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REQUIREMENT OF COMPULSORY LICENSING IN THE PHARMACEUTICAL DOMAIN

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INTRODUCTION

Compulsory Licenses usually refer to the mandatory agreements between the sellers who are not willing to sell and purchasers who are interested in buying, and the states impose these agreements. A necessary permit is a legitimate instrument mainly for constraining the protected innovation proprietors to permit their legally allowed right to the intrigued outsiders fit for assembling the licensed item at less expensive costs. Anti-trust infringement has likewise been denounced through granting mandatory licenses in certain locales where maltreatment of Intellectual Property Rights prevailed, prompting the prohibition of rivals in the industry. A few peaceful treaties like “WIPO, Paris Convention for the insurance of mechanical property and WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) have ordered for necessary licensing.”¹ “Several contracting states have been given few factors by these treaties such as advancement of general wellbeing and sustenance, advancement of the public areas of essential significance to their financial and innovative importance.”²

Many nations have adopted compulsory licensing to prevent the severe abuse of IP rights by organizations. Compulsory Licensing request was passed newly in our country as the impact of mandatory authorizing of IP rights presently can't seem to be felt for all intents and purposes in our country. While managing necessary authorizing and its different aspects, this venture will impact to anticipate the impact on competition of our country by compulsory licensing.

¹ Article 5(a) of the Competition Act, 2002.

² Articles- 8, 31, & 40 of TRIPS Agreement.

Along with this, our research project would be concentrating on the achievability of necessary licenses request by the Competition Commission of India under the Competition Act 2002. This research paper would also focus on what adds up to be maltreatment of IP Rights with connection to Law of competition.

Literature Review

One of the most significant tasks involved in writing a well-researched paper is reviewing existing literature on the topic chosen by the author. It is essential to refer to and carefully read the previous materials to gain an idea of the topic of research. The first and foremost step to begin a research paper is to overview the previous literature. It helps the researcher get a clearer view of the research topic and provides the researcher with a better understanding of the different facets of the topic. The authors have exposed themselves to various materials available on the given research topic to complete this research paper. This paper mainly draws a nexus between compulsory licensing and competition law. The authors have referred to ***“Compulsory Licensing of Patented Inventions”*** by **“The Congressional Research Service”** (CRS) is an internet article that we have used for our research. It has been beneficial as we could understand the impact of licensing in various countries around the world. The article has been quite informative, but it has failed to mention the connection or link between competition law and compulsory licensing which, is the core element of this research work. The presentation of the article was also very vague. The second work that was referred to is ***“Intellectual Property Rights and the use of compulsory licenses options: For developing countries,”*** by **Carlos M. Correa**. It is a research article that mainly focuses on the concept of compulsory licensing and its grounds. It has mentioned various case laws by explaining every concept clearly. Nevertheless, it has concentrated on compulsory licensing on anti-trust legislation in the US and not of other countries. There is also a lack of proper analysis on unfair competition and IPR. The next literature referred for the research work is ***“The Curious Case of Compulsory Licensing in India,”*** by **Naval Chopra and Dinoo Muthappa**. The authors have broadly covered the topic of compulsory licensing concerning IPRs and competition law. The article has given a detailed description of Nacto vs. Bayer case, India’s first compulsory licensing case and has also discussed the approaches of various countries on compulsory licensing. As the article’s title suggests, it would deal with the development of compulsory licensing mainly in India, but it has failed to concentrate on the Indian scenario adequately.

Research Objective

The primary goal of the present research is to examine the impact of licenses on the competition by emphasizing the Indian legislative environment for intellectual property rights and competition law. This project also aims to assess the viability of the "Competition Act 2002's Compulsory Licensing Order". This research paper aims to look at incidents of compulsory licensing and their impact on competition in different jurisdictions. It also discusses the efficacy of compulsory licensing to check anti-competitive practices in the market and how it can be a legitimate solution to maintain healthy competition in the market.

