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COMPULSORY LICENSING AND ACCESS TO GENERIC MEDICINES IN INDIA: A CRITICAL STUDY

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I. ABSTRACT

The affordability of medications is a critical social health concern in the developing world, and India uniquely straddles the realms of pharmaceutical advancement and social welfare. India has traditionally been recognized as a source nation for the production of generic drugs and the supply of these affordable medications to both domestic and international markets. However, this stance often conflicts with the notion of intellectual property (IP) protection, particularly in the realm of patent law. This research paper offers a critical examination of the concept of compulsory licensing (CL) as a legal and policy tool to balance the right to patent with the fundamental right to health. Mandatory licensing as per the provisions of the Indian Patents Act permits the government or designated entities to produce patented drugs without the consent of the patent owner under certain conditions, such as public health crises, unaffordability, or inadequate supply. Despite being recognized under international regulations like TRIPS, its application remains a political concern and a legal challenge. This study explores the evolution of CL in India, highlighting significant cases such as the Natco-Bayer case.

II. KEYWORDS

Compulsory Licensing; Indian Patents Act; Generic Medicines; TRIPS Agreement; Section 3(d).

III. INTRODUCTION

This study provides an in-depth analysis of India's patent regulations and their influence on the manufacture of generic drugs, exploring how modifications in the patent system over time impacted the accessibility of cost-effective therapies. By

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examining the evolution of patent law in India from the time before independence through the Patent Act of 1970 and later TRIPS-compatible revisions the research demonstrates how India established a legal framework that fosters both innovation and public health.

The narrative of the Indian pharmaceutical sector is one of notable change from reliance on costly foreign imports to emerging as a worldwide frontrunner in generic manufacturing. Before 1970, the patent laws in India were a legacy of British colonial governance, benefiting foreign patent owners and making medication prices unaffordable. The Ayyangar Committee Report[2] changed this trajectory by emphasizing that the patent system should encourage inventions that are actually "worked" in India. This led to the Patents Act of 1970, which prohibited "product patents" for medicines, allowing only "process patents". This legal loophole permitted Indian companies to reverse-engineer expensive drugs, resulting in the birth of the Indian generic industry.

A. Statement of Problem

The main issue is the increasing de facto disparity in access to healthcare despite existing de jure legal protections. While the Patents Act offers CL as a safety valve, the process largely remains idle because of administrative reluctance, potential international trade penalties, and the strategic "evergreening" practices of multinational companies. This leads to a moral dilemma: although India is known as the Pharmacy of the World, its own people often cannot afford the medications produced in their country. The study explores the reasons this connection to generic accessibility is infrequently traversed and how legislation can elevate the Right to Health under Article 21 above commercial concerns.

[2] Justice N. Rajagopala Ayyangar, Report on the Revision of the Patent Law (Government of India, September 1959).

B. Research Methodology

This study adopts a doctrinal and analytical research methodology to examine the legal framework governing compulsory licensing and access to generic medicines in India. The research is primarily based on qualitative analysis of legal texts and does not involve empirical data collection. Primary sources include statutory provisions such as the Patents Act, 1970, relevant amendments, and judicial decisions, including landmark cases on compulsory licensing and patent law. In addition, international instruments such as the TRIPS Agreement, the Paris Convention, and related declarations have been examined to understand the global context.

Secondary sources comprise academic literature, research articles, government reports, and publications by international organizations such as the World Intellectual Property Organization. The study employs an analytical and comparative approach to evaluate the effectiveness of India's compulsory licensing regime in balancing intellectual property rights with public health concerns. While the research provides a comprehensive legal analysis, it is limited by its reliance on secondary data and the absence of empirical validation, which may affect the generalization of findings in practical contexts.

C. Research Objectives

1. To critically evaluate the effectiveness of compulsory licensing under the Patents Act, 1970, in enhancing access to affordable medicines in India.
2. To analyse the statutory grounds for granting compulsory licenses, including affordability, availability, and local working of patents.
3. To examine the interplay between intellectual property rights and the right to health within the Indian constitutional framework.
4. To compare India's compulsory licensing regime with international standards, particularly under the TRIPS Agreement and related instruments.

