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PROPOSAL FOR PATENT WAIVER ON COVID-19 VACCINES AND PHARMACEUTICAL INDUSTRY- A CRITICAL STUDY

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ABSTRACT

The international community is striving very hard to come back to normalcy from COVID-19 pandemic. Even after the advent of vaccines, the mutating strains have kept the world states under threat. Most of the world states learnt lockdowns are not the ultimate solution to survive pandemics. Lockdowns shook the economy. But the irresistible travel situations led to the beginning of the second wave which took many lives and exposed the situation that global medical care is at its worst stage. Most of the countries are on vaccination drive. People get vaccinated free of cost. Cuba is the only country in the world to vaccinate its population above 2 years. This is a concern and most of the medical experts say the third wave would most likely affect the children below 18. Pharma companies are planning to initiate research to develop vaccines for children under 18. The pharmacy industry is forced to tackle the issues of compulsory licensing and patent waivers. This article would be a critical study of how Covid-19 has made an impact on the Intellectual Property Rights of the Pharmacy industry.

Keywords: Covid-19, Pharmacy Industry, Public Health, Compulsory Licensing, Patent Waiver.

INTRODUCTION

December 2018 was the black month of China where many people started to die in clusters. The reasons behind such deaths were high fever and basic symptoms of a cold. None understood the reason behind it. Finally, they recognized it as a virus and named the same as Covid-19. It was a super spreader. Initially, it was thought to have spread from Wuhan's meat market of China. The sudden outbreak of this disease was suspected to be a sabotage of the Chinese Government. There is a study that sees such outbreaks as a bio war and the virus as a bio-weapon. Pandemic was suspected to be the weapon of the third world war. The whole world suspects that China has been researching to find bioweapons to overpower world Countries and to become the sole superpower in this multi-polar world. Till now the source of such a virus is a mystery. Not only did China was affected, but the super spreader virus also crossed boundaries and almost all world countries started seeing raise in cases of Covid-19. Though it is a mystery international community was forced to take quick moves as there was no cure for the same.

The super spreader virus brought countries to look upon its poor medical infrastructure which was not sufficient to treat the affected people. World countries were perplexed and could not foresee the situation. The only solution to escape from this disease was to lock down the Countries. As there was no proper cure and awareness in midst of the people, the world countries saw many causalities. At the advent of this disease, this was compared to the outbreak of the 1919 Spanish flu. Just like history repeats impact of Covid-19 was like the impact of the Spanish flu.[1] During the 1919 flu outbreak, the government imposed very strict lockdowns and subsequently when the cases of the affected individuals dropped movement of people across borders were permitted. Similarly, during the first wave of covid pandemic lockdown rules were liberated and this paved the way for the more severe second wave which led India into a frizzy. Hence lockdown could only control the spread of the virus but it cannot eradicate the virus. [2] Locking down countries borders for months altogether started jolting their economies. This urged the pharmacy industries all over the world to invest in research and to develop Vaccines to save human species from extinction. Finally in January 2021 vaccines were invented and shots were given to people. Now the real problem was inoculating all people as the unvaccinated people remain to be mutant factories for the new virus of Covid-19. The factors that delayed the process of inoculating were the production of vaccines by the pharmaceutical industry, affordability, and accessibility to vaccines by people.

Covid-19 posed new challenges to the pharmaceutical industry. There is a long way to go to stop the spread of infectious diseases in living beings.[3] However, this will result in many deaths and hence an alternative method or a short way of treating the infectious disease by providing resistance. Vaccines are the leading simple tool to cure us of these infections. However, due to global monopolization make even these simple tools unavailable to us at much cheaper and better and faster rates.

COMPULSORY LICENSING

Developed countries view intellectual property as private property and protect them like any other tangible property whereas developing countries view Intellectual Property as the one that is used to promote the monetary development of society. Hence intellectual property is always viewed as public property. The Pre-TRIPs period was an era of flexibility where the only process was patented but now after TRIPs, patenting is allowed for both product and process. Hence compulsory licensing was introduced to overcome the demerits of Intellectual Property Rights.

