

EVOLUTION OF PATENTS AND COMPULSORY LICENSE IN INDIA

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ABSTRACT

This chapter explores how patents and compulsory licensing have evolved in India, looking at both local and global changes. It starts by explaining patents as legal documents protecting people's ideas, covering four types: computer, method, manufacture, and material composition. Patents give exclusive rights for 20 years, rewarding inventors for sharing their ideas. Two main theories justifying patents are discussed: Natural Rights Theory, which focuses on individual entitlement, and Utilitarian Theory, which emphasizes economic incentives for innovation.

The chapter then discusses the history of India's patent laws, beginning in 1856 and leading to the 1970 Patents Act. Key moments include the Tek Chand Committee Report and the Aiyengar

Committee's reforms after independence. The laws were later amended to align with international agreements like TRIPS. Internationally, the chapter looks at events from the 1873 Congress of Vienna to the 1883 Paris Convention and the establishment of WIPO in 1967.

The World Trade Organization's TRIPS Agreement 1995 became crucial in international patent regulation, setting minimum standards for member countries to protect innovations. TRIPS includes flexibilities like compulsory licensing to support public policies in developing nations. It ends by discussing the controversial issue of international exhaustion in patent rights, highlighting India's unique perspective.

Keywords: Patents, Compulsory Licensing, Utilitarian Theory, TRIPS Agreement, International Exhaustion

INTRODUCTION

According to the "Black's Law Dictionary," a patent is a legal text that protects an individual's ideas. Usually granted by a country's Patent Office, the patent is granted to any person or firm. Patents typically consist of four different classes: a computer, i.e., a tool or apparatus produced by a person to perform a particular function, method, and manufacture or material composition. One can sue for patents. The patent is not a right to use or use the invention; it is the right to prohibit others from making, using, selling, or importing for a given time a patented invention. The stipulated period is 20 years, in compliance with the Patent Act. It is an intellectual property privilege given to inventors by the State authority in return for disclosure to the

people of the nature of the patented invention." rights conferred" by the patents act can be transferred to a person patentee An inventor's prior authorization or through the patent controller's issuance of a mandatory license. The applicant has to explain in the patent application before the patent grants the technical details of the invention in such detail that an ordinary person with a good skill set can carry out such invention without any significant difficulties.

The rationale behind patent granting was to reward the inventor's creativity by allowing them to redeem their "research and development" efforts and costs by granting exclusive monopoly rights to exploit the invention and ultimately contribute to the nation's technological development.

Various patent theories have emerged over the years, and these theories generally have that awareness cumulatively to explain patent protection. Through the years, patent theories have evolved. These theories have generally come cumulatively to justify patent protection. Nevertheless, several hypotheses have been questioned in the history of evolution and therefore debunked. Nevertheless, the philosophy of utilitarianism and the principle of natural law are generally accepted. The chapter will deal with the philosophical aspects of granting patents. In relation, the developments in patent and compulsory license regimes are divided into two sections. Namely, the domestic developments consist of the various amendments made due to the recommendations given by various committees and international developments consisting of various treaties and agreements that help present shape to India's current patent regime.

1.1 JUSTIFICATION OF PATENTS

There are broadly two theories for the justification of patents that enumerate the philosophy behind the grant of patents. The two theories are namely Natural rights theory and Utilitarian theory. It is discussed below:

1.1.1. "NATURAL RIGHTS THEORY"

Since time immemorial, the principle of natural law has been used in the legal sphere to determine land ownership. According to this principle, there is no distinction between tangible and intangible types of property. A developer or inventor of a new invention or product is entitled to possess or enjoy the same property.

The Lockean labor theory is one of the most commonly used justifications for IPR. According to John Lock in his book "Two Treaties on Government," he claimed that "Labor being the undeniable property of the laborer, no man but he can have a right to what is once attached, at least where there is ample and good left in common for others.". The theory emphasizes that initially, all the resources are jointly owned in creating something new. The labor put in is the only resource added by the person who creates a new product. So, the right to exclusively enjoy the same remains with the inventor provided it does not hamper the use or utility of resources for the rest of the people. This theory requires respect and recognition from private ownership of all inventions irrespective of the consequences or benefits of recognition. It becomes imperative in countries such as India with a very high population and poor economy.

