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Section 3(d) and Pharmaceutical Patents in India

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In 2005, India amended its Patent Law to bring the country into compliance with the WTO TRIPS Agreement. Criticisms have arisen over a flexibility in the law, Section 3(d), which attempts to reduce *evergreening* by granting patents to only those inventions that enhance the drug's known efficacy. The lack of a clear definition in the law has raised worldwide concerns over its misuse which was exacerbated by the 2013 Supreme Court denial of Novartis's Appeal of Section 3(d)-based patent rejection for the cancer treatment drug, Glivec. To analyze the importance of Section 3(d) and this ruling on patent decisions in India, a database of 500 pharmaceutical patent cases between 2005 and 2016 was created. The determinants of patent decisions were estimated using a binomial logit regression and conducted a statistical analysis to identify their confounding factors. The results show that if a patent application has Section 3(d) objection, the odds of the case being rejected and/or abandoned more than double. Also, although the odds of patent rejections have fallen since the 2013 Supreme Court ruling, this result is driven by non-Section 3(d) cases. Thus, it was concluded that Section 3(d) will play an increasingly important role in patent rejections.

Keywords: Evergreening, Section 3(d), WTO, TRIPS Agreement, The Patents Act, 1970, US-India Business Council, Probit estimation, Logit estimation, Active pharmaceutical ingredients

This paper examines pharmaceutical patent approvals in India since 2005. In 1995, the WTO TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement went into effect, aimed at harmonizing intellectual property rights (IPRs) across the globe. Developing countries such as India had ten years (until 2005) to become compliant with the TRIPS Agreement. Given India's status as a leading generic drug manufacturer, changes to India's patent system, which greatly affected the pharmaceutical sector, had global implications.

India's patent law, The Patents Act, 1970 was amended to become compliant with the TRIPS Agreement. Amendments passed in 1999, 2002, and 2005 (all effective from 1 January 2005) were expected to provide stricter protections for intellectual property, and thus, promote innovation. However, some portions of the amendments that provided flexibility (allowed under TRIPS) have been considered a hindrance to protecting intellectual property rights (IPRs). Specifically, the 2005 amendment that revised Section 3(d) has been controversial. Section 3(d) prohibits the granting of patents for those inventions that do not *enhance the drug's known efficacy*. The goal was to deter *evergreening* (extending the life of a patent through slight modifications) which poses an even greater burden to health care access (compared to the original patent). Critics argue that Section 3(d) has been misused. This paper examines the importance of Section 3(d) in pharmaceutical patent decisions in India.

Restrictions related to *evergreening* are not unique to India. Mexico and Japan have similar clauses and Philippines, Brazil, and Argentina are working toward them.[1] However, the focus on India is important for two reasons. First, changes to India's patent regime could have global repercussions to health access as the country is a significant producer and exporter of pharmaceuticals.[1,2] Second, the flexibilities in the new stricter regime aimed at balancing health access and innovation make India an important case study in the IPRs debate. This is especially significant in the case of Section 3(d) in India's patent law, which is considered controversial because of its lack of clarity and in turn, has raised concerns of its misuse. This has been further exacerbated with the 2013 Supreme Court ruling on the *Novartis* v *Union of India* case, which denied the company's appeal of a patent rejection based on Section 3(d).

The paper seeks to answer three questions: Is Section 3(d) a significant determinant of patent

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rejections? Has the Novartis case had an impact on patent decisions? What factors shed light on cases with Section 3(d) objections? To address these questions, we built a database of 500 pharmaceutical patent cases between 2005 and 2016 and examined various characteristics of these rulings. Using our database a binomial logit regression on the factors [including Section 3(d)] that affect patent decisions, as well as conduct a comparative analysis of cases with and without Section 3(d) objections were estimated. It was found that Section 3(d) is a statistically significant determinant of patent cases being rejected and/or abandoned. This relationship is complicated by the location at which the application is filed and the timing of the decision (pre- or post-the Supreme Court ruling on the Novartis case).

Protection of IPRs is defended on grounds of promoting innovation, however that is heavily debated.[3] However, stricter IPRs can lead to a loss of social welfare in developing countries.[4] This is an even greater concern when the focus is health-related, and played a significant role in the 1995 WTO TRIPS Agreement, which ultimately led to the inclusion of flexibilities.

