U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

March 17, 2023

Ms. Katherine M. Hiner
Acting Secretary to the Commission
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

Dear Acting Secretary Hiner:

The U.S. Chamber of Commerce encourages you to ensure protection of intellectual property (IP) as a core issue throughout the U.S. International Trade Commission's investigation on COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities.

Section 332 investigations provide a critical mechanism for the U.S. government to collect additional data prior to the formulation of policy positions on issues of the utmost importance to the United States. The Chamber strongly supports the numerous country delegations in Geneva that have insisted on an evidence-based debate around the controversial World Trade Organization ("WTO") TRIPS waiver. We believe that study of this issue by the USITC can help ensure data-driven policy discussions and inform the debate regarding the critical role intellectual property plays in advancing a multilateral framework for innovation and creativity.

To that end, the Chamber is pleased to provide the following pre-hearing brief in the referenced investigation. We look forward to providing oral testimony at the upcoming hearing and sharing additional detail and data points in a further statement for the record ahead of the May 5, 2023 deadline.

IP weakening measures, such as the TRIPS waivers that have been agreed to or proposed at the WTO; in the World Health Organization ("WHO") Pandemic Treaty Zero Draft; with respect to revisions to the WHO International Health Regulations; in the United Nations High Level Panel on Pandemic Preparedness and Response; and in the United Nations Framework Convention on Climate Change, are proliferating at the national, plurilateral and multilateral levels. From the outset, we want to emphasize six points about the role of intellectual property rights in innovation and the effects of these IP weakening measures on innovation and access.

Weak IP:

1. Is inconsistent with U.S. national and strategic interests and leadership;
2. Stifles investment in innovation;
3. Hinders knowledge-sharing within the innovation ecosystem;
4. Hinders innovation ecosystem collaboration

5. Leaves too many outside the innovation ecosystem; and
6. Poses a direct threat to human safety.

1. Weak IP Inconsistent with U.S. National and Strategic Interests and Leadership

Given the vital role IP plays in supporting investment in innovation, U.S. leadership to advance strong, rules-based global IP standards is critical. The Chamber is grateful for the U.S. government's legacy efforts to promote and protect IP worldwide. However, the Chamber was alarmed by the U.S. government's unprecedented support for the waiver of WTO TRIPS commitments related to COVID-19 vaccines, which will disrupt the IP ecosystem that enabled American industry's highly effective response to the pandemic and undermine future American innovation. This marks a radical departure from long-standing, bipartisan U.S. policy.

The decision by WTO members in June 2023 to waive IP commitments as applied to COVID-19 vaccines, and the ongoing negotiations over the extension of this "TRIPS Waiver" to COVID-19 therapeutics and diagnostics, have falsely branded IP rights as a barrier to access to innovation. While early U.S. support for these waiver measures may have been justified by some as a willingness to endorse "extraordinary measures" and a "no stone unturned" approach amid a global health crisis, the waiver's realization came long after its ostensible purpose was mooted by a large and growing surplus of COVID-19 vaccine supplies.

Proposals to expand the waiver to therapeutics and diagnostics will only compound these threats to American competitiveness and sabotage investment in other IP-intensive sectors, including digital, green, and agricultural technologies that are central to the response to current and future crises. With renewed U.S. leadership at multilateral organizations in support of a strong, global framework of IP rules, it is not too late to stem the damage from the initial waiver and preserve American jobs, foster ingenuity, and protect U.S. national security.

2. Weak IP Stifles Investment in Innovation

The global pandemic demonstrated the power of IP-enabled innovation, with multiple safe and effective vaccines and therapeutics developed in record time. Innovation occurs along a lifecycle and across a multi-stakeholder ecosystem of private industry, financial markets, government agencies, research universities, and scientific institutions. This ecosystem collectively advances knowledge, and develops, tests, and commercializes new technologies that have revolutionized and enhanced the lived human experience. Public-private sector collaboration across the ecosystem is critical to ensuring that the fruits of the innovation ecosystem are realized and reach end-users in order to save and transform lives.

According to the National Science Foundation, three-quarters of research and development ("R&D") taking place throughout the U.S. innovation ecosystem is performed by the private sector, whose investment relies on effective IP laws and supporting regulatory frameworks backed by a commitment to the rule of law. As in the case of mRNA, many new technologies require decades of R&D before reaching a form where they can reach an end-user as a new product or service. IP rights serve a critical economic function as a guarantor of investment in these long-term, high-risk, capital-intensive projects, without which it would be impossible for private sector actors, especially financial markets, to allocate resources to such activities instead of other less risky or time-consuming alternatives.

