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INTELLECTUAL PROPERTY RIGHTS AS BARRIER TO CONTAIN THE PANDEMIC: WORLD AND INDIA PERSPECTIVE

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Abstract

The COVID-19 pandemic has already infected and claimed millions of lives and adversely impacted the economies around the world. The pandemic has overburdened national health systems, resulting in more deaths and illnesses due to lack of access to public and medical services. India and the world saw the New Year 2021 with great hope and encouragement with the incoming of vaccines to battle the COVID-19 outbreak, but were not efficiently administered due to Vaccine Nationalism which caused the procurement of whole lot of the vaccines by the rich and developed countries to themselves and not distributing it to the rest of world which is dreaded with the pandemic. In this paper, author aims to discuss how the Intellectual Property Rights and Protection which was initially aimed at promotion of research and development has posed a barrier to battle the COVID-19 pandemic. The Vaccines launched have strict patent protection, which restricts the mass production and wields setback to developing and least developed nations. The paper discusses the initiative of the Indian Government proposing the Waiver of TRIPS Agreement to ensure the availability of the pharmaceuticals and vaccines worldwide. The paper discusses India's status on vaccine production and availability, further aims to provide solutions to eradicate the shortage of vaccines till the decision on the waiver of Intellectual Property Laws is obtained.

Introduction

The COVID-19 pandemic has already infected more than 160 Million victims[1] and has claimed the lives of over 3 million people.[2] Out of which India suffering from the disastrous second wave of Covid-19 has seen more than 2.4 Crore (24 Million)[3] cases and more than

[1] Coronavirus cases and Death Toll available at https://www.worldometers.info/coronavirus/coronavirus-death-toll/ last seen on 14 May 2021 at 5:35 PM
[2] Ibid.
[3] Ministry of Health and Family Welfare, Statistics, available at https://www.mohfw.gov.in/ last seen on 14 May 2021 at 5:35 PM

2.62 lakh[4] victims have lost their lives of this virus. Moreover the pandemic has overburdened national health systems, resulting in more deaths and illnesses, and has triggered a severe economic crisis, putting millions of women, infants, and men's lives in jeopardy due to malnutrition, lack of access to public services, and abuse. The coronavirus epidemic posed a political threat to multilateralism and its institutions, and it reintroduced nationalism to the global agenda. The need for greater cooperation and unity, as well as an efficient and sensitive global health protection framework, to combat global pandemics, was highlighted by the urgency of responding to the current pandemic. Uneven supply of pharmaceuticals and critical medical supplies is one of the most important issues that arise in circumstances like the COVID-19 outbreak. This emphasises the significance of reforming the existing global innovation structure in order to increase the manufacture and distribution of drug delivery, vaccines, and other pharmaceutical products and technologies.

India and the world saw the New Year 2021 with great hope and encouragement with the incoming of vaccines to battle the COVID-19 outbreak. Multiple vaccines gained emergency approval across the world particularly the Pfizer, Moderna and AstraZeneca Vaccine in the USA and the European Union. 2 vaccines namely, COVIDSHIELD and COVAXIN were also given Emergency Approval by the Drugs Controller General of India (DCGI) on 2nd January, 2021.[5] Covidshield is a Recombinant Chimpanzee Adenovirus vector vaccine encoding the SARS-CoV-2 Spike (S) which is manufactured by Serum Institute of India for India developed with technology transfer from AstraZeneca and Oxford University.[6] Another Vaccine which received Emergency Approval is COVAXIN, which is a Whole Virion Inactivated Corona Virus Vaccine developed by M/S Bharat Biotech, Hyderabad based Pharmaceutical company in collaboration Indian Council for Medical Research (ICMR) and National Institute of Virology (NIV).[7]

The COVID-19, on the other hand, has uneven consequences, and the gains of scientific advances do not seem to help all at the same time – the pandemic affects countries and societies in a variety of ways, putting a harsh human and economic burden on the poorest and

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[4] Ibid.
[5] Press Statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID-19 virus vaccine, available at https://pib.gov.in/PressReleseDetail.aspx?PRID=1685761 last seen on 14 May 2021 at 18:12
[6] Ibid.
[7] Ibid.

most vulnerable. It is critical to develop a comprehensive strategy to ensure mass vaccination and that people in the poorest regions and the needy have timely, sufficient, and affordable access to all COVID-19-fighting technologies, including the rapid manufacture of billions of doses of high-quality vaccines, financial support for vaccine purchases, and logistics coordination to ensure adequate supply and equity. It is critical to establish political commitments that restrict unilateralism, especially among the wealthiest countries, which have greater capacity to obtain vaccines.

