

# Commentary on India's Economy and Society Series

## 2

### Dimensions of India's Intellectual Property Right System How Many Patents are Commercially Exploited in India?

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**CDS**

Thiruvananthapuram

India's Economy and indeed its society has been undergoing a major change since the onset of economic reforms in 1991. Overall growth rate of the economy has increased, the economy is getting increasingly integrated with the rest of the world and public policies are now becoming very specific compared over arching framework policies of the pre-reform period. Over the past few years, a number of important policies have been enunciated, like for instance the policy on moving towards a cashless economy to evolving a common market in the country through the introduction of a Goods and Services Tax. Issues are becoming complex and the empirical basis difficult to decipher. For instance the use of payroll data to understand growth in employment, origin-destination passenger data from railways to understand internal migration, Goods and Services Tax Network data to understand interstate trade. Further, new technologies such as Artificial Intelligence, Robotics and Block Chain are likely to change how manufacturing and services are going to be organised. The series under the "Commentary on India's Economy and Society" is expected to demystify the debates that are currently taking place in the country so that it contributes to an informed conversation on these topics. The topics for discussion are chosen by individual members of the faculty, but they are all on issues that are current but continuing in nature. The pieces are well researched, engages itself sufficiently with the literature on the issue discussed and has been publicly presented in the form of a seminar at the Centre. In this way, the series complements our "Working Paper Series".

CDS welcomes comments on the papers in the series, and these may be directed to the individual authors.

**DIMENSIONS OF INDIA'S INTELLECTUAL  
PROPERTY RIGHT SYSTEM  
HOW MANY PATENTS ARE COMMERCIALY  
EXPLOITED IN INDIA?**

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May 2018

## **ABSTRACT**

India is perhaps the only country in the world which has a law on working of granted patents. In fact in 2012, the Indian Patent Office invoked this unique provision to grant a compulsory licence for an anti-cancer drug and this policy was much hailed. However, a recent Public Interest Litigation before the Delhi High Court, the issue of largescale non-working of patents was brought to the public. In the context, the paper undertakes a survey of the unique dimensions of India's patent regime, works out the working rate of patents that are in force over the pre and post TRIPS compliant regime and analyses the responses received from all stakeholders regarding policy of annual reporting on the working of patents. The paper thus serves the purpose of initiating an informed conversation on this important policy.

**Keywords:** patent non-use, working of patents, Form 27, compulsory licence, TRIPS, Indian Patent Office

**JEL Classification:** K11, 031, 034, O38

## **Dimensions of India's Intellectual Property Right System, How many Patents are Commercially Exploited in India?**

*“Patents are supposed to spread knowledge, by obliging holders to lay out their innovation for all to see; they often fail, because patent-lawyers are masters of obfuscation. Instead, the system has created a parasitic ecology of trolls and defensive patent-holders, who aim to block innovation, or at least to stand in its way unless they can grab a share of the spoils. An early study found that newcomers to the semiconductor business had to buy licences from incumbents for as much as \$200m. Patents should spur bursts of innovation; instead, they are used to lock in incumbents' advantages”.*

**[Economist, August 8, 2015)**

### **Introduction:**

Recent discussions and events have shown that everything is not alright with the patent system not just in India but across the world including the USA which incidentally originated the patent system as an incentive for innovation and where the patent system is enshrined in her constitution<sup>1</sup> (Economist, 2015). But is also generally held that most patents are never commercially exploited even by the patentee herself. Precise estimates of the percentage of patents that have actually been commercially exploited<sup>2</sup> have not been compiled anywhere in the world as most patent laws across

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1 Patent rights are grounded in the U.S. Constitution. Article I, Section 8, Clause 8 authorises Congress “to promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries.” The First Congress provided for patent protection in the Patent Act of 1790, and patent grants have been authorised under federal law since that time.

