



Mr. Valdis Dombrovskis

Executive Vice-President for an Economy that
Works for the People
European Commission
Rue de la Loi 200
1049 Brussels
Belgium

29 September 2022

Dear Executive Vice-President,

The 12th WTO Ministerial Conference delivered a number of multilateral outcomes that managed to keep the system alive. The European business community is nevertheless deeply concerned about the **Ministerial Decision on the Agreement on Trade-related Aspects of Intellectual Property Rights** and the wider implications it will have for broader discussions regarding Intellectual Property Protection within the WTO, as a possible extension to COVID-19 therapeutics and diagnostics is now being considered.

As expressed in our letter of 6 April 2022, the European business community was already substantially concerned by a waiver of Intellectual Property Rights protection for COVID-19 vaccines, which goes beyond the TRIPS Agreement interfering with the rights of the patent owner and advances the notion that IP has been an obstacle to greater vaccine production and equitable access, despite evidence to the contrary. Concerns are now mounting over a potential extension to therapeutics and diagnostics going beyond the objectives of fighting the COVID-19 pandemic, which would amplify discussions to weaken IP further as the precedent for waiving patents rights is established.

Intellectual property is a bedrock of Europe's economy, with IP intensive industries alone contributing to 44,8% of the EU's GDP¹. Such an extension would send a negative signal to those investing in research and innovation in the healthcare sector but also in other innovative sectors of the economy undermining innovation and Europe's industrial base. In this context, we believe it is essential that discussions take an informed, fact-based approach, and we hope the elements below will be useful in this regard.

¹ All IP-intensive industries contribute to 44.8% and patent-intensive industries to 16.1% of EU's GDP. ECIPE "The Benefits of Intellectual Property Rights in EU Free Trade Agreements", January 2022.



- As with COVID-19 vaccinations, the challenges associated with therapeutics access are multifaceted and require a holistic approach, rather than one narrowly focusing on IP. Low levels of testing, insufficient country readiness, procurement decisions and specificities of national healthcare systems, have meant that the uptake of many treatments has been low, and millions of doses risk being unused and potentially destroyed. Therefore, IP has not been and is not a barrier to therapeutics and diagnostics access, and extending the waiver would try to solve a production issue that currently does not exist.
- The current IP framework has enabled companies to enter into collaborations notably through voluntary licenses² and tiered pricing, which are already in place and working well in promoting access to therapeutics. These collaborations were built on many decades of investments by the private sector which were enabled by strong IP protection. Extending the WTO decision would undermine the trust, and potentially the resources, necessary to make these collaborations work. Moreover, products produced under these conditions may not be subject to the level of quality controls and regulatory oversight foreseen in voluntary licenses. This can lead to the production and use of adulterated, substandard or even counterfeit versions of treatments and diagnostics.
- Waiving IP for COVID-19 therapeutics and diagnostics would inevitably spill beyond COVID-19. Therapeutics are complex, constantly evolving and can have multiple clinical uses. Many of the COVID-19 treatment projects are being used to treat other diseases (e.g. rheumatoid arthritis, Hepatitis-B, HIV, prostate cancer)³. Waiving patents for COVID-19 therapeutics, would immediately disincentivise investments in a specific therapeutic that could also be used for other diseases. There are hundreds of compounds still in the research phase, and multiple potential therapies undergoing development. The extension of the TRIPS waiver would create an uncertain investment environment. A wide array of therapeutics with indications not directly relevant to the pandemic could become easy targets for compulsory licenses. This would significantly undermine the legal certainty industry needs to continue innovating, ultimately hurting patients worldwide.

The extension would further weaken Intellectual Property Rules and would send a signal that instead of modernising and updating existing trading rules, the WTO is backtracking

² So far there are 141 voluntary collaborations on therapeutics, of which 92% involve technology transfers (Airfinity, 2022).

³ According to Airfinity 117 COVID-19 treatment projects are being used in 86 other infectious diseases.

on existing rules and levels of commitment from its members. This would be the very wrong message in a moment we need the WTO to play a stabilising role in view of so many risks and uncertainties.

BusinessEurope remains a strong supporter of the WTO and multilateralism. We recognize the critical importance of an effective WTO as the bedrock of our global trading system, and we commend the EU's active role in championing the multilateral trading system. We truly hope that WTO Members will continue through the path of reforming the WTO including the dispute settlement procedure to help set the rules-based multilateral trading system back in motion. The success of the WTO in effectively tackling the COVID-19 pandemic cannot be narrowly measured through the IP question only. Providing the right response should consider the complexities involved without jeopardising intellectual property rights that are essential to respond to this and future pandemics.

We hope that your services will take the concerns expressed in this letter into consideration. We would be happy to discuss this issue with your services in a follow up meeting at their convenience.

Yours sincerely,



Markus J. Beyrer