The term *Vaccine Nationalism* has gained vast prominence is past few weeks, which insinuates the procurement of whole lot of the vaccines by the rich countries to themselves and not distributing it to the rest of world which is dreaded with the pandemic. The International Chamber of Commerce has predicted that if developing nations do not receive the required doses of the vaccine, the global economy will suffer losses of up to $9.2 trillion.[8]

The *British Medical Journal* also cited *Vaccine Nationalism* as one of the major reasons for shortage of Vaccines around the world. According to Article published on 19th March 2021 in *British Medical Journal,* The US ordered 800 million doses of the vaccine from six vaccine manufacturers, with a billion more doses on the way. The United States has a population of 331.42 million people, which means it has much more resources than it needs. The United Kingdom is in the same boat. The Boris Johnson government has set aside five doses for each resident.[9]

Not surprising, the Intellectual Property Rights and Protection which was initially aimed at promotion of research and development has posed a barrier to battle the COVID-19 pandemic. The effect of intellectual property (IP) rights on production capacity and the availability of technology to react to the pandemic is a critical factor to consider at this time. A number of therapeutics will have to obtain a secondary patent because they are repurposed therapeutics or will be registered for new applications, and the key inventions involved with the treatment of COVID-19, whether medicines or technical devices, are already patented. Vaccines are being subjected to the same fate of IP barriers. The Vaccines launched have

[8] Hindustan Times, Vaccine nationalism hurts the whole world, available at https://www.hindustantimes.com/opinion/vaccine-nationalism-hurts-the-whole-world-101619358008334.html last seen on last seen on 14 May 2021 at 18:43

[9] The BMJ, British Medical Journal, Covid-19 vaccine shortages: what is the cause and what are the implications?, BMJ 2021;372:n781, Published 19 March 2021 available at https://www.bmj.com/content/372/bmj.n781 last seen on 14 May 2021 at 19:54

strict patent protection, and those in the trial phases have the same protection. Their basic elements and background technology is and will be patented as well, which restricts the mass production and wields setback to developing and least developed nations.

To get relieved from the adverse effect of the Intellectual Property Regime in order to effectively and efficiently tackle the wrath of COVID-19 Pandemic, on October 2, the governments of India and South Africa proposed waiver[10] of certain basic clauses of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a legal-institutional response to the COVID-19 emergency. The proposal is in line with significant resolutions[11] passed by the World Health Organization (WHO) and the United Nations (UN) in 2020, as well as other measures aimed at ensuring access to control, medication, and immunisation technologies. The resolution by WHO and UN both stressed the importance of rapidly scaling manufacturing and strengthening supply chains to ensure reliable, effective, accessible, transparent, and equitable access to and supply of diagnostics, medicines, and COVID-19 vaccines to those who need them, especially in developing and least developed nations.[12]

TRIPS AGREEMENT

The World Trade Organization (WTO) is a global organisation that regulates international trade laws. The World Trade Organization (WTO) currently has 164 members.[13] Countries that join the WTO commit to follow the 18 relevant agreements that are annexed to the WTO Agreement. Trade-Related Aspects of Intellectual Property Rights or TRIPS Agreement came into effect in 1995 and is one of most highly comprehensive International Intellectual Property (IP) Agreement till the date. The TRIPS Agreement established basic optimal international standards for protecting and implementing virtually all types of IPR, including patents. Prior to TRIPS, there were no minimum conditions for patents in international conferences. With a few exceptions, the TRIPS Agreement now mandates that all WTO

[10] Waiver From Certain Provisions Of The TRIPS Agreement For The Prevention, Containment And Treatment Of Covid-19, Communication From India And South Africa 2 October 2020 (IP/C/W/669) Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True last seen on 13 May 2021 at 20:18

[11] UNGA Resolution 74/274 - International cooperation to ensure global access to medicines, vaccines, and medical equipment to face COVID-19;
and UNGA Resolution 74/270 - Global solidarity to fight the coronavirus disease 2019 (COVID-19)

[12] Ibid.

