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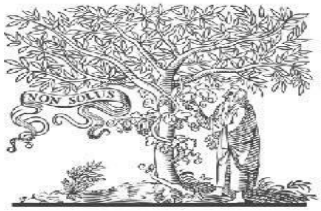

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Indian pharmaceutical patent prosecution: The changing role of Section 3(d)

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Abstract

India, like many developing countries, only recently began to grant pharmaceutical product patents. Indian patent law includes a provision, Section 3(d), which tries to limit grant of "secondary" pharmaceutical patents, i.e. patents on new forms of existing molecules and drugs. Previous research suggests the provision was rarely used against secondary applications in the years immediately following its enactment, and where it was, was redundant to other aspects of the patent law, raising concerns that 3(d) was being under-utilized by the Indian Patent Office. This paper uses a novel data source, the patent office's first examination reports, to examine changes in the use of the provision. We find a sharp increase over time in the use of Section 3(d), including on the main claims of patent applications, though it continues to be used in conjunction with other types of objections to patentability. More surprisingly, see a sharp increase in the use of the provision against primary patent applications, contrary to its intent, raising concerns about potential over-utilization.

Keywords:- pharmaceutical, patents, Section 3(d), patent law.

Introduction

India began to allow pharmaceutical products to become patented in 2005, in compliance with the country's obligations under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In doing so, the Indian government inserted a controversial provision into the patent law, Section 3(d), which tries to limit the grant of "secondary" pharmaceutical patents, i.e. patents on new forms of existing molecules and drugs.

Section 3(d) has been the source of considerable conflict. One prominent case that brought the world's attention to 3(d) was the Indian Patent Office's (IPO) decision to reject a secondary patent on Novartis' cancer drug "Gleevec" (imatinib mesylate), a decision that cited Section 3(d) as one of the grounds for rejection. Novartis challenged the constitutionality of Section 3(d) and appealed the IPO's decision, actions that in turn inspired health activists to embark on a campaign against Novartis and in support of the provision. The legality of 3(d) was upheld, and the decision to reject the Gleevec patent was confirmed by the Intellectual Property Appellate Board in 2009 and then, ultimately, the Indian Supreme Court in 2013.

Debates and controversies over 3(d) have not been limited to this one drug. The provision has triggered heated and polarized views on pharmaceutical patents in India, and more broadly in developing countries adopting pharmaceutical patents in compliance with TRIPS. On the one hand, many legal scholars, civil society groups, and international organizations have lauded India's policy choice, citing 3(d) as a prominent example of a country complying with its international obligations but doing so in a way that can preserve generic competition. In that spirit India's Section 3(d) is commonly held out as model to follow, and other countries where pharmaceutical patenting is also new are encouraged to act similarly. On the other hand, many foreign governments and the transnational pharmaceutical industry regard 3(d) with disdain. The US Government routinely cites 3(d) as among the reasons for including India on the "Priority Watch List" in the United States Trade Representative's annual Special 301 Report, for example, and the provision has drawn repeated criticism from international drug firms and their representatives. The concern that 3(d) makes it difficult to get a patent in India is widespread in the scholarly literature as well. However, these analyses did not look specifically at the role of 3(d) itself, but measures of patent protection on molecules which could be influenced by other factors, including the timing of TRIPS implementation in India.

Previous empirical analyses that did look directly at 3(d) found little independent role of 3(d) in shaping Indian pharmaceutical patent outcomes. Specifically, these analyses found that the provision was involved in a relatively small number of cases, and, where it was, it was almost always used together with other more conventional reasons for rejecting patent applications, such as lack of novelty or inventive step. However, the previous analyses were based on pharmaceutical application filings and examination decisions in the early years after the introduction of pharmaceutical patenting in India. It is possible that the role of 3(d) has changed over time, given implementation lags and updated guidance to IPO examiners. Moreover, where 3(d) and other grounds for rejecting patents were employed, previous analyses were unable to untangle which were the main reasons for rejection.

This paper uses new micro-level prosecution data to examine changes over time in 3(d) and to assess the independent role of this provision. While analyses of patent prosecution process are now common for applications filed at the United States Patent and Trademark Office., there are few empirical analyses of developing country patent prosecution. This is particularly crucial for analyzing patent prosecution in the context of TRIPS, given concerns that developing countries' practices may differ substantially from their laws on the books.

As we seek to understand how the patent office functions and, specifically, the role of Section 3(d) in patent prosecution processes, we focus not just on the IPO's final decisions, but also examiners' initial reports, as well as the exchanges that occur between applicants and the patent office following issuance of the initial reports.

