



April 19, 2021

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

Dear Secretary Raimondo:

We write to you as a coalition of 16 organizations dedicated to advancing, racial, economic, environmental, and social justice. We commend you for the difficult work of entering an executive branch left in disarray by the outgoing Trump administration, and not only organizing an effective strategy for mass vaccination against COVID-19 in a matter of weeks, but thus far successfully enacting that plan nationwide. If, as President Biden hopes, the United States is able to achieve relative normalcy by the fourth of July, it shall represent an historic achievement of American governance for the public good.<sup>1</sup>

However, we are deeply concerned about several prospects regarding the current status of the mRNA and vaccine technologies that enable the production of COVID-19 vaccines, particularly as public health officials now indicate that COVID-19's rapid mutations may require world populations to receive regular boosters and reformulations of the vaccine, similar to the flu.

<sup>1</sup> "Fact Sheet: President Biden to Announce All Americans to Be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th," The White House, March 11, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/11/fact-sheet-president-biden-to-announce-all-americans-to-be-eligible-for-vaccinations-by-may-1-puts-the-nation-on-a-path-to-get-closer-to-normal-by-july-4th/>.

The Pfizer and Moderna vaccines rely enormously on a viral protein discovered decades ago by Dr. Barney Graham, and on the concept of RNA modification developed by Drew Weissman and Katalin Karikó. Graham, Weissman, and Karikó's research was all publicly funded.<sup>2</sup> It is thanks to this research, underwritten by ordinary taxpayers, that the United States has been able to produce COVID-19 vaccines in less than one year. Yet despite this, the technologies needed to actually produce these vaccines are solely held by a handful of private, for-profit firms, who have jealously guarded any other institution's access to this life-saving machinery in part through thickets of intellectual property protections. Anyone seeking to produce COVID-19 mRNA vaccines — which is to say, the whole population of the planet Earth — is forced ultimately to barter with these for-profit corporations, who hold unitary control over this technology for purely artificial, legal reasons.

While the U.S. is nearing the end of its own COVID-19 pandemic, the world at large will still need access to this technology for years to come: current estimates hold that developing-world countries may be unable to secure vaccines for their own populations until 2023<sup>3</sup>, and developed-world populations may need supplemental vaccines and boosters to inoculate against new COVID-19 strains in as little as a few months. Moreover, the more people worldwide remain unvaccinated, and thus susceptible to current COVID-19 strains, the more opportunities the virus has to mutate, only accelerating these cycles of vaccine need worldwide. In other words, so long as the technology needed to produce COVID-19 vaccines remains solely in the hands of private, for-profit entities, who have a strong interest in restricting access to extract better terms, the world will constantly face waves of the crushing supply shortages that have defined American life for the past several months — all for no reason other than private firms jealously guarding the requisite technology.

The administration has tools to prevent such artificial supply shortages both abroad and at home, yet it has thus far failed to mobilize them. Indeed, the conditions which enable manufacturers like Pfizer, Moderna, and Johnson & Johnson to force the entire world into dependence on their for-profit deployment of vaccine creation technologies are driven largely by one aspect of our medicinal supply chain over which the federal government has enormous power: the granting of intellectual property protections, including patents, copyrights, trade secret protections, and more.

We know that voices within the administration have advocated for robust action to use intellectual property policy for the public interest as it pertains to COVID-19 vaccines. We strongly urge you to not only heed those voices, but to use the various executive powers available to the administration to undo the power of intellectual property in the American pharmaceutical industry as maximally as possible. As a general guiding policy principal, public health must be prioritized ahead of the interests of those who ostensibly own intellectual property, both now and in the future, in both appointments and concrete actions. This must begin with COVID-19 vaccines, starting immediately by supporting action in the World Trade Organization to waive requirements under the TRIPS Agreement, and continuing to use

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<sup>2</sup> Arthur Allen, "For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid The Groundwork," Kaiser Health News, November 18, 2020, <https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/>

<sup>3</sup> "More than 85 poor countries will not have widespread access to coronavirus vaccines before 2023," The Economist Intelligence Unit, January 27, 2021, <https://www.eiu.com/n/85-poor-countries-will-not-have-access-to-coronavirus-vaccines/>.

march-in rights under the Bayh-Dole Act, as well as Section 1498 powers. We shall address each of these powers in turn.

