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COMPULSORY LICENSING OF PATENTS AND ITS ROLE IN PROMOTING MARKET COMPETITON

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ABSTRACT

The relationship between intellectual property and competition in marketplaces has been the subject of a protracted legal and economic controversy. Within this framework, Compulsory Licensing represents a key legal tool for allowing governments to bypass patent exclusivity, particularly to protect public interest, affordability and market access. In this article we will discuss the role of compulsory licensing in India and the importance of implementing such provisions to help create market competitiveness, primarily within the pharmaceutical domain.

This paper investigates the legal and policy framework regulating compulsory licensing under the Indian Patents Act, 1970, in particular, Sections 84 and 92, and its consistency with international standards proposed by the TRIPS Agreement. Using the precedent-setting Natco v. Bayer decision as a case study, the article demonstrates the role of compulsory licensing as an antidote to patent monopolies that undermine the right to access to medicines and stifle competition in the pharmaceutical market. The paper also considers the economy-wide effects of compulsory licensing in terms of price reduction, price competition afforded by generic competitors, and terms of consumer welfare, respectively.

This paper considers domestic case law, policy positions, and academic controversy and concludes that in principle, compulsory licensing, properly applied, has the potential to strike the right balance between the protection of innovation and the promotion of competition. A few examples from other jurisdictions (the US and EU) are provided in passing to situate India's current "emergent" approach. Finally, the paper offers recommendations as to how to improve procedural clarity and enforcement of the provisions of compulsory licensing so as to preserve their relevance for a post-TRIPS world economy.

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Key Words: Compulsory Licensing, Patents, Competition Law, Pharmaceutical Industry, TRIPS, Access to Medicines, Natco v. Bayer, Indian Patent Act

INTRODUCTION

The patent system is intended to word that balance to encourage invention while still providing the public access to important items. But when the use of exclusive patent rights results in monopolistic pricing and access impediments, especially in fields such as pharmaceuticals, then the mandatory licensing becomes a tool to bring the level of competition back to equilibrium. Compulsory licenses permit a government or its delegate to use a patented invention without the consent of the patentee under certain conditions established by law. Such a mechanism has an important role to play in the interface between patent law and competition policy by contributing to fostering technology transfer while also ensuring affordable access to life-saving drugs and preventing the abusive exercise of patent power.

As Ghosh[2] explains further, compulsory license is a legal redress to combat anticompetitive behaviour and price manipulation borne out of patent monopolies, especially in the life-saving drug markets. In these circumstances, patent monopoly can restrict affordable access, while compulsory licensing is a regulatory tool that addresses market inefficiencies and promotes competition. Ali and Khan[3] highlighted that the principle of compulsory licensing has solved the gap between intellectual property rights and intellectual monopolies, thereby, ensuring a balanced legal system that encourages the public interest along with maintaining the sanctity of patented rights.

The article by Ullrich draws the relevant but subtle difference between the functions of competition law and patent law in the control of access to technology: both aim to address distinct concerns but together play a "yin-and-yang" role[4]. In patent law, the law grants monopoly rights, whereas in competition law, the law steps in when those rights are abused to the detriment of innovation or market access. The interaction between the two systems is particularly pertinent in cases of EC licences.

[2] Ghosh, R., 2020. Compulsory licensing of patents and its effect on competition. Journal of Medical Society, 34(2), pp.55-60.

[3] Ali, N. and Khan, K.I., 2021. Legal framework for compulsory licensing: a solution to the conflict of intellectual property rights and intellectual monopoly. International Journal of Public Law and Policy, 7(2), pp.122-133.

[4] Ullrich, H., 2014. Mandatory licensing under patent law and competition law: different concerns, complementary roles. In Compulsory Licensing: Practical Experiences and Ways Forward (pp. 333-375). Berlin, Heidelberg: Springer Berlin Heidelberg.

The inclusion of compulsory licensing provisions is not only a reflection of national legal policy, but also one of international obligations such TRIPS Agreement. As McGivern[5] articulates, TRIPS offers significant leeway for members to build public-interest protections, including compulsory licensing, into domestic patent law. This is particularly essential in responding to public health emergencies and providing affordable medicines.

Academics such as Van Overwalle and Léonard[6] also posit that compulsory licensing should not be perceived as a menace to innovation, but as an indispensable means to rebalance access and value in the patent system. This view is also consistent with the worldwide discussion on fair licensing practices, particularly in LMICs. Taware[7] and Vawda[8] also document the significance of government's use licenses and compulsory licenses in circumventing the price and supply obstacles around vaccines and medicine.

