The TRIPS Agreement and Public Health: Understanding the Reform Agenda

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Abstract
Past debates on waiving certain sections of the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have centred on issues such as development and technology transfers. The COVID-19 pandemic has brought more urgency to such discussions, prompting India and South Africa to table a waiver proposal in October 2020. This brief discusses the evolution of the TRIPS Agreement and the link between the agreement and public health issues, and examines the current waiver proposal for COVID-19-related technologies. It argues for a more substantive and proactive debate on the subject, rather than one that only reacts to a health emergency.
The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the main annexes to the Marrakesh Agreement that established the World Trade Organization (WTO). Issues related to TRIPS enforcement began manifesting almost as soon as the agreement entered into force and reemerged amid health emergencies.¹

The COVID-19 pandemic renewed discussions on the agreement, even as the WTO is going through a crisis of legitimacy.²³ The sheer scale and impact of COVID-19 have prompted governments to proactively seek the liberalisation of public health-related goods and services—albeit in the short term. Pandemic-induced lockdowns led to severe delays and supply chain congestion. This led to a disruption in the supply of medicines and other essential goods and services.⁴ Mode 2 services trade, consisting of services consumed abroad (as defined by the General Agreement on Trade in Services), was stopped altogether. Global solutions are thus being sought to ease any barriers to trade that interrupt the treatment and prevention of COVID-19. The TRIPS Agreement and its barriers in bureaucratic notification rules are just one policy under discussion. Others include the reduction of tariffs on medical goods.⁵

In October 2020, India and South Africa co-sponsored a proposal before the WTO members to waive specific provisions of the TRIPS Agreement for technologies needed for the treatment and prevention of COVID-19. Developing countries are making a renewed push for reform on the grounds of affordability and access to public goods like medicines and vaccines. However, developed countries continue to argue against the waiver, citing the so-called “innovation imperative” and research and development costs. The waiver will be one of the main issues up for discussion at the 12th WTO Ministerial Conference (MC12).

While the TRIPS Agreement covers the entire spectrum of intellectual property (IP) rules, this brief focuses on patents and their relation to public health. It explains the impetus for the amendment made to the agreement in 2017 and the India-South Africa waiver proposal. It looks at arguments surrounding innovation and the current patents regime to understand why a waiver is needed despite the amendment made to the agreement. It argues for a more substantive debate on the issue that will help the world prepare for future contingencies, instead of the current one that is merely a reaction to the ongoing pandemic. It also presents policy suggestions for the long term.
The TRIPS Agreement is not the first iteration of multilateral rules on intellectual property rights (IPR). The original General Agreement on Trade and Tariffs 1947 (GATT 1947) had several references to IP. The Uruguay Round of negotiations from 1986 to 1994, which culminated in the Marrakesh Agreement and the establishment of the WTO, included a negotiating group on trade-related aspects of IPR. Their mandate covered the entire gamut of IP rules, not just the 'trade-related aspects'. Multiple detailed proposals were put forward by key negotiating countries, such as the US, Japan, and 14 developing countries, including India. A composite text was finally adopted as Annex 1C of the Marrakesh Agreement after rigorous negotiations on aspects such as the scope of compulsory licensing and dispute settlement. The TRIPS Agreement was adopted as a single-undertaking, minimum standard agreement. As per the WTO organisational structure, the Council on TRIPS is one of only three that reports directly to the General Council and several committees and working parties. This highlights the central position that IP rules occupy in the trade body.

Figure 1: Evolution of TRIPS

Source: Author's own

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The World Trade Organization describes compulsory licensing as "when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself." It is one of the flexibilities in IP protection included in the TRIPS Agreement.
Impetus for Amendment

Several factors impede the access to medicines, such as tariff levels, production capacity, and domestic regulation. However, IP rules remain an important barrier to easy access, given the structure of the global IP regime.

