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The struggle for the TRIPS waiver

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On 1 October 2020, four countries – Eswatini, India, Kenya and South Africa – approached the World Trade Organization's TRIPS Council to seek a waiver from certain obligations on the protection and enforcement of patents, trade secrets, copyrights, and industrial design. The waiver would enable WTO member states to provide policy space around "intellectual property for the prevention, containment, and treatment of COVID-19". Since then, the proposal has attracted widespread support from WTO member states with the co-sponsorship of 63 member states, academia, CSOs and political leadership. On 5 May 2021, the USA announced its support for the waiver of intellectual property (IP) rights for COVID-19 vaccines. The idea is to address the huge global shortage of various medical products required for the COVID-19 response – vaccines in particular – by scaling up production, using multiple manufacturers (including 'local production', which is located and owned in developing countries). Yet so far, WTO member states where big pharmaceutical industries are based – like the EU, Switzerland and the UK – are blocking the negotiations to arrive at a consensus on the waiver decision text.

A global shortage

In the pre-COVID-19 world, trade in medical products was concentrated in a few countries. For instance, 49 percent of medical product exports emanate from five countries – Belgium, Germany, the Netherlands, Switzerland, and the USA.[1] Further, China, Germany and the USA control 40 percent of the global supply of personal protective equipment (PPE), while in 2019 these three countries supplied 50 percent of global mask requirements. China, the Netherlands, Singapore and the USA account for more than half of the exports of ventilators and respirators.[2] Similarly, four multinational corporations – GlaxoSmithKline, Pfizer, Merck, Sanofi – control 90 percent of global vaccines value and 60 percent of the volume.[3]

The surge in demand for medical products during the pandemic has benefited wealthy countries. An UNCTAD report shows that "There is substantial evidence that middle- and low-income countries have been largely priced out from access to COVID-19 related products. Despite efforts to facilitate access to COVID-19 supplies, trade statistics show that only a tiny fraction of the additional world production of COVID-19 related supplies have reached low-income countries".[4] By the end of 2020, developed countries where 13 percent of the global population live had bought up 52 percent of the available vaccine doses for 2021.[5] An even higher percentage of the two vaccines with the highest claimed efficacy rate – Pfizer (80%) and Moderna (78%) – have been booked by developed countries.[6] This inequality in accessing COVID-19 health products is visible in the vaccine coverage. Ten countries account for 76 percent of the 4.31 billion COVID-19

1 WTO, Trade-in Medical Goods in the Context of Tackling Covid 19, https://www.wto.org/english/news_e/news20_e/rese_03apr20_e.pdf
2 Ibid.
3 WHO, Global Vaccine Market Report 2020, p.4, https://www.who.int/immunization/programmes_systems/procurement/mi4a/platform/module2/2020_Global_Vaccine_Market_Report.pdf?ua=1
4 UNCTAD, Global Trade Update, October 2020, p. 6, https://unctad.org/system/files/official-document/ditcinf2020d4_en.pdf
5 Oxfam, https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19
6 Ibid.

vaccines doses administered till 23 July 2021.

Addressing this inequality can be achieved only through scaling up production via multiple producers around the world. There are many barriers to local products, such as access to relevant technologies, capital, human resources, et cetera, but the most significant is the global intellectual property (IP) regime, which legally prevents the production of patented technologies without the permission of the IP holder. Since these technologies are not available in the market at any price, the only option is to emulate these technologies without the permission of the IP holder – so-called 'reverse engineering'. Yet as we have seen in past health crises, notably HIV/AIDS, the IP holder can legally block these efforts to prevent the local scaling up of production.

Intellectual property rights

The rights of the IP holder work in effect as a monopoly by preventing all competitors from using or producing the IP protected technologies or products. All too often, this monopoly is misused by the IP holders, who charge exorbitant prices which prevent people and governments from accessing those products. This IP regime is enforced globally by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which came into force in 1995. It obligates all World Trade Organization member states except least developed countries to provide a minimum level of protection and enforcement of IP rights.

We have seen in the case of the AIDS crisis the effect of this on access to medicines. Though anti-retroviral (ARV) treatments for HIV/AIDS were available in developed countries in the early 1990s, the vast majority of people living with HIV/AIDS in developing countries could not access these lifesaving medicines. Pharmaceutical companies powered with patents charged US$ 10,000-US$ 12,000 per person per year for ARVs.[7] It was not until the introduction of generic ARVs in 2001 by Indian generic pharmaceutical companies, reducing the price to US$ 350, that universal access to ARV treatment started to become a reality.

It's not just in the global South that this is a problem – patent monopolies also deny access to medicines in developed countries. In many European countries, Sofosbuvir, a medicine to treat hepatitis C, is rationed due to the high price, while it is available to hepatitis C patients in many developing countries due to the availability of affordable generics.[8] In the UK, the regulator NICE has refused to approve Sorafenib, a drug that can extend the life of a liver cancer patient by six months, citing the inadequate benefit compared to the high price (US$ 5,000 per month).[9] Yet the same medicine is available in India at US$ 450-US$ 650 for six months from generic manufacturers.

Anticipating the threat of patents on access, a few WTO member states such as Canada, Chile, Colombia, Ecuador, France, Germany and Hungary have initiated steps to amend patent laws to make the issuance of compulsory licences (CL) easier. Israel and Russia have issued compulsory licences on two medicines used experimentally to treat COVID-19, lopinavir/ritonavir and remdesivir. However, the use of CLs is product and country-specific. As a result, free global availability of medical products and easy movement around the world is possible only after the issuance of CLs in a critical mass of countries. Yet past political pressure exerted by developed countries has produced a 'chilling effect' on the use of CL among developing countries, making it very rare. What's more, there is no concept of CL in the context of trade secrets, which are important for emulating vaccine

7 MSF, Patents, prices and patients: the example of HIV/AIDS, 2002, https://www.msf.org/patents-prices-patients-example-hivaids

8 Isaura Santos, Hepatitis C Patients Protest Limited Access to Sofosbuvir, Hepatitis News Today, 14 January 2015, https://hepatitisnewstoday.com/2015/01/14/hepatitis-c-patients-protest-limited-access-to-sofosbuvir/

9 Selina McKee, NICE rejects Bayer's Nexavar for liver cancer, Pharma Times, 19 August 2016, http://www.pharmatimes.com/news/nice_rejects_bayers_nexavar_for_liver_cancer_1103639

technology.[10]

A waiver of these obligations would enable countries to facilitate access to IP-protected medical products at an affordable price. Instead of engaging in the discussion, however, opponents of the waiver, especially the EU, are indulging in a diversionary tactic of placing a new proposal on the table or denying the role of IP in the scaling up of the COVID-19 health products. Maintenance of the IP status quo in the context of COVID-19 vaccines is facilitating the monopoly and rent-seeking from public-funded research and development. The current global shortage of COVID-19 medical products underlines the urgent need to revamp the global IP regime to allow governments to address the health needs of their people.

10 K M Gopakumar, Chetali Rao and Sangeeta Shashikant , Trade Secret Protection and Vaccines: The Role of Regulatory Agencies, TWN Briefing Paper, https://twn.my/title2/briefing_papers/twn/Trade%20secrets%20TWNBP%20Jun%202020%20Gopakumar%20et%20al.pdf