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Patent Waiver on Covid Vaccine: Access for all or Global Supply Crisis?

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The Coronavirus disease 2019 or COVID-19, pandemic has transpired disastrous effects in the world in multiple forms ranging from the high death tolls to the steep fall in global economy. Even so, it had managed to provide a silver lining in the form of unanimity of researchers from several disciplines, who united to contribute blood, sweat and tears to present to the world the miracle of science- vaccines. One can only imagine the extent of investment which has gone into development of the few vaccines we have today. In fact the research continues to be in full swing, with the hope and zest to better. While every country fights the pandemic with vigor, it is the pharmaceutical R&D which is expected of breakthrough discoveries as a solution. Where the pressure to succeed is tremendous, millions invested and no option to fail is it not justified to expect and deserve patent for the same. This paper will dwell into the justification of patent over Covid-19 vaccines, the ongoing debate over patent waiver and analyze whether the waiver will in fact facilitate greater access and affordability of vaccines or prove to be an impediment for global supply.

Keywords: Patent Waiver, Covid-19, Vaccine, World Trade Organization, Intellectual Property Rights

Covid 19 may not have been the first pandemic the world witnessed, but the effects of the same have affected each and every individual around the globe. Loss of lives, dilapidation of business, wreckage of global economy, massive lay-offs are some of the uncountable reverberations the world is striving to fight. The disease managed to uproot the most strongest of people and countries to leave them in a state of despair. One could have never imagined that the 21st century, which has seen the best of technological advancements will encounter a situation that modern science and technology will be helpless against.

It is interesting to note that before 2019 six varieties of human corona viruses were already known to cause illness in humans.[1] Out of the six, four have been recognized as endemic, implying that the diseases caused by the same are mild and self-limiting.

The remaining two namely Human Coronavirus HKU1 and Middle East respiratory syndrome Coronavirus (MERS-CoV) lead to severe illness and are potentially fatal.[2] SARS-CoV2 which is popularly known as COVID-19 has been characterized as a beta Coronavirus and is the seventh known discrete form of Coronavirus strain which results in severe illness in humans and has been the reason for the rapid spread of the disease causing respiratory infections and even fatal pneumonia, known to have begun in Wuhan, China.[3]

While the world at the outbreak of the pandemic was still struggling to understand the disease, researchers were already at work, putting their best foot forward to provide medicine for its cure and prevention. In fact it will not be wrong to state that researchers did not begin from scratch when attempts begun to find a cure. As per the National Institute of Allergy and Infectious Diseases there are many forms of Coronavirus already present and known to mankind.[4] The study on Coronavirus has been ongoing for the last five decades to understand its structure, variants, genome, life cycle, etc.[5] In fact many variants of the virus are already in circulation among animals such as pigs, dogs, cats, etc.[4] Thus the fatality characteristic of CoVs was already known to veterinary virologists.[6] Many forms of canine Coronavirus can be controlled by routine vaccinations which are already in existence.[7] Human Coronavirus on the other handespecially SARS CoV is a "virgin soil" pandemic as it is entirely novel, which has attacked the human population, who lack any kind of preexisting immunity to fight the same. Such a scenario poses two possible outcomes of the pandemic. Herd immunity will develop as a consequence of the spreadthrough susceptible populations but with many deaths of the vulnerable. Also, there may arise waves of infections in many

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communities and nations with varied duration of protective immunity. Prevention being better than cure, it becomes obvious that the sole long term solution to the pandemic is developing an effective vaccine which will greatly reduce the risk of infection by preparing the immune system in the body to recognize the pathogen and fight it.

The genetic sequence of SARS-CoV-2 was published on 12 January 2020, which triggered intense research and development around the world to develop a vaccine.[8] Where vaccines normally take over a decade for development and approval, the COVID-19 vaccines were approved and circulated for use only after eight months of the disease being notified to the World health organization.[9] It is undeniable that both tangible and intangible investments have borne the results in the form of a number of COVID-19 vaccines which are being administered around the world to immunize man against the deadly disease. While prima facie the intention with which globally R&D put efforts in this direction was to curb and cure the disease, it would not be wrong of them to expect and be rewarded for the results.

