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IMPACT OF COVID ON IP REGIME

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Abstract

*This paper focuses on the **key issues** of how the Covid 19 has brought about a change in the IP regime on the all-important tool namely, the vaccine/s to fight the pandemic of the century and primarily focusses on the pros and cons of granting IP protection or otherwise to the vaccines. The gist of the different views and arguments in the current scenario is that currently, a global advocacy effort is attempting to remove COVID-19 vaccines from IP protection's, claiming that doing so will assist to mobilise additional manufacturers and resolve vaccine access gaps. Others say that doing so would discourage further manufacturing investments and jeopardise long-term vaccine development, including for COVID-19 variations that are emerging.*

*The **novelty of idea, is** whether public good at large is to be given precedence over the long-term vaccine development, including for COVID-19 variations that are emerging and threatening mankind, the case in point being of the emergence of the recent variant, the delta variant. The gravity of the situation can be best summed up in the words of Maria Van Kerkhove, the WHO's technical lead on COVID-19[1].*

"The delta variant, the virus, will continue to evolve. Right now our public health and social measures work, our vaccines work, our diagnostics work, our therapeutics work. But there may be a time where this virus evolves and these countermeasures don't,"

*The **specific outcome of the research paper** is the analysis and comprehending of issue at hand namely, would exempting Covid – 19 vaccines from IPR's improve global access and equity from various perspectives and the probable solution to the complex issue.*

INTRODUCTION

[1] Economic Times l June 26, 2021 09.13 AM

The extraordinary Covid-19 outbreak has wrought devastation, killing numerous people and stealing families of their means of subsistence. Economies and social structures are collapsing in countries all over the world. While vaccinations have begun in most countries, there is a significant disparity in the availability and price of vaccines, medications, and other resources needed to battle the Covid-19 epidemic in industrialised, developing, and least developed countries. Furthermore, if current trends continue, the poorest countries may not be vaccinated until at least 2024, and some countries may not even make it that far.[2] However, the arrival of vaccines against Covid-19 had given a hope in ending the pandemic that has claimed close to 3,934,252 lives worldwide[3] and 398,454 in India[4]. However, inoculating millions of people all over the world and to particularly overcome this grim scenario in India would require the massive production of vaccines, followed by their equitable distribution. On an initial understanding of the dynamics at hand it appears that an impediment to production and distribution of vaccines is the intellectual property (IP) rights that their developers enjoy.

Also, however one of the main roles of IP is to provide an incentive framework in which innovation can be encouraged and provided with a safe passage through the many, often perilous, stages from invention to commercial product or service Here it should be emphasised that the private sector funds about 70% of research and development (R&D), while the government funds around 30%. Around 70% of R&D is done by the private sector, while 30% is done by the government.[5] In order to incentivize key funders and performers of R & D to achieve results, a successful strategy or approach to supporting innovation must guarantee that the correct incentives are in place. IP is an important component of such incentives. Thus for Mitigating disaster of covid-19, immediately as well as in foreseeable future, IP policy measures must be in place.

[2]https://www.theguardian.com/society/2021/jan/27/most-poor-nations-will-take-until-2024-to-achieve-mass-covid-19-immunisation
[3] WHO Dash Board Last update: 10:12am CEST, 30 June 2021.
[4] mygov.in/covid-19 update as on: 30 Jun 2021, 08.00 IST
[5] knowledgeportalia.org/covid19-r-d-funding

The covid-19 pandemic is causing widespread and profound suffering and misery across the world. the measures being undertaken by governments to fight the pandemic, to reduce suffering and to stop the further proliferation of the virus are also causing, as a necessary side effect, widespread economic disruption, which, in turn, is causing and will cause widespread suffering as stalling of businesses wherein global value chains are ceasing to be able to function and consequently employees and entrepreneurs and the many participants in the gig economies lose their livelihood.

The IP system recognises, at both the national and international levels that emergencies and disasters may necessitate measures that disturb the normal operation of the incentive structure upon which the IP system is founded during the emergency or disaster period.

Compulsory licences and licences of right of patented technology, embodied in vital medical supplies and medicines, as well as the use of exceptions in relation to cultural and educational works to ensure the availability of vital data, information, and knowledge for the management and mitigation of emergencies and disasters, are among the policy measures available in international and national IP law to manage and mitigate emergencies and disasters.

