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**THE CURIOUS CASE OF
COMPULSORY LICENSING AND
COVID-19**

I. INTRODUCTION

Compulsory license is a government action ordering an exclusive holder of a right to permit the use of that right to a third party, in line with the terms stipulated by the government.¹ In order to combat market failure, Compulsory License of patented pharmaceuticals is perceived to be an appropriate action. Use of Compulsory License is spare and intermittent according to various studies. Though its use can be permitted by the government to address public health problems in compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Hence, national patent legislations can be used as a medium by WTO members to administer Compulsory License through the TRIPS.

**I. GENESIS OF COMPULSORY LICENSE WITH THE
STATUTE OF ANNE**

The roots of compulsory licensing can be traced back to 1710, when the Statute of Anne, known as the world's first copyright law was born, in response to excessive price and an insufficient supply by monopolies.² The Copyright Act of 1783 was passed along similar lines in Connecticut, USA. The Copyright Act later came to be known as a legislative example of the world's first system of

¹ T. Jain, "Compulsory licenses under trips and its obligations for member countries," ICFAI Journal of Intellectual Property Rights, vol. 8, no. 1, February 2009.

² Bracha O. The adventures of the statute of Anne in the land of unlimited possibilities: the life of a legal transplant. Berkeley Technol Law J. 2010; 25(3):1427-73.

compulsory licensing of copyrights.³ Hence, compulsory licensing of patents came much after compulsory licensing of copyrights. United States of America had been the champion of protection against patent abuse during the nascent years of industry development. The state of South Carolina also established the Act for the Encouragement of Arts and Science, which provided privileges and limitations to not just authors (copyrights) but also inventors (patents).⁴ Thus the Act arguably became the tool to portray Compulsory License as a new remedy against in the era when invalidation of patents was on the rise. Some may even say that the survival of certain patents were solely influenced by pitching Compulsory Licensing as an alternative. Similarly, England and Germany discussed compulsory licensing to minimize the adverse effects of patent system and complement the shortcomings of patent system in 1851 and 1853, respectively.⁵

The tides started shifting towards Compulsory Licensing post 1900s.⁶ USA exploited it on a regular basis in 1960s to import pharmaceuticals. Canada went a step further from importation and amended the Patents Act in 1923 to encourage local manufacturing of the pharmaceutical competition.⁷ As a result, it can also be utilised for local production to manage health expenditure.⁸ Amendments to Patents Act had become a necessity to counter the concern regarding the skyrocketing prices of pharmaceuticals.

The outlook quickly changed during the negotiations of The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), especially of high income countries.⁹ On one hand, the issue of Compulsory Licensing to fight the soaring prices of pharmaceutical products was an objective

³ Brand O. The dawn of compulsory patent licensing. *Intellect Prop Q.* 2007; 2:216.

⁴ *Ibid.*

⁵ Penrose ET. *The economics of the international patent system*: Baltimore. Md: Johns Hopkins Press. 1951.

⁶ FM't Hoen E. *Private patents and public health: changing intellectual property rules for access to medicines: health action international*; 2016.

⁷ Kuek V, Phillips K, Kohler JC. Access to medicines and domestic compulsory licensing: learning from Canada and Thailand. *Global public health.* 2011;6(2):111–24.

⁸ Lybecker KM, Fowler E. Compulsory licensing in Canada and Thailand: comparing regimes to ensure legitimate use of the WTO rules. *J Law, Med Ethics.* 2009;37(2):222–39.

⁹ Ford S. Compulsory licensing provisions under the TRIPS agreement: balancing pills and patents. *Am U Int'l L Rev.* 1999;15:941.

solution.¹⁰ On the other hand, there was a rising fear that such issuance of Compulsory Licensing would have a dismissive effect on the profits of such industry and it would further discourage the industry to research and develop in the long term as the patent holder is unable to recoup any investment incurred through research and development so that he can make sufficient profit to remain in the business.¹¹ So, while compulsory licensing can act as a defence against the obstinacy of high-income countries to establish intellectual property rights as new norms of international trade agreements, it can also result in less innovation.¹² But the arguments against compulsory licensing do not end there. Opponents advocate the issuance of compulsory licensing as a tool to replace the traditional patent systems, which would diminish the incentives for innovative medicines for all humanity.

Therefore, the use of compulsory licensing of pharmaceuticals was restricted to highly infectious diseases such as HIV/AIDS in low-income countries and compulsory licensing other than this restricted area was deemed unjustifiable. Meanwhile, WHO adopted the Doha Declaration and affirmed that compulsory licensing is the right of the member countries of the WTO.¹³

II. COMPULSORY LICENSE DURING COVID-19 – A PROGRESSION OR REGRESSION FOR INDIA?

The efficacy of compulsory licensing in curtailing COVID-19 is still an enigma but with the overcrowded hospitals, paucity of medical equipment and augmenting tally of cases in India, any feasible measures that may subside the surge must be considered.