2 Studies have found that 40 to 90 per cent of the patents are never exploited or licensed out by their owners (Saunders 2002). Even in the case of Triadic patents, only 60 per cent of it is commercialized in the case of Japanese and US inventors (Sadao and Walsh, 2009). The remaining ones held as strategic patents to deter entry by competitors.

the world and the TRIPS Agreement<sup>3</sup> which harmonised it does not have anything specific to state on the non working of patents in the world. The U.S. Supreme Court, for instance, has consistently and adamantly held that patents do not require patentees to use or commercialise their inventions. Rather, patents simply grant inventors the right to exclude others from using or producing their inventions. That exclusive right, once granted, cannot be taken away because of a right holder's failure to work the patent (Tyler, Neil S, 2014).

However, in the West, there is now a movement in which patent holders are increasingly making voluntary public commitments to limit the enforcement and other exploitation of their patents. The movement is known as patent pledges, the best example of it is the FRAND (Fair, Reasonable and Non-Discriminatory) commitment, in which a patent holder commits to license patents to manufacturers of standardized products (Contreras and Jacob, 2017). Apart from technical standard setting patent pledges have also been appearing in fields such as open source software, green technology and the biosciences.

The literature that deals with this issue is the one on patent non-use and is almost entirely dominated by references to the non-use of patents in developed countries. Non-use of patents exacerbates litigation when patentees build "thickets" of strategic patents that cover little innovative progress and instead serve as a legal weapon to deter entry by new firms and thereby earn excessive monopoly profits (Shapiro 2001; Hall and Ziedonis 2001).

India is one of the few developing countries which have taken maximum advantage of the flexibilities provided in the TRIPS Agreement and has designed a patent law that is very conducive for incentivising innovations in the country. These flexibilities range from fully utilising the transition period of ten years to make its own patent regime TRIPS compliant to inserting a specific provision (namely Section 3(d)) for raising the bar on the inventiveness criteria for granting a patent in the case of pharmaceutical patents. In fact in the recent celebrated "Glivec case", the supreme court of the country had invoked this specific section not to grant a patent for an anti-cancer drug developed by one of the largest pharmaceutical companies in the world.

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3 TRIPs provide no specific obligations regarding the working of patents. However, Articles 27 to 31 can be interpreted in terms of local working of patents. Article 27(1) establishes the legal framework for patentability, providing that patents must be available for all types of invention – whether products or processes – in all fields of technology, provided that they:

- are new;
- involve an inventive step; and
- are capable of industrial application.

Article 27 (1) further provides that patents must be available – and patent rights enjoyable – without discrimination regarding:

- the place of invention or field of technology; or
- whether products are imported or locally produced.

However, this provision is silent regarding the working of patents. Developed countries have argued in various WTO disputes that the local patent working requirement contravenes Article 27 of TRIPs. However, developing countries have argued that Article 27 should be read in the context of Articles 30 and 31, which provide an exception to it.

Motivation for the paper is from three sources. First, we have been pointing out in our research (Mani and Nelson, 2013) that India's patent regime is characterised by many dimensions like the pre and post-grant opposition to granting of patents, a higher bar on the criteria of inventiveness and on working of granted patents in India<sup>4</sup>. However, we had not gone into the implementation aspects of these laudable characteristics. Beginning with the present study, we are analysing in detail these dimensions one at a time. Second, very recently a writ petition was filed by one of India's leading activist in the realm of IPR laws, Shamnad Basheer<sup>5</sup>, before the Delhi High Court highlighting glaring non-compliance of the Patent Act 1970 by the Indian Patent Office. The writ petition and the court order has prompted the Indian Patent Office to elicit responses from all stakeholders with respect to framing rules for implementing the provisions of the Patent Act with respect to working of patents<sup>6</sup>. Third, there has been a small but growing literature on the issue of non-use of patents. Most of this literature is in the context of the USA where non-working of patents is legally sanctioned. But there are two recent papers in the Indian case that are spot on the no-use of patents. The first one by Chaudhuri (2014) found that only 12.6 per cent of the patented products by MNCs, for which the requisite data were available, were commercially exploited in the country. Further, only less than percent of these were actually manufactured in India, while these MNC patentees imported the rest to the country. Chaudhuri also noted that the Form 27 was inadequately filled in reported with practically no required information. The second and more recent study deals with the issues on non-use of patents in the Indian case by analysing in detail working of patents granted by the Indian patent office in the case of mobile devices (Contreras, Lakshane and Lewis, 2017). The present paper adds to this literature and will serve as a survey of issues on the topic.

