COMPULSORY LICENSING OF PATENT IN INDIAN PHARMACEUTICAL INDUSTRY: AN ANALYTICAL STUDY OF ITS PROVISIONS IN CONSONANCE TO THE TRIPS AGREEMENT

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INTRODUCTION

Over the years, India's patent laws have changed. The British passed India's first patent law, i.e., Act VI of 1856, during the colonial era. Subsequently, changes to the patent regime regulations were made, with the most recent being implemented in 2005. The Ayyangar Report, created by a commission led by Rajagopala Ayyangar, a former Supreme Court Justice, was the primary inspiration for the Patents Act of 1970. The Report's main recommendation was to keep products out of the purview of patentable inventions so that everyone could access affordable food and medicines essential to the community's health. It also suggested that no monopoly should be granted regarding such products. It was further recommended that processes be granted patents using examples of other patent regimes, such as Germany. Allowing process patents and outlawing product patents would promote research and invention by preventing someone else from developing the same method using a completely different process.[i] However, India was forced to amend the Patents Act 1970 and allow the process and product patents, which included pharmaceutical drugs, after the TRIPS Agreement was signed, which set common minimum standards of patent protection to be followed by TRIPS signatories. After several States turned to grant compulsory licenses concerning pharmaceutical drugs to safeguard the public health of their citizens, discussions about the standards of patent protection conferred by various jurisdictions and questions about their compliance with the minimum requirements set forth by the TRIPS Agreement have grown recently.[ii] Chapter VI of the Patents Act of 1970, which contains Sections 82 to 94, contains the present compulsory licensing system for patents in India. It is also governed by international

agreements like the TRIPS Agreement, the Paris Convention, and the Doha Declaration. The Trips Agreement's patent protections are included in Articles 26 and 34 of Section 5.

A license is "a grant by the holder of a copyright or patent to another of any of the rights included in the copyright or patent, other than an assignment of all rights," according to Merriam-Webster's[iii]. It involves the patent owner granting the licensee rights to manufacture, use, offer for sale, sell, import, etc. The patent holder may freely provide such a license, or the licensee may be required to acquire it. The patent holder willingly grants the licensee a license to use his invention on the terms and circumstances agreed upon between the licensor and licensee, whether in exchange for money or other value. The term "compulsory licensing" refers to the granting of intellectual property rights licenses by a national government without the owner's consent to fully utilize the protected right, particularly patent or copyright licenses. It occurs when a government permits a third party to manufacture a copyrighted good or method without the patent holder's permission[iv]. It is one of the patent protection flexibilities of outlined in the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Accord, the WTO's agreement on intellectual property, and the fundamental and obvious differences between an involuntary license and a voluntary license are that voluntary licensing involves the patent holder's consent, whereas a compulsory license does not.

This paper's research methodology is doctrinal and heavily depends on reviewing previous material. The research primarily focuses on reading, analyzing, and providing comments on primary sources of information like the Patents Act of 1970, read along with its amendments in 1999, 2002, and 2005, as well as international agreements, with the TRIPS agreement reading along with the Doha Declaration's clarification and the Paris Convention being the most important. Secondary sources included related books, articles, legal dictionaries, and other readily accessible content on the internet. Availability of jurisprudence about the extent and scope of Article 27.1 and its relationship with Article 31 of TRIPS, which principally took the form of a Panel Report of WTO, is relied upon to determine the compliance of section 84 of India's Patents Act, 1970, with the TRIPS Agreement. The articles, books, journals, and websites produced by numerous associations and specialists in this field are used as secondary data sources and have been cited and footnoted.

STATEMENT OF PROBLEM

A compulsory authorization will also be given to the applicant under section 84(1)(a) because the patentee has not complied with the reasonable expectations of the public. The phrase "reasonable condition" is not defined in the statute and cannot be easily understood.

