



Compulsory licensing:
India's maiden experience



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Abstract: Under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) all parties to the agreement are allowed flexibility in issuing licenses for manufacturing pharmaceutical drugs, in line with their public policy objectives. The licenses may be issued under certain conditions, even if the patent holder (innovator) has an exclusive right to the markets. India made use of this flexibility in March 2012 when it granted its first compulsory license to a domestic company for manufacturing and selling a generic version of an anti-cancer drug. This action was contested at the Intellectual Property Appellate Board, but in March 2013 the final decision was in favor of the issuing of the compulsory license.

This paper details the first attempt by the Indian patent system to strike a balance between the innovator's legal and economic rights and the public interest policies of the Government. The paper attempts to set out the various issues and challenges related to this case. An assessment of the compulsory licensing provisions under the TRIPS agreement and the Indian Patent Act shows that the intellectual property regime in India is World Trade Organization (WTO) compatible, and that public health interests need not always be compromised. The authors reason out the possible implications for the various stakeholders through a cost-benefit analysis approach.

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Key words: Intellectual property rights, compulsory license, pharmaceutical, public policy, patents, rights and obligations.

Contents

Introduction	3
1. Legal provisions	4
1.1. Under the Paris Convention.....	4
1.2. Under TRIPS.....	4
1.3. Under Indian National Legislation.....	5
2. Issuance of compulsory licenses, by country.....	6
3. Case of Natco vs. Bayer	8
3.1. Considerations for granting a compulsory license.....	9
3.2. Final decision and imposed conditionality.....	13
4. Impact analysis	14
4.1. Government	15
4.2. Consumers.....	16
4.3. Multinational enterprises.....	17
4.4. Domestic companies	18
4.4.1. Generic producers.....	18
4.4.2. Local innovators.....	19
4.4.3. Partnership agreements with MNEs.....	19
4.4.4. Rest of the world.....	19
5. The way forward	20
References	22

List of Tables

Table 1: Issuance of compulsory licenses, by country, since 1995

Table 2: Timeline of the Natco vs. Bayer case

Table 3: Sales for Bayer

List of Figures

Figure 1: Impact analysis of compulsory license ruling in India

Introduction

India is one of the largest pharmaceutical manufacturers in the world, ranking third in terms of production volume (9.3 per cent of the global share). Yet 65 per cent of India's population still lacks access to essential medicines (Department of Industrial Policy and Promotion, 2010). This is not surprising considering the high prices of drugs, the low income levels and poor public insurance coverage in India.

Moreover, India accounts for 21 per cent of the world's global burden of diseases (World Health Organization, 2012). Developing countries such as India generally experience a high incidence of diseases because of the poor living conditions, inadequate sanitation and hygiene conditions, and low awareness of diseases and health-care measures. The burden of several diseases is also unusually high in India. For example, in India between 2 million and 2.5 million persons are suffering from cancer and some 2.5 million persons are infected with HIV/AIDS, the latter being the highest number of reported HIV/AIDS cases in the entire South Asian region (Department of Industrial Policy and Promotion, 2010).

In addition, India still continues to suffer from a host of diseases that are typical to developing countries, such as tuberculosis, malaria, dengue fever and diarrhea. It was expected that strengthening the intellectual property (IP) regimes and introducing product-based patents in developing countries under TRIPS would result in innovation and development of medicines that were of particular interest to developing countries. However, the development of new drugs in the developing countries has been limited while access to existing drugs is becoming more and more problematic under a stricter IP regime.

At the heart of any patent system lies the responsibility of policymakers to strike a balance between making an innovation available in a commercially viable form at a reasonable price to the public at large while providing fair returns to the innovator. Compulsory licensing is a tool by which a Government allows third parties (other than the patent holder) to produce and market a patented product or process without the consent of the patent owner. Compulsory licenses ensure that the monopoly rights of the innovator do not undermine the right of the people to have access to medicines at affordable prices.

The current paper discusses the various issues and challenges of India's first compulsory licensing case. Section 1 elaborates on the relevant international and national legal provisions for compulsory licensing. Section 2 cites global instances where compulsory licensing has been used in the post-TRIPS era. Section 3 discusses the legal considerations surrounding the ruling while section 4 gives the economic implications for the Indian pharmaceutical industry. Section 5 concludes by highlighting the conflicting interests of the stakeholders. Compulsory licensing appears to be a viable option that may be explored by developing countries such as India for ensuring continued access to medicines while still working within the ambit of international commitments.

1. Legal provisions

The legal underpinnings for compulsory licensing have been provided in the TRIPS Agreement, which has its antecedents in the Paris Convention. India also included clauses for compulsory licensing in its national legislation, even as it shifted from a process-based patent regime to a product-based one for pharmaceuticals, in compliance with the TRIPS Agreement.

1.1. Under the Paris Convention

The Paris Convention of 1883 envisaged provisions for each contracting State to take legislative measures for granting compulsory licenses. According to Article 5A (2) of the Paris Convention (World Intellectual Property Organization, undated):

“Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory license to prevent the abuses that might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”¹ (Paris Convention, 1883 – amended in 1979).

The Convention provided for the granting of compulsory licenses by the member countries at least in cases of the non-working of a granted patent in a country or union. Thus, the concept of compulsory licensing also existed in the pre-WTO era. In fact, the concept of compulsory license existed as early as the 1850s in the then-named United Kingdom of Great Britain and Ireland.