The paper is organised as follows. Section 2 maps out the provisions of India's Patent Act 1970 dealing with the non-use of patents including the penalties that are imposed on erring patentees who choose not to comply with these stringent provisions. Section 3 works out the extent of non-compliance of this important provision. Section 4 discusses the legal intervention in this non-compliance, which

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- 4 This has manifested in the form of a Section 3(d) in the Indian Patent Act, 1970. Section 3(d) of the Indian Patent Act 1970 (as amended in 2005) does not allow patent to be granted to inventions involving new forms of a known substance unless it differs significantly in properties with regard to efficacy. Thus, the Indian Patent Act does not allow evergreening of patents. This provision has immense implications for the pharmaceutical industry. A recent study by Feroz Ali and Sudarsan Rajagopal of 1723 pharmaceutical patent applications that were rejected by the Indian Patent Office between 2009 and 2016, found that about 45 per cent of the rejections were on grounds of Section 3(d). This findings of the study has been reported by the authors in the Hindu, <http://www.thehindu.com/opinion/op-ed/how-india-rejects-bad-patents/article22282403.ece> (accessed on April 18, 2018). On the contrary, another study by Sampat and Shadlen (2018), based on first examination reports or patent prosecution data from the Indian Patent Office, reached the conclusion that there has been a sharp increase over time in the use of Section 3 (d), though in some cases it was used for rejecting primary patent applications, contrary to its intent.
- 5 For details of the Public Interest Litigations which Shamnad Basheer has been fighting could be seen in his blog. See Basheer (2018).
- 6 The detailed responses from the stakeholders and a summary of these can be found at: <http://www.ipindia.nic.in/newsdetail.htm?402/> (accessed on April 23 2018).

took place recently also summarises government's response to the legal verdict and also marshals the comments received from various stakeholders. Section 5 concludes the paper and speculates on the way forward.

## 2. Patent Law on Working of Patents

Under Indian Patents law, every patentee and every licensee of a granted patent is required to file a statement as to the extent to which the patented invention has been worked on a commercial scale in India. Further, in addition to this the following questions must be answered as well:

- if not worked, the reasons for not working and the steps being taken for the working of the invention;
- if worked, the quantum and value (in rupees) of the patented product which is either manufactured in India or imported from other countries along with the details of each country;
- the licenses and sub-licenses granted during the year; and
- whether the public requirement has been met, at a reasonable price partly, adequately or to the fullest extent.

All these data are to be filed before the Indian Patent Office in a form generally referred to as "Form 27". The form is to be filed annually in respect of all patents granted in India<sup>7</sup>.

Non-compliance with the working statement may increase the risk of compulsory license and revocation of the patent in India. In fact, if the patent is not worked within three years of it being granted, a compulsory license may be issued. If the compulsory license is not implemented by the company receiving the license within two years of receipt of the license, the patent office may revoke it. Hitherto, the patent office has issued only one compulsory license to an Indian pharmaceutical company for manufacturing an anti-cancer drug whose original patent was held by an MNC, which did not work that patent in India. Details of this case are presented in Box 1. All commentators hailed granting of this compulsory license. However, the recent judgment from the Delhi High court showed that the company, which received the compulsory license, does not seem to have reported the quantity and value of the drug, *SorafenibTosylate*, for which it received a compulsory license<sup>8</sup>. However, the website of the company indicates that the company, Natco Pharma, is actually manufacturing and

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7 The time line to file the statement is March 31 every year for the preceding calendar year. For instance, March 31, 2018 for the working of patent in 2017 in respect of all patents which were granted prior to July 2017.

8 High Court of Delhi (2018), See especially paragraphs 7 through 9 of the Order where it clearly stated that the licensee, namely NATCO Pharma in this case, had not submitted any documentary evidence to the Indian Patent Office, that it had actually worked or implemented the compulsory license. See also Mueller and Singh (2018).



selling the drug in question<sup>9</sup>. Further, one more pharmaceutical company, Cipla has also been manufacturing and selling this anti-cancer drug.

