Page 2502 - 2511 **DOI:** *https://doij.org/10.10000/IJLMH.112770*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 5 | Issue 1

2022

Critical Analysis of Natco Versus Bayer: An Eye Opener in India

DEVI. J[1]

ABSTRACT

With the passage of the current Patents Act, inventors were given an exclusive right to their inventions if they fit certain criteria, such as being innovative, beneficial in industry, and not obvious to others. The monopoly granted by the government is only valid for a maximum of 20 years. During this moment, innovative thinkers have a window of opportunity to profit from their creations. For those who can afford it, a patented drug that has been introduced to the market by the creator or patentee is a superior option. The price of these patented drugs rises as a result of the patentee's strict monopolistic policy or control. As a result, those in need must choose between purchasing lower-cost drugs, generics, or none at all. Because they couldn't afford more expensive meds, they had no choice but to accept low-quality health care. Because they couldn't afford more expensive medicines, they had no choice but to accept low-quality health care. From the standpoint of society and morals, such a result is neither acceptable nor ideal. It would be better for the patentee if a special relief plan was established that allowed patented pharmaceuticals to be supplied at a low price in emergency situations for the sake of society as a whole.

Keywords: *Compulsory License, Patent Act, Monopoly, GATT, WTO*

I. INTRODUCTION

With the advent of the contemporary Patents Act, inventors were granted an exclusive right to their inventions as long as they met the patentability standards, such as being new, useful in industry, and not evident to others[2]. The state-granted monopoly is only valid for a maximum of 20 years[3]. Innovative thinkers have a window of opportunity to temporarily cash in on their creations during this time. Unfortunately, consumers must wait until the patent expires before realising the rewards of the patented invention. The benefits of patented pharmaceuticals are available to customers when patents expire. By encouraging inventors to continue their cost-cutting efforts while also making discoveries profitable, F.M.Scherer argues that "it provides

[1] Author is an Assistant Professor at Chennai Dr. Ambedkar Govt. Law College, Pudupakkam, India.
[2] Section 2(1)(j) of the Patent Amendment Act,2005
[3] Section 53 of the Patent Act,1970

 [ISSN 2581-5369]

social benefits while also creating social costs.[4]"

When a patented drug has been released to the market by the inventor or patentee, it's a better alternative for those who can afford it. Due to the patentee's rigorous monopolistic policy or control, the price of these patented pharmaceuticals rises. Because of this, the needy are left with the option of purchasing lower-cost medications, generics, or none at all. They had no choice but to settle for low-quality health care because they couldn't afford more expensive medications. Such a consequence is neither desirable nor ideal from the standpoint of society and morals. But if there is no patent system, there will be no new drugs to be sold. For the sake of society as a whole, it would be best for the patentee if a special relief plan was devised that would allow patented drugs to be sold at a low price in emergency situations.

There were many countries that did not support product patents. Due to India's membership in GATT and WTO, the world's countries forced it to amend its patent legislation. Before 2005, India had never heard of product patents. The patent drugs were opposed by the majority of developing countries. It is, nevertheless, becoming increasingly rare in the international patent landscape to create universal minimum conditions for patent protection. The international patent protection community has attempted to establish a compromise between social responsibility and incentives for novel medications to deal with unforeseen ethical difficulties. This was done. Most businesses and countries benefit from the present patent system. However, in many developing countries, particularly in India, the ethical issues associated with the pharmaceutical industry are more important than in other businesses. In exchange for disclosing his or her invention, an inventor is granted a patent[5]. Most of the society benefits from an invention, not just its creator or patent holder; hence it is necessary to make the patented invention accessible to everyone. As a result, there's a possibility that the patentee may abuse his patent rights. Abuse of the patent can take many forms, including refusal to grant licences, imposing onerous terms and conditions on the licensee, or even setting unreasonable restrictions on the patented goods. Because of the Patent Act, such scenarios are prevented and remedied by the compulsory licencing clause. Compulsory licencing refers to a law that grants licences to third parties for the use of patented drugs without the approval of the patentee. Issuing compulsory licences to access innovative technologies helps the public achieve a number of goals. Patents and other forms of intellectual property are the results of government

[4] Scherer .F.M , The Economic effects of compulsory patent licensing, 1st Edn. (New York University, Graduate School of Business Administration, Center for the Study of Financial Institutions, 1977)
[5] Elizabeth verky, Intellectual property law 1st Edition(Eastern Book Company) P.444

policy[6].

