



JOURNAL OF INTERNATIONAL LAW, POLITICS AND SOCIETY

An International Open Access Double Blind Peer Reviewed

ISSN No.: 3108-0464

Volume 2 | Issue 3 (Jul.-Sep.) | 2026

Art. 14

Why India did not Invoke Section 92: A Post-Covid-19 Institutional Analysis of Compulsory Licensing Underutilization

Amrita Safal M

LLM Student (IPR),

Amity Law School, Amity University, Bengaluru

Dr. Ajoy Jose

Assistant Professor,

Amity Law School, Amity University, Bengaluru

Recommended Citation

Amrita Safal M and Dr. Ajoy Jose, *Why India did not Invoke Section 92: A Post-Covid-19 Institutional Analysis of Compulsory Licensing Underutilization*, 2 JILPS 259-274 (2026).

Available at www.jilps.in/current-issue/

This Article is brought to you for free and open access by the Journal of International Law, Politics and Society by an authorized Lex Assisto & Co. administrator. For more information, please contact jilpslawjournal@gmail.com.

Why India did not Invoke Section 92: A Post-Covid-19 Institutional Analysis of Compulsory Licensing Underutilization

ABSTRACT

The Indian Patents Act, 1970 has one of the strongest emergency compulsory licensing provisions in the WTO a provision that allows the Central Government to grant use of a patented invention within three years of its initiation of a "national emergency" notification, but without the requirement for a public interest hearing. In spite of the high public health impact of the COVID-19 pandemic, no formal notification was issued by the Government of India under Section 92, even though there was a strong call for a TRIPS waiver from the international community. This paper offers an institutional analysis that goes beyond doctrinal explanations of the compulsory licensing regime and explores the administrative, bureaucratic and geopolitical structure which shaped this result. The paper seeks to understand why Section 92 was not used in India during COVID-19 based on the "implementation paradox" literature, and argues that the reasons are threefold: definitional ambiguity regarding statutory trigger conditions, lack of an inter-ministerial fast-track mechanism, and a chilling effect from international trade pressure. The paper ends with recommendations for legislative and administrative changes, such as procedural changes to Sections 92 and 87 and the establishment of a permanent inter-ministerial emergency-licensing body.

KEYWORDS

Compulsory Licensing, Section 92, Patents Act 1970, COVID-19, TRIPS Agreement, Institutional Analysis, Implementation Paradox, Natco v. Bayer, Public Health Emergency, India.

1. INTRODUCTION

At the beginning of 2020, when the Covid-19 pandemic struck India, the country had the most advanced statutory system in the developing world for overriding patents for public health. Section 92 of the Patents Act, 1970 provides for the Central Government to make an authorisation to use a patented invention to be valid until the end of the normal three-year wait period for an application under Section 84, in favour of any use of the invention in a national emergency, extreme urgency or in the public interest without payment of any royalty.¹

India also has the manufacturing potential in its generic pharmaceutical

¹ Ajay Kumar, Patent System and Public Health in India, in Law and Medicine 124 (Manjit Singh & Ranjit Singh eds., 2025).

industry often reported as adequate to support a significant proportion of the medicines consumed in the developing world. But in over 2 years of the pandemic emergency, the Government of India never issued any Section 92 notification for any COVID-19 therapeutic, diagnostic or vaccine technology. This comes despite the fact that India, along with South Africa, presented and led a groundbreaking TRIPS waiver proposal at the World Trade Organization (WTO) for the temporary and temporary suspension of the enforcement of intellectual property rights for COVID-19 medical products.²

This paper dubs this juxtaposition as the main conundrum of India's patent policy after COVID-19 and queries as to why, in the presence of statutory powers, manufacturing capability and public health need, India failed to invoke Section 92? This phenomenon, often referred to as the "implementation paradox", has been well-documented in existing scholarship, where India's compulsory licensing framework has been underutilized despite being fairly sophisticated doctrinally.³

This paper is an attempt to further the discussion in this literature but with a different analytical lens, that of institutions - the bureaucratic, inter-ministerial, and geopolitical mechanisms that shape the likelihood that a legally available power will be exercised in practice.