Focusing on the first examination reports (FERs) provides a fuller picture of the role of 3(d) in patent prosecution, allowing us to understand how 3(d) is used by examiners and how applicants respond to 3(d) objections that are raised in the course of examination. Another novel aspect of our approach is that we examine the role of 3(d) and other substantive grounds for rejection in targeting the first claim of patent applications. This allows us to assess whether 3(d) struck the core of the application, and whether it did so on its own or in conjunction with other aspects of patent law. Analyses of FERs, which we see relatively early in the prosecution process, also avoids the problem of censoring which complicates assessment of grant rates. This is particularly important for examining changes over time. There is a trade-off, however, as we do not see final decisions in most cases, as we discuss more below.

We find a sharp increase in the prevalence of 3(d) in FERs over time, including on applications' most important claims. However, 3(d) rarely works alone: it continues to be invoked along with other more conventional objections, even when it is used on an application's main claim. While the provision does appear to make obtaining a patent more difficult and the prosecution process longer, it is hard to know whether this is due to the independent effects of 3(d), the types of applications that draw 3(d) objections, or the types of examiners that invoke 3(d). Surprisingly, we also find evidence that 3(d) is more commonly used for primary patents than secondary patents, suggesting that it is functioning differently than intended.

The paper has 5 sections. Section 2 provides brief background and context on the introduction of pharmaceutical patents in India and Section 3(d), along with an overview of the patent prosecution process. Section 3 describes the data and empirical approach. Section 4 presents results, examining the changing utilization of 3(d) over time in FERs, the relationship between 3(d) and novelty and inventive step, the association between 3(d) in FERs and final outcomes, and the use of 3(d) on primary vs. secondary patent applications. Section 5 presents discussion of the main findings, indicates directions for future research, and links research on the role of Section 3(d) to broader issues regarding the implications of pharmaceutical patents in India for access to medicines in poor countries in the context of TRIPS.

TRIPS, pharmaceutical patents, and Section 3(d)

The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires all countries to grant pharmaceutical patents. With the exception of "Least Developed Countries," all WTO members that did not already allow pharmaceutical patents as of 1995, when TRIPS went into effect, had until 2005 to begin doing so. During the transition period, from 1995 until the date that a country made pharmaceuticals patentable, TRIPS required members to receive and hold applications in a "mailbox." Thus, if in a given country pharmaceutical patents were to become available as of 1999, from

1995 to 1999 the country would accept applications in the mailbox, and these would be examined as of 1999, along with other applications received from that date onwards.

India was one of the countries that most resisted TRIPS during the Uruguay Round trade negotiations of the late 1980s and early 1990s. India opposed the inclusion of rules on countries' intellectual property policies and practices in the international trade regime, and once the "trade-IP" linkage was established and TRIPS negotiations began, India adamantly resisted the subsequent obligation that all countries allow pharmaceuticals to be patented. Although process patents were available in India, product patents had been prohibited since 1970. The absence of patent protection in India coincided with substantial development of the local pharmaceutical sector, and TRIPS was thus perceived as a serious threat. Perhaps not surprisingly, when forced to allow drug patents but allowed a transition period before doing so, India waited until 2005 to make pharmaceutical products patentable, the maximum period allowed. Indeed, India is one of the only countries to use the full transition period and delay pharmaceutical patenting until 2005. And, also in grudging compliance with the country's new international obligations, as of 1999 India also began receiving applications in a mailbox, to be examined as of 2005 when the product patent regime was in operation.

In 2005, at the point of introducing the final amendments to the Patents Act to allow for pharmaceutical patents, the Indian government included Section 3(d), a provision that establishes a high barrier for secondary patents. Specifically, 3(d) stipulates that many secondary patents are not considered as inventions, and thus not eligible for patents, unless the applicants demonstrate that these have greater efficacy:

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 implemented explicitly to address concerns that additional patents on existing substances could be used to extend market exclusivity and delay generic competition. Basheer and Reddy report that the Minister of Commerce at the time the patent law was being finalized introduced 3(d) to prevent "ever-greening". While some actors sought a more restrictive approach, for example prohibiting all secondary patents, the designers of 3(d) sought a middle ground that would allow patents on modified forms of existing compounds so long as they demonstrated improvements

("efficacy") over the earlier, known substance. This intermediate position was subsequently supported by a government-established committee that was asked to report on whether India should prohibit patents on all "incremental innovations".

Thus to obtain a pharmaceutical patent in India, not only do applicants have to satisfy traditional criteria that are common across all countries, e.g. novelty and inventive step, but also meet Section 3(d) requirements. As indicated in the introduction, Section 3(d) has received considerable attention, but its effects have tended to be exaggerated by both supporters and critics. We use micro-level data to shed new light on India's new pharmaceutical patent system and the role of 3(d).