1.2. Under TRIPS

Compulsory licensing is covered in the TRIPS Agreement by:

- (a) Article 30, which provides limited exceptions to the rights conferred under patents, provided they do not “unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.” The article provides the basis for issuing compulsory licenses;
- (b) Article 31, which refers to compulsory licensing as “other use without authorization of the rights holder”, but allows countries to do so only under certain conditions. As per Article 31, to invoke a compulsory license:

¹ Under the Paris Convention, working a patent means working it industrially, i.e., by manufacturing the patented product, or industrial application of the patented process. Thus, the importation or sale of the patented article, or of the article manufactured by a patented process, is not be regarded as “working” the patent (World Intellectual Property Organization, 2007)

- (i) The party applying for a compulsory license must first make efforts to negotiate authorization from the rights holder with “reasonable commercial terms and conditions”;
- (ii) The requirement in (i), however, may be dispensed with in the case of a “national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use”;
- (iii) The use authorized by the compulsory license must be “predominantly for the supply of the domestic market”;
- (iv) The use will be limited to only the purpose for which it is authorized;
- (v) The use must be non-exclusive and even non-assignable, i.e., authorization given to a company cannot be further assignable;
- (vi) If a compulsory license is granted, the original patent holder must be given adequate remuneration under the TRIPS Agreement of 1995 (TRIPS Agreement, 1995; Abbott and Puymbroeck, 2005).

These requirements created a misunderstanding among developing countries that compulsory licenses may be issued only in emergency situations. Clarification on the issue was sought through the WTO Declaration on the TRIPS Agreement and Public Health of 2001 (hereafter, Doha Declaration) and subsequently the Decision on Implementation of Paragraph 6 of the Doha Declaration of 30 August 2003. In particular, the Doha Declaration contains:

- (a) Paragraph 4, which affirms that the TRIPS Agreement “does not and should not prevent member countries from taking measures to protect public health”;
- (b) Paragraph 5(b), which recognizes that certain flexibilities are built into the TRIPS Agreement, including the right of each WTO member to grant compulsory licenses and the freedom to determine the grounds on which such licenses may be granted;
- (c) Paragraph 5(c), which further elucidates that it is up to each member to determine what constitutes a national emergency or other circumstances of extreme urgency. (Department of Industrial Policy and Promotion, 2010; Doha Declaration on TRIPS Agreement and Public Health, 2001).

1.3. Under Indian National Legislation

The Indian Patents Act, 1970, was amended in 1999, 2002 and 2005, making the patent regime of India compatible with TRIPS. Under the new legislation, patentees were able to exercise greater control over their innovations and their exclusive markets. Keeping this in mind, the flexibilities provided under TRIPS were incorporated in the Indian Patents Act, 1970, in order to safeguard public health and improve accessibility to medicines. Relevant chapters on compulsory licenses include:

- (a) Chapter XVI, which deals with the issue of compulsory licenses. The same is covered in four sections of the Patents Act:
 - (i) Section 84, under which general compulsory licenses are issued by the Controller on application;
 - (ii) Section 91, under which compulsory licenses are issued by the Controller for a related patent on application;
 - (iii) Section 92, under which compulsory licenses are issued by the Controller based upon a notification, by the Central Government, of circumstances of national emergency or in circumstances of extreme urgency or in the case of public non-commercial use;
 - (iv) Section 92(A), under which compulsory licenses are issued by the Controller on application for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product, in order to address public health problems.
- (b) Chapter XVII contains provisions for use of inventions for the purposes of government and the acquisition of inventions by the Central Government.
- (c) Chapter VIII of the Patent Rules 2003, and amended in 2006, provides for the modalities of issue and maintenance of compulsory licenses (Department of Industrial Policy and Promotion, 2010).

2. Issuance of compulsory licenses, by country

Compulsory licenses were initially issued by several developed countries and, more recently, by some developing countries (Table 1). Since the Doha Declaration, about 52 countries have issued compulsory licenses (Department of Industrial Policy and Promotion, 2010). The compulsory licenses have typically covered medicines for which there was excessive demand due to the high incidence of the diseases that the drugs targeted. Governments aimed to provide these medicines at a reasonable cost to the public by using the licenses.

In 2007, for example, Brazil issued its first compulsory license for Efavirenz, a drug used to treat AIDS/HIV, when price negotiations failed with the United States of America-based company, Merck & Co. the company held the patent in Brazil for the drug Stocrin, the brand name used for Efavirenz. Stocrin was being provided by the Brazilian authorities through its free AIDS prevention and treatment programme. Spending on anti-retroviral drugs, however, had doubled since 2001 to nearly US\$495 million by 2005. Merck had offered a 30 percent cut in its prevailing price of US\$1.59 per tablet of Stocrin, but Brazilian officials held out for a US\$0.65 per tablet price. When price negotiations failed with Merck, compulsory license was issued. Under the compulsory license, the Government was allowed to import generic Efavirenz from India rather than buy Stocrin. A year's supply of Stocrin cost US\$580 at that time compared with US\$166 for the generic Efavirenz. The Health Ministry of Brazil had estimated that importing generic Efavirenz from India would help it save US\$30 million in

2007 and as much as US\$236.8 million by 2012 (International Centre for Trade and Sustainable Development, 2007).

Table 1. Issuance of compulsory licenses, by country, since 1995

Country	Income group	Date of issue	Drugs/disease
Brazil	Middle	4 May 2007	Efavirenz (for treating HIV/AIDS)
Eritrea	Low	5 June 2005	HIV/AIDS medicines
Ghana	Low	26 October 2005	HIV/AIDS medicines
Indonesia	Middle	5 October 2004	Lamivudine and Nevirapine (for treating HIV/AIDS)
India	Middle	9 March 2012	Sorafenib (for treating cancer)
Italy	High		Finasteride (for treating prostate enlargement), Sumatriptan Succinate (for treating migraine medicines), Imipenem Cilastatin (antibiotic)
Israel	High	9 October 1995	Hepatitis B vaccine
Malaysia	Middle	29 September 2004	Didanosine (ddl), Zidovudine (AZT) and lamivudine+zidovudine (Combivir) (for treating HIV/AIDS)
Mozambique	Low	5 April 2004	Lamivudine, Stavudine and Nevirapine (for treating HIV/AIDS)
Thailand	Middle	25 January 2007	Kaletra (for treating HIV/AIDS) and Plavix (for treating heart disease)
Zambia	Low	21 September 2004	Lamivudine, Stavudine and Nevirapine (for treating HIV/AIDS)
Zimbabwe	Low	May 2002	HIV/AIDS medications

Source: Compiled from information on compulsory licenses issued by countries. Available at www.cptech.org/ip/health/cl/recent-examples.html (accessed 12 August 2013).

