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Innovation And Access: Compulsory Licensing As A Catalyst For Digital And Green Technology In India

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INNOVATION AND ACCESS:
Compulsory Licensing as A Catalyst for Digital and Green Technologies in India

Kritin Sardana[1]

Abstract

The analysis of compulsory licensing in the Indian patent framework is presented in this paper with complete detail. The introduction explains definitions of patents and compulsory licensing while showing their purpose to enable public access to technological innovations. This paper investigates how the TRIPS Agreement modifies worldwide and Indian compulsory licensing procedures. The specifications for Indian compulsory licensing include explanation of requirements along with license acquisition procedures while encompassing unmet public needs and unreasonable drug pricing conditions. The document explains both procedural aspects of using compulsory licenses along with procedures for applications and grant approvals. This paper studies important case examples to show how Indian courts have used compulsory licensing provisions in practice and how they provide interpretation of these rules. This study shows both successes and challenges that occurred while enforcing these legal regulations. The paper investigates both economic effects and conducts international jurisdictional studies related to compulsory licensing. Compulsory licensing provides solutions to climate change issues alongside digital innovation difficulties. Proposals are recommended to optimize the compulsory licensing administration while supporting quick efficient approaches. This paper emphasizes adopting a balanced method which enables both public health support and technological progress inside India's patenting framework.

INTRODUCTION

The Patent system of India includes Compulsory Licensing as a primary mechanism which promotes equilibrium between patent owner rights and public welfare. Indian Patents Act of 1970 established compulsory licensing as a mechanism allowing governmental authorization of third-party production and sales of patented substances or processes regardless of patent holder consent provided specified conditions exist. The system provides essential support for medicine along with technology accessibility and competitive market creation and public

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health resolution. The large-scale population and developmental status of India produces major obstacles when it comes to delivering vital medications and important technologies to its citizens. Because of this licensing model India can address high costs that result from monopolies while offering more affordable access to healthcare and technology breakthroughs. The Indian government supports compulsory licensing through the TRIPS Agreement of the WTO because member nations are authorized to issue such licenses under specified conditions. India shows its commitment to harmonizing global standards with national needs by using this method of patent protection.

MEANING OF PATENT AND COMPULSORY LICENSING

WIPO defines patents as exclusive rights protecting inventions between product designs and procedures that accomplish fresh solutions to technical problems. The patentholder obtains this right to maintain exclusive control over producing and distributing as well as processing and selling and importing and trading their invention. In India, the government subventions this exclusive right, which is valid for 20 years from the date of publication. still, this exclusivity isn't without exceptions; under certain conditions, third parties may be granted authorization to use the patented invention through the allocation of a mandatory license.[2]

What is a Compulsory License?

Compulsory Licensing happens when a government permits a third party to manufacture a patented product or use a patented process without the patent holder's consent, or when the government plans to use the patented invention directly. TRIPS Agreement's Art. 31, which deals with the use of patents without the right holder's authorization, outlines the conditions under which WTO members can apply mandatory licensing. The crucial provisions include the following:

a) The party seeking a compulsory license must have tried and failed to secure a voluntary license from the patent holder on "reasonable" marketable terms;
b) If a Compulsory License is granted, the patent holder must admit acceptable compensation; and

[2] JAIN AND PARTNERS, *Compulsory Licensing of Patents In India*, *available at*- https://www.jainandpartners.com/blog/details/compulsory-licensing-of-patents-in-india/37 (last visited Aug. 17, 2024).

c) The Compulsory License should primarily be issued to meet the requirements of the domestic request.[3]

A Compulsory License is an authorization handed by the govt. to a third party, permitting them to manufacture a patented product without the patent holder's authorisation, especially when the proprietor is set up to be exploiting the exclusive rights granted by the patent. This medium is designed to help the abuse of patent rights by addressing public health enterprises or bridling anti-competitive practices that could circumscribe trade or obstruct the transfer of technology. Abuse of patent rights can happen in many ways, for instance, it may include not exercising the patented invention within India, thereby hindering the growth of original trade and assiduity. Other exemplifications of abuse involve assessing unreasonable licensing terms, assessing restrictive conditions on the use or trade of the patented product indeed after the patent has lapsed, engaging in price manipulation, or denying a license to a third party that intends to produce the patented product in a particular request.

TRIPS AND COMPULSORY LICENSING

Before 1994, prior to the signing of the GATT, intellectual property laws and international trade policies operated largely independently, with minimal technical or legal connection between the two.[4] In 2001, the Inter-Ministerial Conference of the WTO formally launched the Doha Agenda with a declaration that emphasized the importance of recognizing a sovereign nations right to safeguard the public health of its citizens, even if this means prioritizing it over intellectual property rights.[5] Following this, numerous public systems introduced fresh provisions to grease mandatory licensing. Although mandatory licenses had been issued under some public laws in the history, they frequently failed to deliver essential drugs to the populations in need. The WHO estimates that roughly one- third of the global population lacks access to essential drugs. Indeed, with mandatory licenses in place, numerous countries facing severe health heads warrant the capacity or coffers to manufacture the needed medicines, especially since TRIPS commanded that products made under Compulsory License should primarily serve the domestic request. To address this issue, the WTO reconvened in

[3] TRIPS Agreement, 1994, Art. 31.
[4] Santoro Michael A, *Human rights and human needs: diverse moral principles justifying third world access to affordable HIV/AIDS drugs*, 31 (4) NORTH CAROLINE J. OF INT'L LAW AND COMM. REGULATION, 923, 925 (2006).
[5] WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN (01)/DEC/2, para. 4 (14 Nov 2001).

