BALANCING INNOVATION AND ACCESS: A COMPARATIVE STUDY OF COMPULSORY LICENSING IN INDIA AND THE UNITED STATES

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Abstract

Compulsory licensing is a crucial mechanism in patent legislations, that allows governments to authorise the use of patented inventions without the owner's consent under specific circumstances. In India, the allocation of compulsory licenses is often evaluated in the context of ensuring public access to affordable medicines. In the United States, compulsory licences have largely been granted under antitrust laws, to prevent monopolies from abusing their position, in key sectors. Each country's unique socio-economic context shapes the grant of compulsory licenses. This article addresses the issue of balancing innovation and scientific research with public access, with a special focus on public health and market competition. It attempts to bridge the gaps between the Indian and American approaches, by highlighting the areas where each country can benefit from the other's experience. The analysis is conducted through a comparative study of the patent laws of both the nations, involving a crisp study of statutory provisions, case laws and international agreements. Ultimately, by examining the outcomes of compulsory licenses in both jurisdictions, this article suggests reforms that can enhance the effectiveness of compulsory licensing while maintaining a balance between innovation and access.

Keywords: Innovation, Pharmaceuticals, Antitrust, Accessibility, Competition.

1. Overview of Patents

Since the dawn of times, human beings have, in one way or another, invented articles that have advanced the species as a whole, patent law, in general, gives overall protection to such inventions in order to protect and reward the intellectual hardships that were invested and utilised while creating such an object. The term "patent" was first used for all grants by the Crown and was as wide as the king's pleasure. In time, and with the rise of constitutional government, it has been narrowed in meaning. In contemporary

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times, it may be referred to as a privilege granted by the sovereign to an individual.[1] The fundamental purpose of patents is to promote innovation by granting inventors exclusive rights to their inventions for a significant period of time.[2] A patent is a legal property right awarded to an inventor for their invention, providing them with the exclusive authority to prevent others from making, using, or selling the invention for a specified duration.[3]

In a broad sense, patents may be defined as an exclusive right of ownership, production, and assignment to an individual over his inventions for a certain period of time, granted by a sovereign authority, such as a grant being backed by the force of law. The law governing the grant of such exclusive rights is referred to as Patent Law.

The exclusive right of a patent grants the patent holder a bundle of rights, such as the sole right to manufacture, use, sell or license the patented invention, permitting the patent holder to create a legal monopoly for a limited time period usually, 20 years. These rights allow the patent holder to recover the time, effort and resources invested into developing the product. The grant of a patent allows the holder to seek remedies such as injunctions and damages, in order to protect their intellectual property from unauthorized usage.

Patent law recognizes a patentee's exclusive right to commercially utilize their invention. This serves as an incentive for inventors to invest their creative efforts, ensuring that their inventions are legally protected and cannot be replicated by others for a specified period, during which the inventor retains exclusive rights.[4] The grant of a patent not only recognizes and rewards an inventor's creativity but also inspires further innovations, contributing to the technological progress of a nation.[5]

The Supreme Court in *B. P. R. Shyam* v. *Hindustan Metal Industries*,[6] held that "*the objective behind patent law is to encourage scientific research, new technology and industrial progress. The grant of exclusive rights for a limited time period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure*

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1 Walton Hamilton, Irene Till, "What Is a Patent?," 13 *Law and Contemporary Problems* 245 (1948).
2 Stephen J. Miller, "What do Patents mean?", 35 *Issues in Science and Technology* 84 (2019).
3 William Irwin, "Patents", in Philip Wexler (ed.), *Information Resources in Toxicology* 888 (Academic Press, 2020).
4 B. L. Wadheera, *Law Relating to Intellectual Property* 5 (LexisNexis, Gurgaon, 5th edn., 2018).
5 V. K. Ahuja, *Intellectual Property Rights in India* 455 (LexisNexis, Gurgaon, 2nd edn., 2015).
6 AIR 1982 SC 1444.

of the invention at the Patents Office which after expiry of the fixed period, passes into public domain."[7]

Patent law promotes research and innovation by granting the patent holder the exclusive right to prevent others from manufacturing, using, or selling the patented product for a specified period, thereby ensuring their sole authority over the invention.[8] The Bombay High Court in *Bayer Corporation* v. *Union of India*,[9] stated that, the purpose of patent law is to promote scientific research, advance new technologies, and foster industrial development. The granting of a patent inherently signifies a novel invention with commercial applicability.

This hereby clarifies that grant of patent is not only in the interest of the person developing such an invention, but also in the interest of the state as it generates taxes and fees, with an overall development of the country's scientific temperament, and also the general public, as ultimately the invention becomes free for public reproduction by the public at large, which serves the society's longer-term interests.[10]

2. Overview of Compulsory Licensing

The foundation of patent laws throughout the world is to bestow on the inventor the absolute right of excluding others, during the lifetime of the patent, from indulging with the invention in any manner possible. Such monopolies vested in individuals are bound to restrict the immediate access of the public to the invention, this is seen as a necessary evil by the state actors.