Innovative licencing arrangements, the free-to-use publication of scientific data, the publication of technical specifications of vital equipment, such as ventilators, to enable others to manufacture, and the renunciation of the enforcement of certain patents in certain jurisdictions are all examples of technological actions.[6]

The 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement is a major legal instrument that harmonises intellectual property (IP) protection by putting binding responsibilities on member countries to maintain a minimum level of

[6] Ibid 6

IP protection and enforcement in their territories.[7] As a part of the World Trade Organization (WTO)'s legal regime, the TRIPS agreement also monitor's the enforcement of IP rights through a compulsory and enforceable dispute settlement mechanism.

It is commonly known that developed countries, particularly the United States (US), pushed hard for the TRIPS agreement, aided by pharmaceutical transnational businesses. Larger cross-border IP protection, which could be efficiently managed by a multilateral agreement, was thought to bring in higher rents for pharmaceutical companies in these nations.[8] On the other hand, developing countries were not keen on an agreement on IP in the WTO. This was due to a number of factors, one of which being that a strict intellectual property regime would have an impact on pharmaceutical product prices.[9]

The discussion over TRIPS' impact on people's right to health has continued since then. IP protection, according to proponents, encourages innovation and, as a result, should be strengthened through a network of national and international rules. Meanwhile, detractors claim that intellectual property rights, particularly patents, obstruct the introduction of affordable vaccinations and treatments in developing countries, depriving people of their right to health.

This is precisely the raging debate which has taken centre stage, as the world grapples with Covid-19. The vaccines and other medicines developed to combat Covid-19 are subject to patent protection under the TRIPS agreement, presenting an unmistakable silver lining to the catastrophe. For the full 20-year duration of patent protection following the filing of the patent, the patent holders have the exclusive right to produce, market, and use the vaccine or medication. This type of security protection

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[7] Peter Van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization* (Cambridge: Cambridge University Press, 2013), pp. 952.
[8] Piragibe dos Santos Tarragô, "Negotiating for Brazil" in *The Making of the TRIPS Agreement Personal Insights from the Uruguay Round Negotiations,* ed. Jayashree Watal and Antony Taubman (Geneva: World Trade Organization, 2015), 240-241.
[9] Daniel Gervais, *The TRIPS Agreement: Drafting, History and Analysis* (London: Sweet and Maxwell, 1998), pp. 19.

could prevent vaccines from becoming more widely available, prolonging the epidemic.

The epidemic will be ended by the complete vaccination process, not by the vaccinations themselves, and the key is to ensure that it is universalized. The work is difficult because of rising concerns over vaccine nationalism, in which wealthy countries purchase vaccines for their populations ahead of others, thereby jeopardising the objective of delivering two billion vaccine doses to low- and middle-income countries.[10]

It is in this context that India and South Africa's joint petition to the World Trade Organization (WTO) for a temporary waiver of IP rights on Covid-19 vaccines and pharmaceuticals must be understood.[11] The request for waiver contends that, in addition to patents, other intellectual property may impede access to affordable medical items, and that many nations, particularly developing countries, may suffer institutional or legal obstacles when utilising TRIPS Agreement flexibilities.[12]

It is stated that this will allow all countries to engage with all interested parties, not just IP holders, for research as well as scaling up and distributing vital Covid-19 drugs, vaccines, and other aid.[13] To counter this the proponents of the IP, it has been claimed that pharmaceutical companies, such as Gilead, which owns the API patent for Remdesivir in various jurisdictions, have entered into voluntary licence agreements, albeit royalty-free, with only a few manufacturers, effectively excluding half of the world's population from having to pay for the drugs at Gilead's discretion.[14] As a result, stringent licence agreements may limit access to and affordability of Covid-19 resources.[15]

[10] Chris Kay and Haslinda Amin, "Vaccine Nationalism Threatens WHO's 2021 Goal of 2 Billion Doses", *Bloomberg Quint*, March 17, 2021.
[11] Waiver From Certain Provisions of the TRIPS Agreement For the Prevention, Containment and Treatment of Covid-19, Communication from India and South Africa, IP/C/W/669, 2 October 2020
[12]https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True
[13]https://msfaccess.org/sites/default/files/202011/COVID Brief WTO Waiver Proposal ENG v2 18Nov2020.pdf
[14] https://www.openaccessgovernment.org/trips-covid-19-waiver/103738/
[15] Supra Note 12

Supporters of the waiver also argue that it would give all TRIPS members, whether developed, developing, or least developed, the option of not granting or enforcing any patent or other related IP pertaining to all Covid-19 drugs, vaccines, diagnostics, and other technologies, including masks and ventilators, for the duration determined to combat this pandemic.