The advocates of compulsory licensing argue that local industries will see a boom in employment as a result of compulsory licensing. More importantly, most of the patents operating in developing

¹⁰ McCabe KW. The January 1999 review of article 27 of the TRIPS agreement: diverging views of developed and developing countries toward the patentability of biotechnology. *J Intell Prop L.* 1998

¹¹ von Falck A. Compulsory licenses as a defense in pharmaceutical and biotech patent litigation. *Pharmaceutical patent analyst.* 2016;5(6):351–3.

¹² Heller MA, Eisenberg RS. Can patents deter innovation? The anticommons in biomedical research. *Science.* 1998;280(5364):698–701.

¹³ D. K. DAS, “Intellectual property rights and the Doha round,” *Journal of World Intellectual Property*, 2005, pp. 522

countries are owned by citizens from developed countries. Since developing nations are not always in a position to produce such patents of their own, the progress of such nations would rise exponentially through the use of such licenses. Some also argue that the existence of too many intellectual property rights could result in less innovation.¹⁴ They can very easily become an impediment in economic development of countries struggling with their domestic and technical infrastructure and may hinder the process of making the necessities available to the common man at affordable prices. This can lead up to breaking up of monopolies and cartels which are abusing patent rights.¹⁵ The very threat of non-voluntary licensing may bring the big guns onto the table in order to reach a middle ground.¹⁶ The vehement opposition of the advanced nations may be dubbed as 'neocolonialism' as the patent protection clearly favours them more.

Also, the problem of deadlocks between the improver and the original patentee resulting in delay in the development of important technology can be resolved through compulsory licensing by putting the pressure on the original patentee to come to terms with the improver.¹⁷ So, it is evident that it can fasten up the process of technological progress.¹⁸

Patent suppression is a reality and compulsory licensing is the only inevitable defence to persuade patent holders to work the patent to maximum national advantage, especially in developing countries like India.¹⁹ Compulsory licensing becomes all the more important when its non-utilization will affect another important invention curbing much needed technological advancement. The advocates of compulsory licensing argue that research being discouraged because of compulsory licensing is a flawed argument as the expenses are easily recovered from the sales of such products in the advanced states of the world having strong patent laws.²⁰

¹⁴ Heller MA, Eisenberg RS. Can patents deter innovation? The anticommons in biomedical research. *Science*. 1998; 280(5364):698–701.

¹⁵ Jenkins, *Compulsory licensing: a major IP issue in international business today?* pp. 371

¹⁶ J. Kuanpoth, *Proceed with caution on compulsory licensing*, pp. 26, 2011.

¹⁷ J. A. Yosick, "Compulsory patent licensing for efficient use of inventions," *University of Illinois Law Review*, 2001.

¹⁸ G. J. Arnold, "International compulsory licensing: the rationales and the reality," *PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology*, 1993.

¹⁹ J. Kuanpoth, *Proceed with caution on compulsory licensing*, pp. 58, 2011.

²⁰ T. Jain, "Compulsory licenses under TRIPS and its obligations for member countries," *ICFAI Journal of Intellectual Property Rights*, vol. 8, no. 1, pp. 47, Feb. 2009.

The critics of compulsory licensing argue that the rights behind patents are historically and statutorily granted with the issuance of a patent and should be protected through a limited time period.²¹ Compulsory licensing will lower the incentive to innovate and investment in R & D of new drugs, thereby hurting medical innovation. The inability to recover the costs sunk into the R & D of such drugs, leaves no reason to keep manufacturing. Also, the generics that are made in place of the original drugs may contain impurities that dilutes the effectiveness of the drugs and even render them dangerous in some cases. Moreover, many diseases that run rampant in developing countries are not present in developed ones. Compulsory licensing will further disincentivize research into these illnesses by increasing dependency on developed nations, therefore making developing nations worse off in the long run. Compulsory licensing can also result in reduced foreign investment by the developed country (possessing the drug patent) in the concerned developing country causing trade friction.²²

Actual loss may or may not happen but most of the times even the fear of compulsory licensing having an adverse effect on trade relations between countries is enough.²³ An undeniable fact is that the growth of indigenous industry of developing nations is heavily dependent on investment that comes from outside the country.²⁴ So, granting the compulsory licenses may lead to a huge decline of foreign direct investment (FDI). Because the pharmaceutical companies may easily go for a different venue to conduct their clinical trials which will be a loss of a potential source of economic growth.²⁵ Moreover, a country can easily become less competitive because of a vulnerable intellectual property regime resulting in brain drain. Retaining human capital becomes a herculean job which the government is not equipped to take on and the scientists and researchers leave the country in search for better job prospects.²⁶

²¹ Monte WN. Compulsory licensing of patents. *Inf Commun Technol Law*. 2016; 25(3):247–71.