Most recently, in 2012, India issued a compulsory license for the anti-cancer drug Sorafenib. The details surrounding the case, which involved Natco Pharma Ltd. and Bayer Corporation, and its implications are discussed in the following two sections.

3. Case of Natco vs. Bayer²

In the 1990s, the international pharmaceutical company, Bayer Corporation, invented a drug called Sorafenib (Carboxy Substituted Diphenyl Ureas). The drug is a palliative and is used to treat Stage IV (advanced) liver and kidney cancer patients. In other words, it is not a life-saving drug but only a life-extending one; it extends life by 4-5 years among kidney cancer patients and by 6-8 months among liver cancer patients.

Bayer had originally applied for the patent in the United States in 1999 and subsequently filed a PCT³ International Application in 2000. Bayer launched the drug in 2005, marketing it under the brand name Nexavar. In India, the patent for the drug was granted in March 2008, and subsequently Bayer started importing and selling Nexavar in India in the same year. A month's dosage of the drug was sold in India at US\$ 5,608.⁴

Three years later, in July 2011, Natco Pharma Ltd. (hereinafter referred to as Natco) applied to the Controller of Patents for a compulsory license to manufacture and sell a generic version of Nexavar. Natco is a Hyderabad-based leading manufacturer and distributor of drugs in India. Earlier Natco, in accordance with the Indian Patent Act, 1970, had approached Bayer for a voluntary license to produce and sell the drug. Citing the exorbitant rates being charged by Bayer, Natco proposed to sell the drug at a price lower than US\$ 200. However the application for the voluntary license was rejected by Bayer. As a result, Natco eventually had to apply for a compulsory license under Section 84(1) of the Indian Patent Act, 1970 (amended in 2005), which states that: "At any time after the expiration of three years from the date of the grant of a patent, any interested person may apply to the Controller for a compulsory license for a patent on any of the following grounds:

- (a) That the reasonable requirements of the public with regard to the patented invention have not been satisfied; or
- (b) That the patented invention is not available to the public at a reasonably affordable price; or
- (c) That the patented invention is not worked in the territory of India."

Table 2. Timeline of the Natco vs. Bayer case

Year	Event
1990	M/S Bayer Corporation invents the drug Sorafenib.
1999	Bayer applies for a patent for the drug in the United States.
2000	Bayer files a PCT application for the drug.
2005	Bayer launches the drug in the market under

² Information pertaining to this section is based on the Patent Controller's Order, Mumbai, 2012, and IPAB Order No. 45, Chennai, 2013.

³ Patent Co-operation Treaty, which is an international patent law treaty concluded in June 1970. It provides a unified procedure for filing patents that would simultaneously provide protection in countries of all the contracting parties of the treaty.

⁴ Exchange rate used is US\$1=Rs50.

- the brand name, Nexavar.
- 2008 Bayer is granted a patent for the drug in India.
 - 2011 M/S Natco, a drug manufacturer based in Hyderabad, applies for a compulsory license to the Controller of Patents for manufacturing and selling a generic version of Nexavar.
 - 2010 M/S Cipla, another Indian drug manufacturer, starts selling a generic version of Nexavar.
 - 2012 First compulsory license granted in India to M/S Natco.
 - 2013 Intellectual Property Appellate Board⁵ upholds the decision made by the Patent Controller regarding the granting of the compulsory license.

Sources: Based on information given in the Patent Controller's Order (Application for compulsory licenses under Section 84(1) of the Patents Act, 1970 in regard to Patent No.215758), Mumbai, 2012; and IPAB OrderNo.45 of 2013, Chennai, 2013.

In March 2012, India granted its first compulsory license, permitting Natco to produce and sell a generic version of Nexavar. Bayer appealed against the Controller's decision to the Intellectual Property Appellate Board (IPAB). The Controller's decision was upheld by IPAB and an order was passed to that effect on 4 March, 2013. The compulsory license had been granted on the following grounds: (a) Bayer had failed to fulfill "reasonable requirements" of the public with regard to the patented invention; (b) Nexavar was not available to the general public at a "reasonably affordable" price; and (c) Bayer had "not worked" the patented invention in the territory of India.

The matter was further complicated by the fact that Cipla, an Indian pharmaceutical company, had already started selling a generic version of Sorafenib in 2010 at a much lower price than the one set by Bayer. A month's dosage of the drug marketed by Cipla cost about US\$ 600 at that time. Bayer had already filed a case against Cipla for patent infringement, the decision for which was pending.

3.1. Considerations for granting a compulsory license

Bayer's performance was found wanting in each of the three criteria stated above and, hence, a compulsory license was granted to Natco. Each of these issues are discussed below, taking into account both the Natco and Bayer arguments that shaped the final decision taken by the Patent Controller, Mumbai, and subsequently, by IPAB.

⁵ The Intellectual Property Appellate Board was constituted by the Government of India to adjudicate cases related to trade marks, patents, design and geographical indications of goods. It has its headquarters in Chennai.

Issue (a): Bayer failed to fulfill the “reasonable requirements” of the public with regard to the drug.

According to GLOBOCAN 2008(World Health Organization, 2008), India has some 20,000 liver cancer patients and 8,900 kidney cancer patients. However, Bayer had estimated that only about 8,900 people were eligible for a stage IV drug such as Nexavar. Bayer sold only 593 boxes in 2011, but the firm pointed out that the supply in the Indian market had been greatly improved by Cipla’s generic version of the drug, of which 4,686 boxes were sold in India in 2011.

The Patent Controller disputed Bayer’s claim that the number of patients reported eligible for Sorafenib was only around 8,900. According to the Controller, the figure cited by Bayer was a gross understatement, given the poor state of health infrastructure in India, where the majority of the patients were diagnosed only in the later stages of illness. The Controller estimated that if, on average, each cancer patient required three packets (three months’ dosage) of medicines, Bayer’s 593 boxes would have supplied the needs of less than 200 patients. This means that even with Bayer’s modest estimation of 8,900 patients, it had been able to cater to only about 2 per cent of the patients eligible for the drug.

