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ROLE OF JUDICIARY IN COMPULSORY LICENSING REGIME

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Abstract

This chapter delves into the critical role of the Indian judiciary in shaping the compulsory licensing regime for pharmaceutical patents under the Indian Patents Act, 1970 (as amended), within the context of international obligations and public health imperatives. Employing a doctrinal and case law analysis, the chapter examines key judicial pronouncements, including the landmark cases of *Natco Pharma Ltd. v. Bayer Corporation*, *BDR Pharmaceuticals International Pvt Ltd v. Bristol-Myers Squibb Co*, *Lee Pharma v. AstraZeneca*, and *Novartis Ag v. Union of India and Others*. The analysis highlights the judiciary's general inclination towards a public health-oriented interpretation of compulsory licensing, demonstrated by the granting of the first compulsory license in *Natco v. Bayer* based on unmet public needs and unaffordable pricing. Conversely, the rejections in *BDR Pharma* and *Lee Pharma* underscore the significance of fulfilling statutory prerequisites and demonstrating genuine efforts to secure voluntary licenses. Furthermore, the chapter analyzes the pivotal role of the judiciary in upholding Section 3(d) of the Patents Act, as seen in the *Novartis* case, in preventing patent evergreening and safeguarding the accessibility of generic medicines. The chapter critically reflects on the complexities and potential obsolescence of the current compulsory licensing process and argues for its streamlining. It underscores the significance of India's judicial approach as a potential model for developing nations seeking to utilize TRIPS flexibilities to address public health crises and ensure access to affordable pharmaceuticals.

Introduction

It has long been acknowledged that the most precious asset is healthcare, not only for individuals but also for the economic well-being and unity of a country. Therefore, patent protection for pharmaceutical compositions, in particular, deals with a sensitive subject. One of the most controversial topics in intellectual property has been A. There are five explicit justifications for mandatory licenses in the TRIPS Agreement. It does not, therefore, offer a comprehensive list of explanations. Although some contend that it does not restrict nations' authority to provide mandatory licenses for unspecified reasons, others contend that it does. If developing nations are permitted to impose compulsory licensing on a wider range of grounds, the effectiveness of Article 31 as a tool to combat excessively broad patent rights that impede access to reasonably priced medications will be significantly increased. For this purpose, the patent's inability to work or insufficient work in particular must be a specified ground[1338]. This has all too clear practical and legal justifications.

The localization of a patent is advantageous from the perspective of a developing nation since it facilitates technological transfer and the growth of domestic manufacturing capacity. The ability to produce locally will also help to reduce the amount of foreign exchange that is lost as a result of imports. In order to stop abuses of patent exclusive rights, the Paris Convention for the Protection of Industrial Property allows the authority to issue compulsory licenses based on insufficient work

[1338] Samuel Davis, Compulsory Licensing and the Balance Between Innovation and Public Health, 58 HARV. L. REV. 1023 (2010).

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or an inability to manufacture. Legislation for the issuing of compulsory licenses should be implemented by each state in the Union to prevent monopoly rights abuses, such as failure to function.

This Paris Convention article is included in the TRIPS instruments. Therefore, a patent's failure or poor performance ought to be a reasonable basis for granting mandatory licenses. Some countries, however, advocate for a very strict interpretation in this area, aiming to outlaw mandatory licensing because a patent doesn't operate. They cite Arts. 27 and 28, which assert that the patentee has the sole right to import the patented goods and that patent rights are upheld even in cases when products are imported[1339]. Importantly, a compulsory license for patent exploitation on the grounds of nonworking or insufficient functioning is suitable in countries that already have a reasonably competent industrial base. This potential is currently limited to a small number of developing nations.

Since compulsory licensing may be the only viable option in nations with weak domestic manufacturing capacity, a local market that cannot support local production, or a need for legislation, it is necessary to broaden its application so that the TRIPS document does not prohibit it for the importation of a patented product. A compulsory licensee in another country who has been granted permission to manufacture a patented product may be imported by the obligatory licensee. Furthermore, WTO Members should be authorized to provide mandatory licenses to acquire pharmaceuticals from a generic manufacturer in another nation with the necessary manufacturing capacity in order for compulsory licensing to be successful and promptly address a national health need.

Members have the authority to grant mandatory permits for the importation of a patented product or one made directly using a patented process, as well as for the importation of a patented product or one made directly using a patented procedure from a producer or compulsory licensee in another nation where the product is not protected[1340]." The 2001 adoption of the WTO Doha Declaration on the TRIPS Agreement and Public Health by WTO members helped to define the framework for health policy inside the intellectual property system. In order to solve public health issues affecting the poor and least developed nations, it underlined the importance of integrating the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) into larger national and international initiatives.

The Declaration outlined specific options that nations may use to address public health issues; these options are commonly referred to as "flexibilities," and their significance was recently highlighted by their inclusion in the Sustainable Development Goals. The flexibility outlined in the Doha Declaration includes the "power to give compulsory licenses." A forced license is permission granted by a court or government body to use a patented invention in certain ways without the patent holder's consent. This approach is utilized by the majority of WTO countries in the pharmaceutical industry, is covered by the majority of patent regimes, and is recognized as a workable substitute or flexibility under the TRIPS Agreement.

