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Waiver of IP Protection during Covid-19 in reference to TRIPS Waiver Proposal

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ABSTRACT

The Covid-19 catastrophe has impacted numerous lives, and the arrival of vaccines gave a ray of hope in the times of despair, however inoculating of a massive population is only possible if there is a mass production of vaccines followed by their equitable distribution, but this is only achievable by impediment of the production and distribution rights that the developed countries who are the prominent manufactures of vaccines, enjoy. TRIPS (Trade Related Aspect Of Intellectual Property Rights) agreement is an agreement that provides extensive protection of intellectual property rights to its members, therefore recently India and South Africa have in conjunction proposed the World Trade Organisation to waive certain provisions of the TRIPS agreement for equitable distribution and mass production of covid -19 vaccines.

Though there are certain flexibilities available like compulsory licensing pertaining to the patented products but, that alone is not enough to accelerate vaccine production in any nation as there are a multitude of collateral rights attached to production of vaccines, therefore production based on merely available flexibilities like compulsory licensing is not enough to achieve the mass manufacture of vaccines . Therefore, this paper focuses upon the TRIPS agreement along with other declarations present pertaining to IP protection, and also the dissemination of views between the developed and the developing countries concerning the waiver of certain provisions of the TRIPS agreement, which is making difficult to archive a collateral agreement regarding the waiver.

Keywords: TRIPS, compulsory licensing, waiver, patent, agreement.

I. INTRODUCTION

TRIPS is considered to have a major role in dealing with the current lack of vaccines, healthcare, medical equipment's etc. The vaccines and the medicines that are formed to combat the pandemic is patent protected under the TRIPS Agreement, this protection that is provided can defy the objective of mass production and inoculation and can also prolong the pandemic. Therefore, India and South Africa has made a proposal to WTO to temporarily waive the

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provisions of TRIPS agreement so that vaccine equity can be achieved and the pandemic can come to an end.

But this waiver can be achieved only with the consensus between the member countries which is difficult to achieve as the developed countries are reluctant about waiving of IP Rights.

Therefore, this paper elucidates the issues surrounding the TRIPS waiver, and the alternatives available to the waiver of the TRIPS agreement.

II. TRADE RELATED ASPECT OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

TRIPS is a multilateral agreement under the World Trade Organization. This agreement came into effect on 1st January 1995 and is considered to be one of the most comprehensive agreement for IP Protection because it covers all the areas of intellectual property i.e. copyright, industrial properties as well as related rights.

There are 3 cardinal features of this agreement:

- 1) The **Standard norms**, the substantive obligations of conventions like WIPO, Paris Convention Berne convention is to be complied with, though permissible exceptions to those rights are available.
- 2) The second feature of the agreement is the **enforcement mechanism** of the intellectual property rights. Certain general principles are laid down in the agreement that is made applicable on all IPR enforcement procedures. Civil, administrative, criminal procedures along with the remedies available to the right holders is specified in the agreement.
- 3) **Dispute settlement procedure** is also laid down in the TRIPS agreement with an aim to resolve dispute between the WTO members pertaining to the IPR and ensure the esteem of the principles mentioned in the agreement.

(A) Trips Flexibilities:

There are certain flexibilities that are provided under the TRIPS agreement, but these flexibilities can work either way, it may either amplify the protection above the minimum standards provided in the agreement or it may either to a certain extent restrict the rights and lower the guards pertaining to protection of IPR.

TRIPS flexibilities mitigate the impact of patents mainly. These flexibilities are provided to promote and achieve public health goals, and provide affordable access to life-saving medicines.

One of the main flexibility provided under the TRIPS agreement is compulsory licensing.

Compulsory licensing is mentioned under ART 31 of the agreement which deals with the right of the government to make use of a patented product during the patented term without the consent of the patent holder.

(B) Doha Declaration:

DOHA declaration was adopted by the WTO organization with an objective to encourage the formation of an equilibrium between the interpretation and implementation of the provisions of the TRIPS agreement in a manner that is supportive of WTO members right to protect public health and promote access to medicines for everyone. The ambit of DOHA declaration is not just limited to patents on public health but it also applicable to other IPR's covered under the purview of TRIPS agreement².

But the major drawback of the DOHA declaration is that, that it is more suitable for dealing with an epidemic and not a ravaging pandemic.

