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COMPULSORY LICENSING AND PUBLIC HEALTH: LAW, ACCESS AND PHARMACEUTICAL POWER

AUTHORED BY - B. GIRIPRASAD
B.CA., LL.B(Hons), LL.M

CO-AUTHOR - B. KEERTHANA
B.A., LL.B, LL.M

VELS INSTITUTE OF SCIENCE TECHNOLOGY & ADVANCED STUDIES (VISTAS)
SCHOOL OF LAW Pallavaram, Chennai- 600 117

ABSTRACT:

Compulsory licensing has come to be recognized as a critical tool in patent law that helps to strike a balance between the interests of pharmaceutical companies and the need for the public to have access to cheap medicines. In the Indian scenario, the patent law provides a limited monopoly to the inventor for a certain period of time, which has been further reinforced after the amendment to the Patents Act, 1970, in 2005, when product patents were extended to the pharmaceutical industry. Although patents provide a stimulus to innovation and allocate resources to R&D, they also provide pharmaceutical companies with considerable flexibility over the pricing and distribution of medicines, making them unaffordable to the common man at times(Son et al. 2019).The principle of compulsory licensing allows the government to permit the production of a particular patented drug without the prior consent of the patent owner under certain circumstances. This provision has immense relevance in the context of developing countries like India, where a large number of people depend on cheap generic medicines. Compulsory licensing has a significant interface with public health, access to medicines, and the right to life guaranteed by the Indian Constitution. This study examines the role of compulsory licensing in Indian law and its effectiveness in improving access to medicines. It explores the relevant provisions of the law, key judicial pronouncements (including the Nexavar decision), international agreements such as TRIPS, and recent developments, including those arising out of the COVID-19 pandemic (Flynn et al. 2009). The results show that although there are adequate legal provisions in place to support compulsory licensing, its implementation in practice is impeded by political sensitivities, industry pressure, and bureaucratic delays. The paper argues that compulsory licensing needs to be utilized more

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effectively to protect public health while maintaining the innovation incentives for pharmaceutical investments.

KEYWORDS:
Compulsory license, public health, patent, Incentives, pharmaceutical investments, Medicines.

INTRODUCTION:

Medicines are not like other commodities that you purchase off the shelf. They are the sine qua non of life itself and are directly related to the right to life and health. In a nation like India, where a large number of people are of limited means, being able to afford medicines is not merely a market consideration—it is a matter of grave public health importance. At the same time, pharmaceutical companies invest heavily in research and development to develop new drugs. Patenting gives these companies a monopoly for a period of time so that they can recover their investments and make profits.

The patenting regime in India seeks to balance these two considerations. Prior to 2005, India permitted only process patents for medicines, which facilitated the growth of a large generic drug industry. This meant that Indian companies could develop new drugs at a lower cost by using different processes (Meiners et al. 2011). However, after becoming a member of the World Trade Organization, India was forced to introduce product patents for medicines through the Patents (Amendment) Act, 2005.Product patents meant that the pharmaceutical industry had greater control over their drugs. This led to fears about increased prices and lack of access. However, the Indian patenting regime retained an important safeguard in the form of compulsory licensing. This allows the government to intervene if patented drugs are not available at reasonable prices or in sufficient quantities. This paper will explore how compulsory licensing operates in India, its effects on access to medicines, and how pharmaceutical companies respond to and shape the patent regime. It will also take into account recent developments such as the COVID-19 pandemic and current global discussions about access to vaccines and medicines.

RESEARCH METHODOLOGY:

This study is based on doctrinal and socio-legal research. It examines primary sources such as the Patents Act, 1970, its amendments, and decisions of the Patent Controller and courts. It also uses secondary sources including books, journal articles, policy reports, and public health

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studies.

The research analyses both legal provisions and real-life implementation. It looks at how compulsory licensing operates in theory and whether it actually helps people in practice. The study also considers international developments like the TRIPS Agreement and the Doha Declaration on Public Health.

CONCEPT OF COMPULSORY LICENSING

A patent grants the owner exclusive rights to an invention for a specified period of time. In the pharmaceutical industry, this means that a company has the right to determine how a drug is made and sold (Kumutha et al. 2022). While it encourages innovation, it can also result in monopolies. Compulsory licensing is a legal right that allows the government to grant another company the right to produce a drug even if it is patented. This occurs when drugs are too expensive or when they are not available.