Establishing an international IP regime required a strong institutional base, which was far distant in the majority of poor countries. This foundation included a competent legal system, a healthcare system, and the necessary level of infrastructure to produce pharmaceuticals in domestic markets. Theoretically, the Agreement offers greater flexibility, but in practice, developing nations are rarely permitted to use it efficiently when they are in severe need of assistance. Patent-holding multinational corporations go to considerable measures to

[1339] Ibid.

[1340] TRIPS, Drugs and Public Health: "Issues and Proposals" - Third World Network - September 2001 Report

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protect their "private" rights at the expense of a shared gain because allowing the flexibilities to be used will result in a decrease in the price of patented drugs. For instance, the TRIPS Agreement states that mandatory licensing has only been successfully implemented in a small number of circumstances since 1995.

In most cases, it had been preceded by lengthy talks, court battles, the participation of NGOs, and a powerful government in developing countries that was committed to defending its rights. Access to medications has long been a top concern for the BRICS alliance, which stands for Brazil, Russia, India, China, and South Africa. Each of these countries has been fighting HIV/AIDS independently.[1341]

Developing nations have a poor record of innovation, especially in the pharmaceutical sector, because of inadequate socioeconomic conditions, poor economic globalization, and a lack of suitable manufacturing capacity. This is because significant spending priorities are directed elsewhere.[1342] In the previously indicated context, the implementation of TRIPS-compliant pharmaceutical patent protection has had some extremely negative distributive effects. When coupled with inadequate healthcare, this undoubtedly led to a significant rise in the price of branded essential medications in developing nations and, in certain situations, a decrease in the supply of generics. This must have made it extremely difficult to provide enough medications. Most people around the world can no longer afford medical treatment because of TRIPS-enforced pharmaceutical patent protection, especially in poor countries with weak public health systems. On the other hand, the TRIPS Agreement supports a system that is typical of industrialized nations that hold patents and is distinguished by a robust public health system.

Research Question

Core Research Question:

How has the Indian judiciary interpreted and applied the compulsory licensing provisions under the Indian Patents Act, 1970 (as amended), in light of India's commitment to public health and its obligations under the TRIPS Agreement, as evidenced by key judicial pronouncements and legislative developments?

Supporting Research Questions:

- To what extent have judicial interpretations of Section 84 of the Indian Patents Act, particularly in cases like *Natco v. Bayer*, *BDR Pharma v. Bristol-Myers Squibb*, and *Lee Pharma v. AstraZeneca*, established substantive and procedural precedents for granting compulsory licenses for pharmaceutical patents in India?
- How has the Indian judiciary's stance against patent evergreening, as articulated in the *Novartis v. Union of India* case and through the application of Section 3(d) of the Patents Act, interacted with the potential for compulsory licensing to ensure access to affordable medicines?

Research Methodology

This research adopts a primarily **doctrinal and analytical methodology**, focusing on the interpretation and application of the compulsory licensing regime within the Indian Patents Act, 1970 (as amended). The study draws upon **primary legal sources**, including the Indian Patents Act and relevant case law such as *Natco Pharma Ltd. v. Bayer Corporation*, *BDR Pharmaceuticals International Pvt Ltd v. Bristol-Myers Squibb Co*, *Lee Pharma v. AstraZeneca*, and *Novartis Ag v. Union of India and Others*. **Secondary sources**, including scholarly articles and reports, are utilized to contextualize the legal framework and judicial pronouncements within broader debates concerning access to medicines and international intellectual property obligations, particularly the TRIPS Agreement. The

[1341] The TRIPS Agreement, art.31.
[1342] The Universal Declaration of Human Rights ,art.27.

jurisdictional focus is India, chosen due to its unique approach to balancing patent rights and public health. This doctrinal analysis identifies and examines key legal principles and judicial trends in this specific legal and jurisdictional context.

Research objective

This research aims to analyses the Indian judiciary's role in shaping compulsory licensing for pharmaceutical patents, balancing IP rights and public health.

The specific objectives are to:

- Examine judicial interpretations of Section 84 of the Indian Patents Act in key cases like *Natco v. Bayer* regarding compulsory licensing for pharmaceuticals.
- Investigate the judiciary's approach to granting or rejecting compulsory licenses, as seen in *BDR Pharma v. Bristol-Myers Squibb* and *Lee Pharma v. AstraZeneca*.
- Critically evaluate the impact of Section 3(d) and the *Novartis* case on preventing patent evergreening and ensuring access to affordable medicines.
- Analyse the alignment of Indian judicial decisions with TRIPS flexibilities and the Doha Declaration on public health concerning compulsory licensing.
- Identify challenges and opportunities for enhancing the effectiveness of compulsory licensing in India.

INDIA AND COMPULSORY LICENSING

Regardless of the fact that India's economic growth was weak and only made a significant contribution a quarter of the country's income, the healthcare industry was still completely dominated by global biopharmaceutical corporations, with foreign interests controlling eight of the ten pharmaceutical companies and holding nearly all of the patent protection. Local pharmaceutical businesses saw a rising need for change, believing that the current patent system was incapable of securing adequate intellectual rights to encourage India's industrial growth and development. The policies of the Indian Constitution were created to give the state control and administration of essential community resources[1343].It's worth mentioning that India's second five-year plan placed a strong emphasis on industrialization, with the aim of reaching self-sufficiency and a focus on import substitution.[1344]A commission chaired by *Justice Bakshi Tek Chand* issued a report in April 1950 arguing for a number of measures, including compulsory licensing and the creation of a more rigorous legal framework to combat patent abuse. Due to the fact that a bill based on the committee's recommendations was introduced in Parliament's lower chamber in 1953, it was never passed owing to Parliament's dissolution.

