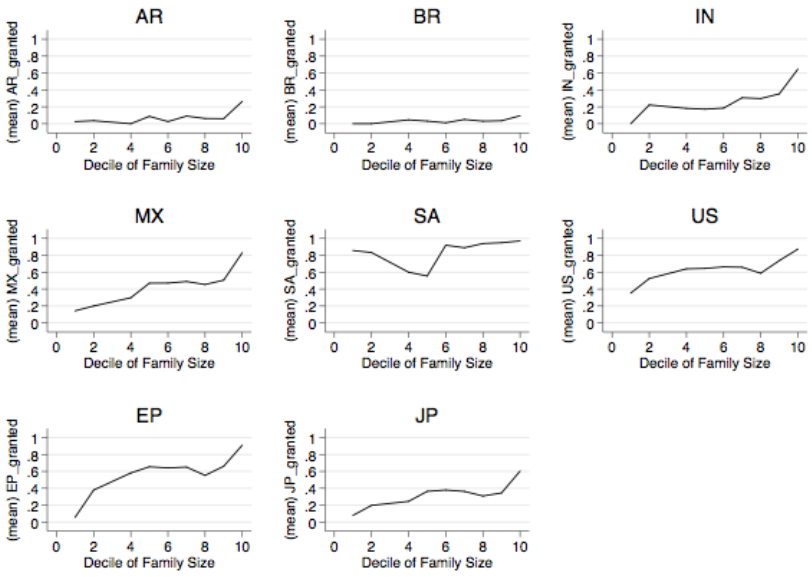

Figure 4: Grant Rates By Country and Family

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. (There are small drop offs at the very top of the distribution for some countries, including India and South Africa, but these are based on a very small number of applications – those granted by all other countries.)

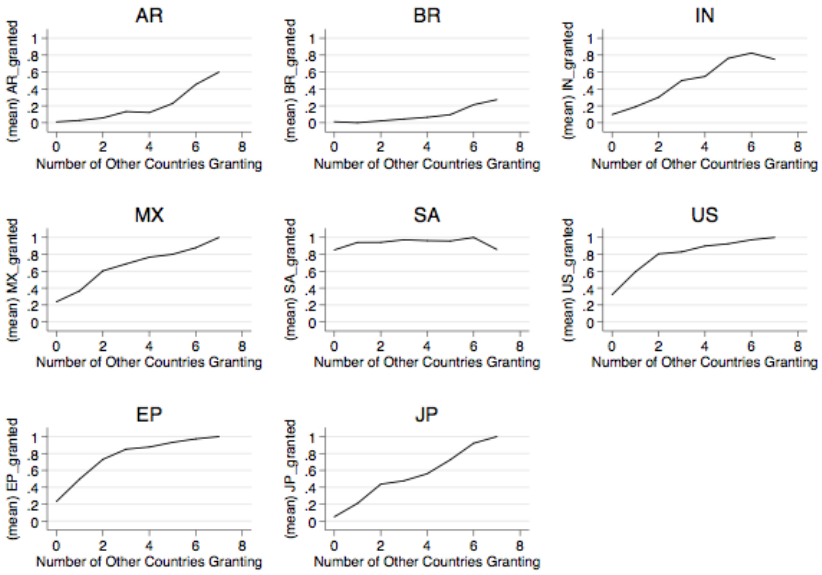

Figure 5: Grant Rates By Country and Number of Other Countries Granting

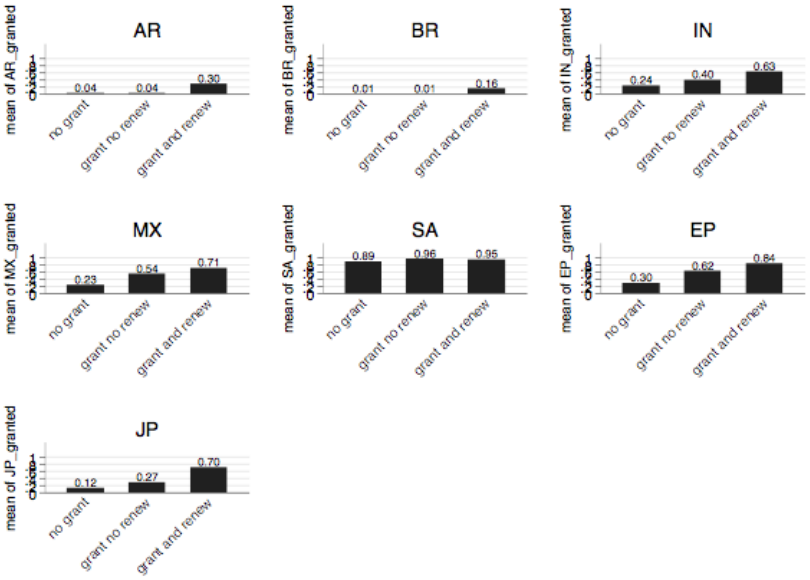

Figure 6: Grant Rates By Country and US Status (US filed applications only)

Of the 3,184 applications with U.S. filings, 39 percent were not granted, 32 percent were granted but not maintained, and 29 percent have been renewed to date. Figure 6 shows other countries' grant rates by these three U.S. outcomes. In countries except South Africa 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 interpet 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 63 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 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 others, 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.