The paper follows the line of: Part 2 provides a statement of the gap addressed by this paper, in the existing literature. Part 3 looks at the relevant scholarship thematically. The aims and methodology for the paper are outlined in Part 4 and Part 5. The institutional analysis itself is presented in Part 6 and structured along the three explanatory variables defined as definitional ambiguity, lack of inter-ministerial coordination, and international chilling effects. Findings and recommendations are provided in Part 7 with conclusions in Part 8.

2. RESEARCH GAP

There is a large body of literature on two aspects of Indian compulsory licensing. First, a considerable body of doctrinal literature describes the statutory structure of Sections 84, 92 and 47 of the Patents Act and places it into the context of the TRIPS obligations, and generally finds that it is

² Chintan Bhardwaj & Sanat Prem, Covid-19 Vaccine: A Case of Compulsory Licensing for Social Utility! (Jindal Global L. Sch., Working Paper No. 3853761, 2021).

³ Shailendra Singh, Compulsory Licensing Under Section 84-92 of Indian Patent Act 1970: An Analysis and Consequences on Life Saving Medicines (2025) (Ph.D. thesis, Mangalayatan University).

a "full set" and on paper one of the best.⁴

Second, a new body of empirical and normative literature has started to report the "implementation paradox" - the apparent disconnection between the statutory promise and the actual non-use in practice - and blamed it on definitional uncertainty with regard to the concept of "reasonable price", on the delay of the implementation process, as well as on the chilling effect of international trade pressure. Second, a new body of empirical and normative literature has started to report the "implementation paradox" - the apparent disconnection between the statutory promise and the actual non-use in practice - and blamed it on definitional uncertainty with regard to the concept of "reasonable price", on the delay of the implementation process, as well as on the chilling effect of international trade pressure.^{5 6}

A study that examines the non-use of Section 92 explicitly in the COVID-19 emergency as an institutional issue in its own right, rather than as an example of the wider Section 84 licensing paradox is, however, comparatively underdeveloped. There is no need to negotiate a Section 92 arrangement, no reasonable efforts to be demonstrated to be willing to obtain a voluntary licence and no waiting period is required as a condition of Section 92. This is not a procedural stumbling block preventing the use of S.84 in normal circumstances; its non-use in a national health emergency is inexplicable. However, the barriers are likely to exist elsewhere – outside the realm of a clear administrative trigger, of a disjointed emergency governance system, or of political-economic factors not related to statutory design.⁷ COVID specific scholarship points to some of these institutional factors, such as the sectoral division between the Epidemic Diseases Act, 1897 and Disaster Management Act, 2005 the international "chilling effect" of USTR watch-listing⁸ Then there is the gap between India's stance of international TRIPS-waiver support and its reluctance to license.⁹

⁴ Shailendra Singh, Compulsory licensing under section 84- 92 of Indian Patent Act 1970, An Analysis and consequences of Life Saving Medicines 2025 (Ph.D thesis, Mangalayatan University)

⁵ Jamal Ibrahim, Compulsory Licensing and its implication on innovation, A study of Indian Pharma Industry (June 2025) (Ph.D .dissertation, Galgotias University)

⁶ Kiriti Kala, Balancing Patent Protection and Public Access: A Study of Compulsory Licensing in India Post-COVID-19, 4 Int'l J. Hum. Rts. L. Rev. 277 (2025).

⁷ Abhinav Gupta & Aqa Raza, Patent Law and Compulsory Licensing: Indian Perspective, 29 J. Intell. Prop. Rts. 5 (2024).

⁸ Muhammad Zaheer Abbas, COVID-19 and the Issue of Affordable Access to Innovative Health Technologies: An Analysis of Compulsory Licensing of Patents as a Policy Option, in Law and Economics of the Coronavirus Crisis 265 (Klaus Mathis & Avishalom Tor eds., 2022).

⁹ Chintan Bhardwaj & Sanat Prem, Covid-19 Vaccine: A Case of Compulsory Licensing for Social Utility! (Jindal Global L. Sch., Working Paper No. 3853761, 2021).

As yet, however, no research has combined these elements into a coherent institutional narrative that is particular to Section 92, nor explored their interactions specifically during the COVID-19 era. This paper fulfills that need.