2003 at the Fifth Ministerial Conference in Cancun and espoused a 'temporary solution' by issuing an interim disclaimer to the Art. 31(f) restriction. This disclaimer temporarily removed limitations on exporting medicines produced under mandatory licenses to countries unfit to manufacture them. Since 2005, Compulsory Licenses for import have been granted, with Canada issuing the first. The *Natco v. Pfizer* case in India brought crucial provisions of the Indian Patents (Amendment) Act, 2005, which extended Compulsory License to include medicine exportation, under scrutiny. Before this interim disclaimer was legislated, the general licensing procedure followed was outlined in Section 84 of the Indian Patents Act. The new 'Paragraph 6' decision of the Doha Declaration was incorporated into Indian patent law in 2005 as Section 92A.[6]

Changes in Compulsory Licensing due to TRIPS Agreement

The TRIPS Agreement, a WTO protocol designed to standardize minimum standards for IP protection across all member nations, required its members to address the issue of patent non-implementation. The aim of the TRIPS Agreement was to encourage global competition and establish a unified patent system. As a result, the agreement contains several provisions focused on protecting public order, morality, and health. Additionally, TRIPS outlines the conditions under which a compulsory license can be issued, including prior attempts to obtain a license from the patent holder, fair compensation to the patent owner, and the non-exclusive and non-transferable nature of the license. Importantly, TRIPS specifies that such licenses should primarily serve the domestic market of the country issuing the compulsory license.

India and the TRIPS Agreement and its impact on Compulsory Licensing

Before India became a signatory to the TRIPS Agreement, its patent laws did not permit the granting of product patents, allowing new and innovative drugs to be introduced without patent protection. However, after India joined the TRIPS Agreement, its patent laws were revised to allow for the patenting of products. This change provided patentees with greater control over the availability, quantity, and pricing of drugs. Consequently, Indian patent laws were updated to include comprehensive provisions for compulsory licensing, aimed at preventing the misuse of patent rights.[7]

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[6] Harshita Mathur, *Compulsory Licensing under Section 92-A: Issues and Concerns* 13 J. OF IPR 464 (2008).

[7] Hana Onderkova, *Compulsory Licensing in India and Changes brought to it by TRIPS Agreement*, EUROPEAN COMMISSION (Oct. 12, 2021) *available at:* https://intellectual-property-

COMPULSORY LICENSING OF PATENTS IN INDIA

The Patents Act, which regulates intellectual property rights related to patents in India, includes specific provisions stating that, after three years from the grant of a patent, any interested party or existing licensee can apply to the Controller for a Compulsory License on certain grounds[8] which are as follows:

1. The public's reasonable requirement needs concerning the patented invention have not been met.
2. The patented invention is not accessible to the public at a reasonable price.
3. The patented invention has not been utilized within India.[9]

If the Controller determines that any of the above conditions are met, they may grant a license under terms they consider appropriate.[10] When considering an application for a Compulsory License, the Controller must evaluate several factors outlined in Clause 6 of Section 84:

1. The nature of the invention.
2. The time elapsed since the patent was granted.
3. The actions taken by the patentee to fully exploit the invention.
4. The applicant's capability to use the invention for the public's benefit.
5. Whether the applicant has attempted to obtain a license from the patentee under reasonable terms.
6. The applicant's efforts to secure a license from the patent holder.

However, the Controller may disregard these factors in certain situations, such as during a national emergency, in cases of extreme urgency, for public non-commercial use, or if the patentee has engaged in anti-competitive practices.[11] The provisions in the subsequent section of the Act specify that the Controller can revoke a patent if an application is submitted by the central government or an interested party two years after a compulsory license has been

helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en (last visited Aug. 19, 2024).

[8] G. Ananthakrishnan, *A historic move to make drugs affordable*, (March 14, 2012, THE HINDU, DELHI) *available at:* https://www.thehindu.com/opinion/op-ed/a-historic-move-to-make-drugs-affordable/article2991869.ece (last visited Aug. 15, 2024).

[9] The Patents Act, 1970, S. 84(1).

[10] The Patents Act, 1970, S. 84(4).

[11] The Patents Act, 1970, S. 84(6).

granted. This can occur if the patent has not been utilized in India, if the public's reasonable needs are not being met, or if the patented invention is not available to the public at a fair price. The application must include evidence supporting these claims. If the Controller is convinced by the evidence, they may issue an order to revoke the patent within one year of receiving the application. However, the process of granting a compulsory license does not entirely favour the applicant. S. 86 provides some protection to the patent holder by allowing the Controller to postpone any application for a compulsory license under Section 84 or for patent revocation under Section 85 if the patentee can demonstrate that they have made substantial efforts to make their invention available at a reasonable price but require additional time. If the Controller finds the reasons provided by the patentee satisfactory, the hearing of the application may be adjourned for up to twelve months.[12]

