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Dear Secretary Barton,

Property Rights Alliance is a global advocacy organization headquartered in Washington D.C. focused on advancing property rights. Our flagship annual report is the International Property Rights Index, a tool used by civic activists, policy experts, journalists, public and private institutions, academics, and many more. The Index measures the underlining institutions of a strong property rights regime: the legal and political environment, physical property rights, and intellectual property rights.

Our mission to work with groups all over the world to advance property rights isn't motivated merely to achieve positive market outcomes. Property rights, including intellectual property rights, are one of the most important pillars of free society. They are human rights as stated in Article 17 of the UN Universal Declaration of Human Rights and enshrined in other legal texts throughout the world including the U.S. Constitution and the WTO TRIPS Agreement. Like the right to speak freely, choose one's religion, or to have equal protection under the law the right to own one's intellectual property for an exclusive period cannot, and should not, be taken away simply because unelected bureaucrats in Geneva claim, contrary to all available evidence, that doing so might advance certain policy objectives.

It is widely recognized that intellectual property rights play a critical role in enabling medical innovation. Specifically, regarding the TRIPS waiver, this is a sentiment shared globally. This World Intellectual Property Day, an event organized by the World Intellectual Property Organization, PRA led an open letter signed by **110 public policy organization in 53 different countries** that reaffirmed the usefulness of the TRIPS agreement in extending the floor of intellectual property protections around the world and faulted countries that "have used the COVID-19 pandemic to try to weaken IP regimes... includ[ing] suspending portions of the very same TRIPS Agreement that allowed them to play a leading role in ending the pandemic."

Members of the USITC and USTR should remember the TRIPS agreement was a hard-fought negotiation by the United States – propelled by the values enshrined in the U.S. constitution. Many of the staunchest supporters of the TRIPS agreement today were initially against it- including Europe and Japan. As the agreement was implemented and their economies evolved to more IP-intensive goods and services they have embraced the full value of the TRIPS agreement. Rather than carve out loopholes, member states should be fact-finding and aiding others to make the same transition to protecting property rights.

This USITC investigation 332-596 is primarily concerned with identifying the universe of "diagnostics" and "therapeutics" in the medical field and their availability in the market in order to improve understanding of how broad and impactful a further TRIPS waiver might be on the market.

The proposal to waive IP protections for COVID-19 diagnostics and therapeutics is deeply misguided. It is undeniable that the right to own intellectual property exclusively for a given time is a critical incentive for healthcare innovators to risk the enormous amounts of capital and time necessary to take a medical discovery to a doctor's script. In exchange for this exclusivity, they generate medical and scientific breakthroughs such as the COVID-19 mRNA vaccines that have saved billions of lives. No economic

impact assessment can fully anticipate the lost value and lost access to future medicines resulting from the added risk of the TRIPS waiver and potential TRIPS waiver extension.

Pushing the boundaries of known science to create new vaccines, diagnostics, and therapeutics is not straightforward. Newly created Active Pharmaceutical Ingredients often fall apart, become ineffective, and some never come close to a clinical trial. In fact, according to the latest studies 91 percent¹ to 86 percent² of new drugs fail to get market approval. Of the drugs that do, the full process from lab to prescription takes on average 10.5 years³ and can cost as much as \$2.6 billion.⁴ Without the incentive of secure exclusive ownership for a temporary period this process wouldn't be possible.

One of the breakthroughs that nearly didn't make it was Moderna's mRNA COVID vaccine. The small startup, like many pharmaceutical companies, had existed for more than 10 years without a product fully approved to earn revenue in the market. All it had was patents on potential medicines, these attracted investors, some from major pharmaceutical companies like Merck. The investment from institutional firms, venture capitalists, and major pharmaceutical companies is a lifeline to the sea of smaller pharmaceutical startups only possible due to the patents they hold.