However, under certain circumstances, an exceptional legal remedy may be provided by the state itself, as a corrective measure against the exclusive right of the patent holder, the chief remedy for executing this task without departing from the basic principles of the patent system consists in empowering the authorities to permit others individually to use the patented invention without the consent of the patentee, in exchange for paying appropriate royalties. This legal remedy is called "*compulsory licensing*."[11]

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7 *Bishwanath Prasad Radhey Shyam* v. *Hindustan Metal Industries*, AIR 1982 SC 1444.
8 V. K. Ahuja, *Intellectual Property Rights in India* 456 (LexisNexis, Gurgaon, 2nd edn., 2015).
9 W.P. No. 1323/2013, Bombay High Court.
10 *Ibid*.
11 Richard Reik, "Compulsory Licensing of Patents" 36 *The American Economic Review* 814 (1946).

Socialist values serve as the core for the entire framework of compulsory licensing, since, it upholds the exclusive rights of the patent holder while maintaining a balance with the broader public interest, especially in situations where such exclusive rights hinder the access to essential and critical technologies and products, such grants are made only under specific circumstances and for a defined purpose.

An instance of such a situation can be war time, as was observed in *Richmond Screw Anchor Co.* v. *United States,*[12] where the Federal Supreme Court of the United States observed that, "*intention and purpose of Congress, was to stimulate contractors to furnish what was needed for the war, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents, to accomplish this governmental purpose, Congress exercised the power to take away the right of the owner of the patent to recover from the contractor for infringements.*"

Various instances of compulsory licenses could be found throughout history, in various jurisdictions,[13] for instance, the German Federal Court of Justice in the Raltegravir case,[14] held that a third party who seeks to produce HIV medicine at a cheaper cost than the original patent holder, shall be given a compulsory license in the larger public interest.

India and the United States both recognize the concept of compulsory licensing through their respective domestic legislations; however, the grounds for the grant of compulsory licenses differ significantly; the Indian approach centers around improving access to essential and affordable commodities, especially medicines, on the contrary, the United States grants these licenses primarily to address monopolistic practices and promote market competition. This study analyses these differences, identifying strengths and weaknesses in both systems to recommend policy reforms. Through a comparative legal approach, examining case studies and international frameworks, it aims to enhance compulsory licensing's role in fostering innovation and ensuring equitable access to critical technologies for the most vulnerable groups in both of these nations.

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[12] 275 U.S. 331 (1928).

[13] European Patent Office, "Compulsory licensing in Europe: A country-by-country overview" (2018), *available at*: https://www.epo.org/en/learning/learning-resources-profile/judges-lawyers-and-prosecutors/compulsory-licensing-europe (last visited on March 18, 2026).

[14] BGH GRUR 2017, 1017 Rn. 22 f.

3. Historical Evolution of Compulsory License in Global Patent Law

In order to maintain equity in the protection of intellectual property and for the benefit of the general public, compulsory licensing has developed into a crucial tool. Compulsory licensing, which permits state agencies to permit third parties to use patents without the owner's consent under clearly specified conditions and circumstances, is fundamental to the goal of guaranteeing public access to necessities, particularly life-saving drugs.

The concept of compulsory licensing is not new; its origins can be traced back to the UK Statute of Monopolies of 1623, which prohibited monopolies deemed harmful to the state or detrimental to trade.[15] At that time, patents served as a means to introduce foreign inventions into the local market and stimulate local industries. Patent holders were required to manufacture or utilize their inventions locally to maintain their patent rights. This "working obligation" was founded on the principle that an invention granted the privilege of exclusivity should be utilized in a manner that benefits society as a whole.[16] This would result in creation of employment and industrial and technological advancement.

The French Patent Law of 1791 and British Patent system since the 1850s[17] have also directly or indirectly included the concept of compulsory licensing. The concept received international acknowledgement to prevent exploitation of patent protection by the patentee, through the Paris Convention. Article 5 of the Paris Convention[18] through its various provisions empowers the contracting state to make legislative exceptions to include compulsory licensing to prevent abuse of the grant of patent, it also empowers the state to revoke or forfeit the patent where mere grant of compulsory license would be insufficient to meet the needs of the population in general.[19]

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15 Deli Yang, "Compulsory Licensing: For Better or for Worse, the Done Deal Lies in the Balance," 17 *Journal of Intellectual Property Rights* 76-81 (2012).

16 Hiroko Yamane, *Interpreting Trips: Globalisation of Intellectual Property Rights and Access to Medicines* (Hart Publishing, United Kingdom, 2011).

17 Justice N. Rajagopala Ayyangar, "Report on the Revision of the Patents Law" (1959).

18 Paris Convention for the Protection of Industrial Property, 1883, art. 5.

19 Abhinav Gupta, Aqa Raza, "Patent Law and Compulsory Licensing: Indian Perspective," 29 *Journal of Intellectual Property Rights* 7 (2024).

