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Compulsory Licensing as a Prospective Solution to Tackle a Pandemic: With Special Reference to COVID-19 Pandemic

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Abstract:

The Covid-19 pandemic has proved to be havoc for every one of us. With over millions of people infected with this deadly disease, there is an urgent need for a vaccine to be invented. It is of no surprise that the innovator will protect the drug under the Patent Act. The lengthy proceeding of registration and the post registration scenario will reduce the access of medicine, especially in low and middle income countries like India. To avoid such scenario, Compulsory Licensing is considered to be a prospective solution to tackle not only COVID-19 pandemic, but any future pandemic of grave nature. The paper seeks to analyse the International as well as National provisions pertaining to Compulsory Licensing and its importance in making the drug affordable and accessible, thereby ensuring that the Fundamental Right of life, which also include Right to health is safeguarded.

Keywords: Compulsory Licensing, TRIPS, Doha Declaration, Public Interest, Extreme Urgency.

Introduction:

The Covid-19 pandemic has caused a huge loss to human civilisation in the social and economic sphere. Though there are few ways to tackle the COVID-19 pandemic, but taking into consideration the current state of economy and social scenario of the world, there is an urgent need to invent a vaccine to eradicate the pandemic, therefore, all the major pharmaceutical companies in the world are in the race to invent a vaccine which will fight against the deadly on-going virus. But merely inventing a drug to eradicate COVID-19 or any pandemic for that matter of fact is perhaps one of the important issues. The United Nation has enacted rules in such a way that it directs the state to foster the health care system. One such initiative is the 3rd Sustainable Development Goal, which pertains to Good health and Well-Being; it was adopted by United Nations member states as a universal holler to secure that all the people around the world, live in peace and prosperity by 2030¹. Even before the crisis, the world was off track ensuring healthcare for everybody by 2030 but the current pandemic had a major setback on the health sector affecting a majority of people worldwide as a result provisional policies like '**compulsory licensing**'. Creating a vaccine to fight against a disease is perhaps one of the important issues, other issues which needs to be tackled are:

1. **Accessibility:** The quantity of drugs produced should satisfy the growing demand of the public.
2. **Affordability:** The price of the drug should be kept reasonable, so as to make it affordable even to the last man. Government should also give subsidies to the people belonging to marginalised section of society.

The invention of drugs requires a substantial level of intellect and hence the role of patent comes into picture in protecting the interest of the parties. The Patent Law of India grants an exclusive right to the patent holder to use manufacture and sell the patent in the market for 20 years before going into the public domain². Patents thus play an important role by encouraging research and development in almost every field. Inventing a drug is no big deal; the Pharmaceutical Company has to invest in skilled employees, huge infrastructure coupled with latest technology and

¹ Goal 3: Good Health and well-being, UNITED NATION DEVELOPMENT PROGRAMME (Aug. 26, 2020, 11:47 PM), <https://www.undp.org/content/undp/en/home/sustainable-development-goals/goal-3-good-health-and-well-being.html>.

² Patent Act 1970 § 53.

machinery. Such large scale investments compel many Pharmaceutical Companies to sometimes keep the price of the drug high, so as to recover all the investment incurred in the process. The drug thus patented renders exclusive rights upon the patent holder, the holder enjoys a competitive edge over other companies in the market, but sometimes, high prices of the drug doesn't serve the purpose of Public Interest. Many people can't afford such drugs making it inaccessible to them.

Such an instant might create a problem in case of a Pandemic or an Epidemic and hence many international forums and organisations in the past have taken cognizance of such issues and have brought suitable solutions, in September 2016 the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines recommended that WTO Members should make full use of the policy space available under the TRIPS Agreement³. Innovation, accessibility and affordability should be seen as two parts of the same coin as a result. And COVID-19's reach is only just beginning to be felt. UNDP estimates global human development a combination of education, **health**, and living standards could fall this year for the first time since 1990, when measurements began. Thus provisional policies like **compulsory licensing** must be implemented by many countries during such unpredictable times as they guarantee both affordability and accessibility.