The procedure for handling applications for the grant of a Compulsory License or for patent revocation is outlined in S. 87: If the Controller preliminarily determines that a case warrants action under S. 84 or S. 85, the applicant will be directed to send copies of the application to the patentee. Additionally, the application must be published in the official journal. The patentee can file a Notice of Opposition[13] with the Controller, outlining the reasons for opposing the application, within the timeframe specified by the Controller. Upon receiving this opposition, the Controller may schedule a hearing to review the arguments presented by both the applicant and the opposing party before making a decision on the case.[14]

Authority of the Controller General of Patents in Issuing Compulsory Licenses: If the Controller finds that the manufacture, use, or sale of a patented product is hindered by the terms set by the patentee, they may grant a license under conditions they consider appropriate or amend an existing license. The Controller will use their authority upon receiving an application under S. 84 to achieve the following objectives:

1. Ensure that patented inventions are utilized commercially and to their fullest potential without unnecessary delays.
2. Protect the interests of individuals working on or developing a patented invention from unfair disadvantage.

[12] *Supra* note 2.
[13] The Patents Act, 1970, S. 87(3).
[14] The Patents Act, 1970, S. 87(4).

As per S. 90 of the Act, when setting the terms and conditions of a license under S. 84, the Controller should ensure the following:

1. The royalty paid to the patentee or any other entitled party is fair and reasonable.
2. The holder of the compulsory license works the patented invention fully and earns a reasonable profit.
3. The public has access to the patented product at a reasonable price.
4. The license is non-exclusive and non-transferable.[15]

Compulsory Licensing upon Notification by the Central Government: S. 92 of the Act states that the Central Government can issue a notification for compulsory licensing in situations involving:

1. National emergency,
2. Extreme urgency, or
3. Non-commercial use of the patent[16]

if it has reasons to believe that a Compulsory License is necessary for a valid patent. Following this, the Controller will grant a Compulsory License to the applicant or an interested party who had previously submitted an application before the government's declaration. However, it is essential that the terms of the license ensure that the patented product remains available to the public at the lowest possible price.[17] In situations of national emergency, extreme urgency, or a national health crisis, the procedures outlined in Sections 84, 85, 86, 87, and 88 of Act, can be bypassed.[18]

Termination of Compulsory License: S. 94 of the Act allows the Controller to terminate a Compulsory License upon receiving an application from the patentee or any interested party. This termination can occur if it is proven that the conditions that led to the issuance of the

[15] The Patents Act, 1970, S. 90(5).
[16] The Patents Act, 1970, S. 92.
[17] IIPRD, *Grant of Compulsory License in India: Its Provisions and Need in Several Industries in India* (March 19, 2024) *available at-* https://www.iiprd.com/grant-of-compulsory-license-in-india-its-provisions-and-need-in-several-industries-in-india/ (last visited Aug. 19, 2024).
[18] Ved Prakash Patel, *Compulsory License: The Exception to Patent Rights*, MANUPATRA ARTICLES *available at*-https://articles.manupatra.com/article-details/Compulsory-License-The-Exception-to-the-Patent-Rights (last visited Aug. 20, 2024).

Compulsory License no longer exist and are unlikely to recur in the future. Before terminating the license, the license holder must be given an opportunity to object to the termination.[19]

Criteria for Securing a Compulsory License in India

Compulsory licensing under the Indian Patent Act is clearly defined and aligns with international agreements. The primary goal of issuing a Compulsory License is to ensure that patented inventions are commercially utilized in India, protecting the interests of those working on or developing the invention. S. 84(1) of the Act, outlines the purpose of compulsory licenses and emphasizes that the general principles specified in this section should be prioritized when granting such licenses.[20] Indian law mandates that patent holders must work their patents within India. According to the Indian Patent Act, a Compulsory License can be issued after three years from the patent's grant date if certain conditions are met:

- The public's reasonable requirements concerning the patented invention are not fulfilled,
- The patented invention is not available to the public at a reasonably affordable price, or
- The patented invention is not being utilized within Indian territory.

The public's reasonable requirements are considered unmet if:

- The patentee refuses to grant licenses on reasonable terms, causing harm to trade or industry,
- Demand for the patented product is not adequately met,
- An export market for the patented product made in India is not being supplied or developed,
- The establishment or growth of commercial activities in India is hindered.

Additional grounds include:

- The patentee imposes restrictive conditions on the patented invention,
- The patent is not being worked in India,
- The commercial use of the patented invention in India is hindered by imports.

[19] Arun S, *Compulsory Licensing in Manufacturing may slow investments*, (February 5, 2016, THE HINDU) *available at-* https://www.thehindu.com/business/compulsory-licensing-in-manufacturing-may-slow-investments-eu/article8194418.ece (last visited Aug. 20, 2024).
[20] The Patents Act, 1970, S. 84(1).

S. 146(2) of the Act requires every patentee and licensee to report on the extent to which the patented invention is being commercially utilized in India.[21] Patentees and licensees must submit relevant information using Form 27, which is required to be filed annually within three months after the end of each calendar year. The information provided must include:

- Whether the invention has been utilized,
- If not, the reasons for non-utilization and the steps being taken to work the invention,
- If utilized, the quantity and value of the patented product,
- Whether the product was manufactured in India,
- If imported, details of the countries from which it was imported,
- Licenses and sub-licenses granted during the year,
- Whether the public's needs have been met at a reasonable price, either partially, adequately, or fully.