To be sure, the TRIPS Agreement contains provisions that allow for a balance between patent holders' rights and the public's right to health.[16]

The moot point herein is that the Covid-19 global pandemic—the largest global health crisis in the last 100 years, claiming millions of lives and causing unparalleled economic and social devastation—undoubtedly qualifies as a "exceptional circumstance" under the WTO Agreement's Articles IX.3 and IX.4. As the epidemic continues to spread, countries must come up with new strategies to not only expand vaccine production but also ensure timely distribution at cheap pricing. The necessity to meet the TRIPS Agreement's rigorous IP criteria may not be a viable choice in this case. In the field of medicines, vaccines, and other medicinal substances, numerous examples of IP operating as a barrier to access have been cited.[17]

The waiver would suspend countries' IP commitments, allowing those with manufacturing capacity to manufacture Covid-19 vaccines and sell them to countries without manufacturing capabilities without fear of a WTO legal challenge. The waiver could be granted for a year at first. At the end of the year, it may be revisited.

Those who oppose India and South Africa's petition for a TRIPS waiver argue that the demand to suspend IP responsibilities is unnecessary because the TRIPS Agreement has many flexibilities that can be utilised to solve public health emergencies.[18] Those flexibilities are included in the TRIPS Agreement. However, as demonstrated above, it

[16] Bryan Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review", *SSRN Working Paper,* (2021).
[17] Supra note 12
[18] Bacchus, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for Covid-19 Vaccines", Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review".

would be incorrect to imply that these flexibilities would be sufficient to address all public health concerns, particularly one as large as the present pandemic.

Also, although the obligatory licencing path is accessible, it is not a helpful flexibility for countries that lack industrial capability. A forced licence may be issued primarily for the internal market of the country providing the licence, according to Article 31(f) of the TRIPS Agreement. As a result, generic pharmaceuticals produced under a mandatory licence are unable to be exported.

As a result, nations with limited pharmaceutical manufacturing capabilities will be unable to benefit from Article 31 of the TRIPS Agreement's compulsory licencing clause. The World Trade Organization (WTO) recognised this concern in 2001, as evidenced by paragraph 6 of the Doha Declaration on TRIPS and Public Health. It states: "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

The General Council of the World Trade Organization (WTO) decided in August 2003 to suspend the obligations imposed by Articles 31(f) and 31(h) to allow countries to export medications made under compulsory licence to countries that lacked the manufacturing capability.[19] Finally, in 2005, the TRIPS agreement was amended, which took effect on 23 January 2017,[20] to include Article 31 *b* is making the 2003 decision permanent. The fact that a waiver was required initially, followed by an amendment to the TRIPS Agreement, shows that the TRIPS flexibilities were insufficient to accommodate all drug scarcity scenarios.

While this modification has been hailed as solving the problem of countries with insufficient manufacturing capacity having access to affordable drugs, there are still

[19] "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".
[20] TRIPS Agreement (as amended on 23 January 2017).

worries regarding the lengthy process that countries must go through to import and export such medicines.[21] Undeniably, in the sole instance where this approach was used in the last decade and a half, including Rwanda and Canada, the problem with economies of scale and the laborious procedure were clear.

As a result, due to the enormity of the problem and the massive demand for vaccines from all over the world, TRIPS flexibility is unrealistic.

Other options include voluntary licencing, which licences are granted by patent holders to generic businesses on mutually agreed-upon terms. A voluntary licencing, for example, is the AstraZeneca Covid-19 vaccine, which has been licenced to India's Serum Institute. The voluntary licencing, on the other hand, are sometimes cloaked in secrecy, with the patent holder controlling key decisions such as who will be the final beneficiaries of the drug and how third-party vendors will be chosen. The same might be argued for AstraZeneca's voluntary licence to Serum Institute.[22] However to meet the high demand for vaccinations, several more enterprises would have to be upgraded, which would necessitate a non-exclusive arrangement, which is unlikely to happen.

So, the question to ask is, Is an IP waiver the solution to India's Covid-19 problems?

