

# Biden's Wink at Global Theft of U.S. Vaccine Patents Is Bad for America and the World

*James M. Roberts*

## KEY TAKEAWAYS

In early May, the Biden Administration said it would support the waiver of international intellectual property rights protections for American-made COVID vaccines.

Federal intervention to weaken property rights with price control or undermining patent protection will kill innovation and destroy markets and economic development.

Congress must reject the waiver of IP protection for U.S. COVID vaccines, oppose the compulsory licensing, and provide countries in need vaccines at low cost.

The world is still reeling from the novel coronavirus that emerged from Wuhan, China, more than one year ago. The most effective mRNA COVID-19 vaccines have been created and manufactured (in record time) by U.S. companies (Pfizer, Moderna, and Johnson & Johnson), and a clear majority of grateful Americans have now been inoculated with them. Meanwhile, much of the developing world is still in desperate need of vaccines, and Americans naturally want to help. The question is how.

In early May, the Biden Administration said it would support the deliberate waiver of international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.<sup>1</sup> The World Trade Organization's (WTO's) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement is the global mechanism to protect member countries'

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IPR. The Administration wants to waive TRIPS protection<sup>2</sup> for U.S. pharmaceutical manufacturers of COVID-19 vaccines and allow countries to issue “compulsory licenses”<sup>3</sup> to permit their domestic pharmaceutical companies to manufacture drugs invented and patented by (in this case) U.S. companies—without adequate compensation to them.

The net result of compulsory licensing is to legalize the theft of the intellectual property of those vaccine makers—and of IPR for other pharmaceutical products. A TRIPS waiver signals that the United States will not seek to enforce IPR protections in cases of infringements of American companies’ patents.

Practically speaking, the actual manufacture and distribution of pirated American vaccines by countries such as India and South Africa—a capital-intensive, state-of-the-art technological process that, among other things, requires an advanced infrastructure for cold supply-chain distribution—is not very realistic.

The U.S. should join other developed countries (Australia, Canada, Japan, Norway, Switzerland, the countries of the European Union, and the United Kingdom)<sup>4</sup> in opposing the waiver of TRIPS Article 31bis.<sup>5</sup> As many defenders of property rights (e.g., the American Action Forum) have observed, waiving TRIPS protections would not solve problems developing countries face when trying to scale up COVID-19 vaccine production. It would, however, “encourage IP abuse and distort market forces and innovation.”<sup>6</sup>

## The Importance of Protecting U.S. Intellectual Property Rights

The extent to which a government enacts and enforces laws that protect Intellectual Property Rights is a factor in calculating the Property Rights’ indicator score in the annual Heritage Foundation *Index of Economic Freedom*.<sup>7</sup> Property rights is one of three indicators in the *Index*’s Rule of Law pillar. Even-handed property rights protection by the government through the enforcement of contracts is essential to ensuring equity and integrity in the marketplace.

As Heritage visiting legal analyst Adam Mossoff has noted,<sup>8</sup> government intervention to weaken property rights through price controls or by undermining patent protection (e.g., through compulsory licensing) would demolish “innovation, destroy markets, and stymie or degrade economic development.” He continues:

We should prevent politicians and activists from exploiting the COVID-19 crisis to undermine both patents and biopharmaceutical advancement—harming people today and preventing an effective response to the next pandemic.<sup>9</sup>

## Background on TRIPS

The primary U.S. law used to protect American IPR internationally is Section 301 of the Trade Act of 1974.<sup>10</sup> Through that statute, a congressionally mandated “Special 301” report is produced annually through which the United States Trade Representative (USTR) is “to identify foreign countries that deny adequate and effective protection of IPR or fair and equitable market access to U.S. persons that rely on IP protection.”<sup>11</sup> A country listed in that report as a priority foreign country (PFC) has been found to engage in or permit onerous and egregious practices. Once a PFC has been so identified, the USTR must open a Section 301 investigation, which may lead to some form of trade sanctions for IPR violations.

As the Office of the USTR notes, the Special 301 report documents address (among other things):

a wide range of concerns that limit innovation and investment, including: (a) the deterioration in the effectiveness of IP protection and enforcement and overall market access for persons relying on IP in a number of trading partner markets; [and] (b) reported inadequacies in trade secret protection in countries around the world, as well as an increasing incidence of trade secret misappropriation.<sup>12</sup>

The theft by actors in foreign countries of the trade secrets in patented pharmaceutical products made by American companies constitutes a Special 301 violation.

Waiving patent protection also opens the door to the overseas production of *counterfeit* vaccines that could be ineffective—even deadly. As the authors of a study commissioned by the National Institutes of Health report:

Counterfeit drugs pose a public health hazard, waste consumer income, and reduce the incentive to engage in research and development and innovation.... [C]ounterfeit drugs may raise concerns among consumers about safety and may reduce patient medication adherence.<sup>13</sup>

Although the amended TRIPS Article 31bis<sup>14</sup> says that the pharmaceutical companies whose patents have been infringed through compulsory

licensing should be remunerated, it leaves the decision as to when and how much compensation should be paid to the patent holders up to the WTO-member government that is demanding the compulsory license.

Since the amended TRIPS agreement is vague and does not prescribe a definite timeline or formula to calculate the amount of remuneration, in practice the compulsory licensing amounts to the legalized theft of patent holder's intellectual property.

## Bipartisan Opposition to TRIPS Waiver

The Biden Administration's policy is a bad one for many reasons. It signals to the world that the United States will not fight to defend the intellectual property rights of American companies. That means the Administration is *actively* undermining innovation and manufacturing in one of the American economy's most vital and leading-edge sectors—health care and medicines.