The "local functioning" condition under section 84(1)(c), which authorizes the issue of a compulsory license because the patented innovation is not used on Indian soil, is unclear in the current Indian context. There are strong allegations that India's patent law regime violates the TRIPS Agreement, specifically violating Article 27.1, which states that there shall be no discrimination between imported goods and domestically produced goods. This accusation stems from the grant of India's first-ever compulsory license, which required the patentees to manufacture patented drugs in India compulsorily.

The Patent Act's section 84(1)'s compulsory licensing process is laborious, drawn out, and far more legalistic than what the TRIPS agreement calls for. Any interested party may only apply to the controller for the award of a compulsory license on a patent after a period of three years has passed since the date the patent was granted. It takes too long for generic producers to wait three years before applying for a mandatory license.

RESEARCH QUESTIONS

1. Does Section 84 (1) (c) of the Indian Patent Act comply with TRIPS?
2. What causes the application process for mandatory licenses to take so long?
3. How should Section 84 (1) (a)'s "reasonable requirements of the public" be construed to award a compulsory license?

OBJECTIVES OF RESEARCH

The work shall be undertaken:

1. To investigate and understand whether the compulsory licensing process under the Indian Patent Act is significantly more bureaucratic and legalistic than what the TRIPS agreement requires, as well as how the reasonable requirements of the public under Sec. 84(1)(a) be precisely interpreted as grounds to grant a compulsory license.

2. To learn about the many conditions and guidelines that India's compulsory licenses may be issued under.
3. To determine whether section 84(1) (c) of the 1970 Patent Act of India complies with the TRIPS Agreement, that is, to determine whether the term "working" under this section could also mean "manufacturing" in some circumstances and whether such an interpretation conflicts with the TRIPS Agreement.
4. To determine the justification of Section 84's requirement that interested parties wait three years before applying for a compulsory license following the grant of a patent.

WHAT IS COMPULSORY LICENSING

A license is "a grant by the holder of a copyright or patent to another of any of the rights included in the copyright or patent, other than an assignment of all rights," according to Merriam-dictionary. Webster's It involves the patent owner granting the licensee rights to manufacture, use, offer for sale, sell, import, etc. The patent holder may freely provide such a license, or the licensee may be required to acquire it. The patent holder willingly grants the licensee a license to use his invention on the terms and circumstances agreed upon between the licensor and licensee, whether in exchange for money or other value. The term "compulsory licensing" refers to the granting of intellectual property rights licenses by a national government without the owner's consent to fully utilize the protected right, particularly patent or copyright licenses. It occurs when a government permits a third party to manufacture a copyrighted good or method without the patent holder's permission. It is one of the patent protection flexibilities outlined in the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Accord, the WTO's agreement on intellectual property. The fundamental and noticeable difference between an involuntary license and a voluntary license is that voluntary licensing involves the patent holder's consent, whereas a compulsory license does not.

NEED AND SIGNIFICANCE OF COMPULSORY LICENSES

In the pharmaceutical sector, patent protection gives the creator monopoly rights that could be abused or misused by the patent holder at the expense of the general public. For example, the patent owner for a life-saving medication may use his exclusive marketing rights by charging

consumers an outrageous price for the drug or by refusing to sell it commercially. In this case, the State must compel other participants to obtain licenses to preserve the public's health. The patent holder's intentions regarding whether he endorses or consents to such a grant of license are irrelevant when the State provides a forced license, and licenses relating to manufacturing, production, sale, etc., of the particular medication are issued to the licensee without the licensor's consent. However, such a grant of a compulsory license is an exception rather than the rule. It is either used by the government as a result of certain acts or omissions on the part of the patent holder himself, such as his act of selling the patented invention at an inflated price or his refusal to make the story available to the general public or is used as a result of a third party. The primary goal of the obligatory license is to make access to pharmaceutical treatments easier. Compulsory licensing is a vital tool that developing nations may deploy in specific situations to ensure that the poor have access to necessary medicines. For whatever reason, granting compulsive licenses to other parties always results in more access to pharmaceuticals that provide life-saving medications[v].

