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Compulsory Licensing in India: Balancing Pharmaceutical Patents and Public Health

Akhilesh Kakade[a]

[a]Judicial Law Clerk, High Court of Bombay, India

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This article explores the evolving landscape of compulsory licensing (CL) in India, focusing on the delicate balance between pharmaceutical patent rights and the need for public health safeguards. It examines the Indian legal framework under the Patents Act of 1970 (as amended in 2005), which allows the government to authorise patented medicines by third parties under specific conditions, such as affordability and public need. Highlighting the landmark NATCO Pharma Ltd. v Bayer Corporation case, the article underscores India's role in leveraging TRIPS flexibilities to improve access to essential drugs. It further analyses the international legal backdrop, particularly the TRIPS Agreement and the Doha Declaration. It assesses how India's approach has been shaped by both internal health priorities and external diplomatic pressures. Case studies on anti-cancer and COVID-19-related drugs are used to illustrate the practical and geopolitical challenges of implementing CL. The article concludes by recommending a more streamlined and inclusive licensing regime that prioritises healthcare without compromising innovation.

Keywords: *compulsory licensing, trips agreement, pharmaceutical patents, public health, patent law.*

INTRODUCTION

The development of compulsory licensing frameworks experienced significant historical changes as a result of competing interests between innovation protection and medicine

accessibility for the public. The conflict of restricted access to fair healthcare worldwide, especially in developing countries, demonstrates that strict patent security systems fail to solve immediate public health crises. India understood at an early stage how flexibility within its intellectual property framework was vital for its complex healthcare system because it serves so many patients with infectious and chronic diseases.[1] India committed to providing affordable healthcare even before its formal fulfilment of the TRIPS Agreement requirements in 2005.[2]

Compulsory licensing (CL) is a means by which the government can approve third parties to manufacture the contents of patented drugs without the patent holder's Legis without the patent holder's to facilitate wider public access.[3] CL under certain conditions is both allowed by the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and supports the balance between intellectual property rights and public health considerations.[4] However, India, as a country that still has yet to overcome seriously a public health concern with a strong generic pharmaceutical sector has continuously exploited the CL (compulsory licensing) provisions under the Patents Act 1970 (as amended 2005) to allow for improved access to medicines as required by the nation's international obligations.[5] In the case of Bayer v Natco, India set out the approach to affordable medicines that it has taken.[6]

Using the above-mentioned context, this article analyses India's legal architecture for CL, the influence of international commitments, landmark judgments on CIs, and the implications of CL for public health and pharmaceutical innovation in India. The tool, which facilitates access to vital healthcare medications, has received continuing opposition through diverse condemnations from multiple perspectives. The controversial unrestricted or politically

[1] Basheer S, 'India's Tryst With Trips: The Patents (Amendment) Act' (2005) 1(1) Indian Journal of Law and Technology < https://repository.nls.ac.in/ijlt/vol1/iss1/2/> accessed 27 March 2025
[2] Chaudhuri S, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (OUP 2005)
[3] Dipika Jain and Jonathan J. Darrow, 'An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India' (2013) 23(2) Health Matrix: Journal of Law-Medicine <https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1072&context=healthmatrix> accessed 27 March 2025
[4] 'Overview: The TRIPS Agreement' (*WTO*) <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 27 March 2025
[5] The Patents Act 1970, s 84
[6] *Bayer Corporation v Union of India* (2014) Civil App No 2706/2013

motivated implementation of CL deters pharmaceutical innovation and foreign sectoral investment, especially in research-based areas.[7]

Excessive use of compulsory licensing raises concerns about developing hostile conditions between national generic companies and international patent owners, which can produce diplomatic conflicts and trade countermeasures.[8] The Government of India uses compulsory licensing as a strategic manoeuvre to address fundamental economic inequalities within the pharmaceutical industry, since they do not completely abandon patent protections.[9]

The Indian approach to compulsory licensing needs re-evaluation, considering global discussions about intellectual property moral standards. Research experts, together with political officials, now challenge whether current global IP systems sufficiently protect human rights and the health needs of developing nations.[10] India continues to work at par with international IP legal systems by engaging in initiatives like TRIPS waivers for instances such as COVID-19, in addition to its established commitment to humanistic IP policy reform. Indian CL evolution functions as more than a national health policy because it represents an essential battleground for shaping debates about global fairness and intellectual property protection.

