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BALANCING PUBLIC HEALTH AND PATENT RIGHTS: INDIA'S COMPULSORY LICENSING POLICY

AUTHORED BY - SANSKRITI UPADHYAY

ABSTRACT

The conflict between patent protection and access to affordable medicines is one of the most pressing issues in international intellectual property law. India, being a major producer of generic medicines, has developed a unique legal framework that attempts to strike a balance between rewarding innovation and ensuring that life- saving drugs are accessible to all citizens, especially the poor. This paper examines, India's compulsory licensing policy under the Patents Act, 1970, as amended by the Patents (Amendment) Act, 2005, focusing on Sections 84, 92, and related provisions[1]. It analyses the landmark case of Natco Pharma Ltd. v. Bayer Corporation (2012), which was India's first compulsory license grant, along with other relevant judicial pronouncements and international agreements such as the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health (2001).3 The project explores how India has used compulsory licensing as a tool of public health policy, and concludes that while compulsory licensing is a legally sound and morally justified mechanism, its full potential in India is yet to be realized due to procedural, political, and international trade pressures.

CHAPTER 1 –INTRODUCTION

Every day millions of cancer patients around the globe cannot get the medicine they need due to the fact that it is patented and therefore costs several thousand dollars per month. This problem affects many millions of Indians who cannot get the same life-saving medications because of high prices set by manufacturers. By granting patent rights, pharmaceutical manufacturers are granted the right to manufacture and sell their medications for 20 years. While the incentive for pharmaceutical manufacturers to create new drugs and improve patient outcomes is positive, the ability to create and sell drugs at high prices comes with very real consequences.

To address this issue, compulsory licensing provides governments with legal authority to give

[1] 1The Patents Act, 1970, Chapter XVI, Sections 84-94 contain all provisions relating to compulsory licensing in India. The Act was significantly amended by the Patents (Amendment) Act, 2005 to comply with TRIPS obligations

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third parties (typically generic manufacturers) the authority to manufacture and sell patented medications without the consent of the patent holder, under defined circumstances. Compulsory licensing functions as a safety net in patent law by providing governments with a mechanism for preventing abuse of their monopoly power, while still providing patients with access to essential health care.

India has played a leading role in the global discussion on access to medicines.

Often called the **"pharmacy of the developing world,"** the country provides lowcost generic medicines to more than 150 nations. The Indian legal system, particularly under The Patents Act 1970, has made extensive provisions for 'Compulsory Licensing' (CL) which demonstrates India's commitment to the protection of public health. One of the First examples of this was India's issuance of its First Compulsory Licence (CL) in the case of **Natco v Bayer in (2012)**;[2] this was a clear signal to the international pharmaceutical industry that there was a commitment on the part of India to provide people with access to essential medications.

This project will study the legal framework that regulates compulsory licensing in India, analyze important judicial and administrative decisions, examine India's obligations under international agreements, and explore the continuing conflict between intellectual property protection and the right to health.

2. CONCEPT OF COMPULSORY LICENSING

2.1 What is Compulsory Licensing?

A compulsory license is a type of authorization issued by a government that allows an individual or entity (that is, all non-patent owners) to make, use or sell a product or method that has been patented. A compulsory license differs from a voluntary licensing agreement, whereby the patent holder has voluntarily granted permission for the other individual or entity to make, use or sell the patented product or process, in that there is no agreement between the parties to grant or receive such authority. In addition to the above-mentioned reasons, a main goal of compulsory licensing in the pharmaceutical industry is to ensure that people can purchase drugs at affordable prices, even when the cost of development has been extremely high. While the patent owner still has a right to receive royalties (by way of a fair amount of compensation) for their work, the patent owner will lose any exclusive rights for making and selling that product. As a result, generic drug manufacturers can produce that medication at a much lower price than the original manufacturer.

[2] Natco Pharma Ltd. v. Bayer Corporation, Order No. 45/2013 (Intellectual Property Appellate Board, Mar. 4, 2013); Bayer Corporation v. Union of India, Writ Petition No. of 2013 (Bombay High Court, July 15, 2014).

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2.2 Why is it Needed?

