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Impact of Compulsory Licensing in Developed and Developing Nations

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ABSTRACT

This paper makes an effort to differentiate between the problems with the present-day legal system's use of compulsory licencing arrangements for pharmaceutical licences and to recommend the best way to resolve them without seriously jeopardising the objectives of the holders, especially in developing countries. The major focus of the paper is on the acceptance of compulsory patent licencing, which can address the issue of drug affordability and accessibility in some developing nations. Unless otherwise noted, "developing countries" includes Least Developed Countries (LDCs) as well. While the Trade Related Aspects of Intellectual Property Right Agreement provisions that can facilitate poor countries' access to medicines are equally pertinent to the subject of compulsory licencing of patents in this study. In a nutshell, it emphasises in especially the measures meant to clarify compulsory licensing. Additionally, the study covers Trade Related Aspects of Intellectual Property Right Agreement provisions that do not specifically address compulsory licencing of patents but may nonetheless have an influence on patients' access to drugs. Additionally, the evolution of patents throughout different nations is examined, with a focus on drug patents. Along with a study of the practises and effectiveness of compulsory licencing in developing countries generally and India in particular, the Trade Related Aspects of Intellectual Property Right regime, which was imposed by rich nations and supported by MNCs to restrict the use of compulsory licencing by nations that are developing, is also examined. The goal of this paper is to investigate the different situations where rich countries and multi-national corporations (MNCS) apply pressure on developing nations to support their monopolistic patent system in the pharmaceutical business.

Keywords: *Trade Related Aspects of Intellectual Property Right (TRIPS), compulsory licensing (CL), developing nations, drugs and MNCS.*

I. INTRODUCTION

The whole point of giving a patent is to advance research and technology. Though it provides extra layers of security to patent holders, which gives them greater power, such protection might

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be an obstacle for nations that are developing. Therefore, failing to fulfil these obligations will result in exclusivity and negatively impact the nation's industrial and economic development, access to public goods, and scientific advancement. There comes the idea of a compulsory licence (CL). These contracts are forced or imposed by the government between an eager licensee and an unwilling licensor. A compulsory licensing is a legal device created to compel holders of intellectual property to grant exclusive rights to interested parties who can manufacture the patented goods more cheaply. The goals of granting compulsory licensing are to ensure well-being of the population, the spread of technological advances and the public's access to patented inventions at a price they can pay. The member countries are free to identify the grounds because Trade Related Aspects of Intellectual Property Right doesn't restrict the justifications for compulsory licencing[2]. The Doha Declaration also specifies that every nation has the authority to decide the standards under which these permits are awarded, as well as the authority to provide them Compulsory licensing[3]. This helped the impoverished world to solve the issue of not having access to the medicines needed to treat illnesses. This idea is entrenched in the Patents Act, 1970 of India as well, which is being given up by the purported, private guarantees by the Indian Government to MNCs that India will not award commercial compulsory licensing. When compulsory licensing provisions are applied, the price falls, resulting in cost savings for patients. The Indian law's Compulsory Licensing provisions have hardly been used, and only one Sorafenib compulsory licensing has been issued thus far. While numerous low-income nations have received compulsory licensing to gain access to expensive proprietary medications[4]. But regrettably, the Indian Government deliberately rejects compulsory licensing requests. In terms of the compulsory licensing provision's enforcement, the Draft National IPR Policy also needs to be improved.

(A) Research Methodology

This study paper showed the significance of secondary data. The research report's data was compiled using information from books, websites, and other academic papers. Secondary sources were used to develop the concepts and materials for the study. I was able to do this by gathering my information at the moment and outlining my worries and ideas about the matter.

(B) Review of the literature

The Intellectual Property Debate: Perspectives from Law, Economics and

[2] Agreement on Trade Related Aspects of Intellectual Property Rights, 15 April 1994
[3] Paragraph 5(b) of Doha Declaration on the TRIPS Agreement and Public Health.
[4] Sorafenib is an anti-cancer drug

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Political economy by Meir Perez Pugatch[5].

In his edited book, the writer views discussions on intellectual property as an effort to strike an equilibrium between the desires of IP owners and IP users. The volume comprises contributors from a numerous domains, including universities, government agencies, law, and the pharmaceutical industry. The sections on intellectual property rights (IPRs), medicines and the field of biotechnology and IPRs, rivalries, availability, and antitrust in the era of data-driven society, respectively, offer a thoroughly researched perspective on the pertinent topics. The book also talks about that although Douglas Lippoldt supports robust intellectual property protection in his writings, he neglects to deal with the problem of getting crucial medications. Whereas in his research, Pfizer Pharma's David Goren comes to a conclusion that is somewhat startling. He recommends enhanced IP protection as a way to address the issue of availability of cheaper drugs. The work primarily concentrates on defending rigorous IP protection, however it is insufficient to address the concerns of emerging nations about it.