Not providing this information may lead to an assumption of non-working, potentially resulting in the issuance of a Compulsory License. This failure is also subject to penalties, with fines reaching up to Rs. 10 lakhs. Deliberately submitting false information can lead to imprisonment for up to six months, a fine, or both. Furthermore, under S. 100 of the Act, the government is empowered to issue a Compulsory License for a patented drug for its own use.[22] In one scenario[23], the Bombay HC permitted 3rd party agencies to utilize a patented invention on behalf of the government. According to S. 102 of the Indian Patent Act, the State has the authority to acquire a pending or granted patent for public use. In return, the government is required to pay the patent holder royalties.

Process for Issuing a Compulsory License

Any party interested in obtaining a compulsory license can file a request either electronically or in writing using Form 17, along with the necessary fees to the Indian Patent Office. The application must outline the applicant's interest and provide relevant facts and details to support the request. According to S. 87 of the Indian Patent Act, upon submission of the application, the Controller at the Indian Patent Office will assess the preliminary case made by

[21] The Patents Act, 1970, S. 146(2).
[22] The Patents Act, 1970, S. 100.
[23] *Garware Wall Ropes Ltd.* v. *A.I. Chopra and Konkan Railway Corp*, (2008) 3 MLJ 599.

the applicant against the patent holder.[24] The Controller has to evaluate certain conditions which are as follows:

- The nature of the invention,
- The applicant's capability to work the invention,
- Whether the applicant made reasonable efforts to obtain a license from the patentee,
- The outcome of these efforts if they were unsuccessful within a reasonable timeframe.

If the Controller is not convinced by the application, a notice will be sent to the applicant, providing reasons for rejecting the request. The applicant has the option to request a hearing with the Controller within one month of receiving the rejection notice. After the hearing, the Controller will issue a final decision. If the outcome is in favour of the applicant, the Controller will set the conditions for the Compulsory License, including the royalty to be paid to the patent holder. In making this decision, factors such as the patentee's investment, the applicant's capacity to utilize the invention, the price of the patented product, and the license terms will be considered. However, if a situation of national emergency or extreme urgency arises, the procedure outlined in S. 87 can be skipped.

Opposition to the Grant: Any party wishing to oppose the application for a Compulsory License must file a notice of opposition using Form 14 within two months of the application's publication in the Official Journal of the Indian Patent Office, along with the required fee. Upon receiving the notice, the Controller will inform both the applicant and the opponent and provide them with an opportunity to be heard before making a decision.

Appeal/Review: Decisions made by the Controller regarding the grant or denial of a Compulsory License can be appealed to the Appellate Board.[25]

LANDMARK CASE LAWS IN INDIA

1) Lee Pharma v. *AstraZeneca*

The following case highlights an attempt to secure a Compulsory License for Saxagliptin, a medicine used to treat Type-II Diabetes Mellitus. On June 29, 2015, Lee Pharma submitted an

[24] The Patents Act, 1970, S. 87.
[25] Radhi Shah, *Compulsory License: India*, KLUWER PATENT BLOG (August 16, 2021) *available at*-https://patentblog.kluweriplaw.com/2021/08/16/compulsory-license-india/ (last visited Aug. 22, 2024).

app. for a Compulsory License for AstraZeneca's Saxagliptin®. The application was denied because it did not establish a prima facie case under any of the three grounds specified in Section 84(1) of the Indian Patent Act. Lee Pharma did not provide sufficient evidence that Saxagliptin's availability was inadequate for public needs, nor did it demonstrate how Saxagliptin's requirements compared to other available drugs. It was found that Saxagliptin was priced similarly to other drugs in the market, so the claim that its price was unaffordable was deemed unjustified. Lee Pharma did not provide detailed information on the specific demand for Saxagliptin in India, making it unclear whether local manufacturing was necessary. As a result, the application was rejected due to non-fulfilment of statutory requirements.[26]

2) BDR Pharmaceuticals v. *Bristol-Myers Squibb*

The following case demonstrates an attempt to obtain a compulsory license for the cancer drug Sprycel. On March 4, 2013, BDR Pharmaceuticals' application for a compulsory license for Sprycel was rejected by the Controller. The Controller determined that BDR did not establish a prima facie case for granting the license. Specifically, BDR had not made a substantial effort to secure a license from the patent holder and had not shown the capability to utilize the invention for public benefit. Consequently, the request for a compulsory license was denied.[27]

3) Bayer Corp. v. *Natco Pharma*

The following case highlights the grant of a Compulsory License for Nexavar, a treatment for advanced liver and kidney cancer. In 2012, Natco Pharma received India's first compulsory license from the Indian Patent Office to produce a generic version of Bayer Corp's Nexavar (Sorafenib Tosylate), a critical medication for these cancers. Bayer had been selling the drug at a high cost, with a month's supply priced at approximately Rs. 2.8 lakh (3,737.89 USD, with Rs. 74.84 per USD). Natco Pharma proposed a significantly lower price of Rs. 9,000 (120.15 USD, with Rs. 74.84 per USD), making the drug more accessible to the public. This case met all three conditions required under S. 84 of the Act.[28]

ECONOMIC IMPACT OF COMPULSORY LICENSING IN INDIA

[26] *Lee Pharma* v. *AstraZeneca*, (C.L.A. No. 1 of 2015).
[27] *BDR Pharmaceuticals* v. *Bristol-Myers Squibb*, (C.L.A. No. 1 of 2013).
[28] *Bayer Corp*. v. *Natco Pharma*, 2014 (60) PTC 277 (BOM).