Patent rights on essential medicines can create three significant issues. First, **High cost**, the prices of patented drugs are often too steep for most people in developing countries. Second, **Limited Availability**, patent owners may not manufacture enough to satisfy local needs. Third, **Restrictive Conditions,** the patent holder might impose rules on distribution that are impractical or harmful. Compulsory licensing helps tackle all three of these challenges effectively.[3]

CHAPTER: 2 STATUTORY FRAMEWORK

2.1 LEGAL FRAMEWORK IN INDIA

2.1.1 The Patents Act, 1970

The primary legislation governing patents in India is the Patents Act, 1970, as amended by the Patents (Amendment) Acts of 1999, 2002, and 2005. The 2005 amendment was particularly important as it brought India's patent law in line with the TRIPS Agreement under the World Trade Organization (WTO). Chapter XVI (Sections 84 to 94) of the Patents Act deals specifically with compulsory licensing.[4]

2.1.2 Section 84 — Compulsory License on Application

Section 84 of the Patents Act, 1970 is the cornerstone provision for compulsory licensing. Under this section, any person can apply to the Controller of Patents for a compulsory license after three years from the date of grant of the patent, if any of the following three grounds are satisfied:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied.
- The patented invention is not available to the public at a reasonably affordable price.
- The patented invention is not worked in the territory of India.

Section 84(6) requires the applicant to prove that they have already made efforts to obtain a voluntary license from the patent holder on reasonable terms and conditions, but have failed to do so within a reasonable period (not less than 6 months).

2.1.3 Section 92 — Compulsory License in Cases of National Emergency

Section 92 of the Patents Act allows the Central Government to issue a compulsory license at

[3] Patents Act, 1970, § 84(1)(a)–(c), No. 39, Acts of Parliament, 1970 (India); see also World Health Organization & World Trade Organization, Compulsory Licensing of Pharmaceuticals and TRIPS (2001), https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm

[4] The Patents Act, No. 39 of 1970, Acts of Parliament, 1970 (India); see Patents (Amendment) Act, No. 38 of 2002; Patents (Amendment) Act, No. 15 of 2005.

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any time after the sealing of a patent if there is a national emergency or extreme urgency, or in cases of public non-commercial use. Unlike Section 84, there is no need to wait for three years under this provision. This section was designed precisely for situations like pandemics, natural disasters, or public health crises. Section 92A further enables compulsory licensing for export of pharmaceutical products to countries that have insufficient or no manufacturing capacity in the pharmaceutical sector, allowing those countactices. The TRIPS Agreement requires that: the patentee must be paid adequate remuneration; the license must be non-exclusive; the license must be predominantly for the supply of the domestic market; and the scope and duration must be limitries to make use of the TRIPS Agreement flexibilities. This is particularly relevant for least developed countries (LDCs) that need medicines but cannot produce them locally.

2.1.4 Section 83 — General Principles for Working of Patents

Section 83 lays down the guiding principles that reflect India's philosophical approach to patents. These include that patents shall not be granted merely to enable the patentee to enjoy a monopoly; patents should be worked in India to the fullest extent possible; and the protection and enforcement of patent rights must contribute to the promotion of technological innovation and the transfer and dissemination of technology to the mutual advantage of producers and users.[5]

2.1.5 Section 3(d) — Prevention of Evergreening

While not directly about compulsory licensing, Section 3(d) is a critical allied provision. It prevents the granting of patents to new forms of known substances (such as new salts, polymorphs, or derivatives of existing drugs) unless they demonstrate significantly enhanced efficacy. This prevents the practice of 'evergreening' — where pharmaceutical companies make minor modifications to an existing patented drug just to extend the patent period. Section 3(d) was famously upheld by the Supreme Court in **Novartis AG v. Union of India (2013).**[6]

2.2 INTERNATIONAL FRAMEWORK

2.2.1 The TRIPS Agreement (1994)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international treaty administered by the WTO, which India ratified in 1995. TRIPS mandates member countries to provide patent protection for 20 years. However, Article 31 of TRIPS explicitly permits compulsory licensing under defined conditions including national

[5] The Patents Act, No. 39 of 1970, Acts of Parliament, 1970 (India)
[6] Patents Act, 1970, § 3(d), No. 39, Acts of Parliament, 1970 (India); Novartis AG v. Union of India & Others, (2013) 6 SCC 1 (India).

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emergencies, other circumstances of extreme urgency, public noncommercial use, and anti-competitive pred to the purpose for which it was granted. These conditions are directly reflected in India's Section 90 of the Patents Act.

2.2.2 The Doha Declaration (2001)

The **Doha Declaration on the TRIPS Agreement and Public Health**, adopted by members of the World Trade Organization in November 2001, was an important political statement that clarified the flexibilities available to countries under the TRIPS Agreement. It made clear that the TRIPS Agreement should not stop member countries from taking steps to protect public health. The declaration also confirmed that each country has the authority to decide what qualifies as a national emergency or a situation of extreme urgency, including public health crises related to diseases such as HIV/AIDS, Tuberculosis, and Malaria, as well as other epidemics. The declaration gave developing countries, including India, greater political and legal confidence to use compulsory licensing without worrying about penalties through the WTO dispute settlement system. It also played a major role in encouraging developed countries to recognize that during public health emergencies, ensuring access to medicines should be more important than protecting commercial patent rights.[7]

CHAPTER: 3 JUDICIAL ANALYSIS

3.1 LANDMARK CASE LAWS

3.1.1 Natco Pharma Ltd. v. Bayer Corporation (2012) — India's First

Compulsory License

Bayer Corporation held a patent for the cancer drug Sorafenib Tosylate, sold as Nexavar, priced at about ₹2, 80,000 per month, which was unaffordable for most patients in India.

