

Biden's Undermining Of U.S. Intellectual Property Rights Is Dangerous And Will Hurt Pandemic Response



Lorenzo Montanari Contributor ⓘ
Policy

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In an abrupt and unprecedented move, the Biden administration plans to strip intellectual property rights from American vaccine manufacturers. The administration completely reframed the debate on the pro IP waiver, originally petitioned last fall, by South Africa and India to the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council.

The leading voice behind the Biden surrender on IP protection was U.S. Trade Representative [Katherine Tai](#), who said, "The administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines." However, the intellectual property rights of innovators are not a barrier to the rapid acceleration of COVID-19 production the world needs.

German Chancellor [Angela Merkel](#) was the first world leader standing strongly against the Biden position. She said, "I made clear here already that I don't believe that releasing patents is the solution to provide vaccines for more people."

EU leaders pushed back against the Biden move during the recent European Council summit in Oporto, Portugal. "On the intellectual property, we don't think in the short term that it's the magic bullet but we are ready to engage on this topic as soon

as a concrete proposal will be put on the table,” European Council President [Charles Michel](#) said. French President [Emanuel Macron](#) clearly stated, “The priority today is not intellectual property — [...] It’s production.” “Today” Macron continues “the [Anglo-Saxons](#) are blocking a lot of these ingredients and vaccines. Today 100 percent of the vaccines produced in the United States of America go to the American market” while the EU has produced 400 million doses while exporting 200 million to 90 countries. “We should be open to this discussion, but when we lead this discussion there needs to be a 360-degree view on it because we need vaccines now for the whole world.” Ursula von der Leyen, President of the EU Commission also critical to White House position says, “And in the short and medium-term, the IP waiver will not solve the problems, will not bring a single dose of vaccine in the short and medium-term.”



WASHINGTON, DC - MARCH 29: U.S. President Joe Biden delivers remarks on the COVID-19 response and ... [+] GETTY IMAGES

It is more than one year since the World Health Organization declared the COVID-19 outbreak a global pandemic—a health crisis that has seriously affected human life and the global economy. Since then, the global economic growth dropped [an estimated 3.9%](#) due to lockdowns. Nevertheless, in record time scientists have pioneered new vaccines. [1.32 billion](#) doses have been administered so far. On

average, pharmaceutical companies and some countries like the [USA](#) and [Germany](#) invested \$300 million to discover new mRNA vaccines without the guarantee of success. Today in the USA about [40% of Americans](#) have received at least one shot and roughly [1 in 4 are fully vaccinated](#). According to the Tufts Center for the Study of Drug Development, on average it takes 12 years from the discovery phase to market approval with an average cost of [\\$2.6 billion](#). Less than 12% obtain the approval and enter the market. IP rights are the only guarantee for inventors to own the know-how and the knowledge and to recoup R&D costs and invest in the next generation of medicines.

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President Biden seems to use the IP waiver more as a geopolitical tool rather than a humanitarian approach. The main beneficiaries of the waiver will be China and India. “In fact,” as former U.S. Undersecretary of Commerce for Intellectual Property [Andrei Iancu](#) says, “the push by India and South Africa appears to be disingenuous, aimed not at curbing the pandemic but at allowing domestic companies to make money off of others' intellectual property.”

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Even if India is the world's biggest vaccine manufacturer, the country is completely behind the national mass vaccinations. Nevertheless, [Adar Poonawalla](#), CEO of the

Serum Institute of India, the world's largest vaccine manufacturer that is licensed to produce millions of vaccines for AstraZeneca and Novax, does not consider IP a barrier to mass vaccine distribution, “No. There are enough manufacturers, it just takes time to scale up.”

