AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

Expansion of the waiver of intellectual property protections afforded under the TRIPS agreement

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Executive summary

The US international Trade Commission (ITC) is currently conducting an investigation to decide whether to extend the Intellectual Property (IP) waiver from COVID-19 vaccines to COVID-19 diagnostics and therapeutics. This extension would not improve access but would undermine research and development efforts of industry in the continued fight against COVID-19 and future pandemics. Therefore, AmCham EU recommendations to policymakers would be to facilitate open trade and address regulatory barriers (including measures to reduce tariffs, limit export restrictions and support developing countries in enhancing their supply chains) and build robust delivery of vaccines and therapeutics addressing bottlenecks.

Introduction

Intense collaboration among the public and private sectors, enabled by a stable IP framework, was essential to face the COVID-19 pandemic. Members from the American Chamber of Commerce to the EU (AmCham EU) contributed in terms of research, development, manufacturing and supply.

The extension being conducted under the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property (TRIPS) Agreement would be detrimental for future industry investments in innovation. Thus, policymakers can find below key items that the ITC should consider during its 332 investigation into expansion of the COVID-19 IP waiver to diagnostics and therapeutics.

COVID-19 therapeutics and diagnostics

More than three years have passed since the COVID-19 pandemic hit the world. In that time, more than 15 billion COVID-19 vaccine doses have been produced and delivered around the world with more than 70% of the global population at least partially vaccinated.[1] By the end of 2022, more than 70 million courses of COVID-19 therapeutics were produced, which exceeded that year's demand (19 million). Existing stockpiles of therapeutics (more than 30 million) are large enough to exceed anticipated total global demand in 2023. Moreover, companies have significantly diversified manufacturing of COVID-19 countermeasures from a geographical perspective, with manufacturing sites present in over 30 countries globally, including some of the proponents of the COVID-19 TRIPS waiver expansion, like India or South Africa. For diagnostics, the unprecedented surge in demand due to the pandemic saw medical technology companies dramatically expanding their global production, peaking in 2021 to meet demand. These products are no longer in short supply.

Beyond production, companies have taken significant steps to support equitable global access to therapies and diagnostics. Among the most significant pillars of this are:

- **Pricing strategies:** Companies created access and affordability principles for diagnostics and therapeutics to ensure equitable access at a fair price, including transparency on allocation and tiered pricing based on a country's ability to pay.

[1] IFPMA, 'Improving health security - Covid-19', viewed in April 2023, https://ifpma.org/areas-of-work/improving-health-security/covid-19/

- **Voluntary licencing:** To support the rapid scale up of manufacturing, manufacturers undertook voluntary licencing agreements, either bilaterally with generic manufacturers, or via organisations such as the Medicines Patent Pool (MPP). Given the urgency of the situation, in a number of instances, companies signed agreements with the MPP before regulatory approval or emergency authorisation.[2] Some therapeutics manufacturers have also undertaken voluntary licencing on a bilateral basis.[3]
- **Bilateral access programs:** Some AmCham EU member companies collaborated with the WHO's Access to COVID-19 Tools Accelerator (ACT-A), signing supply agreements with organisations such as UNICEF and the Global Fund, to be able to provide access pathways to low and middle-income countries.
- **Donations** to UN-defined low-income countries or other specific countries or groups.

Industry has done all of this without resorting to weaking IP rights. Indeed, the barriers to access to vaccines, therapeutics and diagnostics are not related to IP. Instead, they are multifaceted, ranging from regulatory barriers, healthcare system readiness, and lack of clinical consensus. Rather than weakening IP protections, countries and international organisations should enact measures to promote industry R&D, increase regulatory flexibility, encourage support for voluntary industry cooperation, create allocation models tied to need, and repeal trade restrictions that limit the availability of and access to COVID-19 vaccines, therapeutics and diagnostics.

To emphasise, we disagree with waiver proponents' efforts to frame current voluntary licencing efforts as insufficient. Voluntary licencing has a critical role to play, both on its own terms, and as part of the above-referenced holistic approach to ensuring access. More than 130 countries, including all low- and middle-income countries in all regions of the world, are able to receive COVID-19 treatments. This may be generics via MPP or other voluntary licensing, or originators via access agreements with low- and middle-income countries, or both.

Beyond this, we also question assertions that demand levels are 'artificially impacted' by pricing considerations. Under the ACT-A pathway, over 4.5 million units covering three COVID-19 therapeutics have been offered to the 138 participating low- and middle-income ACT-A countries. To date (13 April), just over 310,000 units of these medicines have been procured by 71 countries, about 7% of the total available.[4] With supply significantly outstripping demand, and neither pricing nor IP being a barrier. This talks to a significant range of other issues that impact demand and access, and which require collective engagement. These include pandemic fatigue, healthcare professional education, definition of clinically eligible patient populations for different therapeutics and testing capacity.

