A STUDY ON COMPULSORY LICENSING FOR PHARMACEUTICAL PATENTS UNDER SECTION 84 OF THE PATENTS ACT, 1970

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ABSTRACT

Patents are supposed to encourage innovation. They try to balance the broad goals of scientific progress with private economic interests, giving inventors exclusive rights to their creations. But honestly, there hasn't been serious research on how well Section 84 works after the TRIPS agreement, especially when you think about what "reasonable affordability" really means under India's current drug pricing rules. This paper takes a close doctrinal look at the law digging into statutes, major court cases like *Bayer vs. Natco*, and real-world data on who can actually access medication to help fill that gap. In the end, the study makes the case for a careful recalibration of licensing triggers, guaranteeing the public's continued access to life-saving medications while upholding the fundamental principles of patent protection as a motivator for innovation. On March 9, 2012, the Controller General of Patents, acting under Section 84(1) of the Indian Patents Act, 1970, granted Natco Pharma the country's first and so far, only compulsory licence to produce and market Sorafenib Tosylate, a patented cancer medication sold by Bayer AG under the brand name "Nexavar". Although two further applications have been mandatory licenses have been issued after this historic decision. Section 92A (1) of the Patents Act, 1970, which enables the production and export of patented pharmaceutical items to nations with insufficient manufacturing capacity to fulfil their public health requirements, is another unique compulsory licensing system that India has implemented. Multinational pharmaceutical companies operating in India and seeking patent protection must develop a clear understanding of the country's licensing framework and reevaluate their commercial strategies in light of these developments and the significant economic ramifications of compulsory licensing.

Keywords: Compulsory Licensing, Patent Protection, Section 84 (Indian Patents Act), Reasonable Affordability, Access to Medicines, Bayer v. Natco, TRIPS Agreement.

Chapter I - INTRODUCTION

The Indian patent law has been developed to balance the states duty to protect the welfare and promote innovation through patents. The Patents Act of 1970[1] only allowed process patents in industry to support India's local generic drug makers. This move helped people get medicines and kept global monopolies under control. When the Patents Amendment Act was passed in 2005[2] it changed India's rules to match the World Trade Organizations TRIPS agreement and brought back product patents. This was a change. Although it made India's system follow intellectual property rules it also raised concerns that patent exclusivity might lead to high prices and limit access to essential medicines for many people.

The Patents Acts Section 84[3] is crucial in preventing patent abuse and ensuring that economic interests do not override the right to health. It allows the State to grant licenses enabling other parties to produce without the patent holder's permission if public interest requirements are met. The clause states that the patented innovation must meet the publics demands be produced enough in India and be offered at a reasonable price. How these statutory criteria interpreted continues to shape intellectual property law. The landmark case of *Bayer Corporation v. Natco Pharma Ltd.*[4] set a precedent that prioritizes access to medicines over strict patent exclusivity. However, India has faced conflicts between its foreign trade commitments and public health needs. In light of this study examines Section 84 to see if the current legal framework can handle changing pricing methods and provide fair access, to medicines in the post-TRIPS era.

Studying mandatory licensing requires analysing global intellectual property rules alongside public health and economics. Actually, governments intervene when markets fail to supply affordable medicine to citizens. Simple market failures drive policy changes. People need access, so officials seize control now. Local communities rely on these policy measures as practical safety nets. Relying solely on patents ignores the urgent need for affordable health alternatives. Actually, balancing legal rights with human survival is a messy, difficult process. Nations like India must prioritize public healthcare above corporate profits. That is the reality. Protecting patients remains the ultimate goal during every legislative debate. Real

[1] The Patents Act, 1970, No. 39 of 1970, Acts of Parliament, 1970 (India).
[2] The Patents (Amendment) Act, 2005, No. 15 of 2005, Acts of Parliament, 2005 (India).
[3] The Patents Act, 1970, § 84 (India).
[4] Bayer Corp. v. Natco Pharma Ltd., Compulsory Licence Application No. 1 of 2011, Controller of Patents (Mar. 9, 2012).

improvement happens slowly. When lives are at stake, simple fixes fail.