4. Role of TRIPS in Shaping the concept of Compulsory License

Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a landmark international agreement which established comprehensive standards for the protection of intellectual property of intellectual property right across World Trade Organization member states, it was adopted in 1994 as part of the WTO framework; TRIPS harmonizes global intellectual property regulations by setting various minimum requirements for patents, copyrights, trademarks and other forms of intellectual properties. The key objects of TRIPS are to balance the interests of intellectual property holders with the need to promote technological innovation, economic growth, and access to knowledge. It also includes various exceptions such as compulsory licensing, allowing countries to address public health and developmental needs while respecting intellectual property rights. Article 31 of the TRIPS Agreement[20] allows the member states to include provisions for use of the patentable subject matter by the government or any third party, without authorization of the owner. However, such grant must satisfy a three-point test as laid down under Article 30 of the TRIPS Agreement,[21] which is:

i. The grant/exception shall be "limited".
ii. The grant/exception must not unreasonably conflict with the normal commercial exploitation by the inventor of the patented invention.
iii. The grant/exception shall not unreasonably prejudice the legitimate interest of the patent owner but at the same time must also take into account, the legitimate interest of third parties.

Article 31 of the TRIPS Agreement further lays down the conditions and circumstances under which a compulsory license may be granted to a third party, the provision may be summarized as follows:

i. Each authorization must be considered on its individual merits.
ii. A grant may only be permitted if a prior attempt has been made to acquire a voluntary license, but such attempt had not been successful, however this requirement may be disregarded in cases of national emergencies.

[20] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995, art. 31.
[21] *Id*., art. 30.

iii. The scope and duration of the grant must be limited to the purpose for which it was authorized.

iv. The grant shall be non- assignable.

v. The grant shall be sanctioned primarily for the domestic markets of the state granting the license.

vi. The owner/patentee must be paid sufficient remuneration, depending upon the facts of each case.

vii. The validity of the grant must be subjected to judicial review.

The TRIPS Agreement was strengthened by the Doha Declaration on TRIPS and Public Health, which emphasized the goal of "promoting access to medicines for all." The declaration outlined several provisions ensuring that the TRIPS Agreement does not hinder member states from safeguarding public health and facilitating universal access to medical care.[22] The declaration also provides flexibility to the members states to grant compulsory licenses, and regulate the grounds for such a grant.[23] Article 31 of the TRIPS agreement[24] allows a compulsory license of a product, on a condition that such patented products shall strictly be commercially exploited in the domestic markets of the state granting the license. However, this condition was temporarily dispensed on August 30, 2003.[25] On December 6, 2005, the WTO unanimously adopted the Protocol for amending the TRIPS Agreement to replace the said temporary waiver, making the temporary medium permanent, allowing the less fortunate WTO member states to import generic medicines from other countries at affordable prices.[26] This decision was based on the principle that, the global trade system must take in account the public health needs of the developing and poorer nations, specifically the ones with insufficient manufacturing facilities.

The 2005 Protocol was legitimized by an amendment to the TRIPS Agreement in January 2017, by enacting Article 31bis to the Agreement, which authorized the grant

[22] Doha WTO Ministerial TRIPS, "Declaration on the TRIPS Agreement and Public Health," 2001, Cl. 4.
[23] *Id*., Cl. 5.
[24] *Supra* note 20, art. 31(f).
[25] *Supra* note 22.
[26] M.M.S. Karki, *Intellectual Property Rights: Basic Concepts* 100 (Atlantic Publishers & Distributors Pvt. Ltd., New Delhi, 1st edn., 2009).

of compulsory license to generic drug manufacturers to export patented pharmaceutical products to the countries with no manufacturing facilities.[27]

5. Compulsory Licensing in the United States

The US Patent Law was developed to protect and promote innovation through grant of exclusive rights to the inventors upon their inventions. It is governed by Title 35 of the U.S. Code, which ensures that an inventor can benefit from his invention while enhancing the viability of technological and economic growth of the nation.

5.1. Legal Framework

The United States does not have any provisions in the Patent law that regulates the grant of compulsory licenses. Supporters for Compulsory licensing in the U.S. often argue that non-use or misuse of a patent defeats the very purpose for which it was granted, hence the protection shall not be granted any further, it is also argued that, the benefits that the society gets from the proper use of a patent outweigh the added burden that compulsory licenses cause for a patent holder,[28] this ensures that in cases where a patent has not been put to public use, shall not halt public access to such a patented product.[29]

However, it cannot be said that there are absolutely no legal provisions that govern the grant of a compulsory license. Under the Clean Air Act, if the Attorney General is of the opinion that for the implementation of the statute a patent right is a hurdle, or such a patented product is not reasonably available, and there are no reasonable alternative methods for the achievements of the same, or such a patent halts competition in a particular sector, then he may certify to a district court, which may issue an order the patent holder, to license the patented product to a third party, on the terms and conditions which the court may deem fit after hearing.[30]

Also, under the Atomic Energy Act, 1948,[31] there was a provision for compulsory licensing to promote the use of atomic energy to expand energy supply,

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27 World Trade Organisation, Annex and Appendix to the TRIPS Agreement, 2017.
28 Arnold, Janicke, "Compulsory Licensing Anyone?," 55 *Journal of Patent Office Society* 674 (1973).
29 The debate for a legislation governing the grants of compulsory licenses in America is age old, however, till date no concrete legislation exists that regulates the same. *See also*, Cole M. Fauver, "Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come", 8 *Northwestern Journal of International Law & Business* 670 (1988).
30 The Clean Air Act, 1970, 42 U.S.C., s. 7401.
31 The Atomic Energy Act, 1954, 42 U.S.C., s. 2183.