What is Compulsory Licensing and why do we need it?

Compulsory Licensing refers to a phenomenon where the government is empowered to acquire the patent in force under certain conditions which are prescribed in law. Many scholars are of the opinion that property belongs to oneself and the person has an exclusive right over his/her property. Right from early 20th Century, when humans started investing their intellect to create novel commodities, the scope of property has expanded taking Intellectual Property a part of it.

In the words of President John Adams "Property is surely a right of mankind as real as liberty". Many early philosophers gave emphasis on the concept of private property and the protection of the same. John Locke in his work argues that, though earth is equal to all, there is a property which he himself possesses. He put his own labour into the property and thus the property belongs to him⁴. But the concept of compulsory licensing is deep rooted in the utility theory of Jeremy Bentham. His theory of utilitarianism stands for 'greatest happiness of the greatest member'⁵. He stated that the interest of the few can be sacrificed for the collective interest of Public. Hence the current concept of compulsory licensing is somewhat identical to that of Bentham Utilitarianism mode, that is to say, in certain situations, where the rights of the public at large are getting affected, then individual rights shall cease to exist.

International Perspective to Tackle COVID-19:

One of the most important elements of patents is the **commercial exploitation** of an invention, but any commercial exploitation of patented invention, which reduces the access to the medicines, is detrimental to the public health⁶ especially in the case of public health emergencies. Article 27(2) of TRIPS agreement defines that members of WTO are excluded from the patentability inventions, it states that if the member country carries out commercial exploitation of the drug which affects the health of humans then such invention shall not come under the purview of patent laws. Amid such stringent provision compulsory licensing could be a prospective solution as the pharmaceutical company is entitled to adequate remuneration and royalty. Article 31 under the TRIPS agreement does not specifically use the term compulsory licensing but it states that "a patent can be used by the government or third parties authorized by the government, without the authorization of the right holder (owner of the patent)". But such authorization right is only given if the applicant has made previous efforts to acquire the patent from the patentee but this is not applicable during extreme urgency or national emergency, non-exclusive use, non-commercial use etc. but even when a compulsory license is issued proper remuneration amount should be paid to the owner of the patent the article exclusively states that, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" but there is no proper mention of either adequate remuneration nor the "economic value"- Article 31(h). Exactly when a country can issue a compulsory license is not explicitly addressed by TRIPS although it does mention national emergencies, other circumstances of extreme urgency, and anti-competitive practices as possible grounds for compulsory licensing. Along with the freedom to allow parallel imports, the option to use compulsory licensing constitutes one of the major flexibilities

³ Report of the UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES, UNITED NATION (Aug. 28, 2020, 11:18 PM), <http://www.politico.eu/wp-content/uploads/2016/09/HLP-Report-FINAL-Sept-2016.pdf>.

⁴ O.P.GAUBA, AN INTRODUCTION TO POLITICAL THEORY 398 (5th ed. 2009).

⁵ *Id.*

⁶ Dr. Victor Vaibhav and Dr. Akanksha Wadehra Tandon, *Revocation, Special compulsory licensing, patent strategies & COVID-19: A note on Indian Patent Law*, IPKat (Aug. 28, 2020, 12:12 PM), <http://ipkitten.blogspot.com/2020/05/guest-post-revocations-special.html>.