The present paper examines compulsory licensing as a strategic legal tool to break down monopolistic barriers, pave the way for generic competition and safeguard the interest of consumers' especially in the Indian pharmaceutical market through lenses of the actor network theory and game theory.

CONCEPTUAL AND LEGAL FRAMEWORK OF COMPULSORY LICENSING

Compulsory licensing (CL) strikes the balance between patent rights and societal access to inventions. A government allows the third party to use a patent invention on given legal conditions without the consent of the holder. It is fundamentally based on the notion of public interest, especially when patenting takes away access to vital resources such as medicines. CL started as a tool for trade and its focus has now shifted towards public health, competition, and public interest.

[5] McGIVERN, L.A.U.R.E.N., 2023. Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation. The Milbank Quarterly, 101(4), pp.1280-1303.

[6] Van Overwalle, G. and Léonard, A., 2023. The public interest in compulsory licensing: examining the complementarity between IP and competition law. In A Critical Mind: Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property (pp. 331-365). Berlin, Heidelberg: Springer Berlin Heidelberg.

[7] Taware, M.R., 2023. Compulsory Licensing under Patent Laws and Pharmaceuticals: Impact, Issues and Way-out. Issue 2 Indian JL & Legal Rsch., 5, p.1.

[8] Vawda, Y.A., 2022. Compulsory licenses and Government Use: challenges and opportunities. Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law, pp.73-104.

The aim of the CL is to find a middle ground between intellectual property rights (IPRs) and social good especially when patents are prone to create monopolies. Compulsory licensing works as a "corrective tool" for the overly competitive damage inflicted by patents[9].

The set of licenses evolved from overly stringent requirement to more considerate and adaptable systems for public health. And access innovative patented ideas balanced out over the years further acknowledging the need for definitive licenses[10]. Compulsory licensing has evolved from a "last resort" option to an active policy tool in various jurisdictions.

Compulsory licensing gains international credibility from the TRIPS Agreement (Article 31), which allows member countries to grant these licenses under particular conditions, such as public health crises and anti-competitive behaviours. The Doha Declaration of 2001 reaffirmed nations' sovereign authority to utilize TRIPS flexibilities, such as compulsory licensing, to safeguard public health and enhance access to medications[11].

The European Union's framework[12] as inadequate and seldom utilized, highlighting the absence of procedural clarity and political commitment. They advocate for a stronger system that promotes legal use of compulsory licensing, particularly during emergencies such as pandemics. This comparative perspective is important for placing India's somewhat proactive position in context.

India has formalized compulsory licensing in Sections 84 to 92 of the Indian Patents Act, 1970, integrating TRIPS-compliant elements and considerations of public interest. The Indian system permits compulsory licensing based on reasons like the unmet reasonable needs of the public, the unaffordability of patented products, and the patent not being utilized in India[13]. They claim that this framework acts as a legal balance to "intellectual monopoly," facilitating competition in markets that would otherwise be monopolized. The Indian scenario, highlighting the Natco v. Bayer case as a significant moment in reinforcing the state's power to grant compulsory licenses

[9] Ghosh, R., 2020. Compulsory licensing of patents and its effect on competition. Journal of Medical Society, 34(2), pp.55–60.

[10] Gillat, A., 2003. Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry. Food and Drug Law Journal, 58(4), pp.711–740.

[11] McGivern, L.A.U.R.E.N., 2023. Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation. The Milbank Quarterly, 101(4), pp.1280–1303.

[12] Lamping, M., Batista, P.H.D., Correa, J.I., Hilty, R., Kim, D., Slowinski, P.R. and Steinhart, M., 2023. Revisiting the framework for compulsory licensing of patents in the European Union. Max Planck Institute for Innovation & Competition Research Paper, (23-07).

[13] Ali, N. and Khan, K.I., 2021. Legal framework for compulsory licensing: a solution to the conflict of intellectual property rights and intellectual monopoly. International Journal of Public Law and Policy, 7(2), pp.122–133.

for the overall benefit of the public. The law is well-organized but needs more robust institutional enforcement and consistent policies[14].

