



India-South Africa proposal for a waiver from certain obligations under the TRIPS Agreement

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Access to medicines at prices that the patients can afford has been a recurrent concern for the global community ever since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted as one of the covered agreements under the World Trade Organization (WTO). The TRIPS Agreement is a charter for strengthening intellectual property rights (IPRs) protection and enforcement. Over the past 25 years since the Agreement came into force, there have been instances galore where holders of intellectual property have exercised their rights to extract exorbitant rents from the users of proprietary products. Possibly the most glaring of such examples was the exceptionally high prices that several large pharmaceutical companies charged after the onset of HIV/AIDS, the last major pandemic to have worldwide ramifications. In South Africa, where the per capita gross domestic product (GDP) was \$3,550, a year's treatment using the HIV antiretroviral medicines marketed by these companies would cost the South African health service \$10,000 (*The Guardian* 1999).

Responding to the growing incidence of HIV/AIDS, the Government of South Africa amended its Medicines and Related Substances Control Act, 1965 to include several provisions aimed at ensuring that medicines were available at affordable prices. Besides controlling the prices of medicines, the amendments allowed the issuing of compulsory licences for producing medicines in South Africa. These amendments were challenged by 40 major pharmaceutical companies, which argued that they violated South Africa's constitution and the TRIPS Agreement (High Court of South Africa 1998). The pharmaceutical companies contended that the rights enjoyed by patentees in the patent regime introduced after the implementation of the TRIPS Agreement would be severely truncated if the provisions of the South African law on affordable medicines were used by the government (Dhar 2001).

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The response against such excessive rent seeking came from the developing countries, led by India, South Africa and Brazil, which proposed that additional flexibilities must be incorporated in the TRIPS Agreement enabling WTO member countries to address public health concerns. The proposal was backed by 60 developing countries, including 41 belonging to the African Group, and led to the adoption of the Declaration on the TRIPS Agreement and Public Health at the WTO's Doha Ministerial Conference in 2001 (WTO 2001).

The Doha Declaration was important on several counts. Firstly, it recognized the “gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”. Secondly, while it recognized that intellectual property protection is important for the development of new medicines, it also recognized the concerns about the effects of the TRIPS Agreement on the prices of medicines. And, finally, WTO members emphasized that the “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health ... and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (WTO 2001: paragraph 4).

In operational terms, the Declaration affirmed that WTO members could have recourse to three sets of tools to address the problem of high prices of medicines arising from the exercise of IPRs. These are: (i) the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; (ii) the right to determine what constitutes a national emergency or other circumstances of extreme urgency; and (iii) the freedom to establish their own regimes for exhaustion of intellectual property rights without challenge, subject to the most favoured nation and national treatment provisions. Further, for the WTO members with insufficient or no domestic manufacturing capacities in the pharmaceutical sector and which could thus face difficulties in making effective use of compulsory licensing to produce the necessary medicines, the Declaration, in paragraph 6, called for the creation of a window through which these countries could import cheap medicines from any country. This window was finally provided through a decision adopted in 2003 (WTO 2003) – subsequently incorporated as an amendment to the TRIPS Agreement (WTO 2015) – to allow “eligible” countries to import the necessary medicines and potential exporters to export them. However, the cumbersome procedural requirements make this mechanism non-attractive for users and to date, there is only one instance of its use.¹ Nevertheless, the adoption of the Doha Declaration as a whole provided clarity with regard to the flexibilities in the TRIPS Agreement and many developing countries used these flexibilities to facilitate access to medicines especially in the HIV/AIDS context.

I. Waiver Proposal of India and South Africa

The COVID-19 pandemic has now once again brought a similar response from India and South Africa as fresh concerns arise over IPR barriers to medicine access. The two countries have tabled a joint proposal, which is being discussed by the WTO's TRIPS Council, seeking a waiver from certain obligations under the TRIPS Agreement for the “prevention, containment and treatment of COVID-19” (WTO 2020a). Kenya and Eswatini have also since co-sponsored this proposal.

Invoking the provisions of Article IX of the Marrakesh Agreement Establishing the WTO, the proposal makes a request to the General Council of the WTO to waive the implementation, application and enforcement of four forms of IPRs covered by the TRIPS Agreement for some years for the prevention, containment and treatment of COVID-19. The scope of the proposed waiver covers copyright and related rights, industrial designs, patents and trade secrets. It should be noted here that a waiver from legal obligations under a WTO agreement is not new. From 1995 to 2015, of the waivers that were granted, three were from TRIPS obligations (WTO 2016).²

¹ The only time this mechanism was used was when Rwanda decided to import a triple-combination antiretroviral drug (zidovudine, lamivudine and nevirapine) from Apotex Inc. in Canada (WTO 2007). The supplier could provide the medicine only after two years, testifying to the limited utility of the mechanism (South Centre 2011). See also Rao (2006).

