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IS A WAIVER DURING AN EMERGENCY - A REQUISITE?

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''The essence of the beautiful is unity in variety'' - W Somerset Maugham

ABSTRACT

A waiver in IP-related Inventions was proposed by two developing countries to the WTO in 2020 which was backed & withheld by many powerful & high-income countries. The current study examines the importance of IP in further protection of R&D for facilitating and enabling solutions. Looking at the history of unavailability of vaccines or drug supply during smallpox, HIV/AIDS, and now COVID-19, the world came in terms of it by significant collaboration among the nations, regulators, and scientists working in tandem, fast-tracking the whole process without any compromises on the protocols or any step and keeping the foremost focus on healthcare, whether producers or consumers varied with the span of time. Even, the flexibilities of TRIPS & technological advancement have indeed accelerated the manufacturing and accessibility of the vaccine to society.

INTRODUCTION

In COVID-19 pandemic, during the constant spread & mutation of viruses, the only way which was established to resolve the transmission, was by achieving global immunity, vaccinating a large proportion of the population persistently. But, initially more than 80% of the doses were subjected to the high income[2]& upper middle-income countries, and only 2.5% of people in low-income countries[3]. Hence, the inequitable reach & distribution of vaccines resulted in transmission & risking millions of lives around the globe.[4]

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[2] https://www.nature.com/articles/d41586-021-01762-w.
[3]Our World in Data, Coronavirus (COVID-19) Vaccinations.
[4]Padma TV. COVID vaccines to reach poorest countries in 2023

To equitable distribution & access of vaccines: India & South Africa asked the World Trade Organisation (WTO) for temporary suspension of certain rules in (Trade-Related Aspects of Intellectual Property Rights) TRIPS[5], stating that the IP waiver would exempt countries from the mandatory requirements for patents, trade secrets, and other IP rights to avoid barriers to the timely access to affordable medical products including drugs and vaccines or to scaling-up of research & development, manufacturing, and supply of essential medical products which was supported by various countries like New Zealand, Ukraine, The United States (for covid vaccines only)[6] but was also opposed by several WTO members including EU, Norway, UK, Switzerland objectively opposed the waiver claiming for the flexibilities of TRIPS.[7]

HISTORY OF WAIVER

During the outbreak of HIV/ Aids in the late 1990s, Antiretroviral drugs for the treatment of HIV were non-accessible & unaffordable due to the Patent monopoly by Pharmaceutical companies for the least - developed & developing nations. An interim waiver was imposed on countries'& such supply was restricted predominantly for the domestic market. But the decision of 30 August 2003 in Doha declaration on TRIPS & Public health,[8] allowed the importation of cheaper generics made under compulsory licensing for the low-income countries that were unable to manufacture the medicines or vaccines for themselves.[9] Such waiver was only apt for public health issues but not for commercial objectives, keeping the balance of both the interest of the patent owner & public.

MERE FALLACY OF WAIVER

The IP waiver is not just mere patents but covers all the other domain of Intellectual property rights such as copyright, designs, trademark, and most important trade secret also known as know-how i.e. the valuable information in the distribution & manufacturing of vaccines.

[5] World Trade Organization (WTO), document IP/C/W/669. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filenam e=q:/IP/C/W669.pdf&Open=True
[6]Hyo Yoon Kang, Aisling McMahon, Graham Dutfield, Luke McDonagh, and Siva Thambisetty, "Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal", Policy Briefing Paper, No. 46 (LSE Law, 13 July 2021). Available from https://ssrn.com/abstract=3885568.
[7] Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver, Office of the United States Trade Representative Press Release, 5 May 2021. Available from https://ustr.gov/node/10649
[8] https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
[9] https://www.wto.org/english/news_e/pres03_e/pr350_e.htm

IP rights doesn't put obstruction on R & D[10] (Research & Development) but help to facilitate-

- Development of the new technology & innovations
- Distribution among the countries[11]

Coming to the primary aspect, the proposed waiver wouldn't significantly reduce prices as setting a new production & manufacturing technology of biosimilar vaccines would require high investment in contrast to the generic version of small molecule drugs as practiced before. Secondly, the increasing number of procurements of existing vaccines & their substitutes would increase the competitive price. Lastly, even, the cost of delivery for the vaccine would not be waiver protected and required to be paid irrespective. [12]

CAN IP WAIVER SOLVE THE ISSUE?

The main issue concerns access to technology, vaccines & inequity in distribution. For instance, in The United States where the production of vaccines was in overabundance, and on the contrary in other countries, moderate. The following observation were made to why a waiver would act as an encumbrance.

Firstly, IP gives creative incentives, rewards & protective environment in which the investors & inventors can deploy time, capital to develop the technology, removing it would result in bare innovation with time. IP even enables companies to collaborate so that technology can be moved from the laboratory into the market with security & reliance on rule of law to protect their invention & capital. Throughout the Pandemic, we saw many examples of collaboration between companies, one being BioNTech & Moderna for the development of mRNA technology platform, others like AstraZeneca licensing Serum Institute of India to make vaccines, BioNTech licensing Pfizer to manufacture & distribute its vaccine[13]. If the waiver is imposed it would jeopardize such historic collaboration not only between companies but also countries.

Secondly, forced transfer of trade secrets, use of their technology & know-how of the companies for immediate use, further questions the huge investment done by the private entities

[10] https://eml.berkeley.edu/~bhhall/papers/BHH13_KDI_paper.pdf
[11] https://phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver
[12] https://regproject.org/wp-content/uploads/Paper-COVID-Vaccine-IP-Waiver-A-Pathway-to-Fewer-Not-More-Vaccines.pdf
[13] https://launchandscalefaster.org/covid-19/vaccinemanufacturing

& domestic taxpayers of the country for R&D.[14] Even when the know-how is transferred in contractual transfer backing the voluntary patent licensing via NDA (Non-disclosure agreement) the implementation of the high trade secret protection would be improbable. If such an act, would result in breach of such trade secrets & know-how by strategic & economic competitors would discourage innovative hard-earned rights.