Although patent law provides exclusivity, competition law prevents the misuse of those rights, compulsory licensing as a legal tool at the junction of these areas, serving as a "balancing instrument"[15] when exclusivity results in market exclusion. The success of compulsory licensing relies on its integration with antitrust enforcement, particularly in situations involving dominant markets[16]. Connecting compulsory licensing to additional access methods like parallel imports and voluntary licenses. In critical fields such as pharmaceuticals, compulsory licensing frequently represents the most straightforward and effective means to surmount market obstacles and guarantee fair access[17].

Governments may grant compulsory licenses not only to private entities but also for direct public utilization. The significance of this tool during public health emergencies, particularly when postponements in negotiation or licensing could result in widespread human suffering. The effectiveness of these licenses relies not only on legal regulations but also on institutional preparedness and political determination[18].

Compulsory licensing, while grounded in the concept of patent exception, is progressively viewed as an active mechanism for promoting competitive markets, public accessibility, and cost-effective innovation. Both national and global legal systems support its validity, yet its efficacy relies on prompt implementation, strong procedural systems, and consistency with competition law principles. As patent landscapes change, particularly in healthcare and technology, the necessity for precisely tuned licensing policies becomes increasingly important.

[14] Taware, M.R., 2023. Compulsory Licensing under Patent Laws and Pharmaceuticals: Impact, Issues and Way-out. Issue 2 Indian JL & Legal Rsch., 5, p.1.

[15] Ullrich, H., 2014. Mandatory licensing under patent law and competition law: different concerns, complementary roles. In Compulsory Licensing: Practical Experiences and Ways Forward (pp.333–375). Berlin, Heidelberg: Springer Berlin Heidelberg.

[16] Van Overwalle, G. and Léonard, A., 2023. The public interest in compulsory licensing: examining the complementarity between IP and competition law. In A Critical Mind: Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property (pp.331–365). Berlin, Heidelberg: Springer Berlin Heidelberg.

[17] Garagancea, L., 2021. Access to medicines: the interplay between parallel imports, compulsory licensing, and voluntary licensing. EPLR, 5, p.37.

[18] Vawda, Y.A., 2022. Compulsory licenses and Government Use: challenges and opportunities. In Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law, pp.73–104.

COMPULSORY LICENSING AND MARKET COMPETITION

The point of intersection between market competition and compulsory licensing is the key to appreciating the extent to which patent regimes can be tempered in order to prevent monopolistic tendencies. Although patents necessarily grant monopolistic rights to innovators, such rights can be exploited to create artificial scarcity, slow down market entry of generics, and skyrocket prices—especially in the drug industry. Compulsory licensing is a regulatory policy that not only opens up public access but also re-establishes competitive conditions in the market.

Patents grant a legally enforceable monopoly for a short period to the inventor, allowing them to stop others from manufacturing, selling, or utilizing the patented product. This monopoly encourages innovation, it may be used to suppress market competition if the owners of the patents fix high prices or fail to sufficiently supply the market[19]. This is particularly relevant in the context of developing economies, where access to affordable medicine is a matter of significant public concern.

The market distortions are likely to be brought about by monopolistic behaviour facilitated by patent protection, particularly when patented drugs are either prohibitively expensive or unaffordable by the majority of consumers[20]. In such conditions, compulsory licensing is a salvaging tool that provides access for generic producers and enhances consumer welfare.

Forced or compulsory licensing promotes competition by judicially breaking up patent monopoly in a controlled manner. The Indian example of Natco v. Bayer is a good one: the grant of a compulsory license allowed Natco Pharma to produce and supply a generic form of the patented cancer drug Nexavar at a much lower price than Bayer's. This intervention not only enhanced the availability of the drug but also created price competition, without undermining the integrity of patent rights[21].

Similarly, compulsory licenses ensure a leveller playing field by allowing new entrants to legally manufacture and supply major products. The policy encourages price competition and supply-side

[19] Ali, N. and Khan, K.I., 2021. Legal framework for compulsory licensing: a solution to the conflict of intellectual property rights and intellectual monopoly. International Journal of Public Law and Policy, 7(2), pp.122–133.

[20] Ghosh, R., 2020. Compulsory licensing of patents and its effect on competition. Journal of Medical Society, 34(2), pp.55–60.

[21] Taware, M.R., 2023. Compulsory Licensing under Patent Laws and Pharmaceuticals: Impact, Issues and Way-out. Issue 2 Indian JL & Legal Rsch., 5, p.1.

diversification, thus improving product availability and improving public health facilities' resilience[22].

