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Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship.He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi.Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi.He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

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COMPULSORY LICENSES AND THEIR EFFECTS, ESPECIALLY ON VACCINES AND OTHER DRUGS DURING THE COVID-19 PANDEMIC

Authored By- Gopikrishnan A B

INTRODUCTION

In the present-day world of innovation and rapid technological advancement, individuals and companies have taken to the act of patenting their products and the production methods to protect their investments and other interests. A patent is a time-limited exclusive right granted for an innovative invention in exchange for a comprehensive disclosure of the invention. This process has acted as an incentive for companies to invest in R&D and in the innovation of newer products, which ensures that the companies maintain a competitive spirit and push each other to put out newer products. Some companies also allow other companies to sell or produce their products or use their production method in return for royalties which can act as a source of revenue for the patent holder. However, there are also drawbacks. [1]

While patenting a product, the company or individual has to make certain technical information about the product or process publicly available. Getting a patent is also a time-consuming process, and by the time the patent is acquired, there may be a possibility for the market to change or for technology to overtake the invention[2]. The cost to obtain a patent and defend against anyone infringing upon it can be expensive, taking a chunk out of the company's annual profit. While these are disadvantages that the patent holder can face, there are certain drawbacks that other companies and consumers face.

Patenting a product or a process will prevent other companies from selling or producing the product or using the patented process. This will make the competitors miss out on the profits that could have been earned from the manufacture or sale of the product or from using the patented process. Lesser companies producing the products mean lower accessibility, availability, and affordability

[1]Arthor et. al, *Compulsory Licensing of Pharmaceutical Patents*, ECONOMIC AND POLITICAL REVIEW, vol. 45, no. 39, 2010, pp. 8–9, http://www.jstor.org/stable/25742108 Accessed 4 May 2022.
[2]Reik, R. (1946), *Compulsory Licensing of Patients*, THE AMERICAN ECONOMIC REVIEW, *36*(5), 813–832. http://www.jstor.org/stable/1801800

with respect to the consumers. This especially becomes a problem in the case of vaccines and other drugs. Accessibility, availability, and affordability of life-saving pharmaceutical medicines are crucial aspects that should not be avoided. Making pharmaceuticals readily available at affordable prices is key, especially during these trying times of the Covid-19 pandemic.[3] One way that is available to tackle this problem, among many, is the process of compulsory licensing. Compulsory licenses refer to the clearance given by the authorized official to a third party to make use or sell a particular product or to use a specific process of manufacturing that has been patented earlier, and this authorization means the permission of the patent owner is not required. This concept is accepted at national and international levels and is part of the Indian Patent Act, 1970, and the TRIPS Agreement. This paper looks into the effects of compulsory licenses on both the patent-holding companies and the consumers, specifically vaccines and other drug manufacturing companies, especially on price control and innovation, during the Covid-19 pandemic, and the available legislation regarding compulsory licenses and drug price control in India and internationally.

Effects Of Compulsory Licensing

Granting a compulsory license allows the third party to sell or manufacture a patented product or make use of a patented process without the express permission of the patent holder.

The process of granting a compulsory license is most often seen in developing or underdeveloped countries to allow their domestic industries to produce or sell the patented product or use the patented process. This is done to help their economy grow, and their domestic industries develop and provide products to their citizens at affordable prices. In these countries, almost all the patent holders are foreign companies, which means that their domestic industries cannot produce or sell the product or use the specific process that has been patented.

This causes the indigenous industries to stagnate and not develop, which lowers the country's rate of economic development. Compulsory licensing also has the benefit of offering more job opportunities for the citizens of the country granting the license, as the company holding the patent being the sole competitor in the market means job opportunities are scarce. In the case of pharmaceutical drugs, granting a compulsory license helps increase the accessibility and

[3]Federico, P. J. (1948), *Compulsory Licensing in Other Countries,* LAW AND CONTEMPORARY PROBLEMS, *13*(2), 295–319. https://doi.org/10.2307/1190000

availability of the drugs and control their price.[4] The patent holder being the sole provider of the drug means that they can set the price as high as possible, making it unaffordable for all the citizens. Compulsory licensing allows other third-party players to enter the market, lower the cost, and solve drugs' inaccessibility, unavailability, and unaffordability. This can be a massive help during the Covid-19 pandemic, as it helps in making vaccines readily available and affordable, as cases have emerged of vaccine shortage in various parts of the world.