Article 31 of the TRIPs agreement gives rights for the government and the third party to use the patented technology.[4] This helps the third party and government to use the patented technology. The uses permitted under Article 31 are not infringed use. The following are the provisions of such use without authorization of member. Article 31 (a) mentions the rights of the users to get authorization from the owner for a reasonable amount and these efforts also. In case of a national emergency and extreme urgency, Government will try reasonable steps to notify the right holder whereas in case of public non-commercial use member countries or contractors will start using the patented technology only after informing the right holder. Article 31 (c) states the scope and duration of such use. The duration of such use shall come to an end when the purpose for which such use is permitted. Hence the user should come to an end with the purpose for which it was authorized. Article 31 (d) states that such use shall be a non-exclusive one and Article 31 (e) states that such use shall be non-assignable. Article 31 (f) puts restrictions on such use by permitting members to supply patented products only in the domestic market. Article 31 (g) ensures that use shall be subject to protect the legitimate interests of the persons so authorized. Article 31 (g)articulates that competent authority shall have the authority to review and terminate such unauthorized use. Article 31 (h) supports the right holder to be paid with adequate remuneration considering the economic value of the authorization. It is mandatory for any member countries to TRIPs to comply with the above provisions. Though Article 31 seems to be a far-reaching provision in providing access for patented technologies Art 31(f) makes it stringent to access limiting it only to domestic requirements. In case of access to medicines Article 31 (f) impedes supplying life-saving drugs to countries that lack manufacturing capacity. Lack of manufacturing capacity and poverty should never be a hurdle in caring for public health. [5]

Health is a fundamental human right that was denied to us during this pandemic. [6] The pandemic exposed the need for proper medical care facilities across the globe. The Human Rights Council making consultation with experts in Geneva, Switzerland, on 11 October 2010, highlighted that “To ensure human rights it is very important to consider access to medicine as one of the fundamental elements and in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” [7] Health is vital for survival. Trips provision Article 31 (f) impedes by restricting the accessibility of patented products only to domestic accessibility. There is no reservation in article 31 (f) of TRIPs concerning pharmaceutical products or for any life-saving drugs. This made many low-income countries that relied desperately on other countries for essential drugs to grieve. Hence to address the issue generated by Article 31 (f) Doha Declaration on public health was held in 2001. [8]

World Trade Organization after the Doha declaration held in 2001 designed a policy to address the issues of health concerning intellectual property rights. It wanted all countries to be part of this international and national action to address the public health problems. [9] Doha declaration recognized certain flexibilities included in sustainable development goals that allowed world countries to enshrine in their Intellectual Property laws to address their health needs. The most important flexibility enshrined in Doha declaration was to permit member countries to use compulsory licenses without the consent of the patent holder and export the same to countries that cannot support the medicinal need of their people. [10] Doha declaration

flexibility overcame the actual restriction imposed on the member countries to issue compulsory licensing only for their domestic purpose. The TRIPs amendment of additional forms of compulsory licensing has facilitated in removing the impediment. This flexibility is an additional bliss to developing and least developed countries. This new form of compulsory licensing is designed for the export of medicines to countries in need concerning compensation the effect of Trade on public welfare. This mechanism is also called as Paragraph 6 decision.

Paragraph 6 decisions were considered and Article 31 bis were adopted by World Trade Organization's General Council and member countries were given the choice to adopt the same in their Intellectual Property Laws. [11] The protocol provided additional flexibilities to grant special compulsory licensing for the export of medicines. WTO has taken 11 long years to include flexibility by providing for compulsory licensing since the inception of the TRIPs agreement in 1995 to address the conflict between patents and public health. [12] This has indeed made TRIPs agreement to raise and standardize Intellectual Property protection and enforcement for all members of the World Trade Organization. Epidemics like malaria and HIV have made least developed countries, especially the South African countries to access the flexibilities of TRIPs. TRIPS flexibilities allowed using the compulsory licensing beyond the public health emergencies by the exportation of medicines. Inclusion of Article 31 bis by amending TRIPs has helped in waiving Article 31(f) for the least developed countries allowing them to issue compulsory licensing for public health reasons through the importation of drugs. [13] Article 31 bis contain an exhaustive definition of "Pharmaceutical products" and some formalities which should be complied with by importer and exporter countries to prevent fraud. Though Article 31 bis got enacted in 2005 this came into effect only from January 2017 after getting ratified by two-thirds of the members of WTO. Article 31 bis have been ratified by only 87 countries and out of it, only 20 countries are from Africa.

