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Compulsory Licensing of Patents: Balancing Innovation and Access to Essential Technologies

Adya Nair[a]

[a]ICFAI Law School, Hyderabad, India

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Compulsory licensing is a government-sanctioned mechanism that allows a third party to manufacture or use a patented invention without the patent holder's consent. This policy aims to strike a balance between encouraging innovation through intellectual property rights and ensuring public access to essential technologies. The article explores compulsory licensing in India, examining its purposes and how it is implemented. The provisions within the Patents Act 1970[1] are explained, outlining the grounds on which a compulsory license can be granted, such as if the patented invention is not being made affordable or accessible to the public. The crucial role of compulsory licensing during public health emergencies is highlighted, exemplified by the COVID-19 pandemic. The article also acknowledges the potential drawbacks of compulsory licensing, including its potential discouragement of innovation. Landmark cases like Bayer Corporation v Natco Pharma[2] and Novartis AG v Union of India (2013) 7 SCC 241[3] are explored to illustrate the legal battles surrounding access to medicine and the use of compulsory licensing in India. The importance of striking a balance between intellectual property rights and public health access is emphasized. The article concludes by calling for open communication and collaboration between governments, patent holders, and generic drug manufacturers to create a system that fosters innovation while guaranteeing access to life-saving technologies.

[1] The Patents Act 1970
[2] *Bayer Corporation v Natco Pharma* (2014) 60 PTC 277 (BOM)
[3] *Novartis AG v Union of India* (2013) 7 SCC 241

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INTRODUCTION

One of the main pillars of intellectual property (IP) law, the patent system, is essential for encouraging innovation. Patents provide a financial incentive that propels scientific and technological growth by providing inventors exclusive rights to their inventions for a certain amount of time. But there's a fundamental conflict here: how can we encourage innovation while guaranteeing widespread public access to copyrighted technologies?[4] Compulsory licensing presents a possible resolution to this intricate problem.

A government-approved system known as compulsory licensing gives authorities the authority to allow someone else to manufacture or use a patented invention even when the patent holder is not present. This intervention usually takes place in certain situations, such as when the patented technology is not easily accessible to the general public at a fair cost or when it is thought to be crucial for national security or public health.

Compulsory licensing is a notion that requires careful balance. On the one hand, it encourages policies that protect the general welfare by guaranteeing that copyrighted innovations have a wider social use. Enforcing compulsory licensing may increase competition, which might result in cheaper consumer costs and quicker adoption of innovative technology. However, it causes innovators to be concerned. When patents do not confer exclusive rights, the financial benefits of their efforts are uncertain perhaps deterring large-scale research and development expenditures.

This first investigation just establishes the framework for a more comprehensive examination. The reasoning behind compulsory licencing will be thoroughly examined in the parts that follow. We will examine the precise terms under which it is awarded and conduct a thorough analysis of the possible advantages and disadvantages for inventors as well as society at large.

[4] 'Compulsory Licensing' (*INSIGHTSIAS*, 27 April 2021) <https://www.insightsonindia.com/2021/04/27/compulsory-licensing/> accessed 19 April 2024

CHANGES IN COMPULSORY LICENSING DUE TO THE TRIPS AGREEMENT

An important factor in determining how intellectual property (IP) is seen across the world is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[5]. It is a treaty that is appended to the World Trade Organisation (WTO) framework and sets minimal requirements for intellectual property protection that each member state must follow. Encouraging international competitiveness and a single patent system is one of its main goals. The TRIPS Agreement, however, acknowledges the necessity of striking a balance between the rights of innovators and more general social issues like equal access to technology and public health. This is where the idea of required licencing becomes relevant.

Without the express permission of the patent owners, a government can authorise a third party to manufacture or use a patented product by compulsory licencing. Article 31[6] of the TRIPS Agreement requires WTO members to provide procedures in their national legislation to deal with circumstances in which a patent may not be serving the public interest. These requirements are meant to protect patent holders' rights without unreasonably jeopardising the public interest. First, every request for compulsory licencing is considered individually. Second, the prospective licensee has to show that, despite their best efforts, they were unable to obtain a licence from the patent holder on acceptable commercial terms within a reasonable amount of time. In situations of exceptional urgency, national emergency, or public non-commercial use, this criterion may be waived. Even under these circumstances, though, the patent holder needs to be informed right away.

Moreover, the length and extent of the compulsory license cannot be exclusive and must be tightly restricted to the approved purpose. Furthermore, the licence can only be transferred to a new entity through a business transfer in which the use of the patented invention constitutes a fundamental function. The TRIPS Agreement further states that if the conditions for the issue of the license for compulsory licencing are no longer met, it may be cancelled.