A decade after independence, the Indian government formed a new committee, headed by *Justice N. Rajagopala Ayyangar*, to assess the soundness of the Indian patent system. The study was broken into two parts, the first of which dealt with basic patent law problems that are associated, and the second of which provided comments and suggestions on the expired bill of 1953[1345]. It should be noted that some of the committee's opinions on how food patenting and pharmaceutical discoveries can affect medication access and compulsory licensing continued to be the basis for some of the WTO arguments in the walk to the TRIPS Agreement's signing. The report, which is credited with laying the groundwork for post-independence India's patent laws, advised that India depart from industrialized countries'

[1343]The Indian Constitution, art. 39(b)
[1344] India's Second Five Year Plan (1951- 1956) was headed by P.C. Mahalanobis.
[1345] Justice N. Rajagopala Ayyangar Committee on Review of Patent System in India.

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patent policy and made significant revisions to the country's existing patent laws. The committee determined that the exorbitant price of medicine in post-independence India was due to the monopoly on drug production in India held by foreign-based drug industry. It was of the opinion that food and medicines, which are crucial in everyday life and essential for the community's health and well-being, should be made available to the public at a fair cost, and hence vehemently opposed the award of product patents in these fields.

The Act of 1970's process patent regime enabled Indian pharmaceutical businesses in producing generic medications based on expired patents. In the event of life-saving pharmaceuticals, the Act established a legal entitlement to license (compulsory license). The Indian Patents Act of 1970 is significantly responsible for the rise of the Indian generic pharmaceutical sector. A second modification to the 1970 Act was passed in 2002, establishing a twenty-year patent period[1346], for the first time, the burden of proof for process patent infringement has been reversed, the compulsory licensing criteria have been changed, and the term "inventive step" has been defined for the first time. One of the notable changes made by the 2002 Amendment was the grounds for pursuing a compulsory license on pharmaceutical patents. In general, a compulsory license can be sought if the patented work has not been used for three years after the patent has been sealed, if the government declares a national emergency, or in certain scenarios if patents are essential for the effective operation of other protected patent technologies. In order to meet its commitments as a WTO member, India had to pass the Patent (Amendment) Act 2005. Concerns were raised by non-governmental organizations' (NGOs) and the World Health Organization (WHO) about the misery of HIV/AIDS patients in developing countries who were heavily depended on Indian generic medications.

Due to a lack of indigenous drug manufacture and a lack of a competent healthcare system, access to medications was limited and largely restricted to the wealthy nation. The jurisprudence of the courts and quasi-judicial agencies on the Amended Act of 2005 reveals India's strong stance on patent ever greening, the use of pre-grant and post-grant opposition, and compulsory licensing. Even though there is clear judicial precedent in industrialized countries such as the United States and the United Kingdom wherever greening is frowned upon, India has took the lead in enacting legislation to prohibit the unethical practice of ever greening. A combination of the updated legislation, the TRIPS Agreement's clauses, and recent Indian court and quasi-judicial judgements creates an intriguing research subject. They appear to imply that developing countries can use the TRIPS flexibility to their advantage while dealing with national crises such as access to affordable medications. The wider interpretation applied by the Indian judiciary will determine whether poor countries in the WTO may benefit from India's strategy of giving compulsory licenses and barring pharmaceutical patent holders from ever greening their patents.

INDIA'S FIRST COMPULSORY LICENSING CASE

In order to prevent patent rights abuses, which can occur when a patent holder tries to utilize their legal rights to keep competitors out of the market, compulsory licenses are essential. Compulsory licensing of patented medications, which is a key component of the patent system and was established under international agreements, provides access to vital medications that would otherwise be unaffordable in times of need[1347]. By replacing the exclusivity of a patent when the patent owner is unable to fulfill their obligations, compulsory licensing enables the government to strike a balance between rewarding inventions and rewarding the government.

[1346] Ibid.

[1347] The Paris Convention for the Protection of Industrial Property, art.5A.

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Make items available for public use even throughout the patent period if necessary. The new Act gives the government the power to grant a mandatory license for national health emergency and lays out procedures for manufacturing and bringing copyrighted medications into countries without the necessary infrastructure for pharmaceutical production. The Indian government and the patent administrator clearly have the broad power to grant forced licenses under the right conditions. In cases where the public is dissatisfied with a patentable idea, it is processed outside of India and they cannot afford to buy it. However, the strategic ramifications are too onerous and could cause delays because neither the Indian Competition Act 2002 nor the Patents Act gave precise grounds for evaluating anticompetitive behavior in India. It is also unclear that granting a compulsory license would be an immediate solution in the event that an applicant declined to provide a voluntary license on reasonable terms.

