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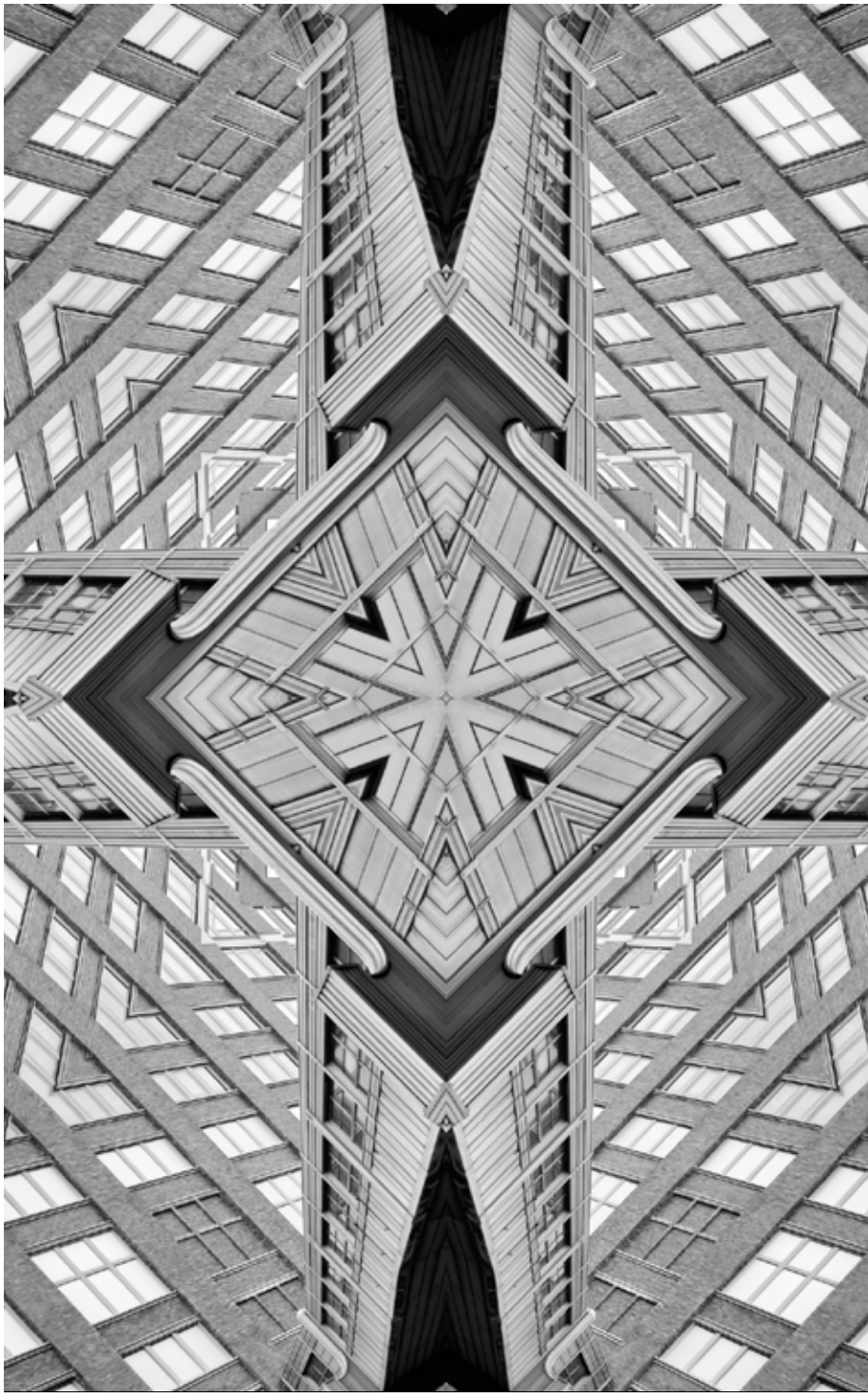

The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines

Prabhash Ranjan

Abstract

The arrival of vaccines against Covid-19 gives hope in ending the pandemic that has claimed close to 2.84 million lives so far. However, inoculating millions of people all over the world would require the massive production of vaccines, followed by their equitable distribution. An impediment to production and distribution of vaccines is the intellectual property (IP) rights that their developers enjoy. India and South Africa have together proposed that the World Trade Organization waive certain provisions of the TRIPS agreement when it comes to Covid-19 vaccines, drugs and therapeutics. This brief makes the case for such a waiver, noting the exceptional circumstances that exist. It argues that the flexibilities provided by TRIPS are insufficient in dealing with the current pandemic especially for countries that lack manufacturing capability in the pharmaceutical sector.