D. Research Questions

1. To what extent does the compulsory licensing framework in India balance private patent rights with public health obligations?
2. How are the criteria of "reasonable affordability" and "public requirement" interpreted in the grant of compulsory licenses?
3. What has been the impact of judicial decisions on the evolution and application of compulsory licensing in India?
4. Can voluntary licensing serve as an effective alternative to compulsory licensing, or does it facilitate indirect evergreening practices?

E. Review of Literature

1. This part offers a thorough analysis of different academic publications, governmental documents, and legal interpretations that underpin this study. The reviewed literature comprises:
2. Scholars have extensively examined the influence of international agreements on India's patent regime. Carlos M. Correa, in Intellectual Property Rights, the WTO and Developing Countries (2000), analyses how agreements such as the Paris Convention and the TRIPS Agreement shape domestic patent frameworks in developing countries, including India. Similarly, the role of the World Intellectual Property Organization and the Patent Cooperation Treaty in harmonizing procedural aspects of patent law has been discussed in WIPO's official publications.
3. The TRIPS Agreement has been the subject of significant academic debate, particularly concerning its implications for access to medicines. Frederick M. Abbott, in "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" (2005), evaluates the balance between intellectual property protection and public health. Further, Ellen 't Hoen in The Global Politics of Pharmaceutical Monopoly Power (2009) critically examines how TRIPS affects drug availability in developing countries.

4. The historical evolution of India's patent law has been analysed by Shamnad Basheer, whose work India's Tryst with TRIPS: The Patents (Amendment) Act, 2005 (2005) provides a detailed account of the transition from a process patent regime to a product patent system. Basheer highlights how legislative reforms were shaped by international obligations while attempting to safeguard domestic public health interests.
5. The issue of evergreening and the interpretation of Section 3(d) has been critically examined in academic literature. Shamnad Basheer and Prashant Reddy, in Create, Copy, Disrupt: India's Intellectual Property Dilemmas (2017), discuss how Section 3(d) serves as a safeguard against trivial modifications being granted patents. They argue that this provision plays a crucial role in preventing unjustified extensions of patent monopolies while promoting access to affordable medicines.
6. Compulsory licensing under Section 84 of the Patents Act, 1970 has been widely analysed as a public health safeguard. Srividhya Ragavan, in "Patent Law and Access to Medicines: India's Experience" (2005), examines how compulsory licensing provisions are designed to address affordability and accessibility concerns. The provision has also been evaluated in the context of the Natco v. Bayer decision, highlighting its practical application in ensuring access to life-saving drugs.
7. The transition from a process patent regime to a product patent system in India has been analysed by Jakkrit Kuanpoth in Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future (Edward Elgar, 2010). The author provides a comparative perspective on how developing countries, including India, have adapted to TRIPS obligations while attempting to preserve access to medicines.
8. The broader significance of the TRIPS Agreement in shaping India's patent landscape has been discussed by Daniel Gervais in The TRIPS Agreement: Drafting History and Analysis (2012), which provides insights into the scope

and interpretation of TRIPS provisions and their implications for domestic legal systems.

9. The alignment of Indian patent law with TRIPS obligations has also been critically evaluated by UNDP in its report Using TRIPS Flexibilities to Improve Access to HIV Treatment (2010), which highlights how countries like India utilize flexibilities such as compulsory licensing to balance international commitments with public health needs.
10. The distinction between generic and branded medicines has been explored in academic literature, including studies such as Aaron S. Kesselheim et al., "Clinical Equivalence of Generic and Brand-Name Drugs" (2008), which affirm that generic medicines meet the same standards of safety and efficacy as branded drugs, thereby supporting their role in enhancing healthcare accessibility.
11. Jakkrit Kuanpoth's comparative analysis in Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future (Edward Elgar, 2010) further highlights the structural challenges faced by developing nations in ensuring access to affordable medicines while complying with international patent obligations.

This literature review highlights the complex dimensions of the research topic, offering a solid basis for examining the relationship among patent laws, public health, and the generic pharmaceutical sector.

