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COMPULSORY LICENSING UNDER THE PATENTS ACT 1970: BALANCING PUBLIC HEALTH AND PATENT RIGHTS IN INDIA.

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Abstract:

By providing inventors temporary exclusive rights over their creations, the patent system serves a crucial role in promoting innovation. These exclusive rights must, however, be weighed against society's greater interests, especially when it comes to guaranteeing access to necessities like medications and medical equipment. One of the most significant legal tools that permits this balance is compulsory licensing, which permits the use of a protected innovation without the patent holder's permission in certain legally specified situations. The patents act of 1970's notion of compulsory licensing is examined in this study, with focus on its legal stricture, legislative provisions, grant reasons and procedural criteria. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Indian Patent System are also examined in the paper, along with the importance of the Doha Declaration on Public Health. The study also examines significant court rulings, including Bayer Corporation vs NACTO Pharma Ltd. and contrasts India's mandatory licensing system with that of a few other countries. Adopting a doctrinal research technique, the study examines international legal instruments, government reports, books, journal article, legislation and court rulings. It also looks at the benefits, drawbacks and real-world difficulties of mandatory licensing and offers solutions to enhance its use. The study comes to the conclusion that mandatory licensing is meant to guarantee that patent rights are used in a way that serves the public interest rather than to weaken patent protection it promotes access to reasonably priced medications, technical advancement and general welfare while acting as a crucial barrier against the general welfare while acting as a crucial barrier against the abuse of patent monopolies. According to the report, India's legal system effectively strikes a balance between social justice and innovation protection while still mostly adhering to its duties under the TRIPS Agreement.

Keywords: Compulsory Licensing, Patent Law, Intellectual Property Rights, Public Health, Pharmaceutical Patents, Access to Medicines, Patent Monopoly, Innovation

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Introduction:

Every country's economic and social progress depends heavily on innovation and technical improvement. In order to promote innovation, patent law gives inventors temporary exclusive rights over their creations, allowing them to stop anyone from producing, using, importing, or selling the patented invention without their permission. These exclusive rights encourage more invention and provide innovators a chance to recoup their R&D expenses. Although patents advance science, they also establish a transient monopoly that may occasionally be at odds with the greater good of society.

In industries like medicines, healthcare, agriculture and vital technology, the conflict between patent rights and public benefit become more important. sometimes patented goods are not made accessible in large enough numbers or are marketed at prices that are out of the grasp of the general people. Access to life-saving medications and other necessities may be negatively impacted by such circumstances, particularly in developing nations like India where accessibility and cost are significant issues. As a result, it becomes imperative to find a compromise between safeguarding patent holders, rights and guaranteeing that the general public gets fair access to crucial ideas.

One of the significant legal tools used to accomplish this balance is compulsory licensing. Under certain legally regulated conditions, it permits the government or the appropriate authority to let a third party to use, produce to sell a patented innovation without the owner's approval. The exclusive right to use the innovation is limited for the benefit of the public, even if the patent holder still owns the patent. Therefore, the goal of compulsory licensing is to guarantee that patents meet their wider social purpose and to prevent the exploitation of intellectual rights rather than to diminish patent protection.

The patents act of 1970, specifically sections 84 to 94, governs the idea of forced licensing in India. These clauses provide the controller of patents the authority to issue compulsory licenses in situations when the public's reasonable needs are not met, the patented innovation is not reasonably priced, or the invention is not developed within India. The act upholds the idea that patents should support economic growth and public benefit in addition to scientific advancement. Section 83 of the act, which establishes the broad guidelines governing the operation of patented innovations, further supports this strategy.

Additionally, India's mandatory licensing policy complies with its international commitments under the agreement on Trade-Related Aspects Of Intellectual Property Rights (TRIPS Agreement). Although the TRIPS Agreement sets a baseline requirements for patent protection, it also acknowledges member governments authority to give mandatory licenses under specific circumstances. Adopted in 2001, the Doha Declaration on the TRIPS Agreement and public health reiterated that member nations are free to use strategies like mandatory licensing to safeguard public health and advance access to medications. While maintaining adherence to international norms, India has integrated these flexibilities into its native patent legislation.

The historic ruling in Bayer Corporation vs NACTO Pharma Ltd (2012), in which the first compulsory licence for a patented anti -cancer medication was obtained, made the importance of compulsory licencing in India clear. the case demonstrated India's dedication to making sure that patent rights are used in a way that promotes access to reasonably priced healthcare and the public good. It also spurred global conversations about striking a balance between promoting innovation and safeguarding public health.

The purpose of this research is to analyse the legislative framework that governs compulsory licensing under the Patents Act of 1970 and assess how well it balances the demands of society with the interests of patent holders. in order to ascertain weather the current framework effectively accomplishes its intended goals, it also examines pertinent statute provisions, court rulings, and international legal principles. The purpose of this research is to evaluate the function of mandatory licensing as a crucial protection that fosters innovation and the greater good of society.

Research Problem:

Patents promote innovation by granting inventors exclusive rights over their creations. However, these exclusive rights may occasionally render vital goods – particularly medications – expensive or inaccessible to the general population. this puts the public's desire for reasonably prised access to necessities at odds with patent holder's rights.

To remedy this problem, the patents Act of 1970 established compulsory licensing, which permits third parties to use a patented invention under specific circumstances without the owner's permission. Despite its goal of safeguarding the public interest, this clause has been applied in a few instances.

Thus, the primary research challenge is to determine if the patents act of 1970's mandatory licensing provisions successfully balance patents holder's rights with the public interest and whether the current legal structure is enough to accomplish this goal.

Research Questions:

1. What is the concept and purpose of compulsory licensing under the Patents Act, 1970?
2. What are the legal provisions governing compulsory licensing in India?
3. Under what circumstances can a compulsory licence be granted under the Patents Act, 1970?
4. How have Indian courts and the Controller of Patents interpreted the provisions relating to compulsory licensing?
5. Does the existing framework of compulsory licensing under the Patents Act, 1970 effectively balance the rights of patent holders with the public interest?

Objectives of the Study:

The present study is undertaken with the following objectives:

1. To examine the concept, purpose, and significance of compulsory licensing under the Patents Act, 1970.
2. To analyse the statutory provisions governing compulsory licensing, with particular reference to Sections 84 to 94 of the Patents Act, 1970.
3. To study the grounds, procedure, and conditions for the grant of a compulsory licence under the Indian patent regime.
4. To examine important judicial decisions and administrative rulings relating to compulsory licensing and understand their impact on the development of patent law in India.
5. To evaluate the relationship between India's compulsory licensing framework and the provisions of the TRIPS Agreement, particularly in the context of public health and access to essential medicines.
6. To assess whether the existing legal framework effectively balances the exclusive rights of patent holders with the larger public interest and to suggest suitable measures for improving its implementation, where necessary.

Research Methodology:

Nature of the Study

This work is Doctrinal in nature. By analysing legislative provisions, court rulings and legal concepts, it investigates the legal framework regulating forced licensing under the patents act, 1970.

Sources of Data

All the data included in the study came from secondary sources. The patents Act of 1970, the patent rules, court rulings and international agreements like the TRIPS Agreement are examples of primary sources. Books, Journal articles, Research papers, commentary, government reports and other pertinent legal publications are examples of secondary sources.

Method of Analysis

The statutory requirements and court rulings pertaining to mandatory licensing have been interpreted analytically. The study also assess how well the current legal system strikes a balance between patent holder's rights and the greater good of society.