"Pharmaceutical Industry, The Health System And Intellectual Property Policy In India" in Carlos M. Correa, Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing by Arti Malik[6].

Her research centres on the Patents Act of 1970's obligatory licencing rules as they relate to pharmaceutical patents. She is aware that these regulations might be crucial for fulfilling the demands of people's wellbeing. She states that India has given a sizable amount of secondary patents, demonstrating a lax registration practise. Free Trade Agreements are being criticised According to her, if India signs any data exclusivity agreements, it might have a negative effect on the country's pharmaceutical business and make it more difficult for pharmaceutical patents to function, even if they are authorised by compulsory licencing.

II. COMPULSORY LICENSING OF PATENTS IN DEVELOPED AND DEVELOPING COUNTRIES

Several wealthy countries have employed compulsory licensing often for many years, even before the treaty on Trade-Related Aspects of Intellectual Property Rights became effective. Contrarily, only a small number of developing nations have adopted Trade Related Aspects of Intellectual Property Right moldable despite intense pressure and criticism. This can be attributed to a number of factors, such as ignorance or a lack of understanding of the various

[5] Meir Perez Pugatch, The Intellectual Property Debate: Perspectives from Law, Economics and Political Economy, Edward Elgar Publishing Ltd., UK, 2006

[6] Arti Malik, "Pharmaceutical Industry, The Health System And Intellectual Property Policy In India" in Carlos M. Correa, Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, South Centre, 2013.

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flexibilities. Despite persistent pressure, a lot more developing nations have since the Doha Declaration's passage exercised their rights and used the existing flexibilities to get affordable medications. Antiretroviral medications for the treatment of HIV/AIDS were initially the emphasis, but this has expanded to include other critically important medications. The present section examines the material that is currently available on the application of compulsory licencing in emerging nations. The following descriptions of the instances take into account three primary concerns: the legal foundation for the compulsory licensing's (or government usage authorizations) granting; information of the decision-making procedure, if accessible; and the advantages of using forced licencing for public health.

III. COMPULSORY LICENSING IN DEVELOPED COUNTRIES

Developed nations have utilised compulsory licensing extremely successfully. It creates a significant amount of impetus for the developed world's economy, job opportunities, and expansion of infrastructures and industry. Today, wealthy countries do not favour the compulsory licensing, mainly because target markets have changed and there is more competition from new industrial lobbies.

(A) Use of Compulsory Licensing in U.S.

The U.S. Constitution's Article I, Section 8, Clause 8 serves as the foundation for the patent system. If they want to be granted patent protection, innovator must create and comply the applications to the U.S. Patent and Trademark Office (USPTO)[7]. Damages awards are also permitted by the patent statute[8]. The U.S. patent statute doesn't contain a generalised obligatory licencing clause, in contrast to the laws of many other countries. There are a small number of other compulsory licensing for U.S. patents, all of which are pertinent to the particular subject matter. The Sherman Antitrust Act makes the compulsory licensing usable in antitrust actions as well. The SC determined that Glaxo Group and Imperial Chemical Industries Ltd. (ICI) were involved in restricting sale of the patented anti-fungal medicine griseofulvin in the anti-trust case United States v. Glaxo Group. The American government has the authority to acquire private property for public use[9]. However, this privilege is not unrestricted. In some cases, government agencies are required to pay the landowner for using the asset in particular. Thus, the US government essentially possesses the power to grant a compulsory licensing allowing it to utilise a patented idea without the patentee's consent.

[7] 35 U.S.Code § 111.
[8] 35 U.S.Code § 271(a).
[9] United States v. Glaxo Group 410 U.S. 52 (1973)

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(B) Use of Compulsory Licensing in EU

Considering that there are 27 Member States in the European Union, the law on compulsory licencing is no less complex. The compulsory licensing is frequently issued in Europe to stop and prevent monopolistic abuses. The compulsory licensing is a procedure outlined under international and domestic laws of EU Member States as well as the Treaty on the Functioning of the European Union. It is defined in Article 34, which specifies the parameters of forced licencing in terms of both freedoms and remedies, together with Articles 35, 36, 101, and 102.

(C) Use Of Compulsory Licensing in Japan

By integrating some aspects of French and American patent rules, the Patent Monopoly Ordinance created the Japanese Patent System in 1885. After a thorough review and analysis of the patent systems in developed nations, the Patent Monopoly ordinance was replaced with the Patent Ordinance of 1888. The goals of the Japanese Patent Laws are to promote inventions through advocating their use and protection, which will aid in the growth of industry and "to encourage the advancement of such tools and so help foster the growth of business; by fostering safeguarding and making use of gadgets relating to the layout or framework, or a mixture of both; of products." Industrial progress is explicitly emphasised in Japanese patent law as the ultimate purpose of patent protection. Despite not using the term "compulsory licence," the Japanese Patent Law does contain a system of "award granting non-exclusive licences." that, in certain circumstances, serve the same purpose as a compulsory licensing.