### **World Trade Organization TRIPS Waiver**

As you know, developing nations worldwide have pleaded in the World Trade Organization for months for countries whose pharmaceutical industries have developed COVID-19 vaccines, most especially the United States, to support a proposal to waive intellectual property protections over both those vaccines' formulas and the technologies and trade secrets needed to produce them.<sup>4</sup> Doing so would allow the United States and other countries to temporarily waive their patent, trade secret, copyright, and industrial design obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights, better known as TRIPS. Thereafter, upon the United States implementing the waiver domestically, any manufacturer with the proper tools could produce COVID-19-related health technologies to detect, prevent, treat, vaccinate, and otherwise mitigate COVID-19. India and South Africa have led an effort at the TRIPS Council now supported by more than 100 member-states, as well as over 775 civil society organizations both domestic and international.<sup>5</sup>

Even aside from the moral urgency of preventing unnecessary deaths in developing nations, the United States has a profound national security interest in ensuring the planet achieves mass inoculation to COVID-19 as fast as possible, to prevent new and unpredictable strains from developing that could overwhelm our current vaccine protections. Simply put, unvaccinated populations anywhere are a threat to public health everywhere. Moreover, seeing the United States use every tool at its disposal to vaccinate world populations is a once-in-a-lifetime diplomatic opportunity to recapture global faith in the United States as a world leader, and in Western democracy as the most effective form of government. In the absence of U.S. action, China and Russia have mounted campaigns to vaccinate global populations, most especially in emerging middle-income countries like Pakistan and Brazil.<sup>6</sup> The generosity of our nation's rivals in a time of global desperation, and our own inaction, will not be forgotten by these countries.

The United States thus has deep ethical, national security, and diplomatic interests in doing everything possible to achieve global COVID-19 vaccination as fast as possible. Moreover, even after initial COVID-19 vaccines are distributed worldwide, public health officials worldwide will still need to regularly redistribute new boosters and reformulations to address novel COVID-19 variants. The rate at which these revaccination campaigns will be needed depends on the rate at which world leaders can

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<sup>4</sup> Reuters Staff, "Rich, developing nations wrangle over COVID vaccine patents," Reuters, March 10, 2021, <https://www.reuters.com/article/us-health-coronavirus-wto/rich-developing-nations-wrangle-over-covid-vaccine-patents-idUSKBN2B21V9>.

<sup>5</sup> "Presser: 400+ US Civil Society Organizations Call on Pres. Biden to Stop Blocking COVID-19 WTO Waiver to Boost Vaccines, Treatments Worldwide," Public Citizen, February 26, 2021, <https://www.citizen.org/news/hundreds-of-prominent-us-civil-society-organizations-call-on-pres-biden-to-stop-blocking-covid-19-wto-waiver-to-boost-vaccines-treatments-worldwide/>; "Over 100 civil society organisations call on the European Parliament to support COVID-19 WTO waiver proposal," MSF Access Campaign, November 19, 2020, <https://msfaccess.org/over-100-civil-society-organisations-call-european-parliament-support-covid-19-wto-waiver-proposal>.

<sup>6</sup> Yanzhong Huang, "Vaccine Diplomacy Is Paying Off for China," Foreign Affairs, March 11, 2021, <https://www.foreignaffairs.com/articles/china/2021-03-11/vaccine-diplomacy-paying-china>; Lionel Laurent, "China and Russia Are Beating the West at Vaccine Diplomacy," Bloomberg, February 23, 2021, <https://www.bloomberg.com/opinion/articles/2021-02-23/covid-vaccines-the-west-is-letting-china-and-russia-win-the-diplomacy-g?ref=6QyUvLUJ>; Daria Litvinova, "Russia scores points with vaccine diplomacy, but snags arise," AP, March 7, 2021, <https://apnews.com/article/europe-global-trade-middle-east-diplomacy-moscow-e61ebd3c8fe746c60f5ecc1ec323c99a>.

vaccinate their populations per cycle — the faster we can inoculate the world to each new COVID-19 strain, the fewer opportunities the virus will have to mutate.

A high vaccination rate requires supply, and the sooner and more widely the capacity to produce vaccines proliferates, the better hope people have to constrain viral spread. The most efficient and effective path to exponentially increasing this vaccination rate, both currently and in the future, is to waive the intellectual property rights held by Pfizer, BioNTech, Moderna, and Johnson & Johnson, as well as those for any future American-made COVID-19 vaccines that are approved by the Centers for Disease Control.

