European Parliament

World Trade Organization TRIPS waiver to tackle coronavirus

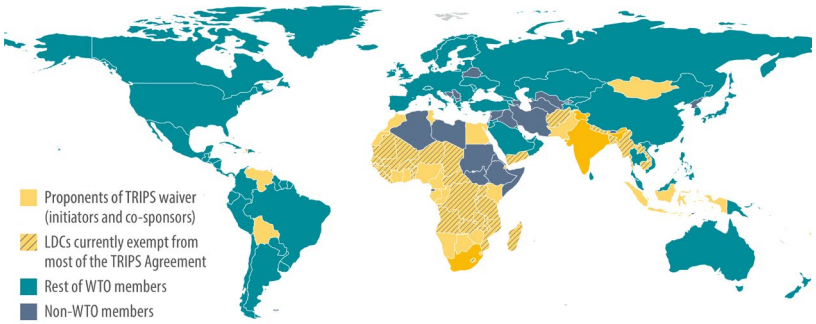
The coronavirus pandemic has rekindled the global debate on whether the multilateral trade regime for intellectual property rights (IPR) protection limits access to essential medical products. Despite embedded flexibilities in the World Trade Organization (WTO) Agreement on Trade-related Intellectual Property Rights (TRIPS), India and South Africa, co-sponsored by a large number of developing countries, submitted an initial proposal for a temporary waiver in response to Covid-19 in October 2020, followed by a revised proposal in May 2021, which continues to divide opinion. The US administration voiced its support for a vaccines waiver. EU leaders indicated an openness to discussion, while putting forward an alternative plan with a focus on limiting export restrictions, compulsory licensing and using the existing TRIPS flexibilities.

Background

The WTO TRIPS Agreement has, since 1995, set the minimum standard of protection of, inter alia, copyright, trademarks, geographical indications, industrial designs, and trade secrets. TRIPS also includes flexibilities to depart from the IPR protection requirements, including in the case of a health emergency. For example, members can do compulsory licensing, which authorises an entity to produce a patented product or process without the consent of the patent owner. In this way, members can produce generic copies for the domestic market (but not for export), and implement fast-track procedures in health emergencies. In addition, the Implementation Decision of the Doha Declaration on TRIPS and Public Health (2001) allows producing members to adopt a compulsory licence for the production of pharmaceuticals for export. This provision enabled Canada to make and export a generic version of a patented AIDS drug to Rwanda, which lacked the manufacturing capacity, in 2007-2009. However, TRIPS flexibilities have been criticised as burdensome and legally challenging.

The WTO Agreement enables members to waive an obligation in exceptional circumstances by consensus-based decision-making; in the past, members have successfully agreed to waive specific articles of the TRIPS Agreement with respect to pharmaceutical products and least-developed countries (LDCs). In October 2020, India and South Africa made a landmark proposal to waive several sections of the TRIPS Agreement, to address the prevention, containment and treatment of Covid-19. The waiver would enable members to not grant or enforce patents (section 5) or other IP obligations on copyright (section 1), industrial designs (section 4), and the protection of undisclosed information (section 7) related to Covid-19 products and technologies. The revised proposal of 25 May 2021 was supported by a number of members in Africa, Asia and Latin America (see Figure 1), and specified the scope would apply to health products and technologies. These include diagnostics, therapeutics, vaccines, medical devices and personal protective equipment to tackle Covid-19. The waiver would be in force for a minimum of three years, and be reviewed annually. LDC members are exempt from applying most of the TRIPS Agreement until July 2034 or until their graduation from the LDC category.

Figure 1 – World map of WTO members in favour of waiver



Source: Revised proposal for TRIPS waiver (May 2021).

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EU position

In May 2021, the Council of the EU decided to support the extension of LDCs' transitional period for the implementation of the TRIPS Agreement by another ten years, or until the member graduates from LDC status. With regard to the temporary TRIPS waiver, notably Germany, Portugal, Estonia and Belgium are reportedly reserved, while Greece, France and Italy are somewhat supportive. On 4 June, the Commission issued a communication to the WTO on TRIPS and Covid-19, reiterating the alternative proposal that focuses on compulsory licensing, limiting export restrictions and expanding production, rather than on waiving patent rights. On 18 June 2021, the Council adopted conclusions on the role of IP in tackling the Covid-19 pandemic. The Council highlighted the EU's engagement in the WTO and its readiness to find pragmatic approaches, such as patent pooling, licensing, and knowledge sharing platforms, and that it stands ready to discuss other flexibilities in the TRIPS agreement.

European Parliament position

During its June I plenary session, Parliament adopted a resolution on meeting the Covid-19 challenge, calling for support for text-based negotiations of a temporary TRIPS waiver in order to enhance global access to Covid-19 related medical products. In the preceding plenary debate of 19 May, there was a lack of consensus in Parliament over the TRIPS waiver. In the same plenary session, the Parliament also adopted a resolution on the trade-related impacts and implications of Covid-19 (rapporteur: Kathleen Van Brempt, S&D, Belgium), urging the Commission to revisit the global framework for IPR, and open a constructive dialogue on the TRIPS waiver in order to ensure that countries do not face retaliation over Covid-19 related patent infringements during the pandemic.

The Parliament's resolution (of 20 May 2021) on accelerating progress and tackling inequalities towards ending AIDS as a public health threat by 2030 also called on the EU to support the TRIPS waiver.

International developments

Third countries' positions

Several WTO members (Australia, Japan, Norway, Singapore, South Korea, Switzerland and Taiwan) hold reservations about starting text-based negotiations on a temporary TRIPS waiver. The Ottawa Group, including the EU, have put forward a WTO trade and health initiative, which would include trade facilitation and liberalisation of tariffs for pharmaceutical and medical products. The USA and China have endorsed the negotiations on the TRIPS waiver on vaccines, but have not mentioned further items of the revised proposal such as health technologies, therapeutics or diagnostics.

Stakeholder views

The WTO TRIPS Agreement has long been criticised by humanitarian organisations for setting an overly stringent level of IPR protection in access to medicines, notably in the context of HIV/AIDS and drug-resistant tuberculosis. Science and research institutes have signed a statement urging all WTO members to endorse the TRIPS waiver proposal, including provisions on copyright. Nurses and civil society organisations including trade unions have urged the 'TRIPS Council' to support the waiver. Proponents have argued the TRIPS waiver could spur innovation and competition by prompting the sharing of undisclosed information, while critics hold that the waiver could disincentivise research and development, and set a precedent that could in the future deter firms from investing in innovation. The American Chamber of Commerce (AmCham) expressed concerns that the waiver could jeopardise vaccine roll-out by diverting raw materials and disrupting supply chains. The biotechnology industry has questioned the breadth, vagueness and feasibility of implementing the waiver in national laws across the world.

The revised decision text of the TRIPS waiver proposal and the statement by co-sponsors were presented to the TRIPS Council on 8-9 June 2021. The EU would need to adopt a common position in the Council of the EU in the event it decided to support the waiver. In July 2021, WTO members also discussed the alternative EU proposal for a global trade response for universal vaccination, i.e. limiting export restrictions, support expanding vaccine production and facilitating the use of existing licensing flexibilities in the TRIPS agreement. The positions remain divergent and the TRIPS waiver will likely be on the agenda of the next WTO Ministerial Conference in late 2021.