It was also argued that Bayer could not consider Cipla’s sales when accounting for the drug supply in the market while pursuing an infringement case against Cipla in the same breath. The case filed against Cipla meant that an injunction could be issued and the generic version of the drug pulled out of the market at any time. Under Section 84(6)(i), only the actions of a patentee (or a licensee) – in this case Bayer – are to be considered when judging whether or not the reasonable requirements of the invention were being fulfilled.

The possibility that Bayer did not have sufficient time to make the drug available was also rejected. Although Bayer, a well-known brand name in India, had been marketing the drug globally since 2006, the company had made little effort to sell the drug in India since its introduction in the country in 2008. This was evident from Bayer’s figures for sales of the drug in India, which were abysmally low, especially when compared with its figures for global sales. India’s sales of the drug accounted for not more than 1.6 per cent of the drug’s total sales worldwide in the previous three years, as estimated by Natco.

Bayer also alleged that its low sales could be attributed to the fact that Cipla’s generic version of the drug was being sold at a considerably lower price, thus undercutting Bayer’s market significantly. However, Cipla did not start selling the drug until 2010, giving a two-year window of opportunity to Bayer, which it had not utilized. The argument that Bayer had not made adequate efforts to exploit its patent in the three-year period was also backed by the fact that Bayer had not begun importing the drug until 2008 and had continued to do so only in small quantities in 2009 and 2010.

Table 3. Sales for Bayer

	2006 ^a	2007 ^a	2008	2009	2010
Sales worldwide (US\$ million)	165.0	371.7	677.8	843.5	934.0
Sales in India (US\$ million)	Nil	Nil	Nil	3.2 ^b	Unknown

Source: Compiled from the Compulsory License Application before the Controller of Patents, Mumbai, in the matter of Natco Pharma Ltd. and Bayer Corporation. Available at www.ipindia.nic.in/iponew/compulsory_licence_12032012.pdf.

^aPatent granted in India in 2008.

^b Corrected to only 0.4 by the Patent Controller as per the information provided in Form-27 filed by Bayer for 2009.

Issue (b): Nexavar was not available to the public at a reasonably affordable price.

The concept of “reasonably affordable” price is clearly notional and there is a need to establish what is reasonably affordable on a case-by-case basis. In this particular case, there were mainly two considerations to be taken into account: the R&D costs incurred by Bayer and how “affordable” that price was from a patient’s perspective.

Reasonable signifies “in accordance with reason, the right reason, propriety or fairness” (Aiyar, 2006). The term affordable is indicative of the purchasing power of the public who are consumers of the drug. It can be logically construed that the drug price of US\$ 5,608 per month was not indicative of a “reasonably affordable price” where a large chunk of the population have access to only private health care systems and the annual per capita income was only about US\$ 1,489 in 2012 (World Bank 2013)

Bayer justified charging US\$ 5,608 for the drug on the basis of the huge R&D costs that its development had involved. Consequently, the price of Nexavar had been fixed at a considerably higher rate than its generic versions as, in the latter case, the drug companies had to merely replicate the original drug. The failed versions prepared before the actual drug was invented accounted for about 75 per cent of the total R&D costs incurred. Further R&D costs did not end once the drug was discovered; additional costs were also incurred in follow-up investigations. Thus the sales of the product, according to Bayer, had to help recoup not only the cost of the present version of Nexavar, but also the costs of rejected past versions as well as fund investigations for discovering future possible uses of the drug. Bayer claimed that it took some US \$2 billion in investment to bring any new molecule to the market. Bayer also submitted evidence showing how comparable drugs were priced similarly to Nexavar.

Bayer highlighted the “orphan drug” status of Sorafenib during the case, which meant that the drug was used to cure a disease that afflicted only a limited number of people.⁶ Hence the huge R&D costs in Nexavar’s case had to be recouped from a relatively smaller pool of patients.

Another dimension that Bayer highlighted was that the “public” comprised the wealthy, middle and poor classes and that the notion of “reasonable affordability” could therefore vary

⁶ The exact criteria for granting “orphan drug” status may differ from country to country. For example, in the US it is meant to signify drugs for diseases that affect less than 200,000 patients while in the EU the disease should not affect more than 5 in 10,000 people.

according to the strata of the society being considered. Therefore a more nuanced definition of the term “reasonably affordable” was required while issuing a compulsory license as the drug would be sold to all sections of the society at the same price. Bayer had claimed that its Patient Assistance Programme (PAP) and the various health insurance schemes available in India could help improve accessibility to the drug by the needy sections of society.

Natco countered Bayer’s claim that R&D costs should be used as a criterion for fixing the price of the drug. The price, according to Natco, was a huge barrier to accessing the medicine. Bayer had also failed to give an accurate figure for the cost of inventing the drug. Furthermore, the drug was eligible for a 50 per cent orphan drug tax credit during the extensive clinical trials conducted by the company, which would have lowered its costs. The sales revenue generated in the first three years on the global market was US\$ 1.2 billion. Thus, it appeared likely that Bayer had or at least would be able to recoup its R&D costs from sales within a few years of the drug’s launch.

Natco also argued that the price of product should not be fixed on the grounds that the entire R&D costs for the drug had to be collected from the Indian market. The PAP did not count either as it was uncertain and could be withdrawn from the market at any time by Bayer. In fact, Natco said, the existence of PAP was an admission that the price of the drug was unaffordable.

The Patent Controller was also of the view that a reasonably affordable price should be seen from the public’s perspective rather than the patentee’s. According to the Controller, the low sales of Nexavar in India could be accounted for by the high price of the drug, which rendered it unaffordable among large sections of public. The Controller also agreed with Bayer’s strategy for differential pricing as the meaning of “reasonably affordable” might vary from class to class, and from country to country. In this context, the Controller therefore questioned Bayer as to why it charged the same price across all sections of society and across all countries.