²² R. Holbrooke and A. F. Holmer. Applying U.S. Antitrust’s “rule of reason” to trip’s compulsory licensing provision. *New England Law Review*. [Online]. 36(3). pp. 697.

²³ *Ibid*.

²⁴ F. M. Abbott, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, Quaker United Nations Office, Geneva, 2002, pp. 160

²⁵ R. Bird and D. R. Cahoy, “The Impact of compulsory licensing on foreign direct investment: a collective bargaining approach”, *American Business Law Journal*, vol. 45, no. 2, 2008, pp. 284.

²⁶ J. Kuanpoth, *Proceed with caution on compulsory licensing*, pp. 1, 2011.

III. STANCE OF INDIA AND THE WORLD

Several countries have been laying the legislative groundwork to issue compulsory licenses for products that patent holders refuse to make accessible, given the uncertainty over access to treatments for COVID-19.

India

The concept of compulsory licensing is recognised with express mention in *Patent Act, 1970*. In compliance with sections 84-92, a set of conditions need to be fulfilled if a compulsory license is to be granted in favour of someone. So far, India has utilised voluntary licenses only (where IP holders voluntarily grant licenses to their patents or other IP) and *Remedisivir* developed by the US based Gilead Pharmaceuticals is one such example. But the concerns about whether such an arrangement is ideal for ensuring the availability and affordability of Remedisivir and other future drugs still needs scrutiny. Regardless of whether future drugs will be compulsorily licensed in India or not, some key changes will be made in the domain of patents. For instance, government facilitated voluntary licensing may increase and PPPs may be used to overcome funding, legal and logistical challenges.

Israel

A generic version of AbbVie's Kaletra from India was imported for the treatment of coronavirus patients. Section 104 of the patent statute allows the state to circumvent the law for national defence purposes and the licence was issued under this section. The move assumes all the more importance because it is the first compulsory licensing issued under Section 104 since the provision's introduction in 1967 in Israel.

Canada

Canada has amended Bill C-13, the *COVID-19 Emergency Response Act*. Unlike existing compulsory licensing provisions, the new law allows the government to issue a licence without first negotiating with the rights holder or establishing its own ability to supply a product. No patent permit can be granted after the expiry of the provision in September 2020.

Germany

Prevention and Control of Infectious Diseases in Humans Act came into force, with a range of extra powers in the advent of a national epidemic, which includes the ability to issue a compulsory

license under the existing Section 13(1) of the Patent Act, which has never been used before. Section 13(1) permits the bypass of patent rights by the government or the third parties in the interest of public welfare or public security of the country as a whole. If the Bundestag decides that Germany no longer faces an epidemic, any orders issued as a result of the new legislation will be revoked automatically or when the law expires in March 2021.

France

A new law (No 2020-290) was enacted which introduced a new article - L.3131-15 to the country's public health code, providing enough goods and services essential to curb sanitary disaster, temporarily control the product prices and implementation of any measures necessary to make relevant medicines available to patients. The Prime Minister would now be allowed to permit the seizure of drugs and direct the launch of generic products on French territory before the expiry of patents, if the need arises.

Chile

A resolution was passed by Chile's Chamber of Deputies to declare its support for issuing compulsory licenses on patented products for coronavirus patients. Additionally, the document calls for information on the R&D costs associated with relevant treatments to be enquired with WHO. Though the resolution is not binding on the country's government.

Ecuador

Third parties are allowed to access a patentee's data, including clinical test data in accordance with Article 501 of the Código Ingenios. A resolution was passed by the commission of the Ecuadorian National Assembly requesting the Ecuador's health minister to issue compulsory licenses on products whose availability is important to the public health response to covid-19. The resolution is not binding on the government.

IV. ANALYSIS

Although patent encourages monopoly and overpricing, it is a pertinent element without which companies have no incentive to develop new products.²⁷ Thus, patent protection is necessary to ensure innovation. It is therefore an imperfect but effective instrument to promote the development of new products. Compulsory Licensing is yet another necessary evil. In order to protect the human

²⁷ 'The Pros and Cons of Compulsory Licensing: An Analysis of Arguments' by Muhammad Zaheer Abbas

right to health and also to prevent abuse of the right of monopoly in the developing nations, violation of the rights of the patent holder often becomes necessary. Therefore, it must be used judiciously as it is an exception to the general rule of patent. While the safety clauses of patent protection are paramount to support constant innovation, the compulsory license exception exists for public health emergencies such as the current COVID-19 crisis.²⁸



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²⁸ 'The case for compulsory licensing during COVID-19' by Hillary Wong