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[5] 'Compulsory licensing of pharmaceuticals and TRIPS' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 19 April 2024

[6] TRIPS Agreement 1995, art 31

Making sure the patent holder receives just pay is a crucial component. Under the TRIPS Agreement, the patent holder must get 'adequate remuneration' for the permitted use, taking into account the license's economic worth. Lastly, by mandating that decisions about compulsory licencing be subject to judicial or independent review by a higher authority within the member nation, the agreement highlights the significance of accountability and transparency.

In the international patent system, the TRIPS Agreement regulates forced licencing in a big way. It aims to achieve a balance between promoting innovation by defending the rights of inventors and guaranteeing that patented technology can be accessible for the benefit of the general public under certain criteria and protections.

PROVISIONS RELATED TO COMPULSORY LICENSING IN THE THE PATENTS ACT 1970

A foundation for patent protection is established under The Patents Act 1970[7], which also includes measures for compulsory licensing. Through this process, the government can, in some situations, grant permission to a third party to manufacture or use a patented innovation without the patent holder's approval. After at least three years have passed following the patent's issue, compulsory licencing in India may be granted, subject to Section 84(1) [8]of the Act. Three primary reasons are available for the pursuit of a compulsory licence:

Unfulfilled Public Needs: The first basis concerns circumstances in which the patented innovation fails to sufficiently satisfy the 'reasonable requirements of the public.' This can happen if there isn't enough domestic demand being met by the manufacturing or importation of the patented goods. For example, a patent may exist for a life-saving drug, but the patent holder may not be manufacturing enough of it to satisfy the demands of the public. To guarantee that the medication is more widely accessible, another producer can be given a required licence.

[7] The Patents Act 1970
[8] The Patents Act 1970, s 84(1)

Expensive Prices: The second reason deals with the matter of affordability. If the public cannot purchase the patented idea at a 'reasonably affordable price,' a forced licence might be issued. This clause aids in preventing patent holders from abusing their monopoly rights by imposing unreasonably high fees that limit access to the technology that is protected.

Non-Working of the Patent: The third ground deals with situations where the patented invention is not being 'worked in the territory of India'. This implies that the patent holder is not actively manufacturing or using the invention in the country. The rationale behind this provision is to prevent the stifling of innovation by 'patent hoarding,' where a patent holder simply sits on the invention without bringing it to market. A compulsory license could be granted to another entity that is willing to utilize the invention productively within India.

Under section Section 92[9] in an emergency, gives the central government the authority to take immediate action. This clause gives the government the authority to publish a notice in the official gazette declaring a state of extraordinary urgency or a national emergency. This declaration initiates accelerated compulsory licensing, enabling a quicker and more efficient procedure in cases when prompt access to a patented invention is essential. Such circumstances can include natural disasters that endanger public health or epidemics of infectious illnesses like malaria, HIV/AIDS, or TB.

After the declaration, based on petitions from interested parties, the appointed body, the Controller of Patents, may award compulsory licenses. The terms and conditions for these licences may be determined at the Controller's discretion, provided that they are reasonable and well-rounded. A vital component of this procedure is guaranteeing that the public can purchase the goods produced under the obligatory licence 'at the lowest rates possible.' During public health emergencies, this provision seeks to maximise affordability and guarantee that the most vulnerable people have access to critical technology.

In India, Section 92 of the Patents Act[10] provides essential protection for the public's health. By making copyrighted technologies easier to obtain, it gives the government the ability to respond

[9] The Patents Act 1970, s 92
[10] *Ibid*

quickly to public health emergencies like pandemics and epidemics. This clause highlights how the Indian patent system is dedicated to striking a balance between the rights of inventors and the vital requirements of the public in times of grave urgencies and national emergencies by facilitating the development of life-saving medications and technology at reasonable costs.

Compulsory licensing, a mechanism allowing the generic production of patented goods, has a surprisingly narrow application in India.[4], Unlike some countries, India only permits compulsory licensing for a select few industries, but the countries are free as to what they think constitutes a national emergency and the grounds for compulsory licensing.

The following are the industries where India allows for compulsory licensing:

Alcoholic Beverages: Production of distilled spirits and brewed alcoholic drinks can be undertaken under compulsory licensing.

Tobacco Products: The manufacture of cigars, cigarettes, and tobacco substitutes can be done through compulsory licenses.

Defense and Aerospace Equipment: This category encompasses all types of electronic equipment used in the aerospace and defense sectors.