1.1.2. “UTILITARIAN THEORY / ECONOMIC INCENTIVE THEORY”

The utilitarian theory or economic incentive theory is arguably the most renowned and widely used theory to justify patent protection and has had approval from other countries. According to this principal outcome of an action to decide if the action serves a greater good for the community and the people benefiting from it is excellent or poor, the action should be continued and promoted even if it has some negative consequences for a specific segment of the society. Patent justifies innovations. It offers a powerful economic incentive for both the business and the inventor to spend more in research and development to create improved drugs, which can benefit a society's overall advancement welfare. The basic logic behind this theory is that in a completely competitive market with no entry and exit restriction, firms without patent protection shall lose the incentive to innovate. It tends to create a non-rival characteristic in the market as each player can use the inventions without paying for them. It strongly discourages businesses, especially in the pharmaceutical industry, from investing in research and development as a large amount of investment and effort tends to increase the efficacy of an existing drug or create new ones to cure diseases and encourage better health facilities in society. However, without the economic benefit offered by patent protection, which grants the inventor the exclusive right to exploit the product, it would be complicated for the "pharmaceutical industry" to recover its "research and development" costs and make money for them. It would only result in less perusal of inventions and accomplishments in the field of healthcare than before. The utilitarian theory strikes "a balance between" public

access to healthcare and innovation; on the one hand, the inventors receive an incentive for a fixed period to cover up their cost of research and development. It reaps benefits in the form of profits to make the innovation and the steps to its discovery public. This theory prominently highlights two arguments to justify patent protection incentive to innovate and incentive for public disclosure. An incentive for innovation is to maximize a firm's profit and set up firms in countries like India, which possesses many resources and brings down unemployment and poverty levels. This economic incentive, in many ways, also reflects the social contract. The exclusive right provided under the modern patent system encourages the firm to disclose the discoveries and ways to achieve innovation in the public domain, which results in the diffusion and transfer of technology. Many firms must achieve similar results and monopoly over the invention to keep such information a trade secret.

Like other ideas, this theory also faces criticism as it does not extend to developed and developing countries fairly. In the book, *Knowledge as Capital: Problems in the Moral Foundations of "Intellectual Property Rights,"* "Rajshree Chandra" pointed out that creativity is encouraged by patent security in the industry. It leads pharmaceutical firms to see creativity as an opportunity to increase market shares, revenues, and revenue rather than serve society as a whole. Thus, drug prices vary from other ex-prices. One of the main issues with the existing patent system is that it creates a "global drug gap" where meager investments that initiate medical research and development affect a minimal number of people in developed or developing countries, given high opportunities. The pharmaceutical industry still ignores such diseases." This phenomenon. It refers to

the 10/90 gap as 90 percent of global disease burden attracts as low as 10% investments". Nonetheless, this theory remains the most widely accepted theory for patent protection regimes and has been employed numerous times in international conventions. According to "Article 7 and 66 of the TRIPS Agreement, the protection, and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, and the Member States shall provide incentives to enterprises and institutions in their territories to promote and encourage technology transfer".

1.2. THE PATENT LAWS AND COMPULSORY LICENSE EVOLUTION

The evolution of patent laws and compulsory licenses further bifurcates into two categories, namely domestic and international developments.

1.2.1 DOMESTIC DEVELOPMENTS

In the area of patent laws, India has comparatively long innings. "India's history of patent law dates back to the 1850s." The first Patent legislation came to India in 1856, which provided exclusive rights to the inventor for 14 years as a recommendation of Lord Macaulay Law Commission. India's patent law underwent a few changes in 1859 to include clauses identical to those of the British Patent Act, of 1852. The Act also passed several subsequent revisions before being replaced by the 1911 "Indian Patents and Design Act." Some significant improvements in the trajectory of India's new patent and compulsory license regime are as follows:

THE INDIAN PATENTS AND DESIGN ACT, 1911”

"The Indian Patents and Development Act of 1911" was authorized on March 2, 1911, by the Governor-General.⁴⁸ This Act offered mandatory licenses for cases of patent infringement and misuse. This Act developed India's first patent system, and the Controller of Patents was to administer the exact functioning and management. "Under this Act, any interested party may apply to the Controller of Patents for the compulsory grant license as follows after the expiry of three years of the grant of a patent":

- (a) That the patented work has not been put forward to the whole degree that is reasonably possible in the territory of India, even after it has been able to be used commercially.
- (b) The patented product demand is not met adequately or on fair terms in the territory of India or met substantially by importation from other countries.
- (c) That the patented item, "manufactured in India," is not supplied on the export market on the grounds of refusal by the patent proprietor on fairgrounds.

