INNOVATION COUNCIL

Submitted electronically via EDIS

Ms. Lisa Barton
Secretary
U.S. International Trade Commission
500 E. Street, SW
Washington, DC 20436
United States of America

5 May 2023

Submission from Innovation Council regarding COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Investigation no. 332-596

Innovation Council thanks the International Trade Commission for the opportunity to submit perspectives about the impact of waiving intellectual property protection for additional COVID-19 products, to inform the ITC investigation "COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities" (no. 332-596).

Based in Geneva, Switzerland, Innovation Council is a resource for government officials and other decision-makers, providing insights and analysis about policy choices and other factors that facilitate the development and dissemination of new technology solutions to communities at all levels of development.[1] We seek to shed empirical light on topics ranging from healthcare innovation to connectivity and standards, from trade policy to intellectual property (IP) diversity. Supporting the creation of inclusive innovation ecosystems is a key priority for our organization.

Innovation Council's membership is diverse, including public-private partnerships, companies, industry groups, technology incubators, and investors from all geographic regions. Innovation Council members are united by their desire to share real-world experiences and perspectives with policymakers in Geneva and abroad, to inform innovation policymaking. Innovation Council was founded in 2020.

Our members use IP rights, such as patents, to bring new health and other technologies to society. Some are at the start of their commercialization journey, and others are established innovation leaders in their respective fields of technology. To support our membership, Innovation Council advocates for policies that facilitate innovation, collaboration, and the broad global availability of new technology solutions. We gather and share the experiences of our members with policymakers.

The ITC hearings in April focused to some extent on the business model and practices of the larger biopharmaceutical companies based in the United States and other developed countries, and their possible implications for the availability of COVID-19 products, particularly therapeutics. This focus reflects the highly visible roles and leadership of the established players in this sector during the pandemic response. We consider it important for the Commissioners to
also hear about the experiences of smaller companies and biopharmaceutical manufacturers in developing countries, and about the role of IP in efforts to build capacity across regions.

Intellectual Property and the TRIPS Waiver

[1] *See* innnovationcouncil.org.

Stable IP systems and quality IP rights are an important part of the policy environment for technological advancement, alongside appropriate trade policies, investments in education and workforce development, physical and digital infrastructure, and good governance. The WTO TRIPS Agreement advances the implementation of such IP systems among WTO Members, providing limited exceptions as needed.

Individual IP rights create clarity of ownership and confidence that proprietary technology will not be misappropriated by competitors. This is critical in the context of contributions to a collaborative effort, wherever located. With quality IP rights embedded in a stable legislative and policy environment, organizations can contribute background know-how and technology, along with financial and other resources, to a partnership. They can be confident that the boundaries of what they bring to the table are clearly defined, and that those boundaries can be enforced in the event of misappropriation or disagreement. Collaboration is undermined when the policy environment is not subject to clear rules, such as IP protections aligned with TRIPS minimum standards, or where governments do not commit to clear and longstanding policy choices.

Extending the TRIPS waiver's product coverage would slow biomanufacturing capacity-building across regions, limiting global efforts to build the inclusive health innovation ecosystems that are needed to confront public health challenges now and in the future. This is because weakening the IP assets on which developed and developing country enterprises rely during the technology transfer process will reduce global collaboration, along with investments needed to bolster supply chains and improve resilience in healthcare delivery.

In particular, the extension of the TRIPS waiver is likely to create uncertainty and reduce incentives for local companies and their global technology partners to invest in the further development and commercialization of COVID-19 products. Organizations in developing countries were critical partners for innovators during the scale-up of COVID-19 vaccine and therapeutics manufacturing. Expanding the waiver risks depriving these and other biopharmaceutical companies in developing countries of opportunities to access knowledge, technology, and services to build capacity that could ultimately be applied towards other health challenges. Waiving IP protection would slow efforts to extend biopharmaceutical manufacturing networks in developing country markets where they are most needed to support healthcare and pandemic preparedness and response.

IP Supports Biomanufacturing Capacity-Building

How best to ensure adequate global manufacturing capacity for health technologies has long been a priority of policymakers and the WHO. Biopharmaceutical R&D and supply chains have been globally distributed for many years, well before COVID-19, with more participation from producers from developing countries over time. Industrial policy, commercial goals, and lean manufacturing technology advancements have helped drive this process. After decades of experience, it is feasible today to identify factors that make success likely – and those that can hold fledgling producers back.