Also, the patentee or the licensee shall be punishable with a fine, which may extend to INR 1 million for non-submission of the working statement (namely Form 27). Despite the risk of revocation and huge penalty, it seems that the compliance mandate requirement by the right-holders is not fulfilled at the Patent Office. See Figure 1 for trends in submission rate during 2010-2016 as the Indian Patent Office started publishing this information only since 2010 despite it being statutorily required to be reported every year. Further, a mere submission of Form 27 does not necessarily mean that the most crucial piece of information on working of patents is reported. In fact, many firms do not furnish any data on working of patents excepting to religiously report Form 27 year after year<sup>10</sup>. See Figures 2a and 2b, which present the relevant portions of Form 27 reported by an MNC company and by the CSIR with respect to the working of several of its patents granted by the Indian Patent Office. This clearly shows that firms and institutions are filing the required Form 27 with practically no information. So a submission rate of 89 per cent with blank forms is a clear mockery of the Law. We will analyse the working of patents or patent non-use in some detail in the subsequent section.

It may be added that patentees are not required to furnish Form 27, if the reasons for that fall into any of the following categories:

- Due to lack of market potential for the invention; Market is being developed;
- May be worked in the future depending on market demand and when technology is mature;
- The patentee is actively working to develop a market for the patented product/process in India. The technology may be available for licensing;
- The patentee is in the lookout for appropriate working opportunities in a large scale.

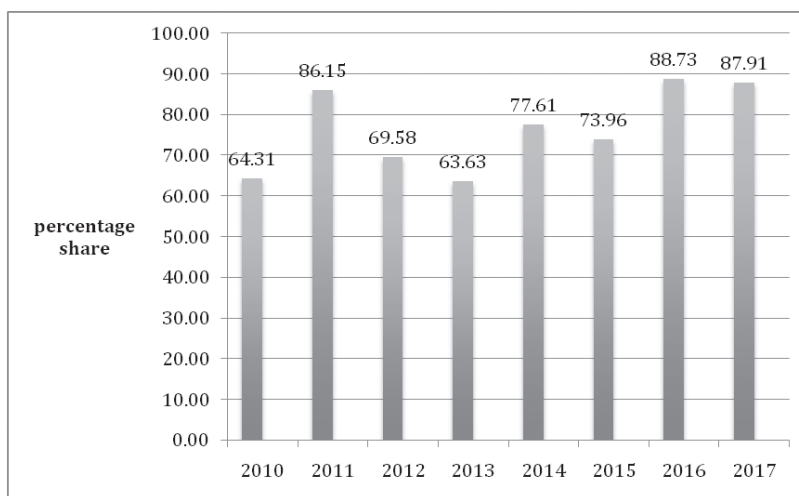
It would have been instructive to find out how the propensity to report Form 27 would have varied across different types of patentees, namely between MNCs and domestic patentees, between private sector and the public sector, between firms, institutions and individuals. Such a detailed data are available only for two years, namely 2012 and 2013 as the patent office has made the submissions of only these two years public.

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9. See Natco Pharma, <http://www.natcopharma.co.in/our-business/blockbusters/> (accessed on May 4, 2018). Further NATCO Pharma has responded to the stake holder discussions on provisions on working of patents Act and Rules. Two of their responses are worth noting:

- “Form 27 should be modified in such a way that the patentee should require to file working statement even for the period prior to the patent grant. The reason is that the working statement of the patented invention is filed from the date of grant of patent only and the term of patent is 20 years from the date of application”.
- “A certificate from Company Secretary/Chartered Accountant/Cost Accountant should be attached as a supportive document for Form-27 to substantiate the quantity and value of the patented product, so that the Company/professional giving such certificate will be cautious as, if found incorrect statement of facts and figures, they are held responsible and liable”.

10. The Indian Patent Office has made available on its website all Form 27s that were reported to it by patentees during 2012 and 2013. These could be accessed at: <http://ipindiaonline.gov.in/workingofpatents/> (accessed on April 21, 2018).