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Introduction

The 1995 agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a key legal instrument that harmonises intellectual property (IP) protection by imposing binding obligations on member countries to ensure a minimum level of protection and enforcement of IP rights in their territories.[1] As a part of the World Trade Organization (WTO)'s legal regime, the TRIPS agreement also polices the enforcement of IP rights through a compulsory and enforceable dispute settlement mechanism.

It is well-known that in the Uruguay Round of negotiations, held from 1986-1994 that led to the formation of the WTO in 1995, the discussions on the TRIPS agreement were contentious.[2] Developed countries, especially the United States (US), backed by its pharmaceutical transnational corporations, aggressively pushed for the TRIPS agreement.[3] These countries considered that higher cross-border IP protection—which could be effectively monitored through a multilateral agreement—would bring in greater rents for their pharmaceutical corporations.[4] On the other hand, developing countries were not keen on an agreement on IP in the WTO.[5] The developed countries won: using both threats of trade sanctions and allurements in the form of concessions in trade in agriculture and textiles, they compelled developing countries to agree to include IP in the Uruguay round of negotiations.[6]

Since then, the debate on TRIPS' impact on people's right to health has not ceased.[7] Proponents say that IP protection incentivises innovation[8] and should therefore be strengthened through a network of national and international laws. Meanwhile, critics argue that IP rights, especially those on patents, hinder the introduction of affordable vaccines and drugs in developing countries[9] and deny people their right to health.

Today the debate takes centrestage, as the world grapples with Covid-19. The vaccines and other treatments that have been developed to combat Covid-19 —providing an unmistakeable silver lining to the crisis — are subject to patent protection under the TRIPS agreement. The patent holders have the exclusive right to manufacture, sell, and use[10] the vaccine or the drug for the entire term of patent protection of 20 years from the date of the filing of the patent.[11] Such protection could impede wider accessibility of vaccines and prolong the pandemic. The entire vaccination exercise, and not the vaccines themselves, will

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end the pandemic, and the challenge is to ensure that it is universalised. The task is profound due to the increasing concerns of vaccine nationalism, whereby richer countries are procuring vaccines for their population ahead of others which, in turn, could derail the goal of delivering two billion vaccine doses to poorer and middle-income countries.[12]

It is in this context that the joint proposal of India and South Africa at the WTO asking for a temporary waiver of the IP rights on Covid-19 vaccines and drugs[13] needs to be understood. The proposal argues that IP rights could hinder the supply of vaccines and drugs at affordable prices.[14] Therefore, India and South Africa, at a time when production of vaccines needs to be scaled up to meet demand, have proposed that the WTO's TRIPS Council recommend to the General Council "a waiver from the implementation, application, and enforcement of" certain provisions of the TRIPS Agreement (waiving IP rights like patents, copyright, and trademarks) for prevention, containment or treatment of Covid-19.[15] 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 drugs, vaccines, and other treatments. This will immunise the measures adopted by countries to vaccinate their populations from claims of illegality under WTO law.

Since then, the proposal has been co-sponsored by other developing countries.[a,16] In the last five months, the TRIPS Council has discussed this issue both formally and informally.[17] A consensus is not in the horizon, as many developed countries have reservations about waiving IP rights.[18] They argue that protecting IP rights boosts research and innovation, and that suspending these rights will not lead to a surge in the manufacturing of the Covid-19 vaccines.[19] To be sure, the TRIPS Agreement itself contains flexibilities that allow for a balancing of the rights of the patent holder with the people's right to health.[20] This brief argues that such flexibilities are insufficient.

a These countries include Kenya, Eswatini, Mozambique, Pakistan, Bolivia, Venezuela, Mongolia, Zimbabwe, Egypt, the African Group, and the Least Developed Countries Group.

