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GRANTING OF COMPULSORY LICENSES AMIDST COVID-19 PANDEMIC: A NECESSITY OR THREAT?

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ABSTRACT

The outbreak of Coronavirus has ripped the world apart causing havoc in the public. Many laboratories and pharmaceutical companies around the world are striving to find a treatment for COVID-19 and more clinical trials are conducted for the same. On the other hand, some of the countries have already started working on the legal mechanisms to acquire the treatment or vaccine through compulsory licensing affordably and easily without any intellectual property right constraints. The ongoing debate concerning compulsory licensing during the COVID-19 pandemic led to the fundamental issues discussed in the article. The concept of compulsory licensing is accompanied with various stumbling blocks starting with the grounds under which it can be given to the legislative framework. For the legality of compulsory licensing, this article explores various international patent regimes for compulsory licensing including the TRIPS agreement and the Doha Declaration. Further, the article provides an introduction to the issues between the capitalist and socialist for the grant of compulsory licensing. It is observed that both the parties have a firm footing and strong contentions in their favour relating to the issuance of compulsory licensing. Primarily, the capitalists emphasize on how intellectual property rights work as an incentive for them whereas as the name suggests, the socialists or the government focuses on the social welfare and wellbeing of its citizens. This article also discusses the innovative initiatives and measures taken by various organisations and countries amidst the coronavirus outbreak. The article concludes with the view that the public welfare and wellbeing is of utmost priority and not only effective steps must be taken to provide accessible

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and affordable medicine/vaccine to the people during these uncertain times but also the interest of pharmaceutical companies should not be totally ignored.

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I. INTRODUCTION

The spread of coronavirus has abruptly brought the world to a halt. The last few months have been entirely unexpected; a panic caused worldwide by curfew announcements, hundreds of people were seen fighting for the last piece of food available inside the supermarkets and grocery stores; dearth of medical supplies and thousands of people infected and dead by a virus that was discovered nearly nine months ago. Moreover, this pandemic has hit the economy badly; millions of workers and employees have been furloughed, businesses and small organisations have shut down, many big companies have closed their outlets and some of them have declared themselves bankrupt. But one of the sectors which have not been affected during these uncertain times, is the pharmaceutical sector. Since the discovery of the virus, the pharmaceutical companies are racing to develop a vaccine at the earliest. With the surge in COVID-19 cases, the developing countries will require a considerable amount of vaccines once developed.

One of the risks to pharmaceutical companies and researchers, as the research on coronavirus progress, is the concept of Compulsory Licensing. Considering the seriousness of the health issues and the economic pressure, it is no surprise that the issue of compulsory licensing has come to light in a number of countries. The concern of almost every country is to ensure that the exclusive rights do not deprive them from producing enough medicine to curb the virus and provide the vaccine to all the people at a reasonable rate.

Compulsory Licensing refers to the grant of patent or copyright licenses by the government to the companies or individuals other than the owner without his consent, for the said purpose of substantial utilisation of the protected right. It is one of the relaxations mentioned in the World Trade Organisation's (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

In this article, we shall be focusing on the concept of the international patent regime for compulsory licensing, contrasting perspectives of capitalists and socialists and initiatives taken to battle against COVID-19.

II. INTERNATIONAL PATENT REGIME FOR COMPULSORY LICENSING

In 1995, the adoption of the WTO's TRIPS agreement along with the 2001 WTO's Doha Declaration on the TRIPS Agreement brought significant changes at a global standard, since most countries are members of the WTO. These agreements grant all the WTO member countries the right to issue compulsory licenses on patented medicines and other health related inventions.

A. TRIPS AGREEMENT

The Annex 1C of the Marrakesh Agreement[1] provides for the TRIPS Agreement, establishing the WTO, signed in Marrakesh, Morocco in 1994. The TRIPS Agreement provides an international law framework for the member countries of WTO to grant special compulsory licences exclusively for the production and export affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities.[2] The international community has reacted positively to the TRIPS Agreement. Prior to the adoption of the TRIPS agreement, most of the countries did not issue or implement product patents or limited patent holders' rights on essential goods such as medicines, since patents on such types of goods were widely considered against the public interest.