Consider that supply shortages remain the greatest hindrance to the current global vaccination effort, but only a portion of the world's possible production capacity for COVID-19 vaccines is being used. Simply permitting other potential manufacturers, most especially those in developing countries, to develop these vaccines immediately overcomes the first hurdle toward increased global vaccine supply. All regions of the world have at least some sites ready to begin manufacturing immediately — they simply require access to the trade secrets currently guarded by pharmaceutical firms' intellectual property thickets.

The United States and its allies, moreover, can and should help other sites procure the necessary equipment and expertise. Doing so will be a straightforward logistical necessity in the long term, as the virus mutates and new vaccine formulations are regularly needed. The World Health Organization's head of vaccine development Martin Friede has stated that in the long-term, every world region will need a facility that fully owns its production know-how.<sup>7</sup>

Drug manufacturing knowledge, moreover, is not zero-sum: by open-sourcing vaccine creation technologies, the United States does not sacrifice any of its own vaccine supply, even as current estimates hold that the United States has purchased more vaccines than it shall need to end its immediate pandemic. The only things keeping this vaccine production knowledge restricted — and thus severely hampering the planet's potential vaccine production capacity — are government-granted legal barriers, namely intellectual property rights.

Critics of the TRIPS waiver proposal have argued that patent-holding companies are already negotiating private deals to share IP-protected information, increase production, and reconfigure factories.<sup>8</sup> The scale at which this can occur is limited by corporate profit incentives and relationships. Waiving IP rights around COVID-19 vaccine production would enable any facility with the requisite equipment to pursue forced technology transfer, as needed, and to begin production. Waiver opponents' argument also tacitly concede that sharing manufacturing knowledge currently protected by intellectual property rights is indispensable to ending the pandemic globally — if it is good for private firms to share their knowledge in a limited, profit-driven capacity, why would it not be better still to share this information at a global scale?

While manufacturing mRNA vaccines does require specific equipment and technical knowledge, again nothing prevents the United States and its allies from coordinating installation of this equipment and

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<sup>7</sup> Aisling Irwin, "What it will take to vaccinate the world against COVID-19," *Nature*, March 25, 2021, <https://www.nature.com/articles/d41586-021-00727-3>.

<sup>8</sup> Editorial Board, "Watch Out for a Vaccine Patent Heist," *Wall Street Journal*, March 28, 2021, <https://www.wsj.com/articles/watch-out-for-a-vaccine-patent-heist-11616959785>.

sharing of this expertise worldwide — in the long term, doing so is both necessary and likely far cheaper, as new vaccine formulations are needed to stop new COVID-19 variants. Moreover, warnings that companies will refuse to invest in drug development without the profit guarantee of intellectual property are ludicrous. Private industry is almost never the primary financial backer of vaccine development. This is due to high costs, low chance of success, and as Xue and Ouellette have argued, the fact that vaccines are single-use, preventative, durable goods rather than more lucrative treatments requiring repeated purchase.<sup>9</sup> Instead, companies like Novavax, Moderna, Pfizer and others profiteer from research breakthroughs principally funded by governments and non-profits worldwide — \$17.2 billion from the U.S. government alone — using intellectual property protections and benefitting from market concentration to extract higher rents. Refusing these firms their rent-seeking off of research that the federal government paid for is not only just, it makes sound economic sense.

Consider, in plain terms, the moral implications of inaction. If it refuses to waive intellectual property protections on the technologies and trade secrets needed to produce COVID-19 vaccines, the Biden administration would be tacitly stating that it believes the profiteering of one of the world's most lucrative industries off of the entire world outweighs the basic moral case for aiding the sick and preventing unnecessary death;<sup>10</sup> the health needs of both the United States and all humanity to eradicate a deadly and fast-mutating virus; and the specific diplomatic goals of the United States to compete against Russia and China.

We urge the administration to consider the national security, diplomatic, and moral cases, and immediately support the TRIPS waiver proposal.

### **March-in Rights Under The Bayh-Dole Act**

While U.S. support of a TRIPS waiver at the WTO is necessary to free the existing COVID-19 vaccines from intellectual property protections, the United States federal government must still enact domestic policy to carry out the waiver's intent. Thankfully, there are measures under American law to waive at least some of the requisite intellectual property rights through existing executive power.