Compulsory licensing is at the intersection of patent law and competition law. When patent rights are employed to monopolize markets or shut out competitors, competition law needs to intervene to avert such misuse. Compulsory licensing can be regarded as a hybrid remedy[23], a basis in patent law but also performing the overarching objectives of market regulation and consumer welfare protection.

Compulsory licensing public interest justification closely connects with the goals of competition law, especially the prevention of abuse of dominant position under competition laws such as the Indian Competition Act, 2002 or Article 102 of the TFEU of the European Union[24].

While theoretical benefits of compulsory licensing as a means of encouraging competition are shared across the board, its application is often hindered by legal ambiguity, political hesitation, and procedural lethargy[25]. Increased competition regulation and coordination of intellectual property enforcement to make compulsory licensing a more powerful and effective remedy.

The broader market impact of compulsory licensing along with other solutions like parallel imports and voluntary licenses. Transparency and predictability in using compulsory licensing increase consumer choice, reduce dependence on a single supply, and create market-based pricing dynamics[26].

Compulsory licensing is not so much a statutory exception to patent rights; it is a pro-competitive tool that, if used judiciously, can avoid abuse of monopoly power, enhance market efficiency, and provide public access to essential goods. By facilitating market entry for generic producers and counterbalancing the impact of exclusivity-based pricing, compulsory licensing strengthens the

[22] Gillat, A., 2003. Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry. Food and Drug Law Journal, 58(4), pp.711–740.

[23] Ullrich, H., 2014. Mandatory licensing under patent law and competition law: different concerns, complementary roles. In Compulsory Licensing: Practical Experiences and Ways Forward (pp.333–375). Berlin, Heidelberg: Springer Berlin Heidelberg.

[24] Van Overwalle, G. and Léonard, A., 2023. The public interest in compulsory licensing: examining the complementarity between IP and competition law. In A Critical Mind: Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property (pp.331–365). Berlin, Heidelberg: Springer Berlin Heidelberg.

[25] Lamping, M., Batista, P.H.D., Correa, J.I., Hilty, R., Kim, D., Slowinski, P.R. and Steinhart, M., 2023. Revisiting the framework for compulsory licensing of patents in the European Union. Max Planck Institute for Innovation & Competition Research Paper, (23-07).

[26] Garagancea, L., 2021. Access to medicines: the interplay between parallel imports, compulsory licensing, and voluntary licensing. EPLR, 5, p.37.

objectives of intellectual property law as well as competition law. But it requires transparent regulatory structures, vigilant oversight, and political resolve for the public good.

JUDICIAL DEVELOPMENTS AND CASE LAW ANALYSIS

Judicial decisions have a pivotal role to play in interpreting and enforcing compulsory licensing provisions under patent law. Judges, patent regulatory authorities, and competition authorities often have the role of custodians of public interest when patent exclusivity conflicts with the ethos of accessibility, affordability, and fair competition. Judicial precedents of compulsory licensing suggest its potential as a judicial remedy for market exploitation, especially in life sciences areas like healthcare.

Indian Court Case: Natco Pharma Ltd. v. Bayer Corporation 2014(60) PTC 277 (BOM).

The most significant ruling on compulsory licensing in India is Natco Pharma Ltd. v. Bayer Corporation, Compulsory License Application No. 1 of 2011, dated 9 March 2012 by the Controller of Patents, Mumbai.

In this case, Natco had sought a compulsory license to produce a generic form of Bayer's patented oncology drug Nexavar (sorafenib tosylate) that cost approximately ₹2.8 lakhs per month—unaffordable for the majority of Indian patients. The Controller of Patents granted the license under the Indian Patents Act, 1970, Section 84 on three grounds:

- The legitimate expectations of the public were not being fulfilled,
- The patented innovation was not within a reasonable affordable price,
- The patented invention was never utilized within the territorial limits of India.

This decision was received as pro-access, TRIPS-compliant, and a significant step towards achieving a balance between intellectual property rights and public health and competition in the marketplace (Taware, 2023; Ali & Khan, 2021).

The judgment allowed Natco to market its generic version for ₹8,800 per month—a price well over a 95% reduction from Bayer's price—thereby significantly enhancing access. Further, it established the precedent that patent rights are not absolute, particularly with regard to issues pertaining to issues of public interest and market access (Ghosh, 2020).

Judicial Principles Declared in Natco v. Bayer

- Failure of patent in India warrants compulsory licensing even if the patentee is distributing the product by import.