In 2011, Natco Pharma applied for a compulsory license under Section 84 of the Patents Act, arguing that the drug was not reasonably available, not affordable, and not manufactured in India.

Decision: In 2012, the Controller of Patents granted Natco a compulsory license.

Natco was allowed to sell the drug at ₹8,880 per month and had to pay 6% royalty to Bayer. The decision was later upheld by the Intellectual Property Appellate Board in 2013 and the Bombay High Court in 2014.

[7] World Trade Organization, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 (Nov. 14, 2001).

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Result: The case made the drug affordable and became a landmark example of compulsory licensing in India.[8]

3.1.2 Novartis AG v. Union of India & Others (2013) — The Glivec Case

This Supreme Court case, though not directly about compulsory licensing, is deeply linked to the same debate about access to medicines. Novartis sought a patent for a modified (beta-crystalline) form of Imatinib Mesylate, the active ingredient in its anticancer drug Gleevec/Glivec. The Supreme Court rejected the patent application under Section 3(d) of the Patents Act, holding that the new form did not show significantly enhanced efficacy over the known substance.

The Supreme Court affirmed that Section 3(d) was specifically designed to prevent evergreening and to ensure that only genuine inventions get patent protection. This judgment reinforced the foundation on which compulsory licensing stands.[9]

3.1.3 BDR Pharmaceutical International Pvt. Ltd. v. Bristol-Myers Squibb (2013)

BDR Pharmaceuticals applied for a compulsory license for Dasatinib, an anticancer drug manufactured by Bristol-Myers Squibb. The Controller of Patents rejected this application because BDR had not made genuine efforts to obtain a voluntary license from BMS before applying for a compulsory license.

This case clarified that the prior negotiation requirement under Section 84(6) is amandatory condition, not a mere formality. It also demonstrated that the compulsory licensing mechanism has inbuilt safeguards to prevent frivolous applications.[10]

3.1.4 Lee Pharma Ltd. v. AstraZeneca AB (2016)

Lee Pharma applied for a compulsory license for Saxagliptin, a diabetes drug. The application was rejected by the Controller of Patents on the ground that the applicant had not adequately proven that the drug was not available at a reasonably affordable price for patients.19 This case highlighted that the burden of proof lies on the applicant and that a mere claim of high pricing is not sufficient concrete evidence is required.[11]

3.1.5 Cipla Ltd. v. F. Hoffmann-La Roche Ltd. (2008)

This case arose when Roche, which held a patent on Erlotinib (sold as Tarceva), sued Cipla for manufacturing and selling a generic version without a license. The Delhi High Court refused

[8] Natco Pharma Ltd. v. Bayer Corporation, Order No. 45/2013 (Intellectual Property Appellate Board, Mar. 4, 2013); Bayer Corporation v. Union of India, Writ Petition No.of 2013 (Bombay High Court, July 15, 2014)
[9] Novartis AG v. Union of India & Others, (2013) 6 SCC 1, ¶ 191
[10] BDR Pharmaceutical International Pvt. Ltd. v. Bristol-Myers Squibb, C.L.A. No. 1 of
[11] Lee Pharma Ltd. v. AstraZeneca AB, C.L.A. No. 1 of 2015 (Controller of Patents, 2016

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to grant an injunction to stop Cipla, giving significant weight to the public health interest.[12] The case showed that Indian courts are willing to balance private patent rights against the constitutional right to life and health of citizens.

CHAPTER: 4 CRITICAL ANALYSIS

4.1 KEY ISSUES AND ONGOING DEBATES

4.1.1 Right to Health vs. Right to Patent

The right to health is protected under Article 21 of the Indian Constitution (right to life and personal liberty), as interpreted by the Supreme Court in numerous judgments. It is also enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which India has ratified. Patent rights, on the other hand, are private property rights. When a life-saving medicine is inaccessible due to a patent monopoly, there is a direct conflict between the right to life and private property rights. Indian courts have generally interpreted Article 21 broadly to include the right to access affordable healthcare, and the compulsory licensing framework reflects this constitutional priority.[13]