Literature Review:

Legal experts, legislators, and researches have given forced licensing a lot of thought, especially when it comes to striking a balance between patent protection and the public interest. The legal, economic and social ramifications of mandatory licensing are examined in a sizable body of research, particularly with regard to access to reasonably priced medications, technological advancement, and adherence to international intellectual property norms. The extant literature highlights the ongoing conflict between promoting innovation and safeguarding the public interest while also offering insightful information on the development of mandatory licensing under the patent act 1970 P. Narayanan, in his authoritative work *Patent Law*, provides a comprehensive explanation of the Indian patent system and discusses the objectives and operation of compulsory licensing under the Patents Act, 1970. The author explains that compulsory licensing is not intended to diminish the rights of patentees but to prevent the misuse of patent monopolies where public interest demands intervention. His work serves as one of the principal references for understanding the statutory framework governing compulsory licences in India.¹

N.S. Gopalakrishnan has extensively written on intellectual property law and emphasizes the

¹ P Narayanan, *Patent law* (4th edition, Eastern Law House, 2006)

importance of maintaining a balance between the exclusive rights of patent holders and the socio-economic needs of society. His writings explain that the Indian patent regime has been deliberately designed to ensure that patents contribute to technological advancement, public welfare, and economic development rather than functioning solely as private monopolies. His analysis highlights the significance of compulsory licensing as a mechanism to safeguard public interest.²

Carlos M. Correa, in his work *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, examines the flexibilities available under the TRIPS Agreement, particularly those relating to compulsory licensing. He argues that the Agreement permits member states to adopt measures necessary for protecting public health and ensuring access to essential medicines. His work has become an important reference for understanding the relationship between international intellectual property obligations and domestic patent laws.³

Shamnad Basheer has made significant contributions to the study of Indian patent law, particularly in the field of pharmaceutical patents and public health. His writings critically analyse India's compulsory licensing framework and discuss the landmark decision in *Bayer Corporation v. NACTO Pharma Ltd.*⁴ He argues that compulsory licensing should be viewed as an exceptional but legitimate legal remedy that ensures patent rights are exercised in a manner consistent with public interest. His analysis has influenced both academic discussions and policy debates relating to patent law in India.⁵

W.R. Cornish, David Llewelyn, and Tanya Aplin, in *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, provide a comparative perspective on patent law across different jurisdictions. Although their work primarily focuses on international intellectual property principles, it explains the rationale behind compulsory licensing and its acceptance as an important limitation on exclusive patent rights. Their comparative analysis assists in understanding how different legal systems address the conflict between innovation and public

² N S Gopalakrishnan and T G Agitha, *Principals Of Intellectual Property* (2nd Edition, eastern Book Company, 2014)

³ Carlos M Correa, *Trade related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press, 2007)

⁴ *Bayer Corporation vs NACTO Pharma Ltd* (Compulsory Licence Application No 1 of 2011, Controller of patents, 9 March 2012)

⁵ Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act, 2005,

welfare.⁶

Following the Bayer ruling a number of studies that have been published in legal journals have also looked at the actual implementation of mandatory licensing in India. These studies include topics including India's adherence to the TRIPS Agreement, the cost of patented medications, and the difficulties in getting mandatory licenses. While many academics agree that India should prioritise public health, others warn that an over-reliance on mandatory licensing might deter international investment and innovation. The difficulty of striking a balance between private intellectual property rights and more general society interests is reflected in this difference of view.

A through grasp of the legal structure governing mandatory licensing and its importance in advancing public welfare may be found in the body of extant literature. However, a large portion of the material that is now accessible focuses on either specific court ruling or the legislative restrictions. To determine whether the current compulsory licensing regime successfully balances the rights of patent holders with the greater public interest, a through analysis that incorporates the statutory framework, judicial interpretation and international obligations under the TRIPS Agreement is still required.

By conducting a doctrinal examination of the patents Act of 1970's mandatory licensing requirements, the current study aims to meet this demand. In order to assess the efficiency of compulsory licensing in accomplishing its intended goals and to pinpoint areas where the current legal framework may be reinforced, it critically reviews the legislative framework, significant court rulings, and international legal principles.

Evolution Of Patent Law In India:

India's evolving economic interests, industrial expansion, and dedication to public welfare are all reflected in the country's patent legislation. The Indian patent system has developed from a colonial framework that predominantly protected foreign interest to balanced legal structure that strives to stimulate innovation while guaranteeing that copyrighted innovations remain available to society. Judicial interpretation, international duties, especially under the agreement on trade- related aspects of Intellectual property Rights (TRIPS), and domestic policy concerns

⁶ William R Cornish, David Llewelyn and Tanya Aplin, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights* (9th edition, Sweet & Maxwell 2019)

have all impacted this growth.

The Indian Patents and Designs Act, 1911

The Indian patents and designs Act, 1911⁷, which was passed during British rule, was the first comprehensive law controlling patents in India. The act gave inventors exclusive rights over their creations and combined the regulations already in place regarding patents and industrial designs. However, foreign businesses, especially British ones who controlled the Indian market, benefits greatly from the regulations.

Under the 1911 act, product patents were granted for pharmaceutical products, chemicals, and food items. Because of this, multinational firms have broad monopoly rights that allowed them to regulate the production and cost of necessities. due to India's small domestic manufacturing base, many patented goods were imported and sold at exorbitant costs, rendering them unaffordable for a significant portion of the populace. The act did not sufficiently address the public interest and provided very few protections against the misuse of patent rights.

The Ayyangar Committee Report, 1959

Concerns about whether the colonial patent system was approaching for a developing country emerged after India gained its independence. In order to review the current patent legislation and suggest changes, the Indian government established the Justice N. Rajagopala Ayyangar Committee in 1957⁸. The committee's 1959 report served as the basis for contemporary Indian patent law.

The Ayyangar Committee noted that the current patent system frequently led to monopolistic behaviour by foreign patent holders and failed to support domestic companies. It highlighted that patent protection should promote technical advancement while guaranteeing that inventions were accessible to the general public at fair pricing. In order to prevent the abuse of patent rights, the committee strongly advised restricting patent monopolies in fields that impact public health and enacting laws like mandatory licensing.

One of the most important reports in the history of Indian intellectual property law, the Ayyangar committee's recommendations were ultimately included in the patents Act, 1970.

The Patents Act, 1970

The Patents act, 1970, which went into effect in 1972, was passed by parliament in response to

⁷ Indian Patents and designs Act 1911(Act II of 1911)

⁸ N Rajagopala Ayyangar, Report on the Patents Law (Government of India, 1959)

the Ayyangar committee's recommendations. By giving the public interest and national development more weight, the act signalled a dramatic change in India's patent policy.

The elimination of product patents for food, chemicals, and medicines was one of the most significant aspects of the 1970 Act. Instead, in these industries, only process patents were allowed. This created competition and significantly reduced drug prices by allowing Indian pharmaceutical businesses to produce medications using different methods. The program significantly increased access to reasonably priced medications and contributed to the expansion of India's pharmaceutical sector.

Important protections were also added by the act, such as mandatory licensing, regulations requiring protected innovations to be developed in India, and the revocation of patents should promote economic development, public welfare, and scientific advancement in addition to granting private monopoly rights.