The healthcare needs of India's public demand compulsory licensing for pharmaceutical patents since it supports a vital balance between the interests of rights holders and public welfare. The practice enables essential treatment availability for people yet creates major economic effects on pharmaceutical companies together with healthcare research and medical infrastructure. This analysis explores the economic impact of compulsory licensing in India, focusing on how it affects the pharmaceutical industry, fosters innovation, and improves access to medicines.

Effects on the Pharmaceutical Industry

1. Market Dynamics and Competition: Compulsory licensing introduces generic competition, which can dramatically alter market dynamics. When a generic version of a patented drug is introduced under a compulsory license, it typically leads to a reduction in drug prices. This price reduction is due to the increased competition and the lower production costs associated with generic drugs. For instance, after Natco Pharma was granted a compulsory license to produce Sorafenib (Nexavar), the price of the drug decreased by nearly 97%, making it more affordable for patients in India.[29] While this is beneficial for consumers and public health, it presents challenges for the original patent holders. Pharmaceutical companies often rely on high drug prices during the patent protection period to recoup the significant costs associated with drug research and development (R&D). The introduction of generic competitors through compulsory licensing can lead to reduced revenues for these companies, potentially impacting their overall profitability and future investment in R&D.
2. Investment and Foreign Direct Investment (FDI): The pharmaceutical industry in India is a significant contributor to FDI. However, the use of compulsory licensing can influence investment decisions by foreign pharmaceutical companies. Companies may perceive a higher risk in markets where compulsory licensing is more likely to be used, particularly if it affects their patented products. This perception can result in reduced FDI or hesitance to introduce new products in such markets. For instance, after India issued its first compulsory license for Nexavar, concerns were raised about the potential impact on future FDI in the pharmaceutical sector. Despite this, when looked upon India's stance to compulsory licensing, it has been consistent with its international obligations and the country has taken steps to assure investors that compulsory licenses will only be issued in

[29] *Ibid.*

exceptional circumstances, where public health needs cannot be met otherwise. Moreover, in the financial year 2022-23, the pharmaceutical sector, including both pharmaceuticals and medical devices, received FDI inflows totalling Rs. 19,077 crores. For the ongoing financial year 2023-24, from April 2023 to September 2023, FDI inflows have amounted to Rs. 4,456 crores.[30]

Impact on Innovation

1. Research and Development (R&D) Investment: Innovation in the pharmaceutical sector is driven by substantial investments in R&D, which are often recouped through the exclusivity provided by patents. Compulsory licensing can disrupt this model by reducing the period during which a company can exclusively benefit from its patented product. As a result, there is concern that the threat of compulsory licensing could deter pharmaceutical companies from investing in the development of new drugs, particularly for markets where compulsory licensing is more prevalent. However, it is essential to balance this concern with the public interest. While compulsory licensing may reduce the exclusivity period for certain drugs, it does not eliminate the incentive for innovation entirely. In the 2020–21 period, in the private sector, industries such as pharmaceuticals, textiles, information technology, transportation, and biotechnology took the lead in R&D. Within industrial R&D, the pharmaceutical sector claimed the top spot, accounting for 33.6% of the total share, followed by textiles with 13.8%, information technology at 9.9%, transportation at 7.7%, defence industries at 7.3%, and biotechnology at 4%.[31] But to foster innovation and growth in India's pharmaceuticals and medical technology sectors, significantly more investment in Research and Development (R&D) is crucial. Despite strong fundamentals, India is way behind from other countries in R&D investment, which is vital to developing advanced medical products and reducing dependence on imports. Strengthening R&D will be key to transforming the sector into a global leader in drug discovery and medical technology.[32]

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[30] PRESS INFORMATION BUREAU, GOI, *Year-end review of Department of Pharmaceuticals* (Dec. 29, 2023) *available at:* https://pib.gov.in/PressReleseDetail.aspx?PRID=1991501#:~:text=FDI%20inflows%20in%20pharmaceutical%20sector,4%2C456%20crore (last visited Aug. 2, 2024).

[31] Ministry of Science and Technology, RESEARCH & DEVELOPMENT STATISTICS AT A GLANCE 6 (2023) *available at:* https://dst.gov.in/sites/default/files/R%26D%20Statistics%20at%20a%20Glance%2C%202022-23.pdf (last visited Aug. 16, 2024).

[32] Vinod K Paul, *Fostering R&D and innovation in pharma and Medtech sector*, BUSINESS STANDARD (Jan 2, 2024) *available at:* https://www.business-

2. Encouragement of Local Innovation: Compulsory licensing can also stimulate local innovation and manufacturing capabilities. By allowing domestic companies to produce generic versions of patented drugs, compulsory licensing enables technology transfer and the development of local expertise in drug manufacturing. This, in turn, can lead to the growth of the domestic pharmaceutical industry, increased employment opportunities, and enhanced capacity for producing essential medicines within the country. The compulsory licensing system of India has developed a major generic drug industry which provides low-cost medicines at a worldwide scale. The Indian generic drugs market demonstrated a valuation of USD 24.91 billion during 2024 yet projectors estimate it will rise to USD 35.62 billion by 2030 while maintaining a compound annual growth rate (CAGR) of 6.02% from 2025 to 2030.[33]

Compulsory License enhances public health outcomes through its ability to deliver necessary medicines to the people. Through compulsory licensing the government becomes empowered to handle national health crises and persistent diseases better. Compulsory licensing emerges as a crucial instrument during HIV/AIDS, tuberculosis and cancer situations because high treatment prices are unaffordable and also the availability of inexpensive generics leads to health benefits for the population which include better treatment outreach and a decline in medical challenges. Such health improvements from compulsory licensing create both well-being benefits for employees and financial savings within national healthcare expenditures.