In 2001, WTO declared that all the members of WTO have the right to grant compulsory licences and have the freedom to determine the grounds upon which the compulsory licenses are granted.[3] Further, WTO has also affirmed that situations relating to public health crises, such as HIV/AIDS, malaria, tuberculosis and other epidemics can qualify as situations of national emergency or extreme urgency.

The expression "compulsory licensing" is not explicitly used in the TRIPS agreement. Conversely, the phrase "other use without authorization of the right hold" is used in the title of Article 31 of the agreement.[4] The compulsory licensing or government use of the patent without the authorization of its right holder can only be done within the conditions mentioned in Article

[1] Marrakesh Agreement Establishing the World Trade Organization, Apr.15. 1994. 1867 U.N.T.S. 154.
[2]TRIPS Agreement: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M.1197 (1994).
[3] Declaration on the TRIPS agreement and public health, WT/MIN (01)/DEC/2 (adopted Nov. 14, 2001).
[4]TRIPS Agreement, *supra* note 2, art. 31.

31 to protect the well-founded interests of the right holder. It does speak about the situations like national emergencies, extreme urgency and anti-competitive practices as grounds, when some of the common requirements for compulsory licensing do not appertain, such as the necessity to seek a voluntary license first.[5] Article 27 of the TRIPS agreement provides a government to issue a compulsory license to a third party for the industrial production and importing of essential drugs in the situations of mortal-peril.[6] Also, Article 7 of the agreement states that the protection and enforcement of the intellectual property rights must contribute to the promotion of technological innovation in a manner favourable to the social and economic welfare, as well as to balance rights and obligations.[7]

However, since the ratification of TRIPS in 1995, the developing countries have been hesitant of their right to promote essential medicines. There were several conflicting notions as to how the developing countries would be able to exercise their rights relating to pharmaceutical patents. All the African members of the WTO were among the members pressing for elucidation. A significant part of this was resolved at the Doha Ministerial Conference in November 2001.[8]

B. THE PITH OF DOHA DECLARATION

In November 2001, the WTO'S Fourth Ministerial Conference took place in Doha, Qatar. The Doha Ministerial Declaration emphasized the importance of implementation and interpretation of the TRIPS agreement in a way that would promote public health- by promoting the access of the subsisting medicines and invention of novel medicines.[9] Therefore, an independent declaration on TRIPS and public health was adopted.

The question as to provide supplementary flexibility to the compulsory licensing, so that the countries which lack industrial production of the pharmaceuticals can receive the stocks of copies of patented drugs from other countries was put to further discussion before the TRIPS Council. This matter in most is recognized as the "Paragraph 6" issue as it is embodied under that paragraph in the Doha Declaration on TRIPS and public health. In 2003, the TRIPS Council announced its decision regarding the implementation of Paragraph 6 and reached on a temporary waiver.

[5] Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and Exceptions, WTO (Sept. 2006).
[6] TRIPS Agreement, *supra* note 2, art. 21.
[7] TRIPS Agreement, *supra* note 2, art. 7.
[8] The Doha Round, World Trade Organization (WTO) Fourth Ministerial Conference in Doha, Nov. 2001.
[9] Doha WTO Ministerial Declaration 2001, WT/MIN (01)/DEC/1 (adopted Nov. 14, 2001).

Article 31(f) of the TRIPS agreement provides that a compulsory license can be exercised principally for the supply of the domestic market of the member country.[10] The WTO General Council in August 2003, announced a waiver to the obligations of exporting countries under Article 31(f) in respect to the granting of compulsory license to a patented drug and export to an eligible importing member country under the mentioned terms.[11] Since then, the TRIPS Council has been reviewing the Paragraph 6 system annually and submits the reports to the WTO General Council regarding the implementation and usage of the system. Therefore, Paragraph 6 of the Doha Declaration was an attempt to ease the access of affordable medicines and to provide suppleness to the restrictive provisions of TRIPS agreement.