When the matter was brought up for appeal, IPAB concurred with the Controller when it stated that the question of “reasonably affordable” prices should be addressed solely from the viewpoint of whether US\$ 5,608 per month was a reasonably affordable price to the public or not; as such, IPAB said, R&D costs and subsidizing programmes could not be taken into consideration under such a context. This is in keeping with the comprehensive Report on Revision of Patent Law⁷ by Shri Justice N. Rajagopala Ayyangar (1959), which quoted from the “Principal National Patent System” that patent rights were created “not in the interest of the inventor but in the interest of the national economy”.

Issue (c): Bayer had not worked its drug, Nexavar in the territory of India.

Bayer had cited “economies-of-scale”⁸ as the principal reason for not establishing a manufacturing base for Nexavar in India. According to Bayer, while the R&D costs incurred for the drug were huge, both global demand and, therefore, the volume of production were small. Thus it had decided to consolidate its manufacturing facility in one place. The

⁷ The new Patents Act, 1970 was based on the recommendations contained in the Report.

⁸ Economies-of-scale refers to the phenomena of reduction in costs per unit of output incurred by an enterprise as its size increases, since the fixed cost is spread over a larger output.

production units were based in Germany, which had the advantage of having a good infrastructure in place for supplying global markets.

However, the concern arose from the fact that the term “worked in the territory of India” had not been explicitly defined in the Indian Patent Act. Bayer defended its claim to the patent by interpreting the phrase to mean ensuring an adequate supply to the Indian market. On the other hand, both Natco and the Patent Controller were of the view that “working” precluded importation of the drug, and that the drug had to be locally manufactured for it to fulfill this criterion. However, IPAB had deviated from this understanding of “working the patent”, which excluded importation and sought to adopt a more flexible definition of the term, one which could be decided individually, on a case-by-case basis.

In the present case, IPAB ruled that Bayer had not proved “working” its patent in Indian territory as it had not provided any evidence as to why Nexavar could not be locally manufactured, and why it had to rely solely on imports of the drug for supplying the Indian market. This was despite the fact that Bayer already had manufacturing facilities in India for several products, including oncology medications, as pointed out by Natco. Moreover, the fact remained that even if Bayer’s imports were taken into account, they were nowhere near the commercial scale required to satisfy the requirements of the public in India.

3.2. Final decision and imposed conditionality

Taking all these issues into account, in March 2012 the Patent Controller granted Natco a compulsory license to manufacture and distribute the generic version of Nexavar in India. The decision was subsequently upheld by IPAB in 2013. The Controller ruled that the price of the drug sold by Natco under the compulsory license was not to exceed US\$176 for a 120-tablet pack, equivalent to a month’s dosage. In addition, Natco had to supply the drug to at least 600 needy patients free of cost. Details of the patients and the treating oncologists had to be supplied to both the Controller and IPAB on an annual basis.

Under the decision, Natco had to pay a royalty fee of 7 per cent of its net sales of the drug to Bayer on a quarterly basis. This was 1 per cent higher than the rate originally fixed by the Controller at 6 per cent. The rate was fixed as per the recommendation of the United Nations Development Programme (UNDP), which had suggested a range of 2 per cent to 6 per cent as the royalty rate. As per the UNDP recommendation, the rate should normally be set at 4 per cent and adjusted by as much as 2 per cent if it was of particular therapeutic value or reduced by as much as 2 per cent when development was partly supported by public funds (UNDP, 2001). The Patent Controller set the rate at a higher end, in cognizance of the huge R&D costs incurred in developing the drug and the relatively smaller patient base. This was revised upwards by the IPAB who felt that the original innovators should be paid an even higher royalty fee, given that the distributors and stockists were getting a margin of 30 per cent.