India's Obligations under the TRIPS Agreement

India's 1995 entry into the world trade organization (WTO) was a significant turning point in the development of Indian patent law. The Agreement on Trade-related Aspects of Intellectual property rights (TRIPS Agreement) Which set basic requirements for the defence and enforcement of intellectual property rights, bound India as a WTO member. Members of the TRIPS Agreement were required to submit product patent in all technological domains, including agricultural chemicals and medicines. India had to change its patent laws during the agreement's transaction period since the patents act, 1970 did not completely comply with these standards.

Simultaneously, the TRIPS Agreement acknowledgement that member governments had the authority to take the necessary steps to safeguard public health and stop patent misuse. It explicitly allowed for mandatory licensing under specified circumstances, enabling nations like India to uphold public safety measures.

Amendments to the Patents Act

To comply with the TRIPS Agreement, India amended the Patents Act in three phases.

The Patents (Amendment) Act, 1999 Introduced the "mailbox" mechanism for accepting patent applications for agricultural and medical chemicals and established Exclusive Marketing Rights (EMRs).

The Patents (Amendment) Act, 2002 introduced considerable modifications to the patent system by increasing the patent period from fourteen years to twenty years, revising the criteria

for patentability, strengthening enforcement measures, and implementing procedural reforms. While maintaining clauses that safeguarded the public interest, these changes attempted to bring Indian patent law closer to international norms.

The major change occurred through the Patents (Amendment) Act, 2005, which reinstated products patents medicines and chemical innovations in conformity with TRIPS Agreement. The provisions pertaining to compulsory licensing under section 84 to 94 were kept by Parliament, despite the fact that this amendment strengthened patent protection. It also introduced additional safeguards, such as section 3(d), to prevent the granting of patents for minor modifications of existing inventions without enhanced efficacy. These regulations highlighted India's commitment to balancing innovation with public benefit.

The Doha Declaration and Public Health

The legal foundation for mandatory licensing was further reinforced in 2001 with the ratification of the Doha declaration on the TRIPS Agreement and public health. The declaration reaffirmed that the TRIPS Agreement should be construed in a way that upholds public health protection and encourages universal access to medications. It acknowledged that each member state has the authority to choose the criteria for granting mandatory licenses.

India's policy of upholding mandatory licensing as a crucial defence against the abuse of patent rights, especially in circumstances involving public health emergency and access to necessary medications, was reaffirmed by the Doha declaration.

Contemporary Patent Law in India

India's current patent system aims to strike a balance between two crucial goals: promoting innovation by defending inventor's rights and making sure that patent protection does not negatively impact the public interest. The patent Act, 1970, as modified, includes a number of protections against the misuse of patent monopolies, such as mandatory licensing, government use of patents, and patent revocation under certain conditions.

The practical importance of these protection was illustrated by the historic ruling in Bayer Corporation vs NACTO Pharma Ltd. (2012), which resulted in the granting of India's first mandatory licensing for a patented anti- cancer medication. The ruling recognised that patents serve more general societal and economic goals in addition to being private rights.

India's efforts to establish a fair intellectual property system that fosters innovation while guaranteeing access to necessary technologies and medications are demonstrated by the development of patent law in the nation. India's commitment to safeguarding the public welfare

without compromising the legal rights of patent holders is shown in the inclusion and ongoing maintenance of mandatory licensing under the Patents Act of 1970 is based on this historical history.

Meaning Of Compulsory Licensing:

For a certain amount of time, a patent gives an inventor the exclusive authority to create, use, market, or issue licenses for their inventions. By enabling inventors to recoup the time, money, and effort required to create new goods and technology, this exclusive right promotes innovation. Patent rights are not unqualified, though. To prevent the exercise of these rights from negatively impacting the public interest they are subject to specific restrictions. The idea of mandatory licensing is one of the most significant restrictions.

A government or other appropriate body may allow an individual or organization to utilise a patented innovation without the patent holder's permission through a legal process known as compulsory licensing. Such a license is only given in certain legally mandated situations and is often accompanied by the patent owner receiving a fair amount of remuneration or royalties. Therefore, in circumstances where the public interest necessitates such action, compulsory licensing limits the exclusive character of the patent rights rather than depriving the patentee of ownership of the patent.

Ensuring that patents meet their wider social purpose is the main goal of compulsory licensing. In addition to rewarding inventors, patent protection is meant to advance technology and advance society, The law may allow someone else to produce or use a patented innovation through a forced licence if the patented innovation through a forced licence if the patent holder does not make the product available to the public, charges an excessive price, or does not adequately work the invention. This system guarantees that the advantages of invention are distributes more broadly and aids in preventing the abuse of patent rights.

In India, compulsory licensing is governed by the Patents Act, 1970, particularly Sections 84 to 94. These laws authorise the controller of patents to give compulsory licenses in instances where the reasonable requirements of the public are not being satisfied, the patented innovation is not offered at a fairly affordable price, or the invention is not worked in the territory of India. The act acknowledges that patents should contribute to industrial growth, public health, and economic prosperity rather than operating just as tools of corporate monopoly.

In the pharmaceutical industry, the idea of mandatory licensing has become especially significant. Patented drugs are generally expensive because pharmaceutical companies devote enormous resources in research and clinical studies. While patent protection fosters medical innovation, overly high pricing may render vital medications unavailable to many people. In such cases, compulsory licensing acts as a crucial precaution by permitting the manufacturing of inexpensive generic copies of patented medications, according to the criteria set by law. This strategy aims to reconcile the legitimate interests of patent holders with the healthcare requirements of the public.

Compulsory licensing also plays a significant role during national catastrophes, public health crises, or other situations where quick access to patented items is vital. During outbreaks of deadly illnesses or other emergencies, governments may rely on compulsory licensing to assure the timely provision of crucial medications, vaccines, or medical technology. International law also recognizes this flexibility through the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) and the Doha declaration on the TRIPS Agreement and public health, which affirm the right of member states to issue compulsory licenses under specified conditions.

Differentiating between mandatory and voluntary licensing is crucial. In a voluntary license, the patent holder voluntarily allows another party to utilize the patented innovation under terms and circumstances that have been mutually agreed upon. In contrast, a compulsory license is issued by a competent body in compliance with legislative provisions without the patent owner's approval. The patent holder is nonetheless entitled to fair compensation for the use of the patented innovation, when their approval is not necessary.

The historic case of Bayer Corporation vs NACTO Pharma Ltd.(2012), in which the controller of the patents issued the nation's first forced licence for a patented anti-cancer medication, amply illustrated the significance of compulsory licensing as a crucial legal protection against the misuse of patent monopolies and that patent rights should be used in a way that serves the public interest.

Compulsory licensing essentially strikes a delicate balance between two conflicting goals of patent law, promoting innovation by defending inventor's rights and guaranteeing that society has access to necessary ideas at fair costs. It embodies the idea that intellectual property rights

include social obligations in addition to being private rights. Because of this, mandatory licensing is still essential to upholding a just and equitable patent system, especially nations like India.

Legal Framework:

The compulsory licensing provisions under the Patents Act, 1970 reflect India's effort to maintain a fair balance between the interests of patent holders and the needs of society. While the law recognizes the importance of rewarding inventors for their contributions, it also ensures that patent protection does not become an obstacle to public welfare, access to affordable medicines, or technological development.