Nevertheless, after Independence in 1947, the Indian Government unanimously agreed that India's patent law required major reform as the "Indian Patents and Designs Act" was formulated under British rule and was not in line with independent India's aspirations. Consequently, the "Government of India" formed a "Tek Chand Committee in 1948" to review precisely the current legislation and significantly strengthen India's patent regime.

“TEK CHAND COMMITTEE REPORT” AND “THE PATENT AMENDMENT ACT, 1950”

The "Tek Chand Committee" adopted the analysis of existing legislation and found its shortcomings as their fundamental strategy to improve the patent regime of India. The main aim of the Tek Chand Committee was to strengthen and use "Public Interest" as a means to promote the availability and accessibility of food and medicines to the general public by examining an effective system of a compulsory license for agricultural, technological, and pharmaceutical inventions.

The Committee went through huge dilemmas related to whether to keep process patents or product patents as process patents shall provide inventors with absolute monopoly rights. However, the Joint Committee later tried its best to prevent process patents from products to deter monopoly rights to the inventor.⁵² The interim report submitted by the Committee was highly influenced by the recommendations that look like as Patent and Design Bill 1949, which was pending in the UK Parliament and still required assent. The recommendations made under the report are as follows:

- (a) The compulsory license is submitted to the controller three years after the patent license is issued to the inventor.
- (b) An application for a compulsory license may be triggered if the Indian trade and industries have been substantially affected.

Nevertheless, most of the above amendments were taken into account and influenced by the "1950 amendment" to the "Patent and Design Act, 1911," i.e., before the publication of the Tek Chand Report. The report only widened the grounds of "Compulsory Licensing," the main grounds added to the existing grounds were:

- (I) That the conditions put on the selling or use of the proprietary product of manufacture hindered the economic activities of the countries.
- (ii) That, in "the interests of public or industrial development, the Government apply for a compulsory license I to allow private parties to work the patent in the territory of India";

The Tek Chand Committee Report includes clauses that issue the compulsory license to foster in furtherance to "public interest" and relatively depends on patent infringement cases. The Act amends section 23 CC, which, in 1952, provided for compulsory approval of the correct license in respect of advances in food and medicinal drugs. Nevertheless, even after reforms made to India's patent law, it did not prove to be very successful in solving the problems as the procedure and enforcement were tedious when it came to the actual mandatory license application. Therefore, the "Ayyangar Committee" was established to address the shortcomings of the patent regime and find viable means to combat the same.

AYYANGAR COMMITTEE REPORT

"In 1957, Justice Rajagopala Ayyangar" re-examined and reviewed India's patent system and advised the Government on the necessary reforms to be made to improve laws in favor of national interest. "Justice Ayyangar highlighted the major problems for applicability of the patent system in India and noted that 80 to 90 percent of the patents, owes by foreign individuals that collaborate, 90 percent of the patents did not work in India".The Committee given that foreigners heavily abused the system to monopolize a market,

particularly in food, chemical, technology, and pharmaceutical industries. The Committee concluded by pointing out that the law will function in developed, emerging, and developing countries because of their technological and economic growth differently. "The price of medicines was skyrocketing and unaffordable to the general Public price of drugs, and it became a very general problem for people that became difficult to afford." The Committee further observed that the provisions related to compulsory licenses to prevent patent abuse are entirely inadequate as the grant of compulsory licenses was minimal during those days for the following reasons:

- (a) Although the deterrent effect generally promoted the issuance of a large number of voluntary licenses, they also failed to curb the problems resulting from the monopoly actions of international companies. No quantitative data were available to show precisely how many voluntary licenses were issued, but unreliable.
- (b) That "the technical know-how does not transfer from the licensor to the licensee. It became necessary that mandatory licensing laws do not allow technical know-how to transfer".

This detailed report, submitted in September 1956 by the Committee headed by Justice Ayyangar on the reform of patent law, became the basis of the 1965 Patents Bill. "The bill incorporated several amendments on patents for food, chemicals, and medicines introduced in 1965 in Lok Sabha. It referred to the Joint Committee during which", however, a few changes made to the bill; when it put in Lok Sabha, and the same lapsed as the Lok Sabha dissolution of Lok Sabha in 1967 of a lack of time and debate.

The Patent Bill was enactment in 1970, and it passed by both houses. The same came into force in "April 1972."