[13] WTO, TRIPS, available on https://www.wto.org/english/docs_e/legal_e/27-trips.pdf last seen on 10 May 2021 at 20:38

members amend their laws to meet minimum IPR security requirements. About 40 countries around the world did not offer pharmaceutical products patent rights when the negotiations started.[14]

The TRIPS Agreement had been recipient of various criticisms in the context of interests of the least developed and the developing countries and had been time and again referred as the barrier to the access of nations who do not have modern technology and are abused by the extravagant prices charged by the Multi National Enterprises. The major criticism came in the light of pharmaceutical and therapeutic sector as the TRIPS agreement had the paramount adverse impact on the availability and the access to medicines, and other medical equipment and technology.[15]

PATENT PROTECTION UNDER TRIPS

Patent security is a type of intellectual property protection that The TRIPS Agreement allows WTO members to provide protection for any innovation, including pharmaceutical products and processes, for a period of 20 years from the filing date of a patent application.[16] Many countries' patent durations were considerably shorter prior to the TRIPS Agreement. Patent terms ranged from 15 to 17 years in both developed and developing countries, while patents in some developing countries were issued for shorter periods of 5 to 7 years.[17] In all fields of technology, the TRIPS Agreement allows countries to have patent rights for both processes and products. Prior to TRIPS, several countries only granted process patents, not product patents. Product patents provide complete protection for the product, while process patents cover the technology as well as the manufacturing process or system. Protection for process patents does not prohibit the manufacture of patented goods using a reverse engineering process, in which a new process or system is used than the one that was invented (and patented).[18] Manufacturers in some countries including India have been able to produce generic copies of licenced drugs thanks to national legislation requiring only process patent

[14] Ibid.
[15] WHO, WHO AND TRIPS Agreement, available on https://www.who.int/medicines/areas/policy/wto_trips/en/ last seen on 11 May 2021 at 02:49
[16] WTO, Article 33, Agreement On Trade-Related Aspects Of Intellectual Property Rights, available on https://www.wto.org/english/docs_e/legal_e/27-trips.pdf last seen on 15 May 2021 at 12:41
[17] WTO, Developing countries' transition periods, available on https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm last seen on 13 May 2021 at 22:19
[18] Ibid.

protection.[19] These countries have chosen to take advantage of the transition era, which allows countries to postpone patent rights in areas of technology that were not covered prior to the TRIPS Agreement until 2005.[20]

PATENTS AND PHARMACEUTICALS

Drug regulatory authorities require pharmaceutical companies to send data demonstrating the product's protection, effectiveness, and efficacy as a condition of allowing it to be sold or marketed. WTO Members must secure undisclosed test data sent to drug regulatory authorities for the purpose of gaining marketing approval under the TRIPS Agreement from improper commercial use.[21] It is argued that while countries have significant latitude in defining "unfair commercial use," they can satisfy their obligations to protect test data by banning "dishonest" data use.

However, data exclusivity is now argued to be a condition of the TRIPS Agreement. The data exclusivity strategy gives the originator exclusive access to their test data and prohibits regulatory authorities from registering generic alternatives based on the test data. Prior to the implementation of the TRIPS Agreement, most countries required generic goods to be approved based on originator test results. The regulatory authorities could use the test data submitted by the originator company to approve subsequent requests for similar products, or they could depend on evidence of prior approval of a similar product in another nation.[22] Manufacturers of generics just need to show that their product is chemically similar to the brand-name, initial product, and that it is bioequivalent in certain countries. This method allowed for the rapid introduction of generics to the market while avoiding the costs associated with registration data. If a company has submitted original test data, no competing manufacturer is entitled to use such data for a period of time under the data exclusivity approach. [23]

