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May 3rd, 2023

Secretary Lisa Barton
U.S. International Trade Commission
500 E Street, SW
Washington, D.C. 20436

Re: Comment on COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Investigation No. 332-596

Dear Secretary Barton,

On behalf of Americans for Tax Reform, we appreciate the opportunity to provide input regarding Investigation No. 332-596, *COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities*[1]. We urge the U.S. International Trade Commission (USITC), in its resulting report, to recognize the vital importance of intellectual property (IP) protections and recommend against any expansion of the TRIPS waiver.

Americans for Tax Reform (ATR) is a taxpayer advocacy organization that opposes all tax increases and supports limited government, free-market policies. Strong IP rights are key feature of the free market, particularly in healthcare – they ensure manufacturers are incentivized to innovate, ensure medicines are safe and effective, and have the resources to invest in the next generation of cures.

IP rights are so important that they are explicitly protected in the Constitution. The Founding Fathers recognized the importance of intellectual property rights in Article 1, Section 8 of the Constitution: "To promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Last year, the Biden administration, with the World Trade Organization (WTO), made the mistake of agreeing to waive IP protections under the TRIPS Agreement for COVID-19 vaccines. [2] During negotiations regarding this agreement, the United States Trade Representative (USTR) failed to consult with Congress, though it is the USTR's duty to provide substantial briefings on negotiations to and share all negotiating texts with Congress. This failure prompted a letter from a bipartisan group of Senators calling on the USTR to be more transparent.[3]

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[1] COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities; Notice of Investigation and Scheduling of a Public Hearing," 88 Fed. Reg. 7757 (Feb. 1, 2023). https://www.usitc.gov/secretary/fed_reg_notices/337/332_596_notice_02012023sgl.pdf

[2] World Trade Organization, Ministerial Decision on the TRIPS Agreement, WT/MIN(22)/30, WT/L/1141 (Jun. 17, 2022), https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True

[3] "Bipartisan Senate Finance Committee Members Call for Improved Transparency from U.S. Trade Representative; Cite Failure to Consult with Congress on Recent Trade Negotiations: The United States Senate Committee on Finance." United States Senate Committee On Finance, 10 May 2022, https://www.finance.senate.gov/ranking-members-news/bipartisan-senate-finance-committee-members-call-for-

As the WTO is considering the expansion of the waiver to include COVID-19 diagnostics and therapeutics, it is the USITC's job to examine the short- and long-term consequences of this policy. According to the USTR, this report will help inform whether the United States will support an expansion of the TRIPS waiver.

Further undermining IP protections will weaken manufacturers' incentives to innovate new cures and treatments, will reduce investment in medical innovation, and will threaten the strength of the U.S. biopharmaceutical sector.

Developing new medicines is a costly, risky, and time-consuming process. Without IP protections, there is no guarantee that manufacturers will recoup the time and money they invested in the project. During an average drug development process, a manufacturer must invest an average of $2.6 billion[4] and spend 11.5 to 15 years in research and development.[5]

Even so, most drug development programs fail.

As detailed by Stephen Ezell of the Information Technology & Innovation Foundation (ITIF), for 5,000 to 10,000 compounds screened during basic drug discovery phases, 250 molecular compounds (2.5 to 5 percent) make it to preclinical testing. Of the 250 molecular compounds, 5 make it to clinical testing. Thus, as little as 0.05 percent of drugs make it from drug discovery to clinical trials.[6]

Of the few medicines that make it to clinical testing, only about 12 percent of medicines that begin clinical trials are approved for introduction by the FDA.[7]

Even if a drug is approved, it is likely that the profits from said drug will not recoup its R&D costs. One study in the Health Economics journal found that 80 percent of new drugs made less than their capitalized R&D costs.[8]

Certainly, drug development is a high-risk business. The last thing this industry and its investors need are more disincentives to innovate; for example, the looming threat of their IP rights being stripped from them by an expanded TRIPS waiver.

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improved-transparency-from-us-trade-representative-cite-failure-to-consult-with-congress-on-recent-trade-negotiations.

[4] Sullivan, Thomas. "A Tough Road: Cost to Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development Is Less than 12%." Policy & Medicine, 21 Mar. 2019, www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html.

[5] Stephen J. Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System" (ITIF, March 2019), 24–25, https://itif.org/publications/2019/03/04/bayh-dole-acts-vitalimportance-us-life-sciences-innovation-system.

[6] Stephen J. Ezell, "Ensuring U.S. Biopharmaceutical Competitiveness" (ITIF, July 2020), https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness.

[7] "Research and Development in the Pharmaceutical Industry." Congressional Budget Office, Apr. 2021, www.cbo.gov/publication/57126.

[8] Vernon JA, Golec JH, Dimasi JA. Drug development costs when financial risk is measured using the Fama-French three-factor model. Health Econ. 2010 Aug;19(8):1002-5. doi: 10.1002/hec.1538. PMID: 19655335.

Most importantly, in healthcare, the consequences of a lack of medical innovation are a matter of life and death. Reduced investments mean less research into cures and/or treatments for cancer, Alzheimer's, heart disease, brain disorders, HIV/AIDS, and more.

Importantly, without IP protections, COVID-19 vaccines would not have been completed or distributed as quickly as they were. Allowing the seizure of IP through an expanded TRIPS waiver would undermine this system of medical innovation which, ironically, paved the way for the products the WTO seeks to strip IP rights from.

Further undermining IP rights will also harm American workers and industry strength. IP supports millions of high-paying jobs across the country.

According to the United States Patent and Trademark Office (USPTO), IP-intensive industries accounted for $7.8 trillion in GDP in 2019, or 41 percent of the economy. These industries accounted for 47.2 million jobs, or 33 percent of total U.S. employment.[9]

Pharmaceutical manufacturers are no exception – these businesses invest over $100 billion in the U.S. economy every year, directly supporting over 903,000 jobs.[10] When indirect jobs are included, pharmaceutical innovation supports 4.4 million jobs and $1.4 trillion in total economic impact.[11] These jobs are high paying – the average compensation is over $145,000 – nearly $60,000 more than other industry averages in the U.S.[12]

Expanding the TRIPS waiver to cover COVID-19 diagnostics and therapeutics would further undermine IP rights, thus threatening medical innovation, vital investment, and American jobs. It is imperative that the USITC, in its report, correctly recognize the dangerous, long-term consequences of waiving IP rights.

Additionally, unilateral decisions by the Executive Branch to waive IP rights under the TRIPS Agreement inappropriately circumvent Congress's constitutional authority over trade policy. Certainly, any conclusion the USTR comes to does not override Congress's Constitutional authority to regulate commerce with foreign nations, or the constitutional mandate to protect IP rights.

Onward,

Grover Norquist
President, Americans for Tax Reform

Isabelle Morales
Federal Affairs Manager, Americans for Tax Reform

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[9] "Intellectual Property and the U.S. Economy: Third Edition." United States Patent and Trademark Office, Department of Commerce, 17 Mar. 2022, https://www.uspto.gov/ip-policy/economic-research/intellectual-property-and-us-economy.
[10] "The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates." PhRMA, Mar. 2022, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-Biopharma-Jobs-ImpactsMarch-2022-Release.pdf.
[11] Ibid.
[12] Ibid.