However, compulsory licensing also has adverse effects. It can lead to foreign companies being hesitant to invest in countries that grant compulsory licenses. This also has the ability to affect the economy of the country and lower job opportunities. Innovating and creating a new product is a costly, time-consuming process. The companies obtain a patent to earn the monopoly rights and profits that come with it to cover the cost and increase their revenue. Compulsory licensing will take away this benefit and discourages companies from innovating and investing in new products.

Countries should not grant compulsory licenses blindly and instead has to weigh the pros and cons and consider what would be best in the specific scenario. Therefore, the grant of compulsory licenses is governed by laws set up in the countries and has to meet certain conditions before it can be granted.

Legislations Regarding Compulsory License And Drug Price Control

International Perspective

- **Trips Agreement on Compulsory Licensing**

The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) is a comprehensive multilateral agreement on intellectual property. It specifies minimum protection standards for intellectual property, enforcement procedures, remedies, and dispute resolution procedures. Under TRIPs, member governments have certain obligations on pharmaceutical patents.

The term "compulsory licensing" does not appear in the TRIPs Agreement. Instead, the phrase "other use without authorization of the right holder" is used in the title of Article 31. The term "other use" includes compulsory licensing and government use of patents without user authorization in specific situations. The TRIPs Agreement specifies guidelines where

[4]Moser, P., &Voena, A. (2012*), Compulsory Licensing: Evidence from the Trading with the Enemy Act*, THE AMERICAN ECONOMIC REVIEW, *102*(1), 396–427. http://www.jstor.org/stable/41408779

such "other use" is possible. Article 31b says that a person or company applying for a compulsory license should have attempted unsuccessfully to obtain a voluntary license from the patent holder on reasonable commercial terms. Article 31h says that adequate remuneration must still be paid to the patent holder even if a compulsory license is issued. Article 31b further states that an initial attempt for a voluntary license is not required in certain situations, namely- "national emergencies," "other circumstances of extreme urgency," "public non-commercial use," "government use," or "anti-competitive practices."[5] Other requirements for compulsory licenses include not giving exclusively to licensees; the patent holder can continue to produce; it must be granted mainly to supply the domestic market.

The Doha Ministerial Declaration of 2001 stressed that it is essential to implement and interpret the TRIPs Agreement to support public health by promoting access to existing medicines and the creation of new medicines.

Individual countries have the right to use the flexibilities that are part of the TRIPs Agreement, including compulsory licensing and parallel importing. Article 31(f) of the TRIPs Agreement says, "products made under compulsory licensing must be predominantly for the supply of the domestic market."

Drug Price Control

There is minimal international consensus on the optimal balance between protecting industry innovation and ensuring adequate access to effective treatments. However, there is general agreement that advances in medical science are of immense value to society, and that access to high-quality medicine and healthcare is vital to improving lives worldwide. This forms one of the targets in the UN Sustainable Development Goals. The WHO has acknowledged that a coherent national pricing policy that takes into account the requirements of the country's population has a significant impact on public health by improving access to healthcare. The WHO feels that "strategies for measuring, monitoring, and managing prices are essential for promoting access to medicines."

- **USA**

The US doesn't directly regulate drug prices, and the companies can fix prices as they deem fit. This results in different prices for different buyers of the same drug. Medicaid, the

[5]Schechter, F. I. (1936), *Would Compulsory Licensing of Patents Be Unconstitutional?*, VIRGINIA LAW REVIEW, *22*(3), 287–314. https://doi.org/10.2307/1066551

federal programme which subsidizes low-income individuals, received a compulsory discount, but Medicare, which provides insurance for Americans over 65 years and is the pharma industry's single biggest consumer,[6] does not receive a similar discount. The private insurance system, which covers those individuals who Medicaid or Medicare does not cover,cannot negotiate steep discounts.