[19] NITI Aayog, Intellectual Property Rights And The Impact Of Trips Agreement With Reference To Indian Patent Law available on https://niti.gov.in/planningcommission.gov.in/docs/reports/sereport/ser/ser_alla.pdf last seen on 14 May 2021 at 21:11
[20] Ibid.
[21] WTO, Article 39, Agreement On Trade-Related Aspects Of Intellectual Property Rights, available on https://www.wto.org/english/docs_e/legal_e/27-trips.pdf last seen on 15 May 2021 at 12:41
[22] Germán Velásquez and Pascale Boulet, Globalization and access to drugs: Implications of the WTO/TRIPS Agreement, EDM Series No. 7
[23] WHO Drug Information Vol 19, No. 3, 2005, Access to Medicines

The TRIPS Agreement had posed a barrier in the distribution of pharmaceuticals, associated technologies and even vaccines across the globe. The rich nations have an extravagant and unequal share of the Drugs and Vaccines due to the developed Research and Development technologies which has resulted in the vast unavailability of the vital pharmaceuticals and vaccines to the Developing and the Least Developed Countries. The TRIPS Agreement entail the provision for the **Waiver** of the TRIPS Agreement in the event of public health emergency. Along with the issue of domestic waiver of TRIPS in the form of Compulsory License, the TRIPS Agreement had allowed waiver of the agreement cross border as well.

TRIPS WAIVER AND COMPULSORY LICENSE

On October 2, the governments of India and South Africa suggested Waiver of some vital provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a legal-institutional response to the COVID-19 emergency, in order to obtain certain relief from the negative effects of the Intellectual Property Regime and to effectively and efficiently combat the wrath of the COVID-19 disaster.

While the TRIPS agreement establishes a minimum standard for patent rights in order to give a temporary monopoly to patent holders, it also establishes a number of exceptions that member countries can use in specific circumstances. Compulsory licence, as established by Article 31 of the TRIPS, nullifies this monopolistic right by authorizing member nations to grant licences to manufacture licenced goods without the consent of the patent holder.[24] Article 31 does not specifically mention the word "compulsory licence," but when read in conjunction with TRIPS Article 2(1) and the Paris Convention Article 5(A)(2), the allowance of compulsory licence is inferred.[25] As a result, developing countries have interpreted Article 31 to allow member countries to grant compulsory licences to third parties in order to produce medication to resolve domestic public health issues.[26] As per Article 31 of the TRIPS, in the event of a national emergency or other extreme circumstances of extreme urgency, or in cases of public non-commercial usage, a Member nation may waive the requirements mentioned for the grant of right to manufacture the patented product. In the event of a national emergency or other situation requiring immediate attention, the right

[24] WTO, Article 31, Agreement On Trade-Related Aspects Of Intellectual Property Rights, available on https://www.wto.org/english/docs_e/legal_e/27-trips.pdf last seen on 16 May 2021 at 11:47
[25] *Anthony P. Valach*, Chicago-Kent Journal of Intellectual Property, Ed. 16, 2005
[26] Supra 24

holder will be informed as soon as reasonably possible. In the case of public non-commercial use, the right holder shall be immediately notified if the government or contractor knows or has demonstrable grounds to know that a legitimate patent is or will be used by or for the government without conducting a patent search.[27]

Developing countries have made limited use of Article 31, which requires member countries to issue compulsory licences according to certain procedures and conditions. According to studies, developing countries have not used compulsory licencing as a method to resolve public health concerns for a variety of reasons, including the fact that successful implementation of compulsory licencing necessitates the fulfilment of certain administrative, financial, and technological preconditions, which are often not met in developing countries.[28]

DOHA DECLARATION

The Declaration on the TRIPS Agreement and Public Health was adopted on November 14, 2001, at the WTO's fourth Ministerial Conference in Doha, Qatar (Doha Declaration). One of the goals of this conference is to clarify the uncertainty surrounding TRIPS' compulsory licence provision.[29]

The WTO General Council approved the Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health on August 30, 2003.[30] The Decision permits any member country to export pharmaceuticals produced under compulsory licences as long as the export meets the conditions of paragraph 2 of the Decision. Despite the fact that the Decision requires all member countries to benefit from the waiver, 23 countries indicated in the Decision that they would not import pharmaceuticals as a result of it, and another 11 countries stated that they will only use the waiver clause if an emergency or extremely urgent situation occurred.[31]

- **TRIPS WAIVER PROPOSAL FROM INDIA & SOUTH AFRICA**

[27] Supra 24
[28] WHO, WHO AND TRIPS Agreement, available on https://www.who.int/medicines/areas/policy/wto_trips/en/ last seen on 11 May 2021 at 02:49
[29] WTO, Doha WTO Ministerial 2001: Tripswt/Min(01)/Dec/2, Declaration on the TRIPS Agreement and Public Health available on https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm last seen on 16 May 2021 at 11:25
[30] WTO, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WT/L/540 and Corr.1, 1 September 2003
[31] Ibid.