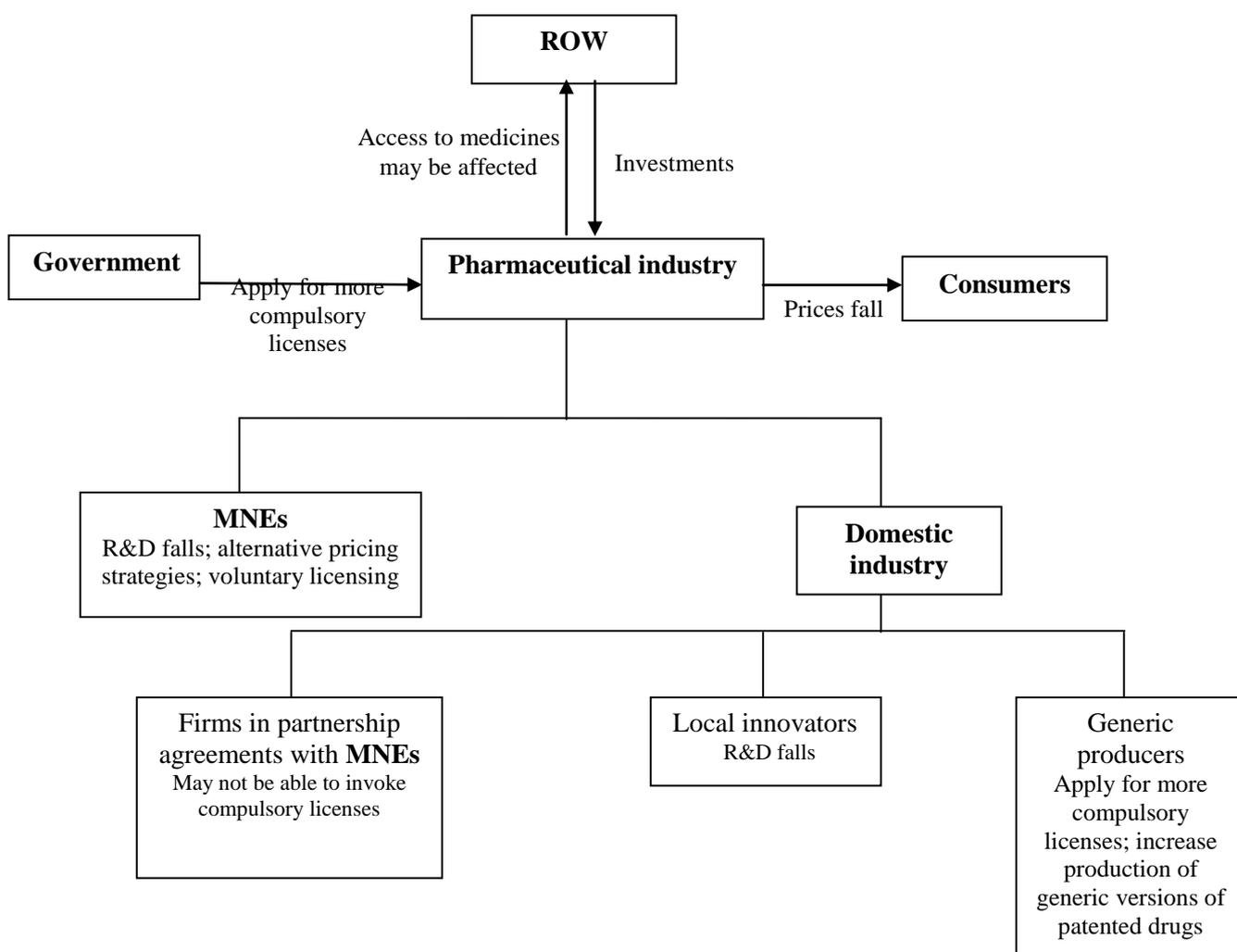
4. Impact analysis

The Controller's ruling set an important precedent in India, which is bound to have far-reaching consequences for the Indian pharmaceutical industry. To understand the impact of the ruling in a systematic manner, it is necessary to first isolate the costs and benefits to the different stakeholders associated with the decision. The method of analysis used has borrowed elements from the methodology employed by the Organization for Economic Cooperation and Development (OECD) Regulatory Impact Analysis (RIA) to assess the impact of a policy. According to OECD (2008), "RIA is a process of systematically identifying and assessing the expected effects of regulatory policies, using a consistent analytical method, such as benefit/cost analysis".

To clearly understand the impact of any policy change, one needs to understand the socio-economic system concerned, which will typically comprise the inter-linkages between different economic agents. It will then be possible to examine the different entry points to the system for the proposed policy and to study the impact of the policy on the different economic agents (Bellù and Pansini, 2009).

The RIA, with its standard cost-benefit method of analysis, identifies a checklist of costs and benefits that the different stakeholders may face. Stakeholders would typically include the business units (cost of compliance, effect on sales and profits earned etc.), consumers (changes in prices, change in range of products available etc.), the Government (improved public health and fulfillment of other objectives, cost of administering and enforcing regulations etc.) and others (distributional effects, improved competition, loss of innovation etc.). Establishment of a similar socio-economic system of economic agents for compulsory licensing, the costs and benefits for different stakeholders and the measures taken by each stakeholder are illustrated by the figure below.

Figure 1. Impact analysis of the compulsory licensing ruling in India



4.1. Government

The Natco-Bayer ruling led to extensive debate within the international and domestic pharmaceutical industry and questions were raised regarding the compatibility of the decision with TRIPS. However the Doha Declaration clearly states that member countries are free to determine the grounds on which such licenses can be granted.⁹ Accordingly, the Indian Patent Act, 1970 included provisions on compulsory licensing, the issuance of which were to be decided on a case-by-case basis. With regard to the Natco-Bayer decision, India maintained that it had not violated any multilateral trade agreement by granting the compulsory license and was well within the requirements of international and national legislation (Press Trust of India, 2012).

⁹ See Declaration on the TRIPS agreement and public health, paragraph 5(b).

The ruling is unlikely to lead to any policy changes as the current legislation is considered robust enough to cover the issuance of compulsory licenses. However, the decision has given the Government of India impetus to start using compulsory licenses as a tool for ensuring affordability of essential medicines. A panel was set up by the Government under the purview of the Ministry of Health to assess the possibility of granting more compulsory licenses in the country. The panel, chaired by R K Jain, Additional Secretary at the Ministry of Health, recommended the application of compulsory licenses for three new anti-cancer drugs under Section 92¹⁰ of the Patent Law. These drugs include Trastuzumab (or Herceptin) for breast cancer, (produced by Roche), and Ixabepilone for chemotherapy and Dasatinib for treating leukemia, (produced by Bristol-Myers Squibb) (Dey, 2013a).

Under Section 92, once the Government invokes a compulsory license for these drugs, pharmaceutical companies will be able to apply directly to the Patent Controller for permission to manufacture and sell generic versions of the patented drug at a lower price in the market. The panel zeroed in on these drugs because of the exorbitant rates at which they are sold. A vial (40 mg) of Trastuzumab costs US\$ 2,480 while 60 tablets of 20 mg each of Dasatinib are priced at US\$ 2340. The Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, is currently considering the granting of compulsory licenses for these anti-cancer drugs (Dey, 2013b).

4.2. Consumers

The primary consideration for the Bayer-Natco ruling was the patients, i.e., consumers of the drug. This is understandable when considering the fact that a quarter of the population in India still lives below the poverty line. Coverage of public insurance is poor and people have to pay out of their own pockets for the majority of their health expenditures. Total expenditure on health is 4.2 per cent of GDP, of which only 1.1 per cent is current public expenditure (World Health Organization, 2012). Public spending contributes to only 4 per cent of the total expenditure on pharmaceuticals, the fifth lowest in the world. Moreover expenditure on medicines constitutes a large portion (some 57 per cent) of the expenditure on health in India (World Health Organization, 2011). Studies also appear to indicate that the poor, both in rural and in urban areas, spend a higher proportion of their income on medical treatment than those who are better off. Hospitalization for illnesses is a major cause of indebtedness, especially for those living below the poverty line.

Affordability of drugs is a key issue in India. Prior to 1970, India had a product patent system and was characterized by a few dominant multinational enterprises (MNEs) and high prices (Chaudhuri, 2012). The process-based patent system saw the Indian generic drug industry grow and the prices of medicines fall sharply, a loose intellectual property regime ensured that there was stiff competition in the domestic pharmaceutical industry, and firms charging high prices were eliminated.