A key tension emerged between the end of the Uruguay Round and the beginning of the Doha Round (1994 to 2001). Developing countries struggled to import generic drugs after the enforcement of the TRIPS Agreement when the HIV/AIDS epidemic was raging. The market price for antiretroviral drugs was between US$15,000 and US$20,000 per patient per year. The South African government enacted the Medicines and Related Substances Act of 1997 to implement negotiated TRIPS flexibilities for compulsory licensing, but this came under fire from pharmaceutical lobbies. South Africa’s attempt to import the drugs at lower rates was termed as TRIPS non-compliance by the US, and the US Trade Representative threatened to impose trade sanctions, which South Africa could not afford.

There are four conditions under which licensing by a right holder takes place—voluntary licensing; compulsory licensing if a voluntary license negotiation is not successful; compulsory licensing for public non-commercial use; and compulsory licensing for countries that lack manufacturing capacity. A crucial problem was that while the TRIPS Agreement allowed for compulsory licenses to be used in case of emergencies, it was largely for domestic production and use. Exporting cheaper versions of the antiretroviral drugs to countries that did not have manufacturing capacity was still not possible. Even so, the patent holder’s rights are protected under Article 31(h) of the TRIPS Agreement, which specifies that “adequate remuneration” must be provided for the ostensible economic loss from enforced licensing.

It was in this backdrop that the Doha Round of negotiations began in 2001, with the Doha Declaration on the TRIPS Agreement and Public Health adopted soon after. The Doha Declaration addressed the tension between IPs for innovation versus IPs for access to medicines—or the development of new medicines versus the impact of IP protection on drug prices. The main change introduced by
the Doha Declaration was what became known as the Paragraph 6 system, or the special compulsory license system. The change was finally adopted by a 2003 decision on a waiver to allow countries that do not have manufacturing capacity for pharmaceuticals to use compulsory licenses to import generic medicines from elsewhere.

This eventually lent itself to the first amendment to a WTO agreement. The changes were approved in 2005 but only accepted and implemented in 2017, with the 2003 waiver in force in the interim. The amendment inserted Article 31bis to the TRIPS Agreement, allowing the export of products manufactured under a compulsory license under three conditions.

First, countries would have to amend their domestic laws to make use of these flexibilities to allow compulsory licensing and imports of licensed generics by countries that do not manufacture. Second, a country wanting to import a drug manufactured under a compulsory license would have to make a submission to the TRIPS Council stating the exact quantity required and the emergency it addressed. Third, the calculation of adequate compensation for using a compulsory license would be done in a manner that there would be no double compensation from the importing and exporting country.

However, the amendment has not been the panacea it was thought to be, given the complex bureaucratic requirements for using this flexibility. This complexity is the basis for the renewed push for a TRIPS waiver by India and South Africa.
The submission made by India and South Africa in October 2020 specifically asks for a waiver from Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement for “health products and technologies” for the treatment, containment, or prevention of COVID-19. Part II of the TRIPS Agreement refers to ‘Standards Concerning the Availability, Scope and Use of Intellectual Property Rights’. The sections refer to protections related to copyrights (Section 1), industrial design (Section 4), patents (Section 5), and protection of undisclosed information (Section 7). The October 2020 submission was revised in May 2021 to include a three-year timeline from the date of adoption of the waiver to its expiry. It also clarifies that the waiver will not apply to the protections of performers and broadcasters in addition to being without prejudice to the rights of least developed countries. This implies that it would not impact the IP rights of patent holders outside of those needed for the treatment and prevention of COVID-19. It also means that the timeline for least developed countries to fulfil TRIPS commitments remains 2033.

The proposal also includes a provision to review the waiver one year after its approval. In addition, a ‘peace clause’ has been added as a safeguard that states that WTO members will not challenge measures taken by another member in conformity with the waiver. This was spurred by past experience where any compulsory license applied has been challenged either at the WTO or unilaterally by developed countries.

