COMPETITION LAW AND COMPULSORY LICENSING: INTERRELATION AND WAY FORWARD

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ABSTRACT

The research paper attempts to explore the fundamental question: "whether the state under Section 92 of the Patents Act, in view of extreme urgency and national emergency, issue compulsory license for maintaining timely access to affordable emergency medicines and whether the Competition Law intervene in the strategic patenting by the pharmaceutical companies in view of public welfare?" Human nature constantly evolves and so does society. Coupled with the advancement in technology, science, social structure and politics various stigmas that are attached to society put forth certain questions before the legislation.

The paper attempts to elucidate the conundrum of compulsory license and its constitutionality while analysing the evolving jurisprudence of competition law on essential drugs. There has been extensive research on patent rights however the domain of public welfare in competition law has not been explored much.

The research paper also explores the international perspective on compulsory licensing and competition law, scrutinizing bills and legislations, various arguments and contentions made by the jurists and researcher's acute analysis. Further to support the research, the paper will include a comparative study between India and USA's subsequent socio-economic effects.

The methodology of research is doctrinal and sources are secondary in nature. The basic structure of information is publicly available on various legal databases, books, journals, articles, etc. For legal sanctions, help of legislations, case laws and reports are given due consideration.

Keywords: Compulsory License, Essential Drugs, Competition Law.

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I. INTRODUCTION

In the state of law, right to life, and in consequence right to health,[1] receives upmost attention as one of the basic human rights. The unprecedented COVID-19 pandemic has led to an ab-lib shift in society and the economy wherein the conundrum of market supply of vaccine has led to the re-surfacing of fears related to the past-experience of lack of access to vaccines and medicines for life-threatening diseases which may be hindered by patents. Over the last few months, the market has seen an unprecedented increase in prices of essential drugs for the virus. One of the key reasons for the increase in prices is the elasticity of demand of essential drugs in comparison to lack of supply which may be due to strategic patenting by pharmaceutical companies. While the practice of patenting and innovation secures and protects the rights of the innovators and encourages companies to develop more drugs for the benefit of the public, in situations like that of the pandemic, these patent licenses lead to the larger neglect of the general public. The article outlines the current approach of patenting by companies and provides ways by which there can be a balance between the patent holder and public interest.

Intellectual property rights aim to offer a period of exclusive rights to exploit the property in question[2] whereas competition law seeks to maintain effective access to the market.[3] Further, competition law aims at promoting consumer welfare[4] and to maintain healthy competition in the market. The right to exclude which protects the rights of patent holders is considered an essential part of the pharmaceutical development and investment.[5] Moreover, the loss of competition that the patent creates for other companies is considered justifiable for pharmaceutical companies as they need to accumulate price which is above the marginal cost to recoup significant development expenses of the drug which also lead to their incentive to develop more drugs.[6] However, these exclusive rights to patent holders create an unprecedented increase in the prices of essential drugs in rich and poor countries,[7] despite a

[1]Irina Haracoglou, *Competition Law and Patents* (Edward Elgar Publishing Limited 2008).

[2] William Cornish and David Llewelyn, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (5th edn. Sweet & Maxwell 2003).

[3] Richard Whish and David Bailey, *Competition Law* (2,2005).

[4] Rita Yi man Li and Yi Lut Li, 'The Role of Competition Law: An Asian Perspective' (2013) 9(7) Asian Social and Science 47.

[5] Chandra Mohan and Others, 'Patents - An Important Tool for Pharmaceutical Industry' (2014) 2 Journal of Pharmaceutics and Nanotechnology 12.

[6] Joseph A. DiMasi and Others, 'Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs' (2016) 47 Journal of Health Economics 20.

[7] Joanna M. Shepherd, 'Biologic Drugs, Biosimilars, and Barriers to Entry' (2015) 25 Health Matrix: Journal of Law-Medicine 139.

global call for access to affordable drugs.[8] In order to create a balance between the public and private profit dichotomy, the governments use tools like compulsory licensing in order to mitigate a concord between intellectual property rights and competition law. The term 'compulsory licensing' refers to the process of granting permission to an enterprise which attempts to use another's intellectual property without the consent of the proprietor,[9] and the same is sanctioned by the government entity. It often relates to the pharmaceutical and other inventions pertaining to public health but can be potentially applied to any patented invention.[10]

The paper attempts to explore the fundamental question: "*whether competition law intervene in the strategic patenting by the pharmaceutical companies in view of public welfare?*" There exists a delicate link between intellectual property rights and competition law wherein too high or too low implementation of either of the two laws may lead to trade distortion and hence, a balance has to be found between the two and such a balance must also ensure fulfilment of rationale and aim of the two laws.[11] Hence, the paper seeks to explore compulsory licensing as a means to create a balance between the two laws with the goal of securing public interest at the forefront.

