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Constitutional & Administrative Hurdles of a Covid-19 IP Waiver

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The Biden administration's support for a worldwide waiver of certain intellectual property rights to help fight the Covid-19 pandemic reinvigorated discussions on whether IP rights may act to help or hinder the swift and widespread development and deployment of vaccines and other resources to combat the virus. The member countries of the World Trade Organization (WTO) were at an impasse on the scope and duration of any such waiver, and negotiations are likely to continue throughout the remainder of 2021.

But if and when an agreement is ultimately reached, the responsibility for implementing the waiver on a country-by-country basis will fall to the WTO member nations. And here in the U.S., the fact that many types of IP are property rights protected by the U.S. Constitution may present unique (and potentially substantial) hurdles for Congress.

Yet this would not be the first time that the U.S. government took action to abrogate IP rights in a certain sector, and history may hold clues for potential avenues that the government may use to implement any WTO waiver and minimize any constitutional issues. This article focuses on the existing proposals and—should they be adopted—what hurdles the U.S. government may face in implementation.

WTO Covid IP Proposals

On Oct. 2, 2020, India and South Africa [proposed a waiver](#) of IP protections, including patents, trade secrets, copyright, and industrial design, for Covid-19 related medical technologies. The goal of the proposal was to avoid creating barriers through IP protections “to the timely access to affordable medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat Covid-19.”

Indeed, the proposal recognized the difficulties of meeting global demand for new diagnostics, therapeutics and vaccines for Covid-19 in sufficient quantities and at an affordable price—a problem we have seen throughout 2021, including as the [delta variant proliferates](#).

On behalf of the Biden administration, Ambassador Katherine Tai, the U.S. Trade Representative, [expressed support](#) for waiving certain IP protections for Covid-19 vaccines. The U.S. committed to negotiating in support of this waiver at the WTO “in service of ending this pandemic.” Shortly thereafter, on May 25, 2021, India, South Africa, and several other member countries of the WTO [proposed a revised waiver](#) of intellectual property rights under TRIPS (the agreement on Trade-Related Aspects of Intellectual Property Rights).

The update narrowed the scope of the proposed waiver to “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of Covid-19.” The revised proposal also limited the waiver to three years, which the General Council may extend in the event of exceptional circumstances.

The EU has not endorsed the Covid-19 IP waiver. Instead, the EU's counterproposal relies on the support of pharmaceutical companies, manufacturers, and developers to increase vaccine exports and preserve an affordable vaccine supply chain. The EU also urges WTO members to exercise their authority to grant compulsory licenses, including for the manufacture and export of Covid-19 vaccines. Compulsory licenses require “adequate remuneration” be paid to the rights holder. However, individual member states control the compulsory license process, which is often complicated and time-consuming. Moreover, the patents and know-how necessary for the prevention, treatment, or containment of Covid-19 are held by a variety of companies and would each require their own compulsory license.

Due Process & Takings Challenges in the U.S.

Though the Biden administration stated its support for the Covid-19 IP waiver, implementing any waiver or abrogation of intellectual property protections in the U.S. to effectuate any WTO agreement would take an act of Congress. And if it takes such steps, Congress risks violating constitutional obligations, including under the Due Process and Takings Clauses of the Fifth Amendment.

The Fifth Amendment requires both that no person shall be “deprived of ... property, without due process of law” and that private property shall not be taken for public use without just compensation. Though distinct from real or personal property, intellectual property is private property subject to the Fifth Amendment's protections. The Supreme Court confirmed that “[a] patent confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation[.]” The Supreme Court also explicitly held that property rights in trade secrets are protected by the Taking clause of the Fifth Amendment.

The proposed Covid-19 IP waiver strikes at the heart of both of these forms of IP. Congress explicitly grants a patent owner the exclusive right to make, use, and sell its patented invention. Likewise, trade secrets derive value from being kept secret. Indeed, trade secret owners must take “reasonable measures to keep such information secret”—that is, exclude others from knowing the trade secret.

By allowing companies to practice a patent without fear of liability, or forcing a trade secret owner to disclose valuable confidential information to potential competitors, a Covid-19 IP waiver would prevent the owners of the affected intellectual property from exercising their right to exclude: “one of the most treasured strands in an owner's bundle of property rights.”

Thus, the waiver and potential forced disclosure of valuable confidential information would dramatically undermine the rights holders’ interest in their IP. Under the Fifth Amendment's due process requirement, an IP owner should receive notice sufficient to apprise them of the proceeding—for instance, what property is being taken, by whom, and for what use. Additionally, they should receive some form of hearing—here, for instance, perhaps to contest whether the intellectual property at issue actually falls within the scope of any Covid-19 IP waiver as relevant to the prevention, treatment