Justifying Intellectual Property over Vaccines

Intellectual property Rights are a set of intangible rights provided over products of intellect. A patent, which is a form of intellectual property over novel inventions, is a form of monopoly rights to protect the invention from unauthorized exploitation. Among the many rationales and justifying theories which support the concept of IPR, the most relevant and sound one comes from John Locke's in the form of labour theory which states that if a person utilizes the resources available to all and creates something unique from the same, the outcome becomes his property. His theory, which validates private property as a natural right was extracted from the following excerpt

> *"The labour of his body and the work of his hands, we may say are properly his. Whatsoever then, he removed out of the states that nature has provided with and left it in, he hath mixed his labour with it and joined to it something that is his own and thereby makes it his property."*[10]

Extending this logic to patent over vaccines clarifies that when a person puts in labour to produce an output, which will serve and be utilized by the society at large, the same becomes his property which is worthy of protection from the world at large.[11] When it is undeniable that the vaccines the world is using as a shield against the disease, is the result of unimaginable amount of investments, both tangible and intangible, why is it difficult to reward the deserving via patents.

Another logical explanation to justify patents over Covid vaccines is that one should be allowed to reap the benefits of one's efforts. The governments of many countries have spent trillions of dollars into the R&D in the hope of a miracle medicine. The research organization, whether private or government entities, and the country as well, after the successful production of vaccines looks forward to recuperate their investments which will only be effectively possible when a patented vaccine is sold world over. An added benefit of the same will be in the form of lifting up the rapidly dying economy of the nation as well the world at large, which was caused by the disease.

Patents are essential in serving as the much deserved reward for the efforts but also act as an incentive to keep the inventors motivated to invent. While there are many Covid vaccines in circulation around the world, one must not forget that there is always scope for improved and better vaccines and medicines to fight the ongoing disease, the motivation for which will flow from patent like incentives.

Patent Waiver Talks around the Globe

> ***"****With a fast-moving pandemic, no one is safe, unless everyone is safe."*[12]

World over, more than 43 reputed pharmaceutical and biotech companies have been at work to discover the vaccine against Covid-19. Some countries took the lead in not only developing but moving to the trial phase and eventually getting the regulatory approval to use the same. The scenario reeks of a rat race for profits often leaving aside the very purpose for which the efforts are being made. The competition among companies while on one hand is appreciated as it increases the odds of success, but often also results in unbearable consequences to be borne by public. Sensing the repetition of *Myriad*[13] like situation, and the emergency created by pandemic, two developing countries namely India and South Africa, on October 2, 2020 submitted a proposal to the World Trade Organization for allowing all member countries to opt to neither grant not enforce patents or any other form of intellectual property right over COVID-19 drugs, vaccines, diagnostics and other related technologies

till the pandemic state subsists and global herd immunity is accomplished.

The World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights imposes minimum obligations on member states to provide protection over intellectual property. It is for these very reasons that today majority of the nationshaving a well-established framework for IP protection. The proposal for waiver by South Africa and India is directed towards the same agreement and obligations therein so that an exemption may be allowed in lieu of the ongoing situation. The proposal was welcomed and supported by over 100 member countries while a minority including the European Union, Brazil and Canada withheld support.[14] The United States also initially hesitated, but in May 2021, under pressure from activists and Democratic law makers, the President Mr. Joe Biden announced support.[15] It has been over 11 months since the submission of the proposal that the discussions in TRIPs Council continue on this issue.

