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Patent Rights and Public Interest under Indian Patent Law: A Critical Study of Compulsory Licensing in the Context of TRIPS

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ABSTRACT

The goal of Indian patent law is to maintain a just balance between protecting patent rights and advancing the general welfare. In this context, compulsory licensing is essential, since it permits the limited use of patented technologies without the patent holder's consent in circumstances involving public-health needs, non-availability, or prohibitively high prices. This paper critically examines the relationship between patent rights and the public interest under Indian patent law, with particular emphasis on the mechanism of compulsory licensing in the context of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The study explores how India has attempted to balance the protection of the exclusive rights of patent holders against the need to ensure access to essential goods, particularly medicines, for the wider public. Patents are granted to encourage innovation and technological advancement by conferring on inventors exclusive rights over their inventions for a limited period. Excessive protection of patent rights, however, may lead to monopolistic practices, high prices, and restricted access to life-saving drugs and technologies, thereby affecting public welfare.

The research analyses the evolution of India's patent regime from a process-patent system under the Patents Act, 1970 to a product-patent regime following India's obligations under TRIPS. It further examines the legal framework governing compulsory licensing under Sections 84, 92, and 100 of the Patents Act, 1970, and evaluates the extent to which these provisions comply with TRIPS flexibilities and the Doha Declaration on Public Health. The paper highlights the landmark compulsory-licensing case involving Bayer AG and Natco Pharma concerning the anti-cancer drug Nexavar, which became a significant precedent in balancing patent protection with public-health concerns in India.

The paper further discusses the arguments advanced by multinational pharmaceutical companies regarding innovation incentives and compares them with the concerns of

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developing countries relating to the affordability and accessibility of medicines. It also evaluates judicial interpretations, policy debates, and the socio-economic implications of compulsory licensing in India. The study argues that compulsory licensing serves as an important safeguard against the abuse of patent monopolies and as a vital tool for promoting public health and social justice in developing nations.

The paper concludes that, while India remains committed to its international intellectual property obligations under TRIPS, its patent system continues to prioritise the constitutional values of public welfare and access to healthcare. Compulsory licensing thus emerges as a legally justified and socially necessary mechanism for balancing private patent rights against broader public-interest objectives, and the paper emphasises how India has used international flexibilities to address domestic socio-economic concerns while maintaining adherence to its international commitments.

Keywords: *TRIPS Agreement; Indian Patent Law; Compulsory Licensing; Public Interest; Patent Rights.*

I. INTRODUCTION

The foundation of the patent system is the idea that rewarding inventors for their ingenuity and effort should promote innovation. Patent law grants innovators control over how their ideas are used, manufactured, and sold by conferring exclusive rights for a fixed period. This exclusivity encourages research and development, advances technology, and contributes to the economy. Patent rights, however, also create a form of monopoly, and if exercised unchecked they may have adverse social consequences by limiting the diffusion of technology, raising costs, and restricting access to necessities. This conflict between private rights and public welfare lies at the core of patent law.

The rigorous enforcement of patent monopolies may cause grave concern in a country such as India, where socio-economic realities such as poverty, public-health challenges, and unequal access to resources are paramount. The right to life and human dignity are closely linked to the availability of reasonably priced medicines, life-saving devices, and essential industrial goods. Patent rights are therefore not regarded as absolute under Indian patent law. Instead, the law adopts a welfare-oriented stance, acknowledging that the protection of intellectual property must ultimately serve the greater good of society. The objects and framework of the Patents Act amply reflect this approach.

One of the most important legal tools for preserving this equilibrium is compulsory licensing. It enables the government to intervene where patented inventions are not worked in India, are

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too expensive, or are not sufficiently accessible to the public. Through compulsory licensing, a third party may use a patented invention without the patent holder's consent, provided that fair terms are met and royalties are paid.[1] This mechanism ensures that patents serve their social purpose and are not used merely to maximise profit at the expense of the general benefit.