- Overpricing can lead to inability to deliver the public needs as required under Section 84(1)(b).
- The decision upheld the right of generic producers to appeal to the Controller under clearly established legal standards.
- The case cemented the public interest doctrine as the cornerstone of compulsory licensing law in India.

Although India has established a forward-looking standard, other jurisdictions' courts and regulatory bodies have been slower in coming to compulsory licensing.

Canada: Apotex Inc. v. Wellcome Foundation Ltd[27].

In the current Canadian case, Apotex sought a compulsory license under Canada's previous system of automatic licensing. Although the court rejected the request, the case highlighted the tension between innovation and access on a price basis, which later influenced future Canadian reforms to limit automatic licensing[28].

European Union: Lack of Judicial Activation

The European Union has compulsory provisions for granting licenses as prescribed under Directive 2004/48/EC and Regulation 816/2006, but they are seldom used[29]. Therefore, authors have recommended greater judicial clarity and procedural simplicity in order to make competition-oriented licensing possible in public interest cases.

United States: General Judicial deference to Patentees

In the US, courts have generally adjudicated in favour of patent holders, though government use licenses authorized under 28 U.S.C. § 1498 have served as indirect compulsory licenses,mainly in defence and public health situations. Nonetheless, judicial decisions have generally demonstrated a pro-patent bias, with competition infrequently cited as a ground for licensing[30].

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[27] 2002 SCC 77

[28] Gillat, A., 2003. Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry. Food and Drug Law Journal, 58(4), pp.711–740.

[29] Lamping, M., Batista, P.H.D., Correa, J.I., Hilty, R., Kim, D., Slowinski, P.R. and Steinhart, M., 2023. Revisiting the framework for compulsory licensing of patents in the European Union. Max Planck Institute for Innovation & Competition Research Paper, (23-07).

[30] McGivern, L.A.U.R.E.N., 2023. Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation. The Milbank Quarterly, 101(4), pp.1280–1303.

While the Controller of Patents has acted under powers contained in the Patents Act, the CCI also operates in a complementary capacity under Section 4 of the Competition Act, 2002, and preventing abuse of dominant position. Though CCI has not issued a compulsory license, it has examined some cases of patent abuse in the pharmaceutical and technology industries. There should be cooperative regulation between IP offices and competition authorities to implement compulsory licensing in a pro-market approach[31].

Judicial precedents, perhaps most significantly in Natco v. Bayer, have opened the path for more aggressive use of compulsory licensing in India. The case reiterated that patent law will be made subservient to public purpose and facilitate fair competition. Legal use of compulsory licensing continues to be conservative and under-exploited globally. In the coming years, there must be more aggressive judicial activism and coordination of regulation, particularly between patent bureaus and competition regulators, to maintain compulsory licensing as an effective legal and market tool.

COMPARATIVE ANALYSIS WITH GLOBAL PRACTICES

Compulsory licensing provisions, though widely known under the TRIPS Agreement, are put into practice and governed differently in jurisdictions. Though India has extensively utilized compulsory licensing to resolve issues of affordability and access, most prominently in Natco v. Bayer—other nations have been more conservative or moderate in their approaches. International practice is reviewed and contrasted in this chapter to examine how various legal, institutional, and policy contexts affect the efficacy of compulsory licensing in fostering competition and the public interest.

India remains one of the very few jurisdictions to have granted a compulsory license since the TRIPS adoption in a significant pharmaceutical case. As already noted, the Controller's decision in Natco v. Bayer was based on grounds of affordability, domestic production, and public demand under Section 84 of the Patents Act, 1970. The Indian legal framework is characterized by its:

- Specific statutory authority,
- Procedural transparency,
- Readiness to use TRIPS flexibilities.

[31] Van Overwalle, G. and Léonard, A., 2023. The public interest in compulsory licensing: examining the complementarity between IP and competition law. In A Critical Mind: Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property (pp.331–365). Berlin, Heidelberg: Springer Berlin Heidelberg.

India's policy of licensing is based on the premise of balancing incentives for innovation with wide-ranging public health obligations and that this is an expression of its role as a global generic drug producer[32].

In the U.S., compulsory licensing is not a statutory provision directly compliant with TRIPS. 28 U.S.C. § 1498 does provide for the United States government to use or license use of patented invention without authorization, but only for a reasonable compensation. This "government use license" has served as a practical surrogate under conditions of public emergencies.

