Position and argumentation paper

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WTO decision on the TRIPS Agreement: no expansion to COVID-19 therapeutics and diagnostics

The WTO's decision to repeal certain provisions of the TRIPS Agreement relating to compulsory licensing sets a dangerous precedent and sends the wrong signal to innovative companies. To avoid jeopardising the ability of healthcare systems to prepare for future pandemics, we strongly reject extending the TRIPS vaccine decision to COVID-19 therapeutics and diagnostics.

Background

At the 12th Ministerial Conference (MC12) in June 2022, the members of the World Trade Organization (WTO) adopted a comprehensive package of measures. Although scienceindustries acknowledges the importance of this agreement for the functioning of the WTO, it deeply regrets the decision regarding intellectual property: while it does not repeal the protective rights set out in the TRIPS Agreement regarding the production and supply of COVID-19 vaccines as originally proposed, it facilitates the conditions for the issuing of compulsory licences.

For future pandemics, the WTO's decision to relax patent protection for COVID-19 vaccines sends the wrong signal because it removes the incentive to invest in research and innovation. Voluntary industry collaborations and product partnerships played a fundamental role in COVID-19 vaccine development and delivery. As a solid legal basis for agreements, intellectual property rights have enabled this unprecedentedly rapid ramp-up of vaccine production in the first place.

According to the WTO's decision on the TRIPS Agreement regarding COVID-19 vaccines, member states are required to decide within six months whether to extend the decision to COVID-19 therapeutics and diagnostics. Accepting the extension would be problematic for several reasons and would greatly increase the potential scope of application and collateral damage to the industry.

The following are some important arguments that highlight the risks of extending the decision on the TRIPS Agreement. The following examples illustrate how much has so far been achieved at the global level in the fight against the COVID-19 pandemic with the MPP (Medicines Patent Pool) and voluntary licensing. The use of compulsory licences, on the other hand, is counterproductive.

Arguments against extending the WTO decision to COVID-19 therapeutics and diagnostics

IP is not an access barrier

- Even after more than two years of the COVID-19 pandemic, there is no evidence that intellectual property has hindered access to vaccines, therapeutics or diagnostics. Rather, intellectual property and its protection form the basis for innovation and competitiveness. Weakening IP protection will not improve the global population's access to vaccines, therapeutics and diagnostics.

IP as a guarantor for continuous research

- Thanks to robust patent protection, companies were able to quickly and comprehensively develop vaccines and therapeutics that meet the strictest scientific standards.
- The patent system made it possible for companies to invest in the development and expansion of production at their own risk.
- Companies reacted quickly and with voluntary industry collaborations, technology transfers and new product partnerships thanks to the associated legal certainty.
- COVID-19 is unlikely to go away. Additional research is needed to increase the number of therapeutics in view of the risk of resistance to existing treatment options or non-response.
- Hundreds of drugs are currently under research and several potential therapies are under development, mostly by small biotech companies that rely on venture capital financing. A further weakening of IP protection would lead to an uncertain investment environment with negative impacts on the pipeline of COVID-19 therapeutics.

Spill-over effect on other therapeutic agents

- Some of the therapeutics approved for the treatment of COVID-19 are approved or may be approved in the future for other indications. Therefore, an extension of the decision would not be limited to COVID-19 therapeutics, but could affect products with other applications, such as new oral anticoagulants, anti-inflammatory drugs and anti-infectives.
- According to Airfinity, there are 117 COVID-19 treatment projects that are being used for 86 other infectious diseases. There are 63 diagnostic tests currently in use for COVID-19 and classified as multiplex or “combo” tests that can also be used for other infectious diseases, including influenza.

Use of existing structures

- Both voluntary licences and broader access strategies for therapeutics are already in place.
- Most COVID-19 therapeutics that have reached the market have been subject to a broad voluntary licensing strategy, including through trusted intermediaries such as the Medicines Patent Pool (MPP). Extending the WTO decision would undermine the trust and possibly also the resources needed to make such collaborations work.
- Global access strategies for therapeutics include tiered pricing strategies for countries, depending on their level of development.
- Looking at all research and development, there are 150 voluntary collaborations for therapeutics, of which about 80% involve technology transfer. These collaborations are based on decades of private sector investment made possible by strong intellectual property protection.
- Products manufactured under the WTO's decision might not be subject to quality controls and regulatory oversight as provided for in voluntary licences, such as those of the MPP.

Industrial policy vs humanitarian objectives

- Public statements by key ministers at the MC12 showed that this debate is ultimately driven by industrial policy interests. Countries could try to strategically proclaim “public health emergencies” to appropriate innovations and technologies (with clinical applications beyond COVID-19).

- Europe and Switzerland play a decisive role in the production of therapeutics, with new investments in several European countries. But also when it comes to innovation: many candidates are being developed by small European biotech companies.
- Expansion would undermine at-risk investment in manufacturing and affect the wide range of manufacturing technologies for therapeutics.
- An expansion would have far-reaching negative effects, including the erosion of the industrial base of the EU/Switzerland, future innovations and the weakening of its global competitiveness.

MPP and voluntary licensing

- The licensing agreement signed by MPP and Pfizer covers 95 countries, and MPP has signed sub-licensing agreements with 38 manufacturers in 13 countries for Pfizer's generic version of the oral COVID-19 treatment.
- MPP and MSD entered into a licensing agreement for an oral antiviral COVID-19 investigational product, enabling sub-licensing agreements for deliveries in 105 LMICs. Agreements were signed with 27 companies in 10 countries.
- In May 2020, Gilead announced agreements with nine generic manufacturers to produce and supply Remdesivir to 127 countries.