Compulsory licensing becomes still more important when international patent obligations are considered. Concerns were expressed about the effect of heightened patent protection on access to vital technologies and medicines once India joined the global intellectual property regime under the TRIPS Agreement. TRIPS requires basic standards of patent protection while permitting member States to adopt flexibilities to safeguard the public interest, particularly in matters of public health. India has deliberately used these flexibilities to create a patent system that balances domestic requirements with international compliance.[2]

In light of TRIPS, this paper critically analyses compulsory licensing under Indian patent law. It examines the objectives behind the inclusion of compulsory licensing, the legal framework that governs it, and its practical implementation in India. In doing so, the study shows how Indian patent law seeks carefully to balance the encouragement of innovation against the assurance that patent rights do not override the public interest, constitutional values, and the nation's developmental priorities. The discussion proceeds to a detailed examination of the legal and regulatory framework, the utility of compulsory licensing in addressing problems of access, cost, and patent non-working, and the difficulties attending its practical use, before turning to the legislative and policy changes needed to ensure that compulsory licensing functions as a legitimate and practical tool for advancing public welfare within a fair, TRIPS-compliant patent system.

II. THE CONCEPT OF PATENT RIGHTS AND THE PUBLIC INTEREST

The State grants patent rights to inventors for novel and useful inventions that involve an inventive step and are capable of industrial application. For a fixed period, usually twenty years from the date of filing the patent application,[3] these rights confer on the inventor or patent holder the exclusive right to control how the invention is used. During this period, the patent holder may lawfully prevent others from making, using, selling, offering for sale, or importing the patented invention. Such exclusive rights are granted in order to recognise and reward inventors

[1] The Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 84 (India).
[2] 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 [hereinafter *TRIPS*]; *see also* World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter *Doha Declaration*].
[3] The Patents Act, 1970, *supra* note 1, § 53 (term of patent).

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for their labour, ingenuity, and financial investment in creating new products and technologies. Because patents provide legal protection against unauthorised use, the law encourages individuals, academics, and businesses to devote time and resources to innovation.

The patent system thus functions as an incentive-based mechanism that fosters economic growth and technological advancement. Innovation frequently demands substantial financial outlay, specialised expertise, and years of study and testing. Without legal protection, competitors could simply appropriate an idea and profit from it without bearing the costs of research and development. By granting inventors a limited monopoly over their creations, patent protection helps to prevent such outcomes, enabling inventors to benefit from their inventions and recoup their development costs. The patent system is therefore important for promoting scientific inquiry, technological development, and industrial growth.

Patent rights, however, are not intended to be unfettered or absolute. Because patents confer a form of monopoly, there is always a risk that these rights will be exercised in ways detrimental to the public interest. A patent holder may, for example, charge exorbitant prices, restrict the supply of a patented product, or refuse to license others who could produce the invention more effectively. Such conduct may restrict access to critical technologies and necessities. For this reason, most legal systems recognise that patent protection must be balanced against the broader interests of society, and the concept of the public interest is central to defining the limits of patent rights.

In general, the public interest refers to the welfare, well-being, and general advantage of society. Public-interest concerns arise in patent law where the exclusive rights of inventors impede the accessibility, affordability, or availability of essential products and technologies. This concern becomes especially acute in sectors such as medicines, healthcare, agriculture, and environmental technology, where advances directly affect human lives and social development.

In recognition of these concerns, most patent systems provide safeguards that enable the State to regulate the use of intellectual property rights in the interests of society. These safeguards include compulsory licensing, government-use provisions, limitations on patentability, and competition-law interventions. They ensure that patent protection continues to promote innovation without jeopardising the general welfare, and they reflect the understanding that intellectual property rights should serve as instruments of social and economic development rather than as purely private monopolies.

This balanced approach is reflected in the Indian patent system. A number of provisions in the Patents Act, 1970 acknowledge the importance of the public interest in the operation of the

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patent system, recognising that patents are granted not only to reward inventors but also to ensure that ideas advance the nation's technology and economy. The Act therefore contains measures permitting government intervention where patent rights are used in ways detrimental to society, the most significant of which concern compulsory licensing, the use of patents for governmental purposes, and limitations on the patentability of certain kinds of invention.