however, this was later amended to not only provide for energy related uses, but to secure the common defense and security goals of the nation.[32] Compulsory licenses have been granted in over a 100 United States anti-trust cases, generally at a "reasonable" royalty rate, but occasionally royalty-free.[33] There is another concept in the US known as the "march in rights", it has been legalized under the Bayh-Dole Act, which permits federal government to" "march in" on the patents on inventions created using taxpayer funds and to order the patent holder to license the federally funded patents to other applicants.[34]

In the United States, there have been numerous attempts to have provisions in the patent law for compulsory license and this topic in itself has been very controversial, as early as 1877, and regularly since then the congress has presented various bills[35] for the same, but none transformed into an actual legislation, the main argument presented by those who are against this is, that the idea of compulsory license is in itself opposed to the spirit of American jurisprudence and, particularly the American patent law.[36]

American jurists have pointed that, the original function of Compulsory licensing was to replace the compulsory working provisions by a more efficient legal remedy, it appears to be a logical solution to a patent holder who himself is not willing to work the patent or is incapable of doing so in the patented country, such a person may be compelled to make the invention available on a royalty basis, to those who petition for a permission. However, in various foreign nations,[37] these provisions have proved to be rather ineffective and has been used only a handful of time.[38]

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[32] Staff of Joint Commission on Atomic Energy, 83rd Congress; 2nd Session, Draft in Bill from Incorporating Changes Proposed to be Made in H.R. 8862 and Companion Bill 3323.

[33] Senate Commission on the Judiciary, Sub-Commission on Patents, Trademarks, and Copyrights, 90th Congress, 1st Session, Compulsory Patent Licensing Under Antitrust Judgements.

[34] Till now, "March-in Rights" have never actually been invoked, and the amendment to the act which legalizes the right is yet to be passed by the congress. - Federal Trade Commission, "FTC Submits Comment on March-In Rights to Promote Efforts to Lower Drug Prices", *available at*: https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-submits-comment-march-rights-promote-efforts-lower-drug-prices (last visited on September 21, 2024).

[35] The questions involved were given consideration in the Oldfield hearings in 1912 and 1914, and repeatedly since, most intensively in the hearings before the Temporary National Economic Committee that was created upon the message of April, 1938, to the Congress from President Franklin D. Roosevelt.

[36] Richard Reik, "Compulsory Licensing of Patents", 36 *The American Economic Review* 814 (1946).

[37] German Patent Law, till 1911, had provisions that may penalize the patent holder for non-working of a patent, however the provision was sparsely used, and was discontinued in 1929.

[38] *Supra* note 36 at 816.

5.2. Legal Precedents on Compulsory Licensing

Since there is no legislation to regulate the grant of compulsory license of patents, the judiciary has played an active role in granting such licenses under the guise of antitrust measures.[39] Following are a few of the cases:

5.2.1. Hartford-Empire Co. v. *United States*[40]

Through a series of strategic mergers and patent-pooling agreements, the Hartford-Empire Co. and Owens established a near-total monopoly over the U.S. glassware industry, controlling up to 96% of the machinery market and effectively barring new competitors. This cartel like dominance led to a landmark antitrust suit by the U.S. government, which argued that their restrictive licensing practices violated the Sherman Antitrust Act by stifling competition. While the District Court initially ruled against the corporations for their anti-competitive conduct, the Supreme Court's final decision balanced property rights with market fairness; it affirmed the antitrust violations but overturned the confiscation of patents, ruling them private property. Instead, the Court mandated compulsory licensing at fair royalty rates, setting a significant legal precedent that patent rights cannot be used as a shield for monopolistic practices that eliminate industry competition.

5.2.2. United States v. *United States Gypsum Co.*[41]

United States Gypsum Co. and its co-dependents acquired key patents and enforced restrictive licensing agreements, thereby established a monopoly over the American gypsum industry. It also used price-fixing provisions to control the cost of essential building materials like wallboard and plaster. Although the District Court initially dismissed the government's 1940 antitrust suit, the U.S. Supreme Court ultimately reversed that decision, ruling that an industry-wide cartel disguised as patent licensing constitutes a prima facie violation of the Sherman Antitrust Act. The Court clarified that patent rights do not grant a legal shield for horizontal price-fixing or market manipulation, especially when used to coerce competitors into a unified pricing structure. Upon remand, the District Court confirmed that these practices had willfully stifled competition in the eastern U.S. market, firmly establishing that the misuse of patent

[39] Neal Seegert, "Compulsory Licensing by Judicial Action: A Remedy for Misuse of Patents", 47 *Michigan Law Review* 632 (1949).
[40] 323 U.S. 386 (1945).
[41] 333 U.S. 364 (1948).

litigation and royalties to enforce monopolistic dominance is a clear breach of federal antitrust doctrine.