The waiver proposal stems from three concerns—that IPRs are a threat to the availability and access to affordable medicines; that IP protection will have a slowdown effect on innovation (which differs from the argument made by pharma companies that the lack of IPRs stunts innovation); and that the mechanism within the TRIPS Agreement is too unwieldy. Notably, the 2016 report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines specifically mentions the Paragraph 6 decision. The report recommends that WTO members “adopt a waiver” and consider a “permanent revision of the TRIPS Agreement to enable reform”. The 2017 amendment was adopted based on the 2003 WTO decision whereas the UN recommendation was to amend features of that decision and, therefore, the amendment adopted.
The waiver proposal has found support from various developing countries, such as those in Africa, and the least developed countries. While the US has not supported the current proposal at the WTO, it made a statement supporting a waiver specifically for COVID-19 vaccines.\textsuperscript{19}

The European Union (EU) remains a dissenting voice. According to the EU’s submission to the TRIPS Council in June 2021, the grouping would prefer a clarification of the current flexibilities over waiving any rights.\textsuperscript{20} The EU acknowledged that the requirement for “prior negotiations for adequate compensation” before issuing a compulsory license may be done away with as the COVID-19 emergency fulfils the definition of a national emergency. It also aimed to simplify notification and application processes for this specific emergency by proposing a single notification to tackle the procedural problems with Article 31bis for the COVID-19 pandemic.

As countries scramble to tighten their domestic laws related to the implementation and use of compulsory licenses, the need for the waiver is keenly felt. Canada, France and Germany, all proponents of strong IP rules, have enacted emergency laws empowering their governments to impose compulsory licenses during COVID-19.\textsuperscript{21} Meanwhile, it is important to note that the adoption of the waiver will merely make it legal for countries to waive IP protection of COVID-19-related technologies, and it will be up to each country to adopt the rules into their domestic laws, which in itself is a cumbersome process. Subsequent steps will need to be taken to enable the transfer of technology to developing countries with production capacity. Additionally, investments in capacity building are needed to enable least developed countries to manufacture these essential products.

The multiple waves of the COVID-19 pandemic have shown the importance of widespread vaccination programmes and the need for continuous innovation. The pace at which the coronavirus has morphed into more virulent forms makes it difficult to predict the end of the pandemic. Innovation is racing against the virus’s next variant. Pausing for market imperatives like royalties and adequate compensation must be balanced with curbing the spread of the virus so that developing countries are not left behind.

Vaccine inequity and affordable treatment, the main trigger behind the current waiver proposal (albeit pegged to COVID-19), are longstanding issues. While the fate of the waiver proposal is yet to be determined, it will merely be a stopgap until the next pandemic and a recycling of the same arguments, primarily the development of new medicines (innovation) versus the impact of IP protection on drug prices (access).
To understand the IP for innovation versus the IP for access debate, it is essential to know how a patent works.

A patent grants the inventor a right to ‘exclude’ others from the invention for a 20-year lock-in period. This effectively creates a limited-time monopoly that gives the inventor control over the price of the product or technology and discretion over who is given access to it through licenses. For an invention to be patentable, it needs to be novel, and have an inventive step. There are industry standards for what constitutes novelty and inventiveness. One major component of a patent application is the disclosure requirement. “The invention must be described in sufficient detail to enable those skilled in the particular field to practice it.” This is because the knowledge itself is a public good. The inability of the inventor to detail the best means to use the technology violates the terms of the patents. At the same time, no third party can effectively use the invention until they acquire some form of license or authorisation from the patent holder.

Patents have an inherent antitrust element by design since they enable inventors to earn royalties from their inventions. Proponents of strong patent rules argue that the monopoly period is what enables innovation. For instance, “People will not invest the billions required to create a new drug or vaccine—and to create the follow-on technologies and the commercial production and distribution chains necessary to distribute this drug in the health care market to patients—if the fruits of their productive labors are not secured to them.”

Studies by scholars favouring strict patent rules have found that “the existence of IPRs is neither necessary nor sufficient for the launch of pharmaceutical innovations at the country level.” Meanwhile, the monopoly has allowed big pharmaceutical companies to set prohibitive prices for life-saving drugs.