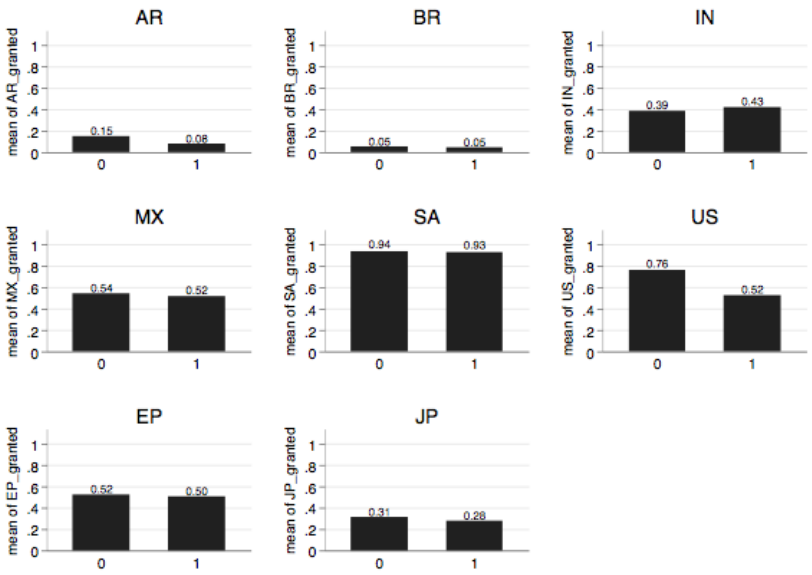

Figure 7: Grant Rates By Country and Whether Application is Secondary (1=Secondary; 0=Primary)

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 290 "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 8 and 9 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 (27 percentage points), followed by Japan (19 percentage points), then the EPO (10 percentage points). In India and Brazil the differences are 4 percentage points and 2 percentage points respectively.

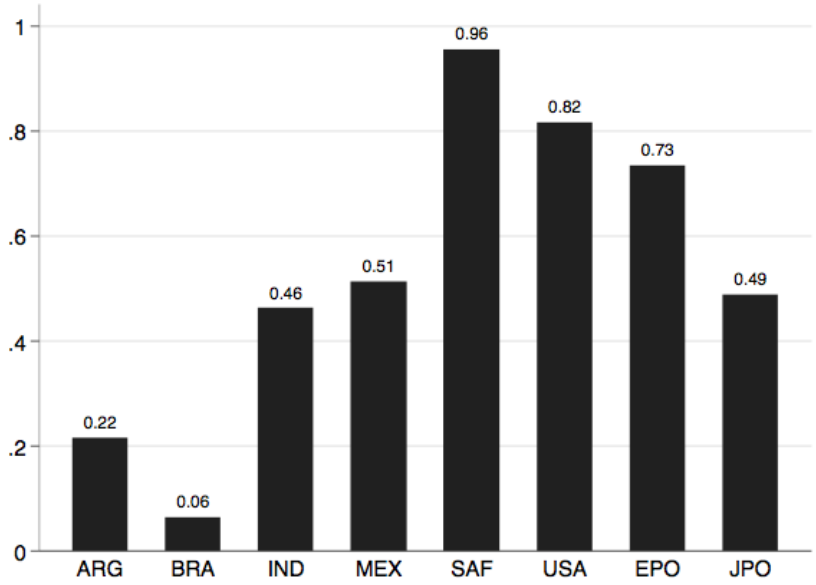

Figure 8: Grant Rates By Country, Primary Twins

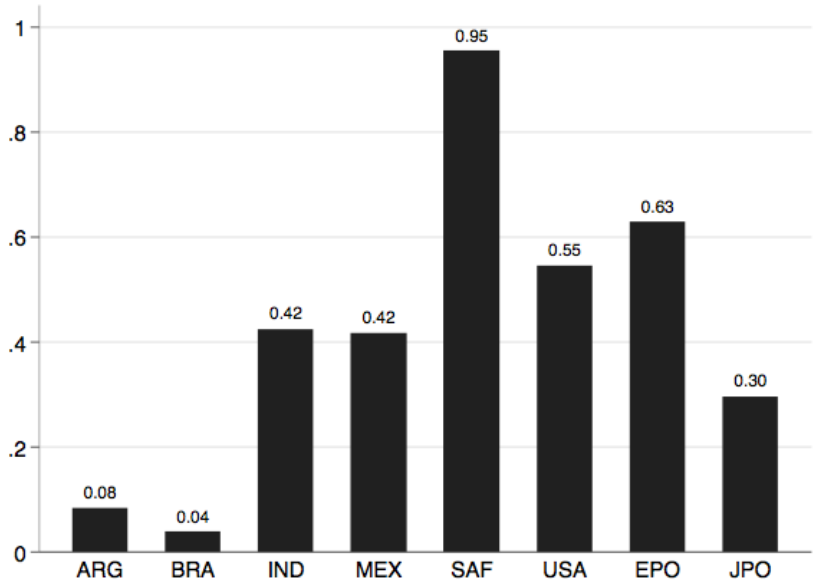

Figure 9: Grant Rates By Country, Secondary Twins

Focusing on applications that "go national" in all three of the US, JPO, and EPO using the PCT may introduce some selection. (E.g., Applications with initial US filings that do not also have US national entries may be systematically different.) We also examined the the 492 applications filed in each of the developing countries that examine patents: Argentina, Brazil, India, and Mexico. This set includes developing country filings regardless of whether they filed in the U.S., EPO, and Japan as PCT national stages or, instead, only as national applications that were the bases for PCT filings in *other* countries.