5.2.3. Case of Fabrazyme, National Institutes of Health[42]

In a significant test of the Bayh-Dole Act,[43] the National Institutes of Health (NIH) denied a request to invoke "march-in rights" for the production of Fabrazyme, despite patient concerns over supply shortages and arguments that third-party licensing would expedite manufacturing. The NIH justified its decision by noting that granting a compulsory license would not provide an immediate solution, as any new competitor would still face years of regulatory hurdles and clinical trials before reaching the market. While Genzyme, the patent holder, successfully argued it was making diligent efforts to restore production, the NIH's refusal highlighted a rigorous legal threshold: march-in rights are generally reserved for persistent market failures rather than temporary supply disruptions. Ultimately, this case illustrates how the lack of specific legislative frameworks can create ambiguity for statutory authorities, often undermining the state's practical power to grant compulsory licenses even in the face of public health pressure.[44]

6. Compulsory Licensing in India

Indian patent law is governed primarily by the Patents Act of 1970, which was significantly amended in 2005 to bring the country's regulations in line with international obligations under the TRIPS Agreement. The objective of the law is to promote innovation, protect inventors rights, and balance public interest by granting exclusive rights to inventors for a limited period, usually 20 years. The Indian Patent jurisprudence is greatly focused on maintaining a balance between encouraging technological advancements and securing public welfare, especially in the fields of health and nutrition. The former Prime Minister of India, Smt. Indira Gandhi, while addressing the Geneva Conference in 1981, stated "Idea of a better world is one in which medical discoveries would be free from patent and there will be no profiteering from life and death,"[45] and the Indian Patent law is largely based on this ideology.

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42 Determination in the case of Fabrazyme, Office of the Director, *National Institutes of Health*, *available at*: https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Fabrazyme.pdf (last visited October 05, 2024).

43 Patent and Trademark Law Amendments Act (Bayh-Dole Act), 35 U.S.C. §§ 200-212 (1980).

44 *United States of America* v. *Microsoft Corporation*, 253 F.3d 34 (2001); *United States* v. *General Electric Company*, 358 F. Supp. 731 (1973).

45 Indira Gandhi at World Health Organization Conference, Geneva, 1981.

6.1. Legal Framework Surrounding Compulsory Licensing

Under the Indian Patent Act of 1970, compulsory licensing is a legal mechanism that allows the government or a third party to produce a patented product or process without the consent of the patent holder under certain conditions. This provision was introduced to balance patent rights with public interest, particularly in cases where patents could hinder access to essential goods, such as life-saving medications.

Section 84[46] states that, after 3 years of the grant of a patent, any interested party may make an application for a compulsory license, under the following grounds:

i. The reasonable requirements of the public for the patented product are not being met in India.
ii. The patented invention is not available to the public at a reasonable affordable price.
iii. The patented invention is not being worked in India.

Section 89[47] imposes a duty on the Controller, that while exercising the power to securing the following general principles:

i. That the patented inventions are commercially utilized within the territory of India without unnecessary delay and to the greatest extent that is practically possible.
ii. Must ensure that the interest of those currently working on or developing the invention under patent protection within the country are not unjustly harmed.

Section 90[48] lays down certain guidelines that the Controller should consider before settling the terms and conditions of a Compulsory Licenses:

i. Royalty and other remuneration shall be reasonable, in relation to the nature and expenditure undertaken by the holder while developing the patent.
ii. That the patented invention is worked to the fullest extent by the person to whom the license is granted, and must ensure that the agreement is profitable to him.

[46] The Patents Act, 1970 (Act 39 of 1970), s. 84.
[47] *Id*., s. 89.
[48] *Id*., s. 90.

iii. The patented articles must be made available to the public at reasonably affordable prices.

iv. The license is non-exclusive and non-assignable.

v. The term of the license is for the remaining term of the patent, unless a short term is desirable in public interest.

vi. The main purpose of the grant is to ensure a stable supply in the Indian market.

Section 92[49] authorizes the Central Government to make a declaration at any time by an official notification and grant a compulsory license. However, the following circumstances must exist for such a declaration:

i. A circumstance of national emergency; or

ii. A circumstance of extreme urgency; or

iii. A case of non-commercial use, which may arise or is required, for any public health crises, including epidemics.

Section 92A[50] empowers the controller to grant a compulsory license to a third party on an application for manufacture and export of patented pharmaceutical products to any country having inadequate or no manufacturing facilities.[51]

Section 94[52] allows the patent holder to apply to the controller for termination of the compulsory license, if such a circumstance that gave rise to the grant of such a license no longer exists and is unlikely to recur. While considering such an application the controller must ensure that, the interest of the person to whom the license was granted is not affected prejudicially.

6.2. Legal Precedents on Compulsory Licensing

India, having a defined legal code for the grant of a compulsory license has simplified the overall process for the grant because of the scope of the grant has been very

[49] *Supra* note 46, s. 92.

[50] *Supra* note 46, s. 92A.

[51] A practical instance of this could be traced back to the Nepal Health Crisis in 2008, where Natco Pharma applied for a compulsory licensing, of an anti-cancer drug, there was a heavy reliance on Section 92A of the Patents Act, 1970, however the application was ultimately withdrawn by Natco, when the Controller noted that majority of the compliances had not been fulfilled by the applicant; Elizabeth Verkey, *Law of Patents* 379 (Eastern Book Company, Lucknow, 2nd edn., 2012).