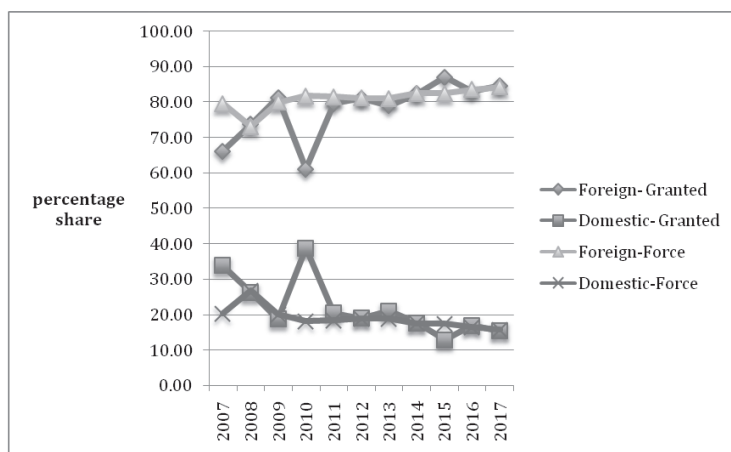


**Figure 1: Submission rate with respect to Form 27 at the Indian Patent Office**

Source: Computed from Controller General of Patents, Designs, Trade Marks and Geographical Indications (Various issues).

### 3. Working Rate of Patents in India

Over 80 per cent of the patents that are in force in India at any particular point in time and the patents granted during a year are by foreign inventors which are largely MNCs. Domestic inventors account for no more than 20 per cent of the patents in force and the patents granted, and these have been declining over time. See Figure 2.



**Figure 2: Share of Foreign and Domestic inventors in patents in force and patents granted by the Indian Patent Office**

Source: Computed from Controller General of Patents, Designs, Trade Marks and Geographical Indications (Various issues).

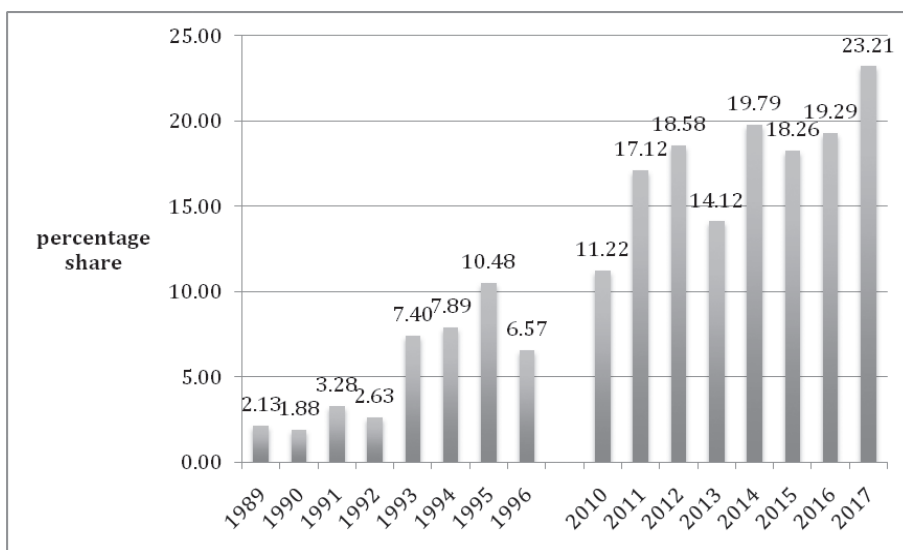
We define the working rate of patents at year “t” as the percentage share of commercially exploited patents at year “t” in total patents in force in year “t”. Figure 3 traces over the two broad phases. Phase 1 refers to the pre TRIPS period 1989 through 1996 and Phase 2 refers to the post TRIPS phase 2010 through 2016. The working rate in the pre TRIPS phase was only 5.28 per cent per annum. This has now increased to 16.91 per cent per annum during the post TRIPS phase. However, this increase masks the fact that over 80 per cent of the patents granted by the Indian Patent Office has not been worked in India. And as seen above, firms have paid callous attention to the working of patents. Our finding with respect to the reporting of Form 27 and the non-working of patents further substantiate the finding of Chaudhuri (2014) although those findings were restricted to a smaller sample of only MNC patentees.

