PATENTS V. PUBLIC HEALTH: THE ROLE OF COMPULSORY LICENSING IN GLOBAL HEALTHCARE

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ABSTRACT

Balancing patent rights against public health is therefore important to ensure broader access to essential medicines. Innovations encouraged through the exclusive rights granted to inventors can sometimes limit access to life-saving drugs, particularly in the LMICs, where high prices make access particularly constricted. Compulsory licensing would serve as one important means for the governments to authorize the use of patented inventions without the authorization of the patent owner, enhancing affordability and access to medicines. The concept of compulsory licensing has been exemplified in India by the Bayer Corporation v. Natco Pharma Ltd. (2013) case for a betterer price of an essential drug. The United States, the European Union, and Brazil have adopted differing approaches to balancing innovation against public health needs. This discussion illustrates the need for a globally coordinated framework aimed at fostering an environment in which innovation and the right to health are met inequitable and efficient distribution of healthcare resources, according to need.

INTRODUCTION

Patents are the currency of invention. They give inventors the exclusive ability to exploit their creativity. However, when the rights of a patent holder encumber a population's ability to access something it needs for life—life-saving endeavours.
For instance: The government, as a civically contracted power, steps in through a process known as compulsory licensing, compulsory licensing is the process by which a governmental agency allows itself to utilize a patented invention without permission from its patentee. Yet what is the advantage of enabling governmental persons access to free interest when they could otherwise render the effort for a protective monopoly? Compulsory licensing is like telling a

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patentee, 'Your work is brilliant, but we need to borrow it—because saving lives beats corporate bragging rights.'

While finite protective rights could grant more socially viable access through invention and revenue generated, when those inventions limit access to basic human options that could preserve the sanctity of life, something has to give.
This is truer in the pharmaceutical sector, where monopolistic pricing creates collateral damage worth millions with no way of bettering. Such access levels are lowered further for the Lower and Middle-income countries (LMICs) and extortionate pricing increases health disparities thus created needlessly.

Thus, compulsory licensing is the realistic approach to an ethical/equitable scale between what issuers of protective intellectual property are owed and what public health catastrophes require; without it, countries would be forever stuck in limbo attempting to achieve universal health care goals while simultaneously trying to appease reputation within global nations. India's compulsory licensing regime is like that one friend who brings snacks to the party but does not always RSVP—great intentions, slightly awkward execution.