[52] *Supra* note 46, s. 94.

limited, as to this day there has been only three cases with regards to grant of a compulsory license, out of which only one has been granted, the following are the cases where the grant of a compulsory license was contemplated by the Indian Judiciary:

6.2.1. Natco Pharma v. *Bayer Corporation*[53]

In a landmark decision for Indian patent law, the Intellectual Property Appellate Board (IPAB) upheld the country's first-ever compulsory license granted to Natco Pharma for the production of *Sorafenib*, a life-saving cancer drug patented by Bayer. The ruling was triggered by Bayer's failure to meet the requirements of Section 84 of the Patents Act, 1970, as the drug's exorbitant price of ₹2.8 lakh per month rendered it inaccessible and unaffordable to the general public. While Bayer challenged the Controller's decision, the IPAB affirmed that compulsory licensing serves the public interest over the patentee's monopoly, especially when a patent holder fails to ensure adequate supply or reasonable pricing within three years of the patent grant. To balance innovation incentives with public health needs, the Board increased the royalty rate payable to Bayer from 6% to 7% in accordance with UNDP guidelines, firmly establishing a precedent that allows the state to intervene in the pharmaceutical market to ensure that essential medications remain within reach of those in need.

6.2.2. Lee Pharma v. *AstraZeneca AB*[54]

In a notable contrast to the Bayer case, the Indian Controller of Patents dismissed Lee Pharma's 2015 application for a compulsory license for the diabetes drug *Saxagliptin*, ruling that the applicant failed to provide sufficient evidence under Section 84(1) of the Patents Act. Although Lee Pharma argued that the drug which patented by Bristol-Myers Squibb and later assigned to AstraZeneca, was both unaffordable and inadequately supplied, the Controller found these claims to be based on assumptions rather than verified market data. The decision highlighted that a lower proposed price alone does not prove the current market price is "unaffordable," especially when similar therapeutic alternatives are priced comparably and widely used. Furthermore, the Controller reaffirmed that under Indian law, the "working" of a patent does not strictly require local manufacturing if the public's needs are being met through imports. By rejecting the

[53] 2013 SCC OnLine IPAB 251.
[54] C.LA. No. 1 of 2015.

application, the Controller established that the burden of proof for a compulsory license remains high, requiring a clear, fact-based demonstration of market failure rather than mere commercial interest by a generic manufacturer.

7. Comparative Analysis of Compulsory Licensing in India and the United States

Compulsory licensing has played a crucial role in the development of patent regime, both in India and the U.S., although the approach undertaken by both the countries are absolutely contrasting due to their idiosyncratic legal frameworks and socio-economic contexts. In both nations, compulsory licensing has been used as a measure to balance the rights of the patentees with the interest of the general public, especially in the areas of public health and innovation.

7.1. Differences in the Judicial and Legal Approaches

The U.S, lacks a proper legislation for the grant of compulsory license, with their Patent Act being silent on the same, and the grant of compulsory licenses have been strictly under the Antitrust measures, granted as a judicial relief, to make the market fair and to restrict monopolies, as observed in *United States* v. *Microsoft*,[55] where the issue stood whether Microsoft was abusing its power in the market, by bundling its product with the sale of its Windows operating system, Microsoft ultimately reached a settlement with the Department of Justice, where it agreed to share its application programming interfaces with third parties, and grant a panel full access to its source code of five years.[56] This further proves how stringent U.S. antitrust regime is, and how a compulsory license is not sought by an individual, rather it is given as a relief to make the market more competitive.

In India, the grant of compulsory licenses is very strictly regulated by the Indian Patents Act, 1970, especially under Section 84(1)[57] of the act, which lays down strict grounds, in the absence of which no compulsory license can be granted, as ascertained in, *BDR Pharma* v. *Bristol Myers Squibb*,[58] where an application for a compulsory license was rejected by the Controller of Patents, as the applicant had failed to prove their attempt

[55] 253 F.3d 34 (2001).
[56] The settlement became necessary as the DOJ, originally planned to break the company into two separate entities, in order to regulate the market.
[57] *Supra* note 46, s. 84(1).
[58] C.L.A. No. 1 of 2013.

at securing a voluntary license, which is a condition precedent for filing an application for compulsory license in India.

While drawing a comparison between the two nations, it becomes comprehensible that, the procedure and grant for a compulsory license is far stringent in India, as compared to the United States, where the judiciary is not bound by such strict provisions for the grant of a compulsory license. The difference in legal approach for the grant of a compulsory license in both the nations can be traced back to the very principles on which both the nations were formed.