The framework also demonstrates India's compliance with the TRIPS Agreement by incorporating internationally recognized safeguards while preserving the flexibility available to member states. The landmark decision in *Bayer Corporation v. NACTO Pharma Ltd.* (2012) illustrates the practical application of these provisions and confirms that compulsory licensing is intended to serve as an exceptional remedy in circumstances where public interest outweighs the exclusive rights of the patentee.

Overall, the legal framework governing compulsory licensing under the Patents Act, 1970 establishes a balanced system that protects innovation without compromising public interest. It recognizes that patents are not merely private rights but legal rights accompanied by corresponding obligations towards society. Through these provisions, India seeks to promote both technological progress and equitable access to essential inventions.

Legal Framework Governing Compulsory Licensing under the Patents Act, 1970

Section 83 to 94 of the Patents Act 1970, provide the main legislative foundation for compulsory licensing in India. These clauses specify the guidelines, justifications, process, and requirements for issuing mandatory licenses. They demonstrate the legislature's goal to guarantee that patent rights be used in a way that both fosters innovation and safeguards the greater public interest. The act acknowledges that while patent holders are entitled to exclusive rights over their ideas, these rights shouldn't be used in a way that impedes technological advancement or limits public access to necessities.

India's dedication to upholding a fair patent system is shown in the mandatory licensing rules. By preventing patent monopolies from acting against the interests of society, they guarantee

that patent protection promotes innovation. The following section discusses the key legal requirements pertaining to mandatory licensing.

Section 83 – General Principles Applicable to Working of Patented Inventions

The board guidelines that direct interpretation and application of the mandatory licensing regulations are outlined in section 83. It states that patents are given not only to provide patentees exclusive rights but also to stimulate creativity, advance technical advancement, and guarantee that the advantages of patented innovations are accessible to the general public at fair rates.

The provision further states that patents should support the advancement of technology and the dissemination of information and should not be misused by the patent holder. These tenets serve as the cornerstone of India's mandatory licensing system and are taken into consideration while evaluating applications for mandatory licenses.

Section 84 – Grant of Compulsory Licences

The main law governing mandatory licensing in India is section 84. After three years have passed after the patent was granted, any interested party may seek for a compulsory licence.

A compulsory licence may be granted on any of the following grounds:

- The public's legitimate demands about the patented innovation have not been met,
- The public cannot purchase the patented innovation at a reasonable cost,
- The patented invention is not used on Indian soil.

When evaluating such an application, the controller of patents looks at the case's circumstances, the applicant's attempts to get a voluntary license, the innovation's character, and the applicant's capacity to use the invention successfully. The balance between safeguarding the patent holder's rights and making sure society gains from the protected technology is reflected in section 84.

Section 85 – Revocation of Patents

Section 85 empowers the Controller the authority to cancel a patent if the circumstances that led to its issuance persist even after a mandatory license has been granted. The patent may eventually be withdrawn if the patent holder continues to fail to meet the legitimate needs of the public or make the innovation cheap.

This clause encourages patent holders to fulfil their legal and social obligations while serving as a barrier against ongoing abuse of intellectual rights.

Sections 86 to 91 – Procedure and Terms of Compulsory Licensing

These sections outline the process for handling applications for mandatory licenses as well as the controller's authority to award them.

They address issues like :

- Examination of the application.
- Notice to the patent holder.
- Opportunity of hearing.
- Determination of the terms and conditions of the licence.
- Payment of reasonable royalty to the patent holder.
- Protection of the legitimate interests of both parties.

With the public interest as first priority the controller must make sure the license is given on fair, reasonable, and non- exclusive conditions.

Section 92 – Special Provision in Cases of National Emergency

The central Government may declare under section 92 that compulsory licenses may be issued in the following circumstances:

- There is a National Emergency,
- Severe urgency,
- Non-Commercial public usage.

In many situations, obtaining a voluntary licensing from patent owners may not be necessary, enabling quicker access to necessary, enabling quicker access to necessary patented goods. When there are epidemics, natural catastrophes, Public health emergencies, or other circumstances that call for quick government action, this clause becomes especially crucial.

Section 92A – Compulsory Licence for Export of Pharmaceutical Products

In order to achieve its international commitments under the TRIPS Agreement and the Doha declaration on Public Health, Section 92A was enacted. It enables the issuance of mandatory licenses for the production and export of patented medicinal goods to nations with inadequate or non-existent manufacturing capability. While adhering to international intellectual property commitments, this clause aims to make inexpensive medications more accessible in poor and least-developed nations.

Sections 93 and 94 – Supplementary Provisions

Additional regulations pertaining to mandatory licensing are included in section 93 and 94.

They handle issues pertaining to the administration, continuation, and termination of mandatory licenses and guarantee the efficient operation of the legal framework. These clauses aid in maintaining operations of the legal framework. These clauses aid in maintaining equality in the application of the mandatory licensing system and offer procedural clarity.

Significance of the Legal Framework

The compulsory licensing provisions of the Patents Act, 1970 demonstrate India's endeavour to strike a fair balance between the interests of patent holders and the requirements of society. While the legislation acknowledges the significance of compensation inventors for their efforts, it also assures that patent protection does not become a hindrance to public welfare, access to inexpensive medications, or technical growth.

By combining globally recognised protections while maintaining the freedom afforded to member states, the framework also shown that India complies with the TRIPS Agreement. The historic ruling in Bayer corporation vs NACTO Pharma Ltd. (2012) demonstrates how these rules are put into practice and meant to be used as an extraordinary remedy where the public interest surpasses the patent holder's exclusive rights.

In general, the Patents Act of 1970's legislative foundation for mandatory licensing creates a fair system, that safeguards innovation without sacrificing the general welfare, It acknowledges that patents are legal rights with associates social duties rather than just private rights. India hopes to advance both technical advancement and fair access to necessary technologies through these rules.

Grounds For The Grant Of Compulsory Licence:

The patents Act of 1970 acknowledges that although patents are awarded to honour inventors and promote innovation, a patent holder's exclusive rights should not work against the interest of society. The act allows for the issuance of mandatory licenses in certain situations to guarantee the responsible use of intellectual rights. The patents act of 1970's section 84 contains the majority of these grounds, with additional provisions under section 92 and 92A for extraordinary circumstances such national emergencies and the export of medicinal items. The idea that patent protection should encourage technical advancement while also guaranteeing that the public has adequate access to necessary inventions is reflected in the grounds for awarding a compulsory licence, The main justifications are covered here.

Reasonable Requirements of the Public

When the public's legitimate needs regarding the patented innovation are not met, this is one of the main reasons for issuing a compulsory licence. This indicates that the patented technique or product is either unavailable in large enough quantities or cannot satisfy the public's genuine demands.

A patent holder is not required by law to simply own a patent without making the innovation available. The controller of patents may think about issuing a mandatory licence if the demand for the patented innovation is far higher than its supply or if just a small portion of society may get it. Instead than limiting access to significant inventions, this clause aims to guarantee that patents advance public welfare.

The controller may look at things like the product's availability, the breadth of its distribution, and whether the patentee has really taken action to meet market demand when assessing whether the reasonable demands of the public have been satisfied.