Medications represent a basic human necessity, creating a strange friction within modern patent law. Pharmaceutical companies hold massive power over the right to life. Actually, if cancer or HIV patients cannot afford their life-saving therapy, the costs become unbearable. States must intervene when private intellectual property rights clash with public health goals. Protecting human life matters more than quarterly profit margins. Adopting mandatory licensing acts as a functional bridge to balance market innovation with patient accessibility. Governments hold this responsibility to ensure that everyone gets the care they need to survive, period.

Compulsory licensing serves as a vital legal flexibility under the TRIPS Agreement worldwide. Nations utilize these protocols to protect public health while expanding access to essential medications. Actually, India attempted to strike a difficult balance between international trade obligations and domestic needs. By incorporating these specific flexibilities into the Patents Act, 1970, and utilizing Section 84, the government preserves its sovereign rights.

Mandatory licensing fuels India's generic pharmaceutical sector. By fostering fierce competition, the policy ensures international health systems gain access to affordable medicine. Actually, local producers breaking restrictive monopolies remains the standard way to lower costs. That is the reality. Pressure mounts on patent holders to expand product availability when facing such competition. Prices drop immediately. It just works. Sustaining universal health access relies heavily on these generic manufacturers today. Global markets shift because those cheaper alternatives exist, proving that widespread medicine distribution is a logistical necessity rather than some impossible dream. Everything hinges on supply.

Mandatory licensing remains a messy, divisive issue today. Critics argue that frequent use hurts foreign investment while stalling actual pharmaceutical innovation across global markets. Truth be told, supporters prioritize public health above all else, particularly in poor regions where life-saving medication stays out of reach. Balancing these conflicting concerns is difficult work. Policymakers must apply these complex legal frameworks with extreme care and absolute fairness.

Section 84 see how it impacts local drug access alongside overall affordability. Expert teams examine the legal code, specific judicial interpretations, and practical implementation hurdles

to gauge actual system effectiveness. Balancing pressing public health needs with pharmaceutical innovation remains incredibly difficult. Millions of people who simply need low-cost medical care to survive depend on every governmental decision made behind closed doors. Mandatory licensure protects modern healthcare against new ailments and rising drug expenses. Inspections act as a primary link between national laws and international health objectives. Maintaining a strict licensing structure keeps quality high, especially since India produces vast quantities of generic medications. That is the reality. Actually, researchers analyze. Reaching this delicate balance determines if clinical systems truly assist the citizens they mean to serve each day. People rely on them for help. Every single policy choice echo through the lives of those suffering right now.

Research objectives

- To analyse the legal framework of Section 84 of the Patents Act, 1970, with specific regard to how it acts as an instrument for achieving the balance between patent monopolies and the need for public access to essential drugs as a matter of socio-legal principle.

- To emphasize the interpretive principles set out in the landmark case of *Bayer Corporation vs. Natco Pharma Limited* (2012), this study aims to trach the evolution of compulsory licensing in India.

- To critically analyse, within the context of the international intellectual property landscape as reshaped by the TRIPS Agreement, the efficacy of the system of mandatory licensing in addressing patent medicine availability and pricing issues.

Research Problem

Through restoring product patents in the pharmaceutical industry, the 2005 modification to the Patents Act, 1970, which was passed in order to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), considerably improved patent protection in India. The changes made India's laws have helped the country come up with new ideas and follow international rules about intellectual property. However, this has also led to concerns about whether people can afford the medicines they need. There's a part of the law, Section 84, that allows for something called compulsory licensing. This happens when the public needs a

medicine but it's not available, or if the company that owns the patent isn't making enough off it in India, or if the price is too high. This rule hasn't been used much, except in one important case involving a cancer medicine called "Sorafenib Tosylate" which is sold by Bayer AG under the name Nexaver. The problem is that it's not clear what "reasonably priced" means, which makes it hard to know when to use this rule. This raises questions about whether the current system is working well enough to make sure people can get the life-saving medicines they need while also protecting the rights if companies that invent these medicines. In simple terms, the goal is to find a balance between helping people get access to important medicines and making sure companies are rewarded for their inventions. The law is trying to achieve this balance, but it's still not clear if it's working as intended. This is an important issue because it affects people's lives and the ability of companies to invest in new medicines.