3. LITERATURE REVIEW

3.1 *The Statutory Promise*

Indian compulsory licensing system is a doctrinally sound one, as has been well established in a significant volume of scholarship. As an ensemble, Sections 84, 92 and 47 create a constitutionally grounded framework that transforms patent law into a tool for human welfare, while the dispensation of the ordinary waiting period is the “emergency cornerstone” of Section 92.¹⁰ The decision of the Controller General in the *Natco Pharma Ltd. v. Bayer Corporation* case has been discussed as being “legally correct” and “compliant with the TRIPS obligations”, and as being the judicial interpretation of “reasonable price” that is at the heart of the emergency provisions.¹¹

The Patents Act 2005 (as amended) is regarded as one of the most comprehensive compulsory licensing systems in the developing world in terms of comparative doctrinal surveys.

3.2 *The Implementation Paradox*

Alongside this sophistication in the statute, India has a significant generic manufacturing capability but as far as the implementation of Compulsory Licensing is concerned, it is almost non-existent with only the single Natco licence granted in more than 50 years of the Act's existence.¹² Three explanatory variables come together when statutory ambiguity in the definition of “affordability” leads to high rejection rates, while the bureaucratic delay of 12 to 24 months, and international trade pressure, have a chilling effect on the executive's willingness to invoke Section 92's emergency powers.^{13 14}

¹⁰ V. Parthasarathi, *Analysis of Compulsory Licensing in India and its Perceived Impact During the Covid Era*, 4 GLS L.J. 23 (2022).

¹¹ Mayuri Gupta, S. Shanthakumar & Deesha Khair, *India's Legislative Response to the COVID-19 Health Emergency: Making the Case for a Comprehensive Public Health Emergency Law in India*, 43 J. L. & Pol. Sci. 502 (2024).

¹² V. Kuek, K. Phillips & J.C. Kohler, *Access to Medicines and Domestic Compulsory Licensing: Learning from Canada and Thailand*, 5 Glob. Pub. Health 111 (2010).

¹³ Padmavati Manchikanti & Michelle Dias, *Pandemic, Patents and Public Health*, 26 J. Intell. Prop. Rts. 187 (2021).

¹⁴ Aisling M. McMahon, *Intellectual Property Rights and Global Access to Health Technologies During Pandemics: Reflecting on Vaccine Nationalism, COVID-19 & the WHO Pandemic Agreement Negotiations*, 53 J.L. Med. & Ethics 398 (2025).

This body of work re-invents the problem of the 'patent barrier' to the public health sovereignty of India as having shifted from a legal to a structural 'capacity barrier', where a validly issued licence could be rendered essentially worthless without the accompanying technical know-how.

3.3 COVID-19-Specific Scholarship

There is a separate body of literature which deals directly with the pandemic period. As the U.S. Trade Representative's watch-listing regime has emerged as a key barrier to Section 92 executive action during the pandemic, scholars have explored the geopolitical factor behind this tool.¹⁵ Some have argued that India had not acted strategically against the implementation of Section 92 and its simultaneous TRIPS waiver at the WTO is proof of this.¹⁶

It has been argued that the normal rules of Section 87 should have been completely waived during the health emergency because otherwise the administration would defeat the purpose of the Act of providing protection to the people and the pandemic has resulted in India only a "highly restricted strategic advantage" and not the desired public health outcome as provided in the Act.¹⁷

The institutional fragmentation has also been attributed: The lack of a well-integrated regulatory framework between the Epidemic Diseases Act, 1897 and Disaster Management Act, 2005 has been cited as a source of ambiguity which translates directly into the intellectual property realm, lending credence to the argument that the lack of an emergency-trigger mechanism in the legislation is a correctable gap.¹⁸

3.4 Comparative Perspectives

Comparative scholarship puts the Indian hesitation in contrast to the more forthright practice of other jurisdictions. Brazil and Thailand's experience with the threat of compulsory licensing but no licenses ever issued is repeatedly mentioned as a prime example of the power of the threat of compulsory licensing as a diplomatic bargaining chip, and a

¹⁵ Lowri Davies, *Compulsory Licensing: An Effective Tool for Securing Access to Covid-19 Vaccines for Developing States?*, 43 Legal Stud. 86 (2023).