India's First Ever compulsory licensing Natco vs Bayer - The Background of the case

The Controller General of Patents, Designs and Trademarks in India (Controller of Patents) granted a mandatory license for the production of Nexavar, a brand name for sorafenib tosylate ester that is patented by Bayer Corporation (Bayer), in India on March 9, 2012. This was a first for the country.
This is the first instance of its kind in the Patents Act of 1970's history. where an application for a compulsory license has been made using the provisions of section 84. A treatment known as sorafenib was created in the 1990s by the Bayer company, a well-known pharmaceutical company worldwide, and is used to treat advanced stage kidney and liver cancer.

This medication was sold in India under the Nexavar trade name by the patent holder, Bayer Corporation, Germany (Patent No. IN 215758). The Bayer Corporation acquired registration for sorafenib tosylate in India in March 2008 after extending its patent application in 2001. The Bayer is a business that was established in accordance with US law. As a result of its research and development efforts, Bayer has created and refined its patented medication to make it easier to administer to humans. People with kidney cancer, including renal cell carcinoma (RCC), hepatocellular carcinoma (HCC), and liver cancer, are treated using patented medications. In addition to relieving patients' pain, the patented medication indicated above also prevents the spread of cancer by slowing the growth of cancer cells.

Additionally, in 2008, Indian authorities granted Bayer regulatory authorization for the medicine's commercialization under the Nexavar trade name. In 2008, the Indian generic company CIPLA began manufacturing and selling sorafenib pills under the brand name "Soranib" and with the description "Sorafenib Tablets 200mg." Bayer filed an infringement complaint against CIPLA in Indian courts. While CIPLA's generic equivalent cost 27,960 INR (US $525) per month for the same amount of tablets, Bayer charged 280,438 INR (US $5280) per month at the time of the lawsuit.

The generic manufacturer Natco Pharma Limited filed a compulsory licensing request against Bayer's patent on Sorafenib with the Controller of Patents and was involved in legal proceedings between Bayer and CIPLA. In accordance with Section 84 (1) of the Indian Patent Act of 1970, as amended in 2005, Natco requested the compulsory license.[1348] The Indian Patent Act, as amended, permits compulsory licensing after three years from the date of patent issuance if one of the following circumstances is satisfied: "the public's reasonable requirements for the patented invention have not been met, or the patented invention is not available to the public at a reasonably affordable price, or the patented invention is not available to the public at all."

[1348] The Indian Patents Act 1970, s.84(1).

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In July 2010, the Indian generic manufacturer Natco Pharmaceuticals Ltd. filed an application for a mandatory license to manufacture Nexavar. Given that Bayer had started pending infringement proceedings against Natco, some industry observers viewed this as a defensive move on the part of Natco. Natco asserted that the public's reasonable goals were not fulfilled at a fair cost and that Bayer's patented medication Nexavar was not made available to the general public. Additionally, it was the case for Natco that Bayer had not considered its obligation to implement the patent in India within the specific three-year period because it had been bringing the drug into the country, even though it had a producer unit there. As a result, the drug was sold in India at an exorbitant price.

The market value of a patented drug must be high enough to support future drug development, and Bayer was in charge of determining a "fairly reasonable price" for both the general public and the patent owner. In addition, Bayer claimed that "operating" in India in relation to patents meant "supplying the medication on a commercial scale to the Indian market," that just 2% of the reported patients in India were receiving Nexavar from Bayer, and that the product's low market demand did not justify its manufacture in India. In 2008, Bayer sent no Nexavar to India, and in 2009 and 2010, it delivered very little. This was considered by the Controller of Patents. According to the Controller of Patents, Bayer did not satisfy the rightful public requests about the patented medication Nexavar, and the conditions necessary for the granting of a compulsory license under the Indian Patents Act were satisfied. Due to its inability to manufacture Nexavar in India, Bayer was unable to meet the "working" requirements of the Indian Patent Act, and its pharmaceutical prices were excessive and did not amount to a "reasonably affordable" price. The Indian Controller of Patents in Mumbai granted the first compulsory license for Natco's application to manufacture and market a generic version of the drug Nexavar on March 9, 2012. Nexavar. The anticipated cost of Natco's medication, which was made under a compulsory license, was about thirty times lower than that of the patent holder's medication. Bayer has been receiving a quarterly royalty from Natco equal to 6% of the drug's net sales.[1349]Bayer appealed the Controller's decision to the Indian Intellectual Property Appellate Board (IPAB).

BDR PHARMACEUTICALS INTERNATIONAL PVT LTD V. BRISTOL- MYERS SQUIBB CO[1350]

The Squibb Corporation, established in 1858 by Edward Robinson Squibb, and the Bristol-Myers Company, established in 1887 by William McLaren Bristol and John Ripley Myers, combined to form the Bristol-Myers Squibb Company in 1989. In India, DASATINIB and its pharmaceutically acceptable salts, solvates, isomers, and prodrugs protected by IN 203937 are solely owned by Bristol-Myers Squibb Company, which also holds patent protection for the same patent in the US, Australia, New Zealand, and Japan.

BDR Pharmaceuticals International Pvt Ltd, the applicant, submitted an application on March 4, 2013, under Section 84 of the Patents Act, 1970 (henceforth referred to as the "Act"), requesting a compulsory license for Patent No. 203937, "A compound 2-amino-thiazole-5-carboxamide," which was awarded to the patentee on November 16, 2006, based on Patent Application No. IN/PCT/2001, 01138/MUM. The patent was claimed to cover the active pharmaceutical ingredient DASATINIB (henceforth referred to as the "drug," unless the context specifies otherwise), which is used by patients with Chronic Myeloid Leukemia (henceforth referred to as "CML"). The patentee marketed the drug under the SPRYCEL brand.