Yet, when COVID hit and nearly every pharmaceutical company initiated clinical trials on their best attempts to create vaccines and therapeutics, vaccine candidates from some of the biggest pharmaceutical companies were unsuccessful.⁵ Fortunately, Moderna's technology proved successful and the company was able to go from manufacturing zero vaccines a year to hundreds of millions in a matter of months.

Now that there is a TRIPS waiver for vaccines and the threat of a TRIPS waiver for diagnostics and therapeutics, the risks associated with drug development are even more significant, particularly for early-stage investors and start-up companies. After billions spent, decades waiting, and sweat equity in forming market partners and supply chains, innovators now face the real threat that a group in Geneva, led by countries like India that never fully implemented the TRIPS agreement, and with a poor record in forming pharmaceutical innovation ecosystems themselves, will undermine their intellectual property protections.

This is a shame, especially considering the revolutionary medical treatments and diagnostic tools on the horizon. These include breathalyzers, liquid biopsies, smart contact lenses, visualization aided augmented reality, electronic noses that can detect viruses and volatile particles in the air, wearable biosensors, and smartphone tools. In the not-too-distant future a diagnosis of what once would take months of stool samples and an entire wing in a lab to analyze could be replaced by an instant diagnosis made on a smartphone app connected to a few simple sensors for a fraction of the cost. Many COVID diagnostics tools in trials include some of these technologies. The disincentives created by a TRIPS waiver expansion will have widespread ripple effects, delaying or preventing their adoption in diagnosing cancers, blood diseases, genetic disorders, and more.

The underlying myth propelling the waiver and its expansion relies on a thoroughly weak premise that the exclusivity protected by patents hinders production and therefore affordable and equitable access. This is not true, never has been true, and is not true for COVID diagnostics and therapeutics. The

¹ <https://archive.bio.org/media/press-release/new-study-shows-rate-drug-approvals-lower-previously-reported>

² <https://mitsloan.mit.edu/press/measuring-risks-and-rewards-drug-development-new-research-mit-shows-success-rates-clinical-trials-are-higher-previously-thought>

³ <https://www.bio.org/blogs/how-long-does-it-take-get-drug-approved>

⁴ <https://www.genengnews.com/news/tufts-study-pegs-drug-development-approval-cost-at-2-6b/>

⁵ <https://www.ft.com/content/657b123a-78ba-4fba-b18e-23c07e313331>

temporary period of exclusivity creates the economic conditions for the rights holder to enter as many markets as it can in the shortest time possible.

Recent experience demonstrates that patents have not been a barrier to scaling up production and supply of COVID-19 tools. In April of 2022, three months before the TRIPS waiver decision for vaccines, India's Serum Institute announced it had stopped making the vaccine as it had accumulated a stockpile of 200 million doses.⁶ Then in May South Africa was turning down vaccines and having to destroy one hundred thousand that were expiring.⁷ A month before the TRIPS waiver was approved South Africa's newly created plant to produce the Johnson & Johnson vaccine nearly closed due to lack of demand.⁸ The vaccines were everywhere in record time, the vaccine demand was not.

It should be noted the excess supply of vaccines in the developing world wasn't due to excessive dumping from foreign countries. India and South Africa made a good share of the vaccines in their region. This was achieved by more than 350 voluntary licensing agreements inked between vaccine innovators and vaccine manufacturers around the world. The national intellectual property laws underpinning these agreements are, in most if not all cases, due to implementation of the TRIPS agreement.

Facilities like COVAX also proved effective in distributing batches of vaccines to groups of countries that opted for the program. In addition, Operation Warp Speed pioneered pre-purchases of vaccines in trials and this is something more countries should be encouraged to try in their future pandemic preparedness plans.