Explosives and Pyrotechnics: The production of industrial explosives, detonators, safety fuses, gunpowder, nitrocellulose, and matches falls under compulsory licensing.

Hazardous Chemicals: The manufacture of hazardous chemicals is another area where compulsory licensing is permitted.

Pharmaceuticals: Notably, the Indian government introduced a modified Drug Policy in 1994 that included pharmaceuticals within the scope of compulsory licensing.

COMPULSORY LICENCES PROVIDE THE FOLLOWING BENEFITS

Promotes the welfare of the general public: The possibility of compulsory licencing to advance public welfare is one of the strongest justifications for it. This is especially true for necessities like life-saving medications. Generics can be produced with a required licence, which will bring

down prices and increase their accessibility to a larger audience. This has the potential to greatly enhance public health results, particularly in underdeveloped nations where access to pricey proprietary medications may be restricted.

Promoting economic development in countries where there are fewer inventions: Additionally, compulsory licencing can spur economic growth, especially in nations with lower levels of innovation. These nations can expand their local manufacturing capacities by having cheaper access to patented technology. Through knowledge transfer and possible future innovation spurred by licenced technology, this can boost regional industries, provide employment, and drive technical growth.

Ensures the protection of intellectual property rights: Ensuring the ongoing protection of intellectual property rights is a critical concern associated with compulsory licencing. For their inventiveness and the money they devote to research and development, inventors need to be compensated. In order to maintain this equilibrium, forced licensing is usually only allowed in certain situations, such as when the patent is not being used or when the patent holder is charging excessively high fees. Furthermore, it's common for license agreements to require just remuneration for the patent holder.

Ensures that major commodities have access to the market: While patents are granted to incentivize innovation, they also create temporary monopolies. Compulsory licensing can act as a safeguard against situations where patent holders restrict access to critical commodities like food or energy resources. Enabling alternative sources of production can help ensure that essential goods remain available in the market and prevent price gouging or disruptions in supply chains.

THE FIRST CASE OF WHERE COMPULSORY LICENSING WAS ISSUED IN INDIA

The conflict between the right to intellectual property (IP) and the public's access to necessary medications is a complicated worldwide problem. This conundrum and the possible

contribution of forced licencing to its resolution are best shown by the seminal Indian case of Bayer Corporation v Natco Pharma Limited & Ors.[11]

The patent on Sorafenib, a life-saving cancer medication sold under the trade name Nexavar, belonged to the German pharmaceutical behemoth Bayer Corporation. However, many patients were unable to afford Nexavar because of its outrageously expensive cost in India. In an effort to close this gap, Natco Pharma, an Indian producer of generic medications, applied for a mandatory licence to create a less expensive generic version of sorafenib.

India's first case of Bayer Corporation v Natco Pharma Limited, 2014(60) PTC 277 (BOM) [12]granting compulsory license was granted by the Patent Office in 2012 to an Indian Company called ***Natco Pharma*** for the generic production of ***Bayer Corporation's*** Nexavar. The public's reasonable requirements had not been met, and it was not available at an affordable price and the patented invention has not been exploited in India, all conditions of The Patents Act, 1970, specifically Section 84[13], go beyond simply granting inventors a patent. It establishes a crucial balance between the rights of the inventor and the public's access to essential technologies. While a patent grants exclusivity, Section 84[14] clarifies that this doesn't translate to an absolute monopoly on imports. The patent holder cannot simply import the invention and claim they've fulfilled their obligations. There's a responsibility to make the patented invention available to the public. This availability should be two-fold: ensuring affordability and catering to public needs. Imagine a scenario where a life-saving drug is patented but offered at an exorbitant price. Section 84[15] prevents such a situation by emphasizing that patent rights must be exercised for the greater social and economic good. It's not just about the rights of the inventor, but also their obligations. This section prevents the patent holder from arguing that someone else's actions, like imports, fulfill their responsibility to make the invention accessible.

Furthermore, Section 84 safeguards public health. The patent holder cannot take any actions that impede the protection of public health and well-being. This is particularly relevant in the context

[11] *Bayer Corporation v Natco Pharma* (2014) 60 PTC 277 (BOM)
[12] *Ibid*
[13] Patents Act 1970, s 84
[14] *Ibid*
[15] *Ibid*

of public health emergencies. For instance, during a pandemic, a compulsory license might be issued to allow generic drug manufacturers to produce essential medications at affordable prices. The section also anticipates potential misuse of patent rights and explicitly prohibits such practices.