In the US, Europe, and Switzerland, DASATINIB was also designated as an orphan drug. Because it is more effective and has a higher tolerance, dastatinib is a successful

[1349] The Indian Patents Act 1970, s.84.

[1350] CLA No. 1 of 2013, Controller of Patents, Patent Office, Mumbai.

chemotherapeutic alternative for treating CML. If a patient is immune to IMATINIB or has developed it, it is given. 100 mg of DASATINIB is administered daily as 50 mg pills. Therefore, two tablets should be given twice day until the disease worsens or the patient can no longer tolerate the therapies.

According to BDR Pharma's filing, the patentee charges Rs. 2761 for each pill, which equates to Rs. 1,65,680 for 60 tablets per patient per month and Rs. 19,88,160 per patient annually. The patent medicine's subject matter is classified as a "orphan drug." Orphan medications, on the other hand, are pharmaceuticals meant to treat people with uncommon conditions. Both US and EU rules use the term "orphan drug" to refer to a medication intended to treat a rare condition, commonly referred to as a "orphan disease."

On the other hand, the patent holder Bristol-Myers demonstrated that it swiftly replied to BDR Pharma's request for a voluntary license, along with a request for additional details regarding BDR's capabilities, intent, and other details, but that it never heard back from the applicant. when coming to the conclusion that BDR did not fulfill the conditions necessary to be granted a section 84 obligatory license. The Controller of Patents claims that the time has come to make a decision on the merits of the case brought under section 84 because BDR Pharma purposefully avoided communicating with the patentee in any way in order to get a compulsory license.

LEE PHARMA V. ASTRAZENECA[1351]

Under Section 84(1) of the Patents Act (sometimes referred to as "the Act"), 1970, Lee Pharma Ltd., an Indian generics company, submitted an application seeking a CL for AstraZeneca to produce and market the medication SAXAGLIPTIN. The patent "A Cyclopropyl-fused pyrrolidine-based chemical" (number 206543) was granted to BMS on April 30, 2007. (Squibb, Bristol Myers). AstraZeneca AB was granted Patent 206543 by BMS in February 2014, and since then, the company has been able to commercialize and distribute the medications in India.

Lee Pharma has since filed for CL, citing the following reasons: the patented innovation is not being used in Indian territory; the public does not have reasonable access to the patented invention; and the majority's reasonable conditions for the patented invention have not yet been satisfied. When Lee Pharma asked AstraZeneca for a license for patent 206546 in May 2014, AstraZeneca replied, requesting clarification and refuting Lee's claim that SAXAGLIPTIN was not reasonably priced for the general public. However, due to a technical communication breakdown, Lee Pharma has decided to submit an application to the Controller of Patents after the two parties have not communicated for a year. Even after eight years of patent issuance, the patentee had not taken the necessary actions to manufacture saxagliptin in India, and the drug was being imported at a cost of Rs. 0.80 a tablet, with a market price of Rs. 41–45. To be clear, saxagliptin is usually used for "life management," not as a cancer treatment that is used in "life threatening" circumstances. According to the facts provided by the applicant, the controller concluded that Lee Pharma had made reasonable attempts to secure a license from the patentee on conditions that were mutually agreed upon and that a reasonable amount of time, as defined by Section 84(6) of the Act, had elapsed without success. The applicant provided data and statistics to show that the claimed invention did not meet the public's reasonable standards under clause (a) of sub-section (1) of Section 84 of the Patents Act, according to the Controller. However, because to the availability of replacements for the medicine in question, the Controller determined that the applicant had failed to establish that the public's reasonable requirements were not being met.

Reasonable public requirements had not been met:

[1351] C.L.A. No. 1 of 2015

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This ground was rejected because Lee Pharma failed to show what the reasonable public requirement was for Saxagliptin, as well as the comparative requirement of Saxagliptin versus other DPP-4 inhibitors.

The patented invention was not readily available to the general public at a reasonable cost: Based on a comparison of the prices of numerous Gliptins available in the Indian market, this argument was rejected. The CGPTM maintained that because all DPP-4 inhibitors were priced similarly, Saxagliptin's pricing could not be said to be unaffordable in India when compared to other DPP-4 inhibitors. Furthermore, the Controller pointed out that Lee Pharma's proposal to sell the drug for Rs 27 to 31.50 per tablet contradicted AstraZeneca's claim that the drug had not been made available to the general public at a reasonable price; Lee Pharma's projected price range would be several times that of AstraZeneca's.