<b>Form-27</b>	<b><u>The Patents Act, 1970</u></b> <b>(39 of 1970)</b>
<b>STATEMENT REGARDING THE WORKING OF THE PATENTED INVENTION ON COMMERCIAL SCALE IN INDIA</b> [See Section 146(2) and rule 131(1)]	
In the matter of Patent No. <b>201716</b> Application no:IN/PCT/01/01248/KOL of 02-Apr-2001	
<b>I/We, MATSUSHITA ELECTRIC INDUSTRIAL CO LTD</b>	
the patentee(s) under Patent No. <b>201716</b> hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year <b>2012</b> .	
(i) The patented invention: [ ] worked* [ <input checked="" type="checkbox"/> ] not worked (tick relevant box [✓])	
If not worked: reason for not working and steps being taken for working of the Invention : <b>Nothing in Particular</b>	
If worked: quantum and value (in Rupees), of the patented product: <b>Not Applicable</b>	
Manufactured in India: <b>Not Applicable</b>	
Imported from other countries. (give country-wise details): <b>Nil</b>	
(ii) the licences and sub-licences granted during the year : <b>No</b>	
(iii) state whether public requirement has been met partly / adequately / to the fullest extent at reasonable price: <b>Not Applicable</b>	
The facts and matters stated above are true to the best of our knowledge, information and belief.	
Dated this 15 day of March 2013	
The Controller of Patents The Patent Office at <b>Kolkata</b>	<b>MATSUSHITA ELECTRIC INDUSTRIAL CO LTD</b> By his/their Agent and Attorney <i>M. Basu</i> (M Basu) REG.NO. IN/PA-377 of De Penning & De Penning

**Figure 2a: A sample Form 27 filed by an MNC at the Indian Patent Office in 2012**

Source: Controller General of Patents, Designs and Trade Marks, <http://ipindiaonline.gov.in/workingofpatents/> (accessed on April 21, 2018).





**Figure 3: Trends in working rate of Patents in India, 1989-2017**

Source: Gupta (undated), Controller General of Patents, Designs, Trade Marks and Geographical Indication (various issues).

#### 4. Legal Intervention to deal with Non-commercial Exploitation

Legal intervention to deal with working of patents started from 1996, and between that year and now (c2018) there have been at least seven interventions. The latest being the Delhi High Court Order of January 10, 2018, in response to a public interest litigation by the legal activist, Shamnad Basheer. Table 1 summarises the cases between 1996 and 2015.

**Table 1: Summary of legal interventions with respect to patent non-use**

Date of Order	Parties & Court	Key discussion
8 <sup>th</sup> March 1996	Franz Xavier Huemer vs New Yash Engineers	In this case, the plaintiff who has registered patents in India in 1984 but has not used them in India cannot, in equity, seek temporary injunction against the respondent.
10 <sup>th</sup> September 2009	Strix vs Maharaja Appliances Delhi High Court	In this case court found that the submission that the Plaintiff has not worked its patent in India is also without merit. It is the Defendant's own case that it was purchased the product from the Plaintiff in the year 2005-2006 and when it found that the products were defective, it started improving the product from China.

27 <sup>th</sup> January 2010	Glaverbel S.A. versus Dave Rose Delhi High Court	Form 27 was found insufficient to test whether there is an actual commercial working/exploitation of Invention in India. Thus, the plaintiff when it files merely forms and an affidavit to depose the working is not able to qualify on the count of commercial working of the invention.... The forms filed by the plaintiff do not clearly reveal commercial sales arising out of the sale of the plaintiff's inventions in India.
9 <sup>th</sup> March 2012	Natco vs. Bayer Patent Office Compulsory License Order	By referring to Form 27, The Patent Office found that Bayer did not import the drug at all in 2008 and only started importing it in small quantities in 2009 and 2010. Seeing that Bayer was not making the drug accessible to more people, Natco applied for a compulsory license under Section 84 of the Patents Act, 1970 which was then granted by the controller and upheld later by the Bombay High Court.
9 <sup>th</sup> May 2014	Sandeep Jaidka versus Mukesh Mittal Delhi High Court	There has been complete non-use of the patented invention by the plaintiff, and the same is evident from the Form 27 filed by the patentee himself before the Patent Office.
9 <sup>th</sup> January 2015	Novartis vs Cipla Delhi High Court	...requirement of law is limited to working the patent in India so that the same is available to the public at large. It is not essential that the patent must be worked by manufacturing the patented product in India. The arguments of the defendant have no force that the rights conferred under Section 48 are subject to Section 83... the Act does not mandate that no patent protection would be granted to a patentee unless the local manufacturers are undertaken.