Research Methodology

The methodology or approach adopted for the Research Project is essentially a Doctrinal Research Methodology. Books, notes, articles, online papers, journals, and various other sources and internet content are all considered relevant. Various talks were informative, edifying, and supporting, providing us with the advantage and authentic course to continue with the study we have thoroughly investigated. This research study is completely doctrinal and based on theory, focusing on case law, legal principles, and legal provisions. This research work involves primary and secondary data sources as a reference has been taken from different legislations, relevant case laws, international conventions, etc. Secondary sources such as articles, blogs, journals, etc., have been used to get a better insight into the topic. Online databases such as Manupatra, SCC, and Jstor are also used as references.

Research Questions

1. Does Compulsory license incite Competition?
2. Whether the Indian Competition Act allows the usage of compulsory licensing to prevent monopolistic practices by IP holders?
3. How does compulsory licensing affect competition in the market?

A BRIEF INSIGHT INTO THE CONCEPT OF COMPULSORY LICENSING IN INDIA

Compulsory licensing can be defined as an authorisation or license granted by the government to interested buyers for using, manufacturing, or vending a patented product or a process without the patent holder's permission. The Patent Authority issues the approval following

the provisions of the Indian Patents Act, 1970. There are several agreements concerning compulsory licensing worldwide. The emergence of compulsory licensing at a global level date back to the Paris Convention, 1967. The idea of compulsory licensing is first acknowledged in Article 5(A) of the Paris Convention, which states that “A compulsory license may not be applied for, on the ground of failure to work or insufficient working, before the expiration of the period of four years from the date of filing of the patent application or three years from the date of the grant of patent, whichever period expire last; it shall be reduced if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferrable, even in the form of the grant of a sub-license, except with the part of the enterprise or goodwill which exploits such license.”³

Even the TRIPS (Agreement on Trade-Related aspects of Intellectual Property Rights) recognise the concept of compulsory licensing and discusses different aspects related to compulsory licensing. Article 31, “Other use without the authorization of Right Holder,” talks about compulsory licensing. Specifically, article 31 (c) states, “the scope and duration of such use shall be limited to the purpose of which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.”⁴ There is a difference in perception regarding compulsory licensing among the nations that are part of TRIP. The developed countries view this provision of compulsory licensing with doubt, whereas the developing nations recognise it as a matter of significance.

In 2012, India made the first of its kind move by granting its first compulsory license to a pharmaceutical product. This move gave rise to many discussions as to the stand taken by India in the global platform. Chapter XVI of the Indian Patent Act, 1970 recognises the principle of compulsory licensing in India and lays down certain conditions that need to be satisfied for the issuance of compulsory licensing. Section 84 of the Indian Patent Act states that it is only after the termination of three years from the day of the grant of patent to the patentee the applicant can request the controller for the issuance of compulsory licensing. This Section specifies three necessary conditions when compulsory licensing can be granted, and

³ Provisions of Paris Convention for the protection of Industrial Property, 1883, http://www.wipo.int/treaties/en/text.jsp?file_id=288514.

⁴ Agreement on Trade-Related aspects of Intellectual Property Rights, <http://www.cptech.org/ip/wto/trips-art31.html>.

those are:

- i. When the patented invention has not come up to the reasonable expectation of the public, or
- ii. When the public is not able to access the patented innovation at an affordable price,
- iii. When the patented innovation is worked outside the territory of India.

Section 92 of the Patent Act of India provides certain other conditions, such as in times of national emergency or dire urgency or non-commercial use of public, where the controller can Suo moto grant the compulsory license in accordance with the notification issued by the Central Government. However, it is desirable to consider compulsory licensing as the last resource, which is to be granted only after all attempts to procure a voluntary license from the patentee have failed. Only after the expiry of the prescribed time limit (6 month has lapsed, an application can be made for compulsory licensing.

Indian laws relating to Intellectual property rights provided for the grant of compulsory license long back. Still, it was only in 2012 that the first compulsory license was granted in India in the landmark case of **Nacto Pharma Ltd vs. Bayer Corporation**⁵. The facts of the case, in brief, are that Bayer Corp was engaged in selling a drug called sorafenib tosylate which was sold under the brand name Nexavar. It was a life-enhancing drug used to treat patients in the advanced stages of kidney and liver cancer. It mainly increased the life span of patients suffering from the last stages of liver or kidney cancer. However, it was not a lifesaving drug. In 2006, Bayer had launched Nexavar and had obtained the patent right for the production of the same.