Research questions

1. Whether Section 84 of the Patents Act, 1970 effectively balances patent holders' rights with the State's duty to ensure access to essential medicines?

2. Whether the decision in *Bayer Corporation v. Natco Pharma Ltd.* significantly influenced judicial standards for granting compulsory licences?

3. Whether Indian courts have developed a consistent approach to compulsory licensing after the Bayer–Natco case to ensure access to medicines?

4. Whether India's compulsory licensing framework ensures affordability and availability of medicines while complying with the TRIPS Agreement?

Research methodology

This study employs doctrinal legal research methods, which involve research methods, which involve researchers analysing existing legal doctrines through systematic methods and critical evaluation. The research study investigates patents through an in-depth analysis of the Patents Act of 1970, which includes a detailed examination of Section 84 to assess how effectively the law protects public healthcare rights against patent rights. The research investigation utilizes secondary sources which include national and international legislation and significant court ruling and reputable treatises and peer-reviewed publications and official reports from institutional and governmental entities as its primary research foundation. The study

concentrates on judicial interpretation of *Bayer Corporation v. Natco Pharma Ltd. (2012)* because this case serves as the primary framework for understanding how public needs and patent local working and reasonable affordability criteria must be met. The study uses descriptive and analytical methods to compare Indian patent practices with global intellectual property standards which include the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) treaty. The paper evaluates whether the current mandatory licensing system effectively solves socioeconomic barriers to medication access while creating a protection environment that promotes pharmaceutical research through the analysis of multiple legal sources.

Chapterization

The study on licensing in India is split into five chapters. This study aims to give an analysis of the topic. Chapter 1 is an introduction to the study It includes the background of the study the problem that the study is trying to solve the goals of the research, the research questions, and the methodology used. Chapter 2 looks at the laws and rules about licensing under the Patents Act of 1970. It focuses on Section 84. How it balances patent rights with what the public needs. Chapter 3 looks at court decisions about licensing. The landmark case of *Bayer Corporation v. Natco Pharma Ltd*. Is analysed. This case highlights legal principles. These principles include requirement local working of patents, and fair pricing. Chapter 4 checks how India follows its compulsory licensing system. This is after the Agreement on Trade-Related Aspects of Intellectual Property Rights. The focus is on how it affects medicine prices and access to medicines. The last chapter sums up the research findings. It gives recommendations to improve the licensing system. The goal is to keep medicines affordable for the public and encourage innovation. The study is about licensing and it aims to make compulsory licensing work better. Compulsory licensing is a topic. The study, on licensing provides detailed insights.

Chapter II- Laws and Rules About Licensing under Patents Act, 1970

India's Patents Act of 1970[5] tries to find a middle ground. On the one hand, it protects inventors and their rights. On the other, it looks out for the public. Compulsory licensing is a good example. When the situation calls for it, the law lets others produce or sell a patented product without getting the owner's OK. This is a big deal, especially for medicines people need to

[5] The Patents Act, No. 39 of 1970, § 1 (India).

survive. At its core, the idea is simple: don't let patents stand in the way of people getting the drugs they need.

The main rule governing mandatory licensing in India is Section 84[6]. So, after three years from when a patent is granted, anyone individuals or organizations can ask for a license. Here's the thing the law outlines three key reasons for granting these licenses: if the public's reasonable needs aren't being met, if the patented product isn't priced fairly, and if the invention isn't adequately developed in the country. These standards aim to limit the misuse of patent rights and ensure that innovation serves society overall.