II. COMPULSORY LICENCES UNDER INDIAN PATENT ACT

Chapter XVI of the Patents Act outlines the rules for obtaining a compulsory licence. In 2002, the Patents Amendment Act revised this chapter[7]. When it was first written, Sections 82 to 98 included a wide range of topics, including what is now known as "licencing for rights." However, the Patents Amendment Act of 2002 omitted it. Sections 82 to 94 of the Patents Act now refer to this process as "working of patents, compulsory licences, and revocation of patents for nonworking." The TRIPS Agreement required a revision of this law. According to TRIPS Agreement, all patents are made available to the public regardless of the nation of origin or the field of technology[8].WTO and TRIPS agreements mandate that the compulsory licence provision be enforced equally and without any prejudice between those who wish to import locally[9]. Here are some things to keep in mind when exercising powers under this chapter when making decisions about compulsory licences regarding the working of patented inventions.

1. India's patent system is designed to stimulate new ideas and ensure that inventions can be manufactured on Indian soil to the greatest extent possible. In order for a patent to remain effective, it is more important for the patent to function properly. Patents must be developed to the fullest extent possible, including domestic manufacture of the patented medication, without any needless delays[10].

2. For the sake of the public, patents aren't merely granted so that a patent holder can exploit his or her exclusive rights when selling the patents. The purpose of granting a patent in India is to put the patented invention into practice[11].

3. As patent rights are protected and enforced, they have an important role in promoting technological advancements and facilitating their dissemination.

4. Efforts to protect public health and nutrition will not be undermined by the awarding of patents in this manner. It should be a beneficial tool for the public in the areas of economic and technological advancement.

5. If a federal agency has taken steps to improve public health, it should not be granted a patent to do so. The Doha Declaration on TRIPS and Public Health provides significantly more information on these subjects in its guiding principles.

---

[6] Ibid
[7] Patent Amendment Act, 2002
[8] Article 27(1) of the TRIPS Agreement
[9] Feroz Ali Khader, the law of patents with a special focus on pharmaceuticals in India (Lexis Nexis Butterworths Wadhwa, 1st edition), P.706
[10] Ibid
[11] Product manufactured with patented technology is considered a patentable product.

 [ISSN 2581-5369]

6. Trade restrictions and technological transfer impediments should not be used as an excuse to abuse patent rights.

7. Patents are generally awarded to the patentee in order to provide the general public with the advantages of patented inventions at a reasonable cost.

According to a clause of the Indian Patent Act of 1970, granting a compulsory licence is based on consideration of the overall aims of compulsory licencing. According to chapter XVI, a compulsory licence can be awarded in a variety of conditions. Guidelines for issuing compulsory licences and the conditions under which such a licence may be issued are outlined in Sections 84, 90, 92, and 92A.

III. POSITION IN INDIA

India's economic growth was weak and only contributed a quarter of the country's income, but the health sector was still totally dominated by multinational pharmaceutical corporations, with international corporations controlling eight of the ten pharma firms and holding well almost all of the patent protection. The current patent system was unable to provide appropriate intellectual property rights to support India's industrial growth and development, according to local pharmaceutical enterprises. Control and administration of critical community resources were a primary goal of the Indian Constitution[12]. Due to a lack of indigenous drug manufacturing and a lack of a competent healthcare system, the wealthy countries had the most access to drugs. Pre-grant and post-grant opposition, as well as compulsory licencing, are all examples of Indian courts and quasi-judicial institutions' steadfast stances on the Amended Act of 2005. Even though the United States and the United Kingdom have established legal precedents against evergreening, India has taken the lead in passing legislation to prevent the immoral practice. There is a strong impression that developing countries may benefit from the TRIPS flexibilities while dealing with national emergencies, such as access to affordable medicines. The Indian judiciary's broader interpretation will determine whether poor nations in the WTO may profit from India's practice of granting compulsory licences and banning pharmaceutical patent holders from evergreening their patents.