The Indian Patents Act was amended in 1999, 2002, and 2005 to bring the country into compliance with TRIPS. However, even before the amendments came into effect in 2005, India's protection of IPRs had been strengthening. The value assigned to India for the index of patent rights rose from 1.23 (out of 5) in 1995 to 3.76 in 2005.[5,6] Stricter laws on IPRs can increase foreign investment and innovation.[7,8] However, this relationship is affected by a country's level of economic development.[9]

Increased levels of economic growth in India in the 1990s, combined with a stricter patent law, was thus expected to have a positive impact on innovation. In fact, the number of patent applications in India increased dramatically from 4,824 in 1999-2000 to 34,287 in 2009-2010.[10] There was a significant number of patent applications originating from domestic firms in India.[11]Also important, was the increase in patent filings from small firms.[12] Some have argued that the shift from process to product patents has hurt domestic innovation in India.[8] There is also evidence of little to no effect on India's pharmaceutical sector since the shift in patent laws.[2] Results from probit and logit estimation show that TRIPS compliance is necessary for innovation but not a sufficient condition for improving export performance.[13] The effect of India's "calibrated approach" (incremental protections) is unclear.[14] In fact, the ultimate impact may be linked to how the law is administered.[15] This is related to the flexibilities in India's patent laws that weaken IPRs protection. The focus is on one such flexibility, Section 3(d), which is designed to deter evergreening (making slight modifications to drugs to extend patent rights).

Proponents support evergreening to promote investment, research, and innovation while critics argue that it denies access to life saving drugs. Through Section 3(d), India "has taken the first step in introducing legislative measures to check the practice of evergreening" and thus makes analyzing this component of the law important.[15] What makes it even more important is that India's law is becoming a model for developing countries even while it is under attack from developed countries.[16] The US-India Business Council has called for the elimination of Section 3(d) and Trans-Pacific Partnership negotiations have sought to curb the spread of similarly focused legislation.[1,16]

The problem is the ambiguity of language in Section 3(d).[17] Specifically, the phrase *enhanced known efficacy* gives the decision-maker a lot of latitude in interpreting the law and can thus be misused. That the language is ambiguous is not in question. Whether this ambiguity has been overused needs further exploration. This paper sheds light on the importance of Section 3(d) in patent decision-making in India.

India's Patent Laws and Pharmaceutical Sector

The Designs and Patents Act of 1911 protected IPRs in India pre-independence and until 1970 when it was replaced by The Patents Act, 1970 (referred hereafter as Patents Act). This law shifted patents from products to processes and reduced patent rights from 16 years to 7 years. Through *reverse engineering*, (which involves breaking down or taking apart a known compound or substance to discover its composition and lead to alternative and cheaper ways to produce them), the Patents Act led to a dramatic growth in India's pharmaceutical sector and empowered the country to become a leader in generic drug production. Between 1970 and 2000, the number of pharmaceutical companies in India increased from 2,000 to 20,000 and by 2006, Indian pharmaceutical companies supplied 95% of the total domestic market compared to 20% in 1970.[8] The country also became a significant supplier of pharmaceuticals to the developing world.[1,2] Exports have exceeded imports in

the pharmaceutical sector since 1987; in the 2000s the industry grew at an annual rate of 10% and exports of pharmaceuticals grew at 20%.[18] In 2005, India had the third largest active pharmaceutical ingredients (API) market in the world, valued at $ 2 billion.[19]

In 1994, India signed the TRIPS (1995) Agreement with changes to be enacted within ten years.[20] The amendments (1999, 2002, and 2005) that brought the Patents Act into compliance with TRIPS included a mailbox system (allowing companies to file for patents before the 2005 law was enacted), increased the term of patents from 7 to 20 years, and added definitions for inventions.[1] Global generic pharmaceutical corporations invested heavily in research facilities in India, making India "the single largest (*generic*) pharma player in the world, post-TRIPS."[21]

The Office of the Controller of Patents, Designs & Trade Marks examines and adjudicates on patent cases. Applications for patents must be sent to the appropriate jurisdictional branch under the Office of Controller General of Patents, Designs and Trade Marks. There are four patent office branches located in Chennai, Kolkata, Mumbai, and New Delhi and each has jurisdiction over neighboring states. Applicants must file at the appropriate office based on their place of residence, business, or service.[22]

Fig. 1 shows the patent process. After an application is made and published, it is examined by the controller who prepares a first examination report (FER). Typically, the FER raises objections which the applicant has one year to address and is considered abandoned after that time. Prior to a decision on the patent, there is a possibility of a pre-grant opposition (criteria listed in Section 25(1) of the Patents Act). A patent is rejected if the controller sides with the pre-grant opposition or if the objections raised in the FER are not satisfactorily addressed; otherwise the patent is granted for a period of 20 years from the date of application. It is referred as round 1. Most cases end here.