The argument has dominated both sides of the debate such that it has become a zero-sum game between innovation and access. But this is not true. Firstly, the TRIPS Agreement was never meant as a means to increase innovation but to improve and support IP standards. Innovation as a concept is mentioned only once in the TRIPS Agreement (in Article 7). The article, which lays out the “objectives” of the agreement, states:
“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.\textsuperscript{27}

In conjunction with the function of a patent, Article 7 reveals how the innovation aspect has been mistakenly conflated with the monopoly aspect. As multiple scholars have observed, true innovation comes from the patent being actively used and the "disclosure" requirement. Since a patented technology will be the latest innovation in the field, other inventors will be able to build on that technology to create new and more efficient systems.\textsuperscript{28} Importantly, they will only be able to use this technology if they have a licensing agreement with the patent holder. Thus, the IP regime will truly support innovation by enabling the "follow-on innovations" that happen on the disclosure of a patent. The 20-year monopoly will ensure that the holder gets royalties for that period.

The problems of pricing, affordability and access are collateral damage to the idea that innovation is driven by the lock-in period of the patent. Attempts at using compulsory licenses are also met with resistance, with trade sanctions being the go-to mechanism to avoid such flexibilities. Take, for instance, American biotechnology firm Gilead Sciences’ challenge of the Russian government’s issuance of a compulsory license for the production of remdesivir, a widely-used drug in the treatment of COVID-19. Gilead has signed non-exclusive voluntary licensing agreements for production in Egypt, India and Pakistan for distribution in 127 countries.\textsuperscript{29} It has also forgone royalties until the WHO announces the end of the pandemic. In the US, the current cost of the Gilead-produced remdesivir (Veklury) is US$390 per vial for patients on government insurance and US$520 per vial for patients on private insurance.\textsuperscript{30} In India, the price of the cheapest generic version of the drug is INR 2,800 per vial (about US$37).\textsuperscript{31}

The Gilead example shows just how much control patent holders have in the current IP regime. In an extreme scenario, if Gilead so wished, it could forgo signing any licensing agreements or even hold on to the technology as a "trade secret". In these situations, there would be no choice but to import the drug at the set price. To this, the costs of tariffs, time taken for approval by drug controllers, and storage facilities will also need to be added. In addition, the ability of one company to produce at scale in proportion to the demand will need to be considered. This possibility also accounts for the scope covered by the waiver proposal, which includes a waiver from Part II Section 7 of the TRIPS Agreement ("Protection of undisclosed information"), currently tabled by India and South Africa.
The issues surrounding the current IP regime are not easily reconciled, and they also concern human rights and ‘global public good’ issues. Civil society movements have also called for TRIPS Agreement related issues to be addressed; the COVID-19 Technology Access Pool (C-TAP) is a case in point. A World Health Organization (WHO) initiative, C-TAP aims to pool rights to “technologies that are useful for the detection, prevention, control, and treatment of COVID-19”. This implies that cross-cutting and multiple licenses would be grouped together for use. This is based on a voluntary system. The challenge, as identified by C-TAP proponents, is creating a model that is attractive to rights holders. Of the 192 WHO members, only 40 or so have endorsed the ‘Solidarity Call for Action’ that enables C-TAP. Unsurprisingly, most of these are developing countries, but India is not one of them.

These initiatives, while laudable, are short term and will only address specific cases. Under the current system, such initiatives and waivers will be required every time a new pandemic emerges. Experts have recommended several compromises to avoid this—from altogether doing away with patents in pharmaceuticals, to the more tempered suggestion to seek clarification of rules and amendments to the regime. Notably, these ideas have emerged over the past decade, not just as a reaction to the COVID-19 pandemic.

Economists Dean Baker, Arjun Jayadev and Joseph Stiglitz recommend developing “knowledge commons” and limiting the patentability of key innovations by making them subject to non-exclusive licenses. They also argue that publicly-funded innovations should remain in the public domain. If such innovations are to be licensed, these should be non-exclusive. Recently, discussions along these lines have focused on the AstraZeneca and Moderna COVID-19 vaccines, which were either partially or wholly publicly funded.