4.1.2 Pressure from Developed Countries

India has faced significant international pressure, particularly from the United States and the European Union, over its compulsory licensing regime. The US Trade Representative (USTR) regularly places India on its Special 301 'Watch List' or 'Priority Watch List' for what it describes as inadequate protection of intellectual property rights. After the Natco-Bayer compulsory license, several major pharmaceutical companies threatened to withdraw investments or clinical trials'. These pressures create a chilling effect and can discourage governments from using compulsory licensing even when it is legally and morally justified.[14]

4.1.3 The COVID-19 Pandemic and Compulsory Licensing

The COVID-19 pandemic brought compulsory licensing back to the centre of global attention. India and South Africa submitted a joint proposal at the WTO in October 2020, requesting a temporary waiver of TRIPS obligations for COVID-19 vaccines, diagnostics, and treatments. After prolonged negotiations, a limited TRIPS waiver was agreed upon in June 2022, applicable only to vaccine patents. India also explored using Section 92 of the Patents Act to

[12] Cipla Ltd. v. F. Hoffmann-La Roche Ltd. & Anr., (2008) 148 DLT 598 (Delhi High Court)
[13] INDIA CONST. art. 21; International Covenant on Economic, Social and Cultural Rights art.
, Dec. 16, 1966, 993 U.N.T.S. 3. from India
[14] Office of the United States Trade Representative, 2023 Special 301 Report 43 (2023), https://ustr.gov/sites/default/files/2023%20Special%20301%20Report.pdf.

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issue compulsory licenses for COVID-19 drugs during the severe second wave in 2021.[15]

4.1.4 Does Compulsory Licensing Reduce Innovation?

One of the most common arguments against compulsory licensing is that it reduces incentives for pharmaceutical companies to invest in research and development. However, critics respond that most pharmaceutical research is funded by governments and public institutions; that the drugs most affected by compulsory licensing are typically old, well-established drugs whose R&D costs have long been recovered; and that the profit motive currently encourages development of 'lifestyle' drugs for rich markets rather than treatments for diseases that predominantly affect the poor.[16]

CHAPTER: 5 CONCLUSION & SUGGESSIONS

5.1 CONCLUSION

India's Patents Act, 1970 has a strong system for compulsory licensing, which helps balance patent rights and public health. It is based on the Article 21 and follows international rules like the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health. Indian courts have supported this system in cases such as Natco Pharma Ltd. v. Bayer Corporation and Novartis AG v. Union of India.

Compulsory licensing does not stop innovation. It helps make sure that important medicines are affordable and available to people who need them.

However, India has not used this power fully because of international pressure, complicated procedures, and fear of trade consequences, even during emergencies like COVID-19.

In simple terms, compulsory licensing is a way to balance patent protection and public health so that life-saving medicines remain accessible to everyone. In the end, the real question is not whether patents or public health should come first. The real question is how to build a system where both can exist together. Compulsory licensing, when used carefully and thoughtfully, is one of the strongest answers that the law can provide to this difficult and important question.

5.2 SUGGESTIONS

5.2.1 Make the Compulsory Licensing Process Faster and Simpler -

The current process of getting a compulsory license takes too long and involves too many steps.

[15] Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669 (Oct. 2, 2020); World Trade Organization, Ministerial Decision on the TRIPS Agreement, WT/MIN (22)/30 (June 17, 2022).

[16] Srividhya Ragavan, Patent and Trade Disparities in Developing Countries (Oxford University Press, 2012).

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India should create a faster system for medicines that can save lives. Fixed time limits should be set for each step so that sick patients do not have to wait for years while court cases go on.

5.2.2 Use Section 92 When It Is Needed-

The government has been too hesitant to use Section 92, even during the COVID19 pandemic when it was clearly needed. The government should make simple and clear rules about when Section 92 can be used, so that during any future health emergency, licenses can be granted quickly without confusion or delay.

5.2.3 Give Clear Guidelines on What Evidence Is Needed-

Cases like Lee Pharma v. AstraZeneca failed because the applicant could not prove their case properly. The Patent Office should publish simple and clear guidelines telling applicants exactly what documents and data they need to submit to prove that a medicine is too expensive or not available. This will help people file better applications.[17]

5.2.4 Make the Entire Process Open and Transparent-

All applications for compulsory licenses, the decisions taken, and the royalty amounts fixed should be made available to the public. When the process is open and transparent, people will trust it more, unnecessary applications will reduce, and future applicants will know exactly what they need to do.

5.2.5 Invest More in Indian Medical Research-

India should spend more government money on researching and developing medicines that Indian patients need the most, especially for diseases like cancer, tuberculosis, and diabetes. If India can develop its own medicines, it will not have to depend so heavily on expensive foreign patented drugs in the future.

[17] See Lee Pharma Ltd. v. AstraZeneca AB, C.L.A. No. 1 of 2015 (Controller of Patents, Aug. 25, 2016) (India).