Finally, Section 84 underscores the core purpose of patents: to benefit the public. It unambiguously states that patents are granted to ensure the public can access the advantages of these inventions at a reasonable and affordable price. This section ensures that the public receives the intended benefits of innovation, striking a crucial balance between promoting innovation through intellectual property rights and guaranteeing public access to essential technologies.

This medicine is used for treating Liver and Kidney Cancer, and one month's worth of dosage costs around Rs 2.8 Lakh. For Rs 9000, Natco Pharma had been offering this potentially life-saving medicine at a fair price to all sectors of society and not only the wealthy. This decision has been taken by the Government in the interests of the general public. However, it was highly criticised by pharmaceutical companies because they did not believe that this authorisation should have been granted.

For several reasons, the Natco Pharma-Bayer case represents a significant ruling. It shows that India is prepared to use compulsory licencing as a tool to guarantee its citizens' access to necessary medications at reasonable costs. The delicate balance between preserving intellectual property rights, which encourages research and development, and advancing public health by guaranteeing access to life-saving medications has come under scrutiny once again as a result of this case. It underscores the potential of compulsory licensing as a tool to address issues of affordability and access to essential medicines, particularly in developing countries. However, it also highlights the ongoing challenge of fostering innovation while ensuring these advancements serve the broader public good.

In the case of ***Novartis A.G. v Union of India***[16] in 2006, the Madras Patent Office rejected Novartis' patent application for its drug Glivec, citing the absence of significant therapeutic

[16] *Novartis A.G. v Union of India* (2013) 6 SCC 1

improvements compared to its existing patented form outside India. This decision was based on Section 3(d)[17], which stipulates that a known substance can only be granted a patent if its new forms demonstrate 'enhanced efficacy'. Since the Patent Office found no enhanced efficacy in Glivec, it deemed the drug ineligible for patent protection under Section 3(d)[18].

In May 2006, Novartis took legal action by filing two writ petitions under Article 226[19] of the Indian Constitution before the High Court of Madras. The first petition appealed against the Madras Patent Office's rejection of its patent application, while the second challenged the compatibility of Section 3(d) of the Indian Patents Act[20] with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Additionally, Novartis argued that the provision was vague, arbitrary, and violated Article 14[21] of the Constitution.

The Writ Petitions filed by Novartis were rejected by the Madras High Court, which determined that it lacked jurisdiction to assess whether a domestic law contradicts an international treaty. Consequently, the court cannot determine whether Section 3(d) complies with the TRIPS agreement. With regard to Section 3(d), the Amending Act aimed to prevent the practice of evergreening and facilitate access to life-saving medications for citizens. Therefore, it should not be considered vague or arbitrary.

Subsequently, a new phase of legal proceedings commenced at the Intellectual Property Appellate Board (IPAB), which serves as the appellate body for patent controllers. The IPAB concluded that the beta-crystalline form of imatinib mesylate was novel and involved an inventive step. However, it refused to grant a patent for Novartis' drug due to its non-compliance with Section 3(d) of the Act. Novartis challenged this decision by filing a Special Leave Petition before the Supreme Court.

The Supreme Court ruled that the primary objective behind the enactment of Section 3(d) was to discourage the practice of evergreening. Therefore, if an invention fails to meet the

[17] The Patents Act 1970, s 3(d)
[18] *Ibid*
[19] Constitution of India 1950, art 226
[20] The Patents Act 1970, s 3(d)
[21] Constitution of India 1950, art 14

requirements set forth in Section 3(d), it cannot be granted a patent. However, the court clarified that this case should not be interpreted as implying that Section 3(d) prohibits all incremental inventions. In the context of the medical field, particularly in cases involving life-saving drugs, it is essential to exercise extreme care and caution to safeguard the right to life of the general public.

The Supreme Court, through its ruling, emphasized that India is a nation in the process of development, and ensuring affordable access to medicines is crucial for the well-being of its one billion inhabitants. Consequently, the Supreme Court's decision to restrict the granting of patents solely to legitimate inventions, rather than frivolous ones, is justified because companies like Novartis are putting the lives of these poor people at stake by obtaining a monopoly over its drugs

Furthermore, the Novartis case reaffirmed India's right to utilize provisions like compulsory licensing. This mechanism allows the government to authorize a third party to produce a patented invention without the patent holder's consent, ensuring access to essential medicines at affordable prices. The case highlighted India's commitment to striking a balance between promoting innovation by protecting intellectual property and ensuring public health by making essential drugs affordable.

The Novartis case serves as a critical turning point in India's patent law and its approach to access to medicines. It demonstrates the country's willingness to challenge powerful pharmaceutical companies and prioritize public health concerns. However, the debate on balancing innovation and affordability continues, with ongoing discussions about how to best leverage the patent system to promote both goals.