One of the most important means by which the Indian patent system protects the public interest is compulsory licensing, which permits a third party to manufacture or use a patented invention without the patent holder's consent in defined circumstances, such as where the product is not reasonably priced or where the reasonable requirements of the public are not being met. Government-use provisions similarly permit the State to use patented inventions for public purposes, particularly in cases of public-health or national emergency.[4]

The Indian patent system thus seeks to prevent patent protection from impeding access to essential medicines. Strict patentability requirements, compulsory licensing, and price-control measures are among the provisions designed to prevent the abuse of patent monopolies in the pharmaceutical sector. Through these safeguards, India has sought to balance the promotion of pharmaceutical innovation against the assurance that medicines remain available and reasonably priced for the public. By recognising that patents should serve both private and public interests, the Indian patent system aims to strike this balance, ensuring that patent protection advances technology without compromising access to important goods and services.

III. COMPULSORY LICENSING UNDER INDIAN PATENT LAW

Compulsory licensing is one of the most important legal tools by which the government seeks to balance private patent rights against the broader interests of society. Although patents confer temporary exclusive rights on inventors, the law recognises that these rights cannot be exercised so as to endanger the public. Compulsory licensing therefore operates as a crucial corrective measure ensuring that patented inventions remain available and beneficial to society.

A compulsory licence is, in essence, a government-issued authorisation permitting a third party to produce, use, or market a patented product without the patent holder's consent. Such licences are not granted arbitrarily; they are issued only where defined legal requirements are met. Their purpose is to prevent the abuse of patent monopolies and to ensure that the public benefits from innovation.

[4] *Id.* §§ 92, 100 (special provision for compulsory licences on Central Government notification, and use of inventions for the purposes of Government).

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Patents are intended to promote innovation by granting inventors a limited monopoly over their creations, which in most jurisdictions, including India, ordinarily lasts for twenty years from the date of filing the patent application. During this period, the patent holder has the exclusive right to manufacture, use, import, or sell the patented product or process. This period of exclusivity is expected to reward inventors for their investment in research and development while encouraging further technological improvement.

The same monopoly that encourages innovation can, however, sometimes erect barriers to entry. The public may be denied access to essential products and technologies where a patent holder refuses to make the invention available within a country, charges exorbitant prices, or fails to produce sufficient quantities. This problem becomes especially serious in sectors such as pharmaceuticals, agriculture, and healthcare, where access to essential products can directly affect human life and well-being. Compulsory licensing therefore serves as a regulatory mechanism to prevent such outcomes and to ensure that patent rights do not conflict with societal interests.

The legislative framework enabling compulsory licensing in India is contained principally in the Patents Act, 1970, in particular Sections 84 to 92.[5] These provisions define the conditions under which compulsory licences may be issued and the procedure for doing so. The Controller General of Patents, Designs, and Trade Marks is the authority responsible for issuing such licences, and carefully reviews each application to ascertain whether the legal requirements have been met.

Section 84 of the Patents Act sets out the general grounds for seeking a compulsory licence. Under this provision, any interested party may apply for a compulsory licence once three years have elapsed since the grant of the patent. The Act recognises three principal grounds on which such a licence may be granted.

The first ground arises where the reasonable requirements of the public with respect to the patented invention have not been satisfied. Where a patent holder fails to manufacture or distribute the invention in sufficient quantities, shortages affecting consumers may arise. In the pharmaceutical sector, for example, inadequate manufacture of a life-saving medicine may prevent patients from obtaining the treatment they require.

The second ground concerns the affordability of the patented invention. A product may be priced so high that a substantial section of the population cannot afford it, even though it is available

[5] *Id.* §§ 84-92.

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on the market. In such circumstances, the law considers whether the invention is reasonably priced and accessible to the public; if the patent holder's pricing strategy effectively excludes the majority of consumers, the Controller may consider granting a compulsory licence to enable other manufacturers to produce a more affordable version.