Overriding patent protection is a dilemma that emerges every time there is a health pandemic. This dilemma is an endless ideological debate driven more by countries that believe in a free-rider and anti-market ideology rather than real innovation based on patent protection. On one hand, the anti-IP block is now led by the USA under Biden, India, South Africa, China as well as more than 100 developing countries and international charity organizations such as Médecins Sans Frontières and Human Rights Watch. On the other hand, the pro IP block, led by the [European Union](#), [Japan](#), Norway, Canada, Australia, U.K., and Switzerland, is defending intellectual property rights as the backbone of innovation noting without it, it would not be possible to discover mRNA vaccines and to prevail over global health emergencies. It is not IP rights that are limiting the access to vaccines around the world but mainly the lack of production sites, distribution plans, logistics, and rule of law without mentioning bureaucracy and corruption.

The IP waiver is an attack on our health because stripping patent protection will affect the quality control of vaccine manufacturing especially on the quality of raw materials. Producing vaccines is not like producing candies, it implies a high standard of production and consolidated manufacturing plants. We should move away from this emotional and ideological approach that removing IP will end the pandemic. We should focus on the real problem that is affecting the global vaccination system: the different export bans implemented until now, for example, by the Biden administration and the United Kingdom.

Again [Adar Poonawalla](#) denounced, during a recent World Bank panel, that Biden's Defense Production Act blocked the export of key raw materials critical for manufacturing vaccines. “If we're talking about building capacity all over the world,” Poonawalla says “the sharing of these critical raw materials is going to become a critical limiting factor — nobody has been able to address this so far.”

The vaccine waiver is a distraction that penalizes the vibrant biotechnology sectors instead of addressing the root of the problem: manufacturing bottlenecks.

According to UNCTAD, “The use of NTMs was noticeable with nearly 300 measures applied, as of March 15, 2021. Trade restricting NTMs included export restrictions of various forms to prevent shortages of essential goods, and stricter SPS requirements to ensure product quality and safety. [...] However, 60% of them are still in place and NTMs on vaccines are starting to appear.”

“The WTO would do much better” IP and trade specialist [Philip Thompson](#) says, “to discuss removing obstacles to the trade of COVID-19 related items than removing intellectual property rights.” The lack of vaccine distribution is related to non-trade measures (NTMS) not on IP rights. WTO created the TRIPS agreement to make sure IP, as well as patents, are protected in a way to create legal access to IP for any countries without stripping the fair IP protection. One solution during pandemic times is an appropriate IP licensing system that aims not only to defend inventors but mainly protect all citizens. While another crucial tool is the WHO’s [COVAX](#) program “aims to ensure all countries have access to a safe, effective vaccine.” COVAX’s goal is to deliver at least 2 billion COVID-19 doses by the end of 2021, hopefully reaching almost 20 percent of people in middle-income countries. An international letter signed by a record [101 think tanks](#) from 47 countries calls the TRIPS agreement “the most comprehensive multilateral agreement on IP and the most effective instrument for ensuring that governments take steps to protect IP.”

Republican Congressman Byron Donalds (R-Fla.) is working on a [new piece of legislation](#) titled "Preventing Foreign Attempts to Erode Healthcare Innovation Act" to block the White House IP waiver position and to "prevent the Biden Administration from senselessly giving away America's intellectual property to countries like China". IP rights are enshrined in Article 1, Section 8, Clause 8 of the U.S. Constitution of 1787, “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.” As a central pillar to American history and constitutionalism for 244 years, IP converges tradition and progress to enrich the lives of citizens and society.

Waiving IP rights not only goes directly against America’s core values and threatens public health but wanes potential for bipartisan efforts. “Congress has spent decades wrangling over the contours of patent protections,” [WSJ’s Kimberley A. Strassel](#) says, “producing bipartisan legislation from the Bayh-Dole Act of 1980 and

the Hatch-Waxman Act of 1984 to the Leahy-Smith Act of 2011.” All these bipartisan efforts to defend American inventors with a strong and fair IP system risk being seriously damaged with this Biden move.

Removing IP rights would make it more difficult for innovators to share the technology and know-how needed for manufacturers to produce genuine and effective vaccines. Without firm IP rights, authorities will have difficulty determining genuine products from the sea of counterfeit, substandard, and falsified vaccines the waiver invites. Vaccine hesitancy will likely increase. It is simple: no IPs, no vaccines, no lives saved.

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Lorenzo Montanari

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