LEGAL FRAMEWORK FOR COMPULSORY LICENSING IN INDIA

India shifted to product patents in 2005, in compliance with the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement, to address patent problems and meet (public) health concerns and better intellectual property protection. A well-defined CL framework for improving access to medicines is built into the conditions under which holders of patents should respond to the public demand, affordability, and, when

[7] Carlos M. Correa, *Pharmaceutical Innovation, Incremental Patenting And Compulsory Licensing* (South Centre 2013)
[8] Frederick M. Abbott and Edward Ball Eminent, 'Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health' (*Quaker UN Office*, 14 February 2002) <https://quno.org/sites/default/files/resources/Compulsory-Licensing.pdf> accessed 27 March 2025
[9] Matthew Rimmer, 'The People's Vaccine: Intellectual Property, Access to Essential Medicines, and COVID-19' (2022) 5(1) Journal of Intellectual Property Studies <https://dx.doi.org/10.2139/ssrn.3914440> accessed 27 March 2025
[10] Peter K. Yu, 'The International Enclosure Movement The International Enclosure Movement' (2007) 82(4) Indiana Law Journal <https://www.repository.law.indiana.edu/ilj/vol82/iss4/1> accessed 27 March 2025

appropriate, to the need for local production, within the Indian Patents Act 1970 (as amended in 2005).[11]

Any party interested can ask for a compulsory license under Section 84[12] Because the patent invention is either not reasonably affordable to the public, is not being met with public demand, or is not 'worked' in India. Moreover, according to Section 92[13]The government has the right to grant compulsory licenses when there is a National Emergency, extreme urgency, or public non-commercial usage (e.g., in a case of public health crisis or pandemic). Further, Section 100[14] permits the government to authorise the use of the patented invention for a public purpose, and Section 102[15] provides the government power to acquire a patent if beneficial in the public interest.[16]

The provisions were put into practice for the first time in the case of Bayer Corporation v Union of India, where Natco Pharma was issued with India's first compulsory license to manufacture the cancer drug Nexavar at a fraction of the price. This judgment doubted India's promise of ensuring access to medicines while balancing patent rights with the need for public health. Overall, though, compulsory licensing continues to be a contentious issue, especially about TRIPS obligations and their influence on pharmaceutical innovation.[17]

JUDICIAL PRECEDENTS: THE LANDMARK CASE OF *NATCO PHARMA LTD. v BAYER CORPORATION* (2012)

The 2012 case of NATCO Pharma Ltd. v Bayer Corporation, decided initially by P.H. Kurian, the then Controller General of Patents, signified a landmark moment in India's intellectual property law as it marked the issuance of the first compulsory license granted under the Patents Act, 1970 in the country.

[11] Akshat Mehta and Nancy Saroha, 'A Comparative Analysis of Compulsory Licensing in Patent Law in the India and the United States' (2023) SSRN <https://dx.doi.org/10.2139/ssrn.4569032> accessed 27 March 2025
[12] Patents Act 1970, s 84
[13] Patents Act 1970, s 92
[14] Patents Act 1970, s 100
[15] Patents Act 1970, s 102
[16] Soumya Srivastava, 'The Indian Patent (Amendment) Act, 2005 & It's Implication On Pharmaceutical Industry, In Reference To Novartis Vs. Union Of India' (2023) 5(4) International Journal Of Legal Science And Innovation <https://doij.org/10.10000/IJLSI.111632> accessed 27 March 2025
[17] Abhinav Gupta and Aqa Raza, 'Patent Law and Compulsory Licensing: Indian Perspective' (2024) 29(1) Journal of Intellectual Property Rights <https://doi.org/10.56042/jipr.v29i1.602> accessed 27 March 2025

Bayer held the patent for Sorafenib Tosylate (Nexavar). But the cost of the drug was ₹2.8 lakh — ₹280,000 per month, which rendered it out of reach for most Indian patients. An Indian generic drug manufacturer, NATCO Pharma, applied under Section 84 of the Patents Act that Bayer's pricing was unaffordable, that the company was not sufficiently supplying the market, and that the patented drug was not 'working' in India.[18]

The Controller of Patents then decided in favour of NATCO that the company could then produce and sell a generic version of Nexavar for a fraction of the patented price, at just ₹8,800 per month, while being ordered to pay Bayer a 6% royalty.[19] This decision was later upheld by the Intellectual Property Appellate Board (IPAB) and reinforced India's pledge to provide affordable life-saving drugs.[20] Bayer appealed against the decision to the Bombay High Court and later to the Supreme Court, both of which confirmed the ruling, establishing an important precedent in balancing public health considerations against the interests of intellectual property.

