PATENTS AND PANDEMIC VIS-A-VIS IMPACT ON COMPULSORY LICENSE IN INDIA

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ABSTRACT

A sudden outbreak of coronavirus has put the world at halt. There has been a continuous debate amongst legal scholars and foreign governments to suspend the patent rights amidst Pandemic. According to article 7 of TRIPS agreement, the objective of an intellectual property regulation is to bring a balance of rights and obligations. One of the many mechanisms is compulsory license under patents. India is a member of the TRIPS agreement. Compulsory license as per the Indian Patent Act,1970, are permissions given to a third party by Controller General of Patents to use, make, sell a product or use a process that has been patented to make a certain product. As declared by World Health Organization that "COVID-19 is a pandemic", India is willing to use compulsory license enshrined under the national legislation, on the other hand, last year India along with South Africa proposed a temporary waiver of intellectual property rights. The patents waiver if approved would allow developing nations to cope up with Pandemic. The article will discuss in brief Doha Declaration and TRIPS agreement on compulsory license. The article will analyze the origin and history of compulsory license in India. The article will study the impact of COVID-19 on pharmaceutical industry and highlight the contradictions involving TRIPS flexibilities and compulsory license in India.

Keywords : Patents, compulsory license , TRIPS, waiver.

Introduction

The pandemic has pressurized the government worldwide to ensure access to vaccines and maintenance of public health safeguards. There should be exemption given in favor of developing countries as the patent holders enjoy monopoly rights, on the other hand those who favor patent protection rely on the incentive theory of intellectual property rights and say that if there is restriction upon the exercise of patent rights, it will decline the urge to create more or will curb innovation in pharmaceutical sector. If a pharmaceutical company is successful in making a vaccine for the coronavirus, it would definitely amount to an invention and will be eligible for patent protection. All the inventors or scientists around the world who are making a vaccine would in all probability apply for a patent and will get a time bound exclusive right to exploit the drug and stop others from further exploitation.

But the question is whether compulsory license is the answer to access of vaccines? The government will grant patent for inventions which pass the trinity requirement of Novelty, Invention: non-obviousness and Inventive step. A patent will give an exclusive right to an inventor.[1]A patent provides an exclusive right to the inventor to prevent the make or use or sell the invention. In a situation where the high price of patented drugs lead to unaffordability and forms a restriction on access of medicines to poor people, Many government opt for a Compulsory license . A compulsory license simply a mechanism to regulate the misuse of patent rights. The government through compulsory license would permit a third party to make a patented product or process without the prior permission of the patent holder.

TRIPS agreement on compulsory license and Doha declaration

The TRIPS agreement seeks to balance the strong patent rights and attempts to promote public health which is visible in Article 8(1) and Article 27(2) . Article 8(1) which says that the public health is a concern and it allows the member states to adopt measures necessary in order to protect public health, nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided it is consistent with the provisions of the agreement. Article 27(2) has excluded the patentability of inventions that are necessary to protect the ordre public or morality which includes the inventions that will also protect human life or health. The TRIPS agreement aims for providing adequate safeguards for

[1] Sudhi Ranjan Bagri & Nishtha Tiwari , *Compulsory licensing in relation to Pharmaceutical sector in India* International Journal of Intellectual property rights 8(1) 1-4 (2017) (July 7,2021,) http://www.iaeme.com/MasterAdmin/uploadfolder/IJIPR_08_01_001/IJIPR_08_01_001.pdf

IPR in line with the priorities of the developing countries concerns on public health and the dissemination of innovation in the world. Article 31 of TRIPS agreement has allowed the member states the right to issue compulsory license subject to some conditions. However in a situation of a public emergency, extreme urgency , all the pre-conditions can be waived off. It is important to note that TRIPS agreement did not define what amounts to "national emergency" or "extreme urgency". Article 31(f) on the other hand is limited the benefits of compulsory licensing to only those members who have sufficient manufacturing capacity and technical know -how and it allows the licensees to only supply the products to their country's domestic market only.[2]