Rationale behind Waiver

Amid the pandemic situation where health and lives of people ideally should be the priority, it is hard to justify granting monopoly rights over vaccines. Proponents of waiver argue that allowing intellectual property rights over healthcare products and services at this point will not serve the very purpose for which the same were created. Scarcity of raw material, inadequate production capacity coupled with the complexity of manufacturing process of vaccines is causing worldwide inaccessibility to the same. Allowing IP rights will add fuel to the fire and further the divide between rich and poor nations.[16]

While it is a fact that the need of the hour is worldwide vaccination at the earliest and the same will be effectively possible when world over pharmaceutical companies are allowed to manufacture the same without any fear or possibility of infringement. Every country should have the right to manufacture its own vaccines instead of waiting for the same and paying exorbitant prices for it. The sole goal of nations should be to reduce barriers between the developed & wealthy and the lowest income nations. Waiving of any kind of IP would result in boosting of production of vaccines and other required drugs and will also be available affordably.

The idea for waiver emerged from situations which arose early in 2020 during the initial spread of the disease wherein hand sanitizers and N95 masks were not only in shortage but sold at unreasonable prices. In fact the proposal cites an example of such a bottleneck wherein United States suffered shortage of N95 respirators which eventually led to the Kentucky Governor, Andy Beshear calling on manufacturers to lift patent over the same.[17] In hindsight also, the *Myriad* fiasco had ensured that waiver be demanded for the welfare of the society at large as opposed to the economic gains of some. While it is undeniable that an unaffordable drug is as good as no drug at all, the practical feasibility of waiver remains questionable especially on the perspective of how the same will effectively increase access.

The Legal Basis of Waiver

The Marrakesh Agreement, which established the WTO, allows "exceptional circumstances" whereby the Ministerial Conference, the premierdecision making body in the WTO, may waive an obligation of the WTO on member states.[18-19] A pre-requite to this exception is that three-quarters of members be in support of the waiver.The Agreement also lays down that if the waiver request pertains to a multilateral trade agreement given under Annexes 1A, 1B or 1C, the request has to first be submitted to Council for Trade in goods, Council for Trade in Services and Council for TRIPS respectively.[20] Thus, for an IP waiver over vaccines and other drugs, the request will be entertained by the TRIPS Council. Further, the WTO Agreement also states that where allowed, the "exceptional circumstances" have to be stated and justified clearly by the Ministerial Conference along with the terms and conditions which shall govern the waiver.[21] The waiver must have a termination date, and for the tenure it exists, be reviewed annually by the Ministerial Conference.

Although the term "exceptional circumstances" as laid down in the Marrakesh Agreement has not been defined in the WTO Agreement, the words are indicative of the authority to waive few obligations, the intention of which is legalizing measures adopted or to be adopted due to emergency like situation, the non-observance of which would otherwise lead to violation of the WTO law. Thus WTO is empowered to consider hardships of a member nation and allow exceptions pertaining to observance of obligations when compliance is not feasible. With power comes great responsibility and this power of waiver should

be exercised with due care and caution[22] too to ensure that the provision, which is intended to help countries during adversities does not become an escape to avoid fulfillment of commitments.

WTO has allowed collective waiver twice in the past.[23] In 2003 a waiver from General Agreement on Tariff and Trade obligations was requested by Australia, Brazil, Canada, Israel, Japan, Korea, Philippines, Sierra Leone, Thailand, United Arab Emirates and United States to legally validate measures taken under the Kimberley Process, which was intended to curb trade in conflict diamonds or 'blood diamonds' while supporting legitimate diamond trade.[24] The other incident wherein waiver was allowed was over concerns to provide extra flexibility for countries which lacked manufacturing capability, to be able to import patented drugs which were manufactured under compulsory licensing.[25] The flexibility of "compulsory licensing" which forms part of the TRIPS Agreement, whereby governments are allowed to issue compulsory license to allow companies besides the patent holder to manufacture or use the patent without the consent of the patent holder subject to certain conditions.[26] As a result, the provision which lays down the obligation of compulsory license to be issued on a patented drug predominantly for supply to the domestic market[27], was waived for exporting countries, subject to the extent necessary for manufacturing a pharmaceutical product and its export to an eligible importing country. Needless to say, the obligation of paying remuneration to the patent holder for using the patented invention[28] is also waived for the importing country.[29]