² For an updated list of waivers, see WTO (2019).

The India-South Africa proposal has been tabled amid the backdrop of what the WTO calls “an unprecedented disruption to the global economy and world trade” caused by the COVID-19 pandemic, as “production and consumption are scaled back across the globe”. The two countries have argued that it is “important for WTO Members to work together to ensure that intellectual property rights such as patents, industrial designs, copyright 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”. Given the large increase in demand for access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of the disease, it becomes imperative that supply-side shocks are eliminated. At the same time, critical shortages in these medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases.

The relevance of the waiver proposal stems from three concerns. The first is that exercise of intellectual property rights has impeded or is threatening to impede availability of medical products at affordable prices (Hillman 2020). Secondly, IP protection on various technologies can have a chilling effect on the innovation process involving COVID-19 medical products as potential innovators may be inhibited in their efforts to develop new products.³ The third concern is that although WTO members have carried out amendments to the TRIPS Agreement to enable access to medicines during public health emergencies, especially in countries which do not have domestic manufacturing capacities, the procedural complexities have not allowed smooth implementation of this mechanism, as stated earlier. In view of the tardy implementation of this mechanism, the United Nations Secretary-General’s High-Level Panel on Access to Medicines had recommended that “WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform” (United Nations Secretary-General’s High-Level Panel on Access to Medicines 2016: 27).

The India-South Africa waiver proposal, if adopted, would provide the policy space to take measures to ensure availability of COVID-19 medical products. Further, it would provide legal clarity and shield WTO member states against political pressures to refrain from taking such measures.

WTO members must not let the obligations under the TRIPS Agreement prevent them from taking measures to meet the urgent needs of humanity. In other words, it is imperative to go beyond the existing flexibilities for addressing public health concerns arising from the exercise of patent rights over medicines, and to cover, as the waiver proposal does, the medical products, including diagnostics, therapeutics, vaccines and medical equipment, required to prevent the spread of and to treat COVID-19. The proposal does not seek a waiver of WTO members’ obligations with regard to IPRs on all other medical products.

In order to effectively respond to the COVID-19 pandemic, a wide range of medical products have become absolutely essential. Many of these products, including their parts and components, are proprietary items; they are protected through various forms of IPRs, mainly, copyrights, trade secrets, industrial designs and patents. The existing flexibilities incorporated in domestic legislations are predominantly to address concerns on access to medicines in the context of patent protection and are not equipped to address the implications of other forms of IPRs on availability and accessibility. Each of these forms of IPRs poses challenges to the mass production of these products. For instance, copyrights on the software source codes of diagnostic platforms can adversely affect their large-scale production, thus increasing the cost of diagnostics for patients. A similar limitation can arise if industrial designs are used to protect medical products or their components.

³ An interesting initiative was undertaken in April 2020 by a group of scientists and intellectual property lawyers who encouraged companies to make their “intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease”. The group argued, “It is a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment.” See Open COVID Pledge (2020).

In this paper, we will elaborate on the importance of seeking waivers from the obligations to implement two forms of IPRs, namely trade secrets and patents.

II. Importance of Waivers from Obligations to Implement Trade Secrets

One important form of trade secret related to pharmaceuticals is covered under Article 39.3 of the TRIPS Agreement. These laws came into prominence after multinational pharmaceutical companies insisted on using them to prevent drug regulatory authorities (DRAs) from relying on their clinical trials' data to grant marketing approval to generic products. The United States and the European Union have been seeking between five and 10 years of protection for such data (Dhar and Gopakumar 2006). The TRIPS Agreement does not provide for a specific duration of protection; it only mandates that regulatory agencies must protect clinical trial data against "unfair commercial use". DRAs are allowed to disclose the data only after taking measures against unfair commercial use. A waiver from the application of trade secrets would allow regulatory agencies to use some of this data in the public interest and to facilitate prompt entry of a COVID-19 medical product manufactured by multiple producers in the market.