Developing countries raised their issues on interpretations of TRIPS flexibilities and its relation with access to medicines. WTO issued a declaration on TRIPS and public health in Doha, Qatar,2001. The paragraph four of the Doha declaration stated that TRIPS should be interpreted and implemented in such a manner which is supportive of WTO's member's right to protect public health and in particular promotion of access to medicines for all and that the flexibilities were provided. The Doha declaration reaffirmed that each country will be able to determine the circumstances for granting the compulsory license , the circumstances that constitute a national emergency and can also establish its own policy on exhaustion. The Doha declaration primarily created a problem done by Article 31(f) which restricted compulsory licenses to manufacturing goods predominantly in the domestic country itself. On August 30,2003 the WTO General Council reached a solution to the issue and created a waiver for Article 31(f) of TRIPS through which the country which lacks manufacturing capabilities can import a specific pharmaceutical product.[3]The Doha declaration clarified the ambiguity of TRIPS provisions. The declaration has allowed each member to grant compulsory licenses and the right to lay down the grounds on which those licenses will be issued, and would allow the states to decide on their own what would amount to a national emergency or extreme urgency, public health crisis. However, nations which have no manufacturing capacities in making an effective use of compulsory license, it would allow the waiver of the domestic market restriction. The Doha declaration highly stressed on the importance of interpretation of TRIPS agreement in order to promote and support public health by promoting both access to the existing medicines and the creation of the new medicines as well. It is crucial to note that the Doha declaration has adopted a

[2] Sapna Kumar , *Compulsory licensing of Patents during Pandemic* University of Houston Law centre 5-6 (2021) (July 9 ,2021) https://dx.doi.org/10.2139/ssrn.3636456

[3] World Health Organization *The Doha Declaration on TRIPS agreement and public health* (July 8,2021, 8:00PM) https://www.who.int/medicines/areas/policy/doha_declaration/en/

positive approach by prioritizing the public health over intellectual property rights. It has recognized a need to strengthen the system of compulsory licenses in the developing or least developed countries as they lack proper infrastructure to fulfill the needs of their people.[4]

COVID-19 and Pharmaceutical Industry

COVID-19 has affected the supply chain of the potential vaccines due to an unprecedented economic and health distress around the world. The immediate impact of India' s lockdown which imposed severe restrictions on the mobility of people which suspended all the commercial and social activities which would require people to come and work together. The threat of compulsory licensing is a useful tool in encouraging patent holder participation in voluntary agreements or even in encouraging patent holders to voluntary pledge /share their IP to even broader IP initiatives or IP pools set up in the time of a crisis[5]. As per the TRIPS waiver proposal , the WTO will allow all members countries to choose to neither grant or enforce patents and other intellectual property related to COVID-19 drugs, vaccines and medical products till the time pandemic exists. The countries explained that the process could be time consuming and complicated as it offers a country-by-country, case-by-case and product-by-product solution. The legal validity of the authorized compulsory license may also be challenged, hindering expeditious supply, the submission added. Covid-19 has mounted pressure on the pharmaceutical industry but also on the government to provide an effective mechanism to ensure that an optimum number of tests and vaccines are effectively delivered with subsidized price. As reflected in news that there was shortage of personal protection equipment kits, N95 masks, Hand sanitizers.[6]

COVID-19 is a golden opportunity for pharmaceutical industry as there will be rise of demand for prescription medicines, vaccines and medical devices. There has been increased hospitalization, incidence of COVID-19 elated pneumonia and increased demand of assigning ventilators, contributed to related prescription medicine shortages. Induced demand for the sake of stocking medication by the public which is panic buying may have caused periodic shortage in the market, specifically for chronic diseases. The regulations have included the fast-track approvals for COVID-19 related treatments, compulsory licensing for potential COVID-19