TRIPS Waiver: The Legal Basis

Article IX.3 of the Marrakesh Agreement establishing the WTO (or the WTO Agreement) provides that in "exceptional circumstances", the Ministerial Conference[b] may waive an obligation imposed on a WTO member country by the WTO Agreement or any other multilateral trade agreement.[21] The same article provides that such a waiver be supported by three-quarters of the members.[22] Article IX.3 (b) says that if the request for a waiver concerns the multilateral trade agreements given in Annexes 1A, 1B, or 1C, then the request should be first submitted to Council for Trade in Goods, Council for Trade in Services, and Council for TRIPS, respectively. In the current scenario, since the waiver request pertains to the TRIPS Agreement, the TRIPS Council has jurisdiction over it. Furthermore, Article IX.4 of the WTO Agreement states that the 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 also have an end date and be reviewed annually by the Ministerial Conference if granted for more than a year.

The term "exceptional circumstances" given in Articles IX.3 and IX.4 has not been defined in the WTO Agreement. However, the words "exceptional circumstances" indicate that the power to waive certain obligations intends to legalise those measures adopted by a country in concrete situations of urgency that would otherwise violate the WTO law.[23] In other words, the waiver power enshrined in Articles IX.3 and IX.4 recognises that there may be certain exigent situations causing hardship to a member country, when compliance with the WTO norms may not be feasible. In such a situation, the WTO, as an institution, for a temporary period—i.e. till the exigent situation last, should legalise non-compliant measures. However, the waiver power should be exercised with caution and interpreted with great care[24] so that it does not become an easy escape route for a country aiming to circumvent its WTO obligations.

b The Ministerial Conference is the highest decision-making body in the WTO.

A waiver under Articles IX.3 and IX.4 may be granted to an individual WTO member country or even collectively. There are two examples of how the WTO system has in the past provided collective waiver. First, a waiver from certain GATT obligations was granted in 2003 to some countries concerning measures they adopted that are necessary to prohibit the export and import of rough diamonds or so-called 'blood diamonds' to non-participant countries in the Kimberley Process Certification Scheme.[25] Second, dealing with concerns regarding the accessibility of medicines in LDCs and other developing countries that lacked the manufacturing ability, the General Council in 2003 (2003 decision) waived the obligations contained in Articles 31(f) and 31(h) of the TRIPS Agreement.[26] Article 31(f), which provides that a compulsory license should be issued on a patented drug predominantly for the supply of the domestic market, was waived for exporting countries,[27] subject to the extent necessary for the purposes of production of a pharmaceutical product and its export to an eligible importing country.[28] The production and subsequent export is further subject to additional conditions.[29] First, the eligible importing country, other than an LDC, notifies the TRIPS Council that it has insufficient or no manufacturing capability to manufacture the product (or drug) in question along with the names and quantities expected.[30] Second, the eligible importing country has already issued or intends to issue a compulsory license if the pharmaceutical product is patented in its territory.[31] Likewise, the obligation under Article 31(h) to pay remuneration to the patent holder is waived for the eligible importing country.[32]

There are other requirements as well for the waiver to work:[33] the generic pharmaceutical company must manufacture only the amount necessary to meet the needs of the eligible importing country;[34] the entirety of the medicines produced under such a license shall be exported to the eligible importing country;[35] and the products manufactured under the license shall be clearly identified as being produced under the arrangement given in the 2003 decision through precise labelling or marking.[36] Thus, this waiver was made available to all WTO member countries provided they satisfied the conditions given in the 2003 decision.

TRIPS Waiver: The Legal Basis

The Covid-19 global pandemic—the worst global health crisis in the last 100 years that has devastated lives all over the world and caused unprecedented economic and social destitution—undoubtedly constitutes an "exceptional circumstance" as defined under Articles IX.3 and IX.4 of the WTO Agreement. As the pandemic continues to rage, countries collectively have to find innovative ways to not just increase the production of vaccines but also ensure their timely distribution at affordable prices. In this situation, the requirement to meet the stringent IP standards given in the TRIPS Agreement may not be a feasible option. There is a clear legal case to be made for a collective waiver of the kind that was granted to the countries participating in the Kimberley Process Certification Scheme.