The justification provided by the major pharmaceutical companies for data protection, which governments in the industrialized world seem to have accepted in its entirety, as elaborated below, is the high cost of clinical trials. According to a Tufts University study conducted in 2003, which was supported by the pharmaceutical industry, clinical trials accounted for more than 58% of costs incurred for developing a new drug (Dhar and Gopakumar 2006: 5077). The study estimated that the average number of patients enrolled for clinical trials while marketing approvals for new drugs were sought was in excess of 5,300. This number was significant, for the enrolment figure formed the basis of the study's estimates of the clinical trials' costs. In turn, based on the costs of the clinical trials, the study estimated the average cost of drug development at \$802 million. Updating their study in 2016, the same group of researchers more than tripled their estimate of drug development costs to \$2.6 billion. As in the 2003 study, the \$2.6 billion figure was based largely on data on clinical trial costs (Love 2019).

The real picture of clinical trials has, however, become known after the Food and Drug Administration (FDA), the drug regulatory agency of the United States, began providing data on these trials from 2015. The FDA has reported that in 2019, the four main therapeutic areas in which drug approvals were granted were haematology, oncology, neurology, and psychiatry and sleep disorders (FDA 2020: 9). A total of 18,853 patients were enrolled for approval of 28 drugs. This implies that the average number of patients enrolled for each drug trial was just over 673.

Notwithstanding the growing evidence that they are inflating the costs of developing new drugs by making exaggerated claims regarding clinical trial costs, pharmaceutical companies have found support from the governments of several industrialized countries. Clinical trial and other test data are provided statutory protection for five years in the United States and eight years in Canada, during which the covered product would enjoy market exclusivity. In both jurisdictions, the criterion for granting exclusivity is that the product must be a new chemical entity that has never been approved by the regulators; a variation of a previously approved entity such as a salt, ester, enantiomer, solvate or polymorph does not qualify for protection (Armouti and Nsour 2016: 291). In the European Union, data protection and market exclusivity is provided for high-tech products, including biotechnology products and those that "represent a significant innovation or therapeutic advance" (Armouti and Nsour 2016: 291).

The current process of producing COVID-19 vaccines has brought forth several instances where companies have not allowed critical information about the safety and efficacy of their vaccine candidates to be put in the public domain. A recent editorial in the journal *Nature* revealed that "a worryingly high number of people around the world" have said that they would not get inoculated. This would keep them susceptible to COVID-19 and would delay the end of the pandemic. According to the editorial, "concerns about approvals being rushed, suspicion of the pharmaceutical industry and a pandemic of vaccine misinformation are combining to erode the public's trust in the process by which vaccines are approved for use" (*Nature* 2020).

These concerns among the public at large can be put to rest, provided national authorities do not allow safety and efficacy data for COVID-related medical products to be treated as trade secrets.⁴

III. Patents and Access to COVID-Related Medical Products

Due to patent monopolies, several countries are facing limitations in accessing technologies for producing medicines for COVID-19, even for a medicine like remdesivir which merely ameliorates the suffering of the patients and is not a cure for the viral infection. The originator company, Gilead Sciences, has issued voluntary licences to some companies in developing countries, including a few Indian companies, to produce remdesivir. However, the developed countries continue to face high prices and supply shortages of the drug in the absence of generic production. Furthermore, the voluntary licences have two limitations: firstly, the prices at which the product is currently available in India are relatively high, and secondly, the medicine cannot be exported to other countries.

Globally, two contrasting sets of initiatives have been undertaken to address the issue of the exclusive monopolies conferred by patent rights. The first is the COVID-19 Technology Access Pool (C-TAP), an initiative by the World Health Organization (WHO) in response to a request by the President of Costa Rica, Carlos Alvarado Quesada, to the WHO Director-General to “undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic” (WHO 2020). Importantly, this is a voluntary mechanism wherein the holders of the rights to knowledge, data and technologies are expected to agree to the pooling of these resources. In contrast, the second set of initiatives involves strengthening the provisions on compulsory licensing that have been written into the laws of several countries, including those from the industrialized world.

What Does the COVID-19 Technology Access Pool Seek to Achieve?

C-TAP is aimed at providing the wherewithal to develop products needed to fight COVID-19, to scale up manufacturing of COVID-related medical products and to remove all barriers so as to facilitate global availability of these products. This initiative is intended to provide the framework for sharing information, knowledge, data and other resources that could expedite the development of such products and to avoid duplication of efforts in this regard. Underlying C-TAP is the “objective of promoting open science in order to accelerate product development and to facilitate access to the resulting health technologies by pooling IP, data, regulatory dossiers, and manufacturing processes and other kinds of ‘know-how’” (WHO 2020: 4). As envisaged, the benefit from this initiative would lie in the sharing of proprietary knowledge and information of all kinds which would promote innovation and manufacturing of the targeted products globally. Non-exclusive and public-health-driven licensing together with arrangements for technology transfer are seen as the added benefits. For example, free licences and pledges offered by the Open COVID Pledge and other initiatives and the waiving of patent rights by some companies on products that may prove effective against COVID-19 could be among the favourable outcomes of C-TAP.