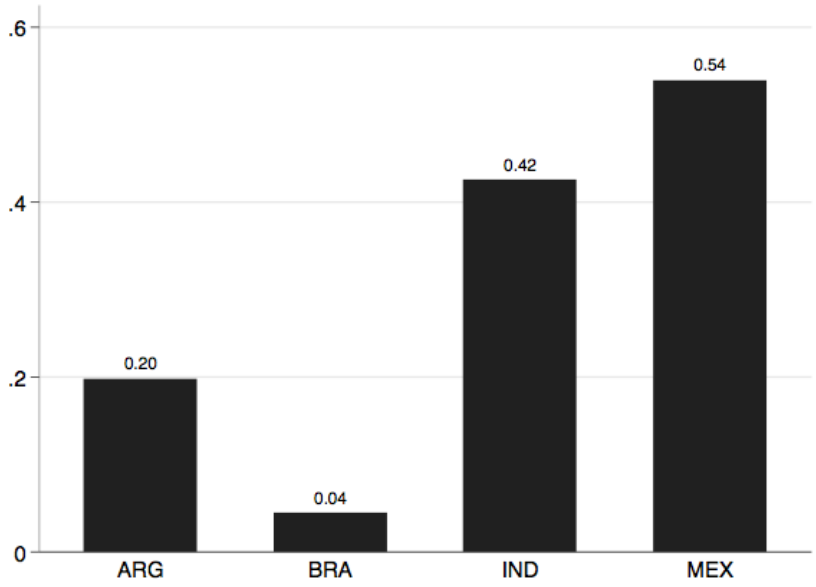

Figure 10: Grant Rates By Country, Primary Four-Way Twins

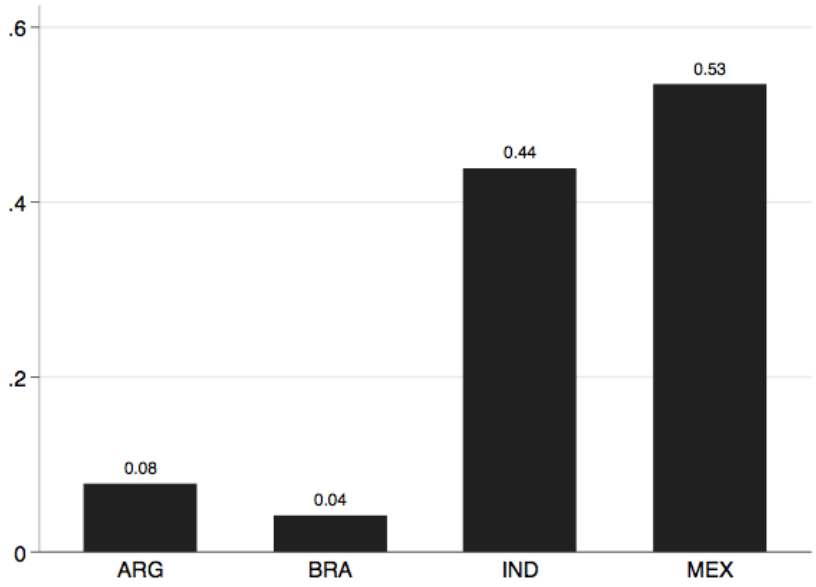

Figure 11: Grant Rates By Country, Secondary Four-Way Twins

The results are similar, with Argentina as the only developing country with large differences in primary and secondary grant rates (Figures 10 and 11). Taken together, these grant-rate comparisons suggest that the restrictions on secondary patenting in India and Brazil 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.

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 1256 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 1699 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.

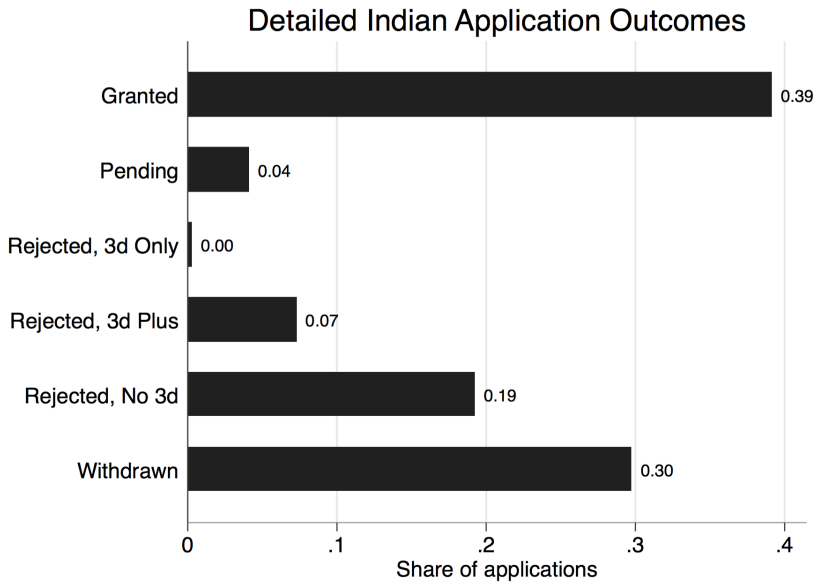

Figure 12: Detailed Indian Outcomes

Figure 12 shows detailed outcomes in India. The grant rate is about 40 percent, as in Figure 4 above. A small number of applications (4 percent) remain pending in India. About 30 percent were withdrawn before examination: their prosecution could not directly have been affected by 3(d). Of the 338 applications that were rejected, the vast majority (242/338) 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.[14]

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.[15] Applications that in-

[14]Because some individual PCT aplications spawn multiple national applications, including divisionals, the 1269 PCT applications in our sample with Indian filings yield 1382 distinct Indian applications.