II. COMPULSORY LICENSING UNDER PATENTS ACT

Through the introduction of compulsory licensing, a state allows third party to practice or use a patented invention without the patent holder's permission wherein the third party pays royalty to the patent holder which serves as a compensation to the patent holder.[12] Under the Indian Patents Act, Chapter XIV deals with compulsory licensing wherein the procedure of granting compulsory licensing comes under Section 84[13] and 92[14]. However, some attributes of Patents Act lack attributes of property wherein the patented subject lacks clear scope and

[8] 'Goal 3: Ensure healthy lives and promote well-being for all at all ages', (United Nations) <https://www.un.org/sustainabledevelopment/health/> accessed 15 July 2021.

[9] Jarrod Tudor, 'Compulsory Licensing in the European Union' (2013) 4(2) George Mason Journal of Comparative Law 222.

[10] John R. Thomas, 'Compulsory Licensing of Patented Inventions' (2014) Congressional Research Service 1.

[11] Mansee Teotia and Manish Sanwal, 'Interface between competition law and patents law: A pandora box' (2020) 1(01) E- Journal of Academic Innovation and Research in Intellectual Property Assets.

[12] Cynthia M. Ho., '*Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights'* (2011) Oxford University Press 127.

[13] Section 84, Indian Patent Act, 1970.

[14] Section 92, Indian Patent Act, 1970.

limits, it only provides basic notices and includes right to exclude and not the right to use.[15] Thus, the state chooses to employ liability rule, wherein the patent holder is entitled to get compensation, and not the property rule wherein the patent holder can preclude use of the invention.[16] This is done via compulsory licensing.

A. Rationale behind compulsory licensing in India

The inherent tussle between welfare-oriented government, which seeks to ensure cheap and equal access to essential drugs, and the profit driven companies has often occupied the global centre stage.[17] Compulsory licensing, in various foreign jurisdictions, has been issued in cases dealing with abusive refusal to supply in order to correct the anti-competitive practices which are a consequence of exclusive patent rights. Under Section 84 of the Patents Act, any person, regardless of whether he is the holder of the licensing of that Patent, can make a request to the Controller for grant of compulsory licensing on expiry of three years, when any of the following conditions is fulfilled –

1. The reasonable requirements of the public with respect to the patented invention have not been satisfied
2. The patented invention is not available to the public at a reasonably affordable price
3. The patented invention is not worked in the territory of India.[18]

Under Section 92 of the Act,[19] compulsory licensing can also be issued, *sou moto*, by the controller in case of either 'national emergency' or 'extreme urgency' or in case of 'public non-commercial use'.[20]

B. Natco Pharma Limited v. Bayer Corporation

The relation between competition law and intellectual property rights is described as the 'tale of uneasy bedfellows' wherein the debate between patent laws which grant exclusive rights to the patent holders and competition law, which aims at ensuring competition market, is

[15] Margo A Bagley, 'Morality of Compulsory Licensing as an Access to Medicines Tool' (2018) 102(6) Minnesota Law Review 2463.
[16] Guido Calabresi and A. Douglas Melamad, 'Property Ules, Liability Rules and Inalienability: One view of the Cathedral' (1972) 85(6) Harvard Law Review 1089.
[17] Reuters, 'Analysis: India Cancer Ruling Opens Doors for Cheaper Drugs' (*Reuters*, March 2012) <https://www.reuters.com/article/us-india-drugs-idUSBRE82C0IN20120313> accessed 17 July, 2021.
[18] Section 84 (n 13).
[19] Section 92 (n 14).
[20] Nayanikaa Shukla, 'India: Compulsory License in India' (*Mondaq*, January 2019) <https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india> accessed 17 July, 2021.

highlighted. In view of this background, compulsory licensing was enforced in the case of *Natco v. Bayer*[21] for the first time in India. The issue in this case was that the drug sold by Bayer for patients suffering from advanced stages of kidney and liver cancer was highly priced and Natco, an Indian Pharmaceutical Company, applied for voluntary licensing in order to manufacture and sell the drugs at a much more affordable price. However, this request was not granted and the Natco company appealed for the grant of compulsory licensing. It was found that due to the lack of ability of Bayer to provide the drugs to only 2 percent of the population in India, it was substantiated that Bayer failed to contribute to transfer of technology which resulted in counterbalance of the exclusive patent right and public interest. Hence, compulsory licensing was granted to the Natco Company wherein certain amount of compensation was decided to be paid to Bayer Company.