IV. INDIA'S FIRST COMPULSORY LICENSE

Natco vs Bayer[13]

Nexavar, a brand name for the sorafenib tosylate ester developed by Bayer Corporation

[12] Article 39(b) of the Indian Constitution
[13] C.L. Application No. 1 of 2011

(Bayer), was granted a compulsory licence by the Controller General of Patents, Designs and Trademarks in India (Controller of Patents) on March 9, 2012, in a groundbreaking move. As far as the Patents Act of 1970 can tell, this is the first instance of its sort. Where the applicant has sought the issuing of compulsory permits under the requirements of section 84. Sorafenib, a medicine created by the Bayer pharmaceutical company in the 1990s, is used to treat advanced liver and kidney cancer. Generic manufacturer Natco Pharma Limited was involved in legal proceedings between CIPLA and Bayer and submitted a compulsory licencing request to the Controller of Patents against Bayer's patent on Sorafenib. Section 84 (1) of the Patents Act of 1970, as amended in 2005, is the basis for this request. "The wider public reasonable requirements for the patented invention have not been met," or "the patented invention isn't really available to the general public at a reasonably low cost, or the patented invention is not publicly available at all," the Indian Patent Act as amended allows for compulsory licencing after three years of a patent's grant[14]. Natco Pharmaceuticals Ltd., an Indian generic manufacturer, applied for a compulsory licence to make Nexavar in July 2010. Observers in the sector interpreted this as a way for Natco to protect itself from anticipated legal action from Bayer. Natco asserted that the public's reasonable goals were not realised at a fair cost when Nexavar, a Bayer-patented drug, has not been made available to the general public. Bayer imported Natco's drug into India; it didn't consider its obligation to implement the patent for a certain time of three years, even though it had its own manufacturing facility in India, which led to the drug's high price in India. As a pharmaceutical company, Bayer was responsible for determining a "quite reasonable price" that would be acceptable to both patent owners and the general public.

For the company, "operating" in India meant, among other things, "providing the medicine on a commercial level to the Market in India," and also that the company's poor market need won't justify its manufacture in India, with Bayer only offering Nexavar to 2% of the reported Indian patients. In 2008, Bayer had sent no Nexavar to India, and in 2009 and 2010, it had given very minimal amounts. This was taken into consideration by the Controller of Patents. It was determined that Bayer could not supply the legitimate public demand for the drug, and hence the Indian Patents Act mandated that the drug be awarded a Compulsory License[15]. By failing to manufacture Nexavar in India, Bayer was unable to meet the Indian Patent Act's "working" standards since its pharmaceutical pricing was too high and didn't qualify as "reasonably cheap." On March 9, 2012, the Controller of Patents in Mumbai granted Natco a

[14] Section 84(1) of the Patent Act,1970
[15] Ibid

 [ISSN 2581-5369]

first compulsory licence to manufacture and distribute a generic version of the medication Nexavar. The patent holder's drug was anticipated to be thirty times more expensive than Natco's drug, which was produced under a compulsory licence. For the past many years, Natco has been paying Bayer an annual royalty of 6% of the drug's net sales[16]. The IPAB looked at the three conditions in the Indian Patent Act,1970 for granting compulsory licences, namely that "the public's reasonable requirements for the patented invention have not been met, and that the patented invention is not available to the general public at a reasonable cost, or that the patented invention is not used in Indian territory[17]."

V. PROCEEDINGS BEFORE IPAB

(A) Basic satisfaction of the public

According to the IPAB, the patent holder did not meet the public's reasonable expectations. These facts led the IPAB to reach its conclusion that reasonable conditions had not been reached. To say that the invention is logical would be an understatement. An invention is not commercially viable if the price is too high or if it doesn't work on a large scale. The reasonable condition is not met. The IPAB found that the drug was out of reach and out of reach for the general public. To meet demand under acceptable terms, the IPAB believes that the quantity of medicine given was insufficient and the pricing was prohibitive for the general people. Another issue addressed by this decision was the idea of a fair price in isolation.

(B) Affordability

According to the IPAB, fair affordability must be evaluated by determining whether the drug may be purchased by the general public. Because the drug's cost was prohibitive for most people, the IPAB agreed with the Controller that it was not properly priced.