However, it is possible that the decision is challenged. A patent grant can be challenged by a post-grant opposition and a patent rejection can be challenged by the applicant. If there is a post-grant

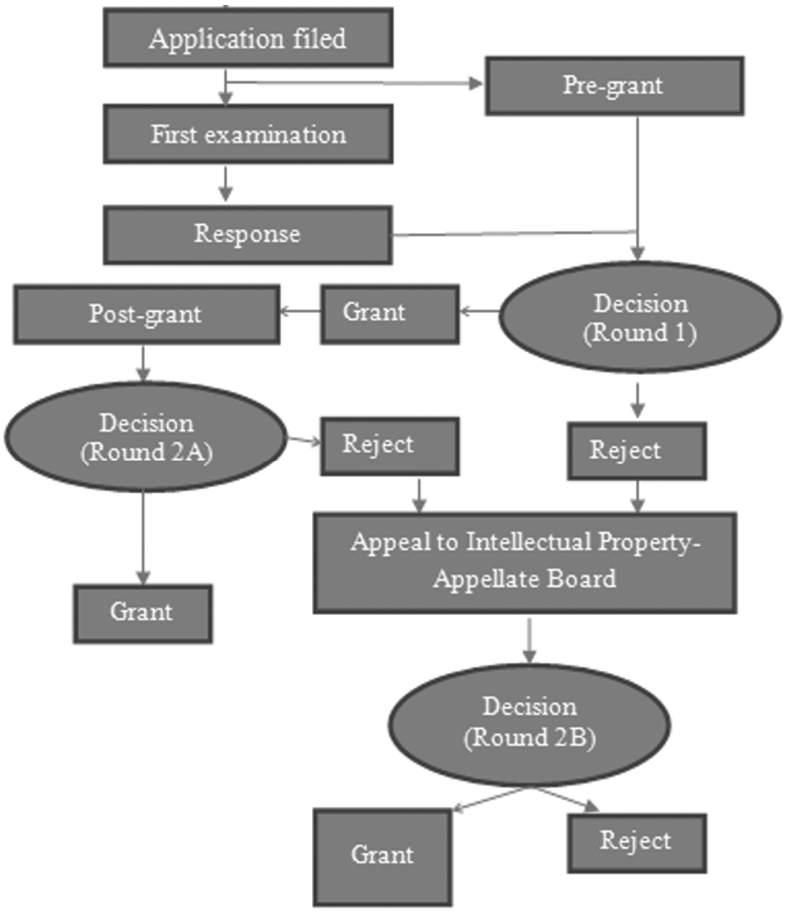

Fig.1 — The process of obtaining a patent

opposition (based on criteria similar to the pre-grant opposition), the Opposition Board hears the post-grant opposition case and the Controller makes the final decision (to keep or revoke the patent). This is round 2A. If a patent is rejected, the applicant has a right to appeal. The case may be submitted to the Intellectual Property Appellate Board (IPAB) and their decision signals completion of round 2B. Challenges to the law may be filed with the High Court, and if necessary, the Supreme Court.[23]

Patent decisions have been affected by the amendments to the law, which have included flexibilities allowed in the TRIPS Agreement. One such flexibility is related to deterring *evergreening* (extension of patent rights). In order to restrict evergreening, the law has to define what is and is not considered an invention. The former is addressed in Section 2(1) (j) of The Patents Act while the limits to inventions are embodied in Section 3(d) of The Patents Act and Patents (Amendments) Act, 2005. Also important are Section 3(e) that narrows the definition of inventions and Section 10(4) which lists the necessary requirements for a complete specification.

According to Section 3(d): "***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 a new reactant" [***the 2005 modification of Section 3(d)***].

Section 3(d) is designed to restrict extension of monopoly rights for minor or inconsequential changes and is under constant attack by pharmaceutical companies who are suspicious that it is a loophole to circumvent patent rights.