III. CONTRASTING PERSPECTIVES OF CAPITALISTS AND SOCIALISTS

In today's global economy, where there is no water-tight division, there always exist conflicts between the government and business or companies. There has been one or the other governmental procedural work from the beginning of the business to its winding up, giving certain powers to the government over them. Likewise, the TRIPS agreement empowers the government to grant compulsory licensing to innovative and patent protected products in the circumstances specified by the countries in their national or local laws.

Since the WHO declared coronavirus outbreak as a pandemic[12], the pharmaceutical companies have upsurge in developing vaccines and medicines to deal with it. The most common discord in the innovation policy is the strife between the company's incentive to innovation and their intellectual property rights and the government's liability to provide accessible and affordable products to the public during the times when the whole world and especially the middle and low- income households are struggling for their basic needs. The pharmaceutical companies are the major contributors in the health care sector. They are incentivised towards inventing new forms of medicines and vaccines through intellectual property rights protected by the World Intellectual Property Organisation (WIPO) and administered by laws of the respective countries.

[10]TRIPS Agreement, *supra* note 2, art. 31(f).
[11]Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WT/L/540 and Corr. 1 (adopted Sept. 1, 2003).

[12] Tedros Adhanom Ghebreyesus, WHO Director-General, Opening remarks at the media briefing on COVID-19 (March 11, 2020).

The policy makers won't be reluctant to stimulate compulsory licensing in the Intellectual Property (IP) laws but the burden lies in having a provision which gives no scope or little scope for controversy or different interpretation, and operating compulsory licensing in a way that stabilizes the interest of all the parties involved. The challenge is to balance the interest of both the issuing authority, i.e. the government and the patentee.

A. CAPITALIST'S PERSPECTIVE

The role of the government is to take care of all the stakeholders of the society and the pharmaceutical companies majorly contribute to the economy. They work towards providing efficient and effective remedies to the diseases through various vaccines and technologies, especially during major outburst of viruses such as COVID-19. The incentive for the companies in this sector is the intellectual property rights that they get for their hard work and hence their side must be listened to before granting compulsory licensing:

1. High risk and huge cost involved

The research and development based pharmaceutical companies are in an insecure and risky business where their business model basically relies on placing smart bets on imperfect market information.[13] The whole process from understanding a new disease to bringing an effective treatment to the patients is cumbersome and lengthy. Scientists and laboratories work to gather the basic cause of the disease, the potentially affected target, and it takes an average of 10-15 years to produce a new vaccine till it reaches the market.[14] Less than 12% of the drugs that entered clinical trials result in an approved medicine.[15] The clinical trial leaves behind a high percentage of new drugs that fail to reach the market and these imply huge financial losses for the pharmaceutical companies.[16]

In a survey conducted among 10 pharma companies, it was found that the investment costs involved are huge for a new medicine or vaccine, it was estimated to be more than $800 million

[13]Ruth Levine, Alice Albright, *Making Markets for Vaccines: Idea to action,* Report of the Center for Global Development Advance Market Commitment Working Group, 11, (2005).
[14]The Pharmaceutical Company and Global health: Facts and Figures, IFMPA (Nov, 2011) https://www.ifpma.org/wp-content/uploads/2016/01/2011_The_Pharmaceutical_Industry_and_Global_Health_low_ver2.pdf.
[15] Pharmaceutical Research and Manufacturers of America, *2016 biopharmaceutical research industry profile,* (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.
[16]Erika Buonansegna&SørenSalomo& Anja Maier & Jason Li-Ying, *Pharmaceutical new product development: Why do clinical trials fail?,*(2014).

up to the stage of regulatory approval.[17] Here, the companies take huge risks with the high probability of uncertain results and invest a fortune of their money in order to make drugs for public health care.