In the case of ***BDR Pharmaceuticals v Bristol-Myers Squibb*** it goes to show that compulsory licensing cannot be misused in India.[22]

[22] Radhi Shah, 'Compulsory License: India' (*Kluwer Patent Blog*, 16 August 2021) <https://patentblog.kluweriplaw.com/2021/08/16/compulsory-license-india/> accessed 19 April 2024

A useful insight into these intricacies is provided by the case of BDR Pharmaceuticals International Pvt. Ltd. v Bristol Myers Squibb Company (BMS)[23], especially with regard to the difficulties and process involved in acquiring an obligatory licence in India.

The Indian generic medicine producer BDR Pharmaceuticals requested a mandatory licence for Dasatinib, a treatment for chronic myeloid leukaemia (CML). The global pharmaceutical behemoth Bristol Myers Squibb sells this drug under the brand name Sprycel. The main point of argument was BDR's assertion that Sprycel was too expensive in India, which prevented many patients who were in dire need of the medicine from accessing it. The following case illustrates the licence sought for Sprycel® which is used in cancer treatment

On 04 March 2013, the Controller rejected BDR Pharmaceuticals' (BDR) application for a compulsory license for the cancer drug Sprycel®. The controller said that BDR had not presented a prima facie case for granting an obligation licence. In particular, the Controller found that BDR did not make a credible attempt to obtain a licence from the patent holder and that the applicant could not exploit the invention in the public interest. Consequently, they rejected the mandatory licence.

The continuous battle in India to strike a balance between protecting intellectual property rights and guaranteeing access to reasonably priced medications is best shown by the BDR Pharmaceuticals v Bristol Myers Squibb[24]. Although mandatory licencing is a viable resolution, generic medication producers may have difficulties in manoeuvring through the legal system and constructing a strong argument. In the context of vital pharmaceuticals, this case emphasises the necessity for precise norms, open processes, and a dedication to promoting innovation while protecting public health.

[23] *BDR Pharmaceuticals v Bristol Myers Squibb* (2013) 1 CLC 123
[24] *Ibid*

COMPULSORY LICENSING DURING COVID-19

The healthcare sector has suffered due to the Covid 19 pandemic.[25] Besides a dramatic rise in COVID cases, the lack of availability of medicinal products like Remdesivir, Tocilizumab and Favipiravir at an adequate level has contributed to the situation. Patent protection of such medicinal products, which confers a monopoly on the patent holder, is one reason why they are not accessible and affordable[26]. In such scenarios, the mandatory granting of a licence can be an essential element in improving access to patented medicines.

CONCLUSION

The topic of compulsory licensing is complicated and calls for a careful strategy. It provides a useful tool for increasing access to vital technology in times of need, but its effect on innovation has to be carefully considered. It is critical to establish a sustainable balance. This may be accomplished by looking at systems that support R&D while also enabling mandatory licencing in certain situations and putting strong quality control procedures in place. In order to successfully navigate this route, governments, patent holders, and generic producers must all engage in open communication and collaboration. Together, we can try to build a system that supports innovation and guarantees fair access to life-saving technology, which will eventually improve health throughout the world. The secret to realizing the full potential of obligatory licensing is to adopt this method.

It's critical to strike the correct balance between access to necessities and intellectual property (IP) rights. Strong intellectual property rights can result in monopolies, even when compulsory licencing appears to violate patent holders' rights. To encourage more invention, it's crucial to guarantee patent holders receive just pay.

For developing nations in particular, compulsory licencing becomes crucial. A country may need to intervene if its resources are insufficient to supply necessities like life-saving

[25] Poonam Chetry, 'Compulsory Licensing - A Panacea For Controlling Covid-19?' (*Mondaq*, 29 June 2021) <https://www.mondaq.com/india/patent/1085400/compulsory-licensing-a-panacea-for-controlling-covid19> accessed 19 April 2024

[26] Sapna Kumar, 'Compulsory Licensing of Patents During Pandemics' (2022) 54(1) Connecticut Law Review <https://dx.doi.org/10.2139/ssrn.3636456> accessed 19 April 2024

medications. If a patented drug is available in another country but is out of reach for the majority of people in a developing country, the government owes it to its people to guarantee access. For such circumstances, compulsory licencing may be an option.

In the end, reaching this equilibrium necessitates candid communication and cooperation between governments, patent owners, and producers of generic medications. Together, we can build a system that supports innovation and ensures that everyone has fair access to life-saving technology, resulting in a more just and healthy global community.