Evidence shows that, with the right infrastructure and funding, manufacturers in developing countries can typically gain the ability to safely and efficiently produce generics and biosimilars by working closely with global technology partners over many years. Global technology partners

share technologies and valuable knowledge about facility design, equipment, manufacturing processes, packaging, and regulatory expertise, and they help to train personnel in order to build the foundation for the partner's success.

It typically takes years of tech transfer collaboration before a new partner can successfully produce and commercialize a health technology, whether a small molecule, diagnostic test, biologic treatment, or vaccine. During this period, both sides make significant investments of resources and time to build the capacity of, and to facilitate market entry for, the local partner. The global technology transfer partner benefits by diversifying its manufacturing network to reach more customers, sometimes at a lower cost, and the local partner secures new market opportunities that may expand over time. At the same time, public health outcomes most likely improve thanks to greater availability of critical products.

In addition to helping to improve the availability of life-saving products, establishing new biopharmaceutical production and R&D capacity enhances skills, boosts competitiveness, and generates economic benefits. The element that is essential for building biomanufacturing capacity is a sound business case. This involves analyzing the economics of the venture, including the impact of tariffs and other policies. It also requires a clearly defined market opportunity, including government procurement commitments. Usually, establishing the business case is a question of assessing regional opportunities, rather than seeking to set up (and possibly duplicate) manufacturing capacity in every country.

Historically, countries have relied on different pathways to biomanufacturing success.[2] The pathways vary in approach, depending on country-specific factors. One element common to all the tracks is a sound regulatory system. This reflects the importance of prioritizing safety and quality, and the need for clear guidelines that producers must respect when bringing health products to market, whether they are novel or follow-on products.

Another common element is partnership. Partnerships with established global technology providers are crucial to enabling local manufacturers to enter the supply chain and accelerate domestic and regional vaccine production. Multinationals have substantial internal expertise in relation to scale, innovation, and resources. It's worth noting that this is not necessarily a one-way process; the local partner provides local market insight and may also own IP assets that are shared with the multinational within the collaboration. The local partner progresses, stepwise, up the value chain.

Over time, local partners typically leverage their growing capacity to launch R&D and become innovators in their own right. At this stage, as they improve upon existing health technologies, or bring their own inventions to market, they are likely to use IP rights that read on their inventions to manage the investments and partnerships that contribute to success.[3] They move into a new chapter where they are IP creators and IP rights owners, as well as technology and IP recipients. Their ability to start – and to progress on – the capacity-building journey requires an

[2] *See* *Making Biologics* (2021) and *Biomanufacturing Resilience* (2023) published by Innovation Council member MilliporeSigma.

[3] Brant, J., Ahmned, S., Nemugumoni, C. and Suri, R., 2023. *Moderated Discussion with Geneva Delegates: Insights from Biomanufacturing Experts* [Online]. Available from: https://innovationcouncil.org/wp-content/uploads/2023/05/FINAL-formatted-biomanufacturing-transcript-.pdf.

enabling environment that allows for the issuance and protection of IP rights, which in turn contribute to sustaining the innovation and technology transfer processes.

Vaccines provide an illustration of this stepwise process for building capacity. A local manufacturing partner often starts with packaging and distribution, or with fill and finish. Compared to other activities in the vaccine value chain, these are lower R&D-intensive activities, but they are nonetheless highly technical and challenging to perform efficiently and safely. Criticism that African manufacturing partners perform "only" fill and finish for vaccines ignores the complexity involved in this stage of manufacturing. Significant voluntary tech transfer, involving working side by side with a global technology partner for years, may be required to build the capacity necessary to perform fill and finish before the local partner can shift to carry out higher value activities like the production of bulk antigen. IP enables such voluntary technology and knowledge exchange.

In the absence of sound intellectual property frameworks, collaborative ventures are generally viewed as carrying more substantial risk by the global manufacturing partners involved in such know-how and technology transfer. Global partners will choose to site R&D and other ventures in locations with effective IP frameworks, where there is less likelihood that misappropriation could take place without recourse. Today, with modular factories that can be rapidly established, production can be moved to another location if the policy or commercial environment changes.

