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TRIPS WAIVER: A SOLUTION TO GLOBAL VACCINE DISPARITY

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ABSTRACT

As the world is slowly moving towards administering booster doses to its population, some poorer countries are in such a deplorable condition that their citizens have not even received the first dose. All the credit goes to vaccine disparity among nations. In order to overcome this problem, India and South Africa came up with a proposal to WTO for temporarily waiving the key provisions of TRIPS Agreement related to Covid-19 vaccines, drugs and therapeutics which provides protection to developers of Intellectual Property (IP) and creates an impediment in its production and distribution. This patent protection which under ordinary circumstances acts as a boon for the developer/creator and scientific innovations, unfortunately, it has led to becoming a curse for the public health in the extraordinary circumstances like Covid-19 Pandemic. This article discusses the global vaccine disparity among nations due to inequitable distribution of vaccines and vaccine nationalism, how lower-income countries are incapable to manufacture and produce the Covid-19 vaccines and how the developed countries have successfully managed to vaccinate most of their population. This article further discusses how compulsory licensing and voluntary licensing under TRIPS Agreement are insufficient to overcome the vaccine disparity and how TRIPS waiver is the only solution to the above posed problem. While critically examining the arguments in favour and against the TRIPS waiver, the article concludes that WTO needs to accept the proposal keeping into consideration the extraordinary circumstances as mentioned under TRIPS Agreement as a justified ground to augment the medical supply of Covid-19 vaccines and related drugs globally.

Keywords: TRIPS, Waiver, Intellectual Property Rights (IPR), Patents, Covid-19 Vaccine.

INTRODUCTION

Intellectual Property Rights (IPR) refers to the legal rights which are given to the creator or

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inventor to protect his invention or creation. IPR is a strong tool which protects investments, time, money, effort which were invested by the creator of an idea/product. It is nothing but an exclusive right given to the creator/developer to enjoy his right of production and distribution of the property which is "creation of his mind". The object behind protecting such rights is to promote creativity and innovation in the field of science, technology, arts, literature and other creative works.

However, as a matter of public policy, IPRs are not absolute and unlimited, but are generally subject to a number of limitations and exceptions that aims to balance the legitimate interests of right holders and users. Along with the well-defined scope of what is protected and the limited duration of protection, these restrictions and exceptions are designed to strike the right balance between competing public policy interests so that the system as a whole can be effective in achieving its intended goals. For the very same reason, in 1995 the TRIPS agreement which expanded the IP protection at a global level included a range of public health safeguards and flexibilities which were further reinforced by 2001 Doha Declaration on the TRIPS agreement and public health.

TRIPS Agreement: -

Trade Related aspects of Intellectual Property Rights (TRIPS) agreement is an Integral part of the Marrakesh Agreement which was signed on 15th April 1994 among member nations and established the World Trade Organisation (WTO) which came into force from 1st January 1995. The WTO provides basic framework for member countries which includes reviewing the operation and implementation of all WTO agreement, provide Dispute Resolution Mechanism, forum for further trade negotiations and achieve great coherence in global economic policy making. TRIPS is a comprehensive multilateral agreement on Intellectual Property which facilitates trade in knowledge and creativity and resolves disputes over IP and also assures the domestic policy objectives of the member countries[2]. TRIPS agreement creates a binding obligation upon each member of WTO from the date WTO agreement becomes effective for that country.

[2] Ranjan, P., 2022. The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines | ORF. [online] ORF. Available at: https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/?amp [Accessed 20 March 2022].