¹⁶ Zhanpeng Li & Peng Guo, *Compulsory Licensing of Pharmaceuticals During Public Health Crisis: A TRIPS Framework Analysis*, 13 Front. Pub. Health 1630586 (2025).

¹⁷ Olga Gurgula & Luke McDonagh, *On Compulsory Licensing of Trade Secrets to Safeguard Public Health*, 84 Cambridge L.J. 630 (2025).

¹⁸ Olga Gurgula & Luke McDonagh, *Access Denied: The Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools* (STOPAIDS, Research Report, 2023).

driver of significant price reductions from multinational originators.¹⁹

At the end of a structured comparison, Canada is found to be "materially inferior on access" to Thailand due to the latter's eagerness to issue licences despite "corporate wrath," a fact that is said to directly affect the Indian scepticism that has been documented in response to TRIPS-Plus pressure.

3.5 The Capacity and Trade-Secrets Barrier

An advanced line of argument asks whether even if compulsory licensing had been deployed, it would have been adequate to meet the particular technological needs of COVID-19. A standard compulsory licence even issued may not be sufficient to allow generic manufacturers to manufacture the complex biologics and mRNA vaccines if it doesn't include the confidential manufacturing know-how, cell lines and tacit knowledge of the process.²⁰

This scholarship is a development of the arguments for the compulsory licensing of trade secrets to be extended under the public interest exceptions as per TRIPS.

Empirical studies have repeatedly shown that MNCs have refused to supply such proprietary information even when it comes via voluntary channels, such as through the Medicines Patent Pool. The TRIPS proposal on waiver of intellectual property rights, and its consequences, are examined as a measure (eventually restricted in scope) to fill just this capacity gap.

3.6 Human Rights and Constitutional Framing

Another strand of scholarship supports compulsory licensing not just as a flexibility within the realm of trade law but also as a constitutional and human-rights obligation, and proposes that the enforcement of IP rights to the exclusion of compulsory licensing may constitute a violation of the right to health and, consequently, the right to life.²¹

The courts interpreting the emergency powers in the context of extreme emergencies, should give greater weight to the "transcendent right" to public health than to a blanket right to private property, as the phrase "public health" may have been underused during the COVID-19

¹⁹ Raadhika Gupta, Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations, 15 J. Intell. Prop. Rts. 357 (2010).

²⁰ Raadhika Gupta, Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations, 15 J. Intell. Prop. Rts. 357 (2010).

²¹ General Council Decision, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 (Sept. 2, 2003).

situation, in accordance with the constitutional analysis directly relevant to the Indian context which suggests this.

3.7 The Counter-Narrative

Last, the literature seriously addresses the concern of innovation incentives raised against compulsory licensing. The most stringent economic analyses make exceptions for IP suspension in cases of informational asymmetries in pharmaceutical markets, and do not oppose compulsory licensing itself, but rather advocate its use alongside other measures such as advance purchase agreements, research subsidies, and voluntary licensing pools.²²

Similar conclusions emerge from analysis of the government use and compulsory-licensing mechanisms in the context of the COVID-19 vaccine. Discrediting the argument that innovation-incentive is enough to justify the lack of use of India's statutory powers.

4. OBJECTIVES

The main purpose of this paper is fourfold: first, to throw light on the statutory framework of Section 92 and why its application was regrettably not made during the COVID-19 pandemic, given that it has been invoked during the pandemic in other instances; second, to identify and analyse the specific institutional and bureaucratic hurdles that explain India's failure to invoke Section 92 during the pandemic; third, to challenge the seeming contradiction of the Indian state's vocal advocacy of TRIPS waiver during COVID-19 and its reticence to exercise the corresponding domestic power; and fourth, to suggest specific institutional and legislative changes that might help address the implementation paradox in the future in the context of a public health crisis.

5. RESEARCH METHODOLOGY

This paper uses a doctrinal and analytical approach, which is backed up by an institutional analysis. It is based on primary legal sources (1970 Patents Act, 1897 Epidemic Diseases Act, 2005 Disaster Management Act, TRIPS Agreement, Doha Declaration and other relevant WTO²³ instruments) and secondary sources (peer-reviewed journal articles, doctoral theses, working papers and international-organisation reports)²⁴ identified through a structured literature review of

²² Mitja Kovac & Lana Rakovec, The COVID-19 Pandemic and Long-Term Incentives for Developing Vaccines: Patent Law Under Stress, 25 J. World Intell. Prop. 292 (2022).

