

COVID 19
Vaccine

**THE INEQUITABLE GLOBAL
ACCESS TO COVID 19 VACCINES**

**A CASE FOR A WAIVER FROM CERTAIN
PROVISIONS OF THE AGREEMENT ON
TRADE-RELATED ASPECTS OF
INTELLECTUAL PROPERTY RIGHTS**

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Introduction

The Covid-19 pandemic pummelled the world and caused severe disruptions to global economies. Therefore, the development of vaccines understandably came as welcome news and an indication that perhaps there is a ray of light at the end of the proverbial tunnel. The development of these vaccines has brought to the fore, historical issues of inequality and dominance in the global marketplace by wealthy countries.

Wealthy nations have ordered Covid-19 vaccines which vastly exceed what they require while developing nations will have to wait a while longer for vaccines to become readily available.¹ On 18th January 2021, at the 148th session of the Executive Board of the World Health Organization (WHO), the WHO Director-General stated that:

“More than 39 million doses of vaccine have now been administered in at least 49 higher income countries. Just 25 doses have been given in one lowest-income country. Not 25 million; not 25 thousand; just 25. I need to be blunt: the world is on the brink of a catastrophic moral failure- and the price of this failure will be paid with lives and livelihoods in the world’s poorest countries... The situation is compounded by the fact that most manufacturers have prioritized regulatory approval in rich countries where the profits are highest, rather than submitting full dossiers to WHO.”²

Agreement on Trade-Related Aspects of Intellectual Property Rights (Trips)

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most comprehensive multilateral agreement on intellectual property.³ It is an international legal agreement between all the member countries of the WTO which came into effect on 1st January 1995. TRIPS establishes minimum standards for regulation by national governments of different forms of intellectual property as applied to nationals of other WTO member countries.

The aim of TRIPS as set out in its preamble includes the reduction of distortions and impediments to international trade, taking into account the need to promote effective and adequate protection of intellectual property rights (IPRs), and to ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade. These are largely achieved by bringing IPRs

¹ <https://theconversation.com/covid-vaccines-rich-countries-have-bought-more-than-they-need-heres-how-they-could-be-redistributed-153732>

² <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board>

³ https://www.wto.org/english/tratop_e/trips_e/trips_e.htm

together under a common international set of rules and establishing minimum uniform standards of IPR protection which allow for trans-national flow of technology.⁴ TRIPS plays a pivotal role in enabling trade in know-how and the resolution of trade disputes over IPRs.

Article 31 Of Trips & The Doha Declaration on Trips

Article 31 of TRIPS provides a flexible situation for patented materials to be used by WTO members under strict terms.⁵ In 2001, a series of meetings were initiated by some developing countries who had concerns over the restrictive interpretation of TRIPS by developed countries. These series of meetings resulted in the Doha Declaration of 14 November 2001 which is a WTO statement that provides clarity on the ambit of TRIPS. The Doha Declaration provides member countries with an avenue to side-step patent rights in a bid to gain access to essential medicines, as follows:

4. *We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member's right to protect public health and, in particular, to promote access to medicines for all.*
In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
5. *Accordingly, and in light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:*
 - a) *In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.*
 - b) *Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.*
 - c) *Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*

⁴ <https://www.lawteacher.net/acts/trips-agreement-intellectual-property.php>

⁵ https://www.wto.org/english/docs_e/legal_e/31bis_trips_e.pdf

- d) *The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to most favoured nation and national treatment provisions in Articles 3 and 4.*

The above provisions in the Doha Declaration permit governments to issue licences on patents for medicines and take any other steps deemed necessary to protect public health. Consequently, WTO members amended Article 31 of the TRIPS Agreement on 23 January 2017 by introducing Article 31bis which permits a waiver of Article 31(f) for countries that lack domestic manufacturing capabilities to instead import cheaper generic drugs produced in other countries.

India & South Africa's Proposal for A Trips Waiver

It is against the foregoing backdrop that India and South Africa on 02 October 2020, presented a proposal for a TRIPS waiver for COVID 19 vaccines⁶ to the WTO. The waiver proposal is predicated on the fact that many developing countries may face institutional and legal difficulties when using flexibilities available under existing WTO rules.⁷ In particular, they noted the concern among developing countries with insufficient or no manufacturing capacity, that the 2017 amendment which permits countries that produce generic medicines under compulsory license to export those medicines to developing countries lacking manufacturing capabilities, will lead to a cumbersome and time-consuming process.⁸ In the proposal, it is argued that:

3. *...it is important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copy right and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat COVID-19...*
5. *An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and*

⁶ IP/C/W/669 - Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19 – Communication from India and South Africa

⁷ James Bacchus, 'An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines' accessible at <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>

⁸ *ibid*

ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need...

9. *There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients...*
10. *Beyond patents, other intellectual property rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the TRIPS Agreement. A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31bis and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products...*
12. *In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1⁹, 4¹⁰, 5¹¹, and 7¹² of Part II¹³ of the TRIPS Agreement in relation to prevention containment or treatment of COVID-19.*

Shockingly, a European Union official is quoted as having said that “*there is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID-19 related medicines and technologies*”¹⁴ It is alarmingly concerning that in this day and age, the European Union’s alleged position to resist the proposed TRIPS waiver is that there is supposedly no evidence of intellectual property creating any impediment for the accessibility of COVID-19 vaccines. This position demonstrates a troublingly myopic understanding of accessibility.¹⁵ In the absence of a consensus, WTO members continue to adjourn discussions on the proposed waiver.

