

Investigation No. 332-596

LES (USA & Canada) Written Submission

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May 1, 2023

Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

Re: Written Submission of LES USA & Canada in Investigation No. 332-596

Dear Secretary Barton,

On behalf of the Licensing Executives Society (USA & Canada), Inc ("LES"), I appreciate the opportunity to submit comments to the U.S. International Trade Commission regarding Investigation No. 332-596.¹

LES is a non-profit, non-partisan professional society that represents the entire innovation ecosystem. It is devoted to the global development and commercialization of intellectual property through education, networking, standards development, and certification. It is the leading professional organization relating to intellectual property licensing – specifically, technology-related commercial transactions involving patents, trade secrets, know-how, trademarks, and copyrights. Our members come from all quarters of the economy and represent diverse industries, from life sciences and healthcare to high technology and communications. Our members are business executives, lawyers, technology transfer professionals, IP valuation experts, entrepreneurs, and inventors.²

The ITC investigation is directed to possible expansion of exceptions to intellectual property protection commitments by member countries of the TRIPS Agreement. LES is concerned that allowing additional exceptions to intellectual property protections for Covid-19 diagnostics and therapeutics will have

¹ https://www.usitc.gov/secretary/fed_reg_notices/337/332_596_notice_02012023sgl.pdf

² https://cdn.ymaws.com/members.lesusacanada.org/resource/resmgr/news/LES_Response_on_Robustness_a.pdf

deleterious consequences for global innovation, and for American inventors, enterprises, and our entire economy. Our concerns speak to central questions presented by the USITC to the public on this issue.

The TRIPS Agreement allows intellectual property rights holders to secure and enforce patents and copyrights in all member countries, regardless where the IP originated.³ As such, the TRIPS Agreement provides a minimum baseline of IP protection among all the various member countries. The Agreement enables intellectual property rights holders to negotiate and enter into voluntary licensing agreements with counterparties. Among other things, this makes it possible for commercial enterprises to work across borders, and to efficiently share diverse resources around the world.

To ensure that critical technologies are made available, the TRIPS Agreement provides limited exceptions in carefully defined cases. In those cases, compulsory licensing may be imposed to balance the legitimate property rights of inventors with the public interest.

Generally, compulsory licensing is available only after attempts have been made to obtain voluntary licenses from rights holders, or to ensure domestic availability where it does not otherwise exist.

By any measure, voluntary collaboration is preferred, and it is a more effective and efficient means for international distribution of technology. Voluntary collaboration, based on the predictability and certainty of a basic international framework, beats compulsory licensing, if only because voluntary agreements preserve the incentives to further innovate, and produce a more robust exchange of information (e.g., trade secrets and know how).

³ https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

Moreover, reports have shown that compulsory licenses are not an effective tool for reducing drug prices, increasing access to medicines, or addressing systemic issues in healthcare delivery systems.⁴

Expanding exceptions to property rights in Covid-19 diagnostics and therapeutics would, in effect, seize the property of innovators who have made these valuable resources possible. LES urges that doing so will not achieve the stated aim of increasing access to diagnostics and therapeutics.

The premise of the argument for adding exceptions to intellectual property protections under TRIPS is flawed. There is no evidence showing that intellectual property protection has been an obstacle to producing sufficient Covid-19 diagnostics and therapeutics. Rather, our experience with Covid-19 has shown that the opposite is true. A reliable international regime of standardized intellectual property protection has facilitated cooperation and collaboration that has produced a global response to the pandemic in record time. That cooperation and collaboration continues all the way through the international supply chain to efficiently produce and distribute Covid-19-related technologies and therapies around the globe.⁵

Multiple Covid-19 diagnostics and therapeutics manufacturers – notably, Pfizer and Merck – have voluntarily licensed their Covid-19-related technology to the Medicines Patent Pool, allowing qualified generic pharmaceutical manufacturers to further expand access by manufacturing those products in low- and middle-income countries.^{6 7 8} Today, due in part to those voluntary license agreements, the global

⁴ <https://ipprogress.world/articles/reasons-reject-compulsory-licensing>

⁵ <https://patentdocs.typepad.com/files/joint-statement.pdf>

⁶ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-medicines-patent-pool-mpp-sign-licensing>

⁷ <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countries/>

⁸ <https://www.merck.com/news/the-medicines-patent-pool-mpp-and-merck-enter-into-license-agreement-for-molnupiravir-an-investigational-oral-antiviral-covid-19-medicine-to-increase-broad-access-in-low-and-middle-income-countries/>

supply of Covid-19 diagnostics and therapeutics exceeds global demand.⁹ Altering a well-established, consensus-based international legal regime for intellectual property protection by adding exceptions to those protections will not improve access.

Expanding exceptions to those property rights would instead have a profoundly adverse effect on innovation and technology licensing, especially in healthcare. It would diminish innovation by raising the risk profile and discouraging investment in emerging healthcare technologies to combat Covid-19, and frustrate our ability to prepare for future pandemics.

Advancing this proposal would tell innovators, both in the U.S. and abroad, that IP rights are not reliable, and thus cannot be counted on for complex and long-term license agreements. Those agreements are the foundation for international collaboration and worldwide distribution of essential, life-saving technologies. Such a signal will discourage investors from devoting resources to developing the next critical technology.