²³ Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001).

²⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15,

compulsory licensing scholarship, and in particular COVID literature from after 2020. The case of Natco Pharma Ltd. v. Bayer Corporation is explored as a comparative baseline: the only successful compulsory licence issued 'outside' an emergency (under Section 84, not Section 92) to be used as a control case from which to evaluate the pandemic's failure to invoke Section 92. This paper's institutional analysis is based on the "implementation paradox" framework that has been developed in the literature, and applied specifically to the emergency-licensing context. A limitation of this paper is that it does not engage in primary empirical research (interviews with officials of the Patent Office or the Ministry of Commerce and Industry); therefore, the claims of the institutions are not based on first-hand knowledge, but on documented secondary evidence and should thus be considered an analytical synthesis and not a description of an ethnographic experience.

6. ANALYSIS: AN INSTITUTIONAL ACCOUNT OF NON-INVOCATION

6.1 Definitional Ambiguity and the Absent Trigger

Section 92 permits the Central Government to notify a compulsory licence upon being "satisfied" that a "circumstance of national emergency," "extreme urgency," or need for "public non-commercial use" has arisen. Unlike comparable emergency powers in other jurisdictions, the provision supplies no statutory definition of any of these three trigger conditions, nor any objective threshold – such as a case count, mortality rate, or WHO declaration – that would compel the executive to act. This definitional vacuum matters because it converts what ought to be a largely automatic administrative trigger into a matter of unstructured executive discretion. Where Section 84 rejection rates are attributed to ambiguity over "reasonable price,"²⁵ the equivalent ambiguity under Section 92 is prior in the causal chain: without a clear definition of what constitutes an "emergency" sufficient to trigger the provision, the Ministry of Commerce and Industry faces no institutional pressure legal, political, or bureaucratic to notify a licence even where the underlying public health facts would self-evidently satisfy any reasonable definition of emergency. The World Health Organization's declaration of COVID-19 as a Public Health Emergency of International Concern in January 2020, and subsequently a pandemic in March 2020, supplied ample international legal cover for a Section 92 notification; that this external validation did not translate into domestic executive action confirms that the barrier lies not in evidentiary uncertainty but in the

1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

²⁵ V. Parthasarathi, Analysis of Compulsory Licensing in India and its Perceived Impact During the Covid Era, 4 GLS L.J. 23 (2022).

absence of a clear, self-executing statutory trigger.

6.2 Fragmented Emergency Governance and the Absence of Inter-Ministerial Coordination

Another institutional hurdle is the fragmented structure of the public health emergency response system in India that is divided into sectors. Epidemic Diseases Act, 1897 and Disaster Management Act, 2005 govern the formal emergency response of India, but both acts have no explicit reference to the Patents Act, 1970 and to the Ministry of Commerce and Industry, which are responsible for implementing Section 92.²⁶ This results in a structural coordination failure, as the ministries with a mandate to declare a public health emergency (Epidemic Diseases Act – Ministry of Health and Family Welfare; 2005 Act – National Disaster Management Authority) are institutionally different from each other and have no statutory mandate to coordinate with each other in the event of a public health emergency. Such an 'inter-ministerial initiative' is therefore required, but is not prescribed by statute and there is no standing institutional mechanism to encourage it, and is therefore at the discretion of the individual minister. India's health emergency response was triggered under both the 1897 and 2005 Acts throughout 2020 and 2021, but there was no "fast-track licensing trigger," or automatic notification obligation, that would have sparked action on compulsory licensing, which was essentially institutionally silent until a discretionary step was taken by an actor, without a clear responsibility, to trigger the mechanism.

6.3 The International Chilling Effect and Strategic Bifurcation

The third and most politically relevant institutional hurdle is the chilling effect of international trade pressure, especially brought about by the Special 301 watch-listing process of the United States Trade Representative (USTR), which is a watch-list of jurisdictions under whose jurisdiction intellectual property is "fundamentally deficient. The third, most politically relevant hurdle is the chilling effect of international trade pressure, most visibly, the Special 301 watch-listing process by U.S. Trade Representative (USTR) on jurisdictions, which is a watch-list of jurisdictions with "fundamentally deficient" intellectual property enforcement regimes.²⁷ This creates an interesting bifurcation in India's pandemic patent policy. At the multilateral level, India (along

²⁶ Mayuri Gupta, S. Shanthakumar & Deesha Khair, India's Legislative Response to the COVID-19 Health Emergency: Making the Case for a Comprehensive Public Health Emergency Law in India, 43 J. L. & Pol. Sci. 502 (2024).