The main objectives of compulsory licensing are:

- To make drugs accessible
- To maintain their affordability
- To prevent the misuse of patent monopolies
- To protect public health

In India, compulsory licensing is viewed as a mechanism to reconcile private interests and public interests.

LEGAL FRAMEWORK IN INDIA

The Patents Act of 1970 provides specific guidelines regarding compulsory licensing.
Section 84 - After three years from the grant of a patent, a compulsory license can be obtained by anyone in the following circumstances:

- The reasonable requirements of the public are not being met.
- The drug is not available at an affordable price.
- The patent is not being worked in India.
- Section 92 - The government can grant compulsory licenses in the following situations:
- National emergency.
- Extreme urgency.
- Public health crisis.

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Section 100 - The government can use patented inventions for public purposes without the need for prior permission from the patent owner.

These sections of the Patents Act of 1970 clearly indicate that the Indian government gives importance to public health, along with the rights of patent owners (Walter et al. 2007).

IMPORTANT CASE: NEXAVAR (2012)

The most prominent example of compulsory licensing in India is the case involving Bayer's cancer medication Nexavar. Since prices were extremely high and unaffordable for the majority of people, Natco Pharma applied for a compulsory licence to develop a more affordable medication. In 2012, the Patent Controller issued the licence for several reasons: the medication was unaffordably expensive, it was not accessible to most patients, and the patent had not been adequately developed in India. After the issuance of the licence, Nexavar's price dropped dramatically, proving the effectiveness of compulsory licensing in improving access to life-saving medications. However, very few compulsory licences have been issued since then.

IMPACT OF TRIPS AND INTERNATIONAL LAW

The TRIPS Agreement and international law have had a great impact on compulsory licensing and public health in India. The TRIPS Agreement, which came into effect under the World Trade Organization in 1995, requires member countries to enhance patent protection, including product patents for pharmaceutical innovations, for a period of twenty years. Before the implementation of the TRIPS Agreement, India followed a process patent system for pharmaceuticals, which allowed Indian manufacturers to develop cheaper variants of existing drugs, thus making them more affordable (Mau et al. 2004). After India implemented the TRIPS Agreement through the Patents (Amendment) Act, 2005, pharmaceutical companies were granted even stronger exclusive rights to their patented drugs, leading to concerns about increased prices and reduced accessibility. At the same time, the TRIPS Agreement allows for the use of certain flexibilities, including compulsory licensing, which allows governments to permit the manufacture of patented drugs without the patent owner's approval in situations such as public health crises, unaffordable prices, or the unavailability of drugs. The Doha Declaration on TRIPS and Public Health in 2001 further clarified that countries have the right to protect public health and ensure universal access to medicines, thus confirming compulsory licensing as a valid tool towards this goal. India has incorporated these international flexibilities

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into its patent system through provisions such as Sections 84 and 92 of the Patents Act, which provide for compulsory licenses in times of public need or emergency. The 2012 Nexavar judgment, in which a compulsory license was granted for a cancer chemotherapy drug, illustrated India's ability to use these TRIPS flexibilities to lower the prices of drugs and make them more accessible. However, the actual use of compulsory licensing in India has been hampered by international trade pressures, diplomatic considerations, and the power of transnational pharmaceutical corporations (Vannier 1999). The COVID-19 pandemic has again highlighted the need for international cooperation and the need for flexible patent systems to guarantee access to vaccines and drugs, triggering an international debate on TRIPS waivers and compulsory licensing. International law has thus simultaneously strengthened patent protection and confirmed the supremacy of public health concerns, with India continuing to balance these competing goals by using compulsory licensing as a safety net to guarantee that patent protection does not preclude access to essential medicines.

LAW IN BOOKS VS LAW IN PRACTICE

The difference between "law in books" and "law in practice" highlights the gap between the legal provisions and the reality of the consequences, which is particularly visible in the area of compulsory licensing and medicine access in India. On the legal front, the Patents Act, 1970 provides strong provisions Sections 84, 92, and 100 that allow compulsory licensing of medicines if they are not available at reasonable prices, if the public requirements are not met, or in cases of national emergencies and public health crises. Internationally, the TRIPS Agreement and the Doha Declaration also provide for the country's right to use compulsory licensing to protect public health (Vannier 1999). Thus, on the legal front, India has one of the most balanced and public health-friendly patent laws in the world.