Source: <http://www.stratjuris.com/requirement-for-working-the-patents-in-india-form-27> (accessed on April 18, 2018).

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The following four issues stand out;

1. Most of the legal interventions have been initiated during the post TRIPS period;
2. Almost all the patentees that were accused of non-use of their patents granted in India are MNCs;
3. There has been only one case where both the plaintiff and the defendant are local inventors; and
4. The only tangible outcome has been the issuance of a compulsory license which, as we know from the 2018 order that there is no quantitative data on the quantum and value of the licensed drug, *SorafenibTosylate*, that has actually been manufactured and sold.

It is thus clear that despite the existence of an important provision in India's IPR legal framework, it was never implemented or taken seriously by the Indian Patent Office.

Since the Delhi High Court Order of 2018 is the most important one in the series of legal intervention, we will discuss mainly the outcome of the order.

### **The Delhi High Court Order and its aftermath**

In view of the order on the non-working of patents, the Indian patent office has sought detailed opinion from all stakeholders about the policy on working of patents, submission of Form 27 with the requisite information on working of patents, the administration of penalties for non-compliance etc<sup>11</sup>. The detailed comments received from a wide variety of stakeholders have been posted on the website of the IPO<sup>12</sup>. As can be seen, detailed comments on the above three aspects have been received from a wide variety of stakeholders, both domestic and foreign. The IPO has compiled the gist of these comments to a very useful summary document<sup>13</sup>. A total of 64 responses were received within the specified time limit. Detailed comments were received from domestic patent attorneys, domestic companies (almost exclusively pharmaceutical), MNCs doing business in India, domestic industry associations, and foreign Intellectual Property Associations and a number of academicians from domestic law schools. Among the foreigners who have responded, there was remarkable regularity in responses

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11 See the circular at: [http://www.ipindia.nic.in/writereaddata/Portal/News/391\\_1\\_Circular\\_for\\_Stakeholders\\_meeting\\_regarding\\_issues\\_related\\_to\\_Working\\_of\\_patents\\_.pdf](http://www.ipindia.nic.in/writereaddata/Portal/News/391_1_Circular_for_Stakeholders_meeting_regarding_issues_related_to_Working_of_patents_.pdf) (accessed on May 5, 2018)

12 These could be accessed at: [http://ipindia.nic.in/writereaddata/Portal/Images/pdf/Response\\_as\\_received\\_from\\_Stakeholders\\_regarding\\_issues\\_related\\_to\\_Working\\_of\\_Patents\\_under\\_the\\_Patents\\_Act\\_1970-min.pdf](http://ipindia.nic.in/writereaddata/Portal/Images/pdf/Response_as_received_from_Stakeholders_regarding_issues_related_to_Working_of_Patents_under_the_Patents_Act_1970-min.pdf) (accessed on May 5, 2018)

13 This could be accessed at: [http://ipindia.nic.in/writereaddata/Portal/Images/pdf/Response\\_from\\_stakeholders\\_on\\_Working\\_of\\_Patents- Copy.pdf](http://ipindia.nic.in/writereaddata/Portal/Images/pdf/Response_from_stakeholders_on_Working_of_Patents- Copy.pdf) (accessed on May 5, 2018)

from two countries, namely the United States of America and Japan. Majority of the responses point to the following propositions<sup>14</sup>:

- i. India's current system of requiring annual working statements through Form 27 is excessively onerous and costly to patentees and ill-suited to the reality of patented technology;
- ii. The current *Form 27* includes ambiguous and subjective fields such as "commercial scale", "value" and "public requirement".
- iii. Even the fundamental concepts of "working" and "non working" in this context are not fully understood by many patentees, it is claimed;
- iv. Form 27 does not align with current trends in the commercialisation of innovation, as it is very rare that a single patent covers the entirety of an individual product. It is far more common that a product may comprise several patented and unpatented elements. This complex reality makes it difficult for patentees to ascertain the "quantum" and "value" of a patent as contemplated in Form 27.
- v. Companies must invest significant amounts of time, effort, and money to produce the information necessary to maintain compliance with Form 27. For MSMEs and those with large patent portfolios in India, the legal and institutional costs can be excessive.
- vi. Doing away with Form 27 will reduce the work on the patent office and thereby help reducing pendency.

