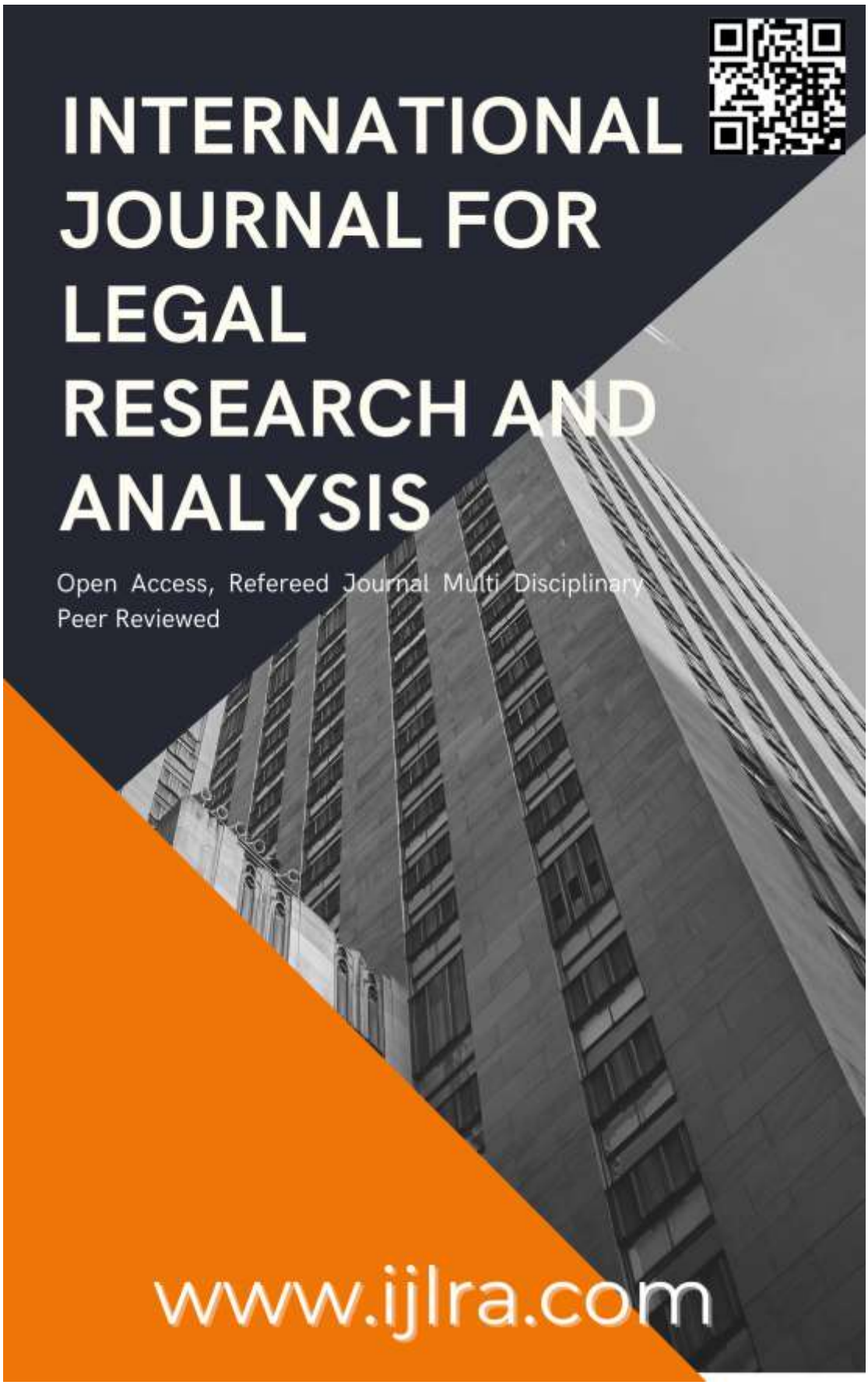

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RESEARCH ARTICLE

NATCO V. Bayer: Public Interest Versus Patent Monopoly In Pharmaceutical Innovation In Pharmaceutical Patents Versus Patent Monopoly

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The Natco v. Bayer case represents a landmark moment in Indian intellectual property law, centering on the grant of India's first compulsory license for a patented pharmaceutical product. Intellectual property rights provide inventors with monopoly protection for a limited period to encourage innovation, but this exclusivity can sometimes lead to abuse, particularly when essential medicines become unaffordable or inaccessible to the public. The compulsory licensing mechanism, as permitted under the TRIPS Agreement, allows governments to override patent rights in specific circumstances—such as when prices are unreasonably high, the patent is not being "worked" locally, or public interest is at stake. In this case, Natco Pharma was granted a license to produce a generic version of Bayer's anti-cancer drug, Nexavar, after it was determined that Bayer's pricing and supply did not meet the reasonable requirements of the Indian public. The decision has been widely discussed as a model for developing countries seeking to balance patent protection with public health needs. It underscores that compulsory licensing is a TRIPS-compliant tool that can be used to protect the health sector and ensure access to essential medicines, especially in developing nations facing public health crises.