Subsequently, it was found out that the drug was accessible to only 2% of the population and was sold at an unreasonably high price of Rs 2.8 lakhs per monthly dose. An Indian pharma company named Nacto requested Bayer Corporation for a voluntary license to produce and sell the drug at a relatively low price of Rs 8800 for a monthly treatment out of which a portion of the amount will go to Bayer Corp. However, Bayer refused to accept Natco's request, following which Natco filed an application before the Indian Patents Office for the grant of

⁵ Nacto Pharma Ltd v. Bayer Corporation, 2014 SCC OnLine SC 1709.

compulsory license after three years of issuing a patent to Bayer. The Indian Patent Office granted a compulsory license to the Nacto Pharma since all the requisite conditions under section 84(1) of the Indian Patent Act for the grant of the compulsory license were fulfilled. Indian people were of the opinion that Bayer's incompetency to justify the amount involved in the development of Nexavar was the primary reason behind the grant of compulsory licensing.

The controller mainly considered the first two grounds of section 84 as only two percent of the target patients had access to the drug. However, the controller's reliance on the last ground that talks about "the patented invention is not worked in the territory of India"⁶ raised concerns as the controller interpreted the expression "worked in territory of India" to mean that the production of the patented product must be in India, or the patentee must license out the patented product to interested third parties to manufacture the same in India. This interpretation leaves behind a dangerous precedent as it would imply that compulsory license can be granted to a product that is available solely by imports and not on domestic manufacturing even though the public's reasonable expectations are being met at an affordable price. Nonetheless, the Nacto vs. Bayer case remains the most cited case in the sphere of compulsory licensing as it stands to be the first case in the world where compulsory licensing has been granted post TRIPS agreement.

The second claim for grant of compulsory license following the case of Nacto vs. Bayer was made in the case of Emcure Pharmaceuticals vs. Roche for a drug called Herceptin. Still, the application was rejected by the Department of Industrial Policy and Promotion (DIPP). In the following case of BDR Pharma vs. Bristol Myers, BDR requested the issuance of a compulsory license for Bristol Myers anti-cancer drug called Dastanib. But the application was rejected on the ground that BDA Pharma didn't have a prima facie case for the grant of license. And, recently in the case of Lee Pharma vs. AstraZeneca, the application made by Lee Pharma was not granted as it couldn't make out a prima facie case. We can see that there is an interconnection between the protection of IP Rights and the issuance of compulsory licenses and hence it is essential to strike a balance between them.

⁶ The Patents Act, 1970, Section 84(1)(c), No 39, Acts of Parliament, 1970 (India).

NEXUS BETWEEN COMPULSORY LICENSING AND COMPETITION LAW

The connection joining IP rights and the law of Competition can be best portrayed as a Story of uncomfortable partners. The application and requirement of the law of Competition for IPRs are profoundly influential and fervently discussed. The justification for the discussion mainly arises when the IPR rules, like patent laws and competition laws, look to guarantee a cutthroat commercial center. The imposing business model provided for the Intellectual Property rights bearer can make hindrances to section and lead to adverse power, the maltreatment of which is denied by Competition law. Thus, courts of law, scholastics, and professionals see an inborn clash between the two groups and have customarily tried to adjust the requirement for boosting development by encouraging insurance to make use of proficiency advantages of Open-access Competition. This view, be that as it may, is excessively oversimplified and silly. While Intellectual Property laws award restrictiveness, and during that process can hinder rivalry, both Intellectual Property laws and Competition law share the usual point of empowering advancement, improving consumers' wellbeing, and empowering productivity.