The waiver would suspend the IP obligations on countries so that those with manufacturing capabilities could produce the Covid-19 vaccines and export them to those nations that lack the manufacturing capability without fearing a legal challenge at the WTO. Initially, the waiver may be granted for a year. It may be reviewed at the end of the year.

> "The Covid-19 pandemic undoubtedly constitutes an 'exceptional circumstance' as defined under the WTO Agreement."

The Insufficiency of TRIPS Flexibilities

Those who oppose India and South Africa's proposal for a TRIPS waiver argue that since the TRIPS Agreement contains several flexibilities that can be used to address public health exigencies, the demand to suspend IP obligations is superfluous.[37] Indeed, the TRIPS Agreement contains those flexibilities. One such important flexibility is *compulsory license* – the right of a government to issue a license to make use of a patent during the patent term without the patent holder's consent, which is regulated by Article 31 of the TRIPS Agreement. Under Article 31, public non-commercial use is also possible—i.e. a government can authorise the use of a patent for its purposes. According to a study, out of 144 instances of the use of TRIPS flexibility measures by 89 countries from 2001-2016, 100 instances were of compulsory licensing or public non-commercial use to increase the production of generic medicines at affordable prices.[38] Likewise, the study also found that a large number of LDCs made use of the long transition period available to them to comply with the TRIPS Agreement[39] – another important TRIPS flexibility.[40]

It would be erroneous to conclude, however, that these flexibilities would be sufficient in dealing with all public health challenges especially one as massive as the current pandemic. The utility of the same TRIPS flexibility, such as compulsory license, is not the same for all countries. While countries that have manufacturing ability in the pharmaceutical sector can effectively employ compulsory licenses, a large number of LDCs do not have such capability. Even developing countries that can use compulsory licenses to produce patented drugs are always under pressure from developed countries not to issue such licenses. For example, India was subjected to relentless attacks by the US government when it issued a compulsory license in 2012 to produce a generic version of Bayer's cancer drug.[41]

As pointed out earlier, for countries that lack manufacturing ability, the compulsory license is not a useful flexibility. Article 31(f) of the TRIPS Agreement states that a compulsory license may be issued predominantly for the domestic market of the country issuing the license. Thus, generic medicines produced under a compulsory license cannot be exported. As a result, countries that have limited manufacturing ability in the pharmaceutical sector will not be able to benefit from the provision on compulsory licensing given in Article 31 of the TRIPS Agreement. This problem was recognised by the WTO in 2001 as

evident in 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."

In August 2003, the WTO's General Council adopted a decision that waived the obligations imposed by Articles 31(f) and 31(h) to allow countries to export drugs manufactured under compulsory licensing to countries that lacked the manufacturing ability.[42] Finally, in 2005, the TRIPS agreement was amended, which took effect on 23 January 2017,[43] to include Article 31 *bis* making the 2003 decision permanent. The fact that first the waiver followed by the amendment of the TRIPS Agreement was needed demonstrates that the TRIPS flexibilities were not adequate in addressing all the situations of drug scarcity.

While this amendment has been touted as having solved the problem of countries with insufficient manufacturing ability to access drugs at affordable prices, concerns remain about the cumbersome process that countries need to follow to import and export such medicines.[44] 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 that the drugs so manufactured are exported to that nation only; the medicines should be easily identifiable through different colour, or shape; only the amount necessary to meet the requirements of the eligible importing country are manufactured; and the importing country has to notify the WTO's TRIPS council.[45]

These conditions disincentivise generic pharmaceutical manufacturers from manufacturing products under compulsory licenses for export.[46] Since often, the countries that lack manufacturing capability are smaller in size, there is less economies of scale to be reaped to attract the interest of generic manufacturers to export drugs to such countries.[47] Indeed, the problem with the economies of scale and the cumbersome procedure were evident in the only instance when this system was put to use in the last decade and a half, involving Rwanda and Canada.[48]

The Insufficiency of TRIPS Flexibilities

In their proposal, India and South Africa identified the unworkable nature of Article 31 *bis* to address the challenges posed by Covid-19. Given that a large number of counties lack manufacturing capability in the pharmaceutical sector and that they would need Covid-19 vaccines for their population, the lengthy and cumbersome procedures listed in Article 31 *bis* would only hobble their efforts at universal inoculation. Following the procedures listed in Article 31 *bis* for a large number of countries simultaneously would severely slow down the export of vaccines, thus proving to be costly when countries need these products urgently amid a pandemic. Therefore, the sheer scale of the problem and colossal demand for vaccines from all countries of the world make the TRIPS flexibility impracticable.