TRIPS Agreement acts as a shield against, even the sleekest possibility of IP rights violation, though some flexibilities are provided under the agreement like compulsory licensing, but only compulsory licensing is not enough to accelerate vaccine production in any nation.

Not all nations have a power pharmaceutical and manufacturing sectors, some of the developing countries can make use of the flexibility of compulsory licensing but there is always a constraint over the developed countries to not to issue such licenses.

III. COMPULSORY LICENSING DURING COVID-19

There are many countries that have accepted compulsory licensing as an integral part of their covid-19 response. Amidst the pandemic, Israel issued compulsory licensing to import generic versions of lopinavir/ ritonavir. There are many countries like Australia, Brazil, Canada, Germany etc. that had either passed resolutions or made changes in their domestic laws to allow compulsory licensing during covid-19³.

There are certain limitations of compulsory licensing. The compulsory licensing under TRIPS is not capable of addressing the key challenges during an ongoing global pandemic. The use of this flexibility available has been inappropriately politicized and the countries are often discouraged from the usage from the fear detoriating of trade relations.

² *The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, SOUTHCENTRE, https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf

³ *THE CASE FOR COMPULSORY LICENSING DURING COVID-19*, NCBI, [HTTPS://WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/PMC7242884/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/)

- i) Compulsory licensing requires a case by case approach and is difficult to coordinate across jurisdictions, the complexity of this procedure results in time delays
- ii) Compulsory licensing does not provide an effective remedy for evolving patent barriers, during the pandemic specifically new patents remain unpublished due to time lag between application and publication.
- iii) As per Article 31(f), compulsory licensing is mainly used for domestic market, and even if the countries want to use the flexibility to export generic products they need to prove that percent of product to be exported does not hamper its need in the domestic market, therefore during the time of pandemic this clause is problematic as an extensive amount of product and humanitarian support is required⁴.

Though there is an availability of this flexibility but its implication is challenging as the developed countries are mostly reluctant to grant such license as that would also has an impact over their economic interest. In 2012, India was granted with compulsory licensing for the production of generic version of the **Bayer's Cancer Drug**, this licensing was proved to be distressing for India as, India had to face relentless attacks from US⁵.

There are multitude of collateral rights that are equally essential for the production of vaccines, for example: trade secret.

During the **AIDS epidemic**, though its severity is trivial when compared to the ravaging covid-19 pandemic, still WTO took an unabridged 5 years to issue the DOHA declaration, therefore considering the severity of the Covid-19 catastrophe, the waiver of TRIPS agreement amidst dissemination of views between developed and the developing nations indicated that the probability of a multilateral negotiation arduous.

IV. GLOBAL VACCINE INEQUITY AND TRIPS WAIVER PROPOSAL

The covid-19 pandemic has accentuated the troublesome relation between intellectual property rights and global health. The emergence of vaccines gave a ray of hope in the times of despair and has marked the beginning of bringing the pandemic to an end, but this aim of conquering over the pandemic and bringing it to a standstill is possible only with mass inoculation and equitable distribution of vaccines.

⁴ *Compulsory licenses, the TRIPS Waiver, and access to Covid-19 medical technologies*, ACCESS CAMPAIGN, <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>

⁵ *Bayer Cancer Drug Faces Patent problems in India*, THEPHAMALETTER, https://www.thepharmaletter.com/article/bayer-cancer-drug-faces-new-nexavar-patent-problems-in-india?__cf_chl_jschl_tk__=pmd_zu9ymBG0eY7XnuKsdVVnRp8VUuIP.uOPVuaaT6F7pzAI-1634584198-0-gqNtZGzNAPCjcnBszQgR

There are two prominent points that rekindled the debate on the trips waiver proposal:

- 1) Vaccine inequity
- 2) insufficiency of existing waiver provisions

Equitable distribution of vaccines is cardinal during the time of pandemic to control the fatality rate but, the world is witnessing adverse i.e. **Vaccine nationalization** that means “**my nation first**” approach to secure and provide vaccine to own nationals before providing it to other nations, therefore TRIPS waiver could be proved to be beneficial to deal with such vaccine production and distribution inequality.

This vaccine inequity is morally inexcusable but also clinically counter-productive. If this vaccine inequity continues to prevail then there is a possibility that low income countries could be kept waiting for getting vaccine doses until 2025. This would also have an adverse effect as unvaccinated population would act as a breeding ground for new virus mutations that would be more deadly and contagious. Therefore in order to prevent disaster to humanity all the IP barriers are to be removed to accelerate production and distribution of vaccines and one such is TRIPS⁶.

