FLEXIBILITIES WITHIN THE WORLD TRADING SYSTEM FOR EQUITABLE PRODUCTION AND DISTRIBUTION OF THE COVID19 VACCINE

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INTRODUCTION

The year 2020 will be remembered in the annals of history as the year when the world succumbed to an invisible virus that has claimed millions of people worldwide. The virus spread rapidly through Europe, Asia, and the Americas and later to Africa. Our fears that once it spreads in Africa, given the weak health systems, the virus would wreak havoc there. So far, this fear has not yet materialized, but we cannot count the virus out doing the same there as it has done in India.

The current debate on the equitable distribution of COVID19 vaccines to arrest the spread of the virus and save lives worldwide, has centered on securing for COVID 19 Vaccines, a waiver to the WTO TRIPs Intellectual Property protection regime that severely restrains the manufacture and marketing of patented products. This article outlines the flexibilities built into the WTO trade rules that WTO Member Governments can employ secure the importation of COVID19 vaccines from WTO exporting Members with the necessary manufacturing capacity.

THE GLOBAL TRADING SYSTEM

The World Trade Organization (WTO), as stated on its website, is "the only global international organization dealing with the rules of trade between nations. At core of this global trading system are the WTO Agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The Agreement on Trade-Related Aspects of Intellectual property Rights (TRIPs), which entered into force in 1995, is one such Agreement. At its core, the TRIPs Agreement was intended to strike a balance between the necessity to protect the intellectual property rights (IPRs)of patent holders and the need to address the public good by assuring access to the fruits of technological knowledge in the interest, especially, of public health. Thus, the TRIPs Agreement itself has built in flexibility

in the protection of IPRs to protect public health and promote the public interest. [1]Over the years, however, it has become necessary to issue clarifications on the extent of such flexibilities to address specific needs such as was necessary to make AIDS drugs affordable to populations in developing and least developed countries in the early 2000s.

FLEXIBILITIES UNDER THE TRIPs AGREEMENT

Article 31 of the TRIPs Agreement provides for Governments to issue compulsory licenses to a person or company to work a patented product without the consent of the owner under certain conditions, especially in emergencies. However, the conditions for issuance of such compulsory licensing, including the requirement of establishing existence of an emergency, the need for the patent holder's first refusal to issue the licence on commercial terms and the limitation of the sale of products worked under such compulsory licence for domestic use proved too onerous to meet the surgent needs to secure anti-viral AIDS drugs are prices poor countries could afford.

In November 2001, the Doha Ministerial Conference at the urging of many countries, issued the Doha Ministerial Declaration that interpreted the TRIPs Agreement as supporting Public Health, allowing Governments determine what measures satisfied the conditions laid in Article 31. The Doha Declaration and the Doha-inspired public health decisions of the TRIPS Council in 2003 and 2005 included components that have directly increased access to medicines in low- and middle-income countries and the use of these flexibilities for introducing generic competition has achieved a reduction in the prices of originator medicines.

In 2017 the Trips Agreement was formally amended by introducing Article 31 *bis*, that eliminates the domestic use limitation on a Member granting a compulsory licence under Article 31 in respect to pharmaceutical product(s) for export to an eligible Member, essentially, developing or least-developed countries, without its own manufacturing capabilities. This was done, in part to

[1] Article 31 of TRIPs Agreement

harness economies of scale for the “purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products. “

THE CASES OF RWANDA AND BOLIVIA

RWANDA

In September 2008 and 2009 Rwanda imported considerable quantities of the ARV AIDS drugs from Canada, as exporter, at considerably low prices than they were being sold on the market, upon notification of WTO, using the compulsory licensing exception under the Doha Ministerial declarations.

BOLIVIA

On May 12, 2021, Bolivia notified the WTO that it needed to import 15 million doses of a COVID 19 vaccine under the legal system introduced in the 2017 amendment to the TRIPs Agreement. It is believed that 50 WTO Members, including Cuba, Australia, India and Canada, have already put in place domestic laws providing for the production and export of medicines manufactured under the compulsory licencing system.

CONCLUSION

It is clear from the discussion above that the Global Trading system already contains mechanism to address the need for equitable distribution of drugs, including vaccines, especially in cases of a pandemic such as COVID19. Rather than a waiver we should concentrate on the mechanics of encouraging patent holders to voluntarily grant licences and build capacities worldwide to manufacture the vaccines in sufficient quantities to rid the world of this deadly disease. The patent holders already secured funding during the research and development. WTO Member Countries should now concentrate on establishing a Fund that will compensate patent holders that volunteer for this scheme. If the patent holders hold out for profits sake, then the 50 or more WTO Members that have the capacity to produce the vaccines should proceed with implementation of the compulsory licensing regime under WTO’s guidance to ensure equity for all.