> *"The "other derivatives of known substances" clause of Section 3(d) of the Indian patent law is nebulous and arbitrary. It could be interpreted to deny nearly any new patent claim since so many drugs are derived, at least in part, from previously known substances. And even if a patent was granted, it could be easily challenged by some party that currently copies it (or would want to). Section 3(d) is so arbitrary that it encourages litigation and undermines incentives for innovation.*"[24]

The controversy surrounding Section 3(d) escalated with the landmark case, *Novartis* v *The Union of India & Others*, which resulted in patent rejection for Glivec, under violation of Section 3(d). Glivec, Novartis's cancer drug, which treats Chronic Myeloid Leukemia, brought in $ 4.71 billion in global sales in 2012 with an annual cost per-patient ranging from $ 25,000 to $50,000, as opposed to a generic version of $2,100.[25] Novartis applied for a patent in India on a chemical compound for Glivec but was denied the patent because the Assistant Controller of Patents agreed with the pre-grant opposition (filed by Cancer Patients Aid Association, other non-profit organizations, and some drug companies) that "the new version of Glivec was not sufficiently different from the old unprotected version to warrant a patent."[15] Novartis sued to change the patent ruling (with the IPAB) and to challenge Section 3(d) which they argued was in violation of TRIPS (with the Madras High Court), but lost both cases.[15] Novartis appealed and the Supreme Court of India ruled that the chemical compound, *imatinib mesylate*, was not an invention as described by 2(1)(j)/(ja) because it was known from the Zimmermann patent and also violated Section 3(d) because it did not enhance therapeutic efficacy.[15]

Supporters of India's ruling on this case argue that Novartis was extending monopoly rights through evergreening and the ruling was a victory for public health access. However, critics are concerned that weak protections hurt innovation and thus, health access.[25] Also having flexibilities by itself does not increase affordable generic drug production; appropriate economic and political conditions are necessary as well.[26] We do not wade through the debate about patent regimes and health access. Rather, the paper focuses on whether the Novartis decision is representative of future rulings, specifically, to explore if Section 3(d) plays a significant role in patent rulings.

The importance of Section 3(d) in patent rulings since 2005 using patent cases from both domestic and foreign pharmaceutical companies were estimated. A database was prepared to include decisions (patents granted, rejected, or abandoned cases), the often-raised objections in the FER (Sections 2(1)(j)/(ja), 3(d), 3(e), 10(4) on the patent law), jurisdiction of the Office where the patent was filed (Chennai, Kolkata, Mumbai, New Delhi), whether the applicant company was domestic or foreign, and whether the decision was pre- or post- the 2013 Supreme Court ruling on the Novartis case (which upheld the High Court ruling

of denying Novartis's appeal of the rejection of the patent for Glivec based on Section 3(d)). The binominal logit regression was estimated to examine the impact of Section 3(d) (and other factors) on patent decisions. Two dependent variables were used, one with focus on rejected cases (versus granted cases), and the other to combine rejected and abandoned cases (*versus* granted cases). While a rejected case is different from an abandoned case, it is possible that various factors that could lead to a rejection may also cause the company to abandon the case. The equation to be estimated is given as:

$$DV_i = \beta_0 + \beta_1 Dom_i + \beta_2 Kol_i + \beta_3 Mum_i + \beta_4 ND_i + \beta_5 SC_i + \beta_6 S3(d)_i + \varepsilon_i \quad \ldots(1)$$

where DV_i is dummy variable that equals 1 if the patent case is rejected or rejected +abandoned and 0 if granted. All of the independent variables are also dummy variables that equal 1 if the condition is met and 0 otherwise. Dom_i refers to the applicant being a domestic firm, which we hypothesize may lead to greater patent grants since domestic firms may benefit from having more knowledge of a country's conventions and patent and legal system. The variables Kol_i, Mum_i, and ND_i refer to three of the four jurisdictional offices where patent applications are submitted, Kolkata, Mumbai, and New Delhi respectively. The omitted jurisdiction office captured in the constant is Chennai. These variables are included to test if jurisdiction of the patent office matters. SC_i represents the period after the Supreme Court delivered its ruling on the Novartis case. This variable is included to test the concern that this landmark case will influence future patent rulings, specifically increase patent rejections (or cases being abandoned). The last independent variable captures the impact of a Section 3(d) objection. The expectation is that this will increase the odds of a case being rejected and/or abandoned.

To gain a better understanding of the factors that affect a Section 3(d) case, we organize the cases as shown in Fig. 2.

The cases with and without a Section 3(d) objections (* and $^+$ respectively) were separated and categorized in granted, rejected, or abandoned cases. The differences in patent rulings for Section 3(d) and non-Section 3(d) cases for various scenarios such as, jurisdiction of patent office, ownership of company, other objections, and pre- or post- Novartis ruling were analyzed. By comparing granted / rejected / abandoned cases with and without Section 3(d) objections (G^*/ R^*/ A^* and G^+/ R^+/ $A,^+$ respectively) in these categories the following questions were addressed: Are Section 3(d) cases more or less likely to be granted/ rejected/ abandoned compared to cases without a Section 3(d) objection? How do other objections impact these decisions? Does jurisdiction matter for Section 3(d) and non-Section 3(d) rulings? Is ownership of the company a differentiator? Did the Supreme Court ruling on Novartis have a different impact on Section 3(d) and non-Section 3(d) cases?