In 2007, Rwanda became the first country in the world to ratify WTO's Article 31 bis regime of its intent to import products based on a compulsory license. There was a tougher phase for Rwanda to implement the legal flexibilities of TRIPs. In 2007 Canada was the country that made the first footstep in exporting generic drugs to Rwanda. Finally, despite making many failed attempts in negotiating with patent holders, the Canadian government issued a contractual license to Apotex Pharmaceutical Company and authorized them to produce a generic version of a drug to treat AIDS. [14] This authorization of the Canadian government facilitated HIV patients of Rwanda to purchase medicine at 0.20 USD per pill. This was comparatively very cheaper and affordable as the patented branded drugs cost 6 USD per pill. This act of licensing and exporting was very tiresome and a prolonged process. However, Rwanda was able to access its medicines in the years 2008 and 2009 respectively. This shows that TRIPs Flexibilities could benefit many African countries. Despite the beneficial amendment of TRIPS flexibility, only 20 African countries have ratified Article 31 bis. The reason for such low approval was to make internal legal amendments and another major concern is Article 31 bis is not self-executing.[15] To make changes in consonance with TRIPs and effective implementation of TRIPS agreement each country should make necessary subsidiary law-making in every country. There are many other alternatives like parallel import and differential pricing strategies to address the public health crisis. Parallel import and differential pricing are not illegal. Parallel import is to import the patented products from the country where it has been sold at a low price. Legal purchases made by customers cannot stop the customer from reselling the same product. Such a way of legalizing the customer's right is said as the first sale doctrine. Parallel import is based on the principle of exhaustion. [16] Some of the national legislation limits such exploitation. Similarly, differential pricing strategy is one where the patent holders or the authorized person themselves. The patent rights are not infringed when customers sell patented products. Even after applying differential pricing strategy by the pharmaceutical industry prices are still unaffordable by the poorest countries. Hence compulsory licensing would be the main legal instrument in addressing the issues of patented drugs and public health in African countries. First, it is very much necessary to have consensus and uniformity in political will by a few African countries in ratifying the amendment of TRIPs and accommodate the same in national legislation as soon as possible. Second, it is mandatory to simplify the procedure to issue compulsory licensing such as filing numerous notifications to get permission from the patent holder to issue the voluntary license. The above measures would help in public crises such as epidemics and pandemics to overcome such a life-or-death situation.

COMPULSORY LICENSING IN INDIA AND COVID-19

India is well known to be the pharmacy of the world. Before becoming a member of TRIPs Indian Pharmacy industries used reverse engineering technology and provided medicines to the least developed country that lacked manufacturing capacity. Indian government supplied the anti-retroviral drugs to African countries which were lacking manufacturing capacity.[17] This was not happening after becoming a member of TRIPs agreement as protection was sought both for product invented and process of inventing. Members cannot supply it to the global market or to countries that lack manufacturing capacity because the government can produce and use the same only for their domestic purpose.[18] Article 31F of TRIPs created a vacuum on the issue of Access to medicine especially lifesaving drugs.

The purpose for which the provisions of compulsory licensing were enshrined in the TRIPs agreement was undermined because of certain clauses mentioned in Article 31. Paragraph 6 facilitated for amendment of TRIPs and enshrining 31 bis in TRIPS came as a panacea to the countries lacking manufacturing capacity. Hence Paragraph 6 decision emphasized the importance of public health and promised a solution for the constraints imposed by TRIPs agreement on accessing the medicines.

Indian Patent Act of the year 1970 was rewritten by the TRIPs agreement. Section 90 lists out the necessary condition and terms for licensing compulsorily. Section 92., Section 94 mentions the conditions on which the compulsory licenses could be terminated. Even after having elaborate mention of the compulsory licensing provision in the Indian Patent Act 1970, there is a lacuna in access to medicines. The lacuna is created due to inevitable clumsy procedures. Hence it takes a very long time to access the medicine by the public. [19]

Natco Vs Bayer was the first Indian case where the controller issued compulsory licensing to a generic pharmacy industry. The decision of the controller of patents raised a discourse that whether granting compulsory licensing would result in the weakening of IPR protection in India. Though it is always said that provisions of TRIPs and the Doha declaration must be interpreted keeping in mind the public health and the provisions of TRIPS.

For a long time, there has been a dispute over the pharmaceutical sector and intellectual property rights. The TRIPS Agreement was signed in 1995, and India was the first country to sign it. As a signatory to the TRIPS agreement, significant changes to the existing patent rules were required. The deadline for meeting the TRIPS agreement's responsibilities was January 1, 2005.[20] The Patents (Amendment) Bill, 2005 was tabled in parliament in March 2005 with the motive of achieving India's patent rules acceptable with international responsibilities.

The award of the compulsory license is proof of the exemption under the TRIPS agreement. By the patent rules in India, the stipulations of compulsory licensing are applied under sections 84, 86, 89 and 93.

This action created a debate about whether giving a compulsory license may destabilize IPR protection in India. On the other hand, the consumer's support of granting compulsory license to Natco pharm would serve the poor by allowing pharmaceutical companies to price drugs based on the affordability of a consumer and attempting to prevent the abuse of monopoly acquired by patents. It was the first case in India for compulsory licensing. [21]

The problem is determining how to make good use of the required license. Is it permissible to award a compulsory license to a private firm for the public good?