As discussed above, India and South Africa have passed a Communication to WTO for the waiver of TRIPS agreement to efficiently and effectively combat the COVID-19 Pandemic assuring the adequate access of pharmaceuticals and particularly vaccines to the Developing and Least Developed Countries. Discussed above about the adverse impact of the patent regime on the production of vaccines for the Developing and LDCs, this led to both the nations to appeal in the WTO for the TRIPS Waiver. Speedy vaccination across the world is the only viable way to counter the pandemic well. The production of vaccines very limited due to the stringent IPR regime because of TRIPS agreement and the access is restricted to first world nations.

Initially the developed nations of the world including USA, Canada, Japan and countries of European Union, were advert to waiver of TRIPS citing the significance of Intellectual Property for driving innovation and inventions.[32] Against it, 57 member nations have backed the proposal initiated by India and South Africa, but the approval requires consent of all the member nations who are signatories of TRIPS Agreement.[33] Failure to approve the COVID-19 waiver for equal access to medicines under the Trade Related Intellectual Property Rights (TRIPS) Agreement, India's ambassador to the World Trade Organization (WTO) addressed to all the member nations, could cost the global economy trillions of dollars at the cost of protecting vaccine makers' $30-40 billion industry.[34] Recently, USA Representative to WTO stated the decision of Biden Government on the waiver of TRIPS Agreement and expressed support to the waiver citing the global health crisis and the need for extraordinary measures to combat the COVID-19 pandemic by ensuring removal of barriers posed by the IPR regime and promoting adequate availability of vaccines across the world and especially to developing and LDCs. [35] With this major change in stance of the US government the other

[32] The Hindu, TRIPS waiver for vaccines key to growth: India's envoy to WTO available on https://www.thehindu.com/business/trips-waiver-for-vaccines-key-to-growth/article33950900.ece last seen on 14 May 2021 at 19:53
[33] WTO, Doha WTO Ministerial 2001: Tripswt/Min(01)/Dec/2, Declaration on the TRIPS Agreement and Public Health available on https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm last seen on 16 May 2021 at 11:25
[34] Supra 32
[35] Office of the United States Trade Representative, Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver, available on https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver last seen on 16 May 2021 at 5:35

opposing nations have stated on reconsideration of their decision on the waiver proposal by Indian and South African Governments.[36]

COMPULSORY LICENSING IN INDIA

The signatories of the TRIPS Agreement are required to draft new legislations or suitable amendments which are in consonance with the Agreement, therefore, to match the international requirements, the Indian legislators amend the Acts related to Intellectual Property in the country with the amendments in TRIPS. One such important statute vital to Indian IPR is the Indian Patent Act, 1970[37] which regulates the law of patents in India. TRIPS Agreement came into force in 1995, and the Indian Patents Act, 1970 was eventually been treated with the amendments required to meet the requirement set by TRIPS Agreement. Compulsory licences are permits granted by the Controller General of Patents to a third party to produce, use, or sell a patented product or to use a patented method to make a patented product without the permission of the patent owner.

INDIAN PATENTS ACT

The rules about compulsory licencing are expressly set out in Chapter XVI of the Indian Patent Act, 1970 ("Act").[38] Sections 84 and 92 of the Act specify the different requirements that must be met in order for a compulsory licence to be issued, such as the grounds for the issuance of a compulsory licence and the considerations that the Controller must consider when determining whether or not to grant a compulsory licence.[39] While in ordinary course a Compulsory License may be applied for and granted after 3 years of original patent granted.[40] Importantly, under Section 92 of the Act, the Central Government can issue a compulsory licence in respect of any patent in force to any individual interested at any time after the patent is sealed, in cases of national emergency, extreme urgency, or public non-commercial usage. Furthermore, in the event of a public health emergency, such as an outbreak, the