COMPARATIVE ANALYSIS WITH OTHER JURISDICTIONS

Although India is sometimes seen as a paradigm case of a country which has successfully used compulsory licensing to reconcile between intellectual property rights and public health needs, other jurisdictions like the US, the EU, Brazil, Japan and Thailand also have their own frameworks and approaches to compulsory licensing. By considering similarities and differences of these approaches, we can learn more about the effects of compulsory licensing on the global public health and how the legal and regulatory conditions may influence that.

Comparative Analysis between India and Japan

standard.com/amp/opinion/columns/fostering-r-d-and-innovation-in-pharma-and-medtech-sector-124010200762_1.html (last visited Aug. 1, 2024).

[33] TECHSCI RESEARCH *available at:* https://www.techsciresearch.com/report/india-generic-drugs-market/10642.html (last visited Aug. 17, 2024).

It has been observed that the intellectual property (IP) framework of Japan has undergone important changes, since the establishment of the Statute of Monopoly Patent in 1885, under the influence of the European and American models. Starting from the Patent Act of 1959 effective from 1960 onwards, there were subsequent amendments, such as in 1990 while under Section 93 of Chapter IV-1 of the Patent Act, provisions for compulsory licensing were introduced. This section empowers the Minister for International Trade and Industry to arbitrate and grant a Compulsory License if negotiations between a patent holder and a seeker fail. However, Japan's interpretation of "public interest" emphasizes stable industrial development over pricing and affordability concerns. Interviews with experts, including Prof. Shigeo Takakura and Associate Professor Akiko Kato, reveal a preference for negotiated settlements and arbitration, with government intervention as a last resort. Consequently, Japan has not issued any Compulsory Licenses to date. In contrast, India's Patent Act of 1970, particularly after the 2005 amendments, incorporates robust Compulsory License provisions to prioritize public health. The first Compulsory License was granted in 2012 to Natco Pharma for Bayer's cancer drug, Sorafenib, due to unmet public requirements, unaffordable pricing, and non-working of the patent in India. This decision underscores India's commitment to ensuring access to essential medicines through Compulsory License mechanisms.[34]

Comparative Analysis between India and the United States

Both India and the United States recognize compulsory licensing within their patent laws, but they apply these provisions differently, reflecting distinct policy priorities. In India, the Patent Act of 1970, especially after the 2005 amendments, emphasizes public health and access to medicines. Section 84 provision provides for Compulsory License if the patented invention does not meet public requirement, is not available in affordable price and is not manufactured in India. An illustrative example is the 2012 grant of Compulsory License to Natco Pharma to Bayer's cancer drug, Sorafenib, which signified India's readiness to use Compulsory Licenses in promoting access to life saving medications. Whereas the use of Compulsory Licenses by the United States is most commonly employed as its remedy for violations of antitrust laws and to counteract anti-competitive practices. The government of the United States may conditionally authorize the use of a patented invention without the consent of the patent holder, but only on payment to the patent holder of fair compensation. This mechanism is mainly utilized for government use, especially in defence. For example, during the 2001 anthrax

[34] V.C. Vivekanandan, *Compulsory Licensing of Patent - A Comparative Analysis of Japanese and Indian Practices*, 25 IIP BULLETIN 2 2016.

attacks, the U.S. government considered issuing a Compulsory License for the antibiotic ciprofloxacin to ensure adequate supply, leading Bayer to reduce its prices. In summary, while both countries have provisions for Compulsory Licenses, India's framework is more oriented towards public health and ensuring access to affordable medicines, whereas the United States focuses on maintaining market competition and addressing antitrust concerns. This distinction reflects the broader policy objectives and public health priorities inherent in each country's approach to intellectual property rights.[35] In the United States, compulsory licensing is not explicitly provided for in the same way it is under Indian law. However, there are mechanisms under US law that can serve similar purposes. For instance, under the Bayh-Dole Act of 1980, the U.S. government can exercise "march-in rights" to grant a license to a third party if the patent holder fails to make the benefits of the invention reasonably accessible to the public.[36] Despite this provision, the U.S. government has never exercised its march-in rights, largely due to concerns over stifling innovation and the pharmaceutical industry's significant influence. Furthermore, during national emergencies, the US government has the authority to use or manufacture patented products without the consent of the patent holder, provided that reasonable compensation is paid. [37] This was notably considered during the anthrax scare in 2001, when the U.S. government threatened to use this provision to procure generic versions of the antibiotic ciprofloxacin, leading to a significant price reduction by the patent holder, Bayer.[38]

European Union: Balancing Patents and Public Health

The EU allows for Compulsory License under its various national laws, with the legal framework differing slightly across member states. EU Directive 2001/83/EC allows for the issuance of compulsory licenses in cases of public health needs, competition concerns, or