Non-Availability at a Reasonably Affordable Price

The fact that the patented innovation is not reasonably priced for the general public is another significant justification for mandatory licensing. Given the time and money invested in research and development. A patent holder is entitled to a fair return on investment. This right, however, does not include setting prices that prevent the majority of people from obtaining necessities. In the pharmaceutical industry, where life-saving medications may be offered at costs that are beyond of the reach of many consumers, this ground is especially important. The controller may give a compulsory license to allow another manufacturer to produce and market a patented medication at a cheaper cost if it is only offered at an unreasonably priced alternatives. The use of this ground is demonstrated by the historic ruling in Bayer Corporation vs NACTO Pharma Ltd.(2012). The controller noted that most Indian patients could not afford the patented anti-cancer medication due to its exorbitant cost. As a result, a mandatory license was issued to guarantee more public access to the medication at a much reduced cost.

Patent Not Worked in the Territory of India

The patented innovation is not being used on Indian soil, which is the third main argument under section 84. In general, the phrase "worked in India" alludes to the patented invention's economic exploitation within the nation. It expresses the belief that patents should not just be used as a tools for importation or market control, but also to support indigenous industrial growth and scientific advancement. The controller may consider issuing a compulsory license

to a patent holder who secures a patent in India but does not develop production facilities, manufacture the product, or otherwise make reasonable steps to use the innovation within the nation.

Nonetheless, there has been legal discussion on the definition of “Working” of a patent. While some say that local manufacture is necessary, others assert that the patented goods may, under specific conditions, be imported into India. As a result, each application must be evaluated according to its unique facts and circumstances.

National Emergency or Circumstances of Extreme Urgency

Apart from the conditions listed in section 84, section 92 enables the Central Government to sanction the award of compulsory permits under instances involving a national emergency, circumstances of exceptional urgency, or public non-commercial usage. These circumstances typically occur when it becomes necessary for general public to have instant access to patented goods. Examples include major outbreaks of illnesses, natural catastrophes, or other situations affecting public health and national security.

Unlike applications under section 84, the obligation of first seeking to secure a voluntary licence from the patent holder may be waived in such instances. This lets the government to move promptly and guarantee that important medicines, Vaccines, or other patented innovations get available without excessive delay.

This clause was included because it acknowledges that temporary restrictions on exclusive patent rights may occasionally be necessary for general good.

Export of Pharmaceutical Products to Countries with Insufficient Manufacturing Capacity

By allowing the production and export of patented medicinal items to nations with insufficient manufacturing capability, section 92A creates another significant justification for mandatory licensing. This clause, which was added in response to the Doha declaration on the TRIPS Agreement and public health, allows India to provide reasonably priced medications to developing and least-developed nations that are struggling with public health issues.

The controller must confirm that the importing nation has either issued its own mandatory license or has otherwise approved the import of the pharmaceutical product in compliance with international law before providing such licence. This clause shown India’s dedication to international public health while adhering to its TRIPS Agreement commitments.

Factors Considered by the Controller

In addition to the statutory grounds, the controller of patents takes in account a number of pertinent criteria when making a decision about an application for a compulsory licensing.

Among them are:

- The patented invention's nature and significance.
- The amount of time that has passed since the patent was granted.
- The applicant's attempts to get the patent holder to provide a voluntary licence.
- The applicant's capacity to efficiently produce and distribute the claimed invention.
- The applicant's ability to satisfy the public's reasonable demands.
- The public's and the patent holder's interests.

These factors guarantee that mandatory licenses are only issued following a through assessment of all pertinent factors.

Importance of the Grounds for Grant

Maintaining an equitable balance between private intellectual rights and the public interest depends heavily on the criteria used to issue compulsory licenses. They promote access to reasonably priced goods, especially necessary medications, prevent the abuse of patent monopolies, and encourage patent holders to share their ideas with the public.

These clauses also reflect India's overreaching policy goal of making sure that patents support social welfare, industrial expansion, and technical advancement. However, mandatory licensing continues to be an unusual cure rather than the norm. until the legal requirements for intervention are made apparent, patent holders maintain their exclusive rights over their creations.

As a result, the reasons outlined in the Patents Act of 1970 provide a significant legal protection that safeguards both the public interest and creativity. They guarantee that the patent system serves as a tool for advancing society's greater interests in addition to compensating innovators.

Procedure for Obtaining a Compulsory Licence:

In addition to outlining the conditions under which a forced license may be given, the patents act of 1970 establishes a thorough process to guarantee that these licenses are awarded in a way that is equitable, open and complaint with the law. The legislation offers procedural protections to protect the interests of both the patentee and the applicant because the granting of a compulsory license restricts the exclusive rights of a patent holder.

The process seeks to strike a balance between conflicting objectives. On the one hand, it guarantees patent holders a fair chance to protect their rights. However, when the legal criteria are met, it allows worthy applicants to get authorisation to utilise a patented idea. Examining applications, assessing evidence, and deciding whether to award a mandatory licence are all crucial tasks for the controller of patents.

Below are the discussion of the main steps in acquiring a mandatory licence.

Eligibility to Apply

Any interested party may apply for the issuance of a compulsory licence under section 84 of the patents act, 1970, three years after the patent was issued.

Manufacturers, pharmaceutical firms, academic institutions, governmental organisations, and anybody else who can show a legitimate economic or public interest in the copyrighted innovation are all considered “person interested” in this wide sense. The applicant must, however, demonstrate that the application was submitted in good faith and that they are capable of using the claimed innovation.

Filing of the Application

In compliance with the patent rules, 2003, the applicant must formally file an application to the controller of patents. The legislative basis or grounds on which the obligatory permission is required should be explicitly stated in the application.

Typically, the applicant must supply information like:

- The species of the innovation that was patented,
- All the justifications mentioned in Section 84,
- Proof that the patented innovation is not produced in India, the public’s reasonable needs have not been met, or the product is not reasonably priced,
- Data proving the applicant can successfully produce or use the claimed invention.

The controller can evaluate the request’s merits objectively if the application is well recorded.

Efforts to Obtain a Voluntary Licence

The applicant is often expected to make reasonable attempts to get a voluntary licence from the patent holder on acceptable commercial terms and conditions prior to requesting a compulsory licence.

This criterion is meant to promote voluntary licensing and negotiation prior to the use of

coercive measures, the applicant must show that sincere endeavours were made to get the patent holder's approval, but that these attempts failed within a reasonable time frame

However, under circumstances described by section 92, such as national crises, situations of exceptional urgency, or public non-commercial use, this provision is not applicable. In some situations, the controller may issue a mandatory licence without first consulting the patents owners

Examination by the Controller of Patents

The controller carefully considers whether the legislative criteria have been met after receiving the application. The procedure's most crucial step is this one. The controller takes into account a number of aspects, such as:

- Whether the public's legitimate demands are being satisfied,
- Whether the patented invention is affordably priced,
- Whether the innovation is being developed in India,
- The applicant's attempt to secure a voluntary licence,
- The technical and financial capacity of the applicant to produce or employ the patented innovation,
- The patented invention's nature and importance.

The Controller evaluates all available evidence before making a decision.

Notice to the Patent Holder

The controller notifies the patent holder when the application is determined to be maintainable. This guarantees adherence to natural justice norms, especially the right to be heard. The patent holder has the chance to protest, provide supporting documentation, and explain why the mandatory license shouldn't be approved.

The patent holder may contend that the product is appropriately priced, that public needs have already been satisfied, or that adequate efforts have been made to implement the innovation in India. Fairness and openness in the decision-making process are ensured by giving both sides a chance to make their case.

Hearing of the Parties

When required, the controller holds a hearing to review the arguments put forth by the patent holder and the applicant. Each side may submit legal arguments, supporting documentation, expert views, and other pertinent items throughout the hearing. In order to establish whether

the legislative requirements for issuing a compulsory licence have been met, the controller looks at the circumstances and assesses the evidence.