Before proceeding to the data and analyses, a quick review of the Indian pharmaceutical patent prosecution process may be useful. Applicants must request examination by the IPO within 4 years after their application's international priority date; failure to do so leads to applications being classified as "withdrawn." When the IPO examines applications, a first examination report is typically issued within six months. FERs range from a few lines to long and detailed documents with extensive discussions of claims. FERs are like "first office actions" in the U.S., which list objections such as novelty and inventive step, as well as other less substantive grounds such as lack of clarity and mistakes in the application. If an applicant does not respond to the FER the application is "abandoned." When the applicant does respond, amending or eliminating claims, or rebutting the objections raised by examiners, the IPO then issues a second report and, typically, invites the applicant to a hearing. If the applicant overcomes these objections the patent is granted. If, however, the applicant stops pursuing the application after initially having replied to the FER, for example the applicant does not respond to the IPO's second report or does not attend the hearing, or does take these steps but is unable to convince the patent office of the merits of the case, the application is refused.

Data and empirical approach

We started with a set of pharmaceutical applications that were filed globally via the Patent Cooperation Treaty (PCT), both to focus on relatively important applications and to allow for comparability of Indian outcomes to those in other jurisdictions. Accordingly, we began with the September 2015 version of the OECD Triadic Patent Families database, which covers all applications filed in the European Patent Office, US Patent and Trademark Office, and Japanese Patent Office. Using this database, we focused on all "pharmaceutical" applications with priority years (first global filing years) 2000–2012. We then collected information from the WIPO statistics database on all Indian national stage applications; since at the time we collected the data the Indian data were truncated in 2012, we focus the subset with Indian applications filed through 2011. For tractability, we focus on applications with priority PCT month July. This resulted in 1,964 PCT applications, mapping to 1,993 Indian national stage applications. (Since India took full advantage of the transitional period to

introduce pharmaceutical patents that was allowed by TRIPS, as explained above, the applications in our dataset that were filed in India from 2000–2005 were held in a "mailbox" until examination commenced in 2005.)

We collected Indian outcomes on all 2000–2011 applications from the Indian patent database as of May 2017. We record five mutually exclusive categories: applications can be granted, pending (still waiting final determination), withdrawn before examination, abandoned after a first examination report issued, or refused. As explained above, if an applicant pursues the application after receiving the FER but is unsuccessful in overcoming the objections raised, the application is considered formally refused. We also collect data on duration of prosecution for granted patents.

As explained, a novel contribution of our work is that we analyze the first examination reports issued by the patent office after applications have undergone their first substantive review. For all applications with FERs we determined if the reports included any 3(d) objections, and also whether they included any novelty or inventive step objections. We also determined whether there were 3(d) objections on the first claim, and, for a subset of applications, whether there were novelty or inventive step objections on Claim 1 as well.

While most of our analyses of 3(d) focus on FERs, we also use the full prosecution record of some applications to gain a stronger sense of the role of 3(d). For all applications where there was a 3(d) objection on claim 1 of the FER and a final outcome of refusal, and for a random selection of applications with 3(d) objections on claim 1 that ultimately were granted by the patent office, we read through the correspondence between applicants and the patent office (e.g. replies to FERs, subsequent examination reports, controller's reports) to understand how applicants respond to 3(d) objections and the role of 3(d) throughout the prosecution process.

To examine the different roles of 3(d) for different types of applications, we code each of the applications in our sample as to whether they claim a new compound ("primary" patent applications) or, alternatively, a modified form, composition, or use of an existing compound ("secondary" patent applications) using the coding scheme from previous research. The claims coding also revealed a handful of pure process applications. After dropping these we were left with 1853 applications.

Results

We use these data to address the following questions:

- How has the use of 3(d) by examiners in FERs changed over time?
- How much overlap is there between 3(d) and novelty/inventive step objections in FERs?
- How does the inclusion of 3(d) objections in FERs, alone or in conjunction with novelty or inventive step, correlate with different outcomes?

- What kinds of patent applications draw 3(d) objections in FERs?
- The changing role of 3(d) over time

To examine the role of 3(d) over time, we focused on applications that have FERs. The share of applications with an FER drops over time (for example, from about 78 percent in the 2001–2004 period to 52 percent in the 2008–2011 period). This is not surprising, as examination has not yet begun on a larger share of more recent applications. We were able to locate FERs for nearly all abandoned, granted, and refused applications (as well as a third of the pending applications, where examination has begun but not yet concluded), yielding 1,283 FERs. Overall, 37 percent of the applications with FERs are granted, 45 percent abandoned, 5 percent refused, and 13 percent pending.