[15]Pending applications are complicated by the introduction of a new workflow in 2012, whereby pharmaceutical patent applications go to ANVISA before INPI examines them.

volved 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.[16]

Figure 13 shows the results. As already discussed, about 5 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, or "arquivado"). Among applications that were rejected, the vast majority were rejected by the patent office itself (INR, or "INPI reject"). Arquivado or rejected applications involving ANVISA (PCR) account for less than 2 percent of the applications overall, and only 9 percent (28 of 323) of rejected applications. Similar to India, the controversial provision restriction on secondary patents in Brazil has little direct effect on prosecution outcomes.[17]

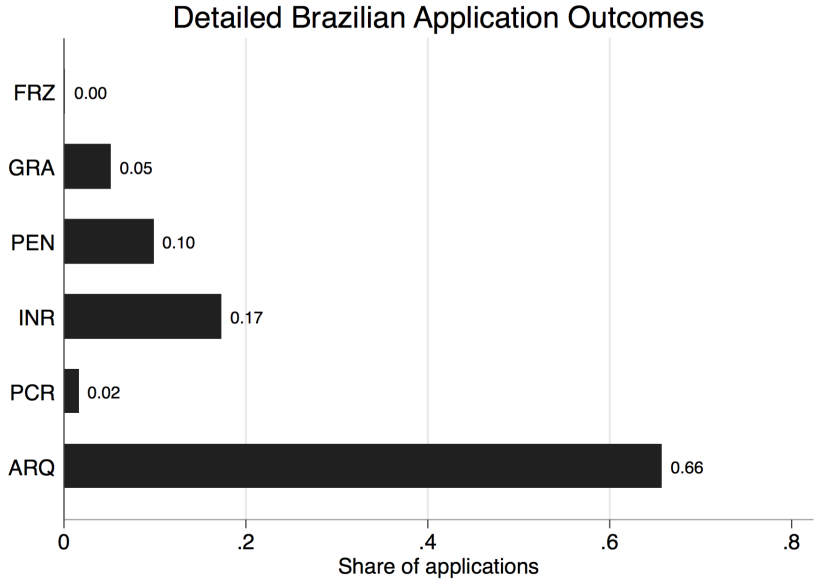

Figure 13: Detailed Brazilian Outcomes

This means that pending applications may be at ANVISA awaiting initial examination, or at INPI awaiting examination after having been returned by ANVISA.

[16]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 the dual examination system itself is dismantled.

[17]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 or withdrawn (Arquivado). Of these, 41 percent were not granted in the U.S., and another 41 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. One interpretation of this is that the backlog is serving as a filter, akin to a deferred examination system.

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.

Our focused analyses of patent prosecution processes in India and Brazil help us understand why there are not large differences between the primary vs. secondary grant rates in these countries. In most cases, neither Section 3(d) nor the Prior Consent system, the two mechanisms that are expected to limit secondary patents, had direct roles in determining the examination outcomes.

One could interpet these results as evidence of ineffective implementation of the instruments to reduce secondary patenting. 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 Prior Consent 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 is 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. Brazil's dual examination system is not simultaneous but rather sequential, and examination rarely reached the second stage of the sequence. 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. Thus Prior Consent appears to have had little direct effect because ANVISA 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, 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 because of another aspect of Brazil's patent system: the guarantee of a minimum 10 years of protection when applications are granted. Thus, while the backlog

may filter out many applications, for applicants that persist and finally get their patents, it effectively *increases* patent terms. Indeed, a high priority among virtually all actors in Brazil 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.

Another country in our analysis that has restrictions on secondary patents is Argentina. As noted, Argentinas patent office does not grant patents on second medical uses, and since 2012 examination has been informed by more restrictive guidelines that aim to reduce secondary patents more systematically. In contrast to India and Brazil, Argentina does exhibit notably lower grant rates for secondary patents, suggesting that efforts to limit secondary patents may indeed be more effective in this country. Yet the restrictions in place for most of the time period were limited to one particular type of secondary patent (new medical uses), while the broader and more restrictive guidelines have not been in effect for long. We also recall that, because Argentina is not a member of the PCT, the propensity to file in Argentina is lower, and that is so even for the most important applications. Thus, while the data reveal that Argentina has a comparatively low grant rate, overall and for secondary patents, the drivers of these patterns are not clear from the research to this point. Understanding the determinants of patent rates in Argentina, and in particular the specific effects of the Argentinian approach to secondary patents, is an area for ongoing research.

Before concluding, we note the possibility that the overall grant rates used in this paper may be too blunt to capture all of 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 Prior Consent 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[18], and one we intend to explore by examining claim changes in detail for a subset of the application in our dataset.

[18] See e.g. Silva et al. [2008].

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7 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.