Compulsory licenses, particularly in developing nations, function in various ways to make life-saving medications accessible to the general public. Compulsory licenses improve competition by allowing new competitors to enter the market, increasing competition due to the arrival of generic manufacturers, and reducing prices. This limits the monopolistic rights that patent holders enjoy and increases competition.

The non-exploitation of paten is another circumstance that justifies the issuance of the compulsory license. Patents that are not used become “sleeping patents.” Patents not utilized or put through the industrial application are “sleeping patents.” It is always a potential that a patent holder will choose not to work on or use their patent for any reason. The granting of a compulsory license is necessary to prevent the loss of numerous lives if the creator of a patented life- saving drug refuses to put his invention into use or does not make it accessible to the general public.

Numerous factors, some of which may even constitute an abuse of rights granted as a consequence of the invention, could cause an inventor to refuse to work on the idea and make it available to the public. For instance, a holder of patent rights may use his patent exclusively to restrict or prevent such entry since patent rights deter competitors from entering a particular sphere of activity, either because he wants to reserve for himself the right to enter this area

shortly or to prevent competitors from strengthening their positions by joining in. In a different scenario, a person can decide not to work on and refuse to permit some other participants to exploit their innovation because they are unsure of the invention's viability as a marketable technology.

When a patent is not being used, the State must act to ensure that the public is not denied access to the invention. In these situations, the State must provide a license to a third party who can and desires to use the patent, making it accessible to all. Many nations now have laws requiring compulsory licensing of patented ideas when the inventor does not want to use the product despite a market.[vi] The Controller General of Patents of India granted Natco a compulsory license in *Natco v. Bayer*[vii], partly because Bayer failed to commercialize the technology in India. A patent holder may abuse his dominating position in intrinsically anti- competitive ways, in which case the appropriate remedy might be the granting of a compulsory license. Different nations provide licenses to prevent the exploitation of intellectual property rights through anti-competitive tactics.

In some cases of a national emergency, such as the spread of an epidemic, the granting of a compulsory license becomes absolutely necessary to meet the needs of the general population. In some situations, the compulsory license may be granted for quantitative reasons, such as to meet public needs that may not be satisfied by the patent holder alone or to lower the cost of these necessary medications so that they are affordable to all. In cases of national emergency or another exceptional urgency, compulsory licenses may be granted under Article 31 of the TRIPS agreement, even if attempts to acquire consent from the right holder have not been made.

COMPULSORY LICENSING UNDER TRIPS

The TRIPS agreement was negotiated in 1994 after the Uruguay rounds and is managed by the WTO. The TRIPS agreement stands out from other contracts made under the aegis of the WTO in that it establishes universal minimum standards for protecting intellectual property that must be upheld by all member states'. It establishes various flexibilities in the form of exceptions to the protection of intellectual property in addition to the common basic criteria. Article 31 of the TRIPS Agreement addresses forced licensing and is titled “usage without the right holder's

authorization." However, not all provisions of TRIPS are free from ambiguity. The scope, extent, and applicability of Article 27.1 are disputed.

It has been alleged against India that the Controller's (and the IPAB's) decision to grant a compulsory license, even if partially based on the innovator's decision to import its product rather than manufacture it in India, violates Article 27.1 of TRIPS.

TRIPS Article 27.1 states that:

"Patents shall be available and patent rights shall be enjoyed without regard to the place of invention, the field of technology, or the origin of the goods"

Therefore, Article 27.1 requires that patent rights be enjoyed without distinction between goods that are imported and those that are locally produced. It was decided to award a compulsory license in Bayer's case because the product was imported from outside the Indian territory.

The Controller opined-

"Article 27.1 of the TRIPS Agreement mandates that WTO Members make patents available for all inventions, including patents for pharmaceutical processes and products, regardless of whether they are goods or processes. Following the Paris Convention, TRIPS also offers a reasonable restraint on the patent holder's rights in Articles 30 and 31. This allows member nations to establish rules such as issuing compulsory licenses to avoid the misuse of patent rights, among other things."