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Article 3 and 5 of the TRIPS agreement[3] provides the principle of non-discrimination according to which a member nation cannot discriminate between the protection provided to the member's own nationals and the national of other members. Part II of the Agreement provides subject matters for the minimum standard of protection of IP to be provided by the WTO members:
(1). Copyright and related rights (i.e., the rights of performers, producers of sound recordings and broadcasting organizations); (2) trademarks, including service marks; (3) Geographical Indications; (4) industrial designs; (5) patents, including the protection of new varieties of plants; (6) the layout-designs of integrated circuits; and (7) undisclosed information, including trade secrets and test data.[4]

TRIPS Agreement represents an attempt to balance the interest of providing incentives for Research and Development of new drugs and making of these drugs widely accessible to patients needing them[5]. The Agreement intends to strike a balance between exclusive intellectual property of an individual and the interest of society at large, however, sometimes, it creates unnecessary restrictions in extraordinary situations (like Covid-19 pandemic) and ends up harming the interest of society.

Global Vaccine Disparity: -

Covid-19 pandemic brought an unprecedented situation and it not only affected the global economy but also lead to the extreme public health crisis across the globe. Around 60 lakhs people lost their battle to Covid-19 across the globe[6] out of which 5 lakhs people died in India only[7]. These deaths are the result of lack of domestic as well as global medical supply creating an inequitable distribution of medical resources between high and low-income countries. Vaccines are subject to patent protection under TRIPS Agreement, according to which exclusive right to sell, manufacture and use of the vaccine/drugs is given to patent holder for 20 years from the date of filing of patent. Thus, a vaccine developer enjoys intellectual property

[3] World Trade Organization, W., 2022. Module I Introduction to the TRIPS agreement. [online] Wto.org. Available at: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules10_e.pdf [Accessed 20 March 2022].
[4] *Ibid.*
[5] World Trade Organization, W., 2022. Module X, TRIPS and public Health. [online] Wto.org. Available at: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules10_e.pdf [Accessed 20 March 2022].
[6] Who.int. 2022. The true death toll of COVID-19: estimating global excess mortality. [online] Available at: https://www.who.int/data/stories/the-true-death-toll-of-covid-19-estimating-global-excess-mortality [Accessed 20 March 2022].
[7] Who.int. 2022. India Country Overview | World Health Organization. [online] Available at: https://www.who.int/countries/ind/ [Accessed 20 March 2022].

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right in production and distribution of vaccines.[8] The pricing of the vaccines developed in a country and distributed by it leads to different price range in different countries and its availability to people depends upon the purchasing capacity of that country as well as the purchasing power of its individuals which leads to inequitable distribution of vaccines among the countries. Another major problem is vaccine nationalism in which rich countries focus on procuring vaccine for their own citizens. All these factors lead to scarcity of vaccine and other medical supplies in under-developed countries and in turn, could derail the goal of delivering 2 billion vaccine doses to poorer and middle-income countries[9].

More than 5 billion people have been vaccinated globally[10]. However, on 16th April 2021, Director General of World Health Organisation (WHO), while addressing a special ministerial meeting of economic and social council, reported that, of the 832 million vaccine doses administered, 82% have gone to high- or upper- middle income countries, while only 0.82% has been sent to their low- income counterparts. In high-income countries alone, 1 in 4 people have been vaccinated, the ratio that drops precipitously to 1 in 500 in poorer countries[11].

Even COVAX, which is a WHO initiative aims to accelerate the development and manufacturing of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world, has distributed 40 million doses to 100 countries, but that is no where enough as WHO had expected to have distributed 100 million doses. Some countries received nothing, none received enough and some didn't receive second time allocation on time. Thus, the problem is not getting vaccines "out of COVAX" rather the problem is "getting them in", vaccine nationalism playing a major role in this[12].

Ngozi okonjo-iweala, Director General of WTO described vaccine disparity as "morally unconscionable". Munir Akram, President of Economic and Social Council, said that, as well as being a moral imperative, universal vaccine coverage is the only realistic way out of the pandemic. He called for scaling up production, addressing Intellectual property issues, supporting weak health systems, and removing export restrictions.

