



May 11, 2021

The Honorable Gina Raimondo
Secretary of Commerce
1401 Constitution Ave NW
Washington, D.C. 20230

The Honorable Katherine C. Tai
U.S. Trade Representative
600 17th St. N.W.
Washington, D.C. 20508

Dear Secretary Raimondo and Ambassador Tai,

The Alliance of U.S. Startups and Inventors for Jobs (“USIJ”) wants to add its voice to the loud chorus of serious concerns already being expressed by experts from many quarters regarding the Biden Administration’s announcement last week that the U.S. will not object to a proposal being advanced by India, South Africa, and others, most notably China, that would allow the World Trade Organization (“WTO”) to abrogate the terms of the TRIPS Agreement as to intellectual property (“IP”) that might prove useful in treating or preventing Covid-19 (“Proposal” or “waiver Proposal”). USIJ represents the views of a number of startups, entrepreneurs, researchers and venture investors who work in highly innovative and patent-intensive fields, and it is our belief that the American proponents of this waiver Proposal, however well-intentioned, wrongly assert that the legal protection of IP is to blame for the current lack of Covid-19 vaccines in less-developed countries. The Editorial Boards of both the Washington Post and Wall Street Journal last week published strong opinions opposing the U.S. government’s concession to this not-so-subtle move by China and other countries to gain access to proprietary IP developed by leading researchers in America and Europe. The Post blasted the concept of a “patent free ‘people’s vaccine’” as just a “slogan,” not a “solution” to anything. The Journal called it the “single worst presidential economic decision since Nixon’s wage-and-price controls.”

More critical to USIJ’s point: there is no evidence to support the underlying premise of the Proposal – namely that IP is to blame for the lack of vaccines in the developing world – and there is a vast amount of evidence to the contrary. Facts here matter a great deal and it is incumbent on the Administration to base impactful decisions on actual facts – not opinions, political expedience or wishful thinking. By these measures, the Proposal should be resoundingly rejected.

It is also worth noting that the CEO of Pfizer, a company that will provide nearly 3 billion Covid-19 vaccine doses to the world in 2021, has noted in an [open letter](#) that their aggressive efforts to offer vaccines to developing countries early in the Covid-19 crisis were largely rebuffed in lieu of “local production options.” Only after those “options” largely failed have patents been blamed for the lack of distribution of high-quality vaccines globally.

The Proposal would allow countries and companies all over the world to gain unfettered access to valuable technology that was developed over the course of many years by American research institutions and companies, often collaborating with the U.S. government, including the Defense Advanced Research Projects Agency. Undercutting these long-term commitments now would, in turn,

make it far less likely that scientists, engineers, entrepreneurs and venture capitalists will want to continue investing time and resources to prepare for the next pandemic that surely will come. Reliable IP protection of the investments made in mRNA technology over the last 20-plus years is one of the key policies that enabled the U.S. and western Europe to rapidly develop vaccines to address Covid-19. The fact that there have been rampant attempts by Chinese actors to hack into western companies and research institutions to steal this IP speaks to its value and to China's aggressive efforts to access it. The proposed WTO waiver would save China the need to steal our technology as we would essentially be handing it to them.

Even if it were true that the proposed WTO waiver would lead to more rapid dissemination of Covid-19 vaccines to the rest of the world, there still would be no justification for this type of massive abandonment of property and contractual rights that are a fundamental underpinning of the global innovation system. The reality, however, is that patents simply are not the problem. In fact, patents have been a major part of the solution, as we have seen far-reaching licensing agreements between companies that developed Covid-19 vaccines and generic manufacturers in less developed countries, including India. We share the view of others that the proposed waiver is largely an effort to empower the well-developed generic drug industries in India, South Africa and China by handing them the blueprint and manufacturing expertise to leverage the breakthroughs in mRNA technology that the U.S. has made.

Following is a link to the USIJ website and a collection of editorials and articles by James Pooley, former Deputy Director General of the World Intellectual Property Organization which collaborates closely with the WTO; Dr. Scott Gottlieb, former Commissioner of the FDA and Dr. Luciana Borio, former director for medical and biodefense preparedness policy at the National Security Council; Andrei Iancu, Esq., former Under Secretary of Commerce and Director of the U.S. Patent & Trademark Office; and Professor Adam Mossoff of George Mason University and Senior Fellow at the Hudson Institute. Collectively, [these articles](#) refute all of the fundamental premises of the India/South Africa proposal.