The United States judicial system is typically pro-patentee, and licensing practices generally only apply in instances of defensive tactics and instances of federal procurement[33]. Moreover, the lack of a full-scale compulsory licensing system for public interest or competitive injury in the U.S. also limits its potential as a mechanism of facilitating access to pharmaceuticals.

While the EU Directive 2004/48/EC and Regulation 816/2006 establish a legal framework for compulsory licensing, application is very rare in practice. Lamping et al. (2023) contend that this is because:

- Bureaucratic complexity,
- Differences between member countries,
- Political reluctance to confront intellectual property holders.

The EU approach promotes voluntary patent pools and licensing and does not have clear judicial precedents against the compulsory regime of licensing in the public interest cases. The judiciary in India has been open to such exploration towards accessibility.

Canada once had extensive compulsory licensing regime for drugs under the 1969 Patent Act, abolished in the 1990s in the course of TRIPS adoption. Canada has since established Canada's Access to Medicines Regime (CAMR), intended to regulate exports of life-saving medicines under compulsory licenses. The regime has been accused of procedural complexity and non-use, although intended.

In other developing nations:

[32] Ali, N. and Khan, K.I., 2021. Legal framework for compulsory licensing: a solution to the conflict of intellectual property rights and intellectual monopoly. International Journal of Public Law and Policy, 7(2), pp.122–133.

[33] McGivern, L.A.U.R.E.N., 2023. Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation. The Milbank Quarterly, 101(4), pp.1280–1303.

- Brazil and Thailand have used compulsory licensing for the HIV/AIDS treatment, invoking public health as a legitimate reason under TRIPS.
- South Africa has been advocating for ambitious health policy reforms before the issue of license allocation, but still favors access-related flexibilities.

These countries are under political pressure and trading sanctions as they seek to impose compulsory licenses, thus highlighting the geopolitical challenges of the implementation of TRIPS flexibilities[34].

India's regime of compulsory licensing is a model of one of the most advanced uses of TRIPS flexibilities among World Trade Organization member states. Conversely, regions such as the United States and the European Union are pursuing a more legally conservative or procedurally restricted approach, which restricts the application of compulsory licenses to serve public health demands or increase market competition. This comparative exercise sheds light on India's future leadership in promoting balanced intellectual property systems that strike a balance between innovation incentives and fair access. International harmonization and increased procedural transparency are, however, necessary for the complete realization of compulsory licensing's potential in international patent law.

CHALLENGES AND POLICY CONSIDERATIONS

While the statutory framework for compulsory licensing in India is one of the most structured and TRIPS compliant in the developing world, its real world application is rare and cautious. Despite the landmark Natco v. Bayer decision, compulsory licensing still faces procedural, political, institutional and interpretative barriers. This chapter explores these challenges and reflects on the broader policy implications for making compulsory licensing a reliable and effective tool to promote competition and public welfare.

1. **Procedural and Administrative Hurdles**

   The biggest challenge is the long and complex compulsory licensing process. The requirement to first seek a voluntary license from the patentee and then wait for rejection or unreasonable delay introduces procedural latency[35]. This delays market entry for generic producers especially during public health emergencies.

[34] Van Overwalle, G. and Léonard, A., 2023. The public interest in compulsory licensing: examining the complementarity between IP and competition law. In A Critical Mind: Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property (pp.331–365). Berlin, Heidelberg: Springer Berlin Heidelberg.
[35] Taware, M.R., 2023. *Compulsory Licensing under Patent Laws and Pharmaceuticals: Impact, Issues and Way-out*. Issue 2 Indian JL & Legal Rsch., 5, p.1.

Moreover ambiguity in interpreting terms like "reasonably affordable", "reasonable requirements of the public" and "working of the patent" creates uncertainty for applicants. Indeterminate thresholds deter potential applicants from approaching the Controller of Patents under Section 84 of the Indian Patents Act[36].

2. **Lack of Institutional Coordination**

   There is no coordination between the Patent Office and the Competition Commission of India (CCI). While patent authorities assess public need and pricing, competition regulators are better equipped to evaluate abuse of dominance and market impact. Lack of inter-institutional coordination weakens the potential of compulsory licensing to correct anti-competitive behaviour[37].

   Also judicial forums, both the IP Appellate Board (now abolished) and High Courts, have often lacked specialized capacity to balance patent rights with competition law perspectives, further delaying or diluting decisions.