available under TRIPS to member countries of the WTO⁷. Post TRIPS, governments across the developing world have tried to improve consumer access to medicines sold by foreign pharmaceutical companies by imposing price controls on them. In 2002 Zimbabwe reduced the price of the drug Lamivudine and Zidovudine in the period of emergency of AIDS under compulsory licensing⁸. Also in 2004 Malaysian issued 2 years compulsory licensing on Didanosine, Zidovudine and combination of Lamivudine and Zidovudine to import drugs from India⁹. Indeed; such controls exist even in rich countries where the public sector plays an integral role in health care. In 2001 USA made compulsory licensing of drug Ciprofloxacin by reducing 54% of original price of the drug¹⁰. Two prominent recent cases where compulsory licensing has been used are by Thailand and Brazil. Both cases involved the compulsory licensing of HIV/AIDS drugs. Thailand had issued compulsory licensing on several pharmaceutical products used to treat HIV/AIDS, heart attack, stroke and cancer. In 2005, more than half a million Thai citizens were HIV positive. Although the Thai government had made a commitment to provide free ARV treatment to all who needed it, the costs rose significantly when better and more expensive treatments became available. The government of Thailand issued a compulsory license for Kaletra, an AIDS drug, to the Government Pharmaceutical Organization (GPO) a government owned Thai producer of medicines¹¹. Following in Thailand's footsteps, in May 2007 Brazil decided to issue a compulsory license for Efavirenz, another patented AIDS drug, after price negotiations with the patent-holder (Merck) had broken down. Brazil had previously used the threat of compulsory licensing to pressure companies to lower prices of patented medicines, but Efavirenz was the first time a compulsory license was actually issued. There are three crucial aspects of the experiences of Thailand and Brazil with compulsory licensing. First, price considerations were a major factor in prompting the use of compulsory licensing. Indeed, the governments seemed to have used their power to bargain down prices as well as the option to use compulsory licensing as tools for improving consumer access to foreign patented goods. Second, in both Thailand and Brazil, there was essentially a single local producer that had the competence to produce the relevant drug under a compulsory license. Third, in both instances, the local producer's quality was clearly inferior to that of the original patent-holder. We believe that these features capture important ground realities confronting the potential use of compulsory licensing in developing countries and the model that we develop below puts them at centre stage around the world¹². Ecuador's IP authority granted a compulsory license to a pharmaceutical distributor with operations in Ecuador. The compulsory license, granted in April 2010, covers a patent relating to the active ingredient ritonavir, which is a retroviral protease inhibiting compound used for the treatment of HIV/AIDS. The license covered all the patent rights, including importation and was limited to use in Ecuador. The license was reportedly intended for public non-commercial use (Article 31b of the TRIPS Agreement). The Ecuadorian authorities informed the patent owner before they granted the compulsory license. The license is valid until the date on which the patent expires in 2014. The licensee is required to pay the patent owner adequate remuneration calculated according to the Tiered Royalty Method, which was based on a royalty of five per cent of the price of the patent owner's product in the United States, adjusted for the difference in gross domestic product per capita, yielding a royalty rate of 0.42 percentage of the United States price. The procedure for the grant of the compulsory license took six months to complete¹³. Though the TRIPS provided a lot of benefits, convenience and welfare but there was need of amendment in TRIPS which was fulfilled by Doha Declaration in November 2001 in which it allowed the member country to issue compulsory license to produce drugs for export to the countries which establish that they have less or no manufacturing capacity of drugs. The Doha Declaration guarantees to protect public health and to promote access to medicines for all without any discrimination. Clause 5 of the Doha Declaration affirms that "each WTO member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted"¹⁴. Considering this in 2003 the first implementation was made in Rwanda and it was the first country to implement this as it managed to import antiretroviral drug TriAvir from a Canadian generic company Apotex.

⁷ THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, WORLD HEALTH ORGANISATION (Aug. 26, 2020, 1:27PM), https://www.who.int/medicines/areas/policy/doha_declaration/en/.

⁸ *The Use of Compulsory Licenses*, WORLD INTELLECTUAL PROPERTY ORGANISATION (Aug.25, 2020, 9:49 PM), https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_t10c.pdf.

⁹ *Example of Health-Related Compulsory Licenses*, CPTECH (Aug. 25, 2020, 11:47 PM), <http://www.cptech.org/ip/health/cl/recent-examples.html#Malaysia>.