Underscoring the importance of the need to implement a baseline for IP protection, the U.S. Chamber International IP Index (the "Index") illustrates the socio-economic benefits associated with a conscious, policy choice to invest in stronger IP frameworks.[1] For example, the Index illustrates that economies with the most effective IP frameworks are 40% more attractive to foreign investment, are 32% more likely to see private-sector investment in R&D, and have almost double the innovative output as economies whose IP system lags behind. The data also clearly illustrates the symbiotic relationship between IP and biopharmaceutical innovation. Economies with robust IP systems see over 10 times more clinical trial activity, over 12 times more clinical research on biologic therapies, and are almost twice as likely to provide environments that are conducive to biotech innovation.

3. Weak IP Hinders Knowledge-Sharing within the Innovation Ecosystem

Additionally, an expansion of the existing waiver for vaccines will jeopardize innovative companies' ability to investigate new uses for existing indications. Many of the treatments used to combat COVID-19 were initially developed or are in development for multiple conditions. Of the 3% of COVID-19 treatments that were successfully launched, 32% of those therapeutics are in development for multiple conditions[2], shedding light on the power of incremental innovation. While companies may enter clinical research with a specific endpoint in mind, often continued research and further testing reveal an additional purpose for which a given treatment could utilized.

Throughout the pandemic, countless companies examined whether existing approved treatments or therapeutics in the pipeline could potentially be applied to COVID-19. Their ability to investigate if medicines could be used for COVID-19 was contingent upon governments creating an enabling environment through IP rights. Expanding the waiver to therapeutics and diagnostics would jeopardize companies' ability to make the

[1] See 2022 Statistical Annex to the U.S. Chamber International IP Index, at https://www.valueingenuity.com/wp-content/uploads/2022/04/GIPC_IPIndex2022_StatAnnex_v2-1.pdf

[2] See 2022 PhRMA report "Expanding the TRIPS Waiver Is unnecessary and Harmful," at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/2022-09-30-PhRMA-TRIPS-Waiver-Expansion-FINAL_November-2022.pdf

high-risk, high-capital investment to examine whether treatments can be used for additional indications, both in response to current pandemic and future global public health challenges.

4. Weak IP Hinders Innovation Ecosystem Collaboration

As previously described, in the U.S. ecosystem, innovation is rarely monolithic: ideas, know-how, data, and rights change hands frequently among public, private and academic stakeholders. Within this ecosystem, IP rights serve as a medium for exchange and a store of value. They enable diverse partners to mutually assess and reach agreement on the relative value of the assets that each brings to a partnership. Where IP rights and/or rule of law are weak, this frictionless exchange breaks down with the result that entities are incentivized to hoard their knowledge rather than make it available to partners on agreed and enforceable terms.

Arbitrary or retrospective changes to the rules are anathema to both investment and partnerships since they often have the effect of invalidating the terms on which those decisions were made. For that reason, the Chamber has long opposed compulsory licenses of IP except in the most extraordinary circumstances. In the pandemic, however, some countries have pursued compulsory licenses based on the mistaken assumption that they will enhance access to medicine.

The Chamber acknowledges that the TRIPS Agreement outlined limited circumstances where compulsory licenses are appropriate. However, these so-called TRIPS flexibilities were intended as a measure of last resort, not as has been the case during the pandemic as a preemptive measure where a specific barrier to access has yet to be identified. Compulsory licenses will also further endanger innovators' ability to examine new uses of existing indications. Once a compulsory license is issued, the innovative company loses its IP rights for all indications of the medicine, not just the one for which the license was granted.

By contrast, licensing agreements—whether commercial or "voluntary" (understood to be on other than commercial terms) —provide a critical tool to enhance access while also preserving the underlying IP that enabled the development of innovative medicines. Voluntary licensing arrangements have been shown to be particularly effective in the pandemic.

Throughout the pandemic, voluntary licenses have allowed innovative industry to share their technical expertise and know-how with local partners. These licenses have also equipped local manufacturers with the tools needed to ensure the innovative treatments are safe and effective for global consumers.

There are currently at least 143 covid-19 licensing agreements for therapeutics with manufacturers in 31 different countries, all supported by the contractual licensing of IP

rights, whether on commercial or not-for-profit terms[3]. While voluntary licenses have been fundamental to the ability to deliver COVID-19 treatments around the world, it is critical that companies can carefully chose local partners and create mutually agreeable licensing terms. However, we are concerned that an expansion of the waiver would further undermine the framework for voluntary licenses, which underpinned the rapid distribution of innovative therapeutics to global markets.