In complicated pharmaceutical or technological instances where comprehensive technical proof can be needed, this step is very crucial.

Decision of the Controller

The collector issues a well-reasoned order approving or rejecting the mandatory licence after taking into account all the reasons and supporting data. The collector documents the reasons for rejection if the application is turned down. The controller outlines the license's scope and the terms under which it is given if the application is approved.

The patents act of 1970's provisions and the evidence offered throughout the procedures must serve as the foundation for the determination.

Determination of the Terms and Conditions

The controller establishes the terms and circumstances in compliance with section 90 of the patents act when a mandatory licence is granted.

While addressing these issues, the controller aims to guarantee that:

- The patent holder is paid a fair royalty or compensation,
- The main purpose of the licence is to meet the demands of the Indian market,
- The licence remains non-exclusive
- Except in specific situations, the licence cannot be transferred,
- The public is granted reasonable access to the patented innovation.

The goal is to advance public benefit while defending the legitimate interests of the licensee and the patent holder.

Grant of the Compulsory Licence

The controller formally issues the mandatory licence after the conditions have been established, following that, the licensee is permitted to produce, utilise, or market the patented inventio in compliance with the license's terms. Nonetheless, the patent holder maintains ownership of the patent and all rights unaffected by the mandatory license. Therefore, compulsory licensing only allows another individual to utilise the copyrighted idea with legislative permission rather than transferring ownership.

Appeal Against the Decision:

According to the patents act, anybody who feels wronged by the controller's decision may contest the order in the relevant court. Before making a judgement, the appeal authority considers whether the controller has appropriately evaluated the facts, accurately interpreted the legislation, and followed all procedural procedures.

The presence of appeal process enhances the compulsory licensing mechanism's accountability and fairness.

TRIPS Agreement:

The protection of intellectual property rights is becoming a crucial component of international law due to the growing globalisation of commerce and technological innovation. A universal framework that would establish basic criteria for the protection and enforcement of intellectual property rights across various nations became necessary as firms and inventions started to cross national boundaries more regularly. As part of the creation of the World Trade Organization (WTO), the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was adopted in response to this requirement and went into effect on January 1, 1995⁹.

One of the most important international accords controlling intellectual property rights is the TRIPS Agreement. It sets minimal requirements that all WTO member nations must adhere to for the protection of patents, copyrights, trademarks, industrial designs, geographical indications, and other types of intellectual property. However, the agreement acknowledges that economic growth and public welfare shouldn't be hampered by intellectual property protection. As a result, it includes a number of protections that enable member nations to deal with matters pertaining to public health, medication availability, and the avoidance of patent misuse.

The idea of mandatory licensing is one of the most significant protection offered by the TRIPS Agreement. Under certain restrictions, Article 31 of the Agreement allows member nations to approve the use of a protected innovation without the patent holder's permission. This clause expresses the knowledge that although being crucial for fostering innovation, patent rights are

⁹ Agreement on Trade Related Aspects Of Intellectual Property Rights

not unqualified and may be restricted when more significant public interests are at stake. Therefore, governments can use compulsory licensing as legal tool to strike a compromise between the rights of patent holders and the requirements to provide access to necessities, especially pharmaceuticals and medical technology.¹⁰

The TRIPS Agreement's mandatory licensing clauses are very important for emerging nations like India. They offer the adaptability to address public health requirements while adhering to global intellectual property commitments. Through the patents act, 1970, especially sections 84 to 94, which allow for the issuance of mandatory licenses under certain conditions, India has integrated these flexibilities into its domestic legal structure.

The Doha Declaration on the TRIPS Agreement and Public Health, which was adopted in 2001, further demonstrated the significance of these clauses. The declaration reiterated that the TRIPS Agreement should be read and used in a way that supports public health protection and encourages universal access to medications. It made clear that WTO member states have the sovereign authority to decide whether to provide mandatory licenses and to respond appropriately to public health emergencies.

In light of this, this chapter looks at the TRIPS Agreement's mandatory licensing clauses and how they affect the Indian patent system. It talks about the Doha Declaration's importance, the pertinent sections of article 31, and how India incorporated these global values into The Patents Act of 1970. The chapter also assess how the TRIPS Agreement aims to strike a compromise between the protection of intellectual property rights and the more general goals of public welfare and access to necessary medications.

Comparative Study of Compulsory Licensing in Different Countries:

India is not the only country with mandatory license. To guarantee that patent rights are used in a way that serves the public interest, a number of nations have included clauses pertaining to mandatory licensing in their patent legislation. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) recognises the idea globally, but each nation has created its own legal framework depending on its industrial policies, healthcare goals, and economic circumstances.

¹⁰ Article 31 of TRIPS Agreement – Other use Without Authorization Of The Right Holder

India

Among emerging nations, India has one of the most extensive mandatory licensing systems. Section 84 to 94 of the Patents Act of 1970 include the requirements pertaining to mandatory licensing. The legislation allows for the issuance of a mandatory license in situations where the public's reasonable needs are not satisfied, the patented technology is not reasonably priced, or it is not developed inside Indian territory.

Public interest concerns have a significant impact on India's strategy, especially in the pharmaceutical industry. In *Bayer Corporation vs NACTO Pharma Ltd.* (2012), the first mandatory licence was granted, indicating India's readiness to employ this approach in cases when necessary medications are too expensive for average consumers. However, India views mandatory licensing as an extraordinary solution rather than a standard one. The legal system seeks to safeguard innovation while preventing patents from impeding public welfare, healthcare, and technological advancement.

United States

Compulsory licensing is handled very differently in the United States. Protecting patent holder's exclusive rights and promoting innovation via robust intellectual property protection are major goals of American patent law. Because of this, standard patent law seldom grants forced licenses.

Rather, in the US, mandatory licensing often occurs under certain conditions, such as government use of patent technology, antitrust enforcement, or settlements pertaining to competition law. Federal law permits the government to employ patented innovations for public use while paying the patent holder. Additionally in situations involving abuse of market dominance or anti-competitive behaviour, courts and regulatory bodies may mandate licensing. In general, the USA has a market-oriented stance, placing more emphasis on patent protection and depending more on government authority and competition legislation than on extensive mandatory licensing regulations.¹¹

United Kingdom

Under the Patent Act of 1977, the UK recognises compulsory licensing, albeit these licenses are only given in specific situations. Applications are often taken into consideration when Anti-

¹¹ Title 35 of USC – Federal Laws Governing U.S. patent Law and Intellectual Property Rights

Competitive activities impact the availability of patented innovations or when the public's reasonable requirements are not being met.

In the UK, striking a balance between the public interest and private rights is highly valued. Authorities carefully consider whether voluntary licensing has been undertaken, if the applicant is capable of exploiting the innovation, and whether granting the licence will serve the public interest before issuing a forced licence. Because negotiated licensing agreements are preferred, mandatory licenses are really rarely issued. However, the laws are still in place as a crucial defence against the misuse of intellectual rights.

Comparative Analysis

Despite the fact that all of the aforementioned nations acknowledge patent protection as a crucial motivator for innovation, they have somewhat different stances on mandatory licensing. Public health and inexpensive access to medications are more important in Thailand, Brazil, and India. Their rules offer somewhat more expensive justifications for mandatory licensure, especially in situations where necessary medications are unavailable or too costly. Compulsory licensing is seen in these nations as a crucial tool for advancing public welfare and limiting the misuse of patent monopolies.