¹⁰ *Id.*

¹¹ Tove Iren S. Gerhardsen, *Thailand Presents Report On Compulsory Licensing Experience*, INTELLECTUAL PROPERTY WATCH (Aug. 25, 2020, 9:57 PM),

[https://www.ip-watch.org/2007/03/12/thailand-presents-report-on-compulsory-licensing-experience/#:~:text=The%20Thai%20government%20has%20issued,%2C%20efavirenz%20\(Merck%20Sharp%20%26%20Dohme's](https://www.ip-watch.org/2007/03/12/thailand-presents-report-on-compulsory-licensing-experience/#:~:text=The%20Thai%20government%20has%20issued,%2C%20efavirenz%20(Merck%20Sharp%20%26%20Dohme's).

¹² Johanna von Braun, *Use of Compulsory Licenses Selected National Experiences*, UNITED NATION CONFERENCE ON TRADE AND DEVELOPMENT (Aug. 26, 2020, 1:23 PM), https://unctad.org/Sections/dite_totip/docs/tot_ip_0018_en.pdf.

¹³ Catherine Saez, *Ecuador Grants First Compulsory Licensing, For HIV/AIDS Drug*, INTELLECTUAL PROPERTY WATCH (Aug. 25, 2020, 11:42 PM), <https://www.ip-watch.org/2010/04/22/ecuador-grants-first-compulsory-licence-for-hivaids-drug/>.

¹⁴ *Supra*, at 4.

Additionally, in situations of “national emergencies” and “other circumstances of extreme urgency,” governments can issue compulsory licenses without normal requirements, such as negotiating with the patent holder¹⁵. In 2003 WTO tried to implement paragraph 6 of Doha declaration which acknowledges the under- developed nations in the pharmaceutical sector which struggle for constructive use of compulsory licensing under the TRIPS agreement for disallowance of Article 31(f)’s domestic market restriction on concession with certain conditions. It permitted any member country to issue compulsory license of generic drugs to export it to the least developed countries and other countries who have no manufacturing or research and development capacity¹⁶

In later years many companies have effectively lowered prices of the drug due to the threat of compulsory licensing. Brazil has actively used compulsory licenses as a threat to negotiate lower prices for AIDS drugs like Nelfinavir, which was a patented product of Roche. The company reached an agreement to sell the drug in Brazil at an additional discount of 40%, in return Brazil will not issue compulsory license¹⁷. In September 2014, Gilead signed non-exclusive licensing agreements with seven India- based generic pharmaceutical manufacturers to manufacture Sofosbuvir and the investigational single tablet regimen of Ledipasvir/Sofosbuvir for distribution in 91 developing countries. The European Union law guarantees to every European Union member state to provide compulsory licensing for drugs to developing or the least developed countries as long as conditions under Article 31 are completed as a result this provision will help to speed the process of getting the COVID-19 vaccine both in Europe and the other countries. Clause 5(c) of the Doha declaration clarifies that: “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics” can constitute “a national emergency or other circumstances of extreme urgency.” There can be no doubt that the COVID-19 pandemic is a public health crisis within the meaning of clause 5(c) that justifies the use of compulsory licenses. Several countries have already publicly considered compulsory licensing as part of their COVID-19 response. On March 24, 2020, Israel issued a compulsory license to import generic versions of lopinavir/ritonavir (AbbVie’s Kaletra). The Israeli Ministry of Health has determined that the antiretroviral drug could be a possible treatment for COVID-19 patients. Israel did not issue the license due to the drug’s pricing. Instead, Israel issued the compulsory license and turned to generic alternatives from India because AbbVie was unable to provide sufficient supplies of lopinavir/ritonavir. AbbVie has announced that it will not enforce its patent in light of the current pandemic¹⁸. For a country to issue compulsory licensing its national laws should have support such provisions. Several countries have already taken legislative steps to ensure their governments can swiftly issue compulsory licenses as part of their COVID-19 response. Thus there are provisions such as TRIPS-flexibility, all WTO Members are free to use the provisions of the TRIPS Agreement in a manner that is supportive of public health and clarifies certain flexibilities that the TRIPS Agreement provides for this purpose.