One company's experience with local manufacturing partners sheds light on the need to ensure the proper framework for voluntary licensing is in place. This innovative company successfully developed a treatment for COVID-19 that was initially used for other indications, including rheumatoid arthritis. Once the treatment was illustrated to be effective for COVID-19, the company signed voluntary licensing agreements with multiple Indian companies to manufacture the treatment for patients in India. Shortly after the licensing agreements were signed, the medicine appeared in countries around the world for treatment of COVID-19 and other indications, including rheumatoid arthritis. The medicine was being sold for other indications despite the fact that the treatment was not improved for those indications in some of these countries.

Without the appropriate safeguards, like regulatory approvals in place, companies cannot conduct the necessary pharmacovigilance to preserve product quality and patient safety. If these types of challenges can occur under voluntary agreements, compulsory licenses could increase these risks ten-fold. As a result, the Chamber believes it is critical that countries create an enabling environment for voluntary licenses—rather than employ policy tools like compulsory licenses—to preserve the safety and efficacy of medicines, while also protecting the underlying IP framework. Expanding the waiver to include therapeutics and diagnostics will jeopardize the framework for voluntary licensing that has been critical to our shared global response to the pandemic.

5. Weak IP Leaves Too Many Outside the Innovation Ecosystem

<u>The WTO TRIPS Agreement as a Reference Point</u>

The U.S. can promote a better understanding of the vital role the TRIPS Agreement has played in building global capacity for both innovation and local production of the fruits of innovation. While the TRIPS Agreement created a global architecture for a baseline of IP protection, to date, too many countries have resisted the IP standards represented by TRIPS, which they have viewed as a cost rather than an investment. The Chamber's Index illustrates that most WTO member countries have never yet fully or faithfully implemented the standards embodied in TRIPS.

[3] See 2022 PhRMA report "Expanding the TRIPS Waiver Is unnecessary and Harmful," at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/2022-09-30-PhRMA-TRIPS-Waiver-Expansion-FINAL_November-2022.pdf

In 1994 when the TRIPS Agreement was signed, it was considered the most comprehensive and ambitious agreement reached to date. However, the TRIPS Agreement largely predates globalization and the technological revolution that has allowed complex flows of information, capital, and talent to move virtually seamlessly around the globe. Thus, the TRIPS Agreement is missing many of the latest iterations of IP rights upon which a modern knowledge-based economy relies.

Measuring the TRIPS Agreement against the standards included in the Index, which represent the gold-standard of protection for an effective IP ecosystem, clearly illustrates the extent to which the Agreement was merely a floor—rather than a ceiling—for global IP protection. Index analysis from 2017 revealed that the standards included in the TRIPS Agreement would result in an overall score of only 47.51%. Remarkably, 25 out of the 45 Index economies measured in the 2017 Index received a score that was lower than the TRIPS benchmark, revealing how many global economies have failed to implement even the minimum standards included in the Agreement[4].

The rapid development of COVID-19-related vaccines and therapeutics during the pandemic provides a case study of the benefits of strong IP policy. Technological leaps were achieved in those countries whose political, legal and commercial environments fostered sustained investment in R&D, promoted public-private and private-private collaboration, and maintained an effective legal framework for the protection of IP rights, backed by the rule of law. Conversely, many economies without such robust IP standards were ill-equipped to advance the technological solutions needed to combat COVID-19. These countries found themselves on the sidelines waiting to be recipients of technological solutions, rather than part of the successful ecosystem that delivered those solutions.

Despite the fact that such solutions were developed and produced in vast quantities in record time, in many countries, inadequate health infrastructure and governance shortcomings left them largely incapable of procuring, delivering, and administering COVID-19 vaccines and therapies when those became available. In those circumstances, political leaders have resorted to inappropriately—and inaccurately—pointing to IP rights as a barrier to access. Sadly, many influential leaders, including in the United States, have wrongly encouraged the misunderstanding, misrepresentation, and stigmatization of the IP system that resulted with dire long-term consequences for innovation.

Rather than weaken IP rights in a futile effort to improve access to innovation, experience suggests that countries would be better served to focus on strengthening domestic IP frameworks, in order to become fuller and more effective partners in the innovation ecosystem, than support a misguided debate to waive IP-related trade commitments and stifle the development of solutions to the next crisis.