III. COMPETITION LAW AND PATENT ACT

A. Rationale behind competition law

The competition law is premised upon the principle of economics that desires a free market and the underlying intent of the law is to ensure that the businesses conducted in India are based on merit and not on the anti-competitive agreements or conduct. [22] In the case of Competition *Commission of India v. Steel Authority of India & Anr*,[23] the apex court held that the primary purpose of the Competition Act is to find remedy to situations which may lead to the breakdown of free market system and promote economic efficiency. Further, in *Re: Distribution of Essential Supplies and Services during Pandemic*,[24] the Supreme Court recognized the insufficient availability and supply of vaccines and elucidated the legal framework of issuing compulsory licensing to meet the demand of the vaccines. In this backdrop, it becomes essential to analyse the Competition Act in order to maintain competition and to ensure access to essential drugs in the market to curb the use of anti-competition practices.

[21] *Natco Pharma Limited v Bayer Corporation* Compulsory License Application No. 1/2011.

[22] 'Competition Laws in India: An overview' (*Kochhar & Co.*) <http://www.kochhar.com/pdf/Rationale%20For%20Competition%20Laws.pdf> accessed 18 July 2021.

[23] *Commission of India v Steel Authority of India & Anr* [2010] INSC 720.

[24] *In Re: Distribution of Essential Supplies and Services During Pandemic* SMW(C) No.- 000003/2021.

B. Patented drugs and public interest

The use of word 'public' has been made more than forty times in the Patents Act, 1970,[25] wherein it confers power to the government to nullify the recognition granted to the patentee for the invention in communitarian interest.[26] The legislative exception is based on the fact that the exclusive right must be an instrument which protects and promotes the socio-economic interest of the nation, availability of patented products on affordable prices to the public, and mandates that the government can take all necessary measures to protect public health.[27] If the reasonable requirements of the public are not satisfied or if the product is not available to reasonable satisfaction or is available at a much higher price than the controller, after the lapse of three of license grant, can issue compulsory licensing on the ground of public health.[28] Compulsory licensing can be granted to the third party, against the will of the patentee, in the case of a national emergency or extreme urgency such as a pandemic. Further, the controller needs to balance the legitimate expectation to earn a reasonable return on the investment by the patent holder and the capacity to pay for the patented product by the public.[29] The monopoly granted to patent holders through the patent laws can lead to a rise of their market power which is prohibited under the competition law.

As stated above, the social bargain is an inherent part of the patent system. The World Health Organisation report reveals that the average availability of essential medicines across the world is only 51.8 percent in public sector health facilities.[30] This involves developing countries advocating towards allowing government autonomy in endowment of compulsory licensing for public health.[31] It is said that in the law of patents, it is not sufficient merely to have registration of a patent. The Court must look at the whole case, the strength of the case of the patentee and the strength of the defence.[32]

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[25] Indian Patent Act, 1970.

[26] Dr. Uday Shankar, 'Prioritising public interest in patent law of India' (*SCC Online Blog*, June 2021) <https://www.scconline.com/blog/post/2021/06/14/patent-law/#_ftn2> accessed 19 July 2021.

[27] Section 83(d), Indian Patent Act, 1970; Section 83(e), Indian Patent Act, 1970; Section 83(g), Indian Patent Act, 1970.

[28] Section 84(1), Indian Patent Act, 1970.

[29] Section 92 (n 14).

[30] 20 MDG Gap Task Force Report, 'The Global Partnership for Development: Making Rhetoric a Reality', (*WHO*, 2012) <http://www.who.int/medicines/mdg/mdg8report2012_en.pdf> accessed July 18, 2021.

[31] Jayashree Watal, 'Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?' (2000) Center for International Development, Harvard University, Science, Technology and Innovation Discussion Paper No. 8 <https://bit.ly/3nvdkOL> accessed July 23, 2021.

[32] *Franz Xaver Huemer v New Yash Engineers* 1996 SCC OnLine Del 243.

C. Competition law under Section 4

Section 4 of the Competition Act, 2002 lays down that abuse of dominant position is prohibited and the conditions and scope of the dominant nature of the enterprises is provided.[33] Dominant position is described as a position which is enjoyed by the enterprise which enables it to:

1. Operate independently of competitive forces prevailing in the relevant market; or
2. Affect its competitors or consumers or the relevant market in its favour.[34]

The rationale of Section 4 of the Competition Act, 2002 is derived from the application of the consumer oriented approach in India wherein, under Section 4, the judicial approach to the granting of compulsory license is dependent on the provision for public welfare.