The patented invention had not been worked in the territory of India

Since manufacturing the medicine in India is not a prerequisite to working in India, this objection was dismissed, and because Lee Pharma had not determined the exact need for production in India, it was difficult to say whether or not it was necessary. As a result, under paragraph (b) of sub-section (1) of section 84 of the Patents Act, no case was made out. Finally, the Controller stated that the Hon. Bombay High Court's decision in the Bayer case, as well as the IPAB's decision in the same matter, had clearly established that "made in India is not a required prerequisite in all situations to prove functioning in India." and The patentee, on the other hand, must establish the reasons why manufacturing the patented medication in India is impracticable or prohibitive, particularly if the patentee possesses manufacturing facilities in India."The Applicant had not provided any evidence relating to the Respondent's manufacturing facilities in India, and hence had failed to prove that the invention was not being used in India, according to the Controller. On the 12th of August, 2015, the Controller issued his decision in favour of AstraZeneca, concluding that a prima facie case could not be made out for issuing an order under Section 84 of the Patents Act. This is the third CL application that has been filed in India so far. The first application for NEXAVAR was approved since all three Section 84 conditions were met, but the second application for DASATINIB was denied because no proper effort was made to obtain a voluntary license. Controller General of Patents and Trade Mark has not only refused to give CL in this case, but has also established guidelines for CL applicants to develop a "reasonable need," particularly if there are other medications on the market that treat the same sickness / condition.

A closer examination of the compulsory license provision

The process for awarding a compulsory license under the Act of 2005 is intricate and time-consuming, and there is no time limit set in the Act or Rules for the authorities to process an application. Due to vagueness in this area, the compulsory license provision may become obsolete and unsuitable for the purposes for which it was enacted. Furthermore, the Act does not fully exploit TRIPS flexibilities because any final decision to utilise a patented invention under compulsory license can be challenged in court and an injunction sought to prevent its use Under the TRIPS Agreement, a member state is not required to allow for an injunction against government use[1352]. In this regard, the practises in the United States and the United Kingdom differ and are less onerous, as both governments have the ability to take over a patent innovation without first obtaining a license or engaging in protracted talks with the patent holder. The patent holder's only option is instead of seeking an injunction, to file a lawsuit for damages. Some studies argued that India should improve and clarify the government use sections in its Patent Act, given its public sector

[1352] The TRIPS Agreement, art.44.

pharmaceutical business. The concern that haunts us is whether such an award of compulsory licenses will in any way fail to offer incentives for India to innovate while also driving international firms away. Compulsory license opponents have long claimed that granting a compulsory license hampers innovation. The granting of a patent is based on the concept that it stimulates innovation by providing the patentee with a limited monopoly, which offers the argument that compulsory licenses will stifle innovation. Compulsory licenses do not appear to have a negative impact on innovation. Compulsory licenses have no noticeable impact on the rate and speed of innovation. Others, meantime, criticise the efficacy of the TRIPS Agreement's compulsory licensing system, which they believe has failed to achieve the goal of universal access to cheap medicines. For the time being, data suggests that granting a compulsory license has no impact on innovation in India's pharmaceutical industry, which is dominated by generics producers.

Novartis Ag v. Union of India and Others[1353]

Novartis submitted a patent and exclusive marketing right petition through the "mailbox" (EMR) in India on July 17, 1998. Customers in India complained that the price of Glivec had increased tenfold after the EMR was approved in 2003. The Cancer Patients Aid Association, a non-profit organization (CPAA), and regional pharmaceutical companies, against which Novartis had filed infringement lawsuits, strongly criticized the company's glivec patent application. The application lacked originality since it lacked obviousness and showed no discernible "efficacy" in meeting the requirements of section 3(d). As a result, it had an incorrect priority. The opposition may be heard before the patent is awarded under section 23 of the 2005 Amendment[1354]. In accordance with the arguments of the patent opponents, the Assistant Controller of Patents rejected Novartis' application on March 8, 2006, concluding that the new Glivec version was not sufficiently different from the old, unprotected version to merit a patent.
In order to have the Assistant Controller of Patents overturn his ruling and declare section 3(d) of the Amendment Act illegal and in violation of India's TRIPS obligations, Novartis filed two appeal cases in the Madras High Court. While the lawsuit was ongoing, the government set up the IP Appellate Board, and the first of the aforementioned petitions was sent to the IPAB.

Novartis additionally claimed that because paragraph 3(d) granted the patent controller unfettered authority, producing discriminatory effects, it violated Article 14 of the Constitution. The court first considered the case contesting the constitutionality of section 3(d) and TRIPS compliance. In a ruling dated August 6, 2007, the court determined that the contested clause did not violate Article 14 of the Indian Constitution and did not grant the Controller of Patents unrestricted authority. The court also decided that the state has a constitutional obligation to provide its citizens with quality healthcare, including access to prescription drugs, and that the necessary laws should be implemented to stop evergreening, which has an adverse effect on the supply of reasonably priced medications. Novartis was given special permission to appeal the aforementioned rulings to the Indian Supreme Court. After receiving five appeals, the Supreme Court rendered a comprehensive ruling on April 1, 2013. The Supreme Court was asked before 1997 whether the mesylate salt form of imatinib had been made public or was generally accepted. under order to satisfy the need for "enhanced efficacy" under section 3(d), Novartis compared the beta crystalline to the well-known mesylate salt.

PATENT EVER GREENING

India has evolved toward a product patent system with the introduction of the process patent system under the Patent Act of 1970, which is the polar opposite of the Justice

[1353] Novartis Ag v. Union of India and Others (2007) 4 MLJ 1153
[1354] The Indian Patents Act 1970, s.84.