However, on the "law in practice" front, it is seen that compulsory licensing has been used only once in a major case—the Nexavar case in 2012—and only a few applications have been successful since then. This shows that even with very strong legal provisions, there is a very cautious and limited use of the same. There are a number of practical considerations that lead to this situation: international trade pressure from developed countries, concerns about foreign investment, lobbying by MNC pharmaceutical companies, lengthy procedural requirements, and administrative delays. Moreover, governments may be reluctant to grant compulsory licenses because of possible diplomatic fallout or concerns about damaging India's reputation as an investment-friendly destination. Thus, compulsory licensing is often used as a last resort

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and not as an active tool of public health policy (Neoral 1980).

This gap between the legal provisions and the practical use of the same highlights that only strong legal provisions are not enough; there is a need for political will, administrative clarity, and confidence in policy to achieve public health goals. Thus, while the "law in books" approach supports access to medicines through compulsory licensing, the "law in practice" approach reflects caution, external pressures, and limited use, thereby creating a gap between the two.

ROLE OF PHARMACEUTICAL COMPANIES

The pharmaceutical industry holds a crucial and complex place in the discussion on compulsory licensing and public health. Pharmaceutical companies are the main innovators, producers, and distributors of drugs. They also have strong economic power based on patents. Pharmaceutical companies invest huge economic and time resources in research and development to find new drugs, conduct clinical trials, and develop drugs. Patents give them exclusive rights for a short period of time to allow them to recover their investments and earn profits. But their exclusive control over patented drugs gives pharmaceutical companies the power to produce, price, and distribute drugs, resulting in high prices and limited availability of lifesaving medicines, especially in developing countries like India. When drugs become unaffordable, public health issues arise, making compulsory licensing a relevant legal tool to resist the misuse of patent monopolies.

Pharmaceutical corporations often argue that strong patent protection is necessary to encourage innovation and future pharmaceutical development, and sometimes object to compulsory licensing on the grounds that it could weaken the incentive to innovate and discourage foreign investment. They are involved in negotiations with governments, shaping policy debates, and participating in international trade negotiations, thereby exercising significant influence over the enforcement of patent laws and public health policies. At the same time, many of these corporations have adopted voluntary licensing, differential pricing, and corporate social responsibility programs to improve access to medicines in poorer countries. As such, the role of pharmaceutical corporations is both constructive and contentious: they drive innovation in the medical field and the provision of medicines, but their control over patents and prices may influence affordability and accessibility(Langosch et al. 2012).Therefore, the dynamic between pharmaceutical corporations and compulsory licensing is characterized by a never-ending

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tension between protecting innovation and ensuring that essential medicines remain accessible to the public.

RECENT DEVELOPMENTS

Recent developments in compulsory licensing and public health have come into focus in the wake of global health emergencies, specifically the COVID-19 pandemic, and the debate surrounding the availability of essential medicines. In the wake of the pandemic, many countries, including India, have faced challenges in obtaining sufficient stocks of vaccines, antiviral drugs, and medical equipment, thus reigniting the debate on compulsory licensing as a public health tool. India and South Africa have made a joint recommendation for a temporary waiver of certain patent obligations under the TRIPS Agreement to facilitate wider production of vaccines and drugs without patent barriers, thus establishing the importance of flexible intellectual property rules in times of crisis. While a general waiver has not been immediately adopted, the debate has brought global attention to the importance of compulsory licensing and technology transfer in safeguarding public health. In India, the government has sought ways and means, such as government use provisions and price control, to make essential medicines more accessible, and the National Pharmaceutical Pricing Authority has continued to regulate the pricing of certain drugs. Another recent development is the growing need to strike a balance between innovation and accessibility, with policymakers encouraging the local production of medicines and vaccines while maintaining patent rights (Langosch et al. 2012; Memon et al. 2010). A cautious and encouraging approach has been taken by courts and policymakers regarding the application of compulsory licensing, holding it back for cases of necessity to avoid discouraging pharmaceutical research and investment. Taken together, these developments suggest that compulsory licensing continues to be a relevant and effective legal mechanism, especially in times of health emergencies, although its application is carefully calibrated to balance international commitments, trade considerations, and the need to encourage innovation in the pharmaceutical industry (Langosch et al. 2012; Memon et al. 2010; Sawyer 1999).