The decision reaffirmed India's position on compulsory licensing to increase access to life-saving medicines, especially in developing countries. The ruling also highlighted India's commitment to making use of the TRIPS flexibilities to address national healthcare needs without violating its international obligations.[21]

INTERNATIONAL LEGAL FRAMEWORK AND COMPLIANCE WITH TRIPS

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which came into force in 1995, within the framework of the World Trade Organisation (WTO), sets out certain minimum standards regarding several areas of intellectual property protection, including patents.[22] Article 31 of TRIPS allows World Trade Organisation (WTO) member states to grant third parties compulsory licenses, enabling the use of a patented invention without the patent holder's authorisation under predetermined conditions.[23]

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[18] Aleksandar Ristanić, *Using Compulsory Licenses to Facilitate Access to Medicines: The Indian Experience* (Lund University Publications 2016)
[19] *Bayer Corporation v Union of India* (2014) Civ App No 2706/2013
[20] *Ibid*
[21] Srishti Chauhan and Ranjana Sharma, 'Breaking Barriers: How Compulsory Licensing in Indian Patent Law Unlocks Access to Essential Medicines' (2024) 5(11) International Journal of Research Publication and Reviews <https://ijrpr.com/uploads/V5ISSUE11/IJRPR34662.pdf> accessed 27 March 2025
[22] Office of the United States Trade Representative, *2021 Special 301 Report* (2021)
[23] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 31

TRIPS allows for flexibility, allowing countries to determine the conditions under which compulsory licenses may be issued. In situations of national emergency or extreme urgency, governments are not obligated to attempt negotiations with patent holders before issuing a compulsory license. In addition, Article 31b, which was introduced in 2005, permits generic drugs produced under compulsory license to be exported to states without adequate manufacturing capacity for pharmaceuticals.[24]

The Doha Declaration on the TRIPS Agreement and Public Health confirmed the public health flexibilities available under the TRIPS Agreement. It confirmed that intellectual property rights should not interfere with countries' ability to protect public health. The declaration made it clear that WTO members could issue manufacturers with compulsory licenses and define the conditions under which the licenses must be granted, making lifesaving medicines available to more people.[25]

Although India has effectively utilised the flexibilities under the TRIPS Agreement, it has faced significant pressure from developed countries and multinational pharmaceutical companies. The U.S. Special 301 Report had always placed India on its 'Priority Watch List' for its intellectual property policies that were pro-generic medicines.[26] Despite pressure from trade partners to reconsider this position, India has not reneged on its commitment to affordable access to essential drugs and remains a major player in global public health efforts.

COMPULSORY LICENSING — CASE STUDIES

CL Requests for Anti-Cancer and HIV/AIDS Drugs: Over the years, India has seen several requests for compulsory licenses (CL) concerning life-saving drugs, especially those used for the treatment of cancer and HIV/AIDS. However, many of these requests were denied or withdrawn for a variety of legal and policy-related reasons. The application was to grant a Compulsory License (CL a provision under patent laws that allows the government to authorize someone else to produce a patented product without the consent of the patentee) to produce Dasatinib, an anti-cancer drug patented by Bristol-Myers Squibb in 2013 and in response to the CL application, the Indian government rejected it. The ruling underscored the challenges of granting CLs, including the influence of foreign pharmaceutical companies

[24] *Ibid*
[25] Doha Declaration on the TRIPS Agreement and Public Health 2001, s 4
[26] Mehta (n 11)

and the need for India to reconcile intellectual property concerns with public health interests.[27] However, India has a historically strong role in promoting affordable medicines via its domestic patent system and TRIPS flexibilities.