Dr. Gottlieb and Dr. Luciana compare the current situation with that in the early 2000s, when AIDS was spreading rapidly in developing countries and there were similar calls to waive patent rights for an emerging class of AIDS treatments. Our government came up with a better plan under a program called the "President's Emergency Plan for AIDS Relief," or PEPFAR, through which the FDA granted emergency approval to the most promising drugs and the U.S. government worked with our drug companies to produce the same high quality and effective drugs that were available in the U.S. Without such coordinated action by the U.S. government, efforts to replicate the American drugs by other countries would have ended up with subpar or adulterated medicines. Dr. Gottlieb goes on to point out that the inability of other countries to accelerate the delivery of vaccines to their populations is not impaired at all by the existence of patents and other IP, but is the result of inadequate raw material supplies and a lack of manufacturing capacity and equipment. If dozens of other countries suddenly try to create this complex manufacturing capacity and access already limited raw materials the current expansion of production being led by established and experienced manufacturers would be severely impacted.

Mr. Pooley, in his article entitled "Covid Vaccine Shakedown at the WTO," points out that India and South Africa have often opposed the availability of patent coverage for the drugs that their generic industries would like to copy and are still harkening back to the AIDS epidemic during the 1980s for support – omitting of course that as soon as reliable drugs became available to address AIDS, the U.S. did in fact make them available to the rest of the world at a fraction of their normal price.

In a subsequent article entitled “How intellectual property rights helped America fight Covid-19,” Mr. Pooley recaps the history of mRNA-based technology, pointing out that the technology had been in the development phase for nearly three decades when the Covid-19 virus hit, with potential targets being Zika virus, rabies and ordinary influenza. All of this work was carried out by a couple of small biotech companies, one in conjunction with Pfizer, who thus were able to pivot and produce a vaccine more quickly than even the most optimistic projections from early 2020, when the virus first was identified. It is because our country values and protects this type of long-term investment of time and resources that Americans have amazingly effective vaccines that are universally available within 18 months of the outbreak of the pandemic. Mr. Pooley also offers some statistics on drug development that the Administration should keep in mind – over \$1.5 trillion has been invested in drug development by private companies and universities over the last 10 years, some of which dealt with mRNA technology. The average cost of bringing to market a single new drug is \$2.6 billion. No one can seriously believe that such levels of investment will continue if the investors and entrepreneurs cannot anticipate reliable patent protection that will allow them to recoup their investments of time and money.

Mr. Iancu’s article, entitled “No evidence that patents slow access to vaccines,” points out that every country on the planet that has the capability to produce Covid-19 vaccines is already doing so, unconstrained by the patents of any company. He quotes the CEO of the Serum Institute of India, which has an agreement with Astra Zeneca to make vaccines, to note that it is not the inability to get licenses to IP that is holding back a faster ramp up of their production, it is the time it takes to scale up – which of course requires buildings, equipment and trained personnel.

Professor Mossoff’s article entitled “Waiving Vaccine Patents Would Imperil Public Health” discusses the history of patents in bringing about drug development and some of the political tensions that are being bandied about by people who are not well informed about such.

USIJ shares the goal of the Biden Administration and every world leader to vaccinate the global community as quickly, safely and effectively as possible. We believe that this is far more likely to occur, however, if our government, instead of agreeing to a suspension of the TRIPS Agreement, made the same concerted effort to expand U.S. manufacturing of vaccines that we made at the outset of the pandemic and encouraged other countries with existing facilities and capabilities to do likewise. The mere existence of effective vaccines for Covid-19 is a staggering accomplishment that speaks to the genius, commitment and capability of America’s innovation system that is supported by strong and reliable IP protection. Through a methodical approach that coordinates government leadership and private sector capability, we can accomplish the dual goal of reaching the world with safe and effective vaccines and also maintaining our commitment to the IP system that empowered their creation.

Alliance of U.S. Startups and Inventors for Jobs

By Chris Israel
USIJ Executive Director