[4] Dina Halaijan, *Inadequacy of TRIPS and Compulsory license : Why broad compulsory licensing is not a viable solution to the access of medicine programme* Brooklyn. Intern'l. J.L. 38(3)1199-1201(2013)
[5] World Trade Organization *The TRIPS Agreement and COVID-19* (July 9 , 2021, 6:00PM) https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf
[6] The Wire *Countries are adapting Intellectual Property laws to prioritize health during COVID-19* (July 11, 2021, 8 :00pm) https://thewire.in/trade/intellectual-property-laws-covid-19

treatments, however this is in the context of those countries who are world trade organizations members and are following intellectual property laws, more regulations to enhance importation in order to maintain integration of supply chain.[7]

There has been shift of communication and promotions to remote interactions through tele communication and tele health: In both global and local levels , due to the social distancing precautions, marketing and promotions of health care products to providers have also been shifted from face to face to remote interactions. There has been a dilemma on the pseudo-researches and industrial investments on medicines which might be identified as non-effective in the near future, which may eventually pose a considerable burden on the health system as well. There will be approval delays in moving towards self-sufficiency in pharma -production supply chain , industry growth slow-down and possible trend changes in consumption that could be seen as long term impacts of COVID-19 on health and pharmaceutical market. As countries were under pressure of the crisis and their priority being COVID-19 management have caused economic crisis, delay in registrations and reimbursement decisions.

Due to potential shortages as a consequence of export ban in India and China even made governments of many countries to consider self-sufficiency in supply chain and they have announced regulations to avoid shortages in such a public health crisis. Coronavirus pandemic has also resulted in slow-downs of many countries which has affected their economic growth. [8]This slow down might be for the reason that there is surge in the entry of new medications to deal with the Pandemic. One of the long-term effects of growing clinical research related to the current pandemic is the use of poorly evidence centered therapies. In confirming the proposed therapies, the long-term clinical effects of the use of these strategies in the coming years should be examined and healthcare providers should make informed decisions on using off-label therapies in clinical practice. Changing habits related to consumption and refilling prescriptions specifically in chronic disease therapeutic areas which might happen and may also be further affected by emerging tele-medicines. public is concerned with personal hygiene maintenance; using mainly nose/mouth protection, anti-infections material for environment and clothing and hand sanitizers. Pharmaceutical companies are trying to adjust their operations with respect to

[7] Mariana Mazzucato, *Capitalism after the Pandemic : Getting recovery Right*, 99 Foreign Aff. 50. (2020)
[8] Aisling McMahon (2020) *Global equitable access to vaccines, medicines and diagnostics for COVID-19 : The role of patents as private governance* Journal of Medical Ethics 47(3) ,142-145(2020), (July 12,2021) https://jme.bmj.com/content/47/3/142

supply planning, clinical trials, product launches and the engagement of physicians and treatment of patients.[9]

Compulsory license under Indian patent law :

Patent laws in India have evolved over the years. Lord Macaulay's Law Commission recommends that there should be law on patents in 1856, it was encouraged to encourage people in creation of new inventions. Several amendments. were made and then in 1911, Indian Patents and Designs Act. The Act provided for the grant of license to curb the misuse of patent rights. It allowed individuals to apply for a compulsory license after three years of its registration on the fulfillment of certain conditions given in the statute. After Independence, The government of India realized the need to reform of patent laws and Tek Chand Committee was appointed to examine and improve the Patent laws. The committee concentrated on inventions related to food and medicine. The committee emphasized on the grant of the compulsory license. To bring further changes in the practical application of compulsory license in emergency situations , Ayyangar Committee was appointed.[10]

Compulsory license is regulated under the present legislation Patents Act,1970 . Compulsory licenses are defined as "authorizations granting permission to a third party to use, make or sell an invention which has been patented without the consent of the patent owner". There is an unlimited power to exploit the patented invention. What a compulsory license seeks to achieve is that it would revoke the exclusive right of a patent holder which would allow him to control the use of a patent.[11] A compulsory license is basically granted by the government which is popularly used for the "non-commercial, public use" or the "government use" by a private entity. Chapter XVI of the Indian Patent Act,1970 contains the provision regarding the compulsory licensing. Special conditions have been provided to be fulfilled for the grant of a license as enshrined under section 84 and 92 of the Indian Patents Act,1970.[12]