The TRIPS Waiver Debate: In the Age of COVID-19: However, India has a historically strong role in promoting affordable medicines via its domestic patent system and TRIPS flexibilities. Global debates about intellectual property rights and vaccine accessibility were reignited in late 2019 as the COVID-19 pandemic took hold around the world. In October 2020, India and South Africa jointly submitted a proposal to the World Trade Organisation (WTO) for a Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver, suspending intellectual property protections on COVID-19 vaccines and treatments.[28]

The proposal was intended to alleviate the inequity in vaccine access and allow those countries with manufacturing capacity to produce and distribute vaccines without being restricted by patent protections. But the proposal met fierce opposition from the United States, the European Union, and large drug makers, delaying any meaningful decision.[29]

India's call for the TRIPS waiver called out the shortcomings of voluntary mechanisms like COVAX, which failed to provide low-income countries with equitable access to vaccines. This debate highlighted the tension between IP protections and global public health, signalling the importance of a more robust legal infrastructure to respond to future pandemics. India's decided yet cautious approach in offering solidarity to countries facing trade pressure and diplomatic tampering challenges reflecting that it will put public health ahead of pharmaceutical monopolies has been due to the exercise of Indian makers on IPR in emerging markets through strategic diversification, increased effectiveness and excellence and leveraging of IPR strategies as new knowledge drivers in the future.[30]

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[27] Jain (n 3)

[28] 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of Covid-19' (*WTO*) <https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> accessed 27 March 2025

[29] Siva Thambisetty et al., 'Addressing Vaccine Inequity During The Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal And Beyond' (2022) 81(2) The Cambridge Law Journal <https://www.cambridge.org/core/journals/cambridge-law-journal/article/addressing-vaccine-inequity-during-the-covid19-pandemic-the-trips-intellectual-property-waiver-proposal-and-beyond/7F2A8FB2EA5395265DAB44A3BC2BE223> accessed 27 March 2025

[30] Behrang Kianzad and Jakob Blak Wested, ''No-One Is Safe Until Everyone Is Safe' – Patent Waiver, Compulsory Licensing and COVID-19' (2021) 5(2) European Pharmaceutical Law Review <http://dx.doi.org/10.21552/eplr/2021/2/4> accessed 27 March 2025

CHALLENGES & CRITICISM OF COMPULSORY LICENSING

Impact on Innovation and Foreign Investment: Pharmaceutical companies claim that compulsory licensing (CL) hinders research and development (R&D) investments as it diminishes patent exclusivity.[31] One of the major reasons for innovator companies' innovation is that they can recoup their R&D investments, and frequent issuance of CLs and the threat of CLs does dissuade companies from investing in the development of a drug, particularly in developing markets like India.[32] This has raised concerns that multinational corporations may move toward markets with better patent protections.

Trade & Diplomatic Pressures: Developed countries, notably the United States and the European Union, have consistently put pressure on India to tighten its intellectual property regime and curtail the exercise of compulsory licensing.[33] The United States has often placed India on its Priority Watch List in its Special 301 Report due to its IP policies being unfavourable to American businesses.[34] In addition, India has been threatened with trade sanctions and legal action under bilateral investment treaties for issuing CLs, highlighting the geopolitical ramifications of patent rights and public health.

Slow and Complex Process: Compulsory licensing (CL), for example, is an important tool for public health, but the bureaucratic and judicial procedures to obtain a CL are long and complicated. Indian courts and patent authorities impose strict scrutiny on these claims, leading to only a few CL approvals, but producing no easy access to patents for generic drug manufacturers.[35] This has led to the development of an alternative model known as voluntary licensing (VL), specifically when patent holders conjure agreements with generic manufacturers.

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[31] Cristiano Antonelli, 'Compulsory Licensing: The Foundations of an Institutional Innovation' (2013) 4(2) WIPO Journal: Analysis of Intellectual Property Issues <https://iris.unito.it/bitstream/2318/135740/2/compulsory_unito.pdf> accessed 27 March 2025

[32] Cristiana Sappa, *Research Handbook on Intellectual Property Rights and Inclusivity* (Edward Elgar Publishing 2024)

[33] Mohammad Rauf and Rajesh Tamang, 'Access to Medicines and Intellectual Property Law: Balancing Innovation and Public Health' (2023) 2(3) Interdisciplinary Studies in Society, Law, and Politics <https://doi.org/10.61838/kman.isslp.2.3.5> accessed 27 March 2025

[34] K. D. Raju, 'Compulsory v Voluntary Licensing: A Legitimate Way to Enhance Access to Essential Medicines in Developing Countries' (2017) 22 Journal of Intellectual Property <https://nopr.niscpr.res.in/bitstream/123456789/41444/1/JIPR%2022(1)%2023-31> accessed 27 March 2025