Additionally, Competition Law helps in forestalling the maltreatment of selectiveness in specific conditions. It has been proven through the banning of Exclusivity agreements where ventures in an upward relationship appreciate market power or where a predominant undertaking forces exclusivity courses of action. It is likewise shown in the fundamental judgment of *Consten and Grundig v. Commission*⁷. Here, in this case, the court recognized the presence of an Intellectual Property right and the inappropriate exercise of something similar. Appropriately, Intellectual Property rights and competition law are being seen as corresponding.

NATURE OF COMPULSORY LICENSING AND COMPETITION LAW

A divestment of IP assets could be deemed a remedy for anti-competitive activity, much as it is usually considered proper for a competition authority to compel disposal of physical assets as a condition to accepting an otherwise anti-competitive merger. Nevertheless, both in the European Union and the United States, the history of non-merger compulsory licensing by competition regulators has been uneven and in conflict with the present worldwide view of Intellectual Property laws and competition rules. Despite identical restrictions in Intellectual

⁷*Consten and Grundig v. Commission*, (1966) Case 56/64.

Property laws, competition officials in different states have given forced licenses under the competition provisions of their statutes⁸.

Licensing has been made mandatory during situations of a harmful refusal for supplying, addressing the counter cutthroat works coming about because of the selectiveness conceded by an Intellectual Property right, and where denial forestalls interest for another item. A careful investigation is performed in the middle of the need to energize advancement and the objective of advancing and cultivating competition.

The Indian Context:

If we talk about the Indian setting, we cannot confidentially say when the "CCI" will provide a permit for licensing though the Act provides power under sections 27 and 28. After investigating contracts or abuse of a position of dominance, the commission can give commands under Section 27 of the Act. The Competition Commission may consider issuing a compulsory licenses order under "Section 28" for correcting a situation in which Intellectual Property exclusivity has been used to gain undue power. The commission could also arrange for the divestment and transfer of property ownership, particularly IP rights, under section 28. While under the previous government, the Competition Act, like other governments across the world, focuses on corporations only when they are dominant and prevents misuse of their dominance. This shift in method reflects India's transforming socio, economic, and political views. That kind of method, particularly considering the Controller's decision in the case of such a methodology, particularly considering the Controller's choice in *Natco v Bayer*, leads to genuine worry that the CCI might consider the award of a necessary permit during the non-existence of any unusual conditions and that customer wellbeing or communist contemplations might slant the harmony between the security of Intellectual Property and free competition. Mandatory licensing under Intellectual Property laws is allowed upon open revenue contemplations using mandatory licenses based on public benefit concerns. On the other hand, under "Competition Law," they are frequently granted because they need to re-establish an efficient, competitive market. According to the Competition Act, a firm is accused of misusing its superior role by imposing unreasonable prices, limiting the goods'

⁸ Study concerning Mandatory Licensing Granted by World Intellectual Property Organization's member states to tackle Anti-competitive Uses of Intellectual Property Rights.

manufacturing of products and services, restricting the products' technological and scientific advancement, and refusing access to the market.

IS REFUSING TO ISSUE A LICENSE AN UNFAIR BUSINESS PRACTICE?

It is a common rule that IPR-acquired monopolies are not bad. In the case *SCM v. Xerox 24*⁹ the Circuit Court failed to hold Xerox liable for anti-trust violations based on its unwillingness to license its patents to competing manufacturers of blank paper copy machines, even though patents had previously been licensed to companies that created coated paper copiers.

Be that as it may, there are certain exemptions for this standard; in the case of *Eastman Kodak Co v. Picture Technical Services, Inc*¹⁰, the Court expressed that authority acquired through some regular and legitimate benefit like patents, copyrights, and business astuteness can lead to risk if a vender takes advantage of his prevailing situation in one market to grow his domain into the following. However, there is no known case where the Court of law has held a company liable for anti-trust violations because of a unilateral refusal to sell or license copyright or patent. Because the patent holder is acting within the context of patent laws, this cannot be considered Exclusionary conduct.

In European countries, however, the Essential Facilities Doctrine has been adopted in the context of intangible asset lawsuits by Europe's anti-trust authorities. “As per this approach, if it is necessary to promote successful competition, a dominating corporation may be forced to offer competitors access to one of its inputs.”¹¹ The India patents act permits a cross-license, although this might lead to anti-competitive patent licensing practices. As a result, using the broad power given to the Competition Commission of India under the Competition Act, an equilibrium among IPRs and competition legislation is required.