PCT Number	US Title	India Title	US First Claim	India First Claim
PCT/EP2002/003119	BIGUANIDE DERIVATIVES	BIGUANIDE DERIVATIVES	COMPOUNDS OF THE GENERAL FORMULA (I) IN WHICH: R1 AND R2, WHICH MAY BE IDENTICAL OR DIFFERENT, REPRESENT A BRANCHED OR UNBRANCHED (C 1 -C 6)ALKYL CHAIN, OR R1	OMPOUNDS OF THE GENERAL FORMULA (I) R2 R4 I H I R1,N N N R3 (I) NH NH IN WHICH: R1 AND R2, WHICH MAY BE IDENTICAL OR DIFFERENT, REPRESENT A BRANCHED OR UNBRANCH
PCT/EP2002/003984	NOVEL THERAPEUTIC INDICATION OF AZITHROMYCIN FOR TREATMENT OF NON-INFECTIVE INFL	A METHOD FOR PRODUCTION OF PHARMACEUTICAL COMPOSITION CONATINING AZITHROMYCIN FO	A METHOD FOR TREATING NEUTROPHIL-DOMINATED, NON-INFECTIVE INFLAMMATORY DISEASES IN HUMAN BEINGS AND ANIMALS COMPRISING ADMINISTERING TO SAID HUMAN BEINGS AND AN	USE OF AN ACTIVE INGREDIENT SELECTED FROM THE GROUP CONSISTING OF AZITHROMYCIN, A PHARMACEUTICALLY ACCEPTABLE DERIVATE THEREOF, A PHARMACEUTICALLY ACCEPTABLE HY
PCT/EP2002/004438	NOVEL PHTHALAZINONES	NOVEL PHTHALAZINONES	(ORIGINAL) COMPOUNDS OF FORMULA I IN WHICH R1 IS 1-2C-ALKOXY OR 1-2C-ALKOXY WHICH IS COMPLETELY OR PREDOMINANTLY SUBSTITUTED BY FLUORINE, R2 IS FLUORINE, BROMIN	COMPOUNDS OF FORMULA I (FORMULA REMOVED) IN WHICH R1 IS 1-2C-ALKOXY OR 1-2C-ALKOXY WHICH IS COMPLETELY OR PREDOMINANTLY SUBSTITUTED BY FLUORINE, R2 IS FLUORINE,
PCT/EP2002/004924	SELECTIVE ANTHRANILAMIDE PYRIDINE AMIDES AS INHIBITORS OF VEGFR-2 AND VEGFR-3	ANTHRANILIMIDE PYRIDINE AMIDE COMPOUNDS OF GENERAL FORMULA 1	COMPOUNDS OF GENERAL FORMULA I IN WHICH A, B AND D, INDEPENDENTLY OF ONE ANOTHER, STAND FOR A NITROGEN OR CARBON ATOM, WHEREBY AT LEAST ONE NITROGEN ATOM IS CON	COMPOUNDS OF GENERAL FORMULA I (FORMULA REMOVED) IN WHICH A, B AND D, INDEPENDENTLY OF ONE ANOTHER, STAND FOR A NITROGEN OR CARBON ATOM, WHEREBY AT LEAST ONE NI
PCT/EP2002/006327	TOPICAL APPLICATION OF THIAZOLYL AMIDES	TOPICAL APPLICATION OF THIAZOLYLAMIDES	A TOPICALLY APPLICABLE PREPARATION COMPRISING FROM 0.1 TO 99% BY WEIGHT OF A COMPOUND OF THE GENERAL FORMULA (I) IN WHICH R 1 IS HYDROGEN, HALOGEN, (C 1 -C 6)-	A TOPICAL PREPARATION COMPRISING FROM 0.5 TO 20% BY WEIGHT OF THIAZOLYL AMIDE OF THE GENERAL FORMULA (I) (FORMULA REMOVED) IN WHICH R1 IS HYDROGEN, HALOGEN, (C1
PCT/EP2002/006644	INTERMEDIATE HALOPHENYL DERIVATIVES AND THEIR USE IN A PROCESS FOR PREPARING AZO	INTERMEDIATE HALOPHENYL DERIVATIVES AND THEIR USE IN A PROCESS FOR PREPARING AZO	HALOPHENYL DERIVATIVES OF THE GENERAL FORMULA WHEREIN R 1 IS HALOGEN, A LEAVING GROUP OR 1H-1,2,4-TRIAZOL-1-YL AND R 2 IS ETHYNYL OR CARBOXY, X 1 IS HALOGEN AND	HALOPHENYL DERIVATIVES OF THE GENERAL FORMULA HO, R1/TN2 I I WHEREIN RT IS HALOGEN, A LEAVING GROUP OR LH-1,2,4-TRIAZOL-1-YL AND R2 IS 5 ETHYNYL OR CARBOXY, XI
PCT/EP2002/007383	BUTYRIC ACID DERIVATIVES	BUTYRIC ACID DERIVATIVES	COMPOUND OF THE FORMULA I: IN WHICH: A REPRESENTS CARBOXYL; (C 6 -C 18) ARYLOXYCARBONYL IN WHICH THE ARYL GROUP IS OPTIONALLY SUBSTITUTED; (C 1 -C 14)ALKOXYCA	COMPOUND OF THE FORMULA I: C' Z IN WHICH: A REPRESENTS CARBOXYL; (CE-C)ARYLOXYCARBONYL IN WHICH THE ARYL GROUP IS OPTIONALLY SUBSTITUTED; (C-C 4)ALKOXYCARBONYL
PCT/EP2002/008322	NOVEL THERAPEUTIC METHOD	USE OF PDE4 INHIBITOR IN COMBINATION WITH AN ANTICHOLINERGIC AGENT FOR THE TREAT	A METHOD OF PROPHYLAXIS OF, TREATING, OR REDUCING THE EXACERBATIONS ASSOCIATED WITH, A PULMONARY DISEASE BY ADMINISTERING TO A PATIENT IN NEED THEREOF AN EFFECT	A METHOD OF PROPHYLAXIS OF, TREATING, OR REDUCING THE EXACERBATIONS ASSOCIATED WITH, A PULMONARY DISEASE BY ADMINISTERING TO A PATIENT IN NEED THEREOF AN EFFECT
PCT/EP2002/014311	PHARMACEUTICAL COMPOSITION COMPRISING A GLITAZONE AND A 4-OXOBUTANOIC ACID, AND	PHARMACEUTICAL COMPOSITION COMPRSING A GLITAZONE AND A 4-OXOBUTANOIC ACID, AND T	PHARMACEUTICAL COMPOSITION COMPRISING, AS ACTIVE PRINCIPLES, (I) AT LEAST ONE GLITAZONE AND (II) AT LEAST ONE COMPOUND OF THE FORMULA (I), IN COMBINATION WITH O	PHARMACEUTICAL COMPOSITION COMPRISING, AS ACTIVE PRINCIPLES, (I) AT LEAST ONE GLITAZONE AND (II) AT LEAST ONE COMPOUND OF THE FORMULA (I), IN COM BINATION WITH.
PCT/ES2000/000019	S-NITROSOTHIOLS AS AGENTS FOR THE TREATMENT OF CIRCULATORY DYSFUNCTIONS	S-NITROSOTHIOLS AS AGENTS FOR THE TREATMENT OF CIRCULATORY DYSFUNCTIONS	S-NITROSOTHIOLS DERIVATIVES OF PENICILLAMINE OR GLUTATHIONE, AND ITS PHARMACEUTICALLY ACCEPTABLE SALTS, WHICH CORRESPOND TO FOLLOWING GENERAL FORMULA(I) IN WHIC	S-NITROSOTHIOLS DERIVATIVES OF PENICILLAMINE OR GLUTATHIONE, AND ITS PHARMACEUTICALLY ACCEPTABLE SALTS, WHICH CORRESPOND TO FOLLOWING GENERAL FORMULA(I) IN WHIC