Thirdly, IP as a part of the solution is not a problem as it allows companies to transfer, share & most importantly license the technology, waiver would undoubtedly weaken IP rights risking investment in R&D, collaboration, transfer, share & licensing of technology.[15]

Lastly, the problem of Global equitable fair accessibility can be achieved by global governance in transparency, safety, accountability & legal compliance amongst the nations. [16]Some International initiatives already contributed to scale up the distribution & production such as:

- COVAX[17] facility, a historic partnership amongst members, to ensure reach of the vaccine by pooling scientific & financial resources
- WHO & Costa Rica COVID-19 technology access pool (C-TAP) to accelerate fast-track development of products by mobilizing additional facilities for manufacturing & open-science research like - transparency of clinical trial results, disclosure of gene data & licensing of a drug or vaccine to UN public health body
- G7 Science & technology (S&T) ministerial declaration to enhance cooperation, utilizing strengths of private entities to research on crucial priority areas, government-related research related data publicly accessible
- Tech access partnership (TAP) knowledge, data transfer between manufacturers of high-income countries & local manufacturers of developing countries
- International Telecommunication Union (ITU) for the strain experienced by telecommunication networks by pooling regulatory measures & innovative policies

All the above initiatives helped to address & eradicate primary issues such as trade, access, distribution & innovation in vaccines but yet few nations had to adopt tailored emergency

[14] https://regproject.org/wp-content/uploads/Paper-COVID-Vaccine-IP-Waiver-A-Pathway-to-Fewer-Not-More-Vaccines.pdf
[15] https://fortune.com/2021/12/24/ip-protections-facilitate-vaccine-access-world-leaders-covid-pandemic-intellectual-property-biden-international-pharma-health-andrei-iancu/
[16] https://en.unesco.org/sti-related-policy-responses-covid-19/global-initiatives
[17] https://www.who.int/news-room/feature-stories/detail/access-and-allocation-how-will-there-be-fair-and-equitable-allocation-of-limited-supplies

solutions to deal with the unresolved issues of medicinal products corresponding to their municipal needs.

TRIPS FLEXIBILITIES AN ALTERNATIVE SOLUTION?

Now coming to the flexibilities, in the TRIPS agreement, Articles 31[18]& 31bis can improve access to essential medical drugs, vaccines, equipment & technology. Article 31 allows the World trade organization (WTO) members to provide for compulsory licenses[19] for patents, including use by the government or third parties authorized by the government.

Some Important features of Compulsory licensing: -

- granted product-to-product basis,
- on existing patents, not on applications (applications only get published post 18 months)
- and territorial

As a rule, a compulsory license can be granted only after the negotiating with the patent right holder to conclude a licensing agreement on 'reasonable commercial terms and conditions but, coming to article 31(b) of the TRIPS agreement, to address a national emergency, no prior negotiations with patent holder is required to grant to either third parties or government use. For countries to implement production for their consumption or import under Article 31bis of the TRIPS Agreement, they should have actual manufacturing capacity and facilities, as well as necessary expertise in mRNA vaccines, which have even been proven to be a challenge in middle income countries.

Secondly, the efficiency of the compulsory licensing mechanism ultimately depends on how it is implemented under municipal laws. [20]

Thirdly, compulsory license of trade secrets which protects different kinds of the exclusive information, including data gathered during the regulatory approval process should be done to make technology transfer an effective transfer.

Fourthly, to commercialize a product, overcome the problem of test data exclusivity protection

[18] TRIPS Agreement, Article 31

[19] http://tripsflexibilities.medicineslawandpolicy.org/

[20]Gurgula and Lee, "COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?

under Article 39[21].

Lastly, a compulsory license requires monetary compensation in form of a license fee. Article 31(h), states payment of remuneration to the patent holder. In case of complication in royalty rates or valuation of IP, practice of use of FRAND[22] (fair, reasonable, and non-discriminatory) has been exercised for the determination of value.

Talking about the implementation, with all its perks & cons, wherever possible, to make this provision more efficient, the countries must revise their municipal law to avoid delays. For example, countries like Canada, Australia, and Brazil[23] already amended their laws for smoother approach.

The solution to the actual bottleneck?

The real problem isn't centred on the waiver or trade secret but on the manufacturing, distribution inputs & channels. The COVID-19 virus is most likely to mutate again, due to which temporary waiver approval wouldn't help in the competency building of each developing country in technology & ability to fight in the future.

Removal of blockades in international trade[24], distribution of surplus vaccines, and assistance in the development of infrastructure & technology in middle-low developing countries would significantly lower the count of destruction in society.

On the contrary, as we've seen, equal access exists neither within nor across countries due to which, international price differentiation i.e. (different prices for different segments of customers) can facilitate more equal access, and the WTO agreement on (TRIPS) outlaws parallel trade – i.e. the reimporting of patented goods, enabling the original vaccine makers to supply poor countries at lower prices without undermining their price-setting power and profits in high-income countries.

[21] TRIPS Agreement, Article 39
[22] https://www.dataversity.net/lessons-information-technology-can-learn-from-the-patent-wars/#
[23] https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies
[24] https://regproject.org/wp-content/uploads/Paper-COVID-Vaccine-IP-Waiver-A-Pathway-to-Fewer-Not-More-Vaccines.pdf