Applying Lessons from the Pandemic

During the COVID-19 pandemic, it was immediately apparent that no organization could, on its own, develop, manufacture, and distribute the necessary health technologies at the scale and speed required to address a global pandemic. To overcome this challenge, innovators quickly identified potential partners, shared technology and knowledge, secured and qualified raw materials, and set up supply chains, seeking regulatory approval where necessary for the new facilities and products. Within months of the pandemic outbreak, there were global manufacturing arrangements in place for COVID-19 therapies; by end-2020, this had been replicated in relation to vaccines as well.[4]

COVID-19 was exceptional for the speed at which new technologies were brought to market, and at which global production and distribution networks were established, especially given the lockdowns, border closures, trade constraints, and other complicating factors. What made the difference was the concentration of resources and attention to target one challenge – COVID-19 – combined with technology and knowledge-sharing rapidly on a global scale. According to senior leaders of the companies that led the response, this approach would have been unduly risky without the existence of clearly defined IP assets delivered by TRIPS-enabled IP regimes.[5]

During and since the pandemic, political attention has (rightly) focused on ensuring adequate supply of COVID-19 vaccines and treatments, as well as future pandemic preparedness and response.[6]

[4] By way of example, *see* Blankenship, K., 2020. *Gilead inks deals with generics makers to supply COVID-19 therapy remdesivir for 127 countries*. *Fierce Pharma* [Online]. Available from: https://www.fiercepharma.com/manufacturing/gilead-sciences-inks-licensing-agreements-to-produce-covid-19-therapy-remdesivir-for [Accessed 5 May 2023].; Pfizer, 2020. *Pfizer and BioNTech to Co-Develop Potential COVID-19 Vaccine | Pfizer UK*. *Pfizer* [Online]. Available from: https://www.pfizer.co.uk/news/media/pfizer-and-biontech-co-develop-potential-covid-19-vaccine [Accessed 5 May 2023].

[5] Brant, J. and Schultz, M.F., 2021. *Unprecedented: The Rapid Innovation Response to COVID-19 and the Role of Intellectual Property* [Online]. Geneva, pp.1–100. Available from: https://www.unpackingip.org/ [Accessed 25 April 2023].

[6] By way of example, *see* WHO, 2022. *Moving forward on goal to boost local pharmaceutical production, WHO establishes global biomanufacturing training hub in Republic of Korea*. *World Health Organization* [Online]. Available from:

Bilateral partnerships and licensing arrangements, in addition to licensing via the Medicines Patent Pool, were essential to the pandemic response.[7] In contrast to the rationale offered by some negotiators for an IP waiver at the WTO, the experience of those who participated in the scale up of COVID-19 manufacturing shows that clearly defined IP assets, deployed in an environment of legal certainty, provide an important conduit through which technology flows in an orderly fashion between willing partners. Rather than blocking technology transfer, the massive technology and know-how transfer that made the COVID-19 response possible was sustained in part by IP assets deployed in TRIPS stabilized national IP frameworks.

Collaboration for the COVID-19 response generated additional manufacturing and innovative capacity in more countries. This provides a solid foundation for future pandemic preparedness, provided the factors that slowed the COVID-19 response are acknowledged and addressed by the global trade and health communities in the near future. These include trade policies such as export restrictions and tariff barriers on critical biomanufacturing equipment, consumables, and raw materials, as well as insufficient healthcare and distribution systems.

Summary

This submission describes the interplay between IP protection, on the one hand, and efforts to build capacity for biomanufacturing and R&D in more regions, on the other. Especially since COVID-19, extending such capacity has become a priority for many national leaders and the global health community. IP protection is an essential enabler of these scale-up efforts in the coming years. For this reason, we do not endorse expanding the TRIPS waiver to apply to a broader range of technologies.

An extended TRIPS waiver will increase uncertainty and make it more complicated for organizations to share COVID-relevant technology and knowledge. It will reduce the likelihood that intellectual assets with application to COVID-19 and other health crises will be deployed in emerging markets, in particular, where IP systems are relatively less developed, and risk is thus already perceived by innovators to be higher. Overall, an extended IP waiver is unlikely to improve availability of COVID-19 products, while interrupting the further extension of biomanufacturing capacity to developing regions.

For more information about Innovation Council or to learn more about the experiences of our members, please contact Jennifer Brant at jbrant@innovationcouncil.org.

https://www.who.int/news/item/23-02-2022-moving-forward-on-goal-to-boost-local-pharmaceutical-production-who-establishes-global-biomanufacturing-training-hub-in-republic-of-korea [Accessed 5 May 2023].;The White House, 2022. *G20 Bali Leaders' Declaration*. *The White House* [Online]. Available from: https://www.whitehouse.gov/briefing-room/statements-releases/2022/11/16/g20-bali-leaders-declaration/ [Accessed 5 May 2023].;European Commission, 2022. *EU Global Health Strategy to improve global health security and deliver better health for all*. *European Commission - European Commission* [Online]. Available from: https://ec.europa.eu/commission/presscorner/home/en [Accessed 5 May 2023].

[7] MPP, n.d. *COVID-19*. *MPP* [Online]. Available from: https://medicinespatentpool.org/covid-19 [Accessed 5 May 2023].