BAYER CORPORATION vs NATCO PHARM

The German-based Bayer corporation invented the anti-cancer drug (Sorafenib Tosylate) which is used to treat kidney and liver cancer. On 3rd March 2008, Bayer corporation got patented for 'Nexavar' (marketing name) under the Indian Patent act.

The generic pharma company (Natco pharm) proposed voluntary licensing for 'Nexavar' but Bayer's corporation denied it. Later, Natco Pharm., approached the Indian Controller of Patents for compulsory licensing and they claimed it under Section 84(1) of the Patent Amendment Act, 2005.

Section 84(1) of the Patent Amendment Act, 2005 states that any person could apply for compulsory licensing to the Controller of Patent, after here years from the date of the issued patent for a certain reason. [22]

- The patented product doesn't meet the public requirement and satisfaction.
- When the patented product is overpriced in accordance the public affordability.
- When the device invented is not operated in Indian territory

1990	1990: Sofraneib Tosylate, anticancer drug was invented by Bayer Corporation
1999	1999: Bayer corp. applied patent for Sofraneib Tosylate in the United States.
2000	2000: Bayer filed a Patent Cooperation Treaty
2005	2005: Bayer corp. introduced the drug into the market with name of Nexavar.
2008	2008 (March): After obtaining the patent from India, Bayer corp was allowed to import and sell Nexavar. The price of monthly dosage is nearly 2.80 lakhs. Natco has approached Bayer about obtaining a voluntary licence to manufacture and distribute the medicine under 200 USD. (in accordance rdance with the Indian Patent Act, 1970). Bayer declined the request.
2010	2010: Generic version of Nexavar was manufactured and sold by M/S Cipla
2011	2011 (July): By undergoing the Section 84(1) of the Indian Patent Act of 2005 (amended), Nacto pharm applied for compulsory licensing(produce and sell Nexavar) to the Controller of Patent.
2012	Natco was awarded the first compulsory licence in India, allowing it to manufacture and sell Nexavar (generic version). Bayer filed an appeal against by the Controller of Patent's judgement with the Intellectual Property Appellate Board (IPAB) at the Bombay High Court, claiming that the verdict undermines the worldwide patent system and jeopardises research. And it was rejected by the framework of Article 21 of the Indian Constitution, due to the concerns from a sociological and health standpoint.

Table 1: Timeline of Bayer Corp. and Natco Pharm.

Case Analysis

India is a hugely populated country and had 8900 kidney cancer patients and 20,000 liver cancer patients in 2008; stated by WHO GLOBOCON 2008. Nexavar drug is specially designed for stage 4 cancer patients. As

per the estimation of Bayer Corp., 8,842 people were allowed to get this drug. Only 593 boxes were delivered to the public in 2011 even when the requirement was high. As per Bayers evaluation, it's just 2% per cent of the total requirement. [23]

The pricing of the product is decided on the research and development and affordability. In this case, the replicated version (generic) of Nexavar costs under 10000 Indian rupees per month. Instead of showing R&D cost evidence, they showed facts. So, their claim is not taken into consideration.

The compulsory license of Nexavar was given to Natco Pharm on 9th March 2012., on certain conditions of Section 90 (Indian Patent Act) states that,

- Natco pharm should give royalty of 6% to Bayer Corp., (7% after a few years)
- A monthly dose must equal 8,800 rupees.
- Natco pharm should not import Nexavar.
- A drug must be physically different from Bayer's.
- No sublicensing is allowed.
- Natco should give 600 dosages free for the patients who deserved it (per year).

In the viewpoint of pharmaceutical industries, compulsory licensing may cause an impact on their research and development. WHO has the huge responsibility to acknowledge the Indian Patent Right authorities? Because of the case, the compulsory license was given for three drugs (Herceptin, Sprycel, Lxempra). [24]

Covid has created a more challenging environment. Vaccines are short of demand. Since the means of production is in the hands of the capitalists, they tend to make a profit out of it. This makes the cost of vaccines skyrocket and in case the vaccines are made available at a low cost to the poor, either the government body or the manufacturing industry will suffer a loss.[25] Hence Pharmaceutical industry does not want to compromise its cost with vaccinating at low cost or free of cost. Then here the government is supposed to pay the cost of vaccines and vaccinate all without any disparity. For fund, Governments relies on taxes and government can attract private companies by providing tax rebate to overcome the vaccine crisis. Governments by providing attractive incentives can stress the innovator company to share their technology to domestic companies to produce and to provide and care in case of an emergency. However western countries were against these provisions. Now India and South Africa wants to invoke the above provision in the USA so that highly-priced covid-19 vaccines invented by the USA can be given to poorer countries.