CHALLENGES

One of the major challenges in the effective use of compulsory licensing in India is the gap between the strong legal framework and the challenges faced in its practical implementation. Although the Patents Act provides for the grant of compulsory licenses in situations such as

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high prices of drugs, unavailability of drugs, or in cases of public health crises, the procedure for obtaining such licenses is complex and time-consuming, involving elaborate applications, hearings, and submission of evidence before the patent office (Ilse et al. 2012). This makes many generic drug manufacturers hesitant to make applications. Another challenge comes from the influence of multinational pharmaceutical corporations and developed countries, which sometimes view compulsory licensing as harmful to innovation and foreign investment, thus raising trade and diplomatic concerns that make governments hesitant to resort to the provision. There is also a fear that if compulsory licensing is frequently used, it may discourage pharmaceutical companies from investing in research and development in India. In addition, a lack of awareness among the general public and even among small pharmaceutical companies about the availability and procedural formalities of compulsory licensing makes the provision less useful. Delays in administration, complexities in regulations, and coordination problems between health departments and patent offices further add to the difficulties. In situations of public health emergencies, quick decision-making is necessary, but administrative procedures often hinder this. Furthermore, the pharmaceutical industry has strong economic and legal capabilities, which make it possible for patent owners to challenge or postpone decisions on compulsory licensing through legal action. Taken together, these factors indicate that, although the provision of compulsory licensing is a strong legal shield in theory, its practical implementation requires a clear policy framework, simplified procedures, and more political will to ensure that the needs of public health are adequately safeguarded.

FINDINGS

The findings of the study suggest that India has a relatively developed legal system for compulsory licensing that aims to balance patent protection and public health concerns; although, the actual implementation of this legal system has been limited. In particular, the legal system provides for compulsory licensing in cases where drugs are not available within affordable prices, when the public needs are not met, or in the event of national emergencies, which reflects the Indian government's efforts to ensure that the population has access to necessary drugs. Moreover, the study indicates that international agreements, such as TRIPS and the Doha Declaration, support the use of compulsory licensing for public health purposes, and India has successfully incorporated these flexibilities into its patent system. Nevertheless, compulsory licensing has been applied only in a few instances, and the Nexavar case is the most notable one, in which the price of a life-saving cancer medication was significantly reduced, indicating the effectiveness of this mechanism. The limited actual use of compulsory

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licensing indicates that international trade pressures, the influence of multinational pharmaceutical companies, complex procedures, and foreign investment considerations may affect the decision-making process. The study also indicates that while patent protection may encourage innovation and R&D, overbearing dominance by patent owners may hinder access to affordable medication, especially for the economically disadvantaged sections of society. Therefore, the major conclusion is that compulsory licensing remains an essential mechanism for protecting public health in India; although, its actual potential has yet to be fully realized because of legal, political, and administrative complexities. A more balanced and assertive approach to this mechanism is required to achieve a balance between innovation and accessibility.

SUGGESTIONS

In order to make the compulsory licensing regime in India more effective, the procedure for issuing compulsory licenses needs to be simplified and made more expedited, especially in the wake of public health crises. There is a need for proper policy guidelines to be developed so that compulsory licenses can be used effectively by the authorities when medicines are unaffordably expensive or not easily accessible. There is a need for better coordination between patent offices, health departments, and drug control authorities so that decisions can be made in a timely manner. The Indian government also needs to create awareness about compulsory licensing and improve manufacturing capacities so that licensed medicines can be produced quickly. At the same time, India needs to strike a balance between innovation and public health by using TRIPS flexibilities appropriately to ensure affordable access to essential medicines (Bauer et al. 2002).

CONCLUSION

Compulsory licensing is a critical tool that strikes a balance between patenting and public health in the Indian legal system. Although patenting is a crucial element that promotes pharmaceutical research and investment, it should not come in the way of people accessing life-saving drugs at affordable costs. The Indian legal system, especially after the 2005 amendment to the Patents Act, has a balanced approach that promotes strong patenting and public health safeguards through compulsory licensing. International agreements such as TRIPS and the Doha Declaration also support the use of such tools to ensure access to medicines (Southall 1985). However, the use of compulsory licensing in the Indian legal system has been hampered by procedural delays, external pressures, and investment and

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innovation concerns. These factors suggest a disconnect between the legal framework and its implementation. In a country with a large population and public health concerns, compulsory licensing should be an active and functional tool that helps to counterbalance the potential misuse of patenting and improve access to essential drugs. There is a need for a delicate balance between promoting research and innovation and protecting public health interests, and with enhanced policy support and administrative facilitation, compulsory licensing can continue to play a critical role in ensuring that patenting is in line with the broader public health goals of universal access to medicines.

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