IV. COMPULSORY LICENSING IN DEVELOPING COUNTRIES

“In undeveloped nations where individuals cannot buy generic medications for ailments like AIDS and cancer, mandatory licensing for drug items is extremely beneficial to the general public”.

(A) Use of Compulsory Licensing in Malaysia

The judicial basis for Malaysia's mandatory licensing requirements is under According to Section 48 of the Patents Act of 1983, "compulsory license" refers to the right to execute in Malaysia, including any activities intended to exploit the invention that has been patented, despite the patent owner's consent. A compulsory license may only be allocated for use with the goodwill or business, or that portion of the generosity or enterprise, in which the patented invention is used. The compulsory licensing is granted by the Intellectual Property Corporation of Malaysia, which conducts operations as the Malaysian Intellectual Property Office. Since adopting compulsory licensing in 2017 to gain possession of generic versions of the Hepatitis

C medication sofosbuvir, Malaysia has come under persistent criticism from pharmaceutical firms and their political allies. However, the cost of therapy is astronomically high, making it less affordable for patients. Both the U.S. and Malaysian lists prices for Sovaldi are RM 300,000 ($71,300 USD). Under Section 84 of the Malaysian Patents Act, 1983 and in conformity with the Trade Related Aspects of Intellectual Property Right, Malaysia has granted a compulsory licensing for Gilead's highly efficient but astronomically costly patented HCV Sofosbuvir (marketed as Sovaldi). As a result, the compulsory licensing would allow the Malaysian government to offer generic Sofosbuvir at a cost that is only 0.33% of the going rate in Malaysia[10].

(B) Use Of Compulsory Licensing in Thailand

The Thai government recognized the necessity for a patent regime as a developing country whose patent laws were invalidated by the Supreme Court of Thailand in 1964. Industrial growth and technological advances are essential for financial growth. In 1979, Thailand enacted its first patenting law. The Thai Assembly incorporated many of the essential concepts into its patent laws outlined in the Paris Convention. The underlying principles included in rich countries' patent laws and the legal framework produced by BIRPI and later WIPO under the Model Law for Developing Countries[11]. In order to recognize pharmaceutical patent protection, forbid parallel imports, and increase patent validity to 20 years, Thailand adopted the TRIPS Agreement, which also amended the Thai Patent Act (TPA).

The local production of efavirenz was given a five-year government usage authorization on November 29, 2006, according to Thailand's Ministry of Public Health. For the treatment of AIDS and HIV, this medication is recommended. Despite being on the market for many years, the medication is still highly expensive. The government-use permit, which was originally created by DuPont Pharma, was granted in accordance with Section 51 of Thailand's According to the Patent Act, any government agency may utilize the compulsory-licensing power either directly or indirectly in means to perform any duty for the general people or that is essential to the nation

(C) Use Of Compulsory Licensing in India

The Indian Patent Act has been modified to make the award of mandatory licensing consistent with the Trade Related Aspects of Intellectual Property Right Agreement to enable India to

[10] Prabhat Kumar Saha and Aditi Mukherjee, ―Compulsory licensing of Pharmaceutical Patents in India a Policy Shift 5 EPW 12 (2019).

[11] Stephanie Skees, ‗Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?' 19 PaceInt'lL. Rev. 269 (2007)

adhere to global responsibilities. The sections of the Act from Section 82 to Section 94 control mandatory licensing. A handful of Asian countries have mandated licenses in recent decades, sparking criticism around the world, particularly the mandate that India implemented during the Natco-Bayer conflict. The income and management of their ideas by the patent owner are impacted by licensing. A mandatory license application may be submitted at any stage following the lapse of the 3-year period starting from the day the patent was granted[12].

There are primarily three significant justifications for the granting of obligatory licensing in India[13].

a. People's reasonable desires regarding the patented idea are not fulfilled.

b. The patented invention cannot be purchased by the general public for a fair price.

c. The patented innovation hasn't been successful in India.

In a historic case involving Bayer Corporation v. NATCO Pharma Ltd in 2012, India issued its inaugural Compulsory License. This action has had a significant influence on the health care industry.

V. CASE ANAYLSIS ON COMPULSORY LICENSING IN INDIA

According to the aforementioned analyses, the Indian Patents Act complies with all of the Trade Related Aspects of Intellectual Property Right agreement's conditions for compulsory licensing. Consequently, it was correct to draw the conclusion that the mandatory licensing The Indian Patents Act's provisions are completely compliant.