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[8] *Supra* at note 1.
[9] *Ibid.*
[10] Bloomberg.com. 2022. Bloomberg - Are you a robot?. [online] Available at: https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/ [Accessed 20 March 2022].
[11] Un.org. 2022. Unequal Vaccine Distribution Self-Defeating, World Health Organization Chief Tells Economic and Social Council's Special Ministerial Meeting | Meetings Coverage and Press Releases. [online] Available at: https://www.un.org/press/en/2021/ecosoc7039.doc.htm [Accessed 20 March 2022].
[12] *Ibid.*

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Flexibilities under TRIPS Agreement: -

The TRIPS Agreement aims to balance the interest of individual developers to achieve the object of incentivizing research and development and the interest of society at large to get access to medicine/drugs. Therefore, it recognizes various kinds of measures in the form of flexibilities to qualify or limit IPRs for public health purposes.

The Doha Declaration on the TRIPS Agreement and Public Health[13], a proclamation at the Ministerial level with an object to implement the TRIPS Agreement in a way that supports public health clarifies the flexibilities provided under TRIPS Agreement. One of such flexibilities is **"Compulsory licensing"** where the government issues a license to make use of patent during the patent term without the patent holder's consent[14], which is regulated by Article 31 of the TRIPS Agreement. According to it, member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Article 31(b) provides that compulsory licenses can be given in situation of national emergencies or other circumstances of extreme urgency and public health crisis, that includes HIV/AIDS, epidemics, TB, Malaria[15].

Another, flexibility is the **"Voluntary licensing"** according to which a license can be granted voluntarily by the patent holders to generic companies on mutually agreed terms. For example, AstraZeneca Covid-19 vaccine has been licensed to Serum Institute of India.[16]

However, both the flexibilities come with their set of problems. The flexibility of Compulsory Licensing is not same for all countries. While countries that have manufacturing ability in the pharmaceutical sector can effectively employ compulsory licenses, a large number of lower developed countries do not have such capacity. Even developing countries that can use compulsory licenses to produce patented drugs are always under pressure from developed countries not to issue such licenses. Thus, for the countries that lacks manufacturing ability, the compulsory license is not a useful flexibility[17].

The Doha Declaration on TRIPS Agreement and Public Health[18] recognized this problem of members not having sufficient manufacturing capacity. However, TRIPS Agreement provides that members can issue compulsory licenses for importation as well as for domestic production

[13] *Supra* at note 4.
[14] *Supra* note 1.
[15] *Id. at 12.*
[16] *Id. at 13.*
[17] *Supra* note 1.
[18] *Supra* note 4.

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where a medicine is patent protected.[19] Still the issue faced by under-developed countries doesn't get resolved as it is doubtful whether the generic producers in manufacturing countries under compulsory license would be able to export sufficient quantities if needed as Article 31(f) of the TRIPS Agreement requires that the production under a compulsory license be 'predominantly for the supply of domestic market', thus limiting the amount such countries can export under a compulsory license.[20]

Furthermore, the countries need to follow lengthy and cumbersome process in order to import and export such medicines. For instance, if a country issues a compulsory license to export drugs to another nation that lacks manufacturing capability, the exporting country has to ensure the drug manufactured are exported to that nation only; the medicines should be easily identifiable through different colour and shape; only the quantity necessary to meet the requirements of the eligible importing country are manufactured; and the importing country has to notify the WTO's TRIPS council.[21] Additionally, as such countries lack economies of scale; the procedure becomes unworkable especially in case of extraordinary circumstances like Covid-19 pandemic where the world economy is already in a turmoil.