Section 3(d) and Patent Rulings

A database of pharmaceutical patent case rulings in India since 2005 was prepared.[27] These include 500 patent applications from domestic and foreign firms (Table 1).

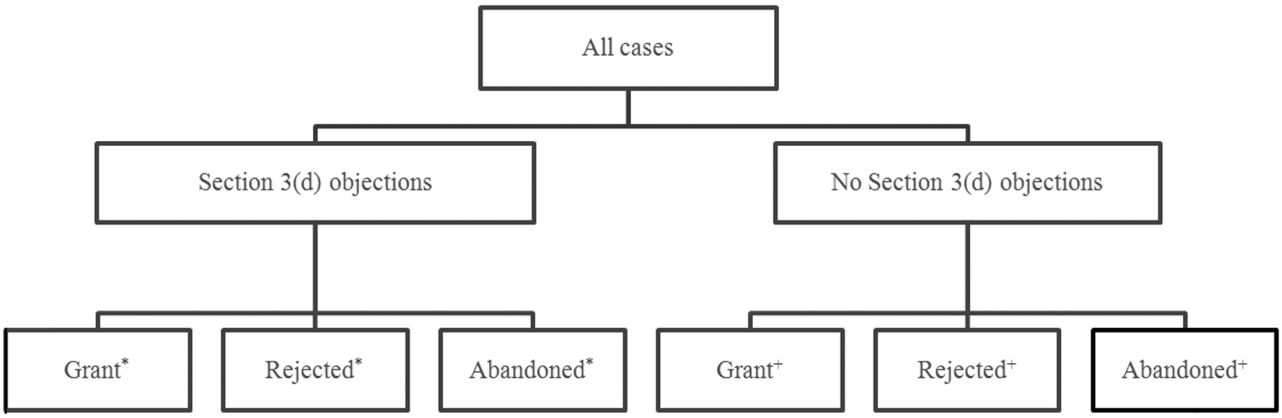

Fig. 2 — Examination of Section 3(d) cases

Notes: * indicates there was a Section 3(d) objection and $^+$ if there is any objection other than Section 3(d) including but not limited to Sections 2(1)(j)/(ja), 3(e) and 10(4).

Table 2 shows out of 500 cases, approximately equal amount of cases were granted (207 or 41.40%) as were abandoned (221 or 44.20%). At 72, only 14.40% of all cases were rejected. A majority of all applications were made in New Delhi followed closely by Mumbai (166 and 157 respectively). Over 71% of total applications (357) were filed by foreign firms. This is likely related to the expertise and financial advantage of large global firms such as Merck (63), Roche (52), and Novartis (49) (Table 1). Importantly, the largest number of applications (65) are from a domestic firm, Cadila (Table 1).

Table 1 — Pharmaceutical companies in sample (Total = 500)

Company	No. of cases
AbbVie (AbbVie Biotherapeutics Inc., AbbVie Biotechnology Ltd., AbbVie Inc.)	13
Amgen (Amgen Inc., Amgen Research (Munich) GMBH)	8
AstraZeneca (AstraZeneca AB, AstraZeneca UK Ltd., AstraZeneca Pharma India Ltd.)	40
Aurobindo Pharma Ltd.	13
Bristol Myers Squibb Company	23
Cadila (Cadila Healthcare Ltd., Cadila Pharmaceuticals Ltd.)	65
Cipla Ltd.	26
Eli Lilly and Company	4
Gilead (Gilead Sciences Inc., Gilead Pharmasset LLC)	5
Glaxo Smith Kline LLC	1
Glenmark Pharmaceuticals (Glenmark Pharmaceuticals Ltd., Glenmark Pharmaceuticals S.A.)	10
Johnson & Johnson (J&J Research PTY Limited, J&J Vision Care, Inc., J&J Consumer Companies, Inc.)	22
Lupin Ltd.	10
Merck (Merck Serono S.A., Merck Sharp & Dohme Corp, Merck Sharp & Dohme Corp UK, Merck & Co Inc USA, Merck & Co Inc., Merck Patent GMBH, Merck Frosst Canada Ltd.)	63
Novartis (Novartis AG, Novartis Vaccines and Diagnostics SRL, Novartis AG of Switzerland)	49
Pfizer (Pfizer Inc., Pfizer Products Inc., Pfizer Limited)	29
Ranbaxy Laboratories Ltd. (acquired by Sun Pharmaceuticals)	8
Roche (F. Hoffmann-La Roche AG)	52
Sanofi (Sanofi Aventis, Sanofi Aventis U.S LLC, Sanofi Aventis Deutschland GMBH, Sanofi Synthelabo, France, Sanofi Pasteur, Sanofi Pasteur Ltd.)	34
Sun Pharmaceuticals (Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Advanced Research Company Ltd.)	6
Teva (Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals International GMBH)	14
Torrent Pharmaceuticals Ltd.	5