In March, legislatures in Canada, Chile, and Ecuador laid the legal groundwork for the issuance of compulsory licenses to address COVID-19. Chile’s Chamber of Deputies (the lower house of its Congress) has passed a resolution granting the use of compulsory licenses for the prevention and treatment of COVID-19. Specifically, the resolution declares that the coronavirus pandemic constitutes sufficient justification to grant compulsory licenses for COVID-19-related technologies. Similarly, a Committee of the National Assembly in Ecuador has passed a resolution requiring the Ecuadorian President and Minister of Health to provide free or affordable access to COVID-19-related preventative, diagnostic, and treatment technologies through the use of compulsory licenses. However, in case compulsory licenses do become necessary when a cure is available, countries should take the appropriate legislative steps to prepare as soon as possible.

¹⁵ Canada is first to notify compulsory license to export generic drug, WORLD TRADE ORGANISATION (Aug. 26, 2020, 1:37 PM), https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm#:~:text=Both%20notifications%20were%20required%20for,are%20unable%20to%20manufacture%20the.

¹⁶ Raadika Gupta, *Compulsory Licensing Under Trips: How Far It Addresses Public Health concerns In Developing Nations* 357, 359 (2010).

¹⁷ Draft reference document on the exception regarding compulsory licensing, WORLD INTELLECTUAL PROPERTY ORGANISATION (Aug. 25, 2020, 10:08 PM), https://www.wipo.int/export/sites/www/scp/en/meetings/session_30/comments_received/brazil_1.pdf.

¹⁸ Thiru, *Israel issues compulsory license to allow the government to import generic versions of Kaletra*, KNOWLEDGE ECOLOGY INTERNATIONAL (Aug. 25, 2020, 10:19 PM), <https://www.keionline.org/32503>.

National Provisions to Tackle the COVID-19 Pandemic: A case of an Extreme Urgency?

The Patent Legislation in India can be traced back to the Act VI of 1856. The main objective of the Act was to promote research and innovation. By providing rights to the inventor, the Act also induced the innovators to disclose their invention. This step was vital for any society to develop.

India being a signatory to the TRIPS agreement had enacted compulsory licensing. It is embedded in Patent Act, 1970, in Chapter 16 (Section 82- Section 94) which talks about Working of Patents, Compulsory licensing and Revocation and Chapter 17 (Section 99- Section 103) which talks about Use and Acquisition of Invention by the Central Government.

Though India is a signatory to the TRIPS agreement, and has been complying with its provisions, there are few areas which should be amended, as India or even the whole world for that matter fact, has never foreseen an event of such extreme urgency for a drug. Various countries have either acquired a license or have made amendment to their existing Patent Laws to safeguard the rights of both, the Patent Holder and Public at large.

The Patent Act, 1970 lays down certain principles which need to be followed for an invention to be called as a working patent. One of the Principles which pertain to public interest states that pharmaceutical companies while manufacturing the drug should take into consideration that they should not hinder the steps taken by the government in the interest of Public health, it gives power to the government either to use or acquire the Patent¹⁹. This has empowered the Government to take necessary steps under Patent Laws to protect the interest of Public at large.

The provisions of Compulsory Licensing were drafted in such a way that it will satisfy the needs of both the Patent holder and Public Interest. Though the Indian Constitution does not provide for any **Medical Emergency**, with over millions of infected patients, there is an urgent need for a vaccine to cure the disease and hence it is reasonable to interpret the COVID-19 pandemic as a case of “**Extreme Urgency**”.