- **UK**

The UK's primary drug price control mechanism is a voluntary system called PPRS (Pharmaceutical Price Regulation Scheme). The PPRS is a non-contractual agreement between the UK Department of Health and the Association of British Pharmaceutical Industry (ABPI) members and is reviewed every five years. It uses a value-based pricing mechanism and limits profits that pharma companies can make from drug sales to the NHS. The National Institute of Health and Care Excellence (NICE) evaluates the cost-effectiveness of drugs based on quality-adjusted life years (QALY), which measures the ability of a treatment to both extend and improve a patient's life. This value-based approach to drug pricing has been criticized in some quarters because it does not support innovation, and patients have to wait longer for newer treatments.[7]

Indian Perspective

- **Indian Patents Act, 1970[8]**

In India, compulsory licenses are issued under the authority of the Controller General under the Indian Patents Act, 1970. The prerequisite conditions are mentioned under Sections 84-92, and these need to be fulfilled for the grant of compulsory license.

As per Section 84, a compulsory license application may be filed by anyone after three years of expiry of the grant of a patent, providing any of the following conditions are fulfilled-

- The patented invention has not satisfied the reasonable requirements of the public.
- The price of the patented invention is not reasonably affordable for the public.
- The patented invention is not manufactured in India.

Under Section 92 of the Indian Patent Act, 1970[9], compulsory licenses can be issued suo moto by the Controller following a notification issued by the Central Government in situations

[6]Epstein, R. A., &Kieff, F. S. ,(2011), *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, THE UNIVERSITY OF CHICAGO LAW REVIEW, *78*(1), 71–93. http://www.jstor.org/stable/41552850.

[7]Fisch, A. M. (1994), *Compulsory licensing of pharmaceutical patents: An unreasonable solution to an unfortunate problem*, JURIMETRIX, *34*(3), 295–315. http://www.jstor.org/stable/29762343.

[8] INDIAN PATENTS ACT, ACT NO. 39 OF 1970.

[9] INDIAN PATENTS ACT, ACT NO. 39 OF 1970.

of "national emergency" or "extreme urgency" or in cases of "public non-commercial use." The factors considered by the Controller include-

- Nature of the invention.
- The applicant's capability to use the product for public benefit.
- The reasonability of the request.

The ultimate decision lies with the Controller.

The patent owner retains rights over the patent even after granting of compulsory license- including the right to remuneration for copies of products made under a compulsory license.

Drug Price Control

India is known for its hard-line stance on regulating drug prices and encouraging generic competition. Strict price controls and encouragement for the development of generic versions of branded drugs for the domestic market, sometimes within a products patent period, have alienated big pharma companies and international trade partners to some extent but have transformed India's generics industry into one of the world's leading producers of low-cost medicines.[10] India's stance is understandable since most of the country's population does not have health insurance, and the cost of healthcare traps many. The Indian Department of Pharmaceuticals is drafting a new pharmaceutical policy by which the National Pharmaceutical Pricing Authority (NPPA) would lose some of its discretionary power over drug prices as the government brings it under its control. The policy also recommends banning the sale of branded generics.[11]

Case Laws Regarding Compulsory License And Drug Price Control

There have been many instances of companies applying for compulsory licenses and the patent-holding company fighting against it. The following is a case law pertaining to the same and drug price control.[12]

(1) Natco Pharma Ltd. v. Bayer Corporation[13]:

Bayer was granted a patent in 2008 for SorafenivTosylate (NEXAVAR), which is a crucial

[10]Subramanian, A. (1990), *Compulsory Licensing in Patent Legislation: Superfluous and Misleading*, ECONOMIC AND POLITICAL REVIEW, *25*(34), 1880–1881. http://www.jstor.org/stable/4396673

[11]Subramanian, A. (1990), *Compulsory Licensing in Patent Legislation: Superfluous and Misleading*, ECONOMIC AND POLITICAL REVIEW, *25*(34), 1880–1881. http://www.jstor.org/stable/4396673.