Source: Intellectual Property India, http://ipindiaservices.gov.in/publicsearch

Cases with patents granted or rejected, or which were abandoned are reported for various objections, jurisdiction of patent office, and ownership of the company. Table 2 also shows the breakdown of Section 3(d) objections raised in these cases. A significant amount of cases include multiple objections, so we present information of cases with *only* a Section 3(d) objection (43 or 8%) and those with multiple objections including Section 3(d) (223 or 45%). Finally, only 15% of all cases were decided prior to the 2013 Supreme Court ruling on the Novartis case.

To examine the importance of Section 3(d) in patent rulings the regression results presented in Table 3 were analyzed. This regression estimates the impact of various factors, including Section 3(d) in

Table 2 — Summary statistics

Cases	Granted	Rejected	Abandoned
All cases: 500	207	72	221
Jurisdiction of Patent Office			
Chennai: 94 (18.80%)	27	27	40
Kolkata: 83 (16.60%)	40	9	34
Mumbai: 157 (31.40%)	69	16	72
New Delhi: 166 (33.20%)	71	20	75
Ownership of company			
Domestic: 143 (28.60%)	59	16	68
Foreign: 357 (71.40%)	148	56	153
Objections			
Section 3(d) objections: 223 (44.60%)	76	34	113
Only Section 3(d) objections: 43 (8.60%)	18	6	19
Novartis ruling			
Pre-Novartis ruling: 71 (14.20%)	23	25	23
Post-Novartis ruling: 429 (85.80%)	184	47	198

Source: Data from Intellectual Property India, http://ipindiaservices.gov.in/publicsearch; authors' computations

Table 3 — Regression results for reject and/ or abandoned cases

	Regression 1 DV = Rejected cases (279)	Regression 2 DV = Rejected and/ or abandoned cases (500)
Variables	Coeff. [p-value]	Coeff. [p-value]
Constant	2.104 [0.028]	3.032 [0.001]
S3(d)	2.192* [0.007]	2.048* [0.000]
Dom	1.240 [0.320]	1.236 [0.277]
Kol	0.261* [*0.001*]	0.398* [*0.014*]
Mum	0.229* [*0.001*]	0.441* [*0.014*]
ND	0.238* [*0.001*]	0.441* [*0.014*]
Rul	0.248* [0.000]	0.599* [0.037]
Chi-square p-value	[*0.000*]*	[*0.000*]*

Source: Data from Intellectual Property India; authors' estimations using Stata 12. *Represents statistical significance at the 5% level of significance.

patent rulings (either for rejections or for a combination of rejections and abandoned cases). The odds ratios are reported. Results show that for both dependent variables, the model is a good fit (based on the Chi-Squire test), meaning that the variables are jointly statistically significant.

The regression estimates the factors that affect cases that are rejected (Regression 1) or rejected and abandoned (Regression 2). For the three Patent Office variables a Wald test for joint statistical significance was conducted and reported (in italics) instead of individual p-values. To test for the fit of the model the chi-square p-value was reported. If the p-value is less than the significance level, it can be concluded that the model without the predictors is a poor fit and thus the variables are jointly statistically significant.

A domestic firm may see fewer rejected or abandoned cases because of their familiarity of conventions and systems. The odds of a rejection and/ or a case being abandoned are higher if the application is made by a domestic firm. This is because the expected home court advantage of domestic firms is reversed by the larger resources (financial and legal) available to foreign firms. Also, some foreign firms (Novartis, Pfizer, Johnson & Johnson, among others) have established the presence in India, and thus would not be at a disadvantage compared with domestic firms. This variable is not statistically significant which may be related to the sure magnitude of foreign patent applications (357 or 71%).