COMPULSORY LICENSING UNDER INDIAN JURISDICTION

Indian patent law has been around for a while. The Controller General may grant a third party a mandatory license to manufacture, use, or sell a particular product or employ a specific procedure covered by a patent without the owner's consent. This idea is acknowledged on both a national and international scale, and it is mentioned explicitly in both the TRIPS Agreement and the (Indian) Patent Act of 1970. If a compulsory license is to be granted in someone's favor, the prerequisite conditions listed in sections 84 to 92 must be met.

As per Section 84, any person, regardless of whether he is the holder of the license of that Patent, can make a request to the Controller for the grant of compulsory license on expiry of three years when any of the following conditions are fulfilled

1. the reasonable requirements of the public concerning the patented invention have not been satisfied.
2. the patented invention is not available to the public at a reasonably affordable price.
3. the patented invention is not worked in the territory of India.

The following reasons, which are stated under section 84(6), must be taken into account by the Controller when deciding whether to award a compulsory license pursuant to section 84:

1. the invention's kind;
2. the period of time since the patent's sealing;
3. the steps that the patentee or licensee has previously taken to fully use the invention the applicant's capacity to use the invention for the benefit of society;
4. If the application for a compulsory license is approved, the applicant's willingness to assume the risk of investing money and developing the innovation;
5. whether the applicant has made an effort to secure a license from the patentee on fair terms and circumstances;

The Controller, under section 84(6), is not required to take into account any events that may have occurred after the application was submitted in evaluating whether the circumstances call for the issuance of a compulsory license or not. [viii] It is important to note that the IPAB stated in Paragraph 43 of an appeal is heard against the Controller's order that the compulsory license proceedings "are in the public interest; they are neither against the inventor nor in favor of the compulsory licensee." It hardly matters if the invention is made readily available by the patentee himself for an affordable price. At the same time, the proceedings are ongoing as long as the controller is satisfied that the high price will not be reinstated because patents are only granted to benefit the public, and the public must benefit from the invention. This line of thinking seems to imply that, even if section 84(6) does not mandate it, the Controller may do so if he thinks it is appropriate and in the best interests of the public.

Before the Patents Act of 1970, the patent holder was under no duty to make an effort to find a willing licensee. The Patents Act of 1970 now places this obligation on the applicant and mandates that the applicant make efforts to acquire the license from the patentee on reasonable terms and conditions. In *Neo Pharma Industries (P) Ltd v Parke Davis & Co*[ix], the Controller held that the provisions of the Act, 1911 did not require the applicant to make efforts to obtain

a voluntary license from the patentee. The Controller denied BDR Pharmaceuticals' request for a compulsory license in October 2013, citing section 84(6) vi. In this instance, Bristol Myers Squibb[x] was selling the medication *dasatinib* for Rs. 2761 per tablet, or Rs. 1,65,680 for each patient's monthly prescription of 60 pills. After paying a royalty to the patent holder Le Bristol Myers Squibb, the applicant, BDR Pharma, requested a compulsory license from the Controller and promised to sell the generic version of the medicine at a price of Rs. 8100/- per month. On February 2, 2012, the applicant addressed the patent holder with a request for a voluntary license in relation to the medication *dasatinib* .