Another interesting proposition is offered by legal scholars Srividhya Ragavan, Brendan Murphy and Raj Davé, who recommend the use of a hybrid of standard essential patents (SEP) and compulsory licensing. This will be useful to the extent that any new technology with promising and widespread

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b When a patented technology or innovation is declared a standard by a Standard Setting Body (SSB), and the patent holder claims that patented technology, declaring their patent an SEP
public applications can be declared an industry standard, and will compel most companies to use the technology to maintain these standards. To preserve their royalties, the patent holder will have to declare their existing patent as a SEP to the standard-setting organisation. They suggest that the “Fair, Reasonable and Non-Discriminatory” (or FRAND) terms of the SEP also be standardised so that all potential licensees are given the same rate. These would be different from SEPs in the technology sector as there will be less need to pool patents, making the system more straightforward. For pharmaceuticals, the International Organization for Standardization and the WHO’s Expert Committee on Specification for Pharmaceutical Preparations are appropriate to be designated as standard setters. Thus, any patent holder will have a first-mover advantage and SEPs will allow for more widespread use of that technology, making it attractive for companies.

One argument against SEPs in pharmaceuticals is the likely impact on national standard-setting. However, the existence of an international standard does not necessarily mean that national standards cannot be set beyond them to further enhance human safety. Harmonised standards will also ease non-tariff barriers to trade in essential public health related sectors. In addition, it will have a positive effect on other regulatory concerns, such as the non-recognition of vaccines disrupting movement and, therefore, a large component of services trade, which requires people to cross borders.

“The issues surrounding the current IP regime are not easily reconciled, and they also concern human rights and ‘global public good’ matters.”
The discussions on the TRIPS waiver proposal in this brief are only part of a larger and longer discourse on WTO reform. There has been growing discontent over the WTO’s lack of responsiveness to the needs of developing countries. Importantly, discussions on the evolution of and changes to the TRIPS Agreement reflects continuity in the issues raised by dissenting voices, such as during the South Africa-HIV/AIDS antiretroviral drugs case. A complex and bureaucratic system is not just cumbersome but also acts as a barrier to trade. Add to this the larger challenges posed by the evergreening of patents and ‘TRIPS-plus’ commitments (provisions that go further than the TRIPS Agreement) that are making their way into free trade agreements and regional trade pacts. One general verdict is the need for a more nuanced understanding of how the patent system enables innovation. Incentivising patent holders to license their inventions is key to both innovation and greater access. In addition, making SEPs, or non-exclusive licenses, the industry norm will go a long way towards addressing the ‘patents as a hurdle to access’ issue. An interesting element of the revised India-South Africa proposal is the safeguard that members will not challenge steps taken under the waiver. This element should undoubtedly make its way into any amendment to the TRIPS Agreement that may be undertaken in the future. Aspects of the EU proposal, such as the single notification, can be adopted for longer-term purposes. A composite solution is possible if all member countries negotiate with a will to have substantive reform.

A ‘third way’, as endorsed by the WTO director-general, is for private entities to provide voluntary licenses to countries with manufacturing capacity, for instance, as with the Oxford-AstraZeneca COVID-19 vaccine. Importantly, this is not a new or reformed position but is a central position that promotes good corporate practices.

Having a diplomatic, middle-ground position has allowed inequity in access to public health goods to fester for over 25 years. The MC12 must be seen as an opportunity for meaningful reform and making multilateralism work for the majority of its members, who are developing countries. While the fate of the India-South Africa waiver proposal will be decided at MC12, what is certain is that a more enduring solution is needed to the TRIPS issue. In its current form, the TRIPS Agreement is not just a barrier to trade but also to the greater public good.

“Evergreening,” is referred to the practice whereby pharmaceutical firms extend the patent life of a drug by obtaining additional 20-year patents for minor reformulations or other iterations of the drug, without necessarily increasing the therapeutic efficacy.

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8 Ragavan, “World Trade Organization: A Barrier to Global Public Health?”


11 Taubman et al., A Handbook on the WTO TRIPS Agreement


17 Dhar and Gopakumar, “Towards more affordable medicine”

18 UNSG, “Report of the United Nation’s Secretary-General High-Level Panel On Access To Medicines”


21 Dhar and Gopakumar, “Towards more affordable medicine”


35 Dhar and Gopakumar, “Towards more affordable medicine”


38 Michael Safi, “Oxford/AstraZeneca Covid vaccine research ’was 97% publicly funded’,” The Guardian, April 15, 2021, https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded


40 Ragavan et al., “Frand v. Compulsory Licensing: The Lesser of the Two Evils”


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