PATENT LAW AND PUBLIC HEALTH: A STUDY ON COMPULSORY LICENSING IN INDIA

Ms. Nirmala R Harish & Gangireddy Vyshnavi, B.A. LL.B. (Hons), CMR University,
School of Legal Studies

ABSTRACT

Patent law sits at the crossroads of intellectual property rights and public health, presenting a unique challenge: how do we foster innovation while ensuring that essential medicines are accessible to everyone? In India, this delicate balance has been shaped by the Patents Act of 1970, which includes provisions for compulsory licensing (CL). This allows the government, under certain conditions, to permit third parties to produce and sell patented drugs without needing the patent holder's approval. This legal tool is especially crucial in a developing nation like India, where many people find high-priced patented medicines out of reach. The framework for CL aligns with the flexibilities allowed under the TRIPS Agreement and is bolstered by the Doha Declaration on Public Health, which stresses the importance of prioritizing access to medicines during critical times. A notable case, Bayer Corporation v. Natco Pharma Ltd. (2012), underscored India's dedication to using CL as a means to lower the costs of essential cancer treatments. This study delves into the legal foundations of compulsory licensing in India, how it has been interpreted by the courts, and what it means for both pharmaceutical innovation and public health policy. Ultimately, it posits that compulsory licensing is a crucial mechanism for achieving a fair balance between protecting patent rights and ensuring public health is prioritized.

Introduction

Patent law sits at the crossroads of innovation and the well-being of society. By granting inventors exclusive rights to their creations, patents allow them to recoup their research and development (R&D) expenses and enjoy financial benefits. However, in the pharmaceutical sector, this exclusivity often stirs up ethical and social dilemmas, especially when soaring drug prices limit access to vital medications. This clash between intellectual property rights and public health has ignited worldwide discussions on how to strike a balance between fostering innovation and ensuring accessibility.

In developing nations like India, where the affordability of healthcare is a significant concern, finding this balance is even more crucial. With a population of over 1.4 billion and a heavy load of both communicable and non-communicable diseases, having access to affordable medicines is not just a constitutional right but a social necessity. That's why the Indian Patents Act of 1970 includes provisions for compulsory licensing (CL) to tackle situations where patented drugs are either unavailable, too expensive, or not sufficiently supplied.

This paper delves into the legal framework surrounding compulsory licensing in India, highlights landmark case law, explores judicial interpretations, and considers the international context, along with the wider implications of this mechanism for innovation, investment, and public health. It posits that when applied thoughtfully, compulsory licensing serves as a crucial safeguard to balance patent protection with the constitutional right to health.

The Legal Framework of Compulsory Licensing in India

Evolution of Patent Law in India

India's patent system has seen some major changes over the years. Back in 1970, the Patents Act didn't allow product patents for pharmaceuticals, which was a move aimed at boosting local manufacturing. However, after India joined the World Trade Organization (WTO) and committed to the TRIPS Agreement in 1995, the country updated its patent laws in 2005 to permit product patents for pharmaceuticals. Lawmakers were mindful of how this could affect the affordability of medicines, so they made sure to keep important protections in place, like compulsory licensing.

Compulsory Licensing under the Patents Act

According to Section 84 of the Patents Act, 1970, anyone can apply for a compulsory license three years after a patent is granted, but only under certain conditions:

1. The public's reasonable needs regarding the patented invention haven't been met.
2. The patented invention isn't available at a price that people can afford.
3. The patented invention isn't being produced in India.

Additionally, Section 92 gives the government the authority to issue compulsory licenses during national emergencies, urgent situations, or for public non-commercial use. This is especially relevant during pandemics, epidemics, or major health crises.

TRIPS Agreement and Doha Declaration

India's framework for compulsory licensing is in line with international law. Article 31 of the TRIPS Agreement allows member countries to grant compulsory licenses under certain conditions. The Doha Declaration on TRIPS and Public Health from 2001 reinforced that WTO members have the right to safeguard public health and enhance access to medicines. India has consistently utilized this flexibility to strike a balance between its international commitments and the healthcare needs of its own population.

Case Studies in India

Bayer Corporation v. Natco Pharma Ltd. (2012)The Bayer v. Natco case was a game-changer in India, marking the very first compulsory license. Bayer held the patent for Sorafenib Tosylate (Nexavar), a crucial cancer medication that came with a hefty price tag of about ₹2.8 lakhs per month. In response, Natco Pharma stepped in, applying for a compulsory license and proposing to sell the drug for just ₹8,800 a month.

The Controller General of Patents approved the license, stating that:

The drug was simply not available at a price that people could afford.

Bayer had not fulfilled reasonable public needs.

The patent wasn't being "worked" in India since Bayer was only importing it in very small

amounts.

This landmark decision slashed drug prices by over 95% and set a global benchmark for balancing patent rights with public health needs.

BDR Pharma v. Bristol Myers Squibb (2013)

In this case, BDR Pharma sought a compulsory license for Dasatinib, another anti-cancer drug. However, their application was turned down because they didn't make a "credible attempt" to negotiate a voluntary license with the patent holder. This case underscored the importance of following proper procedures in compulsory license applications.

Lee Pharma v. AstraZeneca (2015)

Lee Pharma applied for a compulsory license for Saxagliptin, an anti-diabetic medication. The Patent Office rejected their application, pointing out that just being affordable wasn't enough and that there was no proof of unmet public demand.