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[2] Examples include Pfizer's and MSD's respective agreements with the MPP for each of their Covid-19 oral therapeutics in Q4 2021, before either product had received regulatory approval or authorisation. These deals cover 95 and 106 countries respectively.

[3] Examples include: in October 2020, the U.S. FDA formally approved Gilead's remdesivir as Veklury®, the first approved therapeutic to treat COVID-19. Since the beginning of the pandemic, Veklury and licensed remdesivir treatments have been made available to more than 13 million patients globally, over 60% them in Low and Lower Middle-Income Countries. In May 2021 Eli Lilly announced it was undertaking voluntary licensing agreements with eight generic companies in India for its COVID-19 therapeutic baricitinib, in addition to donating an initial 400,000 doses to the Indian Government.

[4] World Health Organization, 'Therapeutics Dashboard – overview', viewed in April 2023, https://medicinespatentpool.org/licence-post/pf-07321332

Ultimately, low demand for COVID-19 therapeutics and diagnostics also undermines one of the very objectives pursued by the proponents of the expansion of the COVID-19 TRIPS waiver, ie enabling manufacturing in developing countries. Low demand suggests manufacturing may not be commercially viable without more holistic strategies to drive sustainable ecosystems. Other potential signals of this can be seen where MPP sublicensee manufacturers have withdrawn from their agreements, citing lack of commercial prospects (see example below).[5] Beyond this, some therapeutics are clinically indicated for a relatively small population of COVID-19 patients. Global supply for such specific therapeutics is therefore much easier to fulfil.

An effective existing IP framework

In record time, companies from the US, Europe and other regions were able to partner to discover, develop, manufacture and distribute vaccines and therapeutics to tackle COVID-19 globally. The existing IP framework enabled this through:

- **Safeguarding and accelerating innovation**: Prior to the pandemic, the development of technology such as Messenger RNA (mRNA) involved decades of prior research, without any commercial return. Clinical science evolved from discovery of mRNA in 1961, to first in vitro use in 1990, to use of lipid nanoparticles to protect mRNA, to resolving immune reactions in 2005. IP-protected investments in developments to translate this platform into clinical application. Moderna had raised billions of dollars from venture capitalists and other investors into research in the years prior to the pandemic. As with its competitor BioNTech, the confidence to enable this - without actually having launched any products – was due to the protections of an IP framework. [6]
- **Enabling partnership**: Partnerships supported both rapid development of vaccines, diagnostics and therapeutics. BioNTech and Pfizer's work researching and developing their vaccine or MSD and Ridgeback for their therapeutic.[7]
- **Supporting manufacturing scale up**: IP gave certainty that allowed companies to collaborate to conduct tech transfer. With the largest scale up in our industry's history, currently there are 381 manufacturing and production deals for COVID-19 vaccines and 138 manufacturing and production deals for COVID-19 therapeutics to enable production across the globe.[8]
- **Role of therapeutics and diagnostics:** Besides R&D in new vaccines, therapeutics and diagnostics, companies also carried out clinical testing of existing treatments for a potential treatment of COVID-19. As expanded on in the next section, since IP cannot be waived for individual indications (such as COVID-19), the IP holder would lose protection for all current and future indications as well, thereby endangering their entire commercial market for a product.

[5] Medicines Patent Pool, 'Licenses – NIRMATRELVIR', viewed in April 2023, https://medicinespatentpool.org/licence-post/pf-07321332

[6] J. Brant, M. F. Schultz, *'Unprecedented The Rapid Innovation Response to COVID-19 and the Role of Intellectual Property'*, IFPMA, 2021, pp. 20-22, https://ifpma.org/wp-content/uploads/2023/01/i2023_Unpacking-IP_2021_Final.pdf

[7] MSD, 'MSD and Ridgeback's Molnupiravir, an Oral COVID-19 Antiviral Medicine, Receives First Authorization in the World', viewed in April 2023, https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-further-details-collaboration

[8] IFPMA, 'Technology transfer', viewed in April 2023, https://ifpma.org/areas-of-work/fostering-innovation/technology-transfer/

As the virus continues to evolve, and with risk of future health emergencies, IP will continue to play an indispensable role and should be protected as such.

Negative consequences of weakening IP

While voluntary licencing has been one of the main successes of the pandemic response, eroding IP protections could actually weaken the foundation for its success. Products manufactured under a compulsory licence are not bound by the same pharmacovigilance obligations or product quality standards as seen in the MPP or bilateral voluntary licences. Facilitating compulsory licensing would undermine adverse event reporting, especially important for clinically new products, and could allow bad actors to use less regulated environments to produce adulterated, sub-standard, or even counterfeit medicines.