The legislation in its wisdom has drafted the provisions in such a way that it safeguards Public interest and thus it empowers any person to file an application for compulsory licensing any time after the expiry of three years from the grant of Patent, provided that, the original Patent holder has failed to satisfy three essential elements namely (i) Public requirement is not satisfied by the use of Patent, (ii) Public cannot afford the drug available in the market and (iii) that the patented invention has not worked in the territory of India²⁰. This will make sure that the patent holder is not abusing his right. The classic example of Section 84 was in a landmark case of **Bayer Corporation v. Union of India, The Controller of Patents and Natco Pharmaceutical Ltd**²¹. The Bayer Corporation (hereinafter referred to as Appellant) invented a drug called “Nexavar” for the treatment of Renal Cell Carcinoma (RCC) and Hepato-Cellular Carcinoma (HCC) at IVth stage. The appellant's Patent was granted in India in January 2008. The price of Nexavar was set at Rs. 2, 80,000 per month by the Appellant. On December 6, 2010 the Natco Pharmaceutical Company (hereinafter referred to as Respondent) communicated with the Appellant for voluntarily licencing their drug for the manufacturing process. The letter stated that, 2, 80,000 was a huge amount and a common Indian man was not able to afford it, the Respondent stated that they are in a position to manufacturer the drug and sell it in a market for less than Rs 10,000 a month. The said proposal was refused by the Appellant, compelling the Respondent to file a case for Compulsory Licensing in Intellectual Property Board, which ruled out in the favour of Natco Pharmaceutical Corporation by keeping the royalty at 6%. The said decision was challenged by the appellant to the high authority (Intellectual Property Board, Chennai). The Controller in its wisdom checked whether the essential elements under Section 84(1) are met or not. The board held that for a country like India Rs 2, 80,000 is a huge amount and thus many people won't be able to receive proper treatment. The Controller also stated that, the word ‘or’ after each criterion indicates that, Compulsory License can be granted even if one of the criteria mentioned under Section 84(1) is proved. It was held that the Appellant failed the test of Section 84(1) and hence in the Interest of Public, the Controller granted the Compulsory License to Natco. The board while granting the Compulsory Licensing increased the royalty by one percentage and made it 7%. The Controller while interpreting “Reasonable price” was of the opinion that the drug should be sold at Rs 8000.

Though this was not the case of “extreme urgency” and all the due proceedings were followed, it still indicates that, Compulsory Licensing could be a prospective solution for making the drug affordable and accessible to the Public.

Amid COVID-19, few important organisations and corporations have a Philanthropic blend. Considering the damage done by COVID-19 pandemic, Andrew Pollard, the Director of Oxford Vaccine Group stated that, many

¹⁹ Patent Act 1970 § 83(e).

²⁰ Patent Act 1970 § 84.

²¹ Bayer Corporation v. Union of India, The Controller of India and Natco Pharmaceutical Limited, MIPR 2013 (2)97.

Governments, International Forum and other organisations are willing to invest in their Research and Development. The Partnership between Oxford University and Astra Zeneca is a **non-profit partnership** and thus the vaccine which will be readily available in the market will either be free or at a very low cost²². Apart from the Oxford University and AstraZeneca's non-profit research, Serum Institute of India who is a manufacturing partner to both Oxford University and a U.S based company called Novavax has recently announced that the price for one dose of COVID-19 will be Rs. 225. It also stated that, because of the large funding received by them, the company is able to produce 100 million doses for lower-and middle-income countries like India²³. The price set by Serum Institute for one dose of COVID-19 seems to be a reasonable price for the majority of the population, but still the doses may not be affordable for the extremely marginalised section of the society, hence the government should introduce subsidies or cap the price of the drug for extremely marginalised sections of society. It is presumed that we may not need to invoke compulsory licensing for drugs manufactured by Serum Institute as it satisfies the provisions of Section 84 of the Patent. But if the prices went high, it would further be detrimental to public health and under the ambit of 'extreme urgency' the Government will have to invoke the clause.

Section 84 of the Act also gives three years to the patent holder to enjoy monopoly rights over the market in order to incur all the investments put in for production.

But the provision of Section 84 comes with certain limitations which are mentioned under Section 92. Sub-Clause 1 of the said section, empowers the Government of India, to grant compulsory license of a patent in force, under three circumstances. (i) National Emergency, (ii) Case of extreme urgency and (iii) a case of public non-commercial use²⁴.