There are other flexibilities as well such as voluntary licenses—i.e. licenses given by patent holders to generic companies on mutually agreed terms. The AstraZeneca Covid-19 vaccine, for instance, that has been licensed to India's Serum Institute is an example of a voluntary license. However, the voluntary licenses are often shrouded in secrecy where the patent holder controls important decisions such as who would be the ultimate beneficiaries of the drug and how the third-party sellers are to be selected. The same can be said about the voluntary license issued by AstraZeneca to Serum Institute.[49] To boost the production of vaccines to meet huge demand, several other companies would have to be upgraded, requiring a non-exclusive deal which is unlikely to happen.[50]

> "The sheer scale of the health crisis and colossal demand for vaccines make the TRIPS flexibility impracticable."

Conclusion

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The global community began this year with the singular aim of ending the Covid-19 pandemic. This would only be possible if more and more people all over the world are vaccinated, and as quickly as possible. Given the enormous demand, the production of vaccines has to be increased manifold and followed by ensuring wider and equitable distribution. An IP waiver alone cannot accomplish such task. Increasing the production of vaccines and ensuring their equitable access would also require building the institutional capacity in several countries, overcoming systemic bottlenecks, and undertaking the necessary reforms in the administrative machinery and the legal framework. Nonetheless, a TRIPS waiver could be an important step in scaling up the production of the vaccines.

Voluntary efforts like COVAX that aim to accelerate the development and production of vaccines might not be enough, given the enormity of the challenge. While countries that have manufacturing capability can make use of TRIPS flexibilities like compulsory licenses, the same cannot be said about those that lack such capacity especially LDCs in Africa and Asia. The argument that suspending IP rights would be a disincentive for the pharmaceutical sector is untenable: given the huge demand, these companies are assured of returns. Moreover, pharmaceutical companies often benefit from public grants and public money[51] including in the development of Covid-19 vaccines.[52] Therefore, it is legitimate that the benefits should be shared with the society at large. As the World Health Organization rightly says, "with a fast-moving pandemic, no one is safe, unless everyone is safe."[53] Therefore, the global community needs to pull out all stops including a temporary TRIPS waiver.

Endnotes

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13 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 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (hereinafter "TRIPS Waiver Proposal").

14 TRIPS Waiver Proposal, paras 9 and 10.

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15 TRIPS Waiver Proposal, para 12.

16 "Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic", *World Trade Organisation,* February 23, 2021, https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm.

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18 "Rich, developing nations wrangle over COVID vaccine patents", *Reuters*, March 10, 2021, https://www.reuters.com/article/us-health-coronavirus-wto-idUSKBN2B21V9.

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20 See James Bacchus (2020), "An Unncessary Proposal: A WTO Waiver of Intellectual Property Rights for Covid-19 Vaccines", *CATO Institute, Free Trade Bulletin,* 78 (February 2021); Bryan Mercurio, "WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review", *SSRN Working Paper,* (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820

21 For a detailed discussion on WTO's Waiver power, *See* Isabel Feichtner, "The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests", *European Journal of International Law,* 20, no. 3, (August 2009): 615-645.

22 On 15 November 1995, the General Council of the WTO decided that although support of three-fourths is needed to adopt a waiver, it would first try to decide by consensus. If consensus cannot be reached, then the matter shall be decided by the three-quarters majority – WTO, Decision Making Procedures under Article IX and XII of the WTO Agreement, WT/L/93, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/93.pdf&Open=True

23 Feichtner, "The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests", 620.

24 Appellate Body Report, EC – Bananas III, WT/DS27/AB/R (WTO, 2008), para. 185

25 General Council, *Waiver Concerning Kimberley Process Certification Scheme for Rough Diamonds*, Decision, (WTO, 15 May, 2003), WT/L/518. In 2006, the General Council extended the waiver.

26 General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision, WT/L/540 (WTO, 30 August, 2003) https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.

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