Based on the Wald test, jurisdiction of the patent office matters. The odds for a rejected and/ or abandoned case are highest for Chennai (the omitted condition) and lowest for Mumbai, although the difference is very small for Kolkata, Mumbai, and New Delhi. This indicates that Chennai is the strictest of the four patent offices. Chennai receives about the same number of applications as Kolkata but far fewer than New Delhi or Mumbai (Table 2).

The Novartis case may have led to greater rejections (or abandoned cases) because the Supreme Court upheld the earlier decisions of a patent rejection based on Section 3(d). The results however, show lower odds for rejection for cases decided after the 2013 Supreme Court ruling on Novartis. Specifically, the odds of a patent being rejected fall by 75% after this decision. Thus, rather than being precedent-setting in increasing patent rejections, the Novartis ruling has had a reverse impact. Perhaps the global controversy has led to greater scrutiny of patent decisions making examiners more cautious. One caveat is that the regression results are for all patent cases, not just those based on Section 3(d) objections. Therefore, it is possible that the ruling may still hurt Section 3(d)-based patent applications even though overall patent applications are more likely to be granted after this landmark ruling.

As noted earlier, approximately half of the cases in the sample had a Section 3(d) objection (Table 2). The regression results in Table 3 show that this clause is a statistically significant determinant of rejection and/ or abandoned cases. As expected this objection increases the chances of a case being rejected and/ or abandoned. At a value of approximately 2, the odds of a patent case being rejected and/ or abandoned double when there is a Section 3(d) objection. This clearly highlights the importance of this clause and the difficulty of overcoming this objection.

One reason for this difficulty is the phrase "therapeutic efficacy" which as noted earlier is ambiguous and too restrictive.[28] Thus, it is important to identify the factors that are associated with a Section 3(d) objection and rulings. Table 4 compares patent decisions of cases with and without Section 3(d) objections. *Granted* v *rejected* cases (denoted as GR), and *granted* v *rejected or abandoned* cases (denoted as GRA) are analyzed in Table 4.

The patent grant, reject, or abandoned cases are separated based on Section 3(d) or non- Section 3(d) objections. The number of cases granted, rejected, and abandoned for each category as well as granted cases as a percentage of granted and rejected cases (G/ GR) and granted cases as a percentage of granted, rejected, and abandoned cases (G/ GRA) are reported. A greater portion of non-Section 3(d) cases are granted. There are 76 granted cases with Section 3(d) objections which make up 69% of GR cases and 34% of GRA cases. For non-Section 3(d) cases, these numbers are 131 granted cases which are 78% and 47% for GR and GRA cases, respectively.

Chennai has the lowest percentage of granted cases for both Section 3(d) and non-Section (d) cases. For Section 3(d) cases, 50% of Chennai's GR cases and 25% of Chennai's GRA are granted compared with 68%-75% of GR cases and 35%-36% of GRA cases for the other jurisdiction offices. For non-Section 3(d) cases, granted cases in Chennai are 50% of GR cases and 30% of GRA cases. These numbers range from 84%-93% of GR cases and 48%-63% of GRA cases for other jurisdiction offices. This supports the

Table 4 — Patent decisions for Section 3(d) and non-Section 3(d) cases

	Section 3(d) objections cases (223)			No Section 3(d) objections cases (277)		
Category	G^*/ R / A^*	G / $(GR)^*$	G^*/ $(GRA)^*$	G^+/ R^+/ A^+	G^+/ $(GR)^+$	G^+/ $(GRA)^+$
	76/ 34/ 113	69%	34%	131/ 38/ 108	78%	47%
Jurisdiction of Patent Office						
Chennai (28, 66)	7/ 7/ 14	50%	25%	20/ 20/ 26	50%	30%
Kolkata (43, 40)	15/ 7/ 21	68%	35%	25/ 2/ 13	93%	63%
Mumbai (50, 107)	18 / 6/ 26	75%	36%	51/ 10/ 46	84%	48%
New Delhi (102, 64)	36/ 14/ 52	72%	35%	35/ 6/ 23	85%	55%
Ownership of company						
Domestic (51, 92)	17/ 6/ 28	74%	33%	42/ 10/ 40	81%	46%
Foreign (172, 185)	59/ 28/ 85	68%	34%	89/ 28/ 68	76%	48%
Objections						
Section 2(1)(j)/(ja) (149, 116)	42/ 25/ 82	63%	28%	44/ 25/ 47	64%	38%
Section 3(e) (74, 34)	29/ 10/ 35	74%	39%	15/ 7/ 12	68%	44%
Section 10(4) (34, 33)	10/ 12/ 22	83%	29%	10/ 6/ 17	63%	30%
Novartis Ruling						
Pre- (23, 48)	10/ 6/ 7	63%	43%	13/ 19/ 16	41%	27%
Post-(200, 229)	66/ 28/ 106	70%	33%	118/ 19/ 92	86%	52%

Source: Data from Intellectual Property India; authors' computations.

regression result that Chennai is a more difficult jurisdiction for patent applications in general, but also shows that the unusually high odds of rejection in Chennai are associated with non-Section 3(d) cases.