Under the Bayh-Dole Act of 1980, a federal agency which provided funding toward the creation of an invention — such as a vaccine — can require the invention's patent-holder to grant licenses to responsible applicants. Two of the three COVID-19 vaccines currently in use in the U.S. were created in part thanks to \$13 billion worth of government-sponsored research under Operation Warp Speed, and previous vaccine related investments totalling \$17.2 billion prior to 2020.<sup>11</sup>

The Bayh-Dole Act narrowly allows forced licensing of patented technologies, but has no power over other forms of intellectual property, such as copyrights or trade secrets. Still, it is a powerful tool that has gone underutilized even since the Bayh-Dole Act's passage in 1980, most especially in the field of pharmaceuticals. Where COVID-19 vaccine-related technologies that were developed through

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<sup>9</sup> Qiwei Claire Xue and Lisa Larrimore Ouellette, "Innovation policy and the market for vaccines," *Journal of Law and the Biosciences* Volume 7, Issue 1 (2020): 1-41, <https://doi.org/10.1093/jlb/ljaa026>.

<sup>10</sup> Fred D. Ledley et al., "Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies," *JAMA* Volume 323, Issue 9 (2020): 834-843, <https://jamanetwork.com/journals/jama/fullarticle/2762308>.

<sup>11</sup> Reuters, "Moderna gets further \$472 million U.S. award for coronavirus vaccine development," CNBC, July 27, 2020, <https://www.cnbc.com/2020/07/27/moderna-gets-further-472-million-us-award-for-coronavirus-vaccine-development.html>.

government funding are specifically patented, and not protected through other forms of intellectual property, the administration must utilize these provisions of the Bayh-Dole Act immediately.

However, the Bayh-Dole Act provisions — known as “march-in rights” — is now imperiled by a late-Trump era rulemaking process. The National Institute of Standards and Technology (NIST) recently concluded its comment period on a rulemaking process that would narrow interpretation of the Bayh-Dole Act to eliminate march-in rights on drug patents.<sup>12</sup> The technical provision being addressed is a rule change to interpret a requirement that the subject inventions be made “available to the public on reasonable terms” to preclude price as allowable grounds for march-in, no matter how unreasonable or extortionate such pricing might be and no matter how much the government had de-risked research & development and even clinical trials.

NIST is under no obligation to proceed with enacting the rule after the comment period closes. If NIST Acting Director Dr. James Olthoff does not affirmatively commit to refusing further activity on the Trump-era rule, the administration must immediately replace him. In fact, the U.S. should reverse course 180 degrees and adopt a new regulation clarifying that unreasonable pricing provides legitimate grounds for march-in.

This ahistorical rule would ignore the clear arguments in favor of march-in rights over drug prices at the time of Bayh-Dole’s passing.<sup>13</sup> The only beneficiaries of such a rule would be multibillion-dollar pharmaceutical corporations. Average Americans, moreover, would lose access to one of the federal government’s strongest potential tools for curbing the price of prescription drugs and medications, which is a priority for the President.

### **Section 1498 Powers**

The federal government can also invoke 28 USC § 1498, also known as Section 1498, to pay patent holders for immediate use of patented technologies. This statute has been used during both world wars, and in the aftermath of 9/11,<sup>14</sup> so its usage during a time of global crisis is unquestioned. Thus, it can and should be used during the COVID-19 crisis to pay for immediate usage of patented vaccine technologies, where applicable. Moreover, nothing requires Section 1498 to solely be used during discrete national emergencies. Using Section 1498 would directly save lives at home and abroad, and it merely requires some discretionary funding and a Presidential signature.

### **Personnel And Intellectual Property**

The COVID-19 pandemic had powerfully demonstrated how the artificial constraints of intellectual property can drive public health outcomes that lead to unnecessary loss of life, solely for the sake of the

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<sup>12</sup> Lee Fang, “Last-Minute Trump Rule Would Let Vaccine Makers Hike Prices Unchecked,” The Intercept, April 2, 2021, <https://theintercept.com/2021/04/02/covid-vaccine-price-hikes/>.

<sup>13</sup> Peter S. Arno and Michael H. Davis, “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research,” Tulane Law Review Volume 75, Issue 631 (2001): 631-693, <http://www.cptech.org/ip/health/bd/arnodavis012001.pdf>.