<u>IP Waivers are the Wrong Prescription</u>

[4] See 2017 U.S. Chamber International IP Index, at https://www.valueingenuity.com/wp-content/uploads/2021/03/GIPC_IP_Index_Report_2017.pdf

Of the 80 million courses of COVID-19 treatment purchased by governments in 2022, only 18 million doses have been administered so far[5]. Moreover, media reports indicate that Covax may soon suspend its efforts to supply covid-19 vaccines to poor and middle-income countries as a result of decreasing demand (not to be confused with need) around the world. Proceeding with an IP waiver on therapeutics and diagnostics as the global attention to the pandemic wanes will only diminish the world's ability to prepare for and respond effectively to the next pandemic.

6. Weak IP Environment Threatens Human Safety

Outside of the challenges with local licensing partners described above, companies also encountered counterfeiters selling substandard and adulterated products around the world. One innovative company with an approved medicine for COVID-19 reported the many counterfeiting-related challenges associated with providing the treatment throughout the pandemic.

Following the approval of the branded treatment for COVID-19, the company received reports of a proliferation of counterfeits in global markets, with a significant concentration in Mexico and Turkey. Testing revealed that the counterfeit product contained no active pharmaceutical ingredient for the branded treatment. As a result, the company worked closely with local health officials, law enforcement authorities, and the relevant multilateral organizations to further investigate the prevalence of counterfeit versions of the product in the market. In mid-2021, U.S. Customs and Border Protection (CBP) officers seized over 100 shipments containing an illicit version of the branded product. Upon investigation, the authorities reported each shipment contained 10 to 30 vials of an unapproved and unlicensed version of the medicine. By the end of 2021, CBP seized nearly 300 shipments containing an illicit version of the product.

While this is just one company's story, the Chamber is concerned that an expansion of the waiver would lead to a drastic increase in the sale of substandard and adulterated products. The waiver would also jeopardize the existing, successful public-private sector collaborations to stem trade in illicit medicines. We appreciate the USITC's work to examine the landscape for COVID-19 therapeutics and diagnostics, and we urge the Commission to given careful consideration to the negative, unintended consequences that an expansion of the waiver could bring to bear.

[5] See 2022 PhRMA report "Expanding the TRIPS Waiver Is unnecessary and Harmful," at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/2022-09-30-PhRMA-TRIPS-Waiver-Expansion-FINAL_November-2022.pdf

Conclusion

The TRIPS waiver is proving to be the proverbial camel's nose under the tent. Speaking about renewable energy, United Nations Director General Antonio Gutteres said, "[R]enewable energy technologies, such as battery storage, must be treated as essential and freely-available global public goods. Removing obstacles to knowledge sharing and technological transfer—including intellectual property constraints—is crucial for a rapid and fair renewable energy transition[6]." Similarly, asked recently if she would "support an intellectual property waiver for climate technologies in order to tackle the climate crisis, WTO Director General Ngozi responded: "I could not agree more. We're going to see more of this type of argument. And I hope we'll find a way because really trade needs to help to spread green technologies. That's one of the things we can do for adaptation, and mitigation, and decarbonization[7]."

For all of these reasons, as it considers the economic impacts of the existing and proposed TRIPS waivers for vaccines and therapeutics, respectively, the Commission should look broadly at the impact not just on a particular set of companies, or even an affected sector, but at the entire U.S. ecosystem for innovation. The upstream and downstream effects of a policy philosophy that declares IP a barrier, rather than a means, to innovation will be extreme. Likewise, a lapse in U.S. leadership in this critical policy area will forfeit the strategic investment in innovation that has made the United States the global technological leader and envy of the world.

The Chamber appreciates the Commission's leadership on this investigation, and we are grateful for the opportunity to share the business community's perspective as part of the Section 332 investigation. We look forward to testifying at the hearing on March 29.

Sincerely,

Patrick Kilbride
SVP, Global Innovation Policy Center
U.S. Chamber of Commerce

[6] "Secretary-General's video message on the launch of the World Meteorological Organization's State of the Global Climate 2021 Report," May 18, 2022 - https://www.un.org/sg/en/content/sg/statement/2022-05-18/secretary-generals-video-message-the-launch-of-the-world-meteorological-organization%E2%80%99s-state-of-the-global-climate-2021-report-scroll-down-for-languages

[7] London School of Economics, "In Conversation with Ngozi Okonjo-Iweala," February 8, 2023 - https://www.youtube.com/watch?v=PakRMjwEF6Y