IP protection is an essential element of healthcare innovation. Given the cost, risk, and long timeline, it is critical to encourage discovery and development of new drugs, diagnostics, and treatments. IP protection provides a limited property right in newly invented technologies that did not previously exist. It encourages discovery, and it protects against the theft of inventions by unscrupulous actors – whether private or state-sponsored.

Diminishing those property rights creates a perverse incentive. It encourages the misappropriation of the mental labor that produced something useful and valuable. Investors would be forced to conclude that the

⁹ <https://www.bloomberg.com/news/articles/2022-12-05/us-won-t-back-2022-patent-waivers-for-covid-tests-and-treatments?leadSource=verify%20wall>

products of innovation can be arbitrarily taken away, and thus will not yield a return on investment. Investors will turn away from expensive, risky healthcare R&D, and we will all suffer an inability to respond to the next public health crisis.

From its inception, the United States has recognized the economic and societal importance of intellectual property protection. The Framers expressly provided for it in our Constitution.¹⁰ The United States has consistently been at the forefront of international efforts to promote innovation around the world by providing reliable legal regimes for the benefit of all countries, and all people. The United States should not now reverse course. Supporting global initiatives to undermine intellectual property protection will not only compromise American jobs and economic growth, it will reduce incentives to innovate anywhere and everywhere, and restrict the ability of other countries to invent their way up the economic ladder.

The United States currently boasts one of the premier patent systems in the world. It provides innovators and job creators with a compelling reason to invent and invest in America. Today, U.S. pharmaceutical manufacturers alone employ – directly or indirectly – nearly 4.5 million Americans.

Suppose the United States decides to, once again, support an erosion of global IP protection by supporting still more exceptions to the TRIPS Agreement. What would that say to those interested in investing in biopharmaceutical R&D to address future challenges? We believe those investors will look at other industries or options – concluding that this presages further diminishment of IP protection the world over. It's a slippery slope toward reduced innovation, economic stagnation, and fewer cures.

LES supports international efforts to increase the availability of vaccines, therapies, and diagnostics in putting the Covid-19 pandemic finally to rest. The world's biopharmaceutical industry has done a

¹⁰ U.S. Constitution, Art. I, Section 8, cl. 8.

remarkable job in doing just that – under existing intellectual property legal regimes. In the waning days of the pandemic, we should honor that success. We should not dismantle the system that made it possible, but look for opportunities to make it more robust and reliable. We strongly urge the U.S. government to oppose any further diminishment of intellectual property rights by adding exceptions to global intellectual property protections under the TRIPS Agreement.¹¹ Instead, the U.S. government should return to its traditional role as a leading advocate for intellectual property protection the world over.

Respectfully,

/Brian P. O'Shaughnessy/

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¹¹ <https://www.lesusacanada.org/les-explains-flaws-in-letter-from-lawmakers-to-hhs-secretary-becerra-regarding-drug-price-controls/>

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Additional Materials:

LES' 500-Word Summary For Inclusion in the USITC's Report

"The Licensing Executives Society (USA & Canada), Inc ("LES") is an independent, non-profit, non-partisan, professional association devoted to the global commercialization of intellectual property through education, networking, standards development, and certification.

LES opposes additional exceptions to IP protections under the TRIPS Agreement for Covid-19 diagnostics and therapeutics. This would diminish global innovation, and adversely affect U.S. innovators and our economy. Our concerns speak to central questions presented by the USITC to the public on this issue.

The very premise is flawed. IP is not an obstacle to access to Covid-19 diagnostics and therapeutics. Instead, IP has been an essential element in the development, production, and distribution of Covi-19-related technologies. IP forms the foundation on which cross-border collaborations and technology sharing agreements have been formed to efficiently utilize diverse resources and capabilities to create vaccines, diagnostics, and therapeutics, and to make them available around the world.

Many manufacturers of Covid-19 technologies have voluntarily licensed their technology to the Medicines Patent Pool, allowing qualified generic producers to make and sell those technologies in low- and middle-income countries. These and other voluntary networks have now over-produced, and global supply exceeds demand. Expanding exceptions to the TRIPS Agreement – and unraveling a carefully orchestrated regime of global IP rights – will do nothing to increase supply or enhance access.

However, enlarging the IP exceptions to the TRIPS Agreement would have an adverse effect on innovation and investment. Not least, it would increase risk and discourage investment in technologies to fight the next pandemic. It would signal to innovators and investors everywhere that their intellectual property rights are not reliable, and their return on investment is at greater risk.

Intellectual property rights encourage investment in life science research and development. They offer protection against theft of the fruits of our mental labors. Removing those protections creates a perverse incentive – to misappropriate rather than innovate. Investors will conclude that, without a global system of respect for intellectual property, their investments in healthcare will not produce a return comparable to the risk. They will not back expensive, long-term R&D projects, and we will be left without the tools needed to fight the next pandemic.

From its inception, the United States recognized the importance of intellectual property protection. We have consistently been at the forefront of efforts to enable all countries to innovate their way to prosperity through IP protection. The U.S. boasts one of the best patent systems in the world, and this provides a compelling basis for inventing and investing in America. Today, most of the world's new drugs originate in American laboratories, and U.S. pharmaceutical companies employ – directly or indirectly – nearly 4.5 million Americans.

LES is deeply concerned about the proposed new exceptions to IP protections under the TRIPS Agreement, and the overall weakening of international intellectual property protection. We urge the U.S. to oppose diminishment of intellectual property rights. Instead, the U.S. should return to its traditional role as a leading advocate for innovation and intellectual property protection the world over."