The objective of bringing protection together the intellectual property rights was successful due to the advent of TRIPS agreement which was mainly driven by developing countries and accepted by World Trade Organization. After almost a decade later of the Doha declaration, on

[9] Nayyereh Ayati Parisa , Parisa Saiyarsarai & Shekoufeh Nikfar (2020) *Short and Long term impacts of COVID-19 on the pharmaceutical sector* Journal of Pharmaceutical sciences 28, 799- 802 (2020) (July 9, 2021) https://link.springer.com/article/10.1007/s40199-020-00358-5

[10] Yashi Agrawal , Spoorti Reddy & Pravalika Balaram , *A study of compulsory licensing in the time of COVID-19* Internat'l J. Legal. Dev. and allied Issues. 6 , 143-146 (2020)

[11] Kamban Socretes, *Compulsory Licensing under the Patent system in India* , 6 Indian J.L. &Just. 63 (2015)

[12] Raju KD , *Compulsory licensing provisions to deal with access to patented medicines in India* Nuals law Journal 6 21-25 (2012)

9th March,2012 , India finally granted its first compulsory license to Natco for the drug named " Nexaver" after the full consideration of all the conditions prescribed under section 84 of the Indian Patent Act is fulfilled. Natco was the Indian generic manufacturer who was selling Sorafenib Tosylate at Rs. 8,800 per month therapy in comparison to Nexaver cost of Rs. 2.88 lacs. "Emcure Pharmaceuticals v. Roche, the compulsory license claim was made for Roche's Drug "Trastuzumam" better known as Herceptin under section 92 of the Act." After 3 years, Hyderabad based Indian Pharma Company, Lee Pharma, filed an application for Compulsory Licensing for manufacturing and selling the compound on June 29, 2015 at the Patent Office, Mumbai. The Compulsory license filed for the patented drug 'Saxagliptin' named AstraZeneca to treat Type II Diabetes Mellitus.

Compulsory license would also allow the government of the developing nation like India to produce generic versions of the patented medicines and also sell them at an affordable price.[13] Compulsory license would definitely lead to competitiveness in generic drugs market. The phenomenon of compulsory license however will be helpful for financially challenged patients in developing nations like ours and will give them easy access to the medicines and into the utilization of the innovation at a cheaper price. Compulsory licensing can be a valuable tool for the production of the small molecule drugs during the public health emergencies . Compulsory licensing has come out to be the direct way of protection of public health in the developing countries and is necessary for the adequate supply of needed drugs. [14]

The General Council amended the TRIPS agreement through a protocol for the implementation of the paragraph 6 of the Doha declaration of TRIPS agreement and Public health. The 2005 amendment is made clearly to implement the 2003 decision on the permission given to the developing and the least developing countries which do not have any manufacturing capability for pharmaceutical products to import under this scheme at present so given. The Indian Patent Act,1970 is a comprehensive legislation which was enacted after the Independence of India . [15]The Act has a clear strategy for a compulsory licensing provision and seeks to eliminate the monopoly of the multinational corporations and will remove the bottlenecks in the older regime which always prevented the indigenous firms from the production of patented dugs. India constituted the National Pharmaceuticals Pricing Authority in 1986 in order to control the prices

[13] Mansi Sood, *Natco Pharma Ltd v. Bayer Corporation and the Compulsory Licensing Regime in India* , 6 Nujs L.Rev. 99 (2013)
[14] Supra .
[15] Shamnad Basheer & Mrinalini Kochupillai, *The Compulsory license regime in India : Past, Present and Future,* (July 10, 2021, 8:00PM) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1685129

of a list of drugs to facilitate their access to the poor. The Patent (Amendment) Act,2005 provides for a process as well as the product patents. A new section 92A was inserted which provided for the compulsory license for export of patented pharmaceutical products in certain exceptional circumstances. The provision simply included the amended Act according to the Doha Declaration on Public Health.[16]

