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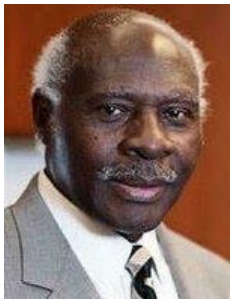
HIV Drug IP Waiver Success Should Guide COVID Vax Rollout

By **Francis Ssekandi** (May 21, 2021, 5:29 PM EDT)



Francis Ssekandi

South Africa and India have recently requested a waiver of the intellectual property rights restrictions imposed by the World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, in order to supply the COVID-19 vaccine to developing countries.

William Bergmann, in his recent Law360 guest article, argues that the biggest huddle to getting adequate vaccines to satisfy the needs of developing countries is not the patent protections provided by the TRIPS agreement but the lack of capacity to manufacture such vaccines by those countries, which he refers to as "limited infrastructure and supply chain bottlenecks." He further disputes the usefulness and, indeed, the legality of President Joe Biden's decision to support the requested waiver by South Africa and India.

The Biden administration's willingness to support the request by India and South Africa for the waiver at the WTO is very significant, because many of the companies involved, such Pfizer Inc., Johnson & Johnson and Moderna Inc., are based in the U.S.

A decision by any WTO members to acquire compulsorily those companies' vaccine patents, as, indeed, permitted under Article 31bis of the TRIPS agreement, would meet with strong opposition from the U.S. accompanied by sanctions that would deter any country from doing so.

While the amendment to the TRIPS agreement that entered into force in 2017 opened the avenues for compulsory licensing of patented drugs or vaccines for public health, not all countries have signed on to it. So far, only 50 WTO members have introduced domestic legislation that permits such compulsory licensing.

As Bergmann points out, doing so in the U.S. is likely to meet challenges by pharmaceutical companies on constitutional grounds. While his discussion of this constitutional issue is interesting, it is not actually material with respect to the requested waiver at the WTO, which relates to an international agreement to which the U.S. is a party.

As Bergmann also concedes, the TRIPS agreement currently contains a sufficient mechanism to permit countries to access patents, compulsorily grant licenses to manufacture COVID-19 vaccines for public health purposes, and supply vaccines to other countries without the capacity to do so.

Prior to the 2017 amendment to the TRIPS agreement that expanded this flexibility in applying the TRIPS agreement in the area of public health, Canada supplied HIV/AIDS antiviral drugs to Rwanda under the Doha Declaration of 2001, by which the WTO Council issued an interpretation of the TRIPS agreement in favor of flexible application to address public health emergencies such as AIDS at the time.

Presently, with the expanded scope of the 2017 amendment, using the broader TRIPS agreement amendment Article 31bis, Bolivia has notified WTO of its intention to acquire several doses of COVID-19 vaccines form WTO members with the capacity to implement the compulsory licensing provisions.

This attempt by Bolivia can only work if it can find a WTO member who is willing to use its domestic legislation to issue the compulsory license for the COVID-19 vaccine and has the capacity to manufacture it in the quantities requested by Bolivia as Canada did for Rwanda with respect to AIDS antiviral drugs.

If there is a consensus at the WTO to grant the waiver, there are a number of countries with the manufacturing capability to produce vaccines and supply them at considerably reduced prices to developing countries.

Indeed, before the current spike in infections in India, an Indian company was already doing so, presumably under a license to supply vaccines under the World Health Organization's COVAX initiative. With the waiver, this manufacturing facility could be expanded by India and even establish additional manufacturing facilities in Africa, where it is badly needed. Again, India did this for AIDS when it established a manufacturing factory in Uganda with the participation of local companies.

It is clear that the requested waiver is necessary given the complexities of the process for manufacturing the COVID-19 vaccine to avoid prolonged litigation between patent holders and governments using the compulsory licensing authority under TRIPS. The process disclosed by the holder upon registration may not be adequate to cover all the aspects for the production of the vaccine, and any use of any part of the process not covered by the patent could expose the manufacturer to lawsuit.

India, South Africa and even Brazil, which have extensive experience in producing vaccines must have considered it prudent to avoid such litigation by seeking a wider waiver. Before the WTO action in 2001, with respect to the AIDS pandemic, Brazil and South Africa faced serious objections from manufacturers, supported by their governments, for violating patents to manufacture drugs for public health emergencies.

Bergmann also defends the manufacturer's right to hold onto its patents for maximum profit, arguing that widespread waivers will discourage innovation and also lead to great losses of private capital invested in the research and invention of the processes leading to the production of the vaccine. This argument is not supported by the evidence.

The waiver granted for production of the HIV/AIDS drugs did not discourage the patent holders from continuing with coming up with better drugs to fight AIDS; in fact, the waivers resulted in saving lives worldwide. It is important to point out that some of these companies still remained able to sell their vaccines in Western countries at market prices.

This will remain the same, as COVID-19 vaccines manufactured under the compulsory licensing scheme will be limited to exporting to developing countries. I believe that the competition in the marketplace

that will result from more companies manufacturing the vaccine will not only lower costs but increase profitability for patent holders selling their products at market prices in the developed world.

Saving lives should be a priority for everyone right now, because, as we have already seen, the ease of travel has meant that no one is safe anywhere in the world unless everyone is safe from this virus.

In fact, patent holders should join hands with WTO members to expand the manufacturing capability under their own tutelage so that everyone, including especially Africans, can be vaccinated not in 2022 but now. If this is done voluntarily, there would perhaps be no need to seek expansion of the TRIPS agreement by waiver; rather, companies and members could work with TRIPS' flexibility in a coordinated manner to ensure equity for all.

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