[35] Jon Matthews, *Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Damaging to the United States Healthcare Industry*, 4(1) THE J. OF BUSI., ENTRE. & THE L. 121-123 2010.
[36] 35 U.S.C. § 203(a).
[37] 28 U.S.C. § 1498.
[38] US GOVERNMENT ACCOUNTABILITY OFFICE, *Bioterrorism:Public Health Response to Anthrax Incidents of 2001* (Oct. 15, 2023) *available at:* https://www.gao.gov/products/gao-04-152#:~:text=In%20the%20fall%20of%202001%2C%20letters%20containing%20anthrax,in%20six%20locations%2C%20or%20epicenters%2C%20in%20the%20country (last visited Aug. 14, 2024).

national emergencies.[39] For example, during the COVID-19 pandemic, some EU member states, including Germany and France, enacted provisions that would allow the government to issue compulsory licenses to ensure the availability of essential medical supplies. However, these measures have been more theoretical than practical, with very few compulsory licenses actually being issued within the EU. The reluctance to issue compulsory licenses in Europe reflects a general preference for negotiation and voluntary licensing, possibly due to the strong influence of the pharmaceutical industry and concerns about maintaining a favourable environment for innovation.

Brazil: A Public Health Pioneer in Compulsory Licensing

Brazil has been a pioneer in the use of compulsory licensing as a tool to promote public health, particularly in the fight against HIV/AIDS. The Brazilian government has made extensive use of compulsory licensing to ensure the availability of affordable antiretroviral drugs. In 2007, Brazil issued a compulsory license for the production of Efavirenz, an antiretroviral drug patented by Merck. [40] This was due to a high price of the drug and the necessity of distributing the treatment to a numerous number of HIV/AIDS patients. The Brazilian government entered into talks with Merck but ultimately decided that so that they could reduce costs and increase access to the drug, a compulsory license was necessary. This reduced the cost of Efavirenz by about 60% and increased the geographic access to treatment. This commitment to public health and reading that was open to compulsory licensing under some conditions is understood to be based in the terms of the TRIPS Agreement read by the Brazilian government. It is shown that compulsory licensing is an effective method of promoting increased access to essential medicines in developing countries.

Thailand: A Controversial Use of Compulsory Licensing

Especially concerning is Thailand's controversial use of compulsory licensing to make it cheaper to patent highly profitable drugs for non-communicable diseases. Thailand has also included in 2006 and 2007 the heart disease drug Plavix (clopidogrel) and the cancer drug Alimta (pemetrexed) in the list of compulsory licenses issued. The actions were also part of Thailand's wider efforts to cut health spending and open up access to essential medicines. But

[39] EUROPEAN UNION, *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use* (Nov. 28, 2001) *available at:* https://eur-lex.europa.eu/eli/dir/2001/83/oj (last visited Aug. 12, 2024).
[40] W. C. Rodrigues, & O. Soler, *Compulsory licensing of efavirenz in Brazil in 2007: contextualization*, 26(6) PAN AM. J. OF PUB. HEALTH 553 (2009).

the issuing of such licenses went against the grain in the international community, with Western governments and pharmaceutical companies leading a charge against the spirit of the TRIPS Agreement. No matter the controversy however, Thailand's application of compulsory licensing has led to a drastic change in drug prices and increased access to treatment in the country. For instance, after the compulsory license the cost of Plavix was reduced by more than 90 percent. As an illustration of the tensions in the realm of public health needs and intellectual property rights in the context of developing countries, Thailand's experience highlights this particular issue. It also points out the restrictions that such countries face in using compulsory licensing as an instrument to tackle public health issues in the presence of the international pressure.

Comparative Insights and Global Implications

Various jurisdictions demonstrate multiple important points during their examination of compulsory licensing regulations. Different countries interpret and execute the TRIPS Agreement differently when it comes to compulsory licensing provisions. Compulsory licensing serves as a public health tool more aggressively in India and Brazil because these countries consider it essential to provide their citizens with necessary medications. The US together with the EU have demonstrated increased restraint when using compulsory licensing due to their worry about pharmaceutical market impacts and research developments. Compulsory licensing applications depend heavily on the political and economic factors between governments alongside their commitment to public health and their position in international trade systems. Brazil together with Thailand has frequently employed compulsory licensing to fight public health needs because they have strong domestic generic medicine production capabilities and pressing healthcare requirements. Compulsory licensing exists as a major economic influence on pharmaceutical industries in both the United States and European Union only in exceptional conditions. The implementation of compulsory licensing generates major global effects which gain importance for medicine accessibility in developing nations. The cases of India, Brazil, and Thailand prove that mandatory licensing becomes an essential instrument to boost the availability of vital pharmaceuticals for both developing and less developed economies. However, these experiences also highlight the challenges that countries face when using compulsory licensing, including the risk of international trade disputes and the potential impact on foreign investment.