Scope of Compulsory license vis-à-vis COVID-19

A blanket compulsory license is not sufficient for certain technologies specially medicines. Prior attempts to negotiate a license for the invention on only reasonable terms must be taken care of. However, this requirement can be waived off in national emergency. The license is non-exclusive in nature. The scope or the duration of the license must be for a limited period of time . The license is non-exclusive so the patent holder will still want to enter into licensing agreements with others. The use of the license is generally permitted predominantly only for the supply in the domestic market of the state where the compulsory license will be granted. Adequate remuneration must be paid to the patent holder as well. Compulsory licenses could act as a check on or safeguard against the patent holder decision making which is contrary to delivering equitable access for COVID-19 . There are certain obstacles regarding the efficiency of compulsory licensing agreements for COVID-19.[17]

WTO sets out the minimum criteria for the compulsory license to be compatible with the international trade law. There is no global patent instead patents are national rights. Therefore, the reason why national laws will generally set out the procedure for compulsory license. The legal requirements for obtaining compulsory licensing in a national level would be bureaucratic and unclear and will even be burdensome on proving their effective utilization.[18]Voluntary licensing agreements have more advantages over compulsory licensing. Unlike, compulsory licensing , voluntary licensing can be set up at International level. They can even act as a broader global /regional mechanism to encourage sharing intellectual property over all kinds of health related technologies and secondly while the compulsory licensing needs to be considered for each medicine or vaccine which would be on case to case basis but on the other

[16] Harshita Mathur, *Compulsory licensing under section 92A: Issues and Concerns* Journal of Intellectual property 13 464-468(2008), (July 14,2021, 6:00PM) http://nopr.niscair.res.in/bitstream/123456789/2034/1/JIPR%2013(5)%20464-472.pdf

[17] Sapna Kumar, *Compulsory License of Patents During Pandemics,* Available from : https://dx.doi.org/10.2139/ssrn.3636456

[18] Harish Chander , Vaibhav Chaudhary & Vikas Sharma, *Current scenario of Patent Act : Compulsory Licensing* Indian Journal of Pharmaceutical Education and Research 47(3) 24-27(2013)

hand voluntary licensing initiatives can be established to cover a suite of treatments/vaccines only for a specific issue which is the current pandemic crisis.

Compulsory licensing is open for challenges and disputes which would potentially delay the effect of such mechanisms and deter states from using them, voluntary licensing are based on the patent holder consent or buy-in options. Even in the context of COVID-19 when the restrictive use of patents have been reported within the media, patent holders have changed practices with the fear of reputational damage to them.[19]If a reputed company already holds a patent in a pharmaceutical or health technology which could be used as a counter-measure , government could consider use of compulsory license This mechanism has been even used in the past to address diseases like HIV/AIDS in Thailand and Leukemia in Columbia. Even recently Chile has also taken steps to permit the use of compulsory licensing for COVID-19 vaccines and medicines . Compulsory licensing has been considered to be a fairly "heavy-handed" option and has been used with the growing infrequency when comes to wealthier, developed countries.

As with the public health related exception to WTO's patentability obligation, the compulsory licensing exception will reflects a concern on access to medicines as well. Previously the WTO members agreed that the "public-health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics were declared as national emergency or circumstances of extreme urgency". If Congress chose to use a compulsory licensing system as a strategy in order to promote access to medical countermeasures during the COVID-19 pandemic, it can rely on the TRIPS agreement authorization provision provided any system which complies with all the Agreement's conditions. As of now there has been no legal challenge before the WTO to a compulsory licensing system introduced during a pandemic.[20]

Gilead, a pharmaceutical company has patented Remdivisir , a broad spectrum antiviral drug which is considered as a potential drug to treat COVID affected patients. They have signed five voluntary license with generic pharmaceuticals manufacturers based in India and Pakistan. The COVID-19 pandemic has forced countries to reassess their compulsory license regime and have

[19] John Willinsky *" Access licensing" : A COVID-19 refresh for Compulsory licensing,* SLAW , (July 11, 2021, 6:00pm) http://www.slaw.ca/2020/09/01/access-licensing-a-covid-19-refresh-for-compulsory-licensing/
[20] The Wire *Should India grant compulsory licenses to increase the supply of vaccines?*(July 10 ,2021, 8:00PM) https://thewire.in/health/india-patent-law-compulsory-licenses-covid-19-vaccines

sought for a government intervention in avoiding drug shortages.[21]In 2020, we have witnessed that the United States also experienced pandemic related drug shortages. Recently in January,2021, India's drug controller General of India has approved Serum institute of India's " Covishield" and Bharat Biotech's "Covaxin" for restricted emergency use. The Serum institute has presented a recombinant Chimpanzee Adenovirus vector vaccine with the help of Technology Transfer from AstraZeneca/Oxford University. The overall vaccine efficacy has been calculated as 70.42%.