The Covid-19 pandemic, which is being considered as the worst global health crisis to have occurred in the last 10 years, has devastated the world in unimaginable and unquantifiable ways. Thus the same undoubtedly constitutes as an "exceptional circumstance" as per the provisions of the WTO Agreement.[30] While it seems that the disease is to stay for a while, nations have to unite to find and fight the same innovatively. Increasing production of vaccines and drugs alone will not suffice unless coupled with timely access at affordable prices. The waiver will only be effective in suspension of IP obligations on countries so that the ones which are capable may begin manufacturing of the vaccines and export the same to the lesser capable ones. Other issues such as access and affordability cannot be sure shot ensured even if waiver is allowed in the near future.

Flexibilities of TRIPS: Efficient or Insufficient?

The objectors to the proposal for waiver content that TRIPS Agreement are packed with flexibilities which can be utilized to address issues such as one which surrounds us at the moment, thus making the waiver demand redundant.[31] There is no denying that TRIPS does carry some flexibilities such as Compulsory license, which is equivalent to a *Bharamastra*, giving the government of a country the right to make use of a patent during its term without the consent of the patent holder, regulated by the provision of TRIPS. Similarly public non-commercial use also falls under the same ambit wherein the government is empowered to use patent for its purposes. A study analyzed and stated that of the 144 times wherein TRIPS flexibility measures were used between 2001-2006, 100 instances were related to compulsory licensing or public non-commercial use to escalate production of generic medicines and provide the same at affordable prices.[32] Another flexibility which was widely used by least developed countries was the long transition period allowed to them to comply with the obligations of TRIPS.

While there aremuch flexibility which are evidently utilized, it would be erroneous to conclude that the flexibilities of TRIPS are sufficient to deal with the current and like situations. The utility of flexibilities such as compulsory license differs country to country as those who have manufacturing capability can well make use of it to produce generic medicines whereas many least developed countries, lacking the required infrastructure will not be able to capitalize the said flexibility. The developing countries are pressured into not issuing such licenses by the developed countries and often end up facing back lashes, such as India did in 2012[33] when it granted compulsory license to produce a generic cancer drug of Bayer's patent.[34]

In 2003 the General Council of WTO amended the TRIPS agreement for the first time since its inception. This decision was taken in consonance with the rules of global trade regarding public health requirements in poor countries. Adopted unanimously in 2005, the amendment makes permanent the mechanism to ease access to affordable generic drugs of poor WTO member nations, which are produced in other nations.[35] The amendment took effect on 23 January 2017[36] to include Article 31 *bis,* which empowers developing and least developed importing countries which face health crisis and are not self-sufficient, to seek the required medicines from third country

manufacturers under "compulsory license" flexibility. The very fact herein that primarily the waiver followed by amendment was required to meet a situation establishes that TRIPS flexibilities may not be adequate after all for addressing concerns such as drug scarcity.

There is also the option of availing the flexibility of voluntary license which is granted by patent holders to generic companies on amicably accepted terms and conditions. Serum Institute of India is currently manufacturing AstraZeneca's Covid-19 vaccine under voluntary license which was granted to it.[37] This appears like a fool proof answer but is often cloaked in secrecy where important decisions such as selection of ultimate beneficiaries or third party sellers are controlled by the patent holder even after the grant of license as it did in the case of license issued to Serum Institute of India.[38] Even though the license has allowed India to supply vaccine to developing countries however, for production boost which is needed to meet the global demand, many companies would necessarily have to be upgraded so as to start producing the vaccine. This would obviously need non-exclusive deals directly between the manufacturing companies and AstraZeneca, a scenario which is very unlikely in the near future.

Effect on Global Supply and Trade: Analysing Short and Long Term Consequences

Intellectual property rights are exceptions to the idea of free trade. The current discussion on providing waiver has its root in a fifty year long debate on the degree of application of IPR rules to the products and services in healthcare industry. Historically, developing countries have always advocated the idea of waiver of IP to make medicines affordable and accessible, while developed countries have had a contrary approach on the pretext of incentive/reward theory for the innovator, which keeps him motivated to progress.