However, Under Section 3(5) of the Competition Act, such restrictions imposed on the patent holders can lead to violation of their rights and hence, in order to preserve the harmony between the two sections, it becomes essential to analyse the interpretation of 'public interest' in the Act.

i. Consumer Oriented Approach in India

Competition stimulates innovation and productivity which leads to optimum allocation of resources in the economy; guarantees the protection of consumer interests; reduces costs and improves quality; accelerates growth and development and preserves economic and political democracy.[35] However, without a sufficient framework, there might be an increase in adverse distortionary practices and anti-competitive activities which in turn would distort healthy competition in the market. The United Nations Guidelines for Consumer Protection is an international framework which advocates consumer protection policy, and that legislations must be aimed at consumer protection i.e., physical safety, economic interest, standards, essential goods and services, redress, education, health and sustainable consumption.[36]

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[33] Section 19, The Competition Act 2002.

[34] S.S. Rana and Co. Advocates, 'India: Abuse of Dominant Position An Anti-Competitive Practice' (*Mondaq*, January 2018) <https://www.mondaq.com/india/antitrust-eu-competition-/668306/abuse-of-dominant-position-an-anti8208competitive-practice> accessed June 18 2021.

[35] Raj Kumar S. Adukia, 'An Overview of Provisions Relating to Competition Laws & Consumers Protection Laws in India' (CAAA), <http://www.caaa.in/Image/competition%20laws.pdf> accessed June 18 2021.

[36] 'United Nations Guidelines for Consumer Protection, (United Nations Conference on Trade and Development), < https://unctad.org/system/files/official-document/ditccplpmisc2016d1_en.pdf> accessed November 11, 2021.

ii. The nexus between Section 4 and Public Interest

As discussed above, Section 4 of the Competition Act deals with the prohibition of dominant position of a company in the market which distorts the market balance. The nexus of this section with public interest comes while analysing the effect of dominance in the market. The dominant position in the market leads to limited goods and services due to which there is an increase in the prices. This, and a restriction in development leads to the violation of public interest. The weight of public interest in forming links between the investment in research and development and the patent development is critical in India where the whole population is dependent on the essential drugs for survival.

In the recent cases before the Supreme Court, it has been ruled that the provisions against anti-competitive practices in the Competition Act and the compulsory licensing provision in the Patents Acts are not in exclusion of each other but have to be read conjunctly.[37] The dilemma if a patentee had adopted anti-competitive practices could also be taken into consideration by the controller. However, if the Competition Commission of India["CCI"] finds a patentee's conduct to be anti-competitive and it comes to such conclusion, then the controller could also proceed on the said basis and on the principle akin to issue estoppel, the patentee would be estopped from contending to the contrary.[38] Hence, the judicial approach to the granting of compulsory license is dependent on the provision for public welfare, however, it cannot be used arbitrarily to diminish the rights of the patent holders and should be made on the ground of 'reasonableness'. There must be a balance between the rights of the patentee and using the product for public welfare. The Supreme Court, in the case of *Samir Agarwal v. Competition Commission of India & Ors,*[39] held that 'public interest' is a valid ground for approaching the CCI and the appellate authority NCLAT to subserve the high public purpose of the Competition Act, 2002.

The CCI, in the case of *La Hoffman Roche Biocon Case*, issued an order for an investigation against the pharma giant Roche for unfair business practices in the cancer drug market under Section 4(2)I of the Competition Act, 2002.[40] Hence, if there is violation of the principle of dominance by the company in respect to the patent rights, as in the *Biocon Case*, then the CCI can issue orders for investigation of the same under Section 4(2)I of the Competition Act. A refusal to grant license of IP exclusively held by the dominant enterprise can be

[37]Nayanikaa Shukla (n 20).

[38] *Koninklijke Philips Electronics N.V. v Rajesh Bansal* 2018 SCC OnLine Del 9793.

[39] *Samir Agrawal v Competition Commission of India* SCC Online SC 1024 (SC).