8 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. 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 and ANVISA. 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 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. It also includes applications under the new workflow that ANVISA approved but were either rejected or arquivado at INPI. 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 published 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. (In fact, because the "free use" gazette is new and remains incomplete, many of the applications we code as pending are likely rejected, withdrawn or abandoned. Because we do not distinguish between these outcomes in the case of Mexico, this issue does not affect our analysis.)

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 data on national stage applications from PatentScope (and verified against DWPI). We searched for these application numbers on the South African Patent Office website: `http://patentsearch.cipc.co.za/patents/patentsearch.aspx?search=advance`

We treated an application as granted if it had a grant date. The majority of the rest were "lapsed" due to failure to pay fees during the examination process. Note that even among granted patents in South Africa, the majority (68 percent) eventually lapsed after grant due to failure to pay post-issue 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 expert coding of the drugs with first generic entry) are correctly categorized as such, and 82 percent of secondary patents (based on the expert coding) are correctly categorized correctly.

We also examined how this would work in other samples, including a different 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:

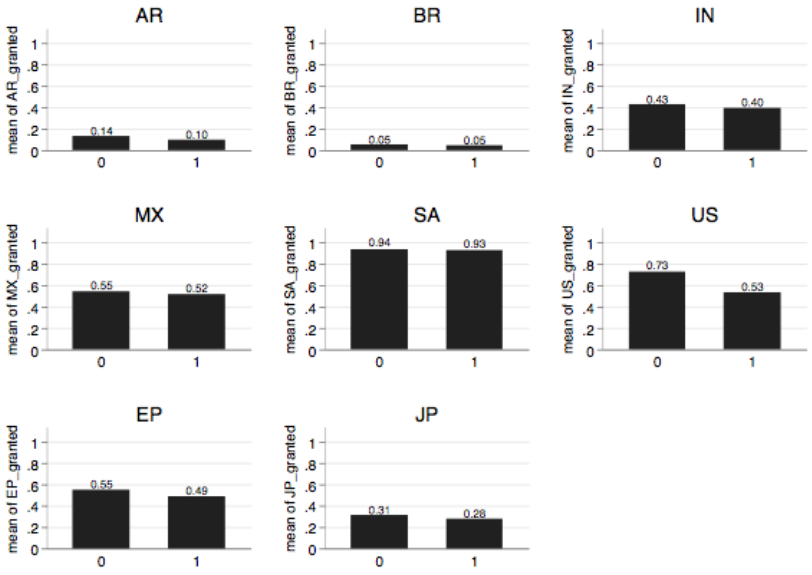

Figure 14: Grant Rates By Country and Whether Application is Secondary (1=Secondary; 0=Primary) Based on DWPI Coding