Therefore recently **India and South Africa** has given a proposal to WTO for temporary waiver of the TRIPS Agreement. The objective while putting forth the contention pertaining to waiver was that, that IP rights could act as a fetter to the supply of vaccines.

If the waiver is granted then there would be no obligation to grant patent rights, and it will also immunize those countries from the claims of illegality under WTO, who aims to accelerate vaccine production by making use of such proposed waiver.

As per the secretary general of WTO Ngozi Okonjo, there is a way other than the mentioned above, that could help in mass production and inoculation at the same time insuring intellectual property rights protection to the investors. This third way is the **voluntary license agreement** between nations and the pharmaceutical companies⁷.

In India's case, there was a licensing agreement between AstraZeneca and Serum Institute of India, this **voluntary licensing** allowed the serum institute of India to manufacture vaccine for export and domestic purposes and at the same time contribute the doses manufactured to the Covid-19 Vaccines Global Access facility, known as COVAX.

⁶ Rajeesh Kumar, *WTO Trips waiver and covid-19 vaccine equity*, IDSA, <https://idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721>

⁷ *The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines*, ORF, <https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/>

But during the menacing 2nd wave, during which the fatality rate hiked, India diverted the doses of vaccines intended for export towards defeating the ferocious 2nd wave, therefore the contention is that even if the developing countries are granted the waiver, there are a multitude of restraining factors such as shortage raw material, inadequate manufacturing infrastructure, that would not ramp up the vaccine production even if the waiver is granted⁸.

Indian government has provided permissions and resources to 3 public sectors to manufacture **Bharat's Biotech Covaxin**, instead it is contended by opposers of waiver that, instead of obtaining an IP Waiver, the Indian government must take steps to expand the manufacturing capacity and limit administrative shortcomings⁹.

It is also argued that Indian government must assure the vaccine producers that they will face minimal risks like regulatory risks, unanticipated price controls. **Pfizer** is ready to manufacture in India provided that freedom of price and export of vaccine is guaranteed¹⁰.

Therefore, developed countries is in support to export more and more quantities of vaccines to developing countries but only on assurance that the countries regulatory and institutional environment is reliable.

V. DISSEMINATION OF VIEWS BETWEEN THE DEVELOPED AND THE DEVELOPING COUNTRIES REGARDING THE WAIVER

The developed countries that are apparently the opponents of the waiver proposal. argue that the flexibilities available under TRIPS is sufficient and, IPR is no barrier to equitable access to vaccines therefore waiver of TRIPS is not required. However history suggests the contrary, once an Indian company **Cipla** provided to Africa at minimal cost, the generic antiretrovirals, but Big Pharma strike back through a patent litigation in Indian and International trade courts and tagged Indian company to be thieves, also a Swiss company once filed a patent infringement case against India's generic version of cancer drug "erlotinib"¹¹

Another contention of developed countries is that, TRIPS waiver would have a negative effect on future innovation as intellectual rights act as an **incentive for innovation**.

Also that US, Germany and other high income countries are prominent producers of vaccine,

⁸ Vivek Dehejia, *A WTO Waiver on Patents wont help us against covid-19*, <https://www.livemint.com/opinion/online-views/a-wto-waiver-on-patents-won-t-help-us-against-covid-11619625719625.html>

⁹ Shivangi Mittal, *Why the TRIPS waiver is unlikely to solve India's Covid-19 vaccine shortage*, THEPRINT, theprint.in/opinion/why-the-trips-waiver-unlikely-to-solve-indias-covid-19-vaccine-shortage/653979/

¹⁰ id

¹¹ supra, note 6

therefore the nationals of their country are first entitled to get vaccines, therefore developed countries are taking the **defense of vaccine nationalization**. Though Art 7 of TRIPS mandated promotion and dissemination of technology from developed countries to low income countries.

Another contention is that the waiver of TRIPS would not insure hike in the production of vaccines, and the inherent shortcoming of developing countries is the lack of the capacity to produce vaccines therefore TRIPS waiver wont help and could not insure improved manufacturing capacity.

The developed countries also argue that production of generic versions of vaccines by the developing countries would jeopardize with the quality of the vaccine, therefore that would have an affect over the trust of people on vaccines.