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Ayyangar Committee's 1959 recommendation. The inclusion of "patent eligibility" under section 3(d) of the Act of 2005 is one of the most significant revisions to the legislation. Patents on derivatives of known chemicals are not granted under Section 3(d) unless the derivatives have significantly improved efficacy. Section 3(d) aims to prevent the practise of ever greening by refusing patents for minor changes to existing patents. Ever greening, also known as stockpiling, life-cycle management, patent-layering, and line-extension, is the process of obtaining multiple patents that cover different aspects of the same product.

Pharmaceutical patent owners plan to increase the lifetime of existing patents by incorporating updated versions of the very same drug, innovative launch systems, and potential uses for the drug, which is known as ever greening. Because India's pharmaceutical business is dominated by generic medicine producers, a tight patentability requirement was essential to ensure that generics could enter the market quickly. The creation of section 3(d) was the answer, as it attempted to raise the patentability threshold limit while also excluding some types of inventions from the Patent Act's scope. Pre- grant examination was the first step toward a fundamental shift in the way pharmaceutical patent applications were scrutinised in India. The practise of ever greening has been deprecated by judicial precedent in the United States and the United Kingdom, both common law countries with a substantial number of pharmaceutical patents. The addition of section 3(d) to the patent statutes should be seen as a decisive legislative move taken by India to combat the threat of ever greening and should be applauded.

THE SAGA OF NOVARTIS

On July 17, 1998, Novartis petitioned for a patent and an exclusive marketing right in India via the "mailbox" (EMR). When the EMR was granted in 2003, consumers in India claimed a ten-fold increase in the price of glivec. Novartis' glivec patent application was met with fierce criticism from local pharmaceutical companies (against whom Novartis had initiated infringement actions) and the Cancer Patients Aid Association, a non-profit organisation (CPAA). The application lacked originality since it did not demonstrate any meaningful 'efficacy' to satisfy the criterion of section 3(d) and had no obviousness and therefore had a wrongful priority. Under section 23 of the 2005 Amendment, the opposition might be heard prior to the award of the patent. The Assistant Controller of Patents denied Novartis' application on March 8, 2006, agreeing with the claims of the patent opponents, ruling found that the new version of glove was not sufficiently distinct from the previous, unprotected version to warrant a patent.

As a result, Novartis filed two appeal cases in the Madras High Court, asking that the Assistant Controller of Patents reverse his decision and declare section 3(d) of the Amendment Act unconstitutional and in breach of India's TRIPS obligations. The government established the IP Appellate Board while the case was pending, and the IPAB received the first of the petitions mentioned above. Novartis further alleged that provision 3(d) was in violation of Article 14 of the Constitution since it gave the patent controller unrestricted powers, resulting in discriminatory effects. The court initially heard the case challenging TRIPS compliance and the constitutional validity of section 3(d), and in a judgement dated August 6, 2007, the court found that the clause in dispute did not violate Article 14 of the Indian Constitution and that it did not provide the Controller of Patents unrestricted authority.

The court also ruled that the state has a constitutional commitment to offer good healthcare to its inhabitants, including access to medications, and that necessary legislative measures to prevent ever greening should be put in place which has a negative impact on the availability of affordable medicines. Novartis was granted special leave to appeal the foregoing decisions to the Supreme Court of

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India. Five appeals were filed with the Supreme Court, and on April 1, 2013, the Court issued a thorough decision. Before to 1997, the Supreme Court was questioned if the mesylate salt version of imatinib had been disclosed or was widely recognised. Novartis compared the beta crystalline to the already known mesylate salt to meet the requirement of "enhanced efficacy" in section 3(d). Imatinib mesylate has been a known substance since 1994, according to the Supreme Court, and does not qualify as a "invention" under section 2 clauses (j) and (ja).

The Court also determined that the beta crystalline form does not meet the requirements of the section 3(d) criterion, concluding that section 3(d) was intended to create a "second tier of qualifying standards" for chemical substances in order to combat "any attempt at repetitive patenting or extension of the patent term on spurious grounds." Despite this, the Supreme Court interpreted effectiveness to mean therapeutic efficacy. The Court endeavored to link patenting to therapeutic benefit, or more accurately, net societal benefits, emphasizing the relevance of a country's individual circumstances in selecting the appropriate patent regime to adopt within the TRIPS Agreement's IP rights regime. The appeal was dismissed because Novartis could not show that the new form of the known ingredient may improve the drug's therapeutic efficacy, according to the court. The decision connects the essential subject of patenting with net societal benefits, emphasizing the relevance of a country's socioeconomic realities in determining the right patent regime to implement. According to the Supreme Court, the purpose of section 3(d) was to outlaw the technique of ever greening. The case will be a result of the TRIPS Agreement's misguided ambition for creating a worldwide harmonized IP protection system. Although section 3(d) is intended to prevent the practice of patent.

From the foregoing, it is evident that the Indian Supreme Court's interpretation of the Patent Act in the Novartis case reveals India's unequivocal position in protecting ever-greening is a tactic used by TNPCs to circumvent their own patent jurisdiction. The Supreme Court's decision establishes limits on patent granting and the practise of patent ever greening, and it is widely regarded as a watershed moment in Indian patent law. Poor countries should follow India's model and implement measures similar to section 3(d) in their patent legislation to make pharmaceuticals more accessible.