Introduction

The pharmaceutical industry often presents a complex interplay between the pursuit of innovation, driven by patent protections, and the imperative of public health, which sometimes necessitates broader access to essential medicines. This inherent tension is acutely observed in cases involving compulsory licensing, where governmental authorities grant licenses to third parties to produce patented products without the patent holder's direct consent, typically under specific public interest provisions[1] (Manu, 2015) (Compulsory Licensing & It's Implication on Innovation: A Study of Indian Pharma-Industry, 2024). The Natco v. Bayer case serves as a seminal example within this framework, illustrating the delicate balance India seeks to maintain between incentivizing pharmaceutical research and ensuring the affordability and accessibility of life-saving drugs to its populace ("Patent Law and Compulsory Licensing: Indian Perspective," 2023). This particular legal battle ignited a global debate concerning the scope of patent rights, particularly in emerging economies, and underscored the moral and ethical dimensions of intellectual property in the context of public health emergencies (Stirner & Thangaraj, 2013). Specifically, this case highlighted the mechanisms available to nations, such as compulsory licensing under Section 3 of India's patent law, to address situations where patent monopolies might impede the availability of essential medicines[2] (Goudra, 2024) (Parthasarthi, 2022). (McGivern, 2023) Such mechanisms are crucial for promoting access to affordable medicines, a key aspect of achieving sustainable development goals (Tyagi, 2018).

[1] (Manu, 2015) (Compulsory Licensing & It's Implication on Innovation: A Study of Indian Pharma-Industry, 2024)
[2] (Goudra, 2024) (Parthasarthi, 2022) (McGivern, 2023)

Background

Bayer Corporation held a patent for Nexvar (Sorafenib Tosylate), which got patented in India in 2008. It was a drug used in the treatment of liver and kidney cancer. The cost of the drug is approximately ₹2.8 lakh per month, making it inaccessible for most Indian patients[3]. Citing the exorbitant amount of price of the medicine, Natco Pharmaceuticals filed for compulsory licensing of the drug under Section 84 of the Indian Patents Act, which allows for such licenses if the patented drug:

- Is not available to the public at a reasonable price.
- Fails to meet the reasonable requirements of the public.
- Is not "worked" in India.

The Indian Patent Office granted the compulsory license to Natco Pharma, reducing the price of the drug to ₹8,800 per month, making it far more affordable. Natco was instructed to sell the patented drug at this specified price and to pay a standard royalty of 6% based on the net manufacturing price. Natco is permitted to sell the drug only within India and is required to provide it free of charge to at least 600 needy patients annually.

Being aggrieved by the order of the controller, the appellant filed for an interim stay before the IPAB.

Issues Raised

1. Procedural Objections: Bayer argued that the Patent Controller failed to give them adequate notice before granting the license, which violated procedural norms.
2. Cipla's Market Presence: Bayer contended that Cipla, another company selling a similar drug at a lower price, should have been considered when determining if public demand was being met.
3. Reasonable Pricing of Nexavar: Bayer claimed that its price was justified given the significant investment in research and development (R&D).

Compulsory licences and the working requirement. How the Natco/Bayer licence fits in

Under Article 31 of the TRIPS Agreement compulsory licences can be issued subject to strict requirements[4]. These conditions limit states' freedom of action (in the following paragraph the author will verify whether the Natco/Bayer licence satisfies each of these requirements). They are also more stringent than the requirements set forth in the Paris Convention, which contains just a few provisions regarding compulsory licences. In particular, Article 5(A)(2) of the latter treaty provides that states shall have the right to take legislative measures providing for the grant of compulsory licences in order to prevent any abuse of patent rights, for example failure to work. It also adds that compulsory licences shall be refused if the patentee justifies its inaction by legitimate reasons[5]. This provision therefore does not mandate strict requirements for the issuance of the licence. It does not even cover other kinds of compulsory licences other than licences for failure of working.