Take the case of Nexavar, for example, where initially the drug was sold in the market at US\$ 5,608 for a month's dosage. Cipla started producing the drug and charged US\$ 600 for Sorafenib. Once Natco entered the picture with the drug priced at US\$ 176 (97 per cent of

¹⁰ Section 92 allows the Government of India to grant a compulsory license "in circumstances of national emergency, or in circumstances of extreme urgency or in the case of public non-commercial use".

the original price), Cipla reduced its prices by 76 per cent and currently, Cipla's version of the drug only costs US\$ 137 for a month's supply (Rajagopala, 2012).

Domestic companies and government agencies could take a cue from this ruling and start applying for more compulsory licenses, and not only for this drug. As a result, consumers might be able to buy generic versions of drugs at prices much lower than the original product. The resultant competition from compulsory licenses in the pharmaceutical industry would help discipline the market and keep prices in check.

4.3. Multinational enterprises

The Bayer-Natco decision met with a great deal of disapproval from the multinational enterprises (MNEs). It has been a concern that the current order, together with the Government's proposal to issue more compulsory licenses, may have an adverse impact on the environment for future innovation in the Indian pharmaceutical industry.

Increased liberalization and emerging opportunities in India have resulted in an increasing dominance of MNEs in the domestic pharmaceutical industry, and a consequent rise in their market shares (Chaudhuri, 2012). Currently MNEs are allowed to invest up to 100 per cent in the pharmaceutical sector through the automatic route. Since 2005, six Indian companies have been taken over by foreign companies. (Department of Industrial Policy and Promotion, 2010)

The idea behind liberalization policies and encouraging MNEs in India was to facilitate technology transfers and boost the local manufacturing base. Initially, MNEs had been required to produce both bulk drugs and formulations¹¹ in a fixed ratio, a requirement that was abolished in 1994. This caused many foreign companies to shut down their bulk drug manufacturing plants in India. Many MNEs are currently importing rather than investing in the production of bulk drugs. The MNEs' ratio of fixed assets to investments in financial securities have declined during the past few years, indicating that MNEs have little intention of setting up a well-developed manufacturing base in India (Jha, 2007).

In the current scenario, one of the chief considerations for compulsory licensing had been whether or not the patent was being worked in Indian territory. Bayer had been importing Nexavar rather than producing the drug, which was taken into account when the Controller granted the compulsory license.

It was also believed at the introduction of TRIPS that stricter intellectual property rights in developing countries would help spur innovation in the production of drugs for neglected diseases such as kala-azar, malaria and tuberculosis. However, according to the Centre for Trade and Development and the Centre for Legislative Research and Advocacy (CENTAD and CLRA, 2009), the evidence appeared to be otherwise, both in India and globally; only 1.3 per cent of drugs reaching the market between 1975 and 2006 were developed for neglected diseases. MNEs, being export-oriented, undertake research mostly on diseases that afflict developed countries. Liberalization measures have attracted some foreign direct

¹¹ A bulk drug (also called active pharmaceutical ingredient) is the chemical in a pharmaceutical product that lends the product the claimed therapeutic effect. Formulations, on the other hand, are the physical manifestation of bulk drugs, i.e., medicines on the market in the form of tablets, capsules, syrup, drops, intravenous fluids etc.

investment, but a closer inspection suggests that the bulk of foreign investment in R&D has been in the clinical trials and not in actual development of the drugs (Joseph, 2011).

Pre-empting the move to issue compulsory licenses, MNEs may start following a dual pricing system wherein different prices are charged for a drug in developed and developing countries. MNEs may also sign voluntary license deals with domestic firms. By signing exclusive product licensing deals with domestic companies for a drug, MNEs can help avoid compulsory licensing action. Under voluntary licensing deals, MNEs have the freedom to dictate the terms at which domestic firms may sell generic versions of their drug, unlike under a compulsory licensing setup that works without the consent of the patent owner. There have already been several such deals. Some examples of such deals are those between: (a) between India's Strides Arcolab Ltd. and the United States-based Gilead Sciences Inc. for a group of HIV/AIDS drugs; (b) Pune-based Emcure Pharmaceuticals Ltd. and Swiss drug manufacturer F. Hoffman La Roche Ltd. for patented cancer drugs; (c) United States-based Merc and India's MSD Pharmaceuticals Pvt. Ltd. and Sun Pharmaceuticals Industries Ltd for patented diabetes drugs; and(d) Swiss drug manufacturer Novartis and Mumbai-based Lupin for a chronic obstructive pulmonary disease drug (Unnikrishnan, 2013).

4.4. Domestic companies

To understand the possible impact that compulsory licenses can have on the domestic industry, it is necessary to differentiate between the different types of Indian companies existing in the pharmaceutical industry today. These include pharmaceutical companies which are generic producers, local innovators or companies in partnership agreements with MNEs.

4.4.1. Generic producers

India has a well-developed generic drugs industry due to its low manufacturing costs, relatively lower R&D expenditure associated with reverse engineering, and the large size of its domestic market. Domestic companies that have strong reverse engineering skills could use this as an opportunity to single out patented drugs that are novel, high-priced and high-value, and sell their generic versions.

In fact, BDR Pharmaceuticals, a Mumbai-based firm, has already applied for a compulsory license to manufacture and sell a generic version of Bristol-Myers Squibb's anti-cancer drug, Sprycel. BDR Pharmaceutical proposes to sell the generic version at US\$ 162 for one month dosage, which is approximately 95 per cent cheaper than Bristol-Myers Squibb's monthly treatment cost of US\$ 3,314 (Dey, 2013b).

4.4.2. Local innovators

Until recently, most of the R&D activities undertaken in the Indian pharmaceutical industry were geared towards discovering new processes for producing patented drugs. Product-based patent systems were encouraged in developing countries in the hope that it would trigger innovation in drugs for countering neglected diseases. However, domestic companies still lack the required technical competence or the financial muscle to develop a drug from start to finish. As a result, a number of Indian companies have entered into collaborative deals with MNEs. Thus, while there has been an increase in R&D expenditure, it has mainly been used to develop drugs for treating diseases that are more prevalent in the developed world¹² (Chaudhuri, 2005; Jha, 2007; and Joseph, 2011). Indigenous ability to produce innovative drugs for neglected diseases will therefore largely be unaffected by the issue of compulsory licenses.

