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A BLOW TO EQUITABLE ACCESS TO ESSENTIAL MEDICINES

Relevant for: International Relations | Topic: World Trade, WTO and issues involved

At the height of the COVID-19 pandemic in October 2020 and in the midst of concerns over the availability of affordable vaccines, medicines and other medical products, India and South Africa had tabled a proposal in the World Trade Organization (WTO) seeking a temporary waiver on these products from certain obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Their contention was that the application and enforcement of intellectual property rights (IPRs) were “hindering or potentially hindering timely provisioning of affordable medical products to the patients”. They, therefore, argued that “rapid scaling up of manufacturing globally” was “an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need”, and for doing so, IPRs must be waived for at least three years. By submitting their proposal, India and South Africa had, thus, taken a firm position that when lives are at stake, these products should be treated as global public goods.

Nearly 18 months later, 164 members of the WTO could not find common ground on the “waiver proposal” even as 63 developing countries have become co-sponsors of the proposal and another 44 countries lent support from the floor. Initially, all advanced countries opposed the proposal, but after the Biden Administration took office, the United States (U.S.) backed the waiver, but only for vaccines. The stance of the advanced countries is hardly surprising as they have always put the interests of pharmaceutical companies ahead of the lives of the ordinary citizens in many countries who are yet to be fully vaccinated. As of today, only 14% of people in low-income countries have received at least one vaccine dose. What is worse, the recent surge of infections in China is a strong warning to the global community that the threat from COVID-19 still remains.

In this complex situation, when one of the consistent opponents of the “waiver proposal”, namely, the European Union (EU), announces that the differences over the proposal had been resolved, there is considerable interest in the details. This interest becomes even greater when it is revealed that India and South Africa, the movers of the “waiver proposal”, are among the four countries that found a “compromise outcome”. The U.S. is the fourth WTO member of the “Quad” proposing the way forward.

The EU, which has unveiled the “solution”, states that this is a “compromise outcome” that will now be “put … forward for [WTO] members’ consideration”. Interestingly, the “compromise outcome” adopts the approach that the EU has been proposing all along — namely, granting compulsory licences to enhance vaccine production.

While opposing the concept of “waiver” of application and enforcement of IPRs, the EU had proposed in a submission in June 2021 that “[c]ompulsory licences are a perfectly legitimate tool that governments may wish to use in the context of a pandemic”. It is, therefore, surprising to find that three of the four “Quad” members, who have been supporting the waiver proposal (the U.S. had extended limited support), have diluted their stand and have accepted the EU’s proposal as the “compromise outcome”.

Generally, patent laws, including that of India’s, allow for the grant of compulsory licences if patent holders charge high prices on the proprietary medicines in exercise of their monopoly

rights. Moreover, such licences can usually be granted if efforts in obtaining voluntary licences from the patent holders have failed. The “Quad” proposal states there that in case of a medical urgency, as is the case now, this condition will be waived. In other words, there is no requirement to make efforts to obtain voluntary licences with the patent holders before granting compulsory licences on the patented products. The “Quad” solution also provides that WTO members would be able to issue compulsory licences even if they do not currently have the provisions to issue them under their national patent laws. Compulsory licences can even be granted using executive orders, emergency decrees, and judicial or administrative orders.

The compulsory licensing system that the “Quad” has proposed contains considerable details, the implications of which need to be understood. The “Quad” solution can be used only by an “eligible member”, defined as a “developing country member” of the WTO that “had exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021”. The eligibility criteria, therefore, implies that the least developed countries are excluded. This means that Bangladesh, which is still a least developed country, but has a growing pharmaceutical industry, is also excluded.

The eligibility condition seems to have been introduced to limit China’s expansion in the global vaccine market. According to the WTO, this was 33.7%, as on January 31, 2022, but the reality is that China is not one of the countries that would benefit from the “Quad” solution. China has developed several home-grown vaccines and hence does not need compulsory licences to expand its production base. At the current juncture, India does not have to be concerned with the export restriction clause, as its share in global exports of vaccines was 2.4% as on January 31.

While introducing the above-mentioned export restriction, the “Quad” solution proposes to waive the obligation under Article 31(f) of the TRIPS Agreement. Article 31(f) provides that the compulsory licences issued by any WTO member must be used “predominantly for the supply of the domestic market”. The “Quad” solution states that the export restriction in 31(f) was removed as there was a “long standing request from the waiver proponents that want to be free to export any proportion of the COVID-19 vaccine”. But while they have proposed removal of Article 31(f), the “Quad” solution includes a more stringent export restriction in the form of the eligibility criteria mentioned above.

The “Quad” solution is a severely truncated version of the “waiver proposal” in terms of product coverage, as only vaccines are included. The proponents of the “waiver proposal” sought to include not only medicines, vaccines, and medical equipment but also the methods and the means of manufacturing the products necessary for the prevention, treatment, or containment of COVID-19.

Further, the “Quad” has introduced additional conditions to using the compulsory licences, some of which are well beyond the developing country obligations under the TRIPS Agreement. For instance, the proposed condition of listing all patents covered under the compulsory licences is not a requirement under the TRIPS Agreement. Similarly, there is no obligation to notify the details of licensee, the quantity and export destination under the TRIPS provisions, but the Quad text proposes mandatory notification.

However, compulsory licences may not result in the outcome that the waiver proponents were aiming for. According to the EU, when compulsory licences are granted, the “patent holder receives adequate remuneration”, but “[t]ransfer of know-how is not ensured”. This plain admission by the EU about the demerits of compulsory licences would make it difficult to scale up production of COVID-19 vaccines, medicines, and medical devices in the developing world, thus constraining their availability at affordable prices.

Finally, it must be said that by accepting the “compromise outcome”, India and South Africa could jeopardise their high moral ground which they had gained through their attempt to make medicines and medical products necessary for COVID-19 treatment or containment as global public goods. Consequently, the global community would lose an important opportunity to ensure that vaccines and medicines are accessible to all.

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