Section 84(7)[7] extends the definition of "reasonable requirements of the public" by including three essential elements, which consist of market demand for patented products, actual product availability, and alternative product market presence. The term "reasonably affordable price" lacks a clear definition, so authorities have the authority to determine its meaning based on market value comparisons and essential public needs and current financial circumstances. The system allows for flexible operation, which enables it to perform assessments. That match India's current social and economic environment.

Apart from Section 84, further requirements reinforce the framework of mandatory licensing. In circumstances such as national emergencies, severe urgency, or public non-commercial use, including public health crises, Section 92[8] gives the government the authority to grant licenses Suo motu. Additionally, Section 92A aligns India's legal system with international commitments under the TRIPS Agreement by allowing the production and export of patented pharmaceutical items to nations that lack enough manufacturing capacity.[9]

Applying for a compulsory license entail submitting an application to the Controller of Patents, who evaluates the request in accordance with legal requirements and accompanying documentation. Any license that is given is often non-exclusive, has time and scope restrictions, and requires the patent holder to get fair royalties. These measures guarantee that the incentives for innovation are not totally compromised while the public interest is

[6] The Patents Act, No. 39 of 1970, § 84 (India).
[7] Id. § 84(7).
[8] The Patents Act, No. 39 of 1970, § 92 (India).
[9] 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.

safeguarded.

India's mandatory licensing laws are an example of a flexible and well-balanced system of laws that takes into account both international intellectual property standards and national public health issues. The law makes it clear that public welfare must come first, when necessary, by making sure that patent protection doesn't make it harder for people to get important medications. It does this by being flexible and having safeguards.

Chapter III- Judicial Interpretation of compulsory licensing: analysis of key cases

Court and quasi-judicial interpretations have made the provisions of the Patents Act, 1970 clearer. This has had a big impact on the scope and use of compulsory licensing in India. The well-known case *Bayer Corporation v. Natco Pharma Ltd*[10]. stands out as a major step forward in Indian patent law, especially for the pharmaceutical industry.

The case was about Sorafenib Tosylate, a Bayer Corporation-patented drug sold under the brand name "Nexavar" that is very important for treating advanced liver and kidney cancer. Most Indian patients couldn't afford the medicine because it was so expensive. Natco Pharma Ltd., a domestic drug company, asked for a compulsory license under Section 84[11], saying that Bayer had not met the legal requirements to keep its exclusive rights.

Natco grabbed India's first mandatory license back in 2012. Approval came directly from the Controller General of Patents, marking a massive shift. Actually, senior judges and the Intellectual Property Appellate Board backed this move later on. That is the reality. Such rulings established binding guidelines for interpreting regional law.[12] These precedents still dictate how officials enforce mandatory licensing today, proving that one single legal victory changes everything moving forward.

Legal experts currently debate what defines reasonable public requirements for healthcare access. Officials argue that mere shelf availability falls short. Truth be told, a significant portion of the population must retain physical access to medication for eligibility. Simple as that. Financial barriers prevented many patients from receiving care here, so the product failed to

[10] Bayer Corporation v. Natco Pharma Ltd., Compulsory Licence Application No. 1 of 2011, Controller of Patents (India Mar. 9, 2012).
[11]The Patents Act, No. 39 of 1970, § 84 (India).
[12] Bayer Corp. v. Natco Pharma Ltd., Order No. 45/2013, Intellectual Prop. App. Bd. (India 2013).

benefit the public. High costs effectively barred common people from essential treatment. Actually, these hurdles create a void where medicine exists but remains unreachable. That is the reality. Patients suffer whenever systemic roadblocks block their path to recovery.

Judges clarified what a reasonably affordable price actually looks like today. National economic health and public perspective dictate these valuations now. Truth be told, Bayer kept costs far too high for average citizens. Meanwhile, Natco offered a much lower rate that helps patients buy vital medication. It was a clear shift in policy.