²⁷ Aisling M. McMahon, *Intellectual Property Rights and Global Access to Health Technologies During Pandemics: Reflecting on Vaccine Nationalism, COVID-19 & the WHO Pandemic Agreement Negotiations*, 53 J.L. Med. & Ethics 398 (2025).

with South Africa) co-sponsored one of the most ambitious TRIPS reform proposals in the history of the WTO, calling for a blanket waiver of patent, trade secret and related IP obligations for medical products related to COVID-19.²⁸ But domestically, the same government used its much more limited and existing Section 92 power not once. This isn't just a contradiction, it's a revealing incongruity. The diplomatic burden of multilateral advocacy of TRIPS waiver is high – it can lead to friction between the country and its trading partners – but low from a bureaucratic perspective because responsibility for managing the waiver lies with several WTO members and the political burden is distributed. A unilateral Section 92 notification, on the other hand, would have left the Indian government with a single bill to process the consequences of unilateral retaliation, Special 301 action and originator-company litigation—consequences that would have fallen completely on the shoulders of the Indian executive. The institutional incentive structure thus encouraged vocal multilateral advocacy, a signal of domestic political support for public health access but no concentrated bilateral cost, over unilateral domestic action, which would have. This asymmetry provides a more thorough institutional account of the paradox than the definitional-ambiguity and coordination-failure accounts do: it accounts not only for the dearth of Section 92, but also the also-ostensible more radical remedy undertaken internationally by the same government.

6.4 The Capacity Barrier as a Secondary but Compounding Constraint

If the two barriers above had been surmounted, a third would have hindered the usefulness of a Section 92 notification for the most important technologies of the pandemic. While such a “capacity barrier”²⁹ doesn't fully account for why the government has not sought to notify a licence, or why the smaller-molecule therapeutic and diagnostic sectors might not see any obvious benefit to compulsory licensing, it does help to explain why the ‘policy makers’ in the government who would have been most inclined to seek such action may have felt that invocation would yield little practical benefit against the diplomatic or administrative costs.

6.5 Natco v. Bayer as a Cautionary Institutional Precedent

Last, but not least, the Natco precedent itself may have been a deterrent and not an enabler. While it is generally accepted in the literature that the

²⁸ Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669/Rev.1 (May 21, 2021).

²⁹ Mayuri Gupta, S. Shanthakumar & Deesha Khaire, *India's Legislative Response to the COVID-19 Health Emergency: Making the Case for a Comprehensive Public Health Emergency Law in India*, 43 J. L. & Pol. Sci. 502 (2024).

compulsory licence was legally valid and TRIPS compliant,³⁰ the long appellate litigation that ensued from the original order of the Controller (before the Intellectual Property Appellate Board and the Bombay High Court) ³¹showed to the bureaucratic stakeholders that even a single carefully reasoned compulsory licence would warrant several years of cross-factional litigation, appeal and international challenges. A Natco experience suggests that compulsory licensing has a significant practical disadvantage because it presents a long-term institutional and reputational burden that is not worth the immediate benefit when a health emergency is ongoing – and serves as a disincentive to action, as noted above.

7. FINDINGS AND RECOMMENDATIONS

7.1 Findings

The analysis suggests that the non-invocation of Section 92 during COVID-19 is attributable to three institutional factors: a lack of a clear statutory basis for invoking the section leaves it institutionally 'unripe' even during an emergency situation; no formal co-ordinating mechanism between India's public health emergency laws and its patent laws means the latter remains 'unlit' even when public health emergency laws are 'lit'; and the international political economy rewards multilateral advocacy widely dispersed across the international community, and punishes concentrated, unilateral advocacy in a single country, explaining the strategic bifurcation that is evident in India's simultaneous TRIPS-waiver leadership and domestic non-action. The capacity barrier is a secondary, compounding issue that also undermined the institutional case for invoking, and so did the Natco precedent.