2. Intellectual Property Rights acts as an incentive

Patents are a form of intellectual property that provides monopoly to the inventor and gives him exclusive right over his property. It allows the patentee to restrict others to commercially exploit his invention for a limited period of time in order to recover the cost of developing the product and then to enjoy the profit from the invention.[18] It means that the invention cannot be commercially used, made, distributed, imported or sold by others without the consent of the patent owner.[19] The patent protection is granted for a limited period of 20 years from the date of filing the application.[20]

The process of developing a drug is timely and expensive, with a risk of failure as mentioned above, the governments are bound to allow the pharmaceutical companies with secured protection rights and higher profit margin than that exist in a competitive system so as to prompt them to take the risks. The protection of intellectual property has empowered the pharmaceutical companies to innovate and develop more than 90% of the drugs available in the world.[21] If there had been no innovation and the rights safeguarding it, there would have been no new vaccines or medicines to cure dengue, malaria, HIV and the other diseases of the world.

The research and development of the pharmaceutical industry has increased because of the existence of property rights in the first place and the threat to use the compulsory license under the TRIPS agreement by the government discourages the patent holders and other companies in the pharmaceutical industry to take the risk and develop a vaccine that costed them a lot of investments. On one hand, the property protection rights incentivise the companies to develop a vaccine and on the other hand, compulsory licensing takes away the liberty from the owners

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[17]Joseph A. DiMasi& Ronald W. Hansen & Henry G. Grabowski, *The price of innovation: new estimates of drug development costs*, JEL 151, (2002).
[18] ACS CHEMISTRY FOR LIFE, *Global Patents: An Introduction to International Intellectual Property*, https://www.acs.org/content/acs/en/acs-webinars/business-entrepreneurship/global-patents.html, (Aug. 14,2020).
[19]WORLD INTELLECTUAL PROPERTY ORGANISATION, *Patents*, https://www.wipo.int/patents/en/#:~:text=A%20patent%20is%20an%20exclusive,public%20in%20a%20patent%20application (Aug. 17, 2020).
[20]*Id.*
[21]Wayne Taylor, *Pharmaceutical Access in Least Developed Countries: On the Ground Barriers and Industry Success*, 8, 10 (2010).

over their property which disheartens the investor and further dampens the investment and the will to research.

3. Varied standards of National Health Emergency causes ambiguity

There is no standardised definition of national health emergency in the international law. Each country has its own definition for the same. Having a common definition among the countries is a difficult task since the countries have their own problems, diseases, and lifestyle. Each country has laid down various criteria for declaring a state emergency in their state. The term "Public Health Emergency of International Concern" (PHEIC) is defined in the International Health Regulations (IHR) (2005) as "*an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response*".[22] The companies are often threatened by the countries to lower the price of their medicine otherwise compulsory license is granted by arguing for national health emergencies.

4. Local company's incompetence to produce the patented vaccine

While granting compulsory licensing, governments primarily focus on the need of emergency and often side-line the fact that compulsory licensing does not produce the anticipated result because of the lack of technical and infrastructure inability of the local factory. The two prominent cases where compulsory licensing was issued but did not turn out in the favour of the Government were in Thailand and Brazil. In January 2007, the Thailand Government issued compulsory licensing to a Thai Government owned producer of medicine. But the quality made by them was so worrisome that Global Fund to fight HIV/AIDS stepped in to contribute but alas it withdrew the fund three years later as the producer was unable to meet World Health Organisation's international quality standards.[23] Later, in the same year, Brazil gave compulsory licensing for a patented AIDS drug named Efavirenz. However, it turned out that the government owned manufacturer, Farraginous, was unable to manufacture the drug due to technical know-how and it took the manufacturer two years to supply the drug in the market.[24]

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[22]WORLD HEALTH ORGANISATION, *WHO Guidance for the use of Annex 2 of the International Health Regulations*, IHR (2010), http://www.who.int/ihr/publications/annex_2_guidance/en/.
[23]K. M. Lybecker and E. Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 JLME 222, (2009).
[24]Eric Bondy and Kamal Saggiz, *Compulsory licensing, price controls, and access to patented foreign products*, JEL 5 (2014).