## 5. The Way Forward

India has a unique law with respect to the granting of patents. It is one of the few developing countries, which have taken advantage of several flexibilities built into the TRIPS agreement. It is also perhaps the only country in the world having an explicit requirement for patents to be worked within its territory within reasonable period of it being granted. This policy on working of a patent makes it a real indicator of innovation and the economy and society benefiting as a result of the new invention. If there is no requirement for working of a patent, it becomes a mere entry deterring strategy by incumbent firms and in some cases the existence of patent thickets can actually reduce the number of new innovations. So, it is only prudent that the government continues with the policy on working of patents. In fact, the introduction of a patent box in the Finance Bill of 2016-17, a new tax regime has been created whereby income earned by a qualifying taxpayer from the exploitation of a patent would be taxed at a preferential rate of 10%. No deduction of any expenditure or allowance would be allowed in computing the income under this regime, and the income qualifying for the preferential rate should be by way of royalty in respect of a patent developed in India. This should encourage not only domestic companies but also foreign companies to commercially exploit patents

<sup>14</sup> Most of the respondents have said the same thing using a different formulation. The views expressed by USPTO can be taken as representative of the majority view.



that are developed in the country. However, based on the submissions by a large number of stakeholders, the IPO may consider simplifying the reporting under Form 27 so that it becomes a credible policy. Companies securing a compulsory licence must also report the working of the licence. On this crucial issue, the country must not buckle under the pressure from any quarter, domestic or foreign<sup>15</sup>, in diluting the unique provisions of India's patent laws.

**Box 1: Issue of a Compulsory Licence for an anti-cancer drug for not working a granted patent in India**

India's first compulsory licence was issued by the IPO for Bayer's patented anti-cancer drug Nexavar (sorafenib tosylate) (IN 215758) on the grounds that Nexavar was unreasonably highly priced at Rs 280,000 for a month's supply of 120 tablets (approximately \$4,200) and available to only 2% of the population. The compulsory licence was granted to Natco Pharma Ltd, a generic Indian company which sold the generic version of Nexavar at the much lower price of Rs 8,800 (approximately \$132).

In its application for a compulsory licence, Natco relied on the working statement filed by Bayer after grant of its patent in 2008. Natco demonstrated to the controller general that:

- the working statements submitted by Bayer for 2008 to 2011 were incomplete and had many discrepancies; and
- Bayer filed no. Form 27 working statement in 2008, despite the patent having been granted that year.

The controller general held that:

- the 2009 Form 27 provided no logical information regarding sales of Nexavar in India; and
- the 2009 and 2010 Form 27s together revealed that Bayer had made an insignificant quantum of the drug available to the public in two years.

The controller general also noted that Bayer's figure for cancer patients' annual requirement of the drug (27,000 boxes per year) varied significantly from that submitted by Natco (70,000 boxes per year). The controller noted that in 2008 Bayer did not import the drug at all, while in 2009 and 2010 it imported the drug only in small quantities. These quantities appeared prima facie to be grossly inadequate. Therefore, the controller general held that Bayer had not satisfied the reasonable requirements with respect to a patented invention under Section 84(1) – an important prerequisite for the grant of a compulsory licence.

Source: <http://www.worldtrademarkreview.com/Intelligence/IP-Lifecycle-India/2017/Articles/Local-working-of-patents-in-India-an-analysis> (accessed on April 19, 2018).

15 Various agencies, both government and private, from the United States has been lobbying hard to get many of the unique provisions of India's IPR laws repealed or watered down. The civil society organization, *Medecins Sans Frontiers* have compiled a timeline of US Attacks on India's Patent Laws and Generic Competition between 2012-2014. During this time, the US agencies tried more than 40 times to influence a change or amendment to India's Patent Laws and Rules so that it is rid of provisions like "working of patents" and "Section 3(d)". See *Medecins Sans Frontiers* (2015). See also Mani (2014) and Mani (2016).

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