PHARMACY INDUSTRY

Covid-19 vaccines are the intellectual property of the pharmaceutical industry which had devoted huge to the research and development of the creation. Naturally, the pharmaceutical industry would be inclined to derive the invested money from their newly invented vaccines. The main aim of Intellectual property rights is to reward the inventor and make the invention available for public accessibility. Though paying incentives for a new medicine is important and it is equally important to make medicine available to the public to save their lives. Hence now in the Covid situation, the pharmaceutical industry would be very keen on producing that medicine and distributing the medicine to meet the requirement of people to address the issues of public emergency. Though the vaccines were available since January 2021, there was a major outbreak of second-wave of covid-19. The list of reasons for the second wave is exhaustive.

In data provided from world-bank, it is noted that till 24 May 2021 only 4.4% of the population in India was inoculated. This shows inequality in vaccination based on the incomes of countries. This will not help in controlling mutating strains of the corona. The only solution is to vaccinate all or develop a herding community. [26] Unvaccinated people would be remaining a mutant factory of a new variant of the Covid virus. This was one of the main reasons for the outbreak of the second wave. In midst of vaccinating, all countries have to address the issue of rewarding and protecting the technology of the pharmaceutical industry and simultaneously check the quantity of production, procurement, pricing and distribution of the vaccines.

Few countries lack the technologies and infrastructure to develop vaccines. Especially the least developed countries like African countries had been always supported by other Countries to overcome their disparity for medicines. Now the situation is adverse as the countries which supplied the medicines earlier don't have the know-how of the Covid vaccine. Hence the world countries have proposed a patent waiver. A patent waiver would pave the way for reversing technology and allow the competitor to free ride the technology to produce vaccines to vaccinate all. Hence patent waiver and compulsory licensing pose a grave threat to the pharmaceutical industry.

Now coming to the present scenario of the Covid era the pharmaceutical industry is trying to come up with effective vaccines to protect people from Covid-19. Vaccine breakthrough infection is another problem as people who are fully vaccinated still get the disease. But in the case of vaccine breakthrough, the chances of death are very minimal. The impact of the virus on a vaccinated person compared to an unvaccinated individual is very less. Especially chances of death due to Covid-19 for a fully vaccinated individual are very less. Hence it is recommended to get vaccinated. In midst of vaccinating, state governments have to address the issue of rewarding and protecting the technology of the pharmaceutical industry and simultaneously to check the quantity of production, procurement, pricing and distribution of the vaccines.

Vaccines from many countries are coming up with vaccine policies to address the issues with vaccines. The two solutions sought for access to vaccines and to overcome exploitation resulting from patent rights is to issue compulsory licensing or patent waiver. Professor Prakash Ranjan in his article says "It is uncertain when the TRIPs waiver would be adopted or on what conditions it would be subjected to". Natco's request to issue compulsory licensing for Baricitinib, a Covid-19 drug proves that the option of issuing a compulsory license is available to the Indian Government. But India besides having the option to issue compulsory licenses Indian government states that it will not be effective to issue compulsory licenses because. [27] If insufficient raw materials are the actual issue, then Why India is stressed about waiving patents? Waiving a patent could sort out issues concerning Intellectual Property rights, but it could not address the issues concerning insufficiency of raw materials. In addition to waiving patents, the Indian Government believes that issuing voluntary licensing would compensate for the shortage of covid-19 medical products. Instead of relying on voluntary licensing of patented technologies and patent waivers, India could make aggressive use of compulsory licensing provisions enshrined under sections 92 to 100 of the Indian Patent Act 1970 to address the issue of emergency and urgency concerning the public health caused by Covid-19. Issuing a compulsory license would save time by avoiding an independent organization to enroll for a voluntary license. On the other hand, Compulsion created by compulsory licensing on the pharmaceutical industry would force Pharmaceutical Industries to issue voluntary licenses without delay.

PATENT WAIVER

Antonio Guterres, Secretary-General of the United Countries said "we are all in this together: Human Rights and Covid-19 response and recovery." He emphasized that the crisis of the public emergency during Covid-19 has led to economic, social crises further turning into a human rights crisis. In February 2021, Antonio Guterres, launched a call to action to put human dignity and the promise of Human Rights at the core of all work. Human rights cannot be an afterthought in times of crisis. Antonio Guterres wanted to put people and their rights in the front and centre of all issues. Hence human rights cannot be left unattended in midst of covid-19 response and recovery. Seeing Covid-19 from the lens of Human Rights will bring everyone in to picture and will confirm that no one is left behind. Human rights can help eradicate pandemics. [28] The human right will ensure health care for everyone. Healthcare for everyone, because the virus does not discriminate, it affects all. There is lagging in health care as the delivery of public services and structural inequalities impede access among people. It is always best to respond to immediate threats while protecting human rights and rule of law. Governments must be transparent, responsive, and accountable. Antonio Guterres, also added that it is very much necessary to ensure emergency measures and such measures should be legal, proportionate, necessary and non-discriminatory.