[12]Janodia, M. D., Rao, J. V., & Udupa, N. (2006), *Compulsory licensing – To what extent is it practicable?*, CURRENT SCIENCE, *91*(8), 998–999, http://www.jstor.org/stable/24093968

[13]Natco Pharma Ltd. v. Bayer Corporation**,** Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), available at http://www.ipab.tn.nic.in/045-2013.htm (Last visited on May 12, 2013).

drug for kidney and liver cancer. NEXAVAR was sold at Rs. 2,84,000 per patient per month was unaffordable to most Indian patients. Consequently, the Patent Controller granted India's first-ever compulsory license to Natco to market a more affordable, generic version of SorafenivTosylate (marketed as Sorafenat), which costs Rs. 8,800 per person per year. Natco was also exporting independently of the compulsory license, the active pharmaceutical ingredient (API) of SorafenivTosylate, to China to facilitate bio-equivalence and bio-availability studies for regulatory approval by the Chinese authorities. Bayer filed a writ challenging this export because if the studies conducted with the exported material resulted in approval for the drug in China, the generic version would be ready for marketing as soon as the patent expired in China, ensuring quick access to an affordable version of the drug. In May 2014, as an interim relief, the Delhi High Court allowed Natco to export only 15 grams of the API of SorafenivTosylate. In November 2014, a single bench allowed Natco's application to export 1 kg of SorafenivTosylate. Bayer challenged this order claiming that the export by Natco was for commercial purposes. The division bench stayed further exports till the final disposal of the writ and remanded it back to a single bench which held that Natco's export of the patented product for submission of data to the Chinese regulatory authority was within the scope of Sec. 107A and did not infringe Bayer's patent. Bayer appealed against the order of the single bench. Natco argued that the patentee's rights were not infringed as Natco was not selling the API for commercial purposes but was exporting it only for data submission to the Chinese regulatory authority, an act which is covered under Sec. 107A of the Patents Act, 1970, was also independent of the grant of compulsory license. The division bench held that Sec. 107A was a special provision that dealt with the rights of the patented invention for research purposes. The court also clarified that a third party holding a compulsory license for a patented product was not barred by the terms of the license from exporting the patented product under Sec. 107A. The quantity that could be exported for research or data submission could be determined on a case-to-case basis. The exporter would need to seek a declaration from the court that the export was for research and the purposes under Sec. 107A.

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(2) Lee Pharma v. AstraZeneca[14]

In this case, a pharma company called Lee Pharma filed for compulsory licensing for producing and selling a patented drug called Saxagliptin, for which AstraZeneca had the patent. The Controller denied the request for the following reasons:

- As per Sec. 84(4) of the Patents Act, 1970, the application for a compulsory license should be filed within six months after the first request to the patent-holding company. Lee Pharma applied 13 months after the first request.
- There are sufficient similar drugs on the market, and there is no requirement for a new one.
- Lee Pharma was not able to show that the patented invention could be made available at a lower price.
- As per Sec. 84 (1)(c), one of the reasons for a compulsory license is if the drug is not previously available in India. Lee Pharma could not show that Saxagliptin was not previously available in India.

These case laws show that compulsory licensing reduces the price of life-saving drugs to an affordable level so that everyone is able to afford them and that it helps in drug price control. It also proves that it stops pharma companies from trying to commercialize the sale of drugs.[15]

[14]C.L.A No, 1of 2015 Patent Office decision dated January 19, (2016).
[15]McRae, J. J., Tapon, F., Gorecki, P. K., &Hartle, D. G, (1984), *Compulsory Licensing of Drug Patents: Three Comments,* CANADIAN PUBLIC POLICY / ANALYSEDEPOLITIQUES, *10*(1), 74–87. https://doi.org/10.2307/3551309

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CONCLUSION

The granting of a compulsory license is a process that has its fair share of pros and cons. It is the duty of the respective governments to weigh them and decide whether to grant one or not. The effect of patenting a drug and its manufacturing process and granting a compulsory license to the same is a much-debated topic with many arguments and counter-arguments but no concrete solution. Thus, further debate and research are needed to solve drugs' accessibility, availability, and affordability.