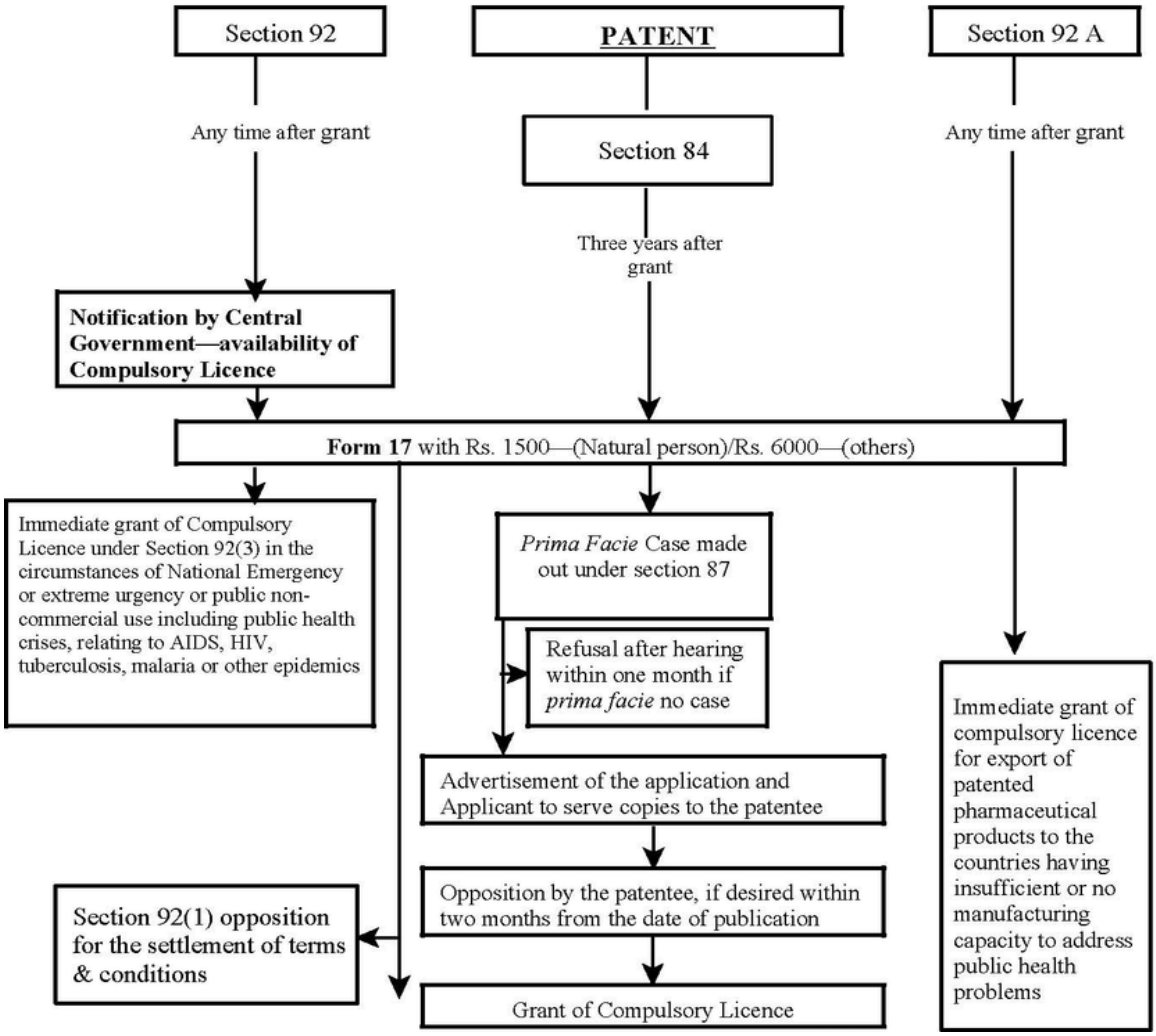
India's Compulsory Licensing Regime. Where Does It Occur and What's The Structure?

India's compulsory licensing regime is situated according to the Patents Act of 1970. For example, in Section 84[1], which a license is granted as follows: A compulsory license may be requested by a third party after three years into the patent. India has been facing wide criticism for its lack of enforcement in IP.

To understand this in a better way, let us follow the flowchart below and see how exactly it functions.

[1] Patents Act 1970, s 84, No 39, Acts of Parliament 1970 (India).

Three Modes of Compulsory Licensing under India's Patents Act, 1970 (as amended 2005)



For instance, in Bayer Corporation v. Natco Pharma Ltd. [2](2013), India's first-ever compulsory license was granted by the Indian Patent Office to Natco Pharma for generic production of Bayer Corp's Nexavar.

When Bayer was charging ₹2.8 lakh/month for sale, it was not a price that many could afford; therefore, the Controller of Patents provided the compulsory license for non-working of the necessary percentage—because it was not accessible—and for failing to manufacture the drug in India by Bayer.

Natco Pharma charged ₹8,800/month for their generic version of Nexavar compared to Bayer's ₹2.8 lakh/month, making it significantly more affordable and accessible.

[2] *Bayer Corporation v Union of India* Writ Petition No 1323 of 2013 (Bom HC).

Public Availability: The Indian government requires Form 27, the "working" of the patent, to demonstrate how much India is interested in publicized/actual use.

India has rarely exercised the "license of right" option, even though some argue it should have done so more frequently. This demonstrates that the concern of India being overly liberal in granting compulsory licenses is largely unfounded.

INTERNATIONAL PERCEPTION: INDEPENDENT COMPARISONS

United States: A Market-Driven Paradigm

The U.S. treats compulsory licensing like a last slice of pizza only for emergencies, and even then, with great reluctance, market solutions dominate, limiting affordability for underprivileged groups.