There is a chance that if the vaccine is effective, these entities will opt for voluntary license first and if the requirement is not fulfilled, we have to wait for their patent grants first and only then can the governments utilize compulsory license. Many countries have been trying to secure anti-covid-19 doses from India , the world's largest manufacturer of vaccines. The Indian government has already started nation wide vaccination programme on January 16. As two vaccines has been approved so far , the Drugs Controller is also reviewing BioTech-Pfizer application[22]. Compulsory license is not required as of now but in coming years , if we keep exporting vaccines, we might be a situation of shortage and availability in reasonable prices. Time will show how strong our compulsory license regime is to tackle the Pandemic after effects.

As there was a spread of a new variant of coronavirus , In January, India and South Africa gave a proposal for a temporary waiver in TRIPS provisions in order to ensure a free flow of medicines, vaccines and medical equipment in between countries on the ongoing COVID-19 pandemic. Hence licenses should only be granted if the inventor is not ready to enter into reasonable licensing agreements to supply the given drug at affordable prices. It is evident that in situation of a pandemic, for all existing patents , a compulsory licensing can be given under section 84. [23]It should be kept in mind that compulsory license regime applies to only existing patents.[24] The Indian government right now is facing a challenge to literally vaccinate its 1.3.

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[21] CNBC *worldwide look to acquire the intellectual property rights of COVID-19 vaccine makers* (July 9, 2021, 6:09PM) https://www.cnbc.com/2021/01/22/countries-look-to-acquire-the-ip-of-vaccine-makers-to-fight-pandemic.html

[22] DW Made for minds , *COVID-19 Vaccine : Can India balance local and International demand* (June 21 ,2021, 5:00pm) https://www.dw.com/en/covid-19-vaccine-can-india-balance-local-and-international-demand/a-56195051

[23] Live Law New Network *DGCI approves Serum Institute COVISHIELD and Bharat Biotech COVAXIN* (July 12 ,2021, 8:00PM) https://www.livelaw.in/top-stories/dgci-approves-serum-institutes-covishield-bharat-biotechs-covaxin-vaccines-for-emergency-restricted-use-167867

[24] The Hindu *India, South Africa proposal for TRIPS waiver to be taken up again at WTO* (July 7,2021, 8:30 PM) https://www.thehindubusinessline.com/economy/india-south-africa-proposal-for-trips-waiver-to-be-taken-up-again-at-wto/article33593244.ece

billion population. Several countries have also made official requests from India for vaccines like Brazil, Saudi Arabia, South Africa, Bangladesh, Morocco. India's health ministry also clarified that it has not banned exports of COVID-19 vaccines to other countries.[25]

Covid-19 and TRIPS Waiver

Waiver in TRIPS agreement is a temporary removal of intellectual property protections which are provided by the WTO . TRIPS waiver will allow the countries to stop implementation of patent rights on health technologies, vaccines, diagnostics, as well as the means to prevent or give treatment of COVID-19. This can further help the developing countries to opt for collaborations in research and development without the fear of any Patent litigations on non-compliance of TRIPS agreement during Pandemic.