IV. INTRODUCTION TO INTELLECTUAL PROPERTY

Intellectual Property (IP) refers to creations of the mind, such as inventions, literary works, and symbols used in commerce. IPR protection is essential to encourage businesses to invest time, money, and energy into new technologies. However, after a prescribed period, these works fall into the "Public Domain," allowing general use without consent.

A. Evolution of Patents in India

1. **Colonial Era:** India's first patent legislation was Act VI of 1856, intended to encourage the disclosure of "novel and useful inventions". This was followed by the Act of 1859 and the Indian Patents and Designs Act, 1911.
2. **Post-Independence:** The 1911 Act was found insufficient for national interests, leading to the 1949 Committee under Justice Dr. Bakshi Tek Chand. It is observed that the Act should ensure food and medicine are available at the "cheapest price".
3. **The 1970 Act:** Following the Ayyangar Committee (1957), the Patents Act of 1970 was passed, emphasizing the public's right to access essential goods.

V. THE CONCEPT OF GENERIC MEDICINES

Generic medications are pharmaceutical products that contain the same active ingredients as their branded counterparts and are designed to be identical in dosage form, safety, potency, method of administration, quality, and intended use. They are typically offered at significantly lower prices because manufacturers are not required to replicate the original research and development costs. These medicines must comply with the same regulatory standards prescribed by authorities such as the Food and Drug Administration in the United States and the Central Drugs Standard Control Organization in India, ensuring their safety and efficacy.

In India, the pharmaceutical market is predominantly driven by the generic sector, which contributes substantially to both domestic healthcare access and global medicine supply. The growth of this sector has been facilitated by India’s evolving patent regime, enabling the production of affordable medicines and improving public health outcomes, particularly in developing countries. Generic medicines function with the same therapeutic efficacy as branded drugs, despite possible differences in appearance such as shape, size, colour, or inactive ingredients, which do not affect clinical performance. Their affordability and regulatory equivalence make them a crucial

component of healthcare systems worldwide, enhancing access to essential treatments and supporting the realization of public health objectives.

A. INDIAN REGULATIONS ON GENERIC MEDICINE

Globally, each nation possesses its own regulatory body tasked with establishing rules and regulations for different sectors. The drug approval process is a regulatory method that allows any company, person, or investor to obtain permission to introduce a medication into the market. In India, specific regulatory authorities oversee the approval, production, and promotion of generic medications:

1. The Central Drug Standards and Control Organization functions under the supervision of the Ministry of Health and Family Welfare. The main task of this organization is to propose standards and criteria for verifying the safety, efficacy, and quality of medicines, cosmetics, diagnostics, and devices in India. It also regulates the quality of new medications and clinical trials, as well as the importation of drugs and the licensing approval process for generic pharmaceutical manufacturer.
2. Drug Regulatory Authorities (DRAs): They possess the capacity to stop illegal drug manufacturing and sales activities.
3. Indian Council of Medical Research (ICMR).
4. Ministry of Health and Family Welfare.
5. WHO guidelines.
6. Legislation such as-
    - The Drugs and Cosmetics Act, 1940
    - The Pharmacy Act, 1948
    - The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
    - Essential Commodities Act, 1955
    - The Narcotic Drugs and Psychotropic Substances Act, 1985
    - The Medicinal and Toilet Preparations (Excise Duties) Act, 1956