TRIPS Waiver: -

To overcome the problem of the inequitable distribution and with intention to bring the pandemic to its end, India and South Africa have proposed at WTO asking for a temporary waiver of Section 1, 4, 5, and 7 of the Part II of the TRIPS Agreement which provides protection to the Copyright, Industrial Designs, Patents, and Protection of Undisclosed Information, respectively related to Covid-19 vaccines, drugs, therapeutics and related technologies[22]. The core idea behind proposal is that IP rights such as patents should not become a barrier in scaling up the production of medical products like vaccines and drugs at affordable prices. If the waiver is granted, WTO member countries will not be under an obligation, for a temporary period, to either grant or enforce patents and other IP related rights to Covid-19 vaccines and other treatments, this will protect the low-income countries not

[19] *Ibid.*
[20] *Ibid.*
[21] *Id.* at 16.
[22] Editor, R., Page, O., 2022, B., Quotes, S., Sports, O., gardens, H. and India, p., 2022. India, South Africa's patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary. [online] Thehindu.com. Available at: https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece [Accessed 20 March 2022].

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having sufficient health infrastructure to vaccinate their population from the claims of illegality under international law.[23]

Article IX.3 of Marrakesh Agreement establishing the WTO provides that in "exceptional circumstances", the Ministerial Conference may waive an obligation imposed on WTO member country by the WTO agreement or any other multi-lateral trade agreement. Such a waiver must be supported by three quarters (3/4th) of the members. According to Clause b of the Article the proposal first needs to be submitted with WTO TRIPS council to be recommended to General Council. Furthermore, Article IX.4 states that Ministerial Conference, while granting the waiver shall state the "exceptional circumstances" justifying the decision and the terms and conditions that shall govern the working of the waiver. The waiver should have an end date and must be reviewed annually if granted for more than a year. The waiver may be granted to an Individual WTO member country or even collectively.

Conditions of the Waiver: -

1. For a Specified Period (Article IX:4):

The function of a waiver is to relieve a member or the members collectively for a specified period of time, from a particular obligation provided for in the covered agreement. Therefore, waiver must be temporary in nature and comes to an end on the expiration of the term. If the waiver is granted for more than one year it must be reviewed at the end of every year.

2. Exceptional Nature:

Article IX of the WTO Agreement emphasize the exceptional nature of Waivers. It provides that waivers must be given only in exceptional circumstances subject to strict discipline and should be interpreted with great care.

3. No modification or addition of obligation:

The purpose of waiver is only to relieve a member from obligations for a temporary period, therefore, its purpose is neither to modify the existing provisions in the agreement nor to create a new law or add to or amend the obligations under a covered agreement.

4. Ratification by three-fourth of the members:

The waiver must be supported by 3/4th of the members. However, the draft on text- based

[23] *Supra* at note 1.

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negotiations must be agreed upon by all the members and any of the members can veto it[24].

CRITICAL ANALYSIS: -

The current debate regarding the TRIPS waiver has its own set of arguments and counter-arguments. The developing and under-developed countries argues that there are various challenges such as trade barriers, blockage in supply chains, shortage of raw materials, and the reservation from the side of rich countries to share doses with poorer nations, in scaling up the production and distribution of Covid-19 vaccines. Thus, in such a situation, supporters of TRIPS waiver contend that people have already paid once or twice for the Research and Development of the vaccine innovation and the huge global demand of vaccines will assure adequate returns to manufacturing companies, therefore, it must not be right for the manufacturer to hold exclusive rights of the vaccine manufacturing as no single vaccine manufacturer can deliver sufficient doses of vaccines to cover the global population, especially, when in the current scenario, it can be seen that high-income countries end up taking the huge chunk of the reserved doses.

On the other hand, the high-income countries are showing reservations on the waiver. They argue that the waiver will disincentives research and innovation and it would not lead to a boost in manufacturing of Covid-19 vaccines. They contend that the TRIPS agreement entails sufficient flexibilities (Compulsory Licensing and Voluntary Licensing) that can ensure balancing of rights of patent holders and public health. However, it would be erroneous to conclude that flexibilities would be sufficient in dealing with all health challenges especially in a pandemic like Covid-19. While the lower-income countries are not capable enough to manufacture vaccines and other related drugs, even the manufacturing by developing countries entails problems like external pressure from developed countries and vaccine nationalism.