Also that the production of covid-19 vaccines is a **symbiosis of events** and a mere patent waiver is not enough to address the issue rightly.

VI. INDIA'S ROLE IN ENSURING VACCINE EQUITY

India has been actively taking steps towards bringing the pandemic to an end, India's response to covid-19 was in two steps

- 1) contribution and involvement at domestic and international platforms.
- 2) policies to provide vaccine worldwide.

Matri is India's vaccine initiative under which the objective of vaccine equity is aimed to be fulfilled, and under which India has supplied 663.698 lakh doses of vaccine to 95 countries¹².

India's and South Africa's say pertaining to waiver is that it would be highly beneficial to ramp up the vaccine production. Primarily it would constraint the pandemic and the subsequent waves, secondly it would strengthen India's generic medicine industry

The contention of India is that, TRIPS waiver would reinforce India's diplomatic soft power, it is due to the scarcity of vaccines that the, vaccine initiative of India is not that efficient¹³.

VII. TRIPS WAIVER AS A CHALLENGE FOR INDIA

There is another facet of the TRIPS waiver that is not eminent, and that is the relation of TRIPS with **bilateral investment treaties** and **investment chapter in free trade agreement**.

The above-mentioned treaties and agreement protect foreign investment under international law by imposing of certain stipulations on the regulatory behavior of the host country and

¹² id

¹³ supra, note 6.

refrain them to use undue influence on foreign investors, and it would also obligate the host country to ensure fair and equitable treatment to foreign investors, and the cardinal portion of this treaty is that the foreign investors can direct claim against the host country for alleged breaches of treaty before **ISDS i.e. investor case dispute settlement**.

Therefore this will create a hinderance even if the waiver is granted, as it would entitle the pharmaceutical companies to adjudicate over the host countries regulatory steps that impair their intellectual property rights via ISDS tribunal. The ISDS tribunal is under no obligation to provide exceptional advantage or higher footing to the TRIPS waiver case over the bilateral investment treaties, for the tribunal TRIPS waiver case would be on a similar footing as any other international law in breach of the investors claim.

In India international treaties do not automatically become a part of the domestic law therefore if a TRIPS waiver is granted then India has to make amends in the domestic IPR laws to enforce and implement the waiver¹⁴.

Therefore, TRIPS waiver might be seen to be a viable option to put all the difficulties regarding vaccine production and distribution at a standstill, but a the possibility of a multilateral agreement is onerous due to the dissemination of views between the developed and the developing countries pertaining to the waiver. The path of obtaining the waiver is not smooth and has multiple facets affecting different entities in different ways.

VIII. CONCLUSION

COVID-19 pandemic is regarded to be as the most lethal pandemic in the history of mankind, the amplitude of lives that has been a victim of this disease is beyond limits, therefore there is a dire urgency to bring the pandemic to an end . This is possible only if there is mass inoculation of people, that would prevent the virus to further mutate and take more vicious form. But the major obstacle to achieve the aim of mass inoculation is that, that not every nation is capable to produce, distribute vaccines and inoculate its citizens, therefore India's and South Africa's proposal to WTO to temporarily waive TRIPS is considered to be a feasible option in the times of despair.

But it is seen that, the waiver of IP is not alone capable to accomplish the task. Waiver of TRIPS cannot insure mass production and equitable distribution of vaccines as many nations has a lack of institutional capacity that would not be able to support the benefits that may be provided with the proposed waiver, also that TRIPS waiver requires a capable administrative

¹⁴ PRABASH RANJAN, *TRIPS WAIVER: A BIT OF A CHALLENGE FOR INDIA*, THEWIRE, [HTTPS://THEWIRE.IN/TRADE/TRIPS-WAIVER-A-BIT-OF-A-CHALLENGE-FOR-INDIA](https://thewire.in/trade/trips-waiver-a-bit-of-a-challenge-for-india)

machinery, making changes in the legal framework and overcoming the systematic blockages. The countries those who are capable and have manufacturing infrastructure can make use of the TRIPS flexibilities, but there are many low income countries that are not even capable of using the available flexibilities, therefore the waiver of TRIPS for those nation would be a distant option. Pharmaceutical companies will be have to face financial disadvantages if the waiver is granted, therefore a mid-way is to be found, as strengthening of institutional and manufacturing framework so that the available flexibilities can be used to its full potential, and the need of TRIPS waiver is discarded with, as it is an intricate process.