(C) Working of Patent

It was decided by the IPAB that the patent was not being worked in India, but with no clarification as to whether that meant "manufactured in India" or "imported to India." When an Indian-made medicine isn't possible, the IPAB agreed that an imported version of the drug would meet all of the requirements for it to be used in India. Imports must be made on a substantial enough significant basis and at a reasonable cost, according to the IPAB. Since India did not use this drug, the IPAB reached this conclusion. Because the appellant's Patient Assistance Program did not play a role in the invention's functioning, IPAB rejected the

[16] On March 9, 2012, the Controller General of Patents, Designs and Trademarks in India (Controller of Patents) awarded an Order in Natco vs Bayer
[17] Section 84(1) of the Patent Act,1970

 [ISSN 2581-5369]

appellant's claim. According to the critics, humanitarian action does not add to commercial activity.

(D) Public Interest

As determined by the IPAB, the public interest outweighed any potential negative consequences of disallowing the appellant's efforts to make their drug widely available after filing for a compulsory license. It was found by the IPAB that the language of the Patent Act does not prevent the inventor from quitting and making his idea available to the general public. Under the terms of the Patents Act, the inventor must divulge all relevant technical information about the patented innovation. Patentees and those seeking a compulsory licence are not favoured by these laws. As a result, the IPAB decided that patents should be affordable to the general people. Further, according to the IPAB, a patentee in India was awarded a three-year gestation period beginning on the date the patent was issued. Afterwards, the IPAB looked into the relevance of a violator's Nexavar sales. The patent owner had not granted CIPLA permission to produce and distribute Nexavar. CIPLA had been sued by the patent owner for alleged infractions. This plea was turned down, but CIPLA is requesting that those responsible for selling the infringing product be held accountable. According to the appellant, a compulsory licence cannot be granted because both the appellant and its infringer meet the Indian public's reasonable criteria. To comply with the Patents Act of 1970, the IPAB ruled that the phrase "patenting invention" shall be defined in S. 84(1) as the innovation that the owner of a patent must make publicly available, as well as as the invention and work that a patent owner must carry out within the country's borders.

VI. PROCEEDINGS BEFORE HON'BLE HIGH COURT OF BOMBAY

- **Bayer Corporation vs Union of India[18]**

Bayer argued that Natco lacks the jurisdiction to award a compulsory licence to the Controller under Section 84 of the Act, which was backed up by the Court. A patent owner must provide a voluntary licence to the applicant on fair terms and circumstances before the Controller as part of an application for a compulsory licence in accordance with Section 84(1) of the Act (iv). First, the applicant didn't try to apply for an optional licence in accordance with Section 84.1(1) of the Act. M/s Natco does not appear to be attempting to get a voluntary licence, as indicated by the notice dated December 6 2010; rather, it appears to provide a voluntary licence in the form of notice or threat to do so. A compulsory licence will only be granted in the above-

[18] 2014(60) PTC 277(Bom)

 [ISSN 2581-5369]

mentioned short terrain, and the challenged order will be nullified. Bayer had failed to meet the reasonable expectations of the public in connection to a patented drug, but that was no reason to award a compulsory licence[19]. The Act stipulates that the awarding of a compulsory licence is arbitrary, and this petition fell under that section's jurisdiction[20]. Bayer's proprietary drug satisfied the public's realistic expectations. There were two aspects to this problem. Patients who are reaching the conclusion of their cancer therapy are first given the unique drug. As a result, the public's need for kidney and liver cancer research is far smaller than the total number of Indians with the disease. Second, the entire quantity of patented medicine made available by the petitioner must be considered. It is indeed, Cipla, Natco, and the other patent infringers to determine whether or not the general public's need for the patented medication has been adequately addressed. The drug, which has been granted a patent, is now affordable to the general public. Act authorities have overlooked the fact that assessing the price at which a patentee can make a profit must take into account not only how much the patented drug costs the user but also the expense of conceiving and creating it.

- **Natco's Contention**

A voluntary licence from Bayer had been sought by Natco, which requested that Bayer define the terms and circumstances for the voluntary license's grant. Bayer Corporation, on the other hand, denied Natco's request for a voluntary licence in a response dated December 27, 2010. At this point, Natco has no choice but to apply to the Controller for a compulsory licence under the Act. The conditions for submitting an application to the Controller for a compulsory licence under the Act have been defined by both statutory agencies[21]. It was stated by both Controller and Tribunal that the Patent Act of 1970 made the patented drug unaffordable to the population.