ENACTMENT OF "PATENTS ACT, 1970"

The "1970 Patents Act" came into effect on April 20, 1972, and resulted from the Ayyangar Committee's recommendation. Nonetheless, some amendments had to be made to the Act later to comply with the travel agreement; the Act was later revised three times, the first attempt made in 1999. This Act was granted retrospective effect from January 1, 1995. The second amendment was 2002 amended in 2003. It came to an end by Lok Sabha disbanded due to elections, but the same was enforced in 2005. "This Act introduced several changes to comply with the TRIPS Agreement. The major changes were related to granting process patents along with product patents and in the compulsory license regime. It was a big blow to the Indian pharmaceutical industry because all of them used reverse engineering to produce generic drugs. It also affected the pharmaceutical market as availability and affordability of medicines reduced due to grant of patents creating a monopolistic market for certain pharmaceutical firms as a result of which the prices of medicines in India rose sharply over the years".

1.2.2 INTERNATIONAL DEVELOPMENTS

The international developments in compulsory licensing bifurcate into two eras, i.e., pre- and Post WTO. The compulsory license has existed since times immemorial the first written mention of a compulsory license the first time published in the English Statutes of Monopolies 1623, it was one of the earliest legal instruments to

recognize and incorporate compulsory licenses; however, the concept ultimately developed in Britain around the 1850s. Patents have always been an important subject of "intellectual property rights." the protection of innovations and technological advancements gives much importance. It treated the individual concern of the state until the 1980s.

In the mid-1980s, as the world advanced and rapid advancements in technology and significant industries set up on technological developments, inventions, and innovations became a trade concern. Therefore, patent protection was a crucial part of the technological industries, so set up and with inter-country trade and globalization, patent protection became a global concern from a mere state concern.

The first International Convention on Patents came to be known as the "Congress of Vienna" for "Patent Reform, 1873". After prolonged debates and weighing the cost and benefits of providing monopoly rights to the inventor, a comprehensive patent protection scheme concludes to provide incentives and promote innovation. However, to create a mechanism to combat the abuse of patents, the compulsory license was seen as a strategic compromise to curb the monopoly rights of inventors and regulate the accessibility of the invention to the general public. According to this convention, compulsory licenses could only be granted for public purposes and prescribed minimum standards that should be necessary to grant these licenses to individuals. These standards are not favored by the majority of countries and therefore failed to produce any legally binding effect.

Paris Convention, of 1883 was the first successful treaty and survived many decades without substantial changes made to the same. "The

main objective of the convention was to develop a system through which inventors could protect their inventions or innovations globally." The inventors before the Paris Convention had monopoly rights and could control the price and working of their inventions in their home country. However, the rights and control over their inventions located outside their home country were negligible. It was, therefore, essential to come out with a comprehensive solution to the problem and globally protect patents.

The World Intellectual Property Organization was established in 1967, intending to bring harmony in intellectual property procedure and legislation of various countries and incorporating comprehensive legislation and procedure. It applies to different countries to bring uniformity in the law and procedure of patent laws on an international level to avoid conflicts and ensure better incentives for innovation. WIPO was the only unified international society that controlled all intellectual property-related matters. Under the WIPO system, several new treaties also came into being effective, revising old treaties such as the 1967 Stockholm Reform Meeting and considering technical developments.

As intellectual property became an essential part of trade and business, its protection and regulation became an international concern rather than a mere state concern. With the advancement in technology and ever-increasing business and investment in the Information technology industry and pharmaceutical industries, protection and regulation of intellectual property became necessary. They treat the international trade concern. To deal with such trade-related matters, the "General Agreement in Tariff and Trade (from

now on referred to as GATT)" was established in 1940 to prevent economic discrimination in countries and reduce uncertainty related to international commercial transactions within countries through multilateral trade agreements. However, GATT only dealt with trade goods; therefore, in the Uruguay Round, the World Trade Organization was established to deal with service and intellectual property matters related to trade and investment.