From both the instances, it is clear that the quality of drugs produced by the local producers were inferior to that of the patent holder. These are the actual ground realities after the issuance of compulsory licensing.

B. SOCIALIST'S PERSPECTIVE

Compulsory licensing is a global mechanism which is crucial to unrestrictive and collaborative research and development and encourages production and supply for leading diagnostics, therapeutics and vaccines. In order to address the unprecedented time of COVID-19 pandemic, collaboration at global level is required to promote developing and least developing countries to expand testing capacity and facilitate affordable access to certified treatments and vaccines.

The following are some of the favourable outcomes of compulsory licensing:

1. Compulsory licensing as a way out to ease the access of essential pharmaceuticals in developing and least developing countries.

Compulsory licensing allows countries to subjugate patent restrictions to ensure availability of affordable generic versions of essential drugs when the extreme situations such as epidemic or pandemic like COVID-19 befall. It helps in ensuring the availability of the life-saving medications by allowing the copies of medication to arrive in the market external to the normal distribution channels.

Patents, essentially the pharmaceuticals have been difficult to obtain for the developing and the least developing countries as they lack their own industrial infrastructure for the production. The data available shows that the market in the developing countries shares less than 20% of the total profits gained by the pharmaceutical companies.[25] Therefore, in such countries, the imminence of compulsory licensing supports the negotiations for a reasonable price of the essential drug satisfactory to both the patent owner and the government.[26] It should be taken into consideration that the prices of the essential pharmaceutical products are fixed looking into the reality of the market in the developed economies. Therefore, compulsory licensing carries off undeniable social benefits, that is easier access to essential pharmaceutical products.

[25] Alberto do Amaral Junior, *Compulsory Licensing and Access to Medicine in Developing Countries*, https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1046&context=yls_sela#:~:text=Greater%20use%20of%20compulsory%20licensing,specific%20needs%20of%20each%20market.

[26] Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments*, VOL. 3, NO. 3, INTERNATIONAL JOURNAL OF SOCIAL SCIENCE AND HUMANITY, (May, 2003), http://www.ijssh.org/papers/239-D00013.pdf.

Relatedly, in 2007, Brazil granted its first compulsory license to manufacture and import a first line HIV medicine and became the first developing country to ensure the global access to Standard antiretroviral therapy (ART) through its National AIDS Program (NAP).[27] Through compulsory licensing of the HIV drug "efavirenz", Brazilian Ministry was able to provide discounts between 50 to 60% to its people.[28] The positive results of this compulsory licensing programme in Brazil have gained universal recognition. It demonstrated that the issues related to health-care should not be commercialized and that the advancement in the research and development must be available to all.

With the increasing reliance on compulsory licensing, the developing and the least developing countries have started to lower the prices below the patent holder would have charged, hence potentially saving lives and improving public health of millions of people.[29]

2. Compulsory licensing helps in safeguarding the public interest

Public interest has been an extraordinary but incessant crucial factor for issuing of compulsory licenses. Compulsory licensing should be imposed in circumstances where the irrepressible adversity caused to the public outweighs the ensured benefits to patent rights holders.

Compulsory licenses issued on the basis of public interest are equivalent to those based on the adequate supply theory, but are only issued to govern the essential life-saving products vital to the public. By enervating intellectual property rights on a limited scale, governments can ensure that the highest-value users are made available patents so that they can help in securing proficient societal innovation and progress. Hence, when the original patent right holders fail to commercialise their patents after a justifiable period of time, such patents shall be subject to the mechanism under compulsory licensing for the benefit and welfare of the society.[30]

One good example can be observed in Japan, compulsory licensing is granted when a patent has not been functioned for at least three years and where the functioning is particularly crucial for

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[27]Dirceu B. Greco & Mariangela Simao, *Brazilian Policy of Universal access to AIDS treatment: sustainability challenges and perspectives*,LIPPINCOTT WILLIAMS & WILKINS, (2007), https://www.who.int/hiv/events/artprevention/greco.pdf.