[40] *Biocon Ltd. & Ors v F. Hoffman La Roche Ag & Ors* CCI Case No. 68 of 2016..

considered as a constructive refusal to supply under the Competition Act as it may be construed to limit the 'production of goods or provision of services or market'[41] or restrict the 'technical or scientific development relating to goods or services to the prejudice of consumers',[42] or result in the 'denial of market access',[43] all three of which amount to abusive conduct under the Competition Act.[44]

iii. Decoding Section 3(5) of the Competition Act

Section 3(5) of the Competition Act provides that nothing contained in Section 3 (prohibition of anti-competitive agreements) shall limit any person's right to prevent infringement or to enforce fair conditions, such as copyright, trade marks, trademarks, designs and geographical indications, that may be appropriate for the defence of his/her intellectual property rights.[45]However, some unreasonable conditions imposed by the patent rights can lead to violation of the right to free flow in market like in the case of patent pooling, tie-in agreement, etc. For instance, CCI in the case of *Shamsher Kataria v. Honda Siel Cards India LTD*,[46] rendered the clarification that though registration of an IPR does not automatically entitle a company to seek exemption under Section 3(5)(i) of the Act and the essential criteria for determining whether the exemption under Section 3(5)(i) is available or not is to assess whether the condition imposed by the IPR holder can be termed as *"imposition of a reasonable conditions, as may be necessary for the protection of any of his rights"*.[47]CCI also manifests it by extending the provision intending that, the reasonable conditions however be imposed whenever imposing such reasonable condition would be indispensable to protect the right of the IPR holder, otherwise they cannot even impose any condition without being reasonable.[48]Further, the Apex Court has also recognised the need to restrict the anti-competitive behaviour of patent holders.[49]

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[41] Section 4(2)(b)(i), The Competition Act 2002.

[42] Section 4(2)(b)(ii), The Competition Act 2002.

[43] Section 4(2)(e), The Competition Act, 2002.

[44] Naval Satarawala Chopra and Dinoo Muthappa, 'The Curious Case of Compulsory Licensing in India' (2012) 8(2) Competition Law International.

[45]'Anti-Competition Agreements under Competition Act 2002' (Helpline Law) <https://www.helplinelaw.com/business-law/ACAU/anti-competitive-agreements-under-competition-act-2002.html> accessed July 19 2021.

[46] *Shamsher Kataria v Honda Siel Cards India Ltd.* Case No. 03 of 2011.

[47] 'Anti-Competitive Agreements and IPR Exemption under Section 3(5) of the Act', (Rama University) <https://www.ramauniversity.ac.in/online-study-material/law/ballb/ixsemester/competitionlaw/lecture-18.pdf> accessed July 19 2021.

[48] *K. Sera Sera Digital Cinema Ltd v Pen India Ltd* 2017 SCC Online CCI 31.

[49] *Entertainment Network (India) Ltd v Super Cassette Industries Ltd.* 2008 SCC OnLine SC 951.

IV. COMPETITION LAW AND PHARMACEUTICAL SECTION

The Indian pharmaceutical industry is one of the largest industries in the world in terms of value and volume and has grown significantly over the decades. Therefore, no wonder, over a period of time this sector has seen several regulatory interventions that have altered the dynamics of this industry quite substantially. Even when compared to the other pharmaceutical regimes in the world, change in patenting regime (product patenting to process patenting to product patenting), unique nature of competition (for example, branded generics), etc. have made the Indian pharmaceutical market unique.[50] The original patents are awarded with the product patent which protects and confers that they will enjoy monopoly profits on the product but once such drug is available in the market the product cost becomes low. The tension between these two leads to the dilemma of finding a balance between need for access of cheap medicines and incentivizing innovation.

The evolution of Indian pharmaceutical industry is divided into three major phases. The first phase come immediately post-independence when the global multinational manufacturers were dominating the Indian pharma industry. Entry in Indian markets, at this stage, was easy for a global manufacturer who came up with new medicines but at high cost. Concerned about such state of affairs, the Government of India (GOI) formed a one-man committee of Justice N. Rajagopala Ayyangar in 1957 to revise the laws of patents and design. In 1970, GOI adopted the recommendations of the Ayyangar Committee and formulated the Patents Act (1970), which allowed only process patent protection for pharmaceutical products for a period of seven years from the date of patent filing.[51] The second stage began with India being the signatory of World Health Organisation in 1995 and it stated to look for a different competition strategy. The third phase saw the change and acceptance of diversity wherein the Indian companies that exist today are a combination of many different types of enterprises that specializes in different aspects of the pharmaceutical industry.