The limitation to Section 84 of the Act was given by Delhi High Court in **Telefonaktiebolaget LM Ericsson v. Competition Commission of India**²⁵. The court in its wisdom stated that the provision of Section 84 of the Patent Act is drafted by the legislature in such a way that it gives full monopoly to the proprietor of the patent for the first three years. **However the protection under Section 84 is diluted by virtue of Section 92 of the said Act.** The court further stated that if any of the conditions mentioned in Section 92 is satisfied then the Controller General is empowered to entertain an application for compulsory licensing of a patent even before the expiration of three years from the date of grant of patent. The step is taken, taking into consideration the public health crisis.

Amid COVID-19, the said limitation should be read in tune with the Indian Constitution, which states that "No person should be deprived of his life or personal liberty except according to the procedure established by law"²⁶. The Supreme Court in its wisdom while interpreting Article 21 had taken a much wider view. The beauty of this article lies in its comprehensive nature which includes various rights to make the word "life" more meaningful one of which includes "Right to good health"²⁷.

Despite the Delhi High Court judgment providing for one possible solution, few changes are required, taking into consideration the current case of "extreme urgency". The process of licensing should be done faster and the procedure pertaining to the application under Section 84 shall cease to exist, thus making it non-prejudicial to the public at large. The Canadian Government has introduced a few similar amendments in Patent Law under COVID-19 Emergency Response Act. The amendment states that the Ministry of Health can authorise the Government of Canada or any other person to use, make, construct or sell the patented invention to an extent which will be able to tackle the existing public health crisis. The Government has not laid down any specific procedure in this regard, making it up to the Government to deal with the entire process swiftly²⁸. This step will ensure that unnecessary time is not spent on procedure, and medicine is available to the public as soon as possible.

Taking into consideration the current health crisis which is increasing at a rapid rate, it is more likely that the Government of India, which has the capacity to invest money to produce an abundance of drugs and sell it in the market at a very cheaper rate, will acquire the license rather than a private pharmaceutical company.

²² Narayan Lakshman, *India will have to deliver vaccine on a scale never seen before: Oxford scientist Andrew Pollard*, THE HINDU (Aug. 16, 2020, 10:00 PM), <https://www.thehindu.com/sci-tech/health/coronavirus-india-will-have-to-deliver-vaccine-on-scale-never-seen-before-oxford-scientist/article32163865.ece>.

²³ Sumi Sunkanya Dutta, *Oxford Covid-19 vaccine to cost Rs. 225 per dose in India: Serum Institute*, THE NEW INDIAN EXPRESS (Aug. 16, 2020, 12:36 AM), <https://www.newindianexpress.com/nation/2020/aug/07/oxford-covid-19-vaccine-to-cost-rs-225-per-dose-in-india-serum-institute-2180417.html>.

²⁴ Patent Act 1970 § 92.

²⁵ Telefonaktiebolaget LM Ericsson v. Competition Commission of India & Anr., MIPR 2016 (2)91.

²⁶ INDIAN CONSTI. art. 21.

²⁷ DURGA DAS BASU, INTRODUCTION TO THE CONSTITUTION OF INDIA 124 (22nd ed. 2015).

²⁸ COVID-19 EMERGENCY RESPONSE ACT, HoC, C-13, § 51(2020).

Chapter 17 of the Patent Act empowers the government to use or acquire the patent. Government is empowered to use the invention to mitigate the crisis without even informing the patentee, such an exception is only applicable in the case of 'Extreme Urgency', 'National Emergency' or 'Non-Commercial Use'.

The Central Government can even use the invention either before or after the Patent is granted. It can further authorise any person to use, exercise or to import the invention. And such authority given by the Government includes right to sell, on non-commercial basis, the goods, and the purchaser of the goods so sold, shall have the rights to sell the goods as if the Central Government itself or any person authorised by the Central Government were the patentee itself. The Central Government is also empowered to use the patent without even informing the patent holder if it is satisfied that there is a case of "Extreme Urgency"²⁹.