4.4.3. Partnership agreements with MNEs

As mentioned above, many MNEs have signed partnership agreements with local companies concerning certain drugs. These domestic companies may not want to invoke compulsory licenses for fear of jeopardizing their relationship with the MNEs.

4.4.4. Rest of the world

The compulsory licensing move, however, has been criticized by many developed countries, especially the United States. India's intellectual property regime has been perceived as not robust, and this may affect India's global image as an investment hub especially with regard to its research-intensive sectors. The United States Trade Representative's Office (USTR) placed India in the priority watch list¹³ in its "2013 Special Report", as it believed that recent developments have raised questions about the "innovation climate in India and the risk of hindering the country's progress towards an innovation-focused economy." USTR is especially worried about India's decision "to restrict patent rights of an innovator, based, in part, on the innovator's decision to import its products, rather than manufacture them in India" (USTR, 2013).

Compulsory licensing policies in India may also have an adverse impact on the access to medicines in other parts of the world. India has often been called "the pharmacy of the developing world" as it supplies generic medicines at low cost to many developing countries. In fact, 67 per cent of the medicines exported from India go to developing

¹² The two exceptions are an anti-malarial drug by Ranbaxy and a study of tuberculosis by Lupin; however, even, these have been developed in collaboration with global public health foundations (Joseph, 2011).

¹³ The United States Priority Watch List is a part of the "Special 301 Report" that is prepared annually by the Office of the USTR under Section 301 of the Trade Act of 1974. Under this list, USTR identifies countries that do not provide "adequate and effective protection of intellectual property rights" as in the United States, and as such are eligible for sanctions.

countries. Low-cost anti-retroviral drugs manufactured in India between 2003-2008 accounted for more than 80 per cent of donor-funded purchases of anti-retroviral drugs for use in developing countries. Moreover, competition in the generic drug industry has helped to lower the cost of HIV/AIDS treatment by 99 per cent since 2000 (CENTAD and CLRA, 2009; Medecins sans Frontieres, 2013). Thus, if generic producers are prohibited from manufacturing and selling low-cost drugs, a large number of patients in poor countries will remain without access to affordable essential medicines.

5. The way forward

The first compulsory license in India came seven years after the introduction of the product patent regime. However the Natco-Bayer case has set down an important precedent, which has given an impetus to both, the industry and the government to apply for more compulsory licenses. This is evident from the fact that BDR Pharmaceuticals, a Mumbai based firm, has already applied for a second compulsory license to manufacture and sell a generic version of Bristol-Myers Squibb's anti-cancer drug, Sprycel. The government is also considering compulsory license applications for three high priced anti-cancer drugs. In fact, the government has set up a panel under the Health Ministry to single out high priced patented drugs for which compulsory licenses may be invoked to ensure affordability.

The outcome of the Natco-Bayer case has also evoked a strong response from MNEs, which have argued that given the huge R&D costs incurred during the development of drugs, they have little choice but to charge high prices for them. Even if that is the case, could a dual pricing system not be practiced wherein differential prices are charged according to the economic status of a country? MNEs could also grant voluntary licenses to domestic companies, allowing them to manufacture and sell generic versions of their drug on mutually agreed terms. This may be a good strategy for MNEs to pre-empt the possibility of compulsory licenses being issued against them. Alternatively, Governments may engage in price negotiations with MNEs. However, experiences in Brazil and Thailand appear to suggest that such negotiations cause inadvertent delays in reducing the cost of medicines and often fail to secure affordable prices (CENTAD and CLRA, 2009). Either way, the prices of MNEs do not match those of the generic producers; even when prices have been reduced, MNEs have done so only from fear of competition from generic producers (International Institute for Sustainable Development, 2003).

However, the Natco-Bayer decision underscores a larger debate: Are patents really necessary for innovation? Can there be no alternative framework to a product patent regime to ensure adequate returns to the innovator, yet one which does not place essential medicines out of the reach of millions afflicted by diseases every year.

Some economists such as Stiglitz (2006) have advocated the use of alternatives – for example, a medical prize system wherein large monetary rewards are given to the innovator, the size of the reward varying with the incidence rate of the disease that the drug cures. Thus drugs such as those that cure a disease like malaria, which affects millions, would be given higher rewards while those that are only slight improvements on existing drugs would receive lower rewards. Competitive markets ensure cheaper drugs, unlike in a patent-based

system; the latter gives the innovators a monopoly over the drugs created and consequently promotes limited availability of drugs at high prices. The money for the prizes should ideally come from the Government. Governments of advanced countries could provide assistance to the developing nations for such a system through their various development assistance programmes (Stiglitz, 2006 and Stiglitz 2013).

There is a need to get things into perspective and set priorities right in the battle of patents and patients. Care must be taken that monopoly rights granted through patents do not always get precedence over public rights. The Universal Declaration of Human Rights states that “everyone has the right to a standard of living adequate for the health and the well-being of themselves....”¹⁴The right to life and, consequently, the right to health also form an essential component of the Indian Constitution.¹⁵The Supreme Court has extended this to mean making life more meaningful, and has emphasized that the improvement of public health is one of the paramount duties of the State (Banerji and Sengupta, 2011)¹⁶

It is true that a mechanism needs to be put in place to ensure adequate returns to the pharmaceutical industry for the capital and effort that they invest in developing new drugs. However, in the end, the State’s objective is to ensure that there are proper channels for the supply of, and access to something as basic as medicines. It is imperative that everyone has access to essential drugs, and high prices should not be a criterion for excluding poor people from the right to enjoy a long and healthy life. By granting its first compulsory license, India has taken a small but definite step in that direction.

¹⁴ See Article 25 of the Universal Declaration of Human Rights.

¹⁵ See Article 21 of the Constitution of India.

¹⁶ See Consumer Education and Research Centre vs. Union of India [(1995) 3. SCC 42].

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