Through pre-purchases, voluntary licensing, and production, the property rights-centered, market-driven system delivered powerful and effective vaccines in huge quantities around the world, meeting demand faster than any other system and without a case of compulsory licensing being made. Nurse Sandra Lindsay received the first COVID vaccine in the U.S. outside clinical trials on December 14, 2020,⁹ 90-year-old Margaret Keenan beat her by about a week to be the world's first to receive a vaccine on December 8, 2020 in the UK.¹⁰ Only 14 months later (and four months before the TRIPS waiver) GAVI declared COVID vaccine supply was outstripping global demand.¹¹

Though IP has not been a barrier to access to COVID-19 vaccines and treatments, trade restrictions have impeded access to these products. For example, India imposes significant import tariffs on medicines – hardly a strategy for improving access at home. India also instituted a ban on COVID-19 vaccine exports and blocked deliveries to COVAX, undermining vaccination efforts in many developing countries.

Fortunately, creating intellectual property is one of the things Americans do best. In the United States, IP-intensive industries account for 44 percent of total employment, and jobs in these industries pay a 60 percent wage premium over jobs in other industries.¹² As of 2019, IP-intensive industries represented 83.3 million jobs in the European Union, or 38.9 percent of total employment. These jobs came with a

⁶ <https://www.bloomberg.com/news/articles/2022-04-22/serum-stops-making-covid-vaccines-with-200-million-doses-spare>

⁷ <https://www.bloomberg.com/news/articles/2022-05-10/south-africa-cuts-back-covid-vaccine-drive-amid-citizen-apathy>

⁸ <https://www.reuters.com/business/healthcare-pharmaceuticals/safricas-aspen-covid-19-vaccine-plant-risks-closure-after-no-orders-executive-2022-05-01/>

⁹ <https://www.wsj.com/articles/queens-nurse-gets-first-vaccine-shot-in-new-york-city-11607958012>

¹⁰ <https://www.gov.uk/government/news/uk-marks-one-year-since-deploying-worlds-first-covid-19-vaccine>

¹¹ <https://www.reuters.com/business/healthcare-pharmaceuticals/covax-vaccine-supply-outstrips-demand-first-time-2022-02-23/>

¹² <https://www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf>

47 percent wage premium over jobs in non-IP-intensive industries in the EU.¹³ Globally, the UN estimates IP-intensive industries provide 6.2 per cent of all employment generating nearly 50 million jobs.

China, Russia, India, South Africa and other adversaries seeking a TRIPS waiver expansion have weak IP systems, and as a result lag far behind the United States in medical innovation. Rather, these countries are a frequent focus on USTR's Notorious Markets list for Counterfeiting and Piracy.¹⁴ If the United States can continue its tradition, and constitutional mandate, to champion intellectual property rights it can continue to lead the world in pharmaceutical innovation. Refraining from expanding the TRIPS waiver ensures the United States can continue growing IP-intensive jobs, especially related jobs in the pharmaceutical sector, faster than others and in accordance with America's comparative advantage.

Alternatively, an expanded TRIPS waiver will jeopardize IP-intensive jobs while giving foreign firms, including state-owned firms from adversarial countries, the opportunity to unfairly benefit from American inventions.

Stopping the TRIPS waiver is crucial to protecting the current success of the global patent system. This system worked during the COVID-19 pandemic, delivering breakthrough innovation equitably in record time. Pandemic preparedness can be improved through stockpiling, pre-purchases, and ensuring a robust global system of property rights that can encourage the growth of pharmaceutical innovation ecosystems. Such an ecosystem can increase the number of manufacturers that can fulfill licensing agreements and even increase the number of entities that can contribute to global innovation.

Sincerely,



Philip Thompson

Policy Analyst for IP and Trade
Property Rights Alliance

722 12th Street, NW | Washington, DC 20005 |

Office: 202.785.0266 | Cell: 571.251.9412 |

pthompson@atr.org |

<https://www.propertyrightsalliance.org> |

<http://www.internationalpropertyrightsindex.org/>

¹³ https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/IPContributionStudy/IPR-intensive_industries_and_economicin_EU/WEB_IPR_intensive_Report_2019.pdf

¹⁴ <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/january/ustr-releases-2022-review-notorious-markets-counterfeiting-and-piracy>