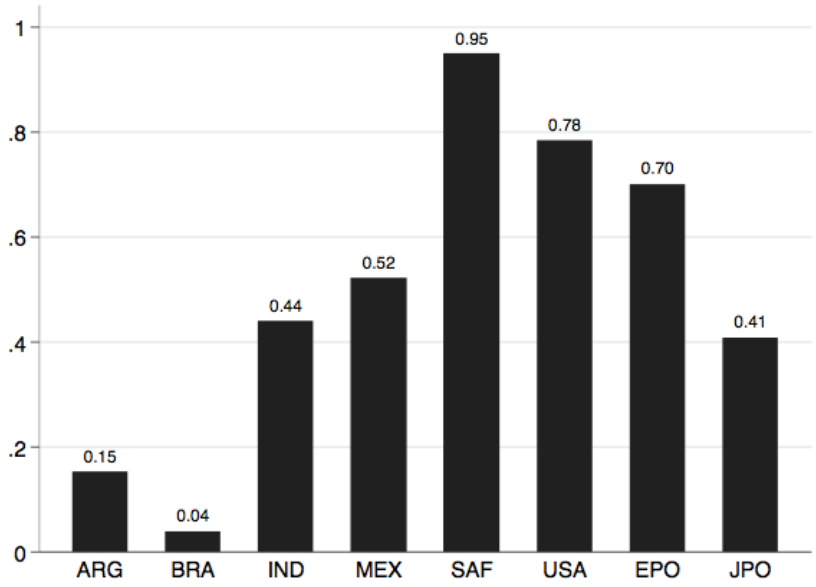

Figure 15: Grant Rates By Country, Primary Twins Based on DWPI Coding

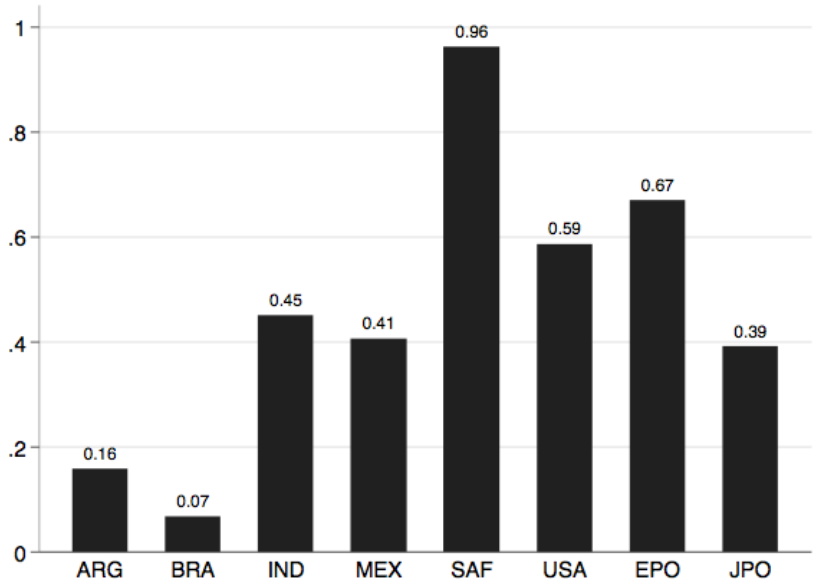

Figure 16: Grant Rates By Country, Secondary Twins Based on DWPI Coding

11 Appendix 5: Regression analyses

We also examined this in a regression framework, which allow us to control for application specific characteristics, and to facilitate inference testing. We exclude South Africa since there is no variation in the dependent variable. The estimation sample includes 19,739 observations for the 5,193 applications, one for each national filing in the US, EPO, Japan, India, Brazil, Mexico, and Argentina. We estimated linear probability models relating the probability that an application i filed in country j is granted. (We estimate heteroskedasticity-consistent robust standard errors, clustered on country). In addition to the variables already discussed, we also collected information on PCT filing year, whether the application includes any domestic inventors (which varies within application, by filing country), the number of claims in the PCT application, and family size.

In Model (1) we relate to indicators for each country (with the US as the left out reference category) and PCT filing year. In Model (2) we bring in an indicator for whether the application is secondary. In Model (3) we bring in controls for the PCT filing year, the number of claims in the PCT application,

family size, and whether any of the inventors are domestic. In model (4) we include these controls, and also allows the difference between primary and secondary patent grant rates to vary by country, after controlling for these application characteristics. Model 4 is thus the basic difference-in-difference specification.

The final specifications include application specific fixed effects. These fixed effects absorb any unobserved differences across applications, i.e. the coefficients on the country specific grant rates are based on within-application variation. (Of the variables listed above, the only one with within application variation, other than the country dummies, is the indicator for whether the application is domestic.) Models 5 and 6 show results from fixed effects models for the whole sample and for secondary patents, respectively. Note that unlike the descriptive "twins" analyses earlier in the paper, identification here comes not from applications filed in *all* countries, but from grant rates for any applications filed in multiple countries.

11.1 Results

Model 1 essentially reproduces the results from Figure 3 in the text, after controlling for application year. For US applications with PCT filing year 2000, the grant rate is 60.4 percent. Each of the other countries has significantly lower grant rates than the U.S., with the differences largest in Brazil, Argentina, and Japan. Not surprisingly, the magnitudes of the differences are nearly identical to those seen in Figure 3. The coefficients on the year dummies show no marked trend over time.

Model 2 adds the "secondary" indicator, which suggests that secondary patents have a 6 pecentage point lower grant rate than primary patents, on average across countries.

Model 3 adds controls for the number of claims in the PCT application, family size, and whether the application has any domestic innovators. The number of claims in the PCT application has virtually no relationship with the grant rate. Increasing family size by one country is associated with a three percentage point increase in the likelihood an application is granted. And consistent with previous work on "home country bias," domestic innovators have a higher grant rate by about 11 percentage points. But including these controls has little effect on the pattern of country specific coefficients.

Model 4 is the main difference-in-difference model. There, only three countries have a significant difference in grant rates between primary and secondary patents: the US (where secondary patents have a 22 percentage point lower grant rate), Argentina (where secondary patents have a 7 per-

centage point lower grant rate), and India (where secondary patents have a 6 percentage point *higher* grant rate). For both India and Brazil we can reject that secondary patents have a differentially lower grant rate, compared to grant rate for primary patents, than in other countries.

The two columns show fixed effects models overall (Model 5) and for secondary patents only (Model 6). These country coefficients in these models are based on within-application variation, i.e. control for any unobserved features of applications. The overall patterns in Model 5 are similar to those observed in Model 1, suggesting the differences seen in Model 1 were not driven by unobserved features of the types of applications filed in each country. Interestingly, when focusing on secondary patents only, Model 6 shows that EPO applications have a slightly higher grant rate than in the US. All other countries, except Mexico, have a significantly lower grant rate for secondary patents than the US, with largest differences in Argentina and Brazil. But, comparing model 6 to model 5, the differences in grant rate in secondary patents in those two countries relative to the US (and India and Japan) are smaller than those for all patents (primary and secondary).

11.2 Robustness

Table 2 shows similar patterns of results if we instead use codings based on DWPI measure of "secondary" patents. In particular, Models 4, 5, and 6 provide no evidence of a differentially lower grant rate for secondary patents in India or Brazil than other jurisdictions.

11.3 Interpreting the results

Overall, the results for Brazil and India are similar to that reported in the main text. Both India and Brazil have a lower grant rate overall than the US. While Brazilian rate is lower than that in just about any country, the Indian grant rate is near the middle of the distribution, and these facts are robust to inclusion of various controls. However, there is no evidence of a *differentially* lower grant rate for secondary patents in either country relative to other countries.

12 Acknowledgements

This research was funded by a grant from the U.K. Economic and Social Research Council (ES/K010999/1).