The united states, on the other hand, has a more stringent stance, depending more on competition law, government usage regulations, and antitrust remedies than on board mandatory licensing. By Acknowledging mandatory licensing but using it rarely and promoting voluntary licensing wherever feasible, the United Kingdom takes a medium ground.

All jurisdiction recognise that patent rights are not unqualified, notwithstanding these variations. Every legal system acknowledges that when the public interest demands it, extraordinary circumstances may warrant restricting exclusive patent rights, the main distinction is between the conditions under which mandatory licenses may be given and the degree to which governments are ready to use these powers.

Lessons for India and Conclusion

The comparative analysis demonstrates that India's mandatory licensing system is generally compliant with international norms, but it prioritises safeguarding the public interest, especially by guaranteeing reasonably priced access to necessary medications. India's socioeconomic circumstances and dedication to striking a balance between intellectual property rights and public benefit are reflected in this strategy. Simultaneously, the experiences of nations like the United States, Brazil, Thailand and the United Kingdom offer important insights for bolstering

India's patent system. The current system may be further enhanced by promoting voluntary licensing implementing clear compulsory licensing procedures, and successfully utilising competition legislation to stop the abuse of patent rights.

Overall, the analysis shows that mandatory licensing is a globally accepted legal tool that aims to strike a compromise between public welfare and innovation. In order to ensure that patent protection fosters both creativity and fair access to necessary ideas, India's legal system effectively attending to the country's healthcare and developmental requirements.

Advantages and Disadvantages of Compulsory Licensing:

One of the most important protections provided by patent law to guarantee that the exclusive rights granted to patent holders do not conflict with the broader interests of society is compulsory licensing. It aims to strike a balance between promoting innovation and safe guarding the general welfare. Although the technique has many social and economic advantages, entrepreneurs, pharmaceutical corporations and legislators have criticised it. Therefore, assessing its efficacy inside the patent system requires an awareness of both its benefits and drawbacks.

Advantages of Compulsory Licensing

1. Improves Access to Essential Medicines

Enhancing public access to life-saving medicines and other necessities is one of the biggest benefits of mandatory licensing. Patented medications are frequently offered at costs that are too high for the average person to afford. Compulsory licensing boosts the availability of reasonably priced alternatives by allowing another company to create the patented product, which benefits patients and improve public healthcare.

2. Prevents the Misuse of Patent Monopoly

Although patents are meant to encourage innovation, they shouldn't be exploited to establish unjust monopolies that hurt consumers. By guaranteeing that inventions are made available to the public when the legal requirements are met, compulsory licensing stops patent holders from abusing their exclusive rights. It inhibits actions like charging too much, creating fake shortages, or failing to use a copyrighted technology for profit.

3. Promotes Public Interest

Protecting the public interest is the main goal of mandatory licensing. It acknowledges that intellectual property rights include social obligation and that society should eventually profit from innovation. When public welfare is under danger, the mechanism

enables governments to step in, especially in areas like healthcare, food security, and vital technology.¹²

4. Encourages Domestic Manufacturing and Technology Transfer

By allowing local manufacturers to make patented goods domestically, compulsory licensing may aid in the growth of domestic industries. This increases the nation's industrial capacity, fosters technological earning, generates job opportunities and lessens reliance on imports. Additionally, it makes technological transfer easier, which is one of the goals acknowledged by the Patents Act of 1970

5. Provides Flexibility During Public Health Emergencies

During national catastrophes, epidemics, or public health disasters, the significance of mandatory licensing becomes especially clear. In certain circumstances, government can quickly approve the production of crucial medications, vaccinations, or medical devices. This adaptability allows nations to protect public health while responding to crises more skilfully.

Disadvantages of Compulsory Licensing

1. May Reduce Incentives for Innovation

One of the most frequent objections to mandatory licensing is that it may lessen the motivation for pharmaceutical firms and inventors to spend money on R&D. it frequently takes a significant amount of money, effort, and technical know-how to develop a new idea. Innovators may be less inclined to invest in upcoming inventions if they worry that their exclusive rights may be restricted too quickly.

2. Concerns Among Foreign Investors

Multinational corporations and international investors may experience uncertainty if forced licensing is used frequently or in an unforeseen manner. In general. Companies want legal frameworks that offer robust and consistent protection for intellectual property rights. Therefore, excessive usage of mandatory licensing may have an impact on international company confidence and investment choices.

3. Possibility of International Trade Disputes

Even while the TRIPS Agreement recognises compulsory licensing, its application can occasionally cause disputes between nations, especially when multinational pharmaceutical corporations are involved. These conflicts need a careful balance of

¹² Section 83 of the Indian Patents Act, 1970,

international duties with domestic public interest and may present diplomatic or trade-related difficulties.

4. Complex Administrative Process

Obtaining a compulsory licensing includes a comprehensive legal procedure, including filing applications, providing evidence, hearing before the controller of Patents, and compliance with legislative criteria. The intricacy of the procedure may deter potential applicants, especially smaller firms that may lack the requisite financial or legal resources.

5. Risk of Misuse

Compulsory licensing may undermine patent holder's trust and have an impact on the patent system as a whole if it is approved without due consideration. As a result, it is crucial that mandatory licenses be only issued in legitimate situations where legal requirements have been precisely defined. Maintaining the legitimacy of the patent regime requires responsible open implementation.

Challenges in the Implementation of Compulsory Licensing :

Limited Use of Compulsory Licensing

One of the biggest obstacle is that mandatory licensing has only been used infrequently in India. Few applicants have been granted a licence, despite the Patents Act's comprehensive provisions for awarding compulsory licensing. The most prominent example is still Bayer Corporation v. NACTO pharma Ltd. (2012), which was the first and only winning Section 84 forced licensing case in India. The restricted application of mandatory licensing calls into question the practicality and accessibility of the current regulations. Some contend that the intricacy of the legal process and the anxiety of protracted litigation deter prospective applicants from pursuing forced licenses, while others think the low number of licenses shows that the patent system is operating well.

Complex Legal and Administrative Procedure

A number of statutory requirements must be met in order to obtain a compulsory licence, attending hearings, and confirming with the controller that all legal requirements have been met. Although these procedural standards guarantee equality, they may also complicate and lengthen the procedure.

Pursuing mandatory licensing procedures may provide financial and legal challenges for applicants, especially smaller businesses and domestic manufacturers. Because of this, even

though they have good reasons under the act, many qualified candidates may decide not to start the procedure.

Balancing Patent Rights and Public Interest

Finding the right balance between defending the public interest and protecting patent holders is one of the most challenging issues. By compensating innovators for their work and financial investments, patent protection promotes innovation. At the same time, society demands that necessary technology and medications be reasonably priced.

International Pressure and Trade Concerns

Multinational pharmaceutical corporations and certain industrialised nations have periodically criticised India's practice of forced licensing. The granting of forced licenses may occasionally raise questions about the preservation of intellectual property rights and foreign investments because many patented medications are held by foreign businesses.

Affordability Versus Innovation

Finding a balance between the need to promote future innovation and the affordability of patented items is another significant difficulty. It takes a significant financial commitment, years of science study, and a high level of commercial risk to develop new medications and technology. Innovators have the chance to recoup these investments thanks to patent protection. However, governments may need to step in through mandatory licensing when patented goods are too expensive for the general people. The difficulty is in making sure that such an intervention preserves consumer welfare and public health without deterring future investments in research and development.