To overcome the public health crisis created by Covid-19 all wealthier countries should join and ensure that all people of every country benefit from vaccine manufacturing. Countries like India and South Africa initiated campaigns for waiving intellectual property protection on coronavirus vaccines to eliminate barriers to countries especially the lowest-income countries in producing their vaccines. This campaign is supported by the World Health Organization and United Countries Aids charity. This year U.S had started to support an IP waiver on all Covid interventions, including testing diagnostics and novel therapeutics.

Though there is support from countries around the world to have IP waivers for Covid treatments the Pharmacy industry like Pfizer and Astra Zeneca had opposed the same in their joint letter to US president Joe Biden. At present, there is no proposal from the pharmaceutical industry or High-income Countries for a patent waiver. Instead, the countries are coming forward to share their vaccines on charitable basis schemes such as COVAX. IP waivers on vaccines were recently supported by the DOI, Russia, and China.

There is another concern as waiving patents will make the pharmacy industry rescind its investment in research and development to invent new medicine for mutating viruses. So, the reward is necessary.

Hence, the Government opposing IP waiver believe it is best to issue a compulsory license as the current WTO rules provide for the same during an emergency. Compulsory licensing is extremely complex and time-consuming according to researchers in the United Kingdom. European Union focuses that the USA has blocked the exports of COVID-19 vaccines and their components. Hence European Union thinks it would be right to erase the restrictions created by patients to overcome the Pandemic.

According to data on vaccine production, the pharmaceutical industry expects to manufacture ten billion vaccines by December 2021. Currently, the industry would be likely to produce only six billion doses by end of 2021. This shortage would make the people in the least developed countries delay access to their first dose of vaccine. [29] The data status as of May 2021 shows that only 2% of the total population of the African continent got vaccinated. As Africa imports 99% of its vaccines, it cannot pay for the same as richer Countries does. Countries currently manufacturing vaccines have set an agenda to manufacture and share their vaccines with low-income countries but few countries like Africa is planning on making their vaccines by 2040. The patent waiver is not sought as charity. The patent waiver is sought by low-income countries to develop and make their vaccines. Hence waiving pandemic is crucial for ending pandemic without having fear to have sued for patent infringement. [30] Countries advocating for patent waiver understand the principle behind the same. Hence Countries opposing patent waivers should understand the seriousness of the issue and start recognizing it. John Nkegasong the Director of African Centers for Disease Control and Prevention rightly said that “they need to be on the right side when the history of the Pandemic comes to be written.”

During the peak rise in Covid, second wave Bill Gates quoted that the developing countries cannot manufacture vaccines for Covid-19 and hence sharing vaccine formulae with them would not help avert the global vaccine crisis. Few days after the co-chair of the Bill and Melinda Gates Foundation issued a new statement welcoming the “narrow intellectual property waiver for Covid-19 vaccines during the pandemic”. So Corporations and developed nations should join hands and take progressive steps to contain the deadly super spreader virus.

CONCLUSION

The German Chancellor, Angel Merkel told reporters early in May 2021 that “I don’t think waiving patents is the solution to supply the vaccine to more people” She also added that “I think that we need the creativity and innovation of the companies and for that, we need patent protection.” There was a big question would waivers boost production? Except for the countries that support Intellectual Property waivers conveyed that in a situation where the removal of the waiver takes place there will still be no progressiveness in the production for the short term and even the medium term. The lack of licensing is the key problem here as developing nations like India, Bangladesh, Canada, Denmark have given a statement quoting that they have the required capacity to produce vaccines but the lack of licensing in the era of the Covid-19 pandemic has made the situation even worse. The members of TRIPs especially India who is known as the pharmacy of the world should share its technology of development of Covaxin with other countries. [31] There should not be any kind of hesitation in sharing the vaccine technology developed using tax payer’s money for public health. This will turn India to rise as a global leader and encourage other Countries with sharing their

technology and know-how to boost supply vaccination. India must provide the right solution to its people to convey the problems of Intellectual Property Rights and public health

The review article emphasizes the need for a proper legal setup to be drafted by the states to balance the interest of the creator and the public. This article highlights that even during pandemics a state should not only consider the public good but should act reasonably towards right holders to protect their interests. The state should continue to protect the rights of the right holders by giving protection and reasonable compensation during the pandemic. Right holders should also realize that business is all about competition and higher pricing towards a poor crowd at the time of need is not going to profit them. A business can only be run with a world of consumers and when there are none to consume either with low purchase power or let's say when everyone is dead a business can't survive. Hence to conduct business we need people and a pandemic like Covid19 is a great threat to human life and therefore life-saving drugs should be made available to the public by right holders. [32] To sustain and survive a pandemic both nations and right holders must go hand in hand to support each other's interests.