According to Section 84(1)(c) of the Act and both the Controller and the Tribunal, the patented drug has not been developed in India. Aside from claiming that the patented medication was imported and manufactured in India, Bayer failed to provide any proof in this case to support either of those claims. Furthermore, working in India would require working on a commercial scale rather than on a patented medication. While reviewing an application for compulsory licencing, the Controller found evidence of inactivity by the patent holder in India, where the patent was issued in 2008. Furthermore, the Bayer Corporation has made no attempt to market the technology in India. Furthermore, the Act expressly states that no adjournment of a compulsory licence application would be allowed unless the Controller is certain that the

[19] WRIT PETITION NO.1323 OF 2013
[20] Section 84(1) (a) of the Patent Act , 1970
[21] Section 84(1) of the Patent Act,1970

patentee has made prompt action to commercialise innovation in India [22]. Bayer failed to act quickly enough, in this case, to commercialise the patented drug in India. Natco has been granted a Compulsory License under the Act's terms and conditions.

- **Has the public's reasonable expectation been fulfilled?**

When filing an application for Compulsory License under the Act, it is the applicant's responsibility to establish a prima facie case that one or more of the grounds stated in Section 84(1) of the Act are prima facie attracted/applicable in respect of the patent for which the Compulsory License is sought[23]. If the Controller is convinced on a prima facie basis, the patentee merely needs to invoke compulsory licence to contest the award of its patent to the applicant, Natco. The patent holder must subsequently allege and submit facts in support of his or her opposition, demonstrating that the public's real need for the patented medication has been satisfied. The best indicator of how far the patent holder, Bayer, is going to make the patented medicine available is the patent holder's knowledge.

- **"Was the patented drug inexpensively available to the broader public?"**

A comparison of Sections 84(1)(b) and 90(1)(iii) of the Act demonstrates this. Section 90(1) (iii) of the Act requires the Controller to ensure that the patented medicine is delivered at a reasonable cost. The Act only requires the government to issue, control, and revoke patents, not to establish prices for patented innovations. Since the Controller is required to ensure that the patented product is available for a reasonable price rather than decide on a reasonable price, Section 90(1) (iii) of the Act is relied upon. In this instance, Bayer is selling the patented medicine for roughly Rs.2,84,000/- per month of therapy, whereas the petitioner was providing it for Rs.8,800/- per month of therapy. In this case, the relatively low price must be the bayer's price, as the bayer's price reveals that it is not a reasonably low price.

- **Has the patent-protected drug been used on Indian soil?**

Patented items will not be subject to any form of discrimination on the basis of where they are manufactured or imported, as provided in Article 27 of the TRIPS Agreement. Form 27 supplied by the Patent Act and its supporting Patent Rules shows Bayer's assertion that the necessity for patented drugs in India has been addressed. For the patent to be valid, Section 83(c) of the Act states that technological know-how must be shared in a way that benefits both the inventors and those who use the patented product. Because the main goal of a compulsory licence is to make patent objects widely and affordably available to society, the Tribunal

[22] Section 86(2) of the Patent Act, 1970
[23] Section 87 of the Patent Act, 1970

 [ISSN 2581-5369]

believes that Section 84 of the Act's proceedings are in the public interest.

VII. Proceedings before Hon'ble Supreme court of India

Natco v. Bayer has come to an end as the Supreme Court of India refused Bayer's special leave to appeal the Bombay High Court ruling on December 12, 2014.

VIII. Conclusion

The non-discrimination principle established by TRIPS may have been violated by India in the Natco v. Bayer case, according to various critics[24]. As far as compulsory licencing is concerned, courts have held that it is in the public interest to balance the rights of inventors and the general public when deciding whether or not to grant such a licence. According to the appropriate legislation, different policy objectives might be pursued through the use of specific compulsory licencing requirements. Many countries' licencing laws have as their primary objective safeguarding the interests of the general public, such as public health, safety, and the advancement of the industry. It is imperative that governments make use of the flexibility provided by the TRIPS Agreement to promote access through compulsory licencing.

*****

[24] Article 27(1) of the TRIPS Agreement

 [ISSN 2581-5369]