Bayer faced pressure regarding the patent working requirement in India. Importing medicine simply failed to satisfy the legal mandate for local manufacturing. Actually, officials rejected their plea. Domestic production remains necessary for these specific mandates to hold water. Authorities prioritized building local plants instead. Such policies aim to force wider distribution of essential drugs across the region. That is the reality. Production clearly stays the primary goal.

Balancing patent protection with public interest remains a messy, delicate necessity. Exclusive rights grant holders significant power, but public health needs often override those claims. Actually, history proves that compromises occur. Natco required Bayer to pay royalties to ensure nobody walked away empty-handed during this legal fight. That is the reality. Protecting innovation while saving lives requires navigating these harsh, complex legal boundaries daily.

Bayer-Natco established a firm precedent, yet forced licensing remains rare today. People rarely litigate these specific claims. To be honest, usage happens only in extreme situations. Regulations from that ruling still anchor future interpretations. Clear legal standards endure regardless of current case frequency. That is just how the system operates now.

Judicial interpretations define mandatory licensing borders throughout India. Courts shaped these regulations following the Bayer-Natco dispute, striving to balance innovation incentives against widespread healthcare access. That is the reality. Maintaining that delicate balance remains difficult, to be honest. Finding a workable middle ground feels elusive. Legal frameworks provide some clarity, yet gaps persist daily. Many people still face barriers. Systemic hurdles prevent affordable medicine from reaching those who need it most effectively today.

Chapter IV - Compulsory Licensing in India in the post- TRIPS era: Impact on access and affordability

Ratifying the TRIPS Agreement marked a major shift for India's pharmaceutical industry. Intellectual property rules tightened in 2005 when the Patents Act, 1970[13] finally introduced product patents again. Actually, international compliance arrived at a steep price. Concerns exploded regarding the accessibility and cost of essential medications for impoverished citizens. Keeping drugs affordable for everyone remains a struggle[14]. That is the reality. Policy changes often force us to choose between profit and human life.

Compulsory licensing serves as a legal safety net, allowing governments to bypass patent restrictions when citizens desperately need affordable medicine. Provisions like Section 84, alongside Sections 92 and 92A[15], create a clear path for generic access at reasonable prices. Actually, these rules rarely see real action. Critics worry about their true impact on the healthcare industry. Laws sit dormant on dusty shelves, failing to help those most in need. That is the reality. It stays stagnant.

Bayer Corporation v. Natco Pharma Ltd[16]. serves as a clear example of how mandatory licensing helps expand access to essential life-saving medications. Prices dropped sharply following the court ruling, allowing thousands of patients to finally afford their treatment. That is the reality. Legal precedents remain rare, though. Actually, the lack of follow-up cases suggests this path faces massive hurdles. Complex legislative demands and heavy administrative burdens keep this tool tucked away in a drawer most of the time. Proponents hope for change, but the system currently drags its feet. Progress remains slow, frustrating advocates who see potential yet encounter only deep silence from lawmakers.

Defining reasonable affordability remains a massive challenge in the post-TRIPS era. Officials often struggle choosing when intervention is needed because laws lack any precise definition. It is what it is. Market dynamics and government regulations influence drug prices across India alongside the National Pharmaceutical Pricing Authority. Actually, assessing real costs

[13] The Patents (Amendment) Act, 2005, No. 15 of 2005 (India).
[14] Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act, 2005, 1 Indian J.L. & Tech. 15 (2005)
[15] Id. §§ 84, 92, 92A.
[16] Bayer Corporation v. Natco Pharma Ltd., Compulsory Licence Application No. 1 of 2011, Controller of Patents (India Mar. 9, 2012).

requires grasping deep social and economic factors. Simple metrics fail to capture the local reality. Fixing these gaps requires better data, yet policymakers continue ignoring the raw complexity involved.

Domestic patent working requirements cause real headaches for global companies. Many firms simply import goods instead of building facilities locally. Actually, legal experts still argue if importing counts as active work. That is the reality. Strict rules might trigger local growth, but they risk scaring off foreign innovation. Balancing these competing interests matters for the long run. Investors need clear guidance to keep funding progress here.