<sup>14</sup> Christopher Morten and Charles Duan, “Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises,” Yale J.L. & Tech. Volume 23, Issue 1 (2020): 1-96, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3685413](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3685413).

institutional, competitive interests of pharmaceutical firms. These outcomes are immoral, antithetical to the strategic and diplomatic interests of the United States, and in part avoidable by merely exerting existing executive-branch powers. Thus, we call on the administration to consider the lessons of the COVID-19 pandemic when nominating appointees to intellectual property-related positions across the federal executive branch, most especially for the Director of the Patent and Trademark Office, the Director of the National Institute of Standards and Technology, and the Commissioner of Food and Drugs.

We urge you and all Biden administration officials to use maximally the executive branch's existing powers to undo the power of intellectual property provisions in responding to the COVID-19 pandemic, whilst looking in the long-term at ways of rethinking and reorganizing IP rights in the pharmaceutical industry altogether, especially through existing executive-branch powers.

Signed:

American Economic Liberties Project  
Center for Economic and Policy Research  
Consumer Action  
Debt Collective  
Democracy For America  
Demand Progress Education Fund  
Electronic Frontier Foundation  
The Freedom BLOC  
Greenpeace US  
Indivisible  
Open Markets Institute  
People's Parity Project  
Project Blueprint  
Revolving Door Project  
Social Security Works  
UNITE HERE



April 19, 2021

Mr. Jeffrey Zients  
COVID-19 Response Team Coordinator  
The White House  
1600 Pennsylvania Avenue NW  
Washington, D.C. 20500

Dear Mr. Zients:

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However, we are deeply concerned about several prospects regarding the current status of the mRNA and vaccine technologies that enable the production of COVID-19 vaccines, particularly as public health officials now indicate that COVID-19's rapid mutations may require world populations to receive regular boosters and reformulations of the vaccine, similar to the flu.

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While the U.S. is nearing the end of its own COVID-19 pandemic, the world at large will still need access to this technology for years to come: current estimates hold that developing-world countries may be unable to secure vaccines for their own populations until 2023<sup>3</sup>, and developed-world populations may need supplemental vaccines and boosters to inoculate against new COVID-19 strains in as little as a few months. Moreover, the more people worldwide remain unvaccinated, and thus susceptible to current COVID-19 strains, the more opportunities the virus has to mutate, only accelerating these cycles of vaccine need worldwide. In other words, so long as the technology needed to produce COVID-19 vaccines remains solely in the hands of private, for-profit entities, who have a strong interest in restricting access to extract better terms, the world will constantly face waves of the crushing supply shortages that have defined American life for the past several months — all for no reason other than private firms jealously guarding the requisite technology.

The administration has tools to prevent such artificial supply shortages both abroad and at home, yet it has thus far failed to mobilize them. Indeed, the conditions which enable manufacturers like Pfizer, Moderna, and Johnson & Johnson to force the entire world into dependence on their for-profit deployment of vaccine creation technologies are driven largely by one aspect of our medicinal supply chain over which the federal government has enormous power: the granting of intellectual property protections, including patents, copyrights, trade secret protections, and more.

We know that voices within the administration have advocated for robust action to use intellectual property policy for the public interest as it pertains to COVID-19 vaccines. We strongly urge you to not only heed those voices, but to use the various executive powers available to the administration to undo the power of intellectual property in the American pharmaceutical industry as maximally as possible. As a general guiding policy principal, public health must be prioritized ahead of the interests of those who ostensibly own intellectual property, both now and in the future, in both appointments and concrete actions. This must begin with COVID-19 vaccines, starting immediately by supporting action in the World Trade Organization to waive requirements under the TRIPS Agreement, and continuing to use

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<sup>3</sup> "More than 85 poor countries will not have widespread access to coronavirus vaccines before 2023," The Economist Intelligence Unit, January 27, 2021, <https://www.eiu.com/n/85-poor-countries-will-not-have-access-to-coronavirus-vaccines/>.

march-in rights under the Bayh-Dole Act, as well as Section 1498 powers. We shall address each of these powers in turn.