Under the Bayh-Dole Act, compulsory licenses may be invoked for federally funded inventions if public demand is not met, but such instances are rare. During the COVID-19 pandemic, there were calls for compulsory licensing of vaccines like Moderna's. However, the government refrained, favouring voluntary licensing and partnerships.

European Union: Balancing Innovation and Equity

The EU adopts a middle-ground approach. The Directive 2004/48/EC facilitates compulsory licensing, this gives them a stronger patent regime and aligns with global trade norms, higher thresholds prioritize patentees' rights, with the public interest as a secondary concern.

Notable Example: In 2020, Germany amended its patent laws to expedite compulsory licensing for COVID-related technologies, highlighting a calibrated response.

Brazil: An Activist's Model

Brazil's approach to compulsory licensing is like a superhero with a public health cape—bold, proactive, and occasionally ruffling a few feathers in the global trade community. Health-centric policies ensure wider access to essential medicines; under the Industrial Property Law, the government's intervention is more frequent and assertive. Brazil faces criticism for "weak" IP enforcement, the same as India.

Notable Case: In 2007, Brazil issued a compulsory license for Merck's HIV drug Efavirenz, slashing costs and expanding access. Unlike India, Brazil's decisions often spark diplomatic and trade tensions.[3]

Policy Recommendations

Policymakers should weigh public health needs against innovation incentives. India's selective approach provides a blueprint for ensuring judicious application. Even simplified processes, like Brazil's expedited licensing, can reduce bureaucratic delays without compromising fairness.

A harmonized framework through TRIPS allows one to settle trade disputes in order to ensure equitable access to medicines and create incentives for voluntary partnerships, as we have seen in the case of COVID-19 which only complements the process of compulsory licensing. Selective application, streamlined processes, global cooperation, and voluntary collaborations could together turn this current patchwork of patents and compulsory licenses into something much more efficient, equitable, and, let's face it, not as messy for everyone concerned.

CONCLUSION

India's compulsory licensing regime underscores the critical role of patent systems in promoting both innovation and accessibility, while stark contrasts exist between India's public-health-oriented approach and the market-driven models of the U.S. and EU, these differences highlight diverse priorities shaped by local socio-economic contexts, a globally coordinated approach could finally make patents the team players they have always pretended to be helping humanity while keeping innovation alive.

An expert opinion by Niharika Payannavar, an associate at Shardul Amarchand Mangaldas.

"Patents totally incentivize innovation, but in healthcare, they must align with public health imperatives; compulsory licensing provides a legal mechanism to ensure access to essential, life-saving medicines without undermining intellectual property rights."

[3] AIDSMAP, 'Brazil Issues Compulsory License for Efavirenz' (2007) https://www.aidsmap.com/news/may-2007/brazil-issues-compulsory-license-efavirenz accessed 4 January 2025.

Another opinion from a member of the IPHA, Mudita Adaniya.

“Barriers to accessible and affordable healthcare remain some of the most pressing challenges of public health in India. In this context, compulsory licensing serves as a vital tool to bridge innovation with equitable access, ensuring that life-saving medicines benefit those in need over monopolies.
-Master of Public Health from IIPHG (pursuing)
-MIPHA (Member of the India Public Health Association)

Endnotes.

1. Bayer Corporation v Union of India [2013] Writ Petition No. 1323/2013 (Bom HC) https://www.casemine.com/judgement/in/5608fd29e4b014971114d709 accessed 10 January 2025.

2. World Intellectual Property Organization, Promoting Access to Medical Technologies and Innovation (WIPO 2020) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_628_2020.pdf accessed 6 January 2025.

3. Lawctopus Law School, 'Reading Resource: Patent Law - Assignment, Licenses, and Compulsory License' (2022) https://www.lawctopuslawschool.com/wp-content/uploads/2022/09/Free-Resource-Patent-Law-Assignment-Licenses-and-Compulsory-License-lawcto.pdf accessed 11 January 2025.