The three-dimensional protection of IPR for right holders, public and new researchers could be a daunting task for any countries legislature to incorporate into their legal system. But it is more daring when it comes to practicality to establish the same. As societal needs would naturally be a great threat to economic development. To strike a balance in line with governmental policy and get benefited right holders must frame policies in such a way to exclude anti-competitive practice by ensuring a healthy competition overcoming the threat of compulsory licensing, parallel imports, exhaustion, counterfeiting and thereby allowing the public to access and afford for essential medicines. In the case of life-saving drugs, it is more important to ensure that the public receives genuine medicines and costs are affordable and available in the territory so that they can be easily accessible by the people. So, the voluntary licenses could be drafted with much due diligence that it could preserve the rights of right holders and would allow the public to access and afford essential medicines in case of emergency and urgency especially during the heinous Pandemic like Covid-19.

REFERENCE

1. Goldstein, J. L. (2020). The Spanish 1918 Flu and the COVID-19 Disease: The Art of Remembering and Foreshadowing Pandemics. *Cell, 183*(2), 285-289. doi:10.1016/j.cell.2020.09.030
2. R. Vellakkat, "IP Waiver during Covid Pandemic-Salvage or Apostacy ?" [Online]. Available: https://ssrn.com/abstract=3861961
3. B. Kianzad and J. Wested, "No-one is safe until everyone is safe – patent waiver, compulsory licensing and COVID-19," *European Pharmaceutical Law Review*, vol. 5, no. 2, pp. 71–91, 2021, doi: 10.21552/eplr/2021/2/4.
4. S. Chaudhuri, M. Dutta, Z. Husain, and A. Sinha, "Patent Protection and Access to Covid-19 Medical Products in Developing Countries Ω," 2021. [Online]. Available: https://ssrn.com/abstract=3902314
5. Dziuba, D. (2010). Trips Article 31bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection? *Indiana International & Comparative Law Review, 20*(2), 195-212. doi:10.18060/17626
6. Lim, L. J., Fong, L. M., Hariram, J., Lee, Y. W., & Tor, P. C. (2020). COVID-19, a pandemic that affects more than just physical health: Two case reports. *Asian Journal of Psychiatry*, *53*, 102200. https://doi.org/10.1016/j.ajp.2020.102200
7. Ooms, G., Keygnaert, I., & Hammonds, R. (2019). The right to health: from citizen's right to human right (and back). *Public Health*, *172*, 99–104. https://doi.org/10.1016/j.puhe.2019.01.019
8. Kongolo, T. (2005). Trips, the Doha Declaration and Public Health. *The Journal of World Intellectual Property*, *6*(2), 373–378. https://doi.org/10.1111/j.1747-1796.2003.tb00206.x
9. G. Gonsalves and G. Yamey, "The covid-19 vaccine patent waiver: A crucial step towards a 'people's vaccine,'" *The BMJ*, vol. 373. BMJ Publishing Group, May 17, 2021. doi: 10.1136/bmj.n1249.
10. Bartelt, S. (2005). Compulsory Licences Pursuant to Trips Article 31 in the Light of the Doha Declaration on the Trips Agreement and Public Health. *The Journal of World Intellectual Property*, *6*(2), 283–310. https://doi.org/10.1111/j.1747-1796.2003.tb00202.x