VI. INTERNATIONAL INSTRUMENTS AND TRIPS FLEXIBILITIES

1. **Paris Convention, 1883:** The Paris Convention for the Protection of Industrial Property was adopted on 20th March 1883. It was further revised at Brussels in 1900, Washington in 1911, Hague in 1925, London in 1934, Lisbon in 1958 and at Stockholm in 1967 but the amendments were made in 1979. It is applicable on industrial property in the widest sense, including patents, trademarks, industrial designs, and utility models.[3]
2. **The TRIPS Agreement and Article 31:** The TRIPS Agreement permits use without permission from the right holder (Compulsory Licensing) according to Article 31. Although it establishes prerequisites like trying to acquire a voluntary license initially, it permits these to be bypassed in cases of national emergencies or extreme urgency.[4]
3. **The World Intellectual Property Organization, 1967:** An International body devoted to defending the rights of intellectual property owners and creators is the World Intellectual Property Organization. It is dedicated to ensuring the rights of creators and owners of intellectual property. It is a self-funding agency created in 1967 and has been established in 1970. WIPO is a specialized agency of the United Nations concerned with developing a balanced and accessible Intellectual Property system which rewards creativity, stimulates innovation and contributes to economic development in public interest.
4. **Patent Co-Operation Treaty, 1970:** The Patent Cooperation Treaty (PCT), administered by the World Intellectual Property Organization, establishes a unified procedure for filing patent applications across multiple jurisdictions through a single "international application." Instead of filing separate applications in each country at the outset, applicants may file one international application, which has effect in all designated member states. The PCT process consists of an international phase and a national phase. During the international phase, an International Searching Authority conducts a prior art search and

[3] The Paris Convention for the Protection of Industrial Property (1883)
[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994

issues an International Search Report along with a written opinion on patentability. Applicants may also request an International Preliminary Examination under Chapter II to further assess the merits of the invention. Subsequently, the application enters the national phase, where individual patent office's examine the application according to their domestic laws. The PCT system is particularly significant for pharmaceutical inventions, as it streamlines multi-country filings and provides applicants, including those in developing countries, additional time to assess commercial viability and regulatory requirements before incurring substantial costs.

5. **The Doha Declaration (2001):** The Doha Declaration emphasized that TRIPS should not hinder members from safeguarding public health. It tackled Paragraph 6 issue, which pertains to countries that lack domestic production capabilities. This resulted in the 2003 waiver and the 2005 TRIPS amendment (Article 31bis), permitting the export of generic medications to those nations. India implemented these modifications via Section 92A of the Patents Act.[5]
6. **Constitutional Perspective:** The Right to Health is recognized as a fundamental right in India, elevated by the Supreme Court as a derivative of the "Right to Life" under Article 21. Directive Principles (Articles 39, 41) also mandate the state to improve public health.
7. **Statutory Grounds for CL (Section 84):** An application for CL can be made three years after a patent grant on three grounds:
    - Reasonable requirements of the public are not met.
    - The invention is not available at a reasonably affordable price.
    - The patent is not worked (manufactured) in India.
8. Section 92 provides for "special" compulsory licenses in cases of national emergency or extreme urgency, where the requirement to seek a voluntary license first is waived.

[5] Doha Declaration (2001)

VII. LANDMARK CASES

The following case laws, as detailed in the dissertation, highlight the critical intersection of patent rights and the public's right to affordable healthcare in India.

A. Bayer Corporation v. Natco Pharma Ltd. (2013) 56 PTC 545

This study explores the evolution of CL in India, highlighting significant cases such as Bayer Corporation v. Natco Pharma Ltd. (2013) 56 PTC 545.[6]

1. **Facts:** Bayer Corporation held a patent for the anti-cancer drug *Nexavar* (Sorafenib Tosylate), used to treat liver and kidney cancer. Natco Pharma applied for a compulsory license under Section 84 of the Patents Act, 1970.
2. **Grounds for Granting CL:** The Controller of Patents granted the license based on three statutory requirements being met:
3. **Affordability:** Bayer sold the drug for approximately ₹2.8 lakh for a month's therapy, while Natco proposed to sell it for ₹8,800.
4. **Availability:** Bayer was supplying the drug to only a small fraction of the eligible patient population in India.
5. **Working in India:** The patented invention was not being "worked" (manufactured) within the territory of India.
6. **Significance:** This case sent shockwaves through the global pharmaceutical industry, demonstrating that India would prioritize public health over patent exclusivity when life-saving drugs were priced beyond reach.

B. Novartis AG v. Union of India (2013)

This case is a definitive study on the issue of "evergreening" and the interpretation of Section 3(d) of the Patents Act.[7]

[6] Bayer Corporation v. Natco Pharma Ltd. (2013) 56 PTC 545
[7] Novartis AG v. Union of India and Others (2013) 6 SCC 1 (Supreme Court of India, 1 April 2013).