The Act's system does not totally exclude the possibility of patent ever greening. **"**While handing down its decision in the Novartis case, The Indian Supreme Court noted that it did not want Indian patent rules to grow in such a way that the scope of a patent is defined by the intrinsic worth of the innovation rather than the intrinsic value of the invention itself rather by the skillful drafting of its claims, and if patents are exchanged as a commodity rather than for the purpose of manufacturing and promoting patented goods, instead of looking for someone who may be prosecuted for patent infringement ".The judgment's reading of the provision, i.e. section 3(d), plainly shows that India has adopted a pharmaceutical patenting standard that is tougher than that of the United States or the European Union. It was not enough to just establish that the compound was different from the old one in the patent application; it had to show that the modification will result in an improvement in the patient's therapy. The Court was attempting to apply the social welfare theory to the understanding of the term "efficacy," as opposed to therapeutic efficacy, in this case.

Following the Justice Ayyangar Committee Report, India decided to adopt a product patent regime in 1970, marking a watershed moment in the country's history because it was in response to domestic issues, such as the country's socio-economic realities at the time. This strategy not only helped India achieve greater self-sufficiency in pharmaceutical access through generic drug manufacture, but it also aided

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other developing nations in the HIV/AIDS fight in the years to come. Pre-grant clauses have been used by some generic medication producers and public interest groups to avoid bogus patents, although the option is underutilized due to information access hurdles. Because the Indian Patent Office does not publish full details of pending applications, denial of access to or non-disclosure of information on them poses a severe concern. This rule needs to be clarified, especially since that India has taken steps to curb the practise of patent ever greening. The process for awarding a compulsory license under the Act of 2005 is complicated and time-consuming, and there is no time limit set in the Act or Rules for the authorities to process an application. The compulsory license provision may become outmoded and unsuitable for the objectives for which it was enacted due to a lack of clarity in this area. Furthermore, the Act does not fully take advantage of TRIPS flexibilities, as any final ruling to utilize a patented invention under compulsory license can be contested in litigation and an injunction requested to prevent its use. TRIPS Agreement does not require a member state to allow for an injunction against government use. In this sense, the US and UK practises differ and are less onerous, as both governments have the right to take over a patent innovation without first acquiring a license or participating in lengthy negotiations with the patentee. State engagement through compulsory licenses has been deemed necessary and important in the event of a pandemic. The WTO emphasized the need to balance major public health concerns afflicting many developing nations in the Doha Declaration of 2001, and recognized a Members of the WTO have the right to protect public health and encourage universal access to medicines. Each member has the authority to determine what circumstances constitute as a national emergency according to the document. The Covid-19 outbreak has raised demand for a variety of medicines around the world, particularly in developing and least developed nations that lack the capacity to manufacture important medicines. Several WTO members, particularly developed nations, are concerned that exclusive rights will hinder them from providing enough medicine to combat Covid-19. Thirty- seven countries, including the US, Canada, Australia, Japan, and the European Union, have chosen to be ineligible to import pharmaceuticals that are created and patented in another country for which a compulsory export license has been given. The WHO accepted Costa Rica's plan to create a pool of rights to diagnostics, treatments, and vaccinations, with free access or licensing on fair and acceptable terms for all countries, in light of the pandemic's spread.

Conclusion

In conclusion, this chapter has demonstrated the pivotal role of the Indian judiciary in shaping the compulsory licensing regime for pharmaceutical patents, navigating the inherent conflict between incentivizing innovation and ensuring affordable access to medicines. Through rigorous case law analysis, including *Natco v. Bayer* and *Novartis v. Union of India*, the judiciary has shown a propensity towards a public health-oriented interpretation of the Indian Patents Act, particularly concerning unmet needs and patent evergreening. However, the complex and potentially protracted nature of the compulsory licensing process remains a limitation. Moving forward, streamlining these procedures and clarifying the grounds for government use could enhance the effectiveness of this crucial TRIPS flexibility. India's experience offers valuable lessons for developing nations seeking to utilize patent laws to protect public health strategically.

Reference :

Based on the document you provided, here are some core references that appear central to the discussion on compulsory licensing in the pharmaceutical industry. Please note that due to the nature of the submitted document (an originality report showing similarity percentages

to other sources), full citation details are not consistently present within the text itself. Therefore, I will provide the information available in the document and indicate where details are missing. I will attempt to provide citations that resemble Bluebook style.

Primary Sources (Legislation):

- The Indian Patents Act, 1970 (as amended
- TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights

Case Law:

- *Novartis AG v. Union of India and Others*
- *Natco Pharma Ltd. v. Bayer Corporation* Secondary Literature (Books and Publications):
- Srividhya Ragavan, Amaka Vanni. "Intellectual Property Law and Access to Medicines - TRIPS Agreement, Health, and Pharmaceuticals", Routledge, 2021
- Duncan Matthews. "Globalising Intellectual Property Rights - The TRIPs Agreement", Routledge, 2003.
- Bryan Mercurio, Daria Kim. "Contemporary Issues in Pharmaceutical Patent Law - Setting the Framework and Exploring Policy Options", Routledge, 2017
- Gopakumar K M.. "Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime", The Law and Development Review, 2010
- Radhika Bhattacharya. "Are Developing Countries Going Too Far on TRIPS? A Closer Look at the New Laws in India", American Journal of Law & Medicine, 2008 Reports and Policy Documents:
- "WTO - Trade-Related Aspects of Intellectual Property Rights", Brill, 2009