COMPULSORY LICENSING IN GREEN TECHNOLOGY: A COMPARARTIVE PERSPECTIVE

The escalating climate crisis necessitates the rapid dissemination of environmentally friendly technologies. However, patents can impede the widespread adoption of these innovations, particularly in developing countries lacking the resources to negotiate licensing agreements. In this context, Compulsory License emerges as a potential mechanism to facilitate access to green technologies. Compulsory License for green technology may not qualify as "public non-commercial use" because such technology is inherently tied to commercial enterprises. However, a strong argument exists that severe environmental pollution constitutes a "national emergency," particularly in developing countries. For instance, 16 of the 20 most polluted cities globally are in China, where air pollution causes 2–3 million premature deaths annually, with around 90% occurring in the developing world. This mortality rate far surpasses fatalities from Bird Flu and Anthrax, emergencies that previously warranted Compulsory License measures. While Compulsory License has predominantly been applied to pharmaceuticals, Article 31 of the TRIPS Agreement could allow states to issue Compulsory Licenses for eco-friendly technologies to address environmental crises. For example, a government might invoke Article 31(b) to use patented technology immediately, rather than waiting for its patent term to expire, to combat carbon emissions. Additionally, Article 31(l) could compel the holder of a foundational patent to grant a license to a second patentee who has developed an improvement (a dependent patent). Implementing Compulsory License for proprietary renewable energy technology could empower domestic firms to produce and deploy clean energy solutions, advancing climate mitigation efforts. Although no country has yet applied Article 31 in the context of climate change, there is no legal restriction preventing such an approach.[41] However, the application of Compulsory License in this domain is not straightforward. Critics contend that compulsory licensing could deter investment in green technology research and development, as innovators may fear inadequate returns on their investments. Moreover, the complexity and diversity of green technologies, often involving multiple patents and stakeholders, complicate the implementation of Compulsory License. Alternative approaches, such as voluntary licensing agreements, patent pools, and international collaborations, may offer more effective means of promoting technology transfer without undermining IP rights.[42]

[41] Robert Fair, *Does Climate Change Justify Compulsory Licensing of Green Technology?*, 6(1) BRIGHAM YNG. UNIV. INT'L. L. & MGMT. REV. 29-30 2010.

[42] Laurence Loumes, *Compulsory Licensing for Green Technologies: A realistic threat?* PLASSERAUD (29 Sep, 2023) *available at*: https://www.plass.com/en/articles/compulsory-licensing-green-technologies-realistic-threat (last visited Dec. 16, 2024).

COMPULSORY LICENSING AND DIGITAL INNOVATIONS

The digital economy thrives on continuous innovation, with patents playing a crucial role in protecting software, business methods, and technological processes. However, the rapid pace of digital advancement can lead to situations where patent holders enforce their rights in ways that stifle competition and hinder further innovation. In such cases, Compulsory License can serve as a tool to promote access and encourage technological progress. For instance, in the realm of standard-essential patents (SEPs), which are patents essential to industry standards, patent holders are expected to license these on fair, reasonable, and non-discriminatory (FRAND) terms. When negotiations fail, and a patent holder refuses to license their SEP, authorities may consider issuing a compulsory license to ensure that the standard remains accessible and that innovation is not impeded. Nonetheless, applying Compulsory License to digital innovations presents challenges. Determining appropriate licensing terms, especially in rapidly evolving technological fields, can be complex. Additionally, the global nature of the digital economy means that actions taken in one jurisdiction can have far-reaching implications, potentially leading to conflicts between different legal systems and IP regimes.[43]

SUGGESTIONS

To improve the effectiveness of compulsory licensing within the Indian patenting system, several key reforms could be implemented. The timely delivery of essential medicines requires efficient streamlining of licensing procedures that prevents interruptions from prolonged legal processes and procedural hold-ups. The implementation of enhanced international collaboration with WHO and WTO would establish national policies based on global healthcare standards while enabling TRIPS Agreement adherence. Pharmaceutical innovation can gain balance with public health benefits from Compulsory License through incentives such as tax breaks and public-private partnerships. A system to monitor and assess Compulsory License effects on public health together with drug prices and pharmaceutical innovation should be established for making knowledge-based policy corrections. The measures would improve transparency and fairness as well as effectiveness of compulsory licensing procedures to support public health benefits and technological innovation advancement.

[43] Erik Habich, *FRAND Access to Data: Perspectives from the FRAND Licensing of Standard-Essential Patents for the Data Act Proposal and the Digital Markets Act*, 53 INT'L REV. OF IP AND COMP. L. 1343–1373 2022.

CONCLUSION

Intellectual Property Rights aim to recognize and reward individuals for their creativity, invention, and design, thereby contributing to the advancement of human welfare. While IPRs are intended to promote innovation and make life easier, there are instances where these rights can restrict public access to new inventions. To counteract potential misuse of these laws, provisions like compulsory licensing were introduced. This concept ensures that valuable inventions remain accessible to the public and prevents patent holders from exploiting their patents for excessive profit. The law also allows for the issuance of compulsory licenses if the terms of a granted license are deemed unreasonable and hinder public access. The Commerce Standing Committee of Parliament, in its report titled 'Review of Intellectual Property Regime in India,' emphasized the need for a reassessment of IPR policies to address emerging trends in innovation and research.[44] The report highlights the importance of identifying current challenges in policy implementation and suggests corrective measures to strengthen the IPR regime. Revisiting and updating the policy is deemed crucial for developing a more effective and robust framework for intellectual property rights.

[44] Our Bureau, *Compulsory Licensing mooted to meet scarcity of covid vaccines,* medicines, (July 23, 2021, THE HINDU BUSINESS LINE) *available at*: https://www.thehindubusinessline.com/news/national/compulsory-licensing-mooted-to-meet-scarcity-of-covid-vaccines-medicines/article35496939.ece (last visited May 22, 2024).