### **World Trade Organization TRIPS Waiver**

As you know, developing nations worldwide have pleaded in the World Trade Organization for months for countries whose pharmaceutical industries have developed COVID-19 vaccines, most especially the United States, to support a proposal to waive intellectual property protections over both those vaccines' formulas and the technologies and trade secrets needed to produce them.<sup>4</sup> Doing so would allow the United States and other countries to temporarily waive their patent, trade secret, copyright, and industrial design obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights, better known as TRIPS. Thereafter, upon the United States implementing the waiver domestically, any manufacturer with the proper tools could produce COVID-19-related health technologies to detect, prevent, treat, vaccinate, and otherwise mitigate COVID-19. India and South Africa have led an effort at the TRIPS Council now supported by more than 100 member-states, as well as over 775 civil society organizations both domestic and international.<sup>5</sup>

Even aside from the moral urgency of preventing unnecessary deaths in developing nations, the United States has a profound national security interest in ensuring the planet achieves mass inoculation to COVID-19 as fast as possible, to prevent new and unpredictable strains from developing that could overwhelm our current vaccine protections. Simply put, unvaccinated populations anywhere are a threat to public health everywhere. Moreover, seeing the United States use every tool at its disposal to vaccinate world populations is a once-in-a-lifetime diplomatic opportunity to recapture global faith in the United States as a world leader, and in Western democracy as the most effective form of government. In the absence of U.S. action, China and Russia have mounted campaigns to vaccinate global populations, most especially in emerging middle-income countries like Pakistan and Brazil.<sup>6</sup> The generosity of our nation's rivals in a time of global desperation, and our own inaction, will not be forgotten by these countries.

The United States thus has deep ethical, national security, and diplomatic interests in doing everything possible to achieve global COVID-19 vaccination as fast as possible. Moreover, even after initial COVID-19 vaccines are distributed worldwide, public health officials worldwide will still need to regularly redistribute new boosters and reformulations to address novel COVID-19 variants. The rate at which these revaccination campaigns will be needed depends on the rate at which world leaders can

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<sup>5</sup> "Presser: 400+ US Civil Society Organizations Call on Pres. Biden to Stop Blocking COVID-19 WTO Waiver to Boost Vaccines, Treatments Worldwide," Public Citizen, February 26, 2021, <https://www.citizen.org/news/hundreds-of-prominent-us-civil-society-organizations-call-on-pres-biden-to-stop-blocking-covid-19-wto-waiver-to-boost-vaccines-treatments-worldwide/>; "Over 100 civil society organisations call on the European Parliament to support COVID-19 WTO waiver proposal," MSF Access Campaign, November 19, 2020, <https://msfaccess.org/over-100-civil-society-organisations-call-european-parliament-support-covid-19-wto-waiver-proposal>.

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vaccinate their populations per cycle — the faster we can inoculate the world to each new COVID-19 strain, the fewer opportunities the virus will have to mutate.

A high vaccination rate requires supply, and the sooner and more widely the capacity to produce vaccines proliferates, the better hope people have to constrain viral spread. The most efficient and effective path to exponentially increasing this vaccination rate, both currently and in the future, is to waive the intellectual property rights held by Pfizer, BioNTech, Moderna, and Johnson & Johnson, as well as those for any future American-made COVID-19 vaccines that are approved by the Centers for Disease Control.

Consider that supply shortages remain the greatest hindrance to the current global vaccination effort, but only a portion of the world's possible production capacity for COVID-19 vaccines is being used. Simply permitting other potential manufacturers, most especially those in developing countries, to develop these vaccines immediately overcomes the first hurdle toward increased global vaccine supply. All regions of the world have at least some sites ready to begin manufacturing immediately — they simply require access to the trade secrets currently guarded by pharmaceutical firms' intellectual property thickets.

The United States and its allies, moreover, can and should help other sites procure the necessary equipment and expertise. Doing so will be a straightforward logistical necessity in the long term, as the virus mutates and new vaccine formulations are regularly needed. The World Health Organization's head of vaccine development Martin Friede has stated that in the long-term, every world region will need a facility that fully owns its production know-how.<sup>7</sup>

Drug manufacturing knowledge, moreover, is not zero-sum: by open-sourcing vaccine creation technologies, the United States does not sacrifice any of its own vaccine supply, even as current estimates hold that the United States has purchased more vaccines than it shall need to end its immediate pandemic. The only things keeping this vaccine production knowledge restricted — and thus severely hampering the planet's potential vaccine production capacity — are government-granted legal barriers, namely intellectual property rights.