As Senator Chris Coons (D-DE) has noted, waiving IP rights for vaccines would disincentivize development of necessary vaccines. To wit:

And that willingness of the key inventors and developers of mRNA vaccines and other vaccines and other therapeutics—their willingness to license and to manufacture and distribute at cost or as donations—these vital tools in the global war on this COVID pandemic suggests that it's not IP rights that are really centrally at issue.

In fact, if anything, IP has enabled historic licensing and partnerships. Some of the IP waivers and some of the collaboration that's happened in the midst of this pandemic I think points to the ways in which IP has actually not been a barrier, but a facilitator of critical, cutting-edge innovation.<sup>15</sup>

Senator Chuck Grassley (R-IA), joined by other Senators, has also registered his strong opposition to the waiver. Grassley objected to the Administration's announcement of a TRIPS waiver without first consulting Congress.

This administration has agreed to give the intellectual property dealing with the virus vaccines away. And I would simply say, from a practical standpoint, that isn't necessary because Pfizer said by the end of the year...they're going to be producing seven billion shots a year.... And just think what that will do if this stuff is produced somewhere else, giving away something that we accuse China of stealing

every day—our intellectual property.... So, here, we're having a trade policy that's supposed to build back better—the president's words—and then last week they just do something that's going to hurt jobs in America," he continued.<sup>16</sup>

European countries also distanced themselves from the Biden proposal to waive patent rights on coronavirus vaccines. They said the emphasis should be on vaccine production. Reuters reported French President Emmanuel Macron as saying that the question of sharing patents “was not the issue of the day,” and that experts believe the “waivers could take years to negotiate, and would not address the immediate need to manufacture more doses fast.”<sup>17</sup>

## The Left's Long War Against Pharmaceutical Patents

Tactics by leftists seeking to break U.S. pharmaceutical patents for what they claim are altruistic reasons have a long history. Perhaps their most notable assault on IPR protection was when, about two decades ago, the activist group ACT-UP successfully pressured the U.S. Food and Drug Administration and the U.S. government to issue compulsory licenses for HIV/AIDS drugs.<sup>18</sup>

The decision (implemented in 2005) to amend the TRIPS agreement (in the Doha Round) to permit compulsory licensing regimes was one of the significant and negative outcomes of that activism.

Those same activists and the same leftist philosophy are at work today through a multi-pronged campaign to permit compulsive licenses at prices that do not reflect the actual value of medications. The left also continues to advocate for “free stuff” in the form of price controls on certain medicines, which has more or less the same negative impact as compulsory licenses.

If fully adopted, these wrong-headed policies would leave pharmaceutical manufacturers with fewer resources to fund the research and innovation needed to develop new drugs.

## Recommendations

Long-standing and vigorous protection of patents in the United States has stimulated unimaginable innovation and growth in the American biopharmaceutical sector. Thanks to Operation Warp Speed<sup>19</sup> and the dedicated efforts of U.S. companies themselves, vaccines to protect Americans and the rest of the world from the deadly COVID-19 virus were created, produced, and brought to market in record time.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats. The best way to prevent and treat those new diseases from again crippling economic freedom is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production. Those U.S.-manufactured vaccines can be made available to all Americans quickly, and governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

The U.S. patent protection system is and has been a bulwark of American prosperity, but the strength of that protection has been weakening in the past few decades.<sup>20</sup> Compulsory licensing contributes to the erosion of that protection.

The following recommendations will preserve innovation and growth:

- Conservatives in Congress and in other influential positions should push back vigorously against the proposed waiver under TRIPS of patent protection for U.S. COVID-19 vaccines. They should also oppose the compulsory licensing of those patents.
- Although getting effective vaccines to the rest of the world is best achieved through market mechanisms that are unimpeded and undistorted by state intervention, conservatives could consider supporting U.S. government assistance to help needy countries import U.S. vaccines at a moderate cost. The American vaccine makers are already on track to make additional billions of doses and have indicated a willingness to help.
- Congress should also consider funding technical assistance to target areas (e.g., infrastructure) that need to improve conditions for vaccine manufacture and distribution. As noted above, the issuance of compulsory licenses is essentially meaningless if countries lack the highly developed resources to produce and distribute highly effective vaccines.

And, finally:

- U.S. willingness to waive patent protection signals to the world that the Biden Administration will not stop the theft of a whole host of other, easier-to-produce patented American medicines. Conservatives have historically and should continue to oppose these wrong-headed policies.

## Conclusion

The Biden Administration claims that its IPR policy is compassionate in that it will theoretically make available more plentiful and cheaper COVID-19 vaccines to needy countries around the world. Actually, the opposite is true. Protecting vaccine IPR will incentivize production of enough vaccines to inoculate the world.

Another important reason for the U.S. to oppose waiving TRIPS is that doing so could hobble future advances in mRNA technology. As the CDC notes, “Future mRNA vaccine technology may allow for one vaccine to provide protection for multiple diseases, thus decreasing the number of shots needed for protection against common vaccine-preventable diseases.”<sup>21</sup>

Waiver of TRIPS protection under Article 31bis, then, threatens not only COVID-19 vaccines, but also future vaccines. Efforts that would hamper and disincentivize the creation and availability of future vaccines would be a terrible outcome for the world.

The U.S. government should join other developed countries opposing the waiver of TRIPS patent protection under Article 31bis. Waiving TRIPS hinders, not helps, developing countries as they seek to purchase vaccines and improve their own pharmaceutical manufacturing sectors’ ability to produce them.

**James M. Roberts** is Research Fellow for Economic Freedom and Growth in the Center for International Trade and Economics, of the Kathryn and Shelby Cullom Davis Institute for National Security and Foreign Policy, at The Heritage Foundation. Gavin Zhao of the Heritage Young Leaders Program assisted in the preparation of this report.

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