11. Shanker, D. (2005). The Paragraph 6 Solution of the Doha Public Health Declaration and Export under the Trips Agreement. *The Journal of World Intellectual Property*, *7*(3), 365–400. https://doi.org/10.1111/j.1747-1796.2004.tb00212.x
12. A. Santos Rutschman and J. Barnes-Weise, "THE COVID-19 VACCINE PATENT WAIVER: THE WRONG TOOL FOR THE RIGHT GOAL." [Online]. Available: https://ssrn.com/abstract=3840486
13. Chatterjee, M. S. (2007). Flexibilities Under Trips [Compulsory Licensing]: The Pharmaceutical Industry in India and Canada. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.1025386
14. Dyer, O. (2014). Generics manufacturer Apotex files lawsuit against Health Canada over import ban. *BMJ*, *349*(dec01 9), g7380. https://doi.org/10.1136/bmj.g7380
15. F. Hassan, G. Yamey, and K. Abbasi, "Profiteering from vaccine inequity: A crime against humanity?," *The BMJ*, vol. 374. BMJ Publishing Group, Aug. 16, 2021. doi: 10.1136/bmj.n2027.
16. Shukla, R., & Diwan, A. (2016). Parallel import: A comparision with different countries. *VIDHIGYA: The Journal of Legal Awareness*, *11*(1), 20. https://doi.org/10.5958/0974-4533.2016.00002.6
17. Bhaskarabhatla, A., & Chatterjee, C. (2012). First-Mover Advantage before and after TRIPS: Evidence from the Indian Pharmaceutical Industry. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.2154510
18. M. Nioi and P. E. Napoli, "The Waiver of Patent Protections for COVID-19 Vaccines During the Ongoing Pandemic and the Conspiracy Theories: Lights and Shadows of an Issue on the Ground," *Frontiers in Medicine*, vol. 8, Nov. 2021, doi: 10.3389/fmed.2021.756623.
19. Ramanujan, A., & Sen, R. (2012). Sowing the Seeds of Change? Patent Policy and Section 3(D) of the Indian Patent Act, 1970. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.2154396
20. S. Sariola, "Intellectual property rights need to be subverted to ensure global vaccine access," *BMJ Global Health*, vol. 6, no. 4. BMJ Publishing Group, Apr. 01, 2021. doi: 10.1136/bmjgh-2021-005656.
21. First Compulsory License Mandated in India. (2012). *Biotechnology Law Report*, *31*(3), 294. https://doi.org/10.1089/blr.2012.9841
22. Agitha, T. G. (2011). International Norms for Compulsory Licensing and the Indian Copyright Law. *The Journal of World Intellectual Property*, n/a. https://doi.org/10.1111/j.1747-1796.2011.00432.x
23. D. Ghai, "Patent protection and Indian pharmaceutical industry." [Online]. Available: www.globalresearchonline.net
24. Three cancer drugs recommended for compulsory licensing in India. (2013). *PharmacoEconomics & Outcomes News*, *678*(1), 11. https://doi.org/10.1007/s40274-013-0413-7
25. P. Erfani, A. Binagwaho, M. J. Jalloh, M. Yunus, P. Farmer, and V. Kerry, "Intellectual property waiver for covid-19 vaccines will advance global health equity," *The BMJ*, vol. 374, Aug. 2021, doi: 10.1136/bmj.n1837.
26. B. G. Davis, "Could You Patent the Sun?," *ACS Central Science*, vol. 7, no. 4. American Chemical Society, pp. 508–509, Apr. 28, 2021. doi: 10.1021/acscentsci.1c00377.
27. F. Tietze, L. Aristodemou, and © Frank Tietze, "Centre for Technology Management Centre for Technology Management working paper series What the United States (US) Intellectual Property (IP) waiver announcement tells us about patent values: A patent premium perspective on Covid-19 vaccine patents Centre for Technology Management (CTM) Working Paper Series What the United States (US) Intellectual Property (IP) waiver announcement tells us about patent values: A patent premium perspective on Covid-19 vaccine patents," 2021, doi: 10.17863/CAM.69515.
28. S. Sariola, "Intellectual property rights need to be subverted to ensure global vaccine access," *BMJ Global Health*, vol. 6, no. 4. BMJ Publishing Group, Apr. 01, 2021. doi: 10.1136/bmjgh-2021-005656.
29. S. C. Law *et al.*, "Santa Clara Law Exclusionary and Diffusionary Levers in Patent Law Exclusionary and Diffusionary Levers in Patent Law 1." [Online]. Available: http://digitalcommons.law.scu.edu/facpubshttp://digitalcommons.law.scu.edu/facpubs/882
30. B. Mercurio, "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," *IIC International Review of Intellectual Property and Competition Law*, vol. 52, no. 8. Springer Science and Business Media Deutschland GmbH, pp. 983–988, Sep. 01, 2021. doi: 10.1007/s40319-021-01083-5.
31. M. Okereke, "Towards vaccine equity: Should big pharma waive intellectual property rights for COVID-19 vaccines?," *Public Health in Practice*, vol. 2. Elsevier B.V., Nov. 01, 2021. doi: 10.1016/j.puhip.2021.100165.

32. N. S. Jecker and C. A. Atuire, “What’s yours is ours: Waiving intellectual property protections for COVID-19 vaccines,” *Journal of Medical Ethics*, vol. 47, no. 9, pp. 595–598, Sep. 2021, doi: 10.1136/medethics-2021-107555.