1. **Facts:** Novartis pursued a patent for the beta crystalline variant of Imatinib Mesylate (marketed as Gleevec), a crucial medication for leukemia.
2. **Issue:** The main question was if this new variation of a recognized substance met the requirements for a patent under Section 3(d), which forbids patenting known substances unless they demonstrate a significant increase in therapeutic efficacy.
3. **Judgment:** The Supreme Court of India denied the patent application, stating that the beta crystalline form failed to show a significant improvement in therapeutic efficacy compared to the original compound.
4. **Importance:** This decision halted the evergreening of patents, a tactic where firms slightly alter medications to prolong exclusivity thus allowing for quicker access for generic rivals.

C. Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996) 4 SCC 37

This landmark case addressed the scope of the State's obligation to provide adequate medical facilities under Article 21 of the Constitution.

1. **Facts:** The petitioner, who suffered serious injuries, was denied timely medical treatment at multiple government hospitals due to lack of facilities.
2. **Legal Arguments:** The petitioner contended that the failure of government hospitals to provide immediate and adequate medical care amounted to a violation of the right to life under Article 21.
3. **Significance:** The Supreme Court held that the State has a constitutional obligation to provide timely and adequate medical treatment to all people. It affirmed that the right to health is an integral component of the right to life under Article 21, thereby strengthening the constitutional foundation for access to affordable healthcare, including essential medicines.

D. Diamond v. Chakrabarty (1980)

While a U.S. Supreme Court case, it is discussed in the dissertation for its foundational impact on biotechnology patents.[8]

1. **Issue:** The primary question was whether a man-made, genetically engineered bacterium (capable of breaking down crude oil) could be patented.
2. **Judgment:** The Court ruled 5-4 in favor of the inventor, stating that "anything under the sun that is made by man" is potentially patentable.
3. **Significance:** This case opened the door for patenting living organisms, which has significant implications for modern pharmaceutical and biotechnological innovation.

E. Evergreening and Section 3(d)

Evergreening is the process of getting fresh patents for little changes made to already-approved medications. This is prevented by Section 3(d) of India, which mandates enhanced efficacy for novel versions of recognized drugs. The Supreme Court denied a patent for a novel type of imatinib mesylate in Novartis AG v. Union of India due to the absence of appreciably increased effectiveness.[9]

F. Barriers to Generic Uptake

1. **Public Perception:** There is a persistent perception that generics are of inferior quality compared to branded drugs.
2. **Prescription Practices:** Despite regulations requiring doctors to prescribe by generic names, many continue to use brand names due to various influences.
3. **Administrative Inertia:** The high evidentiary burden for CL applications and the threat of trade sanctions (e.g., from the US or EU) deter the government from granting more licenses.

[8] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[9] Section 3(d) of the Indian Patents Act, 1970 (as amended in 2005)

VIII. SUGGESTIONS

1. Clarity on Emergency: To make Section 92 easier to apply, the government should specify exactly what a national emergency is.
2. API Self-Reliance: The government should establish subsidized land and service clusters for the manufacturing of Active Pharmaceutical Ingredients (APIs) in order to reduce prices.
3. Mandatory Generic Prescribing: To ensure that physicians prescribe medicines by their generic names, the professional conduct guidelines issued under the National Medical Commission framework, including those administered by the Ethics and Medical Registration Board, must be strictly enforced. These include the ethical obligations derived from the earlier 2002 Regulations, now subsumed under the National Medical Commission regime, as well as the National Medical Commission's August 2023 directive emphasizing generic prescribing practices.
4. Strengthen Jan Aushadhi Kendras: Ensuring physical access to generics requires addressing medicine shortages and increasing the shops' population coverage.

IX. CONCLUSION

The study comes to the conclusion that although India's patent legislation makes an effort to strike a balance between innovation and health, public health policy is presently not given enough weight. The conditions for putting CL into practice are sometimes "onerous" and subject to different interpretations. Patients now pay more because generic manufacturers find it more difficult to offer reasonably priced alternatives while a patent is in effect due to the shift to product patents. Even while India leads the world in exports, a sizable section of its own people still lacks access to necessary generic drugs.

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