Article 5(A)(2) Paris Convention has been incorporated into the TRIPS Agreement as along with Article 5(A)(1). This latter provision, even though not directly related to compulsory licences, is relevant for the purposes of this analysis. Article 5(A)(1) states that importation of patented products by the patent owner does not entail the forfeiture of the patent. However, the Controller of Patents in Natco/Bayer inferred from

[3] (Debapom, 30 October 2024)
[4] See also D. Gervais, The TRIPS Agreement: Drafting History and Analysis, Sweet & Maxwell, London, 2003, p. 250.
[5] Bonadio, E. (2012). Compulsory Licensing of Patents: the Bayer-Natco Case. European Intellectual Property Review, 34(10), pp. 719-728.

this provision that the mere importation of patented goods could still result in and thus justify "something less than forfeiture, such as a compulsory licence". Only the local production of the relevant goods by the patent owner or a company authorized by it could prevent said issuance. Yet, this did not occur in Natco/Bayer as Bayer did not produce any pills of Nexavar in India (even though it could have done so). As the Controller noted, the patentee claimed to have manufacturing facilities in India for several products, including oncology-related drugs, so that there was no obstacle preventing Bayer from locally manufacturing the medicine or in any case from granting a voluntary licence on reasonable conditions to another producer including Natco. The Controller also rejected Bayer's argument that the low quantities of drugs required in India did not justify setting up a manufacturing facility in the country. In reaching its decision, the Controller also relied on three provisions of the Indian Patent Act, ie Sec. 83(b), (c) and (f). The first provision states that patents are not granted merely to allow patent owners to enjoy monopolistic rights for the importation of the patented goods. The second one provides that the issuance of patents should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Sec. 83(f) states that patent rights should not be abused so as to unreasonably restrain trade or jeopardize the international dissemination of technology. In particular, Sec. 83(c) and (f) are very important – stressed the Controller – because they confirm that patent owners are obliged to contribute towards the national and international transfer of technology, so as to balance their rights with their obligations. How can the patentees achieve that? The Controller had no doubts: the patent holder should either produce itself the patented product in loco or grant a local third party a licence to manufacture it. Oddly enough, in this specific regard the Controller made no reference to neither Article 7 TRIPS (which states that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to its transfer and dissemination) and Paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health according to which, as shown above, countries have "the freedom to determine the grounds upon which such licences are granted".

EU law also rejects the local production requirement. In Case C-235/89 the Court of Justice of the European Union (at that time it was called the European Court of Justice) released a decision with reference to the old Italian provisions on compulsory licences, according to which said licences were granted in cases where the patentee did not manufacture locally the relevant products. The Court held that this provision basically had the effect of forcing patent owners to locally produce the patented products rather than to import them from other Member States. The provisions therefore amounted to, the Court found, measures having an equivalent effect to quantitative restrictions on imports under (what is now) Article 34 of the Treaty for the Functioning of the European Union. The arguments put forward by the Court of Justice of the European Union could and should be transposed from the EU to the WTO/TRIPS scenario. Indeed, the WTO and the EU share analogous general principles and similar objectives, ie elimination of barriers to trade. Finally, as we have seen above, the Indian Controller of Patents also based his (incorrect) finding on the local production requirement on inter alia a specific provision of the Indian Patent Act, ie Sec. 83(b). This latter provision states that patents should not be granted merely to allow patent owners to enjoy monopolistic rights for the importation of the patented goods. Yet, relying on a national provision to justify its position does not provide a safe harbor for India and thus exclude the alleged infringement of Article 27(1) TRIPS. Indeed, due account must be taken of Article 27 of the Vienna Convention on the Laws of Treaties which states that "a party may not invoke the provisions of its internal law as justification for its failure to perform a treaty".

The conditions set forth by Article 31 TRIPS. How the Natco/Bayer licence fits in

We now proceed to verify whether the compulsory licence in Natco / Bayer complies with the conditions specifically required under Article 31 TRIPS. The analysis will be preceded by a concise description of each relevant condition.

(i) Article 31(a) states that the "authorization of such use shall be considered on its individual merits". The wording is not very clear. It is believed that this provision should be interpreted as prohibiting the automatic issuance of compulsory licences, e.g. states could not pass laws providing the automatic granting of compulsory licences in a specific field, or vis-à-vis certain patentees. The compulsory licence in Natco/Bayer satisfies this condition as it was granted in the context of an ad hoc administrative proceedings before the Indian Controller of Patents, and not as a result of a local law or regulation automatically providing licences in the pharmaceutical field or just against Bayer.