In essence, the Section 3(d) of the Patents Act states that the new form of the existing drug cannot be patented unless it demonstrates increased efficacy. If it does demonstrate increased

[50]Shamin S. Mondal and Viswanth Pingali, 'Competition Law and the Pharmaceutical Sector in India' (*Indian Institute of Management Ahmedabad Working Paper* November 2015) <http://vslir.iima.ac.in:8080/jspui/bitstream/11718/17052/1/Pingali2015.pdf> accessed on July 19 2021.
[51] ibid.

efficacy, then it is treated as an altogether *"new substance"*. The *"mere new use"* of a known compound cannot be patented.[52]

V. ANALYSING CONTENTIONS FOR AND AGAINST THE CONUNDRUM

A coin has two sides and the dilemma of compulsory licensing as a way to control and promote competition in the market has two contending parties which go for and against it.

A. Arguments against the implementation

The aim of patent licensing is to protect and encourage incentives to the innovators and hence, the right to exclude which is granted by the patent is widely considered essential for development and investment in the pharmaceutical sector. It is believed that the issuing of compulsory licensing is morally wrong as it is done without the consent of the patent holders and leads to harm in the incentive of the innovator to innovate.[53] For some observers, granting of compulsory licensing is derogatory to the right of exclusion awarded to the patent holder. Further, the pharmaceutical giants demand increased patent protection under stricter intellectual property rights citing to be the 'bedrock of their business'.[54] They contend that the high cost of research and development, due to which it is inevitable that the prices of drugs will increase, makes it essential for companies to be protected in order to get the monetary benefit of their invention. As a result, it is contended that having a short-term compulsory licence would stifle the innovation in the long-term.[55]

B. Arguments for the implementation

The supporters of implementation of compulsory licensing believe that the right to exclude granted by the patent law does not mean right to use wherein the pharmaceutical companies can use the patent to create a dominant position in the market while violating public interest in the situations of grave urgency. Observers believe that compulsory licensing may serve

[52] Dr. Shuchi Midha and Aditi Midha, 'Concept of Substantial Similarity In Pharmaceutical Patent Infringement Cases and the Implications of Section 3d of Indian Patent Act' (2014) 2(06) Asian Journal of Pharmaceutical Technology and Innovation 12.

[53] Jon Matthews, 'Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards are the most dangerous to the United Stated Healthcare Industry' (2010) 4(1) Journal of Business, Entrepreneurship and the Law 119.

[54] David W. Opderbeck, 'Patents, Essential Medicines, and the Innovation game' (2005) 58(2) Vanderbilt Law Review 501.

[55] Sara M. Ford, 'Compulsory licencing provisions under TRIPS Agreement: Balancing pills and patents' (2000) 15(4) American University International Law Review 941.

important national interests such as public health and technology transfer.[56] The contention that the monetary incentive of the innovators will be lost does not hold much ground as it is argued that the biggest driving force for innovation is the market[57] and thus, the point of focus for the drugs companies is on development of more saleable drugs rather than the most needed ones.[58] In fact, studies have shown that except for a few exceptional circumstances, there is no link between compulsory licensing and sluggish innovation rates or a decline in research and development.[59] Further, in recent times, there have been cases where the innovators have even used voluntary licensing in order to provide otherwise expensive lifesaving drugs at a cheaper price.[60] Evidence shows that the level of pharmaceutical patent protection, especially in developing countries, is irrelevant in spurring innovation,[61] which means that the suitability of compulsory licensing is not affected by this concern. Hence, it is believed that the supporters of compulsory licensing as a means to promote competition believe that in long run, the pharmaceutical companies will be better off by accounting for such requirements rather than trying to preserve their patent rights and incurring huge litigation loses.

VI. COMPARATIVE ANALYSIS BETWEEN USA AND INDIA IN COMPULSORY LICENSING AND COMPETITION LAW

The pandemic opened the pandora's box in which the global regime failed to cater to the needs of people and protect their right to health. There were three main issues that arose pertaining to the anti-competitive practices, which are: Firstly, the vaccine drives led to the largest vaccine stocking race and data sharing proposal fails which led to a lack of international cooperation. Secondly, the developed countries further refused to support South

[56] Chris Strobel, 'Wind Power and Patent Law: How the Enforcement of Wind Technology Patents May Lead to Restricted Implementation in the US, and Necessary Solutions' (2013) 19(2) Journal of Environmental and Sustainability Law.

[57] Patrice Trouiller and others, 'Drug development for neglected diseases: a deficient market and a public-health policy failure' (2002) 359(9324) The Lancet 53.

[58] The Wall Street Journal, 'Should Patents on Pharmaceuticals Be Extended to Encourage Innovation' (*The Wall Street Journal*, January 2012) <http://online.wsj.com/article/SB10001424052970204542404577156993191655000.html> accessed July 19 2021.

[59] Colleen Chien, 'Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?' (2003) 18(3) Berkley Technology Law Journal 853.