The most significant challenge that C-TAP would face, however, which has been acknowledged by the proponents of the initiative, is to develop an operating model that is attractive enough for the holders of proprietary knowledge, data and technology to forgo their commercial interests. Hence, voluntary pooling mechanisms have little chance of attracting the technology holders.

Strengthening Provisions Relating to Compulsory Licences

Several countries have adopted measures for facilitating the grant of compulsory licences. This instrument allows the grant of a licence for producing a proprietary product in the country of grant in case the patent holder refuses to allow its production in that country.

⁴ Although four companies, Moderna, Pfizer, Janssen and AstraZeneca, have made their vaccine trial protocols public (the last named has released the protocols only for the trials in the United States), several questions are still being raised about the veracity of the data. For details, see Doshi (2020).

Canada's Patent Act was amended (Bill C-13) to empower the Commissioner of Patents, on the application of the Minister of Health, to authorize the Government of Canada or another person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern (WIPO 2020). These amendments also ensured that a patent holder receives adequate remuneration for the use of the patent, placed limitations on the duration of the authorization, and ensured that the patent owner has recourse to the courts if any person authorized acts outside the scope of the authorization (WTO 2020c: 9).

France enacted Emergency Law No. 2020-290 of 23 March 2020 to meet the challenges posed by the COVID-19 epidemic and introduced a new article into the country's public health code. Article L3131-15 of the Public Health Code gives extraordinary powers to the French Prime Minister, enabling him to impose compulsory licences where necessary, bypassing the general provisions in the Intellectual Property Code. These provisions may also affect other IP rights, such as designs, for instance to ensure the availability of personal protective equipment (WIPO 2020).

Germany enacted the legislation "Protection of the Population in the Event of an Epidemic Situation of National Significance" in March 2020 which stipulates that a patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. A patent shall also not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority (WIPO 2020).

A commission of the Ecuadorian National Assembly passed a 20 March resolution asking the country's health minister to issue compulsory licences on products whose availability is important to the public health response to COVID-19. The Education, Culture, Science and Technology Commission also asked the minister to make use of Article 501 of the Código Ingenios, which authorizes third parties to access and use a patentee's data, including clinical test data (Houldsworth 2020).

Israel's Minister of Health issued a permit allowing the government to import generic versions of lopinavir/ritonavir from India for exploring the possibility of treating COVID-19 patients (WTO 2020c: 9).

These legislative initiatives show the implicit acknowledgement of the potential barriers patents pose to the availability of COVID-19 medical products at affordable prices.

IV. Waiver Proposal: The Next Steps

The major task for India and South Africa is to ensure strong backing for their waiver proposal from within the WTO and outside. The most important first step towards this end is to garner the support of like-minded countries, as was done in the case of the proposal that led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health. It seems some ground has already been made in this regard; in a TRIPS Council meeting held on 16 October, 13 member states, including India's South Asian neighbours Bangladesh, Nepal, Pakistan and Sri Lanka, fully supported the proposal, while 14 others, including China and Nigeria, gave qualified support. WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) were also fully supportive of the proposal.

In a member-driven multilateral system, effective coalitions are vital for norm setting. Developing countries understand this very well since they have benefited by adopting this strategy. It is also a fact that such coalitions have relied on effective leadership, which India and South Africa have provided in the past. At this critical juncture for humanity, the two countries must ensure that their important joint initiative realizes the desired objectives.

COVID-19 has triggered huge demand for medical products, which is unlikely to decline soon, if the current predictions about the pandemic are any indicator. But in many countries, supplies have often not been able to keep pace with the growing demand. There is, therefore, a case to be made for treating these medical products as global public goods and for creating an enabling environment for their production by both

private and state-owned enterprises. However, in most developing countries, public funding and access to appropriate technologies have both been seriously inadequate for facilitating production and ensuring availability of these medical products to meet the burgeoning demand. Moreover, IPRs have yet again emerged as an impediment to access to technology and know-how. Adoption of the waiver proposal could provide the legal clarity to address these barriers in an effective way.

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