⁹*SCM v. Xerox*24, 645 F.2d 1195 (2d Cir. 1981).

¹⁰ *Eastman Kodak Co v. Picture Technical Services, Inc*, 504 U.S. 451, 480 n.29 (1992).

¹¹ T. F. Cotter (2008), Essential Facilities Doctrine, University of Minnesota Law School, Legal Studies Research Paper. p. 08-18.

COMPULSORY LICENSING: A LEGITIMATE CURE TO EXPLOITATION OF IP RIGHTS

There is a notion that competition law and Intellectual Property Rights share a harmonious relationship, and both of them seek to boost competition and invention in the market. However, some jurists don't agree to this theory and believe there is a disparity between competition law and IP rights. The safeguard and exclusiveness bestowed by IP rights are immune from the application of anti-trust laws. The protection provided by intellectual property rights grants monopoly status to the IP holders. There are many chances that the IP holders could misuse or exploit their rights to the disadvantage of the general public.

“Compulsory licensing is a fundamental tool that developing countries may use in certain circumstances to ensure that poor people have access to necessary medicines.”¹² The prime objective of compulsory licensing is to ease availability to pharmaceutical drugs as issuing of compulsory licenses to interested third parties in the market for whatever reason provides greater access to life-saving drugs. “The grant of compulsory licenses by developing countries is founded on the premise that higher levels of patent protection would lead to deterioration of public health on account of lack of access to essential drugs.”¹³

Let us say, for example, the patentee of a life-saving medicine may misuse his monopoly rights by selling the drug at an unreasonably high price or by refusing to sell his drug commercially. In such a situation, it becomes vital for the State to grant compulsory licenses of the drug to other players in the market to safeguard public health. As we know, the consent of the patent holder is immaterial in a case where the State grants the compulsory license for the production, use and sale of such drug. Nonetheless, the issuance of the compulsory license by the State is an exception and not a rule and must be the last resort of the government on the grounds of emergency, as discussed earlier.

Many companies acquire a lot of other companies just to obtain Intellectual Property Rights. This acquirement of IP rights is not wrong per se as long as it doesn't violate anti-trust

¹² Alberto do Amaral Junior, Compulsory Licensing and Access to Medicine in Developing Countries, SELA 2005 Law and Poverty. -Panel 5: Poverty and the International Order, Rio de Janeiro, Brazil--16-19 June 2005 (2005), available at http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf (last visited Jun 2, 2014).

¹³ Anthony P Valach Jr, TRIPS: Protecting the rights of patent holders and addressing public health issues in developing countries, 4 J. Intell. Prop. 156 (2004).

provisions. IPRs are spared from the implementation of Section 3 of the Indian Competition Act. However, the abuse of dominant position provided under Section 4 of the Competition Act, 2002 can always be alleged against any group or enterprise involved in anti-competitive practices. This particular Section has a broad application and scope as it encompasses a lot of anti-competitive practices. This Section can charge any IP holder engaged in imposing excessive prices and discriminatory conditions. For example, in the case of Nacto vs. Bayer, the compulsory license granted to Nacto for sale, production and use of Nexavar could also have been brought under the scope of competition act since Bayer was involved in restricting the manufacture of the life-enhancing medication as it was only reachable to 2% of the potential patients and the high price charged by it was violating Section 4 (2) a (ii) of the Competition Act, 2002.

Compulsory licensing is an essential tool to make sure that a sufficient number of manufacturers and producers are present in the market to satisfy the wants of public, promote competition, and ensure consumer protection. People who believe that it hampers the impetus for innovation fail to acknowledge the fact that “with every right there comes a corresponding duty.” Moreover, when there is a failure in the performance of that duty, it might lead to erosion in law. Competition Act of 2002 comprises provisions that are adequately broad to tackle exploitation of IP rights, and compulsory licensing is the right cure to control this, though only in certain extraordinary cases.