[60] Reuters, 'Analysis: India Cancer Ruling Opens Doors for Cheaper Drugs' (n 17).

[61] *Biocon Ltd. Case* (n 40).

Africa and India in their proposal to suspend IPRs for COVID-19 vaccines[62]. Thirdly, the concept of competition has failed in the global regime as there is a lack of system of surveillance of gair competitive rules on global pharma markets.[63]

The courts in United States of America ["USA"] and European Union ["EU"] have held that refusal to license a patent violates competition law but even though these countries are highly advanced in competition law and patents law jurisprudence they lack a clear framework to determine whether such refusal is anticompetitive when it involves IPRs. However, Brazil, under Article 21 of Antitrust Law, enlists that *"non-exploitation or the inadequate use of intellectual property rights and technology of a company"* as a strong indication that the free competition rules have been violated.[64]

Even though the non-fraudulent acquisition of the right of patent through government is not violative of the anti-trust law, antitrust jurisprudence does hold that when a party aggressively engages in accumulation, non-use, and enforcement of IPRs over the essential inputs in a particular market for the purpose of destroying competition in that market, it may be subject to antitrust liability.[65] Further, as regards to the anti-competitive practices, the Competition Act of Canada, for example, gives the Federal Court power to expunge trademarks, to license patents (including setting all terms and conditions), to void existing licenses and generally to abridge or nullify normal patent or trademark rights where the trademarks or patents have been used to injure trade or commerce unduly or to prevent or lessen competition unduly.[66]

There has been friction between the relationship between competition and IPR in USA wherein the early US cases separate the two domains and concluded that patents were beyond the reach of antitrust law.[67] However, this led to the companies to circumvent antitrust laws via licensing which led to the US courts to progressively restrict that the scope of patent immunity doctrine and held that the antitrust law is free to operate when the patent holders

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[62] Ann Danaiya Usher, *South Africa and India push for COVID-19 patents ban,* (Lancet) <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext>, accessed November 10, 2021.

[63] UNCTAD, 'Eleventh Meeting of the UNCTAD Research Partnership Platform' (2019) <https://unctad.org/system/files/non-official-document/ccpb_RPP_2020_01_Present_Alexey%20Ivanov.pdf> accessed 20 July 2021.

[64] Article 21, Brazilian Antitrust Law 1994.

[65] 'Compulsory Licensing and the Anti-Competitive Effects of Patents for Pharmaceutical Products: From a Developing Countries' Perspective (CUTS) <http://www.cuts-citee.org/pdf/Compulsory_Licenses_and_anti-competitive_effects_of_patents.pdf> accessed 20 July 2021.

[66] Section 32, Canadian Competition Act 1985.

[67] *E. Bennett & Sons v National Harrow Co*. 186 US 70 (1902).

reach beyond the boundaries inherent in the patent grant.[68] Further, in 1988, the US Department of Justice's Antitrust Division formally shifted from absolute opposition to certain licensing practices to a *"rule of reason"* approach that balanced pro- and anticompetitive effects of licensing.[69] The Supreme Court of US has recognised compulsory licensing as a remedy for antitrust cases and violation of market competition.[70] Further, the enforcement of antitrust laws in the US by government entities or private parties on compulsory licensing can be done, when it is found that the enterprise is acting in anti-competitive manner in connection to the patents,[71] under the circumstances of public health, inadequacy of supply of patented invention and other public interest rationales.[72]

The general rule under the Antitrust Law of US is that there is no general duty which deals with competitors[73] but the liability under the Section 2 of the Sherman Act, which governs the abuse of dominance, will accrue when the refusal by a holder of patent results in violation of dominant position in market. Further, in the Trinko[74] and Linkline[75] judgements, it was held that 'under certain circumstances, the refusal to cooperate with rivals can constitute of anti-competitive conduct' but this must be done only in exceptional circumstances.[76]The Court of Appeals for the Federal Circuit has held that 'in the absence of any indication of illegal tying, fraud in patent and trademark office', the patent holder should be immune from antitrust law but in other circumstances it is under the jurisdiction of antitrust law.[77]

Further, under EU competition law, it was held that competition law can be violated through misrepresentation of patents, thereby artificially extending the life of the patent as in the 2012 case where the Court of Justice of the European Union ruled that AstraZeneca had violated the competition law through misrepresentation to various patent offices.[78]