[36] WTO, 2021 News Items, TRIPS Council to continue to discuss temporary IP waiver, revised proposal expected in May, available on https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm last seen on 16 May 2021 at 5:56
[37] Indian Patents Act, 1970
[38] Section 84, Indian Patents Act, 1970
[39] Supra 37
[40] Supra 38

process for obtaining a compulsory licence set out in Section 87 of the Act is not required to be followed.[41]

JUDICIARY ON COMPULSORY LICENSING

The case of *Bayer Corporation vs Union of India*[42] (the "Bayer case") is a watershed moment in India's compulsory licencing history. The Bayer case stemmed from a patent issued by Bayer Corporation ("Bayer"), a German company in 2010 for a medical drug known as *Sorafenib Tosylate*, which was marketed as *Nexavar* and used to treat liver cancer and was priced very heavy at around Rs.2.8 lakhs. Natco Pharma ("Natco") an India company approached Bayer in 2010 for a voluntary licence to manufacture and market the patented drug under its own brand name in India at a lower price of Rs. 9000. However, discussions for a voluntary licence did not succeed, and in 2011, three years after Bayer's patent was granted, Natco filed an application with the Controller for a compulsory licence. After considering the various provisions of the Act, the Controller granted Natco a compulsory licence to manufacture and distribute the patented drug in India. Intellectual Property Appellate Boards ("IPAB") upheld the Controller's decision. The aggrieved party Bayer filed a writ petition in the High Court of Bombay, challenging IPAB's decision. The IPAB's decision was upheld by the High Court, which found that Bayer had failed to fulfil the fair demand of the public in respect of the generic drug by not selling it at an affordable price. The Hon'ble Court held that the proceedings under Section 84 of the Act were in the public interest because the whole purpose of the compulsory licence is to make patented articles available to society in sufficient quantities and at a fair price. This was the landmark movement in Indian IPR regime which set judicial precedent of granting Compulsory License in the interest of public health and medical emergency.

USE OF COMPULSORY LICENSE IN COVID-19 PANDEMIC

Given the fact that COVID-19 has been declared a pandemic by the World Health Organization and the severity of the disease's effect across the country, the current situation may be classified as a "national emergency" or a "case of severe urgency." The same would imply that if an inventor develops and patents an effective vaccine or successful medicine, the government would be well within its rights to grant a compulsory licence in order to

[41] Section 92, Indian Patents Act, 1970
[42] 2014 SCC OnLine Bom 963

efficiently tackle the public health crisis. The granting of a compulsory licence would benefit the public interest because it would result in the mass production and selling of the patented pharmaceuticals and vaccines at low prices, speeding up the availability process.

One of the pharmaceutical firms, Gilead, which has licenced Remdesivir, a wide spectrum anti-viral medication that has shown promise in treating COVID-19, has signed non- exclusive voluntary licencing agreements with five generic pharmaceutical manufacturers in India to extend Remdesivir's supply.[43] The agreements not only give the pharmaceutical manufacturers a non-exclusive right to receive a technology transfer of the Remdesivir manufacturing process, but Gilead on the humanitarian grounds, has also agreed to not charge any royalties before the World Health Organization declares the COVID-19 Public Health Emergency to be over, or until a pharmaceutical product other than Remdesivir or a vaccine is approved. Such a measure by the pharmaceutical patent holders of the anti COVID-19 drugs and Vaccine manufacturers enables the government not to take the drastic step of Compulsory Licencing which interferes with the IPR policies of the nation and even at the global level on one hand and benefits the public at large on the other.

In India, 2 Anti-COVID vaccines are majorly administered as discussed above, and till now more than 18 Crore (180 Million) doses have been administered in India.[44] India entails the 2nd largest population in the World and vaccination drive in India is one of the major aspects of the COVID-19 combat globally. Therefore, speedy vaccinations in India is immensely important and with the incoming of devastating second wave the people of India have firmly recognised the importance of COVID-19 vaccination and thus, vaccines are now in vast demand in India. To cater such large population, the current production seems inadequate and measures are required to be undertaken to speed up the vaccination production. The Union Health Ministry mentioned that total of around 8 Crore (80 Million) vaccines will be received in the month of May 2021 and the production of vaccines will be ramped up.[45] According to the PTI Report both Bharat Biotech International Ltd. And Serum Institute of India have