India anchors global healthcare through Section 92A[17], allowing the export of patented medications to nations lacking local production capacity. Intellectual property rights matter, but strict regulations must never block access to essential, life-saving treatments. Actually, providing affordable generics dramatically boosts survival rates across struggling regions. Protecting human lives comes first. That is the reality. India functions as a massive supplier of low-cost medicine, bridging wide gaps for millions who otherwise face ruin.

Following the Doha Declaration on TRIPS and Public Health proves that nations can cooperate effectively to improve stability everywhere. Steady access keeps progress alive, ensuring we meet urgent global demands without trampling on fundamental patient rights. Drugs keep moving. Help reaches the sick. Navigating this complicated legal maze is never simple, but history shows that life eventually finds a path ahead. Challenges persist, yet medicine reaches those in need across borders daily. Humanity depends on this constant flow forward.

Mandatory licensing systems present real problems despite their potential perks. Procedural delays and hazy legal standards often stall progress, actually. Wealthy nations plus international firms exert constant, heavy pressure on the process too. Innovation suffers when companies fear losing patent protection. Pharmaceutical firms prioritize their research investments above all else, so they guard these assets tightly. That is the reality. Striking a difficult balance remains an ongoing, messy struggle.

India's mandatory licensing system for medicine clearly struggles to expand access as intended. Results remain modest at best. A more transparent framework and improved administrative capacity are required to fix these deep systemic flaws. Actually, simplifying the process

[17] Id. § 92A.

remains the only way forward. Modernizing these rules will help prioritize affordability for the general public while encouraging innovation. That is the reality. Striking a better balance ensures that everyone gets the basic treatments they need.

Chapter V- Conclusion and Recommendations

Section 84 of the Patents Act, 1970[18] dictates compulsory licensing rules. Policymakers struggle to balance protecting innovation with keeping essential medicine prices within reach for the average citizen. It is what it is. Actually, navigating post-TRIPS Agreement frameworks complicates matters significantly. Governing bodies must follow global intellectual property standards while prioritizing local health requirements. India faces a hard path forward here. Balancing these conflicting demands requires steady hands, clear vision, and a willingness to confront reality daily.

Compulsory licensing acts as a blunt regulatory tool meant to check the blatant abuse of patent monopolies. Statutory rules define these boundaries clearly. Section 84[19] ensures that patent holders never ignore the public interest, prioritize profits, or block access to essential needs. To be honest, it stops companies from weaponizing their portfolios against common folks. That is the reality. Bayer Corporation against Natco Pharma Ltd stands as a landmark example of this legal strategy in action. By forcing a license, the court widened the local availability of life-saving medicine while slashing high costs. Better health access became a tangible result for many patients.

Current frameworks contain flaws despite clear advantages. Ambiguity regarding terms like reasonable affordability and the obligation to work a patent in India cause major headaches. Actually, legislative standards lack the necessary detail to ensure consistency. Execution remains messy. Strict procedural requirements often stifle the application of a mandatory licence, creating a slow, complex slog for everyone involved. Pursuing these legal channels drains time and resources, leaving innovators stuck in limbo.

Systemic failures are effectively eliminated by replacing obsolete frameworks. Prescription price caps, average income levels, and regional healthcare spending are all realistic and sound affordability factors that improve overall diagnostic accuracy. Regulators uphold particular

[18] The Patents Act, No. 39 of 1970, § 84 (India).
[19] The Patents Act, No. 39 of 1970 (India).

standards to determine the number of licenses required for operation. It just functions. In actuality, updating the antiquated notion of working the patent is still essential for striking a balance between domestic production obligations and a significant reliance on unstable global supply chains. The main way to protect foreign stock is through stability in domestic output. Producers have to make swift changes. They genuinely do. Policy becomes mired in antiquated, dusty notions in the absence of these practical modifications. It is urgent to take concrete action. The public is regularly let down by empty paper promises.