The third ground is the requirement that the patented invention be "worked" within Indian territory. The concept of working generally requires that the invention be manufactured or commercially used within the country so that the domestic market benefits from the technology. Where the patent holder merely imports the product into India without establishing local production or making sufficient efforts to serve the market, it may be argued that the invention is not being effectively worked. In such cases, compulsory licensing can promote local production and improve the accessibility of the product.

A further provision of significance is Section 92.[6] This provision empowers the Central Government to declare, in circumstances of national emergency, extreme urgency, or public non-commercial use, that compulsory licences should be issued. In such situations, the Government may dispense with the ordinary waiting period and authorise the Controller to grant licences more rapidly. This provision is especially important in times of natural catastrophe, public-health emergency, or other circumstances where swift access to vital technologies is crucial.

One of the most well-known instances of compulsory licensing in India occurred in 2012, when the Indian Patent Office granted a compulsory licence to Natco Pharma for the manufacture of a generic version of the cancer medicine Sorafenib Tosylate, first patented by Bayer.[7] Bayer was selling the drug, used to treat liver and kidney cancer, at roughly $5,500 per month, a price beyond the reach of most Indian patients. After examining the matter, the Controller of Patents concluded that the reasonable requirements of patients were not being satisfied and that the medicine was not reasonably priced. Natco Pharma was accordingly granted a compulsory licence, enabling it to manufacture and market the medicine at a far lower cost of about $175 per month. The decision was widely regarded as a seminal case in the history of Indian patent law and significantly expanded access to the drug.

Compulsory licensing is also recognised internationally. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization (WTO), expressly permits member States to grant compulsory licences in defined

[6] *Id.* § 92.
[7] Natco Pharma Ltd. v. Bayer Corp., C.L.A. No. 1 of 2011 (Controller of Patents, Mar. 9, 2012), *aff'd*, Bayer Corp. v. Union of India, 2014 (60) PTC 277 (Bom) (S.L.P. dismissed, S.C., Dec. 12, 2014).

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circumstances. Under Article 31 of the TRIPS Agreement, governments may authorise the use of patented inventions without the patent holder's consent provided that specific procedural requirements are met.[8] India has incorporated these principles into its national patent law since joining the WTO in 1995.

The significance of compulsory licensing is most evident in the pharmaceutical sector. India is widely recognised as one of the world's leading producers of generic medicines, supplying affordable drugs both to its own population and to numerous developing countries. Compulsory licensing supports this role and advances the broader objective of improving global access to medicines by permitting the manufacture of less expensive alternatives where necessary.

At the same time, the law seeks to keep compulsory licensing fair to patent holders. Where a compulsory licence is granted, the patent owner remains entitled to royalties. Although the precise rate varies with the circumstances of each case, such royalties are typically calculated as a percentage of the licensee's sales revenue, often around six per cent.[9] This structure ensures that the inventor continues to receive a fair return even as the invention becomes more widely available.

Ultimately, compulsory licensing is a carefully designed system that seeks to balance two competing objectives. On the one hand, patent law must uphold inventors' rights and promote continued innovation; on the other, it must ensure that vital technologies remain available to society, especially in fields that directly affect welfare and public health. Compulsory licensing helps to preserve this delicate balance by providing a legal avenue for government intervention where patent rights are abused or insufficiently used. Its importance is particularly acute in countries such as India, where access to affordable healthcare and technology remains a major challenge, and it upholds the principle that intellectual property rights, however valuable, must ultimately serve the broader objective of social and economic advancement.

IV. THE JUDICIAL APPROACH TO BALANCING PATENT RIGHTS AND THE PUBLIC INTEREST IN INDIA

The Indian judiciary has played a crucial role in interpreting patent law so as to preserve a balance between the rights of patent holders and the broader interests of society. Although patents confer exclusive rights on inventors, Indian courts have repeatedly emphasised that these rights must not impede access to essential technologies, particularly in fields such as

[8] *TRIPS*, *supra* note 2, art. 31.
[9] The royalty payable to Bayer was fixed at 6% of net sales by the Controller and subsequently raised to 7% by the Intellectual Property Appellate Board. *See* Bayer Corp. v. Union of India, *supra* note 7.