[43] Gilead, Voluntary Licensing Agreements for Remdesivir; available at- https://www.gilead.com/purpose/advancingglobal-health/covid-19/voluntary-licensing-agreements-for-remdesivir last seen on 16 May 2021 at 15:37

[44] Ministry of Health and Family Welfare, Cumulative Coverage Report of COVID-19 Vaccination, available on https://www.mohfw.gov.in/pdf/CumulativeCovidVaccinationCoverageReport15thMay2021.pdf last seen on 16 May at 20:13

[45] Press Information Bureau, Delhi, Ministry of Health and Family Welfare, Dr. Harsh Vardhan reviews Public Health Response to COVID-19 and Progress of Vaccination with 8 States/UT, published on 12 May, available on https://pib.gov.in/PressReleasePage.aspx?PRID=1718098 last seen on 17 May at 18:03

submitted the production plans to DCGI and the Union Health Ministry. Bharat Biotech plans to increase COVAXIN production to 3.32 crore doses in July and 7.82 crore doses in August, according to the schedule. In August, the Serum Institute plans to increase production to 10 crore doses.[46]

The government has been facing criticism over the shortage of supply vaccines due to the limited production and the experts appealed for the grant of Compulsory License for the quick and efficient upscale production of vaccines by the certified laboratories involved in the production of other vaccines. The Compulsory License in the current situation is possible but the production of anti COVID-19 vaccines requires basic infrastructure and facility, a number of vaccination producing companies are already involved in manufacturing or development trials of one or the other COVID-19 vaccines. Six Indian manufacturers including Dr. Reddy's Laboratory have already tied up with Russia's RDIF for the production of Sputnik V vaccine and Zydus Cadilla's vaccine is in its Phase III trials.[47] Therefore, Indian Government is keen on certain measures to be undertaken and a lot more can be done which has been subsequently discussed.

INDIA ON VACCINE PRODUTION

Following the vast demand for vaccines and the only effective way of combat against the deadly virus, the Indian Government is before the WTO to Waive the IPR regime under TRIPS Agreement for the anti COVID-19 pharmaceuticals and vaccines, in order to increase the production of vaccines and pharmaceuticals across the world.

INITIATIVES UNDERTAKEN BY GOVERNMENT OF INDIA

Meanwhile, till the TRIPS Waiver is granted, the Government of India have a robust measure which if rightly implemented can prove to be a revolutionary in battling the pandemic. As stated above, COVAXIN, one of the COVID-19 vaccines administered in India is jointly developed by the Bharat Biotech International Ltd. along with Indian Council of Medical Research (ICMR), which is an organisation established and governed by the Department of

[46] Hindustan Times, Bharat Biotech, Serum Institute submit Covid vaccine production plans for next 4 months to Centre Reports PTI, published on May 13 2021 available on https://www.hindustantimes.com/india-news/covid19-vaccine-production-to-reach-8-crore-doses-by-may-says-harsh-vardhan-101620870311166.html last seen on 16 May at 21:41

[47] The Lancet, VOLUME 397, ISSUE 10285, P1611-1612, MAY 01, 2021, Experts Criticise India's Complacency available on https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00993-4/fulltext last seen on 17 May at 18:54

Health, Ministry of Health and Family Welfare and National Institute of Virology, which comes under ICMR. Therefore, the Government of India is also the developer of the COVAXIN vaccine and can move forward with technological transfer to the eligible laboratories for the manufacture of COVAXIN vaccine. The Government of India took the cognizance of the situation amidst the high demand and shortage of supply and in the month of April decided to bank upon joint patent ownership. As part of its strategy to boost domestic production of the Covid-19 vaccine, the Indian government has tried to engage public sector companies to enter into technology transfer agreements with Indian vaccine manufacturer. Bharat Biotech has entered into a technology transfer agreement with two Central Government PSUs, Indian Immunologicals Ltd. (IIL) and BIBCOL. In addition, the Haffkine Institute, a State Government Undertaking, has entered into a technology transfer agreement with Bharat Biotech. Grants have been made to these PSUs to acquire the adequate infrastructural facilities required for the efficient and speedy production of COVAXIN. Indian Immunologicals Limited will be able to begin producing COVAXIN in September 2021 as a result of the Central Government's constructive intervention, while Haffkine Institute and BIBCOL will begin producing COVAXIN in November 2021.[48] This again is a time taking process and the need for vaccine is immediate, and the experts' advice the government to speed up the vaccination as soon as possible as there's an imminent danger of 3rd wave, which can only be countered well with vast scale vaccination. Very recently, Even 2 private firms from Gujarat named OmniBRx, which is a biotech company and an animal healthcare firm named Hester Biosciences have also been included to manufacture COVAXIN, and Bharat Biotech has signed contract for Technology Transfer with them.[49] This is the need of the hour to involve both Public and Private sector to ramp up the vaccine production even till the time there's no clear decision on the TRIPS Waiver and to continue the same till the requirement is fulfilled.