Apart from the above mentioned provisions, the Central Government is also empowered to acquire the patent instead of merely using it. If it is satisfied that it is necessary for the Central Government to acquire the invention of the applicant or patentee, then it can do so for a '**Public Purpose**' and all the rights will be transferred and be vested into the Central Government or any other person authorised by them³⁰. It should be noted here that the term 'Public Purpose' is nowhere defined under the Act, and thus in a situation where 'public purpose' is to be interpreted, Reference should be made to the Exception under Article 300A of the Indian Constitution. Though Article 300A provides for the Constitutional Rights against the property of any person, it is subjected to reasonable restriction which may include 'Public Purpose'. Public Purpose can be defined as a purpose affecting the interest of the general public and therefore the welfare state is given the power to acquire the property, such deprivation should be reasonable and adequate compensation has to be paid to the owner of the property³¹. Therefore, right to property is not an absolute right, and it not only includes tangible property but also intangible property³².

In case the Government is acquiring the patent under Section 92 of the Patent Act, the inventor is entitled to get 'adequate compensation (including the royalty which will be fixed after negotiation between the Government and the Patent holder)'. The Patent Act upholds the right of the patent holder by giving the High Court the power to settle the dispute between the Government and the Patent Holder in case of a conflict pertaining to the 'adequate compensation' which is to be paid to the Patent Holder³³.

Instead of a Compulsory Licensing, the Government can also adopt a model which is similar to the Bayh Dole Act. The Act states that the government is empowered to acquire the Patent which they have funded³⁴. The main objective of protecting the patent is to make sure that the Patent holder is in the position to recover all the expenditure spent to create the Intellectual Property. Though the Indian Patent System doesn't have an express provision similar to that of the Bayh Dole Act, the Central Government can provide funds to the Pharmaceutical Corporation to invent and manufacture the drug. Such Act will not only encourage the Pharmaceutical Company to invent a drug, but the act of Compulsorily Licensing of drugs will have more legitimacy.

²⁹ Patent Act 1970 § 100.

³⁰ Patent Act 1970 § 102.

³¹ R.C Cooper v. Union of India, AIR 1970 SC 564.

³² V K AHUJA, LAW RELATING TO INTELLECTUAL PROPERTY RIGHTS 5 (3rd ed., 2019).

³³ Patent Act 1970 § 103.

³⁴ Vipin Mathur, Dr. B.P. Nagori and Dr. Mahendra Tiwari, *COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA: A RESEARCH STUDY*, 3 EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH 532, 541 (2016).

Conclusion:

The concept of Compulsory Licensing is perhaps considered to be the most stringent exception to the exclusive rights granted to the Patent holder and hence it is criticised by many Pharmaceutical Companies who have spent millions of dollars for Research and Development of life saving drugs. The United State Trade Representative (USTR) Special 301 report has put India on 'priority watch list' for its implementation on Compulsory Licensing³⁵. Considering the criticism for Compulsory Licensing, compulsory licensing should be granted only in an extremely grave situation, thereby maintaining the balance between Public Interest and Patentee Rights³⁶.

With over million active cases and thousands of cases adding up every day, the vaccine, its affordability and accessibility is a need of an hour. The past experience of Compulsory Licensing in many countries has proved to be a success story during extreme urgency of drug; likewise, given the gravity of the current situation, Compulsory Licensing will play an important role. The Constitutional value of India makes it a 'welfare state', thus India is likely to invoke the clause of compulsory licensing for making the drug affordable and accessible in the future in the interest of Public.



³⁵ USTR Releases Annual Special 301 Report on Intellectual Property Protection and Review of Notorious Markets for Counterfeiting and Piracy, UNITED STATES TRADE REPRESENTATIVE (Aug. 26, 2020, 8:34 PM), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/april/ustr-releases-annual-special-301-report-intellectual-property-protection-and-review-notorious>.

³⁶ Biplab Kumar Lenin and Harsh Rohatgi, *Exception and Limitation of Patent Rights and its Enforcement in India* 297, 302 (2015).