India, was established as a socialist and welfare state, aiming to always cater to the interests of the people in general, U.S. on the other hand, has always been the perceived as a liberal nation which supports the free market.[59] India has been a nation where citizens are treated equitably,[60] as compared to absolute equals; which in principle is a stark contrast to what is followed in the United States.[61]

7.2. Economic and Social Priorities guiding the grants

There are evident differences in the socio-economic conditions of both the nations, which has drastically impacted the grant of compulsory licenses in both the nations, where in India, the only compulsory license granted has been for a cancer treating drug, which was deemed to be excessively expensive for the Indian citizens,[62] and on the other hand, there has never been a compulsory license grant for any patented drugs to secure the interest of the people of the United States in general, all the compulsory license grants have been to restrict monopolies in the market, this further proves the difference in intent and motivation of both the nations, when it comes to securing the interests of its citizens.

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[59] Stephen Tootle, Principle of free market trade, industry, innovation and competition; *Constituting America*, *available at*: https://constitutingamerica.org/90day-fp-principle-of-free-market-trade-industry-innovation-and-competition-guest-essayist-stephen-tootle/ (last visited October 02, 2024).

[60] Mithi Mukherjee, "*An Imperial Constitution? Justice as Equity and the Making of the Indian Constitution*" in *India in the Shadows of Empire: A Legal and Political History (1774–1950)* (Oxford University Press, Delhi, 2009), *available at*: https://doi.org/10.1093/acprof:oso/9780198062509.003.0006 (last visited March 19, 2026).

[61] Andrew Langer, Principle of Equity over Equality; *Constituting America*, *available at*: https://constitutingamerica.org/90day-fp-principle-of-equality-over-equity-guest-essayist-andrew-langer/ (last visited October 02, 2024).

[62] *Bayer Corporation* v. *Union of India, Controller of Patents and Natco Pharma Limited*, 2013 SCC OnLine IPAB 25: [2013] IPAB 31.

India being a developing nation with a huge underprivileged population, the government must ensure that the public health is maintained without overwhelming the economic limits of the nations. The cost of utilizing imported drugs can be quite high for an average Indian household, as has been highlighted in various cases,[63] the compulsory licensing system is a measure which has been employed to ensure access of the public to life saving drugs, this has been done by granting a compulsory license to a domestic generic drug manufacturer.

However, the United States being a developed nation with a strong economy and a robust patent protection mechanism, where the patent holders invest heavily in the research and development of a product, with the expectation of receiving exclusive rights to sell their products at a premium, this is why in the U.S. legal system, compulsory licenses have never been granted to protect the interest of the public in general, but only to break the monopolies, and ensure a competitive market.

The fundamental difference between the rationale behind the grant of compulsory license in both the countries is situated in their social priorities and economic structures. India's use of compulsory licensing indicates the need to ensure reasonable access to medicines for its citizens, especially in life-saving sectors, while balancing economic development. In contrast, the approach undertaken by the United States, is concerned on protecting the rights of the patent holders and has only intervened when the competition laws are threatened. This polarity in approaches reflects the broader societal and economic values, where India prioritises public health and affordability,[64] and the U.S., focusing on protecting innovation and market-driven solutions.

8. Policy Recommendations and Future Directions

As global landscapes of health and technology evolve, it is essential to explore how policies are shaped to address the fresh demands of intellectual property rights,

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63 *Lee Pharma* v. *AstraZeneca AB*, C.L.A. No. 1 of 2015; *BDR Pharmaceuticals International Pvt. Ltd*. v. *Bristol Myers Squibb Co*., C.L.A. No. 1 of 2013 - The main contention of the application in both case has been that the imported drugs are not affordable to an average Indian household.

64 A large number of Indians, often lack the basic access to healthcare, and the expenses these treatments concur often financially destroy Indians, this has led the Indian government to take various measures to ensure that the medicines across India are made more affordable and accessible to everyone despite their financial status - Vandana Roy, Usha Gupta, *et.al*., "Cost of Medicines & Their Affordability in Private Pharmacies in Delhi (India)" 5 *Indian Journal of Medical Research* 829 (2012); Saheb Chowdhury, "Making Medicines Accessible in India: A Critical Analysis of the Laws and Policies" 7 *NLUA Law Review* 56 (2023).

innovation and public health, both the nation will benefit from focusing on enhancing the balance between promoting innovation and safeguarding public welfare.

8.1. Enhancing the effectiveness of Compulsory Licenses

The ways for enhancing the effectiveness of compulsory licenses are enumerated hereunder:

8.1.1. Streamline the Application Process

i. The Indian patent law could be further simplified to ensure an expedited process for applying for compulsory licenses, while the system is already structured to ensure affordable access to essential medicines, applicants often face procedural hurdles that delay the grant which often discourages the applicant from applying altogether, as was argued in *Indoco Remedies* v. *Bristol Myers Squibb*,[65] that the grounds and process under Section 84, were cumbersome and time consuming, and were structured for ordinary situations and not a pandemic, as if the applicant had sought a compulsory license during the pandemic, by the time it would have been granted, in all probability, the pandemic must have been over. This highlights the urgency of clearer guidelines and stricter timelines for decision making by the Controller of Patents.

ii. In the United States, compulsory licenses are rarely granted, due to the complex grounds for such a grant, and no actual legislation governing the same, to solve this, an explicit criterion may be introduced in the existing patent law for granting compulsory license in public health emergencies, ultimately making the system more responsive to societal needs.[66] The Federal Trade Commission and the Department of Justice must play a key role in liberalizing the grant of such licenses in the larger public interest.[67]

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65 AIRONLINE 2020 DEL 1280.