Table 1: Granted (1=Yes) by application characteristics and country

	Baseline Coef./Std. Err.	Baseline, Secondary Coef./Std. Err.	With Controls Coef./Std. Err.	D-I-D Coef./Std. Err.	FE Coef./Std. Err.	FE, Secondary Coef./Std. Err.
EP	-0.080**	-0.080**	-0.052**	-0.189**	-0.030**	0.037*
	(0.009)	(0.009)	(0.010)	(0.014)	(0.011)	(0.014)
JP	-0.313**	-0.314**	-0.301**	-0.432**	-0.280**	-0.212**
	(0.010)	(0.010)	(0.009)	(0.015)	(0.011)	(0.014)
BR	-0.553**	-0.556**	-0.671**	-0.812**	-0.576**	-0.492**
	(0.010)	(0.010)	(0.011)	(0.016)	(0.014)	(0.018)
IN	-0.192**	-0.197**	-0.330**	-0.499**	-0.228**	-0.131**
	(0.017)	(0.017)	(0.016)	(0.024)	(0.019)	(0.025)
MX	-0.084**	-0.087**	-0.176**	-0.322**	-0.090**	-0.004
	(0.014)	(0.014)	(0.014)	(0.021)	(0.015)	(0.019)
AR	-0.481**	-0.490**	-0.593**	-0.692**	-0.510**	-0.449**
	(0.014)	(0.014)	(0.014)	(0.021)	(0.018)	(0.024)
PCT Year 2001	0.010	0.010	0.006	0.005		
	(0.013)	(0.013)	(0.012)	(0.012)		
PCT Year 2002	0.024+	0.023+	0.025*	0.022*		
	(0.013)	(0.012)	(0.011)	(0.011)		
Secondary		-0.053**	-0.034**			
		(0.011)	(0.010)			
Number of Claims			-0.000	-0.000		
			(0.000)	(0.000)		
Family size			0.028**	0.028**		
			(0.001)	(0.001)		
Any Domestic Inventor			0.107**	0.098**	0.131**	0.124**
			(0.015)	(0.014)	(0.016)	(0.020)
Secondary, US				-0.208**		
				(0.017)		
Secondary, EP				0.004		
				(0.015)		
Secondary, JP				-0.004		
				(0.014)		
Secondary, BR				0.013		
				(0.013)		
Secondary, IN				0.066*		
				(0.029)		
Secondary, MX				0.022		
				(0.023)		
Secondary, AR				-0.064**		
				(0.023)		
Constant	0.598**	0.632**	0.343**	0.458**	0.585**	0.504**
	(0.011)	(0.013)	(0.016)	(0.018)	(0.008)	(0.011)
Obs.	15993	15993	15993	15993	15993	9779

Note: Each observation is an application filed in a particular country. Reference Category=US applications with PCT filing in year 2000.

+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$

Table 2: Granted (1=Yes) by application characteristics and country, DWPI definition of secondary

	Baseline Coef./Std. Err.	Baseline, Secondary Coef./Std. Err.	With Controls Coef./Std. Err.	D-I-D Coef./Std. Err.	FE Coef./Std. Err.	FE, Secondary Coef./Std. Err.
EP	-0.104**	-0.104**	-0.073**	-0.155**	-0.048**	0.004
	(0.009)	(0.009)	(0.009)	(0.014)	(0.010)	(0.013)
JP	-0.321**	-0.320**	-0.306**	-0.400**	-0.278**	-0.220**
	(0.009)	(0.009)	(0.009)	(0.014)	(0.010)	(0.013)
BR	-0.556**	-0.557**	-0.671**	-0.792**	-0.572**	-0.491**
	(0.010)	(0.010)	(0.010)	(0.015)	(0.013)	(0.017)
IN	-0.193**	-0.195**	-0.327**	-0.443**	-0.222**	-0.154**
	(0.015)	(0.015)	(0.015)	(0.022)	(0.017)	(0.023)
MX	-0.087**	-0.089**	-0.171**	-0.271**	-0.081**	-0.009
	(0.012)	(0.012)	(0.012)	(0.019)	(0.014)	(0.018)
AR	-0.485**	-0.490**	-0.597**	-0.696**	-0.505**	-0.440**
	(0.013)	(0.013)	(0.013)	(0.019)	(0.016)	(0.022)
PCT Year 2001	0.003	0.004	0.007	0.007		
	(0.012)	(0.012)	(0.011)	(0.011)		
PCT Year 2002	0.011	0.013	0.025*	0.024*		
	(0.011)	(0.011)	(0.010)	(0.010)		
Secondary, DWPI		-0.053**	-0.029**			
		(0.010)	(0.009)			
Number of Claims			-0.000*	-0.000*		
			(0.000)	(0.000)		
Family size			0.028**	0.028**		
			(0.001)	(0.001)		
Any Domestic Inventor			0.100**	0.102**	0.122**	0.143**
			(0.014)	(0.014)	(0.015)	(0.020)
US Secondary (DWPI)				-0.157**		
				(0.016)		
EP Secondary (DWPI)				-0.027*		
				(0.013)		
JP Secondary (DWPI)				-0.007		
				(0.013)		
BR Secondary (DWPI)				0.039**		
				(0.012)		
IN Secondary (DWPI)				0.031		
				(0.027)		
MX Secondary (DWPI)				0.005		
				(0.021)		
AR Secondary (DWPI)				0.007		
				(0.021)		
Constant	0.612**	0.644**	0.350**	0.429**	0.587**	0.514**
	(0.011)	(0.012)	(0.014)	(0.016)	(0.008)	(0.010)
Obs.	19739	19739	19739	19739	19739	12233

Note: Each observation is an application filed in a particular country. Reference Category=US applications with PCT filing in year 2000.

$^{+}$ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$