While incentives to the innovators in the form of IP rights is intended to benefit the society in facilitating enhancement of the quality of human life, if the WTO gives in to the request for waiver of patent in the current scenario, which are created mostly by the private entities, after spending millions (or billions) on research and development on the same, it will set a precedent for future global catastrophes. This one waiver in the times of pandemic, may become a dangerous precedent[39], causing inhibitions towards further research and innovations as inventors will not see any incentive to innovate. Short-sightedly the waiver may boost production and accessibility but in larger scheme of things, it will bog down innovation and consequently the international trade. These are few apprehensions which WTO must take into account as this may not be the only pandemic which the world has to fight.

Another reason why waiver may not be a good idea is that any manufacturing country, may lose faith in the WTO system and eventually head towards non-compliance of its principles. Pharmaceutical companies will not only be discouraged to manufacture products but may also become disinterested in investing in other countries, which is bound to affect the expansion of this particular industry and related investments internationally.[40]

Proponents of waiver contend that in the absence of any IP right, manufacturing companies can utilize the available knowledge to manufacture the required vaccines and drugs. What this assumption fails to take into account is that mere availability of knowledge and technology do not guarantee the exact same outcome. The intangible aspects such as the know-how and trade secrets are the key ingredients to the quality and efficiency of the vaccines, the plausibility of transfer of which is hard to imagine.[41] The obvious consequence of this will be society's loss of faith in the proficiency of vaccines and probably abstinence from the same, affecting trade worldwide.

Countries which lack the required infrastructure or manpower to manufacture vaccines are dependent upon the reasonably priced medicines from the manufacturing nations. Waiver will require exporters and importers to comply with onerous and time consuming rules and regulations related to customs, duties and other negotiations, thereby rendering the waiver of no practical utility towards handling the ongoing pandemic.Anothercredible and drastic result of the waiver which will hit the consumers possibly as hard as the disease itself, is that once the states guarantee or ensure the manufacturers to purchase the vaccines manufactured by them on their own accord, to distribute amongst its citizens, it will end up paying hefty amounts for the same. Few implications of this is cutting of expenses in other sectors and increase in taxes, affecting the citizens ultimately.

Waiver of all kinds of IP over vaccines and drugs may give rise to counterfeit products. To tackle this

concern and to reinstate faith in the genuinely and efficiency of locally manufactured or imported vaccines will require efforts and resources, placing burden on the government of the respective country. As a cherry on the top, this may inadvertently slow down the trade in these vaccines as countries, both importing and exporting, will have to dedicate time and resource to avoid trade of counterfeit or ineffective vaccines. This concern will further the demand for more stringent quality and technical tests before vaccines are cleared for use. Compliance with the provisions of Sanitary and Phytosanitary measures and Technical Barriers to Trade agreement will become inevitable to keep up with the required quality and efficacy of the vaccine, thereby slowing the accessibility to vaccines.

Conclusion

When pandemic struck, the singular aim of R&D worldwide was to end the same by way of drugs and vaccines. Today with the few vaccines with proven effectiveness, the intention remains intact, which is to vaccinate everyone as soon as possible. However utopian the idea may be, ground reality remains in the form of concerns of meeting the enormous demand for vaccine and its equitable distribution. IP waiver solely is not sufficient to accomplish this goal. Manifold vaccine production and distribution requires establishing institutional capacity in different countries, overcoming political fraught and bottlenecks and adopting reforms in the administrative and legal framework. A waiver may prove to be beneficial to step up the production, but it is equally imperative that allocation and affordability issues are dealt with, with equal priority. TRIPS flexibilities may also be utilized by countries which have manageable infrastructure for production. WTO and the member states have to explore beyond waivers to look for both short term and long term solutions since predictions point that the pandemic situation may end but the disease is here to stay.[42]

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