[28]*Brazil:10 Years of a Compulsory License on HIV Drug Efavirenz*,MAKE MEDICINES AFFORDABLE, (July 16, 2020, 15:18 PM), https://makemedicinesaffordable.org/brazil-10-years-of-a-compulsory-license-on-hiv-drug-efavirenz/.

[29] Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines while Minimizing Investment Side Effects*, VOL. 37 ISSUE 2, JOURNAL OF LAW, MEDICINE & ETHICS, (June 1, 2009).

[30] Neil S. Tyler, *Patent Nonuse and Technology Suppression: The Use of Compulsory Licensing to Promote Progress*, (Aug. 17, 2020, 18:45 PM), https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1548&context=penn_law_review.

the public interest.[31] In the United Kingdom, public interest is recognized in the low-priced supply of the goods required in the production of food, medicines and surgical equipment.[32] Also, such licenses are permitted in the United Kingdom, when the original patent right-holder refuses to license its patent on reasonable terms or the refusal to patent license prejudices "*the establishment of development of commercial or industrial activities in the UK*".[33] Likewise, in Switzerland, lowering the prices of any patented good may righteously support an issuance of compulsory license.[34]

3. Compulsory licensing inevitably necessary to deal with the situations of patent tyrannism

Patent tyrannism occurs through the strategic decisions made by the original patent holders, companies which are threatened by the new patented technologies which intend to block their entry into the market by dominating through their patent rights. In such a situation, the products would not only be suppressed or prorogued for them to come to the market, but would be presumably offered at higher competitive prices. As a result, welfare losses are incurred by the consumers when the original patent right holders suppress beneficial patents and overlook to use them on their terms. Patent tyrannism can obstruct or prevent progressive innovations and upgrades to original inventions that could contrary lead to prominent discoveries and developments.[35] Therefore, the major challenge posed by patent tyrannism is to fashion a pragmatic deterrence that would suit the realities of the present patent system.[36]

Compulsory licensing becomes ineluctable to deal with the circumstances of patent tyrannism. Such a mandate mechanism would gently reduce the incidents of patent tyrannism and convince companies to overcome the disputes between freezing patents.[37] With the development of an effective approach of compulsory licensing, governments of the developing and least developing countries may pressurize the patent-right holders to work the patent to optimum national

[31]Tokyo Patent Act, 1959, art. 83, para. 1, art. 93, para. 1, No. 141,1959 (Japan), www.wipo.int/wipolex/en/text.jsp?file_id=299486.
[32]Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*,VOL 8 ISSUE 3, NORTH-WESTERN JOURNAL OF INTERNATIONAL LAW & BUSINESS, (Winter 1988), https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1244&context=njilb.
[33] Patents Act, 1977, c. 37, § 48(a)(3)(d), (United Kingdom)
[34]Cole M. Fauver, *supra* note 32.
[35]Neil S. Tyler, *supra* note 30.
[36]Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, VOL.15 NO. 2, HARVARD JOURNAL OF LAW & TECHNOLOGY, (Spring 2002), http://jolt.law.harvard.edu/articles/pdf/v15/15HarvJLTech389.pdf.
[37] *Id*. at 65.

advantage. The sheer threat of compulsory licensing for non-usage would likely decrease the prevalence of patent tyrannism and inactivity of persuading entities to overcome disputes and grant licenses based on their agreed prices.[38] Patent right holders who are unwilling to procure the necessary resources together to bring the essential products to market or fault to find a suited licensee shall be subject to compulsory licensing.