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healthcare and agriculture. A number of significant rulings demonstrate the effort to balance innovative incentives against public welfare.

A particularly important turning point was the decision in *Natco Pharma Ltd. v. Bayer Corporation* (2012), the first occasion on which a compulsory licence was granted under Indian patent law.[10] The dispute concerned Sorafenib Tosylate, a life-saving medicine used to treat liver and kidney cancer and sold by Bayer under the brand name Nexavar. At the time, the drug was sold at a very high price, roughly ₹2.8 lakh per month, rendering it wholly unaffordable for the majority of Indian patients.

Having recognised the pressing need for affordable medication, Natco Pharma applied for a compulsory licence under Section 84 of the Patents Act, contending that the reasonable requirements of the public were not being satisfied and that the medicine was not reasonably priced. After reviewing the evidence, the Controller of Patents accepted Natco's arguments and granted the compulsory licence, enabling Natco to produce and market a generic version of the drug at a significantly lower cost and thereby opening up the treatment to a much wider population. The Intellectual Property Appellate Board subsequently confirmed the ruling, affirming its legal validity and setting a significant precedent for the use of compulsory licensing as a public-health safeguard. The case demonstrated that, although patent rights are legally protected, they cannot be exercised so as to deny society access to essential medicines.

The emphasis on the public interest in patent law was further reinforced by the Supreme Court's landmark decision in *Novartis AG v. Union of India* (2013), which clarified the requirements for pharmaceutical patents in India.[11] Novartis sought patent protection for the cancer medicine Glivec, and the principal question before the Court was whether the modified form of the drug satisfied the requirement of enhanced therapeutic efficacy under Section 3(d) of the Patents Act.[12]

The Supreme Court ultimately rejected the patent application, holding that the modification did not demonstrate a discernible increase in therapeutic efficacy over the existing form of the drug.[13] In so doing, the Court emphasised that patent law should not be used to confer monopolies over minor modifications to existing medicines, a practice known as "evergreening." Because it prevented pharmaceutical companies from extending patent monopolies through minor changes offering no real therapeutic improvement, the ruling was

[10] Natco Pharma Ltd. v. Bayer Corp., *supra* note 7.
[11] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).
[12] The Patents Act, 1970, *supra* note 1, § 3(d).
[13] Novartis AG v. Union of India, *supra* note 11.

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widely regarded as a significant victory for public health and reaffirmed India's commitment to a patent system that promotes genuine innovation while preserving access to affordable medicines.

The courts have also addressed the tension between patent enforcement and public access in infringement cases. In *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* (2015), the Delhi High Court considered a dispute concerning the cancer medicine Erlotinib.[14] Roche, the patent holder, claimed that Cipla had infringed its patent by manufacturing a generic version of the drug, and the court was required to weigh the validity of the patent against the implications of restricting the supply of a potentially life-saving medicine. Although the case principally concerned patent infringement, it drew attention to the broader policy question of balancing intellectual property rights against the need for affordable healthcare. The court recognised that patent protection is necessary to promote pharmaceutical innovation, but held that the public interest must be taken into account in interpreting such protection, affirming that the social consequences of restricting access to essential medicines should not be overlooked when enforcing patent rights.

The relationship between patent protection and the public interest has also arisen outside the field of medicines. In *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* (2019), the Supreme Court considered the scope of patent protection in relation to genetically modified cotton seeds, the dispute concerning Monsanto's patented biotechnology used in Bt cotton seeds and its licence agreements with Indian seed companies.[15] Although the case principally concerned the patentability and regulation of biotechnological inventions, it illustrated the wider implications of patent law for agriculture and food security. The Court's analysis of the regulatory framework highlighted the need for oversight where patent rights interact with sectors that directly affect farmers and agricultural output, demonstrating that the balance between innovation and the public interest extends beyond the pharmaceutical sector to other fields in which patented technologies have a significant social impact.

Taken together, these decisions show how the Indian legal system's approach to intellectual property rights has evolved. Courts have repeatedly emphasised that patents operate within a broader constitutional and societal framework rather than constituting absolute privileges. The judiciary has thus been important in ensuring that patent law continues to fulfil its primary purpose, namely the promotion of innovation alongside the safeguarding of societal welfare.