(TRIPS)TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS

Developments related to patents on the international front caught pace rapidly after the introduction of WTO, especially in matters related to a compulsory license. The most critical treaty related to intellectual property was "Trade-related intellectual property rights (from now on referred to as TRIPS)" passed and approved by WTO in the year 1994 and came into effect on "January 1, 1995".⁷¹ The primary motive of the TRIPS Agreement was to cure the impediments and reduce distortion related to intellectual property among member countries and to harmonize various domestic laws and provide minimum standards of compliance. Unlike the previous conventions, TRIPS put an obligation on all the member countries to provide intellectual property and mandatory rights to the rights holders. TRIPS does not repeal the Paris Convention; it incorporates it with mandatory obligations and compliances, which have to be followed by all the signatories. Article 27(1) states that all signatories are obliged to protect any innovation, whether product or process, in the field of technology. Article 28 provides exclusive rights to patent holders to prevent the third party from producing, selling,

distributing, and importing patented products and providing monopoly rights. Pre 2005, as many as 50 countries, including India, did not provide patents for pharmaceutical products. However, after the introduction of TRIPS, all member states had to amend their respective legislation to incorporate TRIPS compliances". TRIPS is legally binding on member states; it puts an obligation to protect intellectual property rights; however, specific provisions that are available by developing or least developed nations enable them to promote and pursue their public policies. The flexibilities include Parallel imports Bolar exemption, and compulsory licensing, while parallel imports let countries import medicines from another country at a cheaper rate. Generally, countries with limited resources are inclined towards importing drugs from abroad rather than purchasing the same at high prices from the local market. A patent owner usually tries to avoid such a situation by banning such importation by a third party in exercising their rights. In all the cases, it's not possible, as the will of the patentee to put such restrictions of production and trade of the patented product is highly dependent on the country's treatment to exhaustion of intellectual property rights."The patent holder loses control over their patented product, i.e., all the rights on the patent are exhausted with the first uninterrupted sale abroad. It is known as international exhaustion. The principle of international exhaustion is applied differently in different countries; the USA and EU adopted the principle of national and regional exhaustion, which states that the patent holder shall have full control over their patented product irrespective of the disposal of the patented product abroad. Under Article 6 of TRIPS, the principle of international exhaustion of intellectual property rights from the scope of WTO dispute settlement

is not in the conversation for long. It provided that States do not apply different rules of international exhaustion when dealing with the patented products of different countries. They have to apply a uniform rule to all States". "India, however, is very different and controversial and even considered beyond TRIPS and does not follow the traditional scope of international exhaustion properly. Since the exclusive right is considered exhausted under its patent law even if the product was placed on the market abroad without the patent proprietor's consent, such as in the situation of compulsory licensing, another essential exception under Article 30 is the Bolar exemption. Provides that an interested person can use the inventor's pharmaceutical drug without the patent owner's authorization to obtain regulatory approval of a generic product before the expiry of such patent. It is beneficial for countries like India, being one of the largest producers of generic medicines, as it enables the early launch of a generic product after patent expiry and promotes further R&D. "The Indian Patents Act" provides for an exception in "Section 107A (a)" stating that any act of creating, building, using or importing a patented invention solely for uses reasonably related to the production and submission of information needed under any law in force for the time being. In India or a country other than India, which regulates it shall not be considered an infringement."

CONCLUSION

The evolution of patents and compulsory licensing in India has traversed a complex path, shaped by domestic reforms and international agreements. The two predominant theories justifying patents, namely the Natural Rights Theory and the Utilitarian Theory,

reflect the ongoing debate on the balance between incentivizing innovation and ensuring public access to essential goods like medicines. The historical development of patent laws in India, from the 1856 Patent Act to the significant amendments in 1970, highlights the nation's efforts to align its patent regime with evolving global standards while addressing domestic needs.

The Aiyengar Committee's insights in 1957 revealed the challenges posed by foreign dominance in patents, particularly in crucial sectors like pharmaceuticals. The subsequent amendments, especially the Patents Act of 1970, attempted to balance incentivizing innovation and safeguarding the public interest. However, the journey did not end there, and subsequent amendments, such as those in 2002 and 2005, were made to comply with international agreements like the TRIPS Agreement under the World Trade Organization.

On the international front, the evolution of compulsory licensing can be traced back to early conventions like the Congress of Vienna in 1873 and the Paris Convention in 1883. However, the real paradigm shift occurred with the TRIPS Agreement in 1994, which mandated member countries to align their patent laws with international standards. TRIPS introduced flexibilities, including compulsory licensing, to accommodate public health concerns in developing nations. It compelled countries like India to modify their legislation and opened debates on issues like parallel imports and the Bolar exemption.

In conclusion, India's journey in patent law evolution reflects a dynamic interplay between domestic imperatives and global standards. By fostering a regulatory environment that prioritizes

innovation, public health, and social equity, India can contribute to a balanced and sustainable global intellectual property landscape.

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