With many therapeutics vulnerable to reverse engineering, there is a tangible short-term risk to from any weakening of IP rights via extending the June 2021 decision. In addition, it is almost impossible to provide a definition of a COVID-19 therapeutic or diagnostic that does not risk impacting other therapeutic areas. The nature of biomedical science and innovation means that research into one disease area often leads to breakthroughs in another. Among the several hundred existing therapeutics or potential candidates, 85% of treatments and 23% of antivirals are either redirected or repurposed medicines.[9] Research from 2022 highlighted products or candidates covering 434 non-COVID-19 indications at risk of being impacted, including rheumatological, neurological and cardiovascular therapies.[10] It would be particularly hard to ensure that these drugs, if manufactured under the provisions of the TRIPS waiver, would only be used in the therapeutic areas in the scope of the waiver. In addition, any weakening of IP for manufacturing platform technologies, such as mRNA, may have a cross-cutting impact.

From a med tech viewpoint, there is also a great risk carried through the scope of an extension being incredibly broad. It would capture technologies for the diagnosis, treatment and care of patients with COVID-19 that also serve the critical needs of patients with many other diseases and conditions. The waiver could actually apply to a wide range of products[11] addressing for example, pulmonary, vascular or cardio-vascular diseases, or testing for a variety of diseases or disease states unrelated to COVID-19.

Not only would a waiver lower the incentive for companies to invest significantly in the rapid development of effective treatments or diagnostics for COVID-19 (eg new and more effective treatments including for long COVID etc) and future pandemics, but it could put at risk the viability of drug candidates in other indications that may be caught under an extended IP waiver.

Stepping back, weakening life sciences IP carries a longer-term detrimental risk from both an economic and a healthcare innovation viewpoint. One recent study highlights stark potential impacts

[9] BIO, 'Bio Covid-19 Therapeutic Development Tracker,' viewed in April 2023, https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker

[10] EFPIA, 'Factsheet on Covid-19 therapeutics', viewed in April 2023, https://www.efpia.eu/media/676724/factsheet-covid19-therapeutics.pdf

[11] Examples include: In-patient and Remote patient monitoring systems; X-ray and CT (computed tomography); Ultrasound; Ventilators; Blood pressure devices; and Molecular testing platforms, including PCR platforms.

for medicines: 'overriding intellectual property rights for 10% of drugs would result in a loss of 445,000 jobs (90,000 workers directly employed by life sciences firms and 355,000 employees working in supporting industries) over 30 years. If middle income countries—such as Brazil, Russia, India, and China—decided to override intellectual property protections for all life sciences treatments, the number of new drugs created globally would fall by 24% over a 30-year time frame and the total cost to society would be USD 2.4 trillion on average per year, or 2.5% of global GDP'.[12] Considering the leadership of American life sciences companies in driving biopharmaceutical innovation and the sizable footprint of the sector in the US (4.4 million direct and indirect jobs in 2020), the economic impact of waiving IP rights would be disproportionately higher for the US, while also impacting the operations of American multinational companies in the EU and other regions of the world. This is likely to negatively affect the resources US companies can reinvest in R&D, a significant part of which happens in the US.

The threat of weakening IP beyond life sciences now tangibly extends to other industries. One ramification of the WTO's June 2022 Decision on weakening IP for vaccines was to normalise this approach in public policy, despite the clear lack of evidence of any need for, or benefit from, such a politically driven move. Confirming our concerns, a number of key figures, including the UN Secretary General and Indian trade officials, have already touted the waiving of IP to tackle the climate crisis.[13]

Instead of weakening one of the enablers of an effective response to the current and future pandemics, the US and WTO members should focus on measures that have a real potential to contribute to equitable access to vaccines, therapeutics and diagnostics around the world, as well as to better prepare for future pandemics or health emergencies. These include:

- facilitate open trade and addressing regulatory barriers, including measures to reduce tariffs, limit export restrictions, building on to the proposals under the Trade in Health Initiative submitted initially by the Ottawa Group; and[14]
- support developing countries in enhancing their supply chains and build robust delivery of vaccines and therapeutics addressing bottlenecks (distribution issues, healthcare workforce etc).

Conclusion

The goal of improving access to COVID-19 therapies to patients, wherever they are in the world, is shared among all stakeholders. Politics rather than evidence has driven the debate so far, which ignores or downplays genuine solutions that companies are working on with or alongside governments, international organisations and other stakeholders. Thus, the ITC should bring an analytical lens to this critical issue and involve the relevant stakeholders in future discussions.

[12] FTI Consulting, *'The role of IP in biopharmaceutical sector'*, IFPMA, 2022, https://ifpma.org/wp-content/uploads/2023/01/i2023_2022_The-role-of-IP-in-the-biopharmaceutical-sector.pdf

[13] R. Baruah, 'India to seek IPR waiver for green energy tech at G20'. *Mint*. 27 December 2023, viewed in April 2023, https://www.livemint.com/news/world/india-to-seek-ipr-waiver-for-green-energy-tech-at-g20-11672158909044.html

[14] WTO, *'Ministerial declaration on the WTO response to the Covid-19 pandemic and preparedness for the future'*, 22 June 2022, viewed in April 2023, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True