[14] F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2015 SCC OnLine Del 13619 (India).
[15] Monsanto Technology LLC v. Nuziveedu Seeds Ltd., (2019) 3 S.C.C. 381 (India).

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V. COMPULSORY LICENSING IN THE CONTEXT OF TRIPS

One of the most significant developments in the global regulation of intellectual property rights is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Concluded in 1994 and entering into force in 1995 as part of the founding of the World Trade Organization, the TRIPS Agreement established a comprehensive international framework requiring member States to implement basic standards for the protection and enforcement of intellectual property rights, covering matters such as patents, copyrights, trademarks, industrial designs, and geographical indications.[16]

Before TRIPS, intellectual property rights varied greatly between countries. Developed States such as the United States and Western European nations generally maintained robust intellectual property laws to protect innovation and promote international trade, whereas many developing countries operated comparatively flexible systems enabling them to prioritise industrial development, technology transfer, and healthcare. This divergence frequently strained international trade relations, particularly as multinational firms sought stronger protection for their works and technologies in foreign markets.

The TRIPS Agreement sought to reconcile these differences by establishing consistent minimum standards of intellectual property protection across all WTO member States, which committed to incorporating these standards into their domestic legal systems on joining the WTO. The Agreement was designed to foster innovation, support technology transfer, and provide a stable legal framework for global trade. Its implementation nonetheless alarmed many developing countries, which feared that stronger patent rights would raise the cost of necessities such as medicines and agricultural innovations.

Among the most significant provisions of the TRIPS Agreement is Article 31, which recognises the possibility of compulsory licensing. This provision permits governments, in defined circumstances, to authorise the use of a patented invention without the patent holder's consent; a compulsory licence allows a third party, typically a local manufacturer, to produce or use the patented goods in exchange for paying the patent owner adequate remuneration.[17]

While permitting such licences, Article 31 also establishes a number of procedural safeguards intended to protect the rights of patent holders. In most cases, the government must first attempt to negotiate reasonable commercial terms with the patent owner in order to obtain authorisation, and a compulsory licence may be issued only where these negotiations prove unsuccessful

[16] *TRIPS*, *supra* note 2.
[17] *TRIPS*, *supra* note 2, art. 31.

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within a reasonable period. Adequate compensation must, moreover, be provided to the patent holder, typically in the form of royalties reflecting the economic value of the authorised use.

A further significant restriction under Article 31 is that the use of a patented invention under a compulsory licence must ordinarily be directed predominantly to the domestic market of the country issuing the licence. This rule was intended to prevent the large-scale export of generic versions that might jeopardise the commercial interests of patent holders in other countries. Notwithstanding these safeguards, Article 31 provides governments with a vital legal tool to intervene where patent rights endanger the general welfare.

The practical importance of compulsory licensing under TRIPS became clearer during the global response to HIV/AIDS in the late 1990s. At that time, pharmaceutical companies sold patented, life-saving antiretroviral medicines at very high prices, which placed them beyond the reach of patients in many developing countries, especially in regions such as Sub-Saharan Africa where the epidemic had reached catastrophic proportions. Public-health campaigners, international organisations, and the governments of developing countries argued that strict patent enforcement was preventing millions of people from obtaining life-saving treatment.

Mounting international pressure to address this situation led, in 2001, to a significant political development: the Doha Declaration on the TRIPS Agreement and Public Health, adopted at the WTO Ministerial Conference in Doha, Qatar.[18] The Declaration reaffirmed that member States should be able to take measures necessary to protect public health without being hindered by the TRIPS Agreement, and made clear that the Agreement must be interpreted and implemented in a manner supportive of States' rights to promote universal access to medicines.