7.2 Recommendations

These lead to four changes. First, the criteria in Section 92 need to be amended to establish objective statutory triggers, such as a declaration under the Epidemic Diseases Act, 1897, or a declaration of a Public Health Emergency of International Concern by the WHO or a Disaster Management Act 2005 notification of a disaster of 'severe' category; making executive discretion a rebuttable presumption of emergency once any such external trigger is met. Second, Parliament should establish a Standing Inter-Ministerial Committee comprising of the Ministry of Commerce and Industry, the Ministry of Health and Family

³⁰ V.K. Unni, *Compulsory Licensing of Pharmaceutical Patents in India: Whether the Natco Decision Will Meet the Global Benchmarks?*, 37 E.I.P.R. 296 (2015).

³¹ Natco Pharma Ltd. v. Bayer Corp., Patent No. 215758, Compulsory License Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012), aff'd, Bayer Corp. v. Union of India, (2014) 15 SCC 1 (India).

Welfare and the Department of Pharmaceuticals etc. with the specific statutory duty to examine the invocation of Section 92 within a stipulated time of say 30 days, after the declaration of a qualifying emergency. Third, during any national health emergency, the rules governing the process of invoking Section 87 of the Emergency Relocation Act be suspended to eliminate any administrative delay in invoking the act. Fourth, the reforms above should be combined with ongoing public sector investment in domestic manufacturing and technology transfer capacity, including via the public sector undertaking, so that a Section 92 notification becomes actual manufacturing capacity, not just a piece of paper.

8. CONCLUSION

India's Patents Act, 1970 provides an emergency compulsory licensing power much more robust than the standard Section 84 regime which has garnered the majority of scholarly examination. As India championed a bold global appeal for a similar multilateral solution during the COVID pandemic, what has been neglected is the fact that this power was not used. The reasoning in this paper has been that it is much more about institutional design: the definition of no emergency trigger, no formal coordination between India's public health emergency architecture and its patent law, the international political economy structurally favours diffuse multilateral advocacy over concentrated unilateral action. In the event of a future public health emergency, then, reform of the substantive scope of Section 92 is not enough to solve India's compulsory licensing "implementation paradox" it will be necessary to reform the institutional and administrative scaffolding that determine.

BIBLIOGRAPHY

Statutes

- The Patents Act, No. 39 of 1970, India Code (1970), §§ 84, 87, 92.
- The Patents (Amendment) Act, No. 15 of 2005, India Code (2005).
- The Epidemic Diseases Act, No. 3 of 1897, India Code (1897).
- The Disaster Management Act, No. 53 of 2005, India Code (2005).

International Instruments

- Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.
- Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001).

- General Council Decision, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540 (Sept. 2, 2003).

WTO Working Documents & Reports

- Council for TRIPS, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, WTO Doc. IP/C/W/669/Rev.1 (May 25, 2021) (communication from India and South Africa).
- Ministerial Conference, Ministerial Decision on the TRIPS Agreement, WTO Doc. WT/MIN(22)/30 (June 17, 2022).

Cases

- Natco Pharma Ltd. v. Bayer Corp., Patent No. 215758, Compulsory License Application No. 1 of 2011 (Controller of Patents, Mar. 9, 2012), aff'd, Bayer Corp. v. Union of India, (2014) 15 SCC 1 (India).

Articles

1. Rohaini, Lindati Dwiatin & Dianne Eka R, The Government Use and Compulsory License: Questioning the Patent Application of Drug and Covid-19 Vaccines, 5 Jambe L.J. 207 (2022).
2. Muhammad Zaheer Abbas, COVID-19 and the Issue of Affordable Access to Innovative Health Technologies: An Analysis of Compulsory Licensing of Patents as a Policy Option, in Law and Economics of the Coronavirus Crisis 265 (Klaus Mathis & Avishalom Tor eds., 2022).
3. Chintan Bhardwaj & Sanat Prem, Covid-19 Vaccine: A Case of Compulsory Licensing for Social Utility! (Jindal Global L. Sch., Working Paper No. 3853761, 2021).
4. Lowri Davies, Compulsory Licensing: An Effective Tool for Securing Access to Covid-19 Vaccines for Developing States?, 43 Legal Stud. 86 (2023).
5. Abhinav Gupta & Aqa Raza, Patent Law and Compulsory Licensing: Indian Perspective, 29 J. Intell. Prop. Rts. 5 (2024).
6. Mayuri Gupta, S. Shanthakumar & Deesha Khair, India's Legislative Response to the COVID-19 Health Emergency: Making the Case for a Comprehensive Public Health Emergency Law in India, 43 J. L. & Pol. Sci. 502 (2024).
7. Raadhika Gupta, Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations, 15 J. Intell. Prop. Rts. 357 (2010).