Domestic firms have greater percentages of granted cases. However, whether a case has a Section 3(d) objection or not, does not lead to significant differences in the share of granted cases for domestic compared to foreign firms. Thus, ownership does not appear to be a differentiator in rulings on Section 3(d) cases.

Focusing only on G/ GR, Section 3(d) cases which also have Section 2(1)(j)/(ja) objections have a lower percentage of granted compared with Sections 3(e) and 10(4). The percentages are 63%, 74%, and 83% respectively. The pattern is similar but the differences are not that stark when compared with granted cases as a share of all cases (GRA). Those percentages are 28%, 38%, and 29% respectively. Non-Section 3(d) cases have a lower share of granted cases for those with Section 10(4) objections (63% for GR cases and 30% for GRA cases). The difference between Section 10(4) and Sections 2(1)(j)/(ja) and 3(e) are minor when considering GR cases (64% and 68% for Sections (1)(j)/(ja) and 3(e), respectively) and are bigger for GRA cases, 38% and 44% respectively. Overall, a clear story does not emerge about the importance of these other objections as a distinguishing feature of Section 3(d) cases.

The difference between the percentages of non-Section 3(d) cases granted pre- and post- the Novartis ruling is significant. Before the Supreme Court delivered its final decision, 41% of GR cases and 27% of GRA cases were granted as opposed to 86% and 52% of GR and GRA cases after the ruling. When consider Section 3(d) cases, a greater percentage of GR cases are granted after the Novartis ruling (70%) compared with prior to it (63%). This difference is not as significant as what we see for non-Section 3(d) cases noted earlier. Also, the trend is reversed when we consider GRA cases. This suggests that our regression results of lower odds for rejected and/ or abandoned cases after the Novartis ruling were driven by non-Section 3(d) cases. Thus, while our evidence should alleviate the fears of those who believed that the Novartis ruling would reduce patent grants, it does not eliminate the concerns related to Section 3(d) use.

Conclusion

Critics of Section 3(d) have argued that this piece of the law is misused. Approximately, 45% of the cases in the sample have 3(d) objections which support concerns that this piece of the law may be heavily used. Also, Section 3(d) objection is a statistically significant determinant of patent decisions. The odds of a case being rejected and/ abandoned double if there is a Section 3(d) objection. By itself, this would not indicate misuse of Section 3(d). Two other conclusions from our regression results and case analysis are noteworthy. First is the Supreme Court ruling on the Novartis case, which

was based on a Section 3(d) objection. Surprisingly, the odds of a rejection after this ruling dropped drastically. This may be because examiners are more cautious given the increased scrutiny caused by the controversial case. This may allay the fears of misuse of Section 3(d). However, we find that this decline in rejections is related to non-Section 3(d) cases.

Another conclusion relates to jurisdictional differences in patent decisions. The applications to Chennai Office have the highest odds for cases being rejected and/ or abandoned. The Patent Office denied Novartis the patent based on Section 3(d). Thus, it may be reasonable to conclude that fewer Section 3(d) cases are granted in Chennai compared to other offices. However, that is true for non-Section 3(d) cases as well. Moreover, the differential between Chennai and the other offices (Kolkata, Mumbai, and New Delhi) is much greater for non-Section 3(d) cases. This leads us to conclude that while Chennai is a stricter jurisdiction, it is not because of Section 3(d).

Section 3(d), and similar versions of it in patent laws in other countries, was designed to restrict the extension of monopoly rights for slight modifications. The findings show that the odds of patents being rejected and/ or abandoned increase due to Section 3(d). Supporters of this may thus look at the statistics and argue that this clause is working as it should. Critics of this clause may fear the high and increasing reliance on Section 3(d).

Results highlight the complexity of drawing conclusions since there are contradictory influences of factors that affect Section 3(d) objections and rulings. However, critics of Section 3(d) are correct to be wary. With more Section 3(d) objections, not only will the odds of a patent being rejected or a case being abandoned increase, but the impact of other factors will become less important. Thus, the influence of Section 3(d) on patent decisions will continue to rise.

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