(A) Natco- Bayer Case:

The corporate headquarters of the pharmaceutical firm Bayer Corp. are in Leverkusen, Germany[14]. It developed "Sorafenib Tosylate," a cancer medication used mostly to treat kidney cancer. Bayer Corporation marketed the aforementioned medication under the brand "Nexavar," In the year 2008, Nexavar received a patent from the Indian Patent Office. However, NATCO Pharma Ltd. (Natco) is an Indian pharmaceutical business that produces treatments and medications. Natco approached Bayer Corp. in December 2010 to request a voluntary license to produce "Nexavar." Unfortunately, the request was turned down by Bayer Corp. Natco subsequently requested a mandatory license from the Controller in the year 2011 based on S. 84 of the Patents in India If the aforementioned matter is covered by S. 84, which lists the

[12] Indian Patents Act, 1970 § 84, No 39, Acts of Parliament, 1970
[13] Id.
[14] Legal service India, https://www.legalserviceindia.com/legal/article-8665-compulsory-license-under-the-indian-patents-act.html (last visited on July 17, 2023)

requirements for granting compulsory licensing, the controller was asked to respond. In 2011, Natco submitted a request for mandatory licensing to the controller. On March 9, 2012, the controller granted Natco a forced license. Bayer Corp. complained to the former Intellectual Property Appellate Board (IPAB) about the controller's judgement. By giving Natco a compulsory license, the Controller and IPAB made decisions that were basically comparable to one another; the supporting evidence is provided below.

(B) BDR-BMS DISPUTE:

On March 4, 2013, BDR submitted a request for a mandatory license for DASATINIB. When a patient becomes resistant to the medicine IMATINIB or develops resistance to it, it is given as an appropriate chemotherapeutic choice for the treatment of chronic myeloid leukemia[15]. BDR Pharmaceutical stated that the price per person is approximately INR 19, 88,160 per year. On the other side, According to BDR, the drug would be sold to the general public for a proposed cost of Rs. 135 for every single tablet, or Rs. 8100 for every month. BDR wrote to BMS asking for a voluntary licence so they could produce DASATINIB in India[16]. After reviewing the BDR's CL application, the Controller issued a notice saying that there was a prima facie basis for issuing an decree under Section 84 of the Act not created since, in the non-appearance of DCGI's consent, "The applicant "did not acquire the capability to work the innovation to the people's benefit" and "the applicant also made no attempt to gain a license." The decision to solely conjure the laws in relation to compulsory licenses without taking the necessary steps set the groundwork for the conclusion that the applicant had a purposeful intention to communicate with the patentee. Although BDR Pharma and the Ministry of Health worked hard to obtain the mandatory license for Dasatinib, the mandatory license could not be granted for lack of a firm foundation. The legislation could not be characterized as a "procedural or timeline irregularity" that might be overlooked, excused, or judged to not apply. The petitioner failed to follow the legal process and did not discover a solid legal basis for issuing a decree under Section 87 of the Act. The application for a mandatory license was turned down.[17]

VI. CONCLUSION AND SUGGESTION

Compulsory licensing is a key weapon that policymakers should consider using to increase the production and distribution of medications and medicines in the middle of the crisis, as was

[15] khuranaandkhurana.com, https://www.khuranaandkhurana.com/2013/11/13/indian-patent-office-rejects-compulsory-licensing-application-bdr-pharmaceuticals-pvt-ltd-vs-bristol-myers-squibb/ (last visited on July 17, 2023)
[16] Ibid
[17] Supra note 14.

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highlighted in this paper. The particular circumstances in which the mandatory Licenses are used. Although many governments, including the Indian government, have used it successfully in the past, its limited advantages must be considered. The development of the vaccine has undoubtedly given rise to new hope in the fight against the viral threat, but its use and dissemination to broad populations still pose difficulties. Given the constraints, implementing extreme government policies like compulsory licensing may not be the best course of action.

It is suggested that patent owners exercise sufficient prudence while negotiating voluntary licenses with stakeholders as a means of enhancing obligatory licensing. To promote more efficient drug delivery and to satiate public demand, licensing agreements may be desired. In a similar vein, it's crucial for pharmaceutical companies to thoroughly research obligatory licensing before submitting a request. The unsolved question may be whether compulsory licensing is the most logical way to provide patients with access to patented medications in sufficient quantities, at the appropriate time, and for a reasonable cost. The sector should simultaneously endeavor to implement the best pricing model possible in developing nations. To achieve an innovative, creative, and commercially feasible result that satisfies consumer demand within the appropriate timescale, it is vital to achieve an equilibrium between boosting R&D and price strategies.

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