On March 13, 2013, the patentee responded to the applicant and raised a number of questions aimed at the applicant, including ones about the applicant's litigation history, the ability to consistently supply a high volume of *dasatinib* to the market, the risk of local competition, quality-related facts, and other matters. On March 4, 2013, the applicant submitted a request to the Controller for a grant of a compulsory license after failing to respond to the patentee's inquiries. The Controller denied the application because the applicant had not made the necessary efforts to secure a voluntary license from the patentee as required by section 84(6)(vi). The Controller's comment that "efforts required to be made by the applicant are total and inflexible, and without exceptions and the efforts required to be made are not only reasonable but something more" was the conspicuous focus of the ruling.[xi]

In conclusion, it can be said that even while section 84 gives the Controller the authority to grant a license on his or her own, the Act also establishes some guidelines that the Controller can use to decide whether the situation calls for the granting of a compulsory license. Reiterating that the justifications listed under section 84 are alternative and not cumulative is also essential. Suppose one or more of the grounds related to the failure to meet the reasonable needs of the public, the inability to purchase the patented innovation at an affordable price, or the need for the invention to function may be proven. In that case, a compulsory license under Section 84 may be issued.

Additionally, according to a notification from the Central Government, the Controller may issue obligatory licenses "suo motu" under section 92 in situations of "public non-commercial use," "national emergency," or "severe urgency." The ultimate decision to award the compulsory license rests with the Controller, who also considers the nature of the invention, the applicant's ability to use the product for the benefit of the public, and the reasonability.

Even when a third party receives a compulsory license to use a patent, the patent holder retains ownership of the property and is still entitled to compensation for copies of the products produced under the compulsory license.

"WORKING REQUIREMENT" UNDER THE PATENTS ACT, 1970 AND ITS COMPLIANCE WITH THE TRIPS AGREEMENT

In an effort to better harmonize patent regulations, India ratified the TRIPS agreement on April 15, 1994. The TRIPS agreement primarily establishes uniform baseline requirements for patent protection that were expected to be followed by TRIPS members, India, like other developing nations, initially had lax patent protection rules within of its borders in order to supply goods to its inhabitants at inexpensive prices. Foreign pharmaceutical companies, whose profits in respect to Indian markets were to fall significantly as a result of such agreements, have accused India of having an inconsistent domestic patent law following the awarding of a forced license to Natco. If these pharmaceutical industries lose their rights to exclusive marketability, they risk losing money. When South Africa changed its patent laws in 1997 to permit generic drug manufacturers to produce and sell affordable generic AIDS medications, the legality of granting compulsory licenses was also a topic of discussion. A number of pharmaceutical companies filed legal challenges to block the law's implementation, and the US also imposed trade sanctions on South Africa. The incorporation of compulsory licensing requirements is not a tough issue for Indian legislators; the challenging task is to frame the laws in a way that leaves minimal space for ambiguity and to implement them in a way that balances the interests of all parties.

CONCLUSION

The term "compulsory licensing" refers to the granting of intellectual property rights licenses by a national government, notably a patent or copyright license, without the owner's approval in order to promote widespread use of the protected right. It occurs when a government permits a third party to manufacture a copyrighted good or method without the patent holder's permission. The wishes of the patent holder regarding whether or not he endorses or consents to such a grant of license are irrelevant when the State grants a compulsory license, and the

license relating to the manufacture, production, sale, etc. of such drug is granted to the licensee without the licensor's consent. However, such a grant of a compulsory license is an exception rather than the rule, and is either used by the government in response to certain actions or inactions by the patent holder himself, such as his act of selling the patented invention at an unreasonable price or his refusal to make the invention available to the general public, or is a fundamental tool that developing countries may use in certain circumstances to ensure that marginal sections of the society has an unrestricted reach to the needed medicines.

Articles 27.1, 30, and 31 of TRIPS are the key clauses that deal with forced licensing. Article 31 of the TRIPS Agreement, which deals with forced licensing, is phrased as "usage without the right agreement." holder's It contains several clauses that must be taken into account before a member state can approve the use of a patent's subject matter without the right holder's consent. According to Article 27.1 of TRIPS, "patents shall be accessible and patent rights shall be enjoyed without regard to the site of invention, the field of technology, or whether products are imported or locally produced." Therefore, Article 27.1 requires that patent rights be enjoyed without distinction between goods that are imported and those that are locally produced.

ENDNOTES

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