However, after 2003 amendment, (which has been made permanent into TRIPS agreement in 2017)[25] earlier obligations imposed under Article 31(f) and 31(h) requiring the production under a compulsory license to be 'predominantly for the supply of domestic market' only and adequate remuneration to be paid by importing country to the patent holder respectively, was waived and now the above two conditions which were limiting the scope of producing country

[24] Magazine, A. and Raghavan, P., 2022. Explained: Intellectual property waiver for Covid-19 vaccines. [online] The Indian Express. Available at: https://indianexpress.com/article/explained/explained-ip-waiver-for-covid-vaccines-7304992/ [Accessed 20 March 2022].
[25] *Supra* at note 4.

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under compulsory licensing system to export the patented medicines, no longer exists. However, it's only a partial waiver and applies only to the accepting countries which renders the flexibility still insufficient.

Secondly, the lengthy and cumbersome procedure under Article 31 of the TRIPS agreement would disincentives the generic pharmaceutical manufacturers to manufacture under Compulsory License and severely slow down the export of vaccines by manufacturing countries making the products costly when they are needed urgently amid the pandemic.[26] This makes the scheme unworkable to address the challenges posed by Covid-19 and limps the effort to achieve universal application. Thus, the magnitude of problems and massive demand of vaccines from all countries of the world make the TRIPS flexibility impracticable.

As far as voluntary licenses are concerned, they are subject to secrecy where patent holder takes important decision like who would be the ultimate beneficiary and plays the key role in selection of third-party sellers. Moreover, signing a voluntary license agreement is beyond the economic capability of the low-income country.[27]

Thus, keeping into consideration the above-mentioned factors, the TRIPS waiver will provide other vaccine manufacturers freedom to operate which would lead to scaling up of vaccines across the globe especially in the countries who have the capacity to produce the vaccines and also encourage vaccine producers to transfer and share technology for production of vaccines and other related drugs. However, at the same time, such production and transfer of technology can be a very difficult and complex process especially without the support of existing vaccine manufacturers.

CONCLUSION

It is a pity that even after 15-long months of the initial proposal being laid, the WTO has failed to adopt the TRIPS waiver to date. This hesitance of WTO in the trying and testing times of such public health crisis is affecting the world order and global trade due to the huge discrepancy in vaccine administration between developed countries like USA and under-developed and developing countries like South Africa and India.

[26] *Supra* at note 1.
[27] *Ibid.*

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The TRIPS Agreement which was propounded with an object to incentivize the research and development of new innovations by protecting the rights of the creator/developer was rightly made subject to public health by providing flexibilities in case of national emergencies and extraordinary circumstances. Notwithstanding the fact that no specific definition of extraordinary or national emergency is provided in the TRIPS Agreement, it can be said without an iota of doubt that Covid-19 is a national emergency for every nation and pandemic is an extraordinary circumstance. Therefore, in such a situation where the flexibilities are not sufficient enough to combat such a crisis, waiver is the only solution. It would lead to free flow of information and technology which would enable poorer countries to push their boundaries, overcome limitations and cater the needs of their population which cannot be achieved under the limitations of Compulsory and Voluntary Licensing. The waiver would also lead to manifold increase in the production of vaccine and ensure wider and equitable distribution which would subsequently enable the revival of disrupted global economy. Such IP waiver must be accompanied by increased institutional capacity, removal of systematic barriers, and undertaking of administrative and legal reforms.

WTO should overcome its concern about profits of multi-national pharmaceutical corporations and prioritize global health. It would also allow the world to thrive on moral grounds and exhibit its adaptability to changing circumstances in the era of capitalism. Lastly, the developed countries who aspire to come up with an idea of limited waiver which may exclude some countries like India must realize that "we cannot defeat this virus one country at a time, we can only do it with a coordinated global effort, based on principles of solidarity, equity and sharing"[28].

[28] *Supra* at note 10.

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