None of the arguments in favour of the waiver address the fact that TRIPS protection is the very incentive that has resulted in such rapid advances in Covid-19 vaccine development. As a result, depriving these innovator or originator companies of their exclusivity incentive will negative effect on their ability to provide such early breakthroughs.

In the problem on hand other key factors need consideration. In the case of vaccinations, it is not the IP that is the sole impediment. The key obstacles to ramping

[21] Oxfam International (2006).
[22] Siva Thambisetty "Vaccines and patents: how self-interest and artificial scarcity weaken human solidarity", *LSE British Politics and Policy*, February 9, 2021.

up vaccine manufacturing are a scarcity of raw materials, know-how transfer needs, and limited production capacity due to the complexity of vaccines.[23] Furthermore, even without the waiver, practically all vaccine makers have signed into voluntary licencing agreements around the world to ease vaccine access. These voluntary licencing arrangements ensure that the product's quality or standard is maintained, as well as that the companies' intellectual property is protected.

As a result, there is no need to impose such a blanket waiver for immunizations. Furthermore, executing the waiver would not facilitate the removal of impediments such as a lack of institutional capacities and experience, nor will it result in an immediate increase in vaccine production. The main issues, at least for vaccines, are a lack of raw ingredients and suitable manufacturing facilities. Various burdensome regulatory systems also impede the availability of pharmaceutical medications, vaccinations, and other medical resources. As a result, a TRIPS waiver cannot be a magic wand for expanding access and affordability of Covid-19 vaccinations.

Many key pharmaceuticals used in the treatment of Covid-19 are biologics, which necessitate the transmission of extra information relative to the microbe being employed, the strain of that microbe, cell line being used, standardised culture, and a variety of other manufacturing difficulties. In such a case, patents alone may not be sufficient to secure the finished product. The knowledge gained over time to refine the end outcome would be equally crucial in arriving at the final product.

Finally, when it comes to purely chemical drugs, chemical reagents for test kits, and other tools such as masks, PPE kits, oxygen cylinder tools, and so on that were on the market prior to the Covid-19 pandemic and are now found to be effective for Covid-19, it can still be argued that know-how may not play such an important role and that the same can be reverse-engineered or developed if an IP waiver were in place. However, it cannot be totally denied that without the necessary know-how, it

[23]https://www.livemint.com/opinion/online-views/a-wto-waiver-on-patents-won-t-help-us-against-covid-11619625719625.html

may be incredibly difficult to achieve the appropriate quality of end goods in a relatively short period of time.

Even if it is expected that TRIPS waiver will result in simple access and reasonable prices for these products, it appears to be a formidable mission to successfully facilitate the exchange of know-how to grow the production of such medications and instruments in the absence of voluntary licencing arrangements.

Another aspect is, while Section 7 of Part II of the TRIPS Agreement relates to the Protection of Undisclosed Information, a waiver of the said Section may result in the forced disclosure of know-how and confidential information that these companies have amassed over several years in order to develop vaccines, biologics, therapeutics, and other tools that are being used to combat this unnerving pandemic. In general, know-how or trade secrets may be provided to the licensee in addition to the patent by the completion of a Non-Disclosure Agreement in addition to the patent licence agreement.

Any forced surrender of these rights as a result of waiver would be exceedingly excessive, may be counter-productive, and might erode significant value from these innovative enterprises that are part of a key industry. Finally, any such coercive measures will function as a deterrent to enterprises developing pharmaceutical discoveries so necessary for the mankind at large.

Even after obtaining an IP waiver, each nation has severe regulatory regulations that represent a significant hurdle to such a worldwide production and supply method that is stated to be achievable through TRIPS waiver. Furthermore, most emerging and least developed countries suffer from infrastructural deficiencies such as effective storage and distribution facilities. For example, the devastation caused by the second wave of Covid-19 in India cannot be attributed entirely to a lack of vaccines or treatments; a key reason was a lack of adequate facilities, such as oxygen and ventilators. The government also admitted that there was enough oxygen in the country, indicating that centralised distribution was the problem.

Measures for countering the dilemma

The World Intellectual Property Organisation (WIPO) has taken a number of initiatives to help with the dilemma of technology and investments thereof on one hand and IP regime on the other hand, including:

The creation of a clearinghouse or policy-tracker that provides information on measures made by IP offices to support innovation by addressing distressed economic actors by extending deadlines and establishing grace periods for fee collection. In addition, the policy tracker will offer information on any exceptions, limitations, or obligatory licences that are available or implemented.