4. Opposition of compulsory licensing may awaken the thoughts of "neo-colonialism"

The general critiques, sometimes accuse the current system of intellectual property rights as a proposition of one-sided endeavour. The developed countries which are able to prioritize patent discoveries and innovations are capable to financially support and develop a research infrastructure and therefore, benefit from robust patent protections.[39] However, the countries which lack these characteristics are not benefited thereby awakening the thought of neo-colonialism. Compulsory licensing provides a mid-way between the needs and developments of both: the developed and the developing countries. The opposition of compulsory licensing by the developed countries may raise the ideas of "neo-colonialism" as patent protection anomalously favours the developed countries as the developing or least developing countries have much lesser patents to guard.[40]

IV. INITIATIVES TAKEN AMIDST COVID-19 PANDEMIC

There have been above forty-two million cases of COVID-19 across the world as of 25th October, 2020.[41] The virus is increasing at an alarming rate and the WHO has warned of a potential uncontrolled resurgence in COVID-19 because of the premature lifting of social distancing.[42] There have been some initiatives that are being taken globally by various

[38]Eric Bond & Kamal Saggi, *Compulsory Licensing, Price Controls, and Access to Patented Foreign Products*, (Vanderbilt Univ. Dep't of Econ., Working Paper No. 12-00006, 2012).
[39]Jennifer Bjornberg, *Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation*, VOL. 27 ISSUE 1, NORTH-WESTERN JOURNAL OF INTERNATIONAL LAW & BUSINESS, (Fall 2006), https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1646&context=njilb.
[40] Sudhan R. Bagri &Nishtha Tiwari, *Compulsory Licensing in Relation to Pharmaceutical Sector in India*, VOL. 8 ISSUE 1, INTERNATIONAL JOURNAL OF INTELLECTUAL PROPERTY RIGHTS (IJIPR), (Jan-June, 2017), https://www.iaeme.com/MasterAdmin/uploadfolder/IJIPR_08_01_001/IJIPR_08_01_001.pdf.
[41]WORLD HEALTH ORGANISATION, *WHO Coronavirus Disease (COVID-19) Dashboard*, https://covid19.who.int/ (Oct. 25, 2020).
[42] WORLD HEALTH ORGANISATION, *Coronavirus Disease 2019 (COVID-19) Situation Report)-91*https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200420-sitrep-91-COVID-19.pdf?sfvrsn=fcf0670b_4(Sept. 04, 2020).

organisations in order to make the COVID-19 vaccine available to all. Firstly, the WHO, in May 2020, launched the COVID-19 Technology Access Pool (C-TAP) to assemble in one place all the pledges of commitment made under the Solidarity Call to Action to share the COVID-19 health related technology, knowledge, data and intellectual property.[43] Secondly, COVAX is a global collaboration co-led by Gavi, CEPI and WHO and it is working in partnership with developing and developed countries vaccine manufacturers.[44] It is aimed at speeding up the development of COVID-19 vaccines and treatment and to provide fair and equitable access to each country under the existing patent rules.[45] Till, 24th August, 2020, 80 countries submitted expressions of interest to protect their population as well as of other 90 lower income countries.[46] These 80 self-financing countries along with Gavi will share the financial risk relating to the vaccine development.

The Coalition of Epidemic Preparedness Innovations (CEPI) is an innovative global partnership between public bodies, private pharmaceutical companies, philanthropic and civil organisations to develop vaccines to stop future epidemics.[47] It was launched by the World Economic Forum in 2017. Gavi is a relatively old partnership, launched in 2010 between WHO, UNICEF, the World Bank and the Bill and Melinda Gates Foundation to make vaccines available among them.[48]

Every nation is still looking for cures and ways to make them accessible and affordable for all. One of the ways to achieve this is by granting compulsory licensing and a few countries have already declared compulsory licensing as a part of their response to deal with the virus. In March 2020, Israel issued compulsory licensing for the import of generic versions of AbbVie's Kaletra from India for the purpose of treating the patients suffering from coronavirus.[49] It has