A recent round of discussions on TRIPS waiver at the WTO held on 10 - 11 March 2021¹⁶ . Members restated their common goal of providing timely and secure access to high-quality, safe, efficacious and affordable vaccines and medicines for all, but continued to diverge on what role intellectual property played in realizing that goal. Advocates for the waiver stated that the current vaccine manufacturing capacities in developing countries remain unutilized because of intellectual

⁹ Copyright and Related Rights

¹⁰ Industrial Designs

¹¹ Patents

¹² Protection of Undisclosed Information

¹³ Standards Concerning the Availability, Scope and Use of Intellectual Property Rights.

¹⁴ *ibid* 7

¹⁵ Diane Desierto, ‘Equitable COVID Vaccine Distribution and Access: Enforcing International Legal Obligations under Economic, Social and Cultural Rights and the Right to Development’ accessible at <https://www.ejiltalk.org/equitable-covid-vaccine-distribution-and-access-enforcing-international-legal-obligations-under-economic-social-and-cultural-rights-and-the-right-to-development/comment-page-1/>

¹⁶ https://www.wto.org/english/news_e/news21_e/trip_11mar21_e.htm

property barriers. They further stated that the waiver proposal presents a fast-track global solution for unfettered collaboration in the production and supply of health products and technologies required for an effective COVID-19 response.

On the other hand, antagonists of the waiver stated the role of intellectual property as an incentive for innovation which is required to combat the current and future pandemics. They stated the need for an evidence-based discussion on examples where intellectual property would pose a barrier to manufacturing and access to vaccines.

Since the submission of the proposal for the TRIPS waiver, it has been co-sponsored by Kenya, Eswatini, Mozambique, Pakistan, Bolivia, Venezuela, Mongolia, Zimbabwe, Egypt, the African Group¹⁷ and the LDCs Group¹⁸.

Recently, the United States of America appears to be open to changing its stance on this issue. The previous administration of Donald Trump had opposed the move for a TRIPS waiver.

It is alarmingly concerning that in this day and age, the European Union's alleged position to resist the proposed TRIPS waiver is that there is supposedly no evidence of intellectual property creating any impediment for the accessibility of COVID-19 vaccines. This position demonstrates a troublingly myopic understanding of accessibility. In the absence of a consensus, WTO members continue to adjourn discussions on the proposed waiver.

However, there are indications that the Joe Biden administration is considering supporting the move for a TRIPS waiver after being lobbied by more than 60 lawmakers and a significant number of rights and non-profit pharma bodies¹⁹.

However, in a new twist, the newly installed WTO Director General, Ngozi Okonjo-Iweala who is from Nigeria, a member of the WTO's African Group who have co-sponsored the proposed TRIPS waiver, has come up with a proposed "third way" of addressing vaccine shortages which TRIPS waiver proponents are concerned would distract from their push for the waiver²⁰. The WTO Director General's third way proposes a path to increasing access through facilitating

¹⁷ The African Group consists of all African WTO members which are Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Congo (Democratic Republic), Côte d'Ivoire, Djibouti, Egypt, Gabon, The Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, South Africa, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe.

¹⁸ The Least Developed Countries Group consists of Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Congo, Democratic Republic of the, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, Zambia.

¹⁹ <https://www.livemint.com/news/world/us-considering-supporting-india-south-africa-at-wto-on-trips-waiver-report-covid-vaccine-waiver-coronavirus-11616811708511.html>

²⁰ <https://www.devex.com/news/trips-waiver-tripped-up-in-wto-by-third-way-99329>

technology transfer within the framework of multilateral rules and by pharmaceutical companies striking licensing deals to allow other manufacturers to produce vaccines and other products.²¹

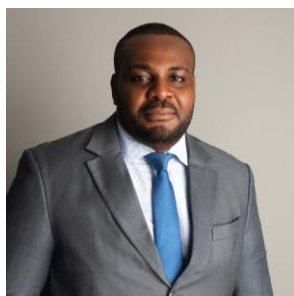
Conclusion

In normal circumstances, the inherent imbroglio between the protection of intellectual property on one hand and the manufacture and distribution of affordable medicines on the other hand is more often than not resolved by a licensing arrangement through which a patent holder permits others to manufacture the protected product for a fee and with some supervision from the patent holder to ensure quality control.

These are however unprecedented times. In a global pandemic such as this, lifting intellectual property monopolies will give governments and manufacturers carte blanche to collaborate in the development, production and supply of COVID-19 vaccines. The current restrictive business as usual voluntary licensing practice is limiting production and artificially constraining supply with detrimental consequences for global public health.

Flexibilities, waivers and exemptions in trade regulations exist for a reason, and surely a global pandemic is as good a reason as any for the WTO to grant the request for a TRIPS waiver for COVID 19 vaccines.

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²¹ ibid