Critics of the TRIPS waiver proposal have argued that patent-holding companies are already negotiating private deals to share IP-protected information, increase production, and reconfigure factories.<sup>8</sup> The scale at which this can occur is limited by corporate profit incentives and relationships. Waiving IP rights around COVID-19 vaccine production would enable any facility with the requisite equipment to pursue forced technology transfer, as needed, and to begin production. Waiver opponents' argument also tacitly concede that sharing manufacturing knowledge currently protected by intellectual property rights is indispensable to ending the pandemic globally — if it is good for private firms to share their knowledge in a limited, profit-driven capacity, why would it not be better still to share this information at a global scale?

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<sup>7</sup> Aisling Irwin, "What it will take to vaccinate the world against COVID-19," *Nature*, March 25, 2021, <https://www.nature.com/articles/d41586-021-00727-3>.

<sup>8</sup> Editorial Board, "Watch Out for a Vaccine Patent Heist," *Wall Street Journal*, March 28, 2021, <https://www.wsj.com/articles/watch-out-for-a-vaccine-patent-heist-11616959785>.

sharing of this expertise worldwide — in the long term, doing so is both necessary and likely far cheaper, as new vaccine formulations are needed to stop new COVID-19 variants. Moreover, warnings that companies will refuse to invest in drug development without the profit guarantee of intellectual property are ludicrous. Private industry is almost never the primary financial backer of vaccine development. This is due to high costs, low chance of success, and as Xue and Ouellette have argued, the fact that vaccines are single-use, preventative, durable goods rather than more lucrative treatments requiring repeated purchase.<sup>9</sup> Instead, companies like Novavax, Moderna, Pfizer and others profiteer from research breakthroughs principally funded by governments and non-profits worldwide — \$17.2 billion from the U.S. government alone — using intellectual property protections and benefitting from market concentration to extract higher rents. Refusing these firms their rent-seeking off of research that the federal government paid for is not only just, it makes sound economic sense.

Consider, in plain terms, the moral implications of inaction. If it refuses to waive intellectual property protections on the technologies and trade secrets needed to produce COVID-19 vaccines, the Biden administration would be tacitly stating that it believes the profiteering of one of the world's most lucrative industries off of the entire world outweighs the basic moral case for aiding the sick and preventing unnecessary death;<sup>10</sup> the health needs of both the United States and all humanity to eradicate a deadly and fast-mutating virus; and the specific diplomatic goals of the United States to compete against Russia and China.

We urge the administration to consider the national security, diplomatic, and moral cases, and immediately support the TRIPS waiver proposal.

### **March-in Rights Under The Bayh-Dole Act**

While U.S. support of a TRIPS waiver at the WTO is necessary to free the existing COVID-19 vaccines from intellectual property protections, the United States federal government must still enact domestic policy to carry out the waiver's intent. Thankfully, there are measures under American law to waive at least some of the requisite intellectual property rights through existing executive power.

Under the Bayh-Dole Act of 1980, a federal agency which provided funding toward the creation of an invention — such as a vaccine — can require the invention's patent-holder to grant licenses to responsible applicants. Two of the three COVID-19 vaccines currently in use in the U.S. were created in part thanks to \$13 billion worth of government-sponsored research under Operation Warp Speed, and previous vaccine related investments totalling \$17.2 billion prior to 2020.<sup>11</sup>

The Bayh-Dole Act narrowly allows forced licensing of patented technologies, but has no power over other forms of intellectual property, such as copyrights or trade secrets. Still, it is a powerful tool that has gone underutilized even since the Bayh-Dole Act's passage in 1980, most especially in the field of pharmaceuticals. Where COVID-19 vaccine-related technologies that were developed through

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<sup>9</sup> Qiwei Claire Xue and Lisa Larrimore Ouellette, "Innovation policy and the market for vaccines," *Journal of Law and the Biosciences* Volume 7, Issue 1 (2020): 1-41, <https://doi.org/10.1093/jlb/ljaa026>.

<sup>10</sup> Fred D. Ledley et al., "Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies," *JAMA* Volume 323, Issue 9 (2020): 834-843, <https://jamanetwork.com/journals/jama/fullarticle/2762308>.