8. Olga Gurgula & Luke McDonagh, Access Denied: The Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools (STOPAIDS, Research Report, 2023).
9. Olga Gurgula & Luke McDonagh, On Compulsory Licensing of Trade Secrets to Safeguard Public Health, 84 Cambridge L.J. 630 (2025).
10. James G. Hodge, Jr., Jennifer L. Piatt, Hanna N. Reinke & Emily Carey, Covid's Constitutional Conundrum: Assessing Individual Rights in Public Health Emergencies, 88 Tenn. L. Rev. 283 (2021).
11. Jamal Ibrahim, Compulsory Licensing and its Implication on Innovation: A Study of Indian Pharma Industry (June 2025) (Ph.D. dissertation, Galgotias University).
12. Kiriti Kala, Balancing Patent Protection and Public Access: A Study of Compulsory Licensing in India Post-COVID-19, 4 Int'l J. Hum. Rts. L. Rev. 277 (2025).
13. Mitja Kovac & Lana Rakovec, The COVID-19 Pandemic and Long-Term Incentives for Developing Vaccines: Patent Law Under Stress, 25 J. World Intell. Prop. 292 (2022).
14. V. Kuek, K. Phillips & J.C. Kohler, Access to Medicines and Domestic Compulsory Licensing: Learning from Canada and Thailand, 5 Glob. Pub. Health 111 (2010).
15. Ajay Kumar, Patent System and Public Health in India, in Law and Medicine 124 (Manjit Singh & Ranjit Singh eds., 2025).
16. Zhanpeng Li & Peng Guo, Compulsory Licensing of Pharmaceuticals During Public Health Crisis: A TRIPS Framework Analysis, 13 Front. Pub. Health 1630586 (2025).
17. Padmavati Manchikanti & Michelle Dias, Pandemic, Patents and Public Health, 26 J. Intell. Prop. Rts. 187 (2021).
18. Aisling M. McMahon, Intellectual Property Rights and Global Access to Health Technologies During Pandemics: Reflecting on Vaccine Nationalism, COVID-19 & the WHO Pandemic Agreement Negotiations, 53 J.L. Med. & Ethics 398 (2025).
19. V. Parthasarathi, Analysis of Compulsory Licensing in India and its Perceived Impact During the Covid Era, 4 GLS L.J. 23 (2022).
20. Kadiyala Venkata Sahitya & K I Pavan Kumar, A Paradigm Shift in Indian and International Patent Regime- Critical Review on Ex-and Current Scenario (Covid-19 Impact), 28 J. Intell. Prop. Rts. 293 (2023).
21. Shailendra Singh, Compulsory Licensing Under Section 84-92 of Indian Patent Act 1970: An Analysis and Consequences of Life Saving Medicines (2025) (Ph.D. thesis, Mangalayatan University).
22. Mayank Sood, Natco Pharma Ltd. v. Bayer Corporation and the Compulsory Licensing Regime in India, 2013 Manupatra Intell. Prop. Rep. 45, 48.
23. Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang & Graham Dutfield, Addressing Vaccine Inequity During

the COVID-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond, 81 Cambridge L.J. 384 (2022).

24. V.K. Unni, Compulsory Licensing of Pharmaceutical Patents in India: Whether the Natco Decision Will Meet the Global Benchmarks?, 37 E.I.P.R. 296 (2015).
25. Khorsed Zaman, Decolonizing Human Rights Law in Global Health – the Impacts of Intellectual Property Law on Access to Essential Medicines: A Perspective from the COVID-19 Pandemic, 14 Asian J. Int'l L. 386 (2024).