3. **Political and Trade Pressures**

   Many countries especially in the Global South face political pressure and diplomatic pushback from patent-holding countries when they try to issue compulsory licenses[38]. India too has faced criticism from multinational pharmaceutical companies and foreign trade representatives post Natco ruling[39].

   Such external pressures may discourage regulators from exercising compulsory licensing powers even when public interest is clearly established resulting in policy inertia.

4. **Underutilization Despite Strong Legal Basis**

   Despite the legal clarity, India has issued only one successful compulsory license (Natco v. Bayer, 2012). Generic companies are reluctant to pursue compulsory licenses due to uncertainty, reputational risk and limited incentives. Also lack of awareness among

[36] Ghosh, R., 2020. Compulsory licensing of patents and its effect on competition. Journal of Medical Society, 34(2), pp.55–60.

[37] Van Overwalle, G. and Léonard, A., 2023. The public interest in compulsory licensing: examining the complementarity between IP and competition law. In A Critical Mind: Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property (pp.331–365). Berlin, Heidelberg: Springer Berlin Heidelberg.

[38] McGivern, L.A.U.R.E.N., 2023. Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation. The Milbank Quarterly, 101(4), pp.1280–1303.

[39] Ullrich, H., 2014. Mandatory licensing under patent law and competition law: different concerns, complementary roles. In Compulsory Licensing: Practical Experiences and Ways Forward (pp.333–375). Berlin, Heidelberg: Springer Berlin Heidelberg.

stakeholders: health ministries, regulators, NGOs and the public, further limits mobilization of this legal mechanism[40].

5. **Recommendations and Policy Considerations**

   To overcome these challenges and make compulsory licensing a tool to promote competition, the following policy measures are suggested:

- **Simplify and streamline procedures**: Define clear timelines, minimize pre-filing requirements and expedite process for essential medicines.
- **Strengthen interpretative guidelines**: Issue regulatory clarifications on key legal terms like "affordability", "working" and "reasonable requirements".
- **Enhance coordination between regulators**: Establish structured coordination between Controller of Patents and CCI to jointly assess cases of market dominance and public health.
- **Institutional capacity building**: Invest in IP and competition training for adjudicators and policymakers to manage complex licensing disputes.
- **Encourage transparency and stakeholder engagement**: Proactively disclose criteria and data behind licensing decisions to build trust and accountability.
- **Resist international pressure**: Reinforce India's commitment to TRIPS flexibilities as sovereign rights especially during public health emergencies.

The gap between India's legal framework and actual use of compulsory licensing shows institutional reform, regulatory clarity and political will is needed. While compulsory licensing is a pro-competitive legal mechanism, its effectiveness depends on removing procedural hurdles, inter-agency coordination and making the law not just legally valid but operationally viable. With global attention shifting towards access, affordability and fair IP practices, India must lead in making compulsory licensing from a symbolic exception to a practical policy tool.

CONCLUSION

Compulsory licensing serves as a vital bridge between the exclusive rights granted by patents and the essential need for accessibility, affordability, and fair competition in society. While patents are designed to encourage innovation, too much exclusivity can lead to market imbalances, particularly in critical areas like healthcare. This study highlights how compulsory licensing is key to preventing

[40] Ali, N. and Khan, K.I., 2021. Legal framework for compulsory licensing: a solution to the conflict of intellectual property rights and intellectual monopoly. International Journal of Public Law and Policy, 7(2), pp.122–133.

the misuse of patent power, allowing generics to enter the market, and restoring a healthy competitive landscape.

India's legal system, particularly through the Patents Act of 1970 and Section 84, showcases a well-structured and TRIPS-compliant approach to issuing compulsory licenses. The landmark case of Natco v. Bayer illustrated how effectively this provision can be used to make life-saving medications more affordable. However, the limited use of this mechanism since that ruling points to ongoing procedural, institutional, and political hurdles that still impede its wider application.

A look at other regions like the United States, European Union, and Canada reveals that even though compulsory licensing is recognized internationally, its actual implementation tends to be inconsistent and cautious. These insights suggest that having a supportive legal framework is just the beginning; there also needs to be regulatory cooperation, clear interpretations, and a strong political will.

In summary, compulsory licensing should not be seen merely as an exception to patent rights but rather as a crucial instrument for promoting public interest and ensuring market fairness. As health challenges evolve and patent ownership becomes more concentrated, applying this tool thoughtfully and promptly will be essential for balancing innovation with equitable access.

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