(ii) Compulsory licences can be granted only where the prospective licensee has made efforts to obtain authorization from the patentee on "reasonable commercial terms and conditions" and that such efforts have not been successful within a reasonable period of time (Article 31(b) TRIPS). This provision implies that before applying for a compulsory licence the proposed user has a duty to negotiate a voluntary licence with the patentee and that a compulsory license can be granted only where the patent holder has arbitrarily refused to enter into a voluntary agreement with the applicant. The concept of reasonableness of terms and conditions is not clearly defined. This is due to the fact that such concept may vary depending on the nature of the technology and on the level of development of the country which grants the licence.

(iii) Article 31(d) TRIPS then provides a proportionality rule by stating that the scope of the licence must be limited to the purpose for which it was granted. For example, compulsory licences could be granted only in relation to certain claims of a patent; in a specific field such as in the military sector (excluding authorization in the civilian sector); for a certain territory. In Natco/Bayer the scope of the licence seems to be limited. This is confirmed by the following terms and conditions of the compulsory licence: Natco has been given the right to produce the patented drug only at its own manufacturing facility and is prohibited to outsource the production; the licence just covers the use of the patent for treating renal cell carcinoma (RCC) and unresectable hepatocullular carcinoma (HCC) in humans within the Indian territory; moreover, Natco has not been given the right to import the patented medicine.

(iv) Compulsory licences must be non-exclusive. It means that the patentee can continue to exploit the invention and directly compete with the licensee as well as grant any voluntary licences it wishes (Article 31(d)). This condition is met in Natco/Bayer. The Controller indeed held that Bayer is free to do whatever it wants with its residual patent rights and in particular is free to compete with Natco and to grant licences to third parties to compete with Natco. A competitive spiral might thus be triggered, which could be even more beneficial to Indian patients as more competition would push prices further down.

(v) Compulsory licences must also be non-transferable except with the part of the enterprise or goodwill which enjoys such use (Article 31(e)). This provision aims at preventing the development of a market of compulsory licences as instruments with independent value. This condition is also met in the case in question.

(vi) The use of the invention must be authorized "predominantly" for the supply of the domestic market of the country authorizing such use (Article 31(f)). This provision compels licensees to sell products for the most part in the country where the compulsory licence is granted. The sale abroad is permitted just in limited cases, eg only involuntary and unintended surpluses may be exported. This condition is also met in Natco/Bayer as the scope of the licence is limited to the production and sale of the patented drug in the Indian territory.

(vii) Under Article 31(g) compulsory licences should expire when the circumstances which led to them cease to exist and are unlikely to recur. The competent authority shall have the authority to

review, upon motivated request, the continued existence of these circumstances. This provision entails that compulsory licences are not automatically granted for the entire duration of the patent. They therefore could be terminated if the conditions under which they were granted are not met anymore. This provision should be read in conjunction with Article 31(c) above.

(viii) Under Article 31(h) TRIPS the patentee must receive an adequate remuneration depending on the circumstances of each case, taking into consideration the economic value of the licence. Thus, even though a compulsory licence entails a curtailment of patentee's rights, the latter is entitled to be paid an adequate compensation. This is in line with the very nature of intellectual property rights and in particular the fourth recital of TRIPS which recognizes that said rights are private rights.

Literature Review

The contentious interplay between pharmaceutical patents and public access to essential medicines has generated extensive academic discourse, particularly in the context of compulsory licensing (Compulsory Licensing & It's Implication on Innovation: A Study of Indian Pharma-Industry, 2024). This debate intensifies during public health crises, such as the COVID-19 pandemic, where the rapid and widespread availability of treatments and vaccines becomes paramount[6]. Compulsory licensing, an involuntary patent override, emerges as a critical mechanism for balancing proprietary rights with societal needs, enabling the production and distribution of patented pharmaceuticals by third parties without the patent holder's direct consent under specific conditions[7] .India's legal framework for compulsory licensing, rooted in the Patents Act of 1970, has evolved significantly, drawing from historical precedents such as the French Patent Law of 1791 and incorporating amendments up to 2005 to align with international agreements like TRIPS ("Patent Law and Compulsory Licensing: Indian Perspective," 2023)[8]. This alignment, particularly concerning Section 3 of the Indian Patent Act, has been pivotal in shaping the nation's approach to incremental pharmaceutical innovations, aiming to reconcile the promotion of invention with the imperative of affordable medicine access[9]. The landmark case of Bayer v. Natco exemplifies this tension, where the Indian Patent Office granted the first compulsory license for Bayer's patented cancer drug, Sorafenib tosylate, to Natco Pharma Ltd., citing reasons of public interest, unmet demand, and unaffordability[10].