Interpretation of "Working of Patent"

One of the most contentious features of mandatory licensing has been the need that a patented innovation be "worked the territory of India". There are sometimes questions about whether this condition may be importing a patented product into India or if the innovation needs to be made there.

Due to conflicting interpretations brought about by the lack of a clear legislative definition, patent holders and applicants are left in the dark. The mandatory license regulations would be implemented more consistently if this obligation were made clearer.

Public Awareness and Institutional Capacity

Many domestic manufacturers, research organisations, and small businesses are still unaware of mandatory licensing. It's possible that many prospective applicants are unaware of the conditions under which mandatory licenses can be issued or how to apply for them.

Additionally, quick application disposal and competent patent administration are essential to the successful implementation of mandatory licensing. The practical efficacy of the mandatory licensing regime would be improved by bolstering institutional capacity, raising awareness, and offering clear administrative advice.

Suggestions by the author:

Simplifying the Procedure for Granting Compulsory Licences

Even though the patents Act specifies a through method for acquiring a mandatory licensing, applicants frequently find the process to be challenging and time-consuming. Genuine applicants, particularly small and medium-sized businesses, may be deterred by the need to submit copious amounts of documents, provide proof, attend hearings, and comply with numerous legal requirements.

The process should be made more efficient and transparent in order to increase the system's efficacy. The patent office may publish through process instructions including the necessary paperwork, the phases of review, and the anticipated timeframes for applicant and the patent holder are sufficiently safeguarded, a streamlined and clear process would cut down on needless delays.

Providing Greater Clarity in Statutory Provisions

Some phrases used in the Patents Act, such "reasonable requirements of the public," and "worked in the territory of India," are purposefully wide in order to be applicable to many factual circumstances. This flexibility, nevertheless, can occasionally result in ambiguity and uneven interpretation.

Regarding the interpretation of these statements, the Indian patent office and the government have to think about releasing comprehensive guidelines or guidelines or practice instructions. Such guidelines will lessen needless disagreements and litigation while assisting patent holders, applicants, and adjudicating bodies in applying the law more consistently.

Encouraging Voluntary Licensing Before Compulsory Licensing

Instead of being the initial line of action, compulsory licensing should remain an uncommon

measure. Whenever feasible, voluntary licensing agreements should be used to settle conflicts between patent holders and interested producers.

Both parties can frequently negotiate advantageous conditions pertaining to royalties, production, distribution and technology transfer through voluntary licenses. By implementing medication procedures or regulatory incentives that foster collaboration between manufacturers and inventors, the government may support such talks. This strategy would increase public access to patented technologies while maintaining business ties.

Strengthening Public Health Preparedness

During public health catastrophes, availability to medications, vaccinations and medical technology may become a national concern, as the covid-19 pandemic showed. Even though the patents act has provisions for mandatory licensing in cases of extraordinary urgency or national emergency, successful execution necessitates careful preparation and collaboration.

Future health emergencies should be addressed by the government through well-defined institutional structures. When mandatory licensing is required, coordination between the patent office, public health authorities, pharmaceutical procedures, and readiness would guarantee that the supply of necessary medical supplies is not hampered by legal proceedings.

Promoting Domestic Research and Innovation

Innovation should not be replaced by mandatory licensing. Rather it should work in tandem with national policies that promote technical advancement and research.

Universities, research centres, new businesses, and local pharmaceutical manufacturers conducting scientific research should receive more funding. India's innovation ecosystem may be strengthened by government initiatives. The nation will become less reliant on foreign innovations as local research capability increase while preserving a sound balance between patent protection and public benefit.

Creating Greater Awareness About Compulsory Licensing

The legislative requirements regulating compulsory licensing and the conditions under which such licenses may be given are not well understood by many companies, research institutes, healthcare organisations, and smaller manufacturers awareness campaigns, workshops, and training sessions outlining the legal framework, application process, and rights and obligations of stakeholders should be held by the Indian patent office, educational institutions and professional associations. Increased knowledge would promote the legitimate application of

mandatory licensing while avoiding misconceptions about its intent and extent.

Improving Institutional Capacity

The effectiveness of the patent office is crucial to the successful implementation of mandatory licensing. The quality and speed decision-making may be greatly enhanced by enough personnel, frequent training of patent officers and examiners, and the use of contemporary digital technology.

Confidence in the patent system would rise if application processing times were shortened and prompt hearings were guaranteed. By increasing clarity and lowering needless litigation, efficient administration would be advantageous to both patent holders and applicants.

Maintaining a Balance Between Innovation and Public Interest

The most crucial recommendation is probably to keep enforcing mandatory licensing in a sensible and balanced way. Because it motivates innovators to spend money on research and development, patent protection is crucial, however, the public interest demands that necessary medications and technology continue to be available and reasonable priced.

Favouring patent holders or consumers of patented innovations should not be the goal. Rather, mandatory licensing ought to be used only in extraordinary situations where the legal requirements are unquestionably met. A well-rounded strategy would guarantee that intellectual property rights continue to serve society's greater good while maintaining incentives for innovation.

Strengthening International Cooperation

India should keep working with international organisations like the World Trade Organisations (WTO) and the World Intellectual Property Organizations (WIPO) as intellectual property rights operate more and more in global setting. India's mandatory licensing system may be improved by exchanging experiences, taking part in global conversations and study other nation's approaches.

Additionally, international collaboration fosters the sharing of best practices in the areas of innovations, technology transfer, and medication access, as well as more uniformity in the interpretation of TRIPS flexibilities.

Conclusion:

One of the most important protections under the Indian patent system is compulsory licensing, which guarantees that patent holder's exclusive rights are used in a way that advances society as a whole. The notion of compulsory licensing under the Patents Act of 1970 has been investigated in this study through an analysis of its structure, historical history, reasons for grant, procedural requirements, and relevance to international commitments under the TRIPS Agreement. The report also looked at significant court rulings, contrasted India's strategy with those of other countries and critically analysed the benefits, drawbacks, difficulties and potential enhancements to the current system.

According to the research, mandatory licensing is not meant to reduce patent protection or deter innovation. Instead, it serves as a unique legal tool that guarantees patent rights are used appropriately and do not impede the general benefit. The Indian legal system aims to achieve a delicate balance between rewarding inventors for their inventiveness and guaranteeing that vital innovations, especially pharmaceuticals and medical technology, continue to be fairly accessible to the general population. This well-rounded strategy mirrors the larger goal of patent law, which is to guarantee that technological advancement benefits society overall in addition to fostering creativity.

The analysis also shows that although India's mandatory licensing laws are extensive and generally in line with international norms, their application is nonetheless hampered by a few real-world issues. Continuous attention is needed to issues such as procedural complexity, low awareness, interpretational difficulties and the need to strike a balance between innovation and public interest. The efficacy of the current framework would be strengthened without jeopardising the lawful rights of patent holders if these issues were addressed through more institutional capacity, better administrative efficiency and clearer rules.

To sum up, mandatory licensing is still a crucial part of the Indian patent system. It encourages innovation and the general benefit when used equitably, openly, and only in suitable situations. A well-balanced and well-executed compulsory licensing system will be essential to ensuring that intellectual property rights support social justice, equitable access to necessary inventions, economic growth and sustainable national development as India advances in science, technology and healthcare.

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