In October, 2020, India and South Africa have given a proposal of temporary waiver on TRIPS obligations with regard to vaccines or drugs produced amidst pandemic. Approximately forty WTO members have discussed the proposal. It was observed that mostly the developing countries have given their support in favor of waiver and the developed nations vehemently opposed. It was clear that the developed countries want to gain profits over public health. Unfortunately , no clear mandate has been set on TRIPS waiver[26]. The waiver has been proposed to apply only on drugs or medicines which will help combat the Pandemic. The proposal has clearly stated that the waiver will be time limited and would definitely end when the vaccination process would be complete. The waiver will not affect any of the policies mentioned in TRIPS. The waiver proposal requires a three- forth approval amongst the WTO member states. It was opposed by the developed nations on the ground that the TRIPS agreement already gives enough flexibilities to the member states in order to exercise discretion and the countries already have the right to allow compulsory license for less expensive drugs available in the market. However, the practical application of compulsory license is a tricky affair. The importing countries have to bargain and negotiate the terms in order to receive the drugs at an affordable price. Also, it cannot be ignored that the right to voluntary license is upon the patent holder to decide . The patent holders can create a negative impact on the private governance of the patented resources available. However , given the situation we are facing, there is a need to propose a balanced mechanism in between patents rights and public health.

[25] Supra note 20.
[26] Id.

Last month, The United States of America has declared its willingness to suspend the intellectual property protection for COVID-19 vaccines which has increased the supply and production of vaccine shots. [27]World leaders have adopted very different approaches to tackle the challenges on vaccine supplies. Big pharmaceutical companies have previously opposed India and South Africa's waiver proposal based on the argument that it will impact upon the potential innovations and production . So far, more than 3 billion COVID-19 vaccines has been delivered worldwide. But unfortunately, most of the doses has been delivered in wealthier countries. In Africa, less than 2 % vaccines have been delivered. It was declared by the United Nations that the inconsistency and disparity amongst countries have led to increase in COVID-19.

The European Union gave an alternative proposal to WTO in relation to Patent's waiver. The proposal has clearly stated to shift focus on removal of exports restrictions and use of already existing [28]TRIPS flexibilities instead of a waiver in totality[29]. The EU in its proposal has stated that a waiver will not in all circumstances promote the manufacturing of vaccines or medicines but by the removal of the export restrictions and encouragement of vaccine developers to enter into collaborative deals with developed nations[30], will boost the production level. It was also contended by EU that many countries already have provisions of compulsory license which can be utilized in an emergency situation like COVID-19. The claims made by India however is tricky as the Indian government is willing to opt for voluntary licensing as a sole solution available , but on the other hand, India is arguing before WTO for Patent waiver as a temporary solution.

Conclusion

The policy to tackle COVID-19 through compulsory license or through TRIPS waiver is yet to be decided. Developed countries approach as capitalists and lack concerns about social welfare. Countries like India holds a strong history of compulsory license but lacks the plan to implement it and would add consequences of unwanted competitiveness amongst big pharmaceutical companies. There is a need to revisit provisions of TRIPS specifically patent

[27] Giro Martinez, Compulsory licensing : A solution to the current debate on anti -covid vaccines? , LEXOLOGY (July 16, 2021, 9:00PM) https://www.lexology.com/library/detail.aspx?g=08e57073-a0ba-4ec8-b64b-3df94899a6fe
[28] Id.
[29] Philip Blenkinsop , *Resisting Patent waiver , EU submits vaccine plan to WTO*, REUTERS (July 15,2021, 8:09PM) https://www.reuters.com/world/europe/eu-executive-submits-vaccine-access-proposal-wto-2021-06-04/
[30] Id.

waiver and realize the importance of Doha declaration. Situation in India is a big mess, there are many stakeholders in favor of compulsory license and many in favor of TRIPS waiver, due to which our country is going to hit third wave of COVID-19. In my opinion, a compulsory license and TRIPS waiver both give a possible solution, however, for compulsory license to work a national implementation plan is required because many pharmaceutical companies don't want to give up their patents. In May, 2021 it was claimed by Indian Drug Manufacturer's Association to issue compulsory license to pharmaceutical companies to manufacture drug Remdisivir due to excessive shortage. But on the other hand, Rajasthan High Court has dismissed the plea for compulsory license naming it to be a policy matter. In my opinion, TRIPS waiver is a much better option. WTO can grant approval for waiver and developed nations must co-operate in public health crisis, keeping aside their profit-making attitude.