International Experiences

Thailand (2006–2007): Issued compulsory licenses for drugs treating HIV/AIDS and heart disease.

Brazil (2007): Granted a compulsory license for the HIV drug Efavirenz.

South Africa: Utilized compulsory license flexibilities to broaden access to antiretroviral medications.

These international examples illustrate that India's approach to compulsory licensing is part of a larger global health movement, not an isolated incident.

Judicial Interpretation and Policy Concerns

Judicial Support

Indian courts have largely backed compulsory licensing, seeing it as a matter of public interest. In the case of Bayer v. Union of India (2014), the Bombay High Court supported Natco's grant of a compulsory license, emphasizing that public health should take priority over high prices.

Criticisms from Industry

On the flip side, multinational pharmaceutical companies are critical of India's compulsory licensing system. They argue that it discourages foreign direct investment (FDI) and diminishes the motivation for innovation. The U.S. Trade Representative has often placed India on the "Priority Watch List" due to concerns about intellectual property.

Support from Public Health Advocates

Conversely, NGOs, public health advocates, and developing nations see compulsory licensing as an essential protection. India's role as the "pharmacy of the developing world," providing affordable generic medications to numerous low-income countries, relies heavily on these flexible policies.

Challenges and Future Prospects

Balancing Innovation and Access

One of the biggest hurdles we face is finding the right balance between compulsory licensing and fostering pharmaceutical innovation. We want to make sure that life-saving drugs are within reach for everyone. If we lean too heavily on compulsory licensing, it might scare off investors; but if we don't use it enough, patients could miss out on affordable medications.

Role in Pandemics

The COVID-19 pandemic brought the conversation around compulsory licensing back to the forefront. India and South Africa made a bold move by proposing a TRIPS waiver for COVID-related technologies at the WTO, emphasizing that global health crises require wider access. While it's not exactly a compulsory license, this action highlights India's commitment to putting public health first.

Strengthening Policy

Looking ahead, we might see some positive changes, such as:

- More efficient processes for emergency licensing.

- Increased collaboration between public and private sectors in drug production.

- A fairer approach to royalties that respects patent holders while keeping medicines affordable

Conclusion

The concept of compulsory licensing in India strikes a careful balance between safeguarding patent rights and ensuring that medicines are accessible to those in need. The landmark Bayer v. Natco case showcased India's commitment to prioritizing public health over corporate profits, all while adhering to international legal standards. Although there are ongoing debates about its effects on innovation and foreign investment, compulsory licensing stands as a valid and internationally recognized approach.

India's stance emphasizes that patents should benefit not just private businesses but also the wider community. The right to health, highlighted in Article 21 of the Indian Constitution, provides a strong moral and legal basis for these actions. As we look ahead, it's crucial for India to keep fine-tuning its compulsory licensing policies to effectively tackle future health challenges, uphold its position as a global provider of affordable medicines, and find a sustainable equilibrium between intellectual property rights and public health.

Endnotes

1. The Patents Act, 1970 — yeah, that's Act No. 39 of 1970, got a facelift thanks to the Patents (Amendment) Act, 2005.

2. TRIPS Agreement, 1995. Yup, that's part of the big Marrakesh Agreement that kicked off the WTO, check out Annex 1C if you're feeling adventurous.

3. Doha Declaration on TRIPS and Public Health, WT/MIN(01)/DEC/2 (2001). Basically, the world admitting health > patents (sometimes).

4. Section 84, Patents Act, 1970 — you want grounds for compulsory licensing? This is it.

5. Section 92, Patents Act, 1970 — where the Central Government can butt in and make compulsory licensing a thing if it feels like it.

6. Bayer Corp. v. Natco Pharma Ltd., Compulsory License Application No. 1 of 2011, Controller of Patents, decision dropped 9 March 2012. The big compulsory license standoff.

7. Bayer Corp. v. Union of India, 2014 (60) PTC 277 (Bom) — basically the bombay high court upholding Natco's right for a compulsory license. Mic drop moment.

8. BDR Pharma Intl. Pvt. Ltd. v. Bristol Myers Squibb, Compulsory License Application No. 1 of 2013.

9. Lee Pharma Ltd. v. AstraZeneca AB, Compulsory License Application No. 1 of 2015. Also a big fat rejection by the Controller.

10. WHO, "Public health, innovation and intellectual property rights: Report of the Commission...", 2006. A looong report, lots of charts, major global vibes.

11. Ellen F.M. 't Hoen, The Global Politics of Pharmaceutical Monopoly Power (AMU, 2009). If big pharma drama is your thing, this book's for you.

12. Carlos Correa, Intellectual Property Rights, the WTO and Developing Countries (Zed Books, 2000). Classic read for IP junkies.

13. South Centre, “Compulsory Licensing and Access to Medicines” — Policy Brief, 2011. Short, snappy, kinda angry.

14. India and South Africa, “Waiver from certain provisions of the TRIPS Agreement for COVID-19,” WTO Doc. IP/C/W/669 (2 Oct 2020). The pandemic forced everyone’s hand. This is their “let’s break some rules” moment.

15. Constitution of India, Article 21 — Right to Life & Liberty. Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996) 4 SCC 37 is where the Supreme Court basically said, “Yo, right to health is part of right to life. Deal with it.”