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[68] *United States v Masonite Corporation* 1942 SCC OnLine US SC 102.
[69] US Department of Justice, Antitrust Enforcement Guidelines for International Operations (Nov. 10, 1988).
[70] *Besser Mfg. Co. v United States* 1952 SCC OnLine US SC 68.
[71] ibid.
[72] Christopher Gibson, 'A look at the compulsory license in investment arbitration: the case of indirect expropriation' (2010) 25(3) American University of International Law Review 357.
[73] *United States v Colgate & Co* 1919 SCC OnLine US SC 177.
[74] *Verizon Communications Inc. v Law Offices of Curtis V. Trinko, LLP* 2004 SCC OnLine US SC 2.
[75] *Pacific Bell Telephone Co. v Linkline Communications, Inc., et al.* 2009 SCC OnLine US SC 21
[76] *Masonite Corporation Case* (n 68).
[77]Rita Coco, 'Antitrust Liability for Refusal to License Intellectual Property: A Comparative Analysis and the International Setting', (2008) 12(1) Marquette Intellectual Property Law Review 1.
[78] Richard Eccles, 'Court of Justice Upholds AstraZeneca Abuse of Dominance Decision' (*Twobirds* February 2013) <http://www.twobirds.com/en/news/articles/2012/court-of-justice-upholds-astrazeneca-abuse-dominance-decision0113> accessed July 23 2021.

VII. CONCLUSION AND WAY FORWARD

The *Nacto v. Bayer case* led to the evidence of Bayer's inefficiency to cater to the need of production and satisfy the reasonable requirements of the public. In the absence of such exceptional circumstances' test in India and the consumer welfare and promotion of competition focus of CCI, it is not impossible for CCI to adopt an approach which finds IP rights, in such cases, restricting the production of goods which violated Section 4(2)(b)(i) of the Competition Act. The fact that the Controller of Patents can issue licences in the case wherein the patentee can disseminate the technology leads to the evaluation that the CCI can potentially use such a failure by the dominant company to disseminate technology or to restrict it as a violation to Section 4(2)(b)(i). Further, Section 21A of the Competition Act provides that CCI has the power to refer to the concerned authority wherever the CCI is faced with a decision whose implementation is entrusted in other authority.[79] Section 90 of the Patents Act states that 'in case the license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be'.[80] Hence, this section deals with the anti-competitive practice determined by the judicial or administrative process, but it does not stipulate which specific authority would decide such practice as anti-competitive.[81]

Section 60 of the Competition Act clarifies the position of Competition Act with reference to other acts as stating that Competition Act has an overriding effect over other acts, thus, setting the stage for exercise of jurisdiction of Competition Commission.[82] In the case of *Competition Commission of India v. M/s Fast Way Transmission Pvt. Ltd. And Others*,[83] the Supreme Court held that Section 60 gives the act an overriding effect over other states in case of clash between them, keeping in view the economic development of the country. Also, Section 62 of the Competition Act makes it clear that the act must be used in addition and not in derogation of the provisions of other laws in India.[84]

The CCI can issue the order for investigation in case the patent holder violated the principle of dominance in the market but the remedy for the same is under the patents act. It is an

[79] Section 21A, The Competition Act 2002.
[80] Section 90, Indian Patent Act, 1970.
[81] Mansee Teotia and Manish Sanwal (n 11).
[82] Section 60, The Competition Act 2002.
[83] *CCI v Fast Way Transmission (P) Ltd* 2018 SCC OnLine SC 111.
[84] Section 62, The Competition Act 2002.

established principle of the patent law and the competition law that they both focus on the goal of innovations and general welfare. Hence, IPRs are covered under competition laws but given special treatment in assessment.[85] Section 3 of the Competition Act exempts reasonable conditions imposed for protection of IPRs and Section 4 relating to the abuse of holding IPRs liable on the account of abuse of dominance considers all the factors under the framework of competition. Hence, the exercise of power vested with the CCI under Section 19 of the Act mandates that if there is violation of Section 4(1) of the Act then under Section 19(4) of the Competition Act, the Commission shall consider an inquiry into the allegations and if there is prima facie case of abuse of dominance, then it shall direct the Director General to cause an investigation and furnish a report.[86]

However, in order to maintain the balance between the right to health of people and the incentives of the pharmaceutical companies, the CCI can use compulsory licensing as a way to negotiate with the companies to grant a voluntary patent too, wherein the companies will be the ones who would set the amount of compensation they will receive. This will not only be a solution for the increased access to essential drugs but also provide greater room for negotiation and profit making between the firms too.

[85] 'Provisions Relating to Abuse of Dominance' (2020) 4 Competition Commission of India, Advocacy Series 1.
[86] Section 19 (n 33).