Methodology

This study employs a qualitative, case-study approach, focusing on the landmark legal proceedings of Natco v. Bayer, to analyze the intricate balance between intellectual property rights and public health objectives in the pharmaceutical sector. This analysis critically examines the implications of compulsory licensing, particularly under Section 98 of the Indian Patents Act, which facilitates the export of patented medications, thereby influencing drug accessibility and challenging patent monopolies (Compulsory Licensing & It's Implication on Innovation: A Study of Indian Pharma-Industry, 2024). Furthermore, the research delves into the economic and ethical considerations surrounding pharmaceutical innovation, particularly in the context

[6] (Choi & Park, 2024) (Parthasarthi, 2022)
[7] (Stirner & Thangaraj, 2013)
[8] (Basheer & Kochupillai, 2005)
[9] (Goudra, 2024) (Tyagi, 2018)
[10] (Manu, 2015)

of compulsory licensing as a mechanism to ensure affordability and wider availability of essential medicines[11]. The study also explores the role of compulsory licensing in promoting public health during crises, such as pandemics, by enabling widespread access to crucial medical innovations (Parthasarthi, 2022). This examination extends to evaluating how India's intellectual property regime, particularly its provisions for compulsory licensing, aligns with TRIPS agreements, thereby legitimizing the "reasonably affordable requirements of the public" as a valid condition for such licenses (Manu, 2015). This legal framework, evolving from the French Patent Law of 1791 to the TRIPS Agreement amendments in 2017, underscores India's commitment to balancing innovation incentives with societal needs, especially concerning access to affordable medicines (“Patent Law and Compulsory Licensing: Indian Perspective,” 2023). Conversely, critics often raise concerns about the potential disincentives to pharmaceutical research and development, arguing that compulsory licensing might undermine the financial viability of innovative drug manufacturers and deter future investments in novel therapies. This debate underscores the necessity for rigorous empirical analysis to assess the actual effects of compulsory licensing on innovation pipelines and pharmaceutical accessibility. The Natco v. Bayer case, therefore, provides a pivotal lens through which to examine these competing perspectives, offering real-world data on the application and consequences of compulsory licensing in a developing economy. This study employs a qualitative research methodology, analyzing legal documents, policy statements, and expert testimonies related to the Natco v. Bayer case, to elucidate the legal interpretations and socio-economic ramifications of compulsory licensing in India's pharmaceutical sector. Furthermore, this methodological approach allows for an in-depth exploration of how domestic court practices, especially within the Indian legal system, interpret international agreements such as the TRIPS Agreement concerning pharmaceutical inventions.

Conclusion

The landmark case of *Bayer Corporation v. Natco Pharma Ltd.[12]marked a pivotal moment in the discourse surrounding pharmaceutical patents and public health, as it represented India's first-ever compulsory license granted for a patented drug. This decision allowed Natco Pharma to produce a generic version of Bayer's patented anti-cancer medicine, Nexavar, at a significantly reduced price, thereby making it more accessible to the Indian public. This ruling underscored the tension between intellectual property rights, intended to incentivize innovation, and the imperative of public interest, particularly concerning access to essential medicines[13]. The ruling not only initiated a global debate on the flexibilities within the TRIPS Agreement concerning public health emergencies but also brought into sharp focus the affordability requirements of the public as a valid condition for granting compulsory licenses, as articulated in Section 84 of the Indian Patent Act[14]. This case subsequently spurred further discussion on the practical implementation of compulsory licensing as a mechanism to balance monopolistic patent protections with societal healthcare needs, especially in developing nations. The legal framework enabling this decision, rooted in the Indian Patents Act of 1970 and its subsequent amendments, reflects a proactive stance by India to leverage flexibilities within

[11] (Choi & Park, 2024) (Stirner & Thangaraj, 2013)
[12] (Nedumpara & Misra, 2012)
[13] (Bonadio, 2012) (Parthasarthi, 2022)
[14] (Manu, 2015) (Compulsory Licensing & It’s Implication on Innovation: A Study of Indian Pharma-Industry, 2024)

international intellectual property treaties, such as the TRIPS Agreement, to prioritize public health objectives.