The solid line in Fig 1 shows the share of applications with an FER with any 3(d) objection, by application year. The sharp increase over time, from less than 40 percent of the early applications to more than 80 percent of the most recent applications, demonstrates an increased utilization of 3(d) by Indian patent examiners. While previous research, based on even earlier sets of applications, revealed a low incidence of 3(d), this is clearly no longer the case.

Is 3(d) redundant?

The data presented so far suggest that 3(d) is a major way in which the Indian Patent Office tries to limit patent grants, and increasingly used over time. This is consistent with concerns that 3(d) makes it harder to obtain patents in India than other jurisdictions (as it was meant to do). However, one wrinkle is that we do not know what work is being done by 3(d) itself. Examiners may also be objecting to patents on other, more traditional grounds, such as lack of novelty or inventive step. Indeed, previous research has suggested just that, that Section 3(d) was rarely used alone, but rather in conjunction with other ways of rejecting applications. We explore this here too, both overall and for the main claim. Specifically, we also identified novelty and inventive step objections on the 427 FERs for applications filed between 2006 and 2007. We focused on applications for which there were electronic FERs, dropping 9, leaving 427. An advantage of looking at this time period is that the applications are more likely to have FERs (86 percent do) and the FERs are more likely to have clearer delineation of specific objections on specific claims.

What kinds of applications get 3(d) objections?

Previous analyses of 3(d) have focused mainly on its effects on secondary patent applications, which is natural since these are the applications it was meant to target. Together with the results (above) on the growth of 3(d) objections, prominent cases of 3(d) being used against primary patents (including, in a preliminary ruling, sobusfovir)—those covering drugs' original molecules–raise the question of whether it is being used more expansively.

Here we return to the full sample of applications with FERs (not just 2006–07), and we use our coding of whether the applications are primary or secondary. As

noted above, and discussed in more detail elsewhere we categorize as "primary" applications those that include at least one claim on a new compound. Secondary applications include those on polymorphs and crystal forms, enantiomers and isomers, salts, metabolites and derivatives, and other modified forms, compositions, or uses of an existing compound that do not also have a new compound claim.

Discussion and conclusion

The data reveal substantial increases in the use of 3(d) over time in FERs, overall and with specific regard to the main claim. Clearly, the IPO is relying extensively on 3(d) to raise a higher barrier for obtaining pharmaceutical patents.

While the increased reliance on 3(d) may reflect characteristics of the applications filed in India, this may also reflect explicit policy. In the initial years of India's new pharmaceutical patent regime, many observers asserted that, notwithstanding the high-profile Gleevec case, 3(d) tended to be under-utilized. The association representing India's leading pharmaceutical firms published a report, authored by the former director of intellectual property in the Ministry of Commerce calling for more aggressive application of Section 3(d), for example, and subsequently worked with the IPO to revise the examination guidelines to that effect. And the defense of 3(d) provided by the Appellate Board and then the Supreme Court may have contributed to this too, by giving examiners greater confidence to use this provision. It is difficult to ascertain the effects of constituent pressures, revised guidelines, and legal support, though it is reasonable to believe they have contributed to the increased use of 3(d).

But Section 3(d) is rarely used alone. Even when 3(d) is invoked as a reason why a patent should not be granted, it is rarely invoked as the only reason. Examiners also use other, traditional, grounds to deny patents, such as lack of novelty or inventive step. Previous work, at the application level, suggested that this was common, and the current findings, based on FERs, are consistent with that research: looking at applications filed in 2006–07 for which we could obtain FERs, we find that when 3(d) objections are raised, in nearly all (94 percent) instances so too are objections based on lack of novelty or inventive step.

Overlap between 3(d) and other patentability criteria at the application level does not necessarily imply redundancy in use, as different provisions of the patent law may be applied to different claims within a single application. Researching the use of 3(d) and other provisions at the claims level is difficult, on account of the quality of FERs. In the initial years of patent examination FERs tended to be too vague, simply indicating that "claims" do not satisfy the tests of 3(d) or other aspects of the patent law, without indicating which claims a given objection was referring to. Looking at a set of applications during the time period when FERs tended to be more specific (but early enough so that FERs have been produced), our findings at the claims level are consistent with what we observed at the application level: in nearly all cases of 3(d) being used against the first claim in an application, so too were

novelty and inventive step. Most of the time, whether looking at applications as a whole or the first claim, 3(d) objections are accompanied by novelty or inventive step objections as well. Although there is increasing use of 3(d), it is not independent use.

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