PATENTSCOPE, a database with over 80 million technology disclosures, multilingual search capabilities, an automatic translation system, and a specially developed COVID-19 search and retrieval facility dedicated to enhancing access to technological information disclosed in published patents with regard to inventions relating to COVID-19 detection, prevention, or treatment. Hundreds of thousands of scientific and technological institutes and commercial organisations use this essential source of technological intelligence on a regular basis all over the world.

Access to Research and Development for Innovation (ARDI), a collaboration with scientific, medical, and technical publishers, provides free online access to major scientific and technical journals to local not-for-profit institutions in least developed countries and access at a low cost to institutions in middle-income developing countries.

Around 900 Technology and Innovation Support Centres have been established around the world to give researchers in least developed, developing, and transition countries with access to patent and scientific data and publications, as well as supplementary resources.

WIPO, as the UN body responsible for IP services, policy, information, and cooperation, is well positioned to handle IP and innovation concerns, having expertise

and experience in policy, economic, and legal elements of IP dating back to its founding in the 19th century.[24]

Conclusion

Thus, it is critical to vaccinate the majority of the world's population as soon as possible in order to reduce the virus's chances of mutation. Furthermore, all countries must have an adequate supply of the equipment necessary to battle any Covid-19 surge. Given the current global context, it is unlikely that the countries will be able to rapidly ramp up production once a waiver is granted. Taking away innovators' or inventors' rights would further deprive them of any incentive to continue making scientific and technological achievements. For accomplishing the task on hand, such a it necessitates strengthening institutional capacity in various countries, overcoming systemic constraints, and implementing the necessary administrative and legislative reforms. Nonetheless, a TRIPS waiver might be a critical step toward increasing vaccine manufacturing.

However, the argument that suspending IP rights would be a deterrent to the pharmaceutical industry is unconvincing: given the enormous demand, these businesses are guaranteed to make a profit. Furthermore, pharmaceutical businesses frequently receive government subsidies and funds[25] encompassing in the expansion of Covid-19 vaccines.[26] As a result, it is reasonable to expect the gains to be shared with the rest of society. Although, shredding off IP rights entirely may not produce the harmony needed to achieve this goal; on the contrary, it may create unwelcome imbalances and have a negative influence on the free transfer of technology across jurisdictions and international trade. In the long run, these have the potential to cause more harm than good. Governments must support voluntary licencing arrangements and discover ways to speed up regulatory approvals or establish specific efficient expedient regulatory frameworks. The formation of joint ventures, in conjunction with

[24] Supra 6
[25] Supra15
[26] Judy Stone, "The People's Vaccine – Moderna's Coronavirus Vaccine Was Largely Funded by Taxpayer Dollars", *Forbes,* December 3, 2020.

government support, can ensure that additional supply chain, industry infrastructure, storage, and distribution channel concerns are addressed in a coordinated manner.

As a result, it is evident that the mutual cooperation and combined efforts of multiple stakeholders, including the government, large pharma firms, generics, and the scientific community, are critical in combating this pandemic, and that TRIPS waiver is not the only option.

As the world health organization appropriately states, "With a fast-moving pandemic, no one is safe, unless everyone is safe." As a result, the international community must use all available resources, including a temporary trips waiver on a case to case basis, only if the situation on hand really warrants.

To put it in the words of Francis Gurry, Director General, WIPO "if innovation generates successful outcomes and countries are unable to receive the invention on reasonable and affordable terms, mechanisms exist to assist access where intellectual property is a barrier. However, the implementation of these restrictions should be targeted and time-limited, because without innovation, there will be nothing to access. thus at present, at this point, the main policy challenge is to encourage innovation that leads to vaccines, treatments, and cures, as well as innovation that aids in crisis management, such as the development of tracing applications based on data about the virus and its infection patterns, or improvements in the manufacturing and performance of ventilators and other life-supporting equipment.

Overall, it appears that IPR is critical to maintaining a current vaccine portfolio which is more so with advent of the new variant 'delta' and given the probability that the virus has the capacity to mutate infinite no of times.

All in all, the issue on hand requires a balanced approach. That really is the need of the hour if mankind is to combat the worst challenge it is faced in over a century.