[43]WORLD HEALTH ORGANISATION, *COVID-19 Technology Access Pool*https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/COVID-19-technology-access-pool (Sept. 04, 2020).
[44] WORLD HEALTH ORGANISATION, *COVAX: Working for Global Equitable Access to COVID-19*https://www.who.int/initiatives/act-accelerator/covax#:~:text=COVAX%20is%20co%2Dled%20by,every%20country%20in%20the%20world (Sept. 05, 2020).
[45] *Id.*
[46]WORLD HEALTH ORGANISATION, *172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility*
https://www.who.int/news-room/detail/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-COVID-19-vaccine-global-access-facility (Sept. 05, 2020).
[47]CEPI, https://cepi.net/about/whoweare/ (Sept. 06, 2020).
[48]GAVI, https://www.gavi.org/our-alliance/about (Sept. 06, 2020).
[49]Francois Pochart, Mathilde Rauline, Océane de La Verteville, *Compulsory Licensing granted by public authorities : an application in the COVID-19 crises in France?*, KLUWER PATENT BLOG (Sept. 08, 2020, 08:43 PM), http://patentblog.kluweriplaw.com/.

also become the first country where compulsory licensing has been granted with regards to COVID-19.[50]

Also, to address COVID-19, some countries such as Canada, Ecuador and Chile have laid down legal groundwork for the issuance of compulsory licensing. Legislature in Canada amended the Canada Patent Act due to the current COVID-19 Emergency Response Act in order to allow for a speedier process for granting compulsory licensing on the public health grounds. In Chile, a resolution has been passed which states that COVID-19 is a sufficient ground to grant compulsory licensing for the affordable and accessible use of the vaccines and technologies related to it.[51] Similarly, a resolution has been passed in Ecuador which requires the President and the health Minister to use compulsory licensing to provide for free and accessible treatments, diagnostics and preventive technologies.[52]

The COVID-19 vaccines are still either under development or some have been to the clinical trial stage. Before such a vaccine is available which works for the COVID-19 patients, it is important for the countries to take the appropriate legislative steps to prepare as quickly as possible.

V. CONCLUSION

The unprecedented situation meted out by the novel coronavirus has represented a global challenge to crucial security interests of all countries. The Constitution of the WHO states that "*the health of people is fundamental to the attainment of peace and security and is dependent upon the fullest cooperation of individuals and states*".[53]

Access to generic medicines, vaccines, diagnostics and medical apparatus and resources to produce them are all inevitable to battle COVID-19. However, it must be taken care that any trading or commercial interests backed by the ownership of the intellectual property rights on those essential technologies must not supersede over saving lives and safeguarding human

[50] *Id.*
[51] Hilary Wong, *The case for Compulsory Licensing during COVID-19*, 10 J. GLOB. HEALTH, 3, (2020).
[52] *Id.* at 4.
[53] WORLD HEALTH ORGANIZATION (WHO). CONST., Preamble, https://www.afro.who.int/publications/constitution-world-health-organization.

rights. Nevertheless, sometimes this premise is overlooked where disequilibria in the development and discrimination are considered to be normal facts.

In this sensitive situation of COVID-19 pandemic, urgent need for global collaboration has arisen. With the help of a powerful mechanism like compulsory licensing, insufficient supplies of affordable generic medicines and procedures as well as prevention of expensive drug prices can be successfully palliated. The rewards guaranteed by the patent protection system are vital to support the constant innovations, however, exception lies under compulsory licensing for public health emergencies such as the present COVID-19 pandemic. Regardless, it also has to be ensured that the patent right holder is satisfactorily compensated for the efforts and hard work that has been put in developing such a medicine/vaccine, so that the innovations and further research is not discouraged. The fact that patent protection is an important incentive for researchers and innovators to produce inventions should not be ignored.

Therefore, in such a challenging situation, every other mankind endeavours, must be subjected to the necessity of preserving and safeguarding human life. The resource deficit in addressing the health challenges is enormous and inequality existing in health issues can be termed as the most intolerable kind of inequity. Therefore, it is a principal matter to remodel the world, where the principles behind the protection of intellectual property rights are well balanced with the public welfare with mechanisms such as compulsory licensing.