66 William Alan Reinsch, Sanvid Tuljapurkar, *et.al*., "Compulsory Licensing: A Cure for Distributing the Cure?," *Centre for Strategic and International Studies*, *available at*: https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure (last visited October 07, 2024).

67 The Federal Trade Commission has already started the crack-down on patent abusers, hoarding and preventing access to essential medicines to the general public. - Elyssa Lacson Wenzel, Megan Hackett, *et.al*., "A New Wave of Agency Challenges to Pharmaceutical Patent Holders: A Survey of Novel and Reinvigorated Tools" *The Antitrust Source* (2024).

8.1.2. Broaden the Grounds for Grant

i. India, may consider widening the scope of grant of compulsory licenses, beyond public health interests,[68] it may potentially include areas like green technology or innovations combatting climate change, this would allow compulsory licenses to be more versatile and adaptive to global challenges beyond healthcare.

ii. In the U.S., the grants of compulsory license have largely revolved around antitrust laws and breaking market monopolies, expanding the legal framework for compulsory licenses to also cover public health concerns directly, would improve access to essential medicines and technologies, without destroying the existing patent incentives.

8.1.3. Public Health and Access to Medicines

i. India, by strengthening its domestic pharmaceutical manufacturing capacity would ensure the grant of compulsory licenses would lead to actual production and availability of medicines, the industry needs to establish itself as a strong alternative to foreign manufacturers, to discourage import of crucial drugs. Further establishing a robust regulatory mechanism for pricing of drugs for which compulsory licenses have been granted, would ensure that drugs produced under the grant remain affordable for all citizens.

ii. In the U.S., the Covid-19 Pandemic accentuated the need for a strong legal framework for compulsory licensing during times of national health emergencies, expanding the scope of Section 1498 to cover cases of pandemics[69]. The U.S., may also establish a policy that allows the grant of compulsory licenses, in case of failure to meet the public health demands or abusive pricing to prevent monopolies in essential drug markets.

9. Conclusion

The main object of intellectual property rights, are to encourage innovation and scientific research, by providing an exclusive right to the inventor, however, such a right

[68] This peculiar view exists as, all the three cases in which grant of a compulsory license has been considered are related to patented lifesaving drugs.

[69] Christopher J. Morten, Charles Duan, "Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises," 23 *Yale Law Journal of Law & Technology* 74 (2020).

is not be absolute and must be subjected to certain duties, and if such duties are not fulfilled by the patent holder, the powers granted to the controller under Section 84 may be imposed.[70] Compulsory license has played a crucial role as a tool for balancing the competing interests of intellectual property protection and public access to essential goods. Both in India and the United States, the grant of compulsory licenses, is a reflection of the varying socio-economic priorities. India has employed it primarily to ensure access to affordable life-saving medicines, as seen in *Bayer* v. *Natco*,[71] while the U.S., has used it as a remedy to foster a healthier market competition under antitrust laws, as observed in, Harford-Empire case.[72] While both countries have some form of a framework regulating the grant of compulsory licenses, each nation's approach is deeply influenced by its economic and public health needs.

Challenges such as pandemics and emerging technologies are reshaping the markets, compulsory licenses must play a crucial role in facilitating access to innovations and access, especially in developing nations. Existing international agreements already regulate and support the grant of compulsory licenses in public health crises, but has industries and nations develop, there is a requirement for a more accommodating and globally harmonized framework for the grant of compulsory licenses. Both India and the U.S., must leverage their position in the global economy to influence the approval of clearer guidelines on compulsory licensing, and ensuring that it continues as an effective tool for equitable access without affecting innovation.

As Sir Issac Newton once remarked: "I have been able to see further than others are because I stood on the shoulders of giants," this provides a fresh perspective to the intersection of innovation and access in patent law. The current breakthroughs in technology and medicine that we as a society are benefitting from today are built on the innovations of the past. Compulsory licensing allows societies to build on these shoulders

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[70] Abhinav Gupta and Aqa Raza, "Patent Law and Compulsory Licensing: Indian Perspective", 29 *Journal of Intellectual Property Rights* 15 (2024).

[71] *Supra* note 62.

[72] *Hartford-Empire Co.* v. *United States*, 323 U.S. 386 (1945), where the U.S. Supreme Court, while addressing the rights of the patent holder, stated: "*When the patent holder so far overreaches his privilege as to intrude upon the rights of the public and does this in such a way that he cannot further exercise the privilege without also trespassing upon the rights thus protected, either his right or the other person's and the public right, must give way. It is wholly incongruous in such circumstances to say that the privilege of the trespasser shall be preserved and the rights of all others which he has transgressed shall continue to give way to the consequences of his wrongdoing*."

by ensuring that essential medicines and inventions are not monopolised, but remain accessible and affordable to those who need them the most. By learning from one another, India and the U.S., can refine their approaches to compulsory licensing, ensuring that future innovation not only thrive but are share equitably for the benefit of the society as a whole.