<sup>11</sup> Reuters, "Moderna gets further \$472 million U.S. award for coronavirus vaccine development," CNBC, July 27, 2020, <https://www.cnbc.com/2020/07/27/moderna-gets-further-472-million-us-award-for-coronavirus-vaccine-development.html>.

government funding are specifically patented, and not protected through other forms of intellectual property, the administration must utilize these provisions of the Bayh-Dole Act immediately.

However, the Bayh-Dole Act provisions — known as “march-in rights” — is now imperiled by a late-Trump era rulemaking process. The National Institute of Standards and Technology (NIST) recently concluded its comment period on a rulemaking process that would narrow interpretation of the Bayh-Dole Act to eliminate march-in rights on drug patents.<sup>12</sup> The technical provision being addressed is a rule change to interpret a requirement that the subject inventions be made “available to the public on reasonable terms” to preclude price as allowable grounds for march-in, no matter how unreasonable or extortionate such pricing might be and no matter how much the government had de-risked research & development and even clinical trials.

NIST is under no obligation to proceed with enacting the rule after the comment period closes. If NIST Acting Director Dr. James Olthoff does not affirmatively commit to refusing further activity on the Trump-era rule, the administration must immediately replace him. In fact, the U.S. should reverse course 180 degrees and adopt a new regulation clarifying that unreasonable pricing provides legitimate grounds for march-in.

This ahistorical rule would ignore the clear arguments in favor of march-in rights over drug prices at the time of Bayh-Dole’s passing.<sup>13</sup> The only beneficiaries of such a rule would be multibillion-dollar pharmaceutical corporations. Average Americans, moreover, would lose access to one of the federal government’s strongest potential tools for curbing the price of prescription drugs and medications, which is a priority for the President.

### **Section 1498 Powers**

The federal government can also invoke 28 USC § 1498, also known as Section 1498, to pay patent holders for immediate use of patented technologies. This statute has been used during both world wars, and in the aftermath of 9/11,<sup>14</sup> so its usage during a time of global crisis is unquestioned. Thus, it can and should be used during the COVID-19 crisis to pay for immediate usage of patented vaccine technologies, where applicable. Moreover, nothing requires Section 1498 to solely be used during discrete national emergencies. Using Section 1498 would directly save lives at home and abroad, and it merely requires some discretionary funding and a Presidential signature.

### **Personnel And Intellectual Property**

The COVID-19 pandemic had powerfully demonstrated how the artificial constraints of intellectual property can drive public health outcomes that lead to unnecessary loss of life, solely for the sake of the

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<sup>12</sup> Lee Fang, “Last-Minute Trump Rule Would Let Vaccine Makers Hike Prices Unchecked,” The Intercept, April 2, 2021, <https://theintercept.com/2021/04/02/covid-vaccine-price-hikes/>.

<sup>13</sup> Peter S. Arno and Michael H. Davis, “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research,” Tulane Law Review Volume 75, Issue 631 (2001): 631-693, <http://www.cptech.org/ip/health/bd/arnodavis012001.pdf>.

<sup>14</sup> Christopher Morten and Charles Duan, “Who’s Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises,” Yale J.L. & Tech. Volume 23, Issue 1 (2020): 1-96, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3685413](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3685413).

institutional, competitive interests of pharmaceutical firms. These outcomes are immoral, antithetical to the strategic and diplomatic interests of the United States, and in part avoidable by merely exerting existing executive-branch powers. Thus, we call on the administration to consider the lessons of the COVID-19 pandemic when nominating appointees to intellectual property-related positions across the federal executive branch, most especially for the Director of the Patent and Trademark Office, the Director of the National Institute of Standards and Technology, and the Commissioner of Food and Drugs.

We urge you and all Biden administration officials to use maximally the executive branch's existing powers to undo the power of intellectual property provisions in responding to the COVID-19 pandemic, whilst looking in the long-term at ways of rethinking and reorganizing IP rights in the pharmaceutical industry altogether, especially through existing executive-branch powers.

Signed:

American Economic Liberties Project  
Center for Economic and Policy Research  
Consumer Action  
Debt Collective  
Democracy For America  
Demand Progress Education Fund  
Electronic Frontier Foundation  
The Freedom BLOC  
Greenpeace US  
Indivisible  
Open Markets Institute  
People's Parity Project  
Project Blueprint  
Revolving Door Project  
Social Security Works  
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