The TRIPS Waiver

The snappily named Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS for short as the full name hardly trips off the tongue) is a World Trade Organization (WTO) agreement badged as "the most comprehensive multilateral agreement on intellectual property to date". It was signed in 1994 and is a "minimum standards" agreement which sets a baseline for IP protection; Members are able to provide more comprehensive protection if they wish and under certain circumstances flexibilities to the minimum standards are permitted.

This agreement made headlines across the world in 2021 following proposals first tabled by India and South Africa at the WTO that a waiver should be agreed enabling Members to have more flexibility than currently allowed under TRIPS in respect of vaccines, therapeutics and diagnostics for the treatment or prevention of COVID-19. I finished my 2021 article on this matter with the following words: *"It remains to be seen whether next year's* IP Federation Review *article is talking about the impact of the introduction of a waiver or not – watch this space!"*

So, what has happened in the intervening year? Following a frantic scurry of activity at the WTO 12th Ministerial Conference (MC) in June 2022, a waiver was adopted to much fanfare and publicity in respect of vaccines only.

The waiver as agreed essentially makes it easier for entities in developing country Members of the WTO to use the compulsory license provisions of TRIPS, i.e. to produce patented vaccines without the need to seek a voluntary license from the patent holder. Opponents of the waiver had argued that there was sufficient supply to meet the WHO targets, and that the true barrier to vaccine access was equitable distribution, vaccine hesitancy and trade barriers. This Bloomberg tracker – More Than 12.7 Billion Shots Given: Covid-19 Vaccine Tracker – shows that vaccine distribution is still uneven, with many of the world's least wealthy nations remaining unprotected at a meaningful level.

The waiver however appears to have made little difference to this since it was passed in June. As far as this author is aware, no companies have yet sought to use the increased flexibilities of the waiver. Could this be because they are not needed? One way forward to increase capability and capacity for vaccines manufacture in developing countries is through voluntary licensing. Hundreds of voluntary licences and agreements have been put in place since the start of the pandemic, and the focus is now moving to increasing vaccine manufacturing capability in Africa in ways that can work for the continent. Consider the innovative "turnkey" manufacturing modules in containers that BioNTech has developed – BioNTech introduces first modular mRNA manufacturing facility to promote scalable vaccine production in Africa.

Another argument made by opponents of the waiver was that the true barriers to access were not related to IP. That still appears to be the case. For the first time since the pandemic began, the global supply of vaccines is not currently a constraint. The key will be to remove barriers to deployment

such as access to refrigeration, provision of syringes with vaccines, training of local healthcare workers and support to overcome vaccine hesitancy.

So, now that the waiver has passed and the world is moving towards full vaccination is the story over? I think not. The Ministerial Decision included the following statement: *"No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics."* The discussion around therapeutics is even more challenging that that around vaccines. A vaccine by its nature is limited to a single indication – it protects against one pathogen. A therapeutic medicine on the other hand can often have many indications as indicated by the fact that half of the approved therapeutics for the treatment of COVID-19 were already approved for the treatment of other conditions. Similar arguments in respect of the true barriers to access also apply. Many pharmaceutical companies are signing voluntary patent licences that enable access in low and middle income countries such as Shionogi and the Medicines Patent Pool (MPP) sign licence agreement for COVID-19 oral antiviral treatment candidate to increase access in low- and middle-income countries.

At the time of writing, WTO Members are holding fortnightly negotiation discussions, but no draft text has yet been circulated. Given this, it seems unlikely that any consensus can be reached before the deadline of 17 December 2022, although many would have said the same ahead of MC12 in June. Once again, I need to finish an article with the words: *"It remains to be seen whether next year's* IP Federation Review *article is talking about the impact of the introduction of a waiver or not – watch this space!"*

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