The Doha Declaration significantly strengthened the legal position of developing countries. It made clear that WTO members are entitled to make full use of the "flexibilities" contained in the TRIPS Agreement, among which compulsory licensing was acknowledged as one of the most important measures available to governments for addressing public-health emergencies. The Declaration also emphasised that each State has the authority to determine the circumstances, such as national emergencies, extreme urgency, or other situations of public need, in which compulsory licences may be granted. By clarifying these principles, the Declaration substantially reduced the uncertainty surrounding the use of compulsory licensing and gave developing countries confidence that they could take measures to protect public health without contravening their international commitments under TRIPS. Many States accordingly

[18] *Doha Declaration*, *supra* note 2.

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began to amend their domestic patent laws to include clearer provisions on compulsory licensing.

India is a significant example of the incorporation of these international commitments into domestic law. Having joined the WTO in 1995, India was required to align its patent system with the TRIPS Agreement, a process culminating in the 2005 amendment to the Patents Act, which introduced product patents in the chemical and pharmaceutical sectors while retaining provisions designed to safeguard the public interest.[19]

One of the key provisions reflecting this balance is Section 84 of the Patents Act, which permits any interested party to apply for a compulsory licence three years after the grant of a patent.[20] The section sets out specific grounds for granting such licences, including where the reasonable requirements of the public have not been satisfied, where the patented invention is not reasonably priced, or where the invention is not being worked within Indian territory. These measures enabled India to align its patent system with international norms while retaining the flexibility required to meet domestic needs. This approach has been especially important in the pharmaceutical sector, where India has developed a robust generic-medicine industry whose products are supplied not only domestically but also to other developing countries worldwide. The Indian model illustrates how States can use the TRIPS Agreement in a manner that balances the protection of intellectual property against the general welfare, combining robust legal protection with measures such as compulsory licensing to ensure that patent protection does not impede access to essential medicines or technological advances.

VI. CHALLENGES IN IMPLEMENTING COMPULSORY LICENSING

Although the Patents Act provides a robust legal framework for compulsory licensing, its practical use remains uncommon, and very few applications have been made since product patents for pharmaceuticals were introduced in 2005. The process is evidentially demanding. An applicant must establish three matters: that the reasonable requirements of the public have not been satisfied by the patentee; that the patented invention is not available at a reasonably affordable price; and that the invention is not being worked within India. Each of these is closely scrutinised by the authorities, and the process may take months or years. In the Natco Pharma case, for example, the first compulsory licence in India was granted in respect of Bayer's Nexavar in 2012, where the monthly cost of the cancer medicine exceeded $5,000 and Natco

[19] The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).
[20] The Patents Act, 1970, *supra* note 1, § 84.

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established that the majority of patients had been left unserved.[21] Few firms attempt the process today, deterred by its procedural burden.

Pressure from developed countries adds further risk. The United States and several European States vigorously advocate for strong patent protection and the interests of large pharmaceutical companies. After India granted the Natco licence in 2012, Bayer challenged the decision in court, and the United States Trade Representative placed India on its "Priority Watch List" for intellectual property concerns. Developing countries that resort to compulsory licensing may face pressure in trade negotiations or threats to development assistance, which can cause governments to hesitate.

Concerns about investment also persist. Pharmaceutical manufacturers argue that compulsory licences deter investment: if governments can authorise low-cost copies of new drugs, the incentive to spend heavily on their development is diminished. India, which seeks to attract international manufacturing and research facilities, derives substantial revenue from pharmaceutical exports, reported by some sources at around $0 billion in recent years, and critics contend that an excessive resort to compulsory licensing could reduce such revenue and lead firms to curtail research-and-development expenditure.

These obstacles together inhibit wider use. The purpose of compulsory licensing is to assist underprivileged patients by enabling generic manufacturers to counter excessive prices, and it is expressly permitted in situations of crisis under the WTO TRIPS framework, the relevant instruments having been incorporated into Indian law. In practice, however, implementation lags, as officials weigh public-health benefits against international relations. Until the governing standards become clear and unambiguous, compulsory licences are likely to remain rare, leaving many medicines inaccessible.

VII. Conclusion

The intricate relationship between patent rights and the public interest lies at the core of modern intellectual property law. Patents are essential for promoting innovation and advancing technology, but maintaining accessibility while protecting intellectual property presents a difficult dilemma, particularly in developing countries.