In order to ramp up the vaccine availability, the Government of India has further liberalised the procurement policy of the internationally developed vaccines under the newly introduced "Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy". The Union

[48] Press Information Bureau, Delhi, Ministry of Health and Family Welfare, Liberal Enabling Environment Created by Government of India for Enhanced Vaccine Supply in the country, , published on 13 May 2021, available on https://pib.gov.in/PressReleasePage.aspx?PRID=1718332 last seen on 17 May at 20:47
[49] The Hindu, More firms get the nod to produce COVAXIN, published on 16 May 2021, available on https://www.thehindubusinessline.com/news/three-more-firms-get-the-nod-to-produce-covaxin/article34567892.ece last seen on 18 May at 03:18

Government has made specific provisions in its new liberalised strategy that vaccines for COVID-19 that have been developed and manufactured in foreign countries and have been granted emergency use authorization by National Regulators in the United States, European Medicine Agency (EU), United Kingdom, Japan, or WHO (Emergency Use Listing), will be granted. It also allows for the execution of a post-approval parallel bridging clinical trial in lieu of a prior local clinical trial, as stated in the Second Schedule of the New Drugs & Clinical Trials Rules 2019.[50] This would make it easier to import Covid-19 vaccines and ensure that they are more readily available in India.

Under the same policy, other than the Government of India channel, which includes state governments, private hospitals, and industrial establishments, 100 percent doses of manufactured and ready-to-use international vaccine will be available.

THE WAY AHEAD: SOLUTIONS AND SUGGESTIONS

The second wave of COVID-19 has caused huge broil in India, while some states considered the pandemic over and referred to it as endemic, the devastation this wave is causing implausible. This led to one the one solution that the waves are uncertain and vaccinating maximum people is the only way out, and therefore, the Union Government launched vaccination for all the adults, which has caused shortage of supply of vaccines as it is not easy to cater the vast population such as India.

Now, in order to rectify the shortage, the government has been trying to ramp up the production through their means but is being criticised for the low production and limited production units. To speed up the production process, since the Union Government is the joint developer of COVAXIN should invite the proposals from vaccine manufacturers and grant the entities with adequate infrastructure the license to produce the COVAXIN, also certain grants can also be made by the government to speed up the process of procuring necessary infrastructure and therefore speeding up the production. In this way, the price of manufacturing the vaccines would go down achieving economies of scale and large number of vaccines could be produced in limited time span. The licenses for manufacturing COVAXIN shall be termed as temporary in nature by the Government and a time limit, for example, of 2 years should be set, which is an approximate time estimated for the total

[50] Supra 48

population of the country. After the lapse of this period, the original patent shall be restored in the name of the original developers and provisions of the Indian Patents Act be made applicable.

India needs large number of vaccines to obtain self-sufficiency, plus the nation has a reputation for being the 'pharmacy of the world', and hence, COVAXIN, which is an Indian vaccine, can be exported to the world to combat the pandemic in the whole world if such method is adopted and implemented well. COVAXIN is special in its nature as it doesn't require extreme cold storage unlike Pfizer, Moderna, which enables the developing nations and LDCs with limited cold storage facility to distribute and administer vaccines well with minimum wastage. The Government of India should make the provision for reasonable Royalties to Bharat Biotech International Ltd. for the vaccines meant for commercial export, in this way the leading innovator gets the recognition for its efforts and IP laws are also appreciated.