[35] Carlos M. Correa and Reto M. Hilty, *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (Springer Nature 2022)

Alternative Strategies of Big Pharma: However, such compulsory licensing of pharmaceutical products would be a radical step that few pharmaceutical companies are willing to take in practice; most prefer voluntary licensing (VL) where they retain control over production, pricing, and distribution.[36] A quintessential case in this regard is Gilead Sciences, which began voluntarily licensing the rights to its Hepatitis C drugs to several manufacturers in India, resulting in affordable pricing while still keeping a strong position in the market. Such a trend is emblematic of a broader strategic pivot, whereby patent holders work out license terms in advance rather than find themselves at the mercy of government-imposed CLs.

FUTURE OF COMPULSORY LICENSING IN INDIA

India's existing compulsory licensing (CL) framework will need to adapt and strengthen concerning public health needs, international trade pressures, and global policy reforms. A key policy consideration is expanding CL provisions beyond cancer and rare diseases to encompass a wider range of essential medicines.[37] Moreover, facilitating the authorisation of CLs for public health emergencies may facilitate access to life-saving medicines during public health emergencies, like pandemics.[38]

From Brazil and Thailand, we learn that compulsory licensing can be a powerful tool if used effectively. CLs in Brazil greatly reduced treatment prices for HIV/AIDS drugs, increasing access.[39] Thailand has also used CLs for heart disease and cancer drugs over the protests of pharmaceutical corporations, showing the power of strong legal frameworks in the face of trade pressures.

India continues to influence global intellectual property (IP) policies. It has been a leading and vocal proponent at the World Trade Organisation (WTO) for reforms to TRIPS to

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[36] Raju (n 34)
[37] Raadhika Gupta, 'Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations' (2010) 15 Journal of Intellectual Property Rights <https://docs.manupatra.in/newsline/articles/Upload/6A48CA82-9412-43DE-8964-1CAC00062503.pdf> accessed 27 March 2025
[38] Harish Chander et al., 'Current Scenario of Patent Act: Compulsory Licensing' (2013) 47(3) Indian Journal of Pharmaceutical Education and Research <https://pdfs.semanticscholar.org/8351/c5c06a9d4f192e6d67301de524040457b86c.pdf> accessed 27 March 2025
[39] Divya Murthy, 'The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health' (2002) 17(6) American University International Law Review <https://core.ac.uk/download/pdf/235401856.pdf> accessed 27 March 2025

promote access to medicines in situations of pandemics and disease outbreaks. By utilising this positive combination, India can both update its legal framework and preserve its status as a forerunner in the field of generic drug manufacturers while promoting a balanced approach that would keep the costs down while ensuring development in the pharmaceutical and biopharma industry.

CONCLUSION

India's CL framework continues to be an important tool for balancing intellectual property rights with public health goals. The landmark case of NATCO-Bayer showed how effective CL can be at making life-saving drugs affordable and cemented India's commitment to providing access to essential medicines. But many barriers remain, including pressure from international trade, slow approvals, and pushback from pharmaceutical companies.

How developed countries react against CL and the trend of multinational pharmaceutical companies opting for VL indicates the politics behind the implementation of CL. There should be a serious review of their respective provisions and amendments/ reforms undertaken to make them more expansive in terms of coverage of essential medicines and a faster approval process in emergencies. India should further pursue its campaign at the WTO for TRIPS flexibilities, especially in times of pandemic medicine.

Finding an equilibrium between patent protection and public health is critical, not only to promote pharmaceutical innovation but also to preserve the inalienable right of the people to access affordable healthcare.

SUGGESTIONS

Particularly during public health crises, the approval procedure must be quicker and more responsive to improve the efficacy of compulsory licensing in India. Amending the Patents Act, 1970, to allow expedited procedures and widening the scope to cover essential and chronic disease medicines can significantly improve access. Establishing a centralised authority to assess and process applications would help streamline decision-making and ensure greater transparency.

Additionally, India should continue advocating for broader TRIPS flexibilities at international forums like the WTO to strengthen global support for equitable access to

medicines. A balanced framework that upholds patent rights while prioritising public health needs is crucial to ensure affordable healthcare without undermining pharmaceutical innovation and investment in research and development.