Indian patent law reflects a diligent attempt to manage this delicate balance. The concept of compulsory licensing is crucial in preventing patent rights from overriding the general benefit of the public. Although India's legal system contains strong provisions for compulsory

[21] Natco Pharma Ltd. v. Bayer Corp., *supra* note 7.

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licensing, its practical implementation presents difficulties, involving procedural complexity, interpretational uncertainty, and external pressures. Overcoming these obstacles requires the establishment of more precise legal standards, the expedition of procedures, and greater confidence in using the flexibilities guaranteed under the TRIPS Agreement.

By adopting such measures, India can develop a patent system that fosters creativity while ensuring that important inventions remain accessible to society. Ultimately, the effectiveness of patent law should be assessed not only by its capacity to protect inventors but also by its ability to promote societal well-being and to enable fair access to technological advances.

VIII. SUGGESTIONS AND POLICY RECOMMENDATIONS

The compulsory-licensing system under the Patents Act, 1970 is essential to balancing the rights of patent holders against the general welfare. It can be made more effective, and made better to serve developmental and public-health goals, through several reforms and policy enhancements.

First, more precise and objective criteria should be developed for identifying the circumstances in which the reasonable requirements of the public have not been satisfied. Although the law offers some guidance, the absence of exact benchmarks can produce interpretational uncertainty; clear standards addressing the availability, price, and accessibility of patented products would benefit both patent holders and prospective licensees by enhancing legal certainty.

Secondly, procedural improvements should be introduced to expedite the application process for compulsory licences. The process can presently be lengthy and complex, which may deter prospective applicants and impede access to essential goods. Establishing fixed timelines for hearings, examinations, and final decisions would significantly reduce administrative delay, and quicker decision-making would ensure that compulsory licensing remains a useful instrument when pressing public needs arise.

Thirdly, India should continue to make use of the flexibilities afforded by international intellectual property law, particularly those recognised in the TRIPS Agreement. By implementing these principles effectively, India can maintain a fair approach that upholds intellectual property rights while ensuring that vital technologies and medicines remain available to the public.

Increasing the operational transparency of the Office of the Controller General of Patents, Designs, and Trade Marks would be a further important improvement. The full disclosure of decisions, including the reasons for granting or refusing applications for compulsory licences,

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would enhance accountability, guide future cases, and increase confidence in the patent-administration system.

Strengthening institutional capacity is also crucial. The patent authorities should be given adequate technical expertise, administrative support, and training in specialised fields such as pharmaceutical patents and biotechnological advances. With improved institutional capability, the authorities could handle complex applications more effectively and ensure well-reasoned decisions.

Encouraging the domestic production of essential medicines and technologies would be another important step. The grant of compulsory licences is more effective where competent producers exist within the country, since production and distribution can then be swiftly expanded. Strengthening the local pharmaceutical and technological sectors would therefore complement the objectives of the compulsory-licensing system.

The calculation of royalty rates payable to patent holders under compulsory licences should also be clarified. Clear and consistent royalty rules would ensure that innovators are fairly compensated while enabling licensees to produce and market goods at reasonable prices.

Judicial support is another crucial factor in ensuring the efficacy of compulsory licensing. The establishment of specialised intellectual property benches, or the more expeditious adjudication of patent-related appeals, would enable disputes arising from compulsory-licensing decisions to be resolved more quickly and with less uncertainty.

Lastly, regular policy reviews and empirical analyses of the compulsory-licensing framework should be undertaken. Examining earlier cases, such as the landmark decision in *Natco Pharma Ltd. v. Bayer Corporation*,[22] can offer valuable insight into practical difficulties and policy implications. Through regular evaluation, legislators and regulators could refine the system and ensure that it continues to promote both innovation and the general welfare. Taken together, a well-balanced and well-implemented compulsory-licensing system can contribute significantly to achieving public-health goals, facilitating access to essential technologies, and ensuring that patent protection operates in harmony with broader social and commercial interests.

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[22] Natco Pharma Ltd. v. Bayer Corp., *supra* note 7.

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