Compulsory licensing is preferred as a means by international covenants for advancement in progressing and under-developed countries. “Doha Declaration on Agreement on Trade-Related aspects of Intellectual Property Rights and Public Health states that we recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”¹⁴ Hence, we can conclude that compulsory licensing is an effective remedy for checking abuse of Intellectual property rights and restrictive tactics undertaken by the companies to affect competition.

¹⁴ “http://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#public_health, Accessed on 27 November 2012.”

IMPACT OF COMPULSORY LICENSING ON COMPETITION LAW

Dominance is acceptable as long as it doesn't result in abuse. An effective competition mechanism can provide a remedy that would help check anti-competitive agreements and boost the economy and consumer protection. "Hence, competition law steps in to prevent such a monopoly situation from getting deep-rooted in the market, and the concept of compulsory licensing is conceived from here in certain specialized cases."¹⁵ The main aim of having an efficacious competition regime is to prevent abuse of dominant position held by the monopoly holder and using it unfairly to the deterioration of the public.

"Compulsory licensing promotes healthy competition as it requires the license seeker to pay a certain fee to the patent holder."¹⁶ The fee paid to the patentee acts as an additional income, and it also helps in retrieving the costs gone into the manufacturing of the product. Moreover, it enhances the cost of production as it is an additional cost for the license seeker willing to supply the same product in the market. Hence, it helps to maintain an equitable balance in the market, thereby protecting the interests of all the shareholders.

There is a doctrine named 'Essential Doctrine' developed by the European courts, which aids in deciding in which circumstances compulsory license should be granted and helps create a requisite equilibrium between IPR protection and safeguarding competition. The Indian Competition Act of 2002 provides broad powers to the Competition Commission of India to charge fines on companies engaged in anti-competitive practices as given in the Act. Section 27 (g) and 28 (2) of the Act extensively cover the power of CCI to grant compulsory licensing within its ambit.

On the other hand, there are arguments that compulsory licensing poses a threat to competition especially in nations where innovation has been stagnant. In advancing and under-progressing nations, compulsory licensing can be granted in specific market sectors to enhance competition where a monopoly holder abuses its dominant position. However, it might result in hampering innovation in the future and is anti-competitive. There are reasonable chances for Foreign direct investment to see a downfall if compulsory licensing becomes a regular

¹⁵ Pantopoulou E. The Status and Legal Effect of Compulsory License in Investment Law, International Journal Of Law (Jol), 2019.

¹⁶ Available from: https://www.ucl.ac.uk/cles/sites/cles/files/cles_4_2013new.pdf.

course of action for controlling the abuse of IP rights and monopolistic practices. Thus, as discussed earlier in this research project, compulsory licensing must only be used as a last resort in exceptional circumstances.

CONCLUSION

This might be reasonably concluded from the preceding explanation that if a firm's rights are protected under IP laws, misuse of Intellectual Property rights PR is a very real possibility. Though the monopolies secured by IPRs are legal, the truth remains that it is extremely vulnerable to exploitation. Organizations are frequently inclined to engage in anti-competitive and "exclusionary activities", attempting to extend their monopoly into sectors where they lack IPR protection. IPR protection is in place for software titans like Microsoft, seed producers like Mahyco Monsanto Biotech, and pharmaceutical producers, and most of the time, these businesses are sole proprietorships. Such monopolies propel these businesses to impose their conditions throughout the whole sector that might be exploitative at times of the laws of free competition.

Compulsory licensing can be considered as a viable solution during these kind of situations with a significant amount of public interest and anti-competitive activities. Legally speaking, businesses frequently harmed interests of customers and competitors. Public health, public order, and national security are important questions to be answered but many countries viewed it as a countermeasure to anti-competitive activities. To some extent, the idea that Compulsory licensing promotes competition is correct, particularly in nations wherein invention or development is lacking. These emerging and under-developed nations may do this for increasing competition in particular markets in which a single company is abusing its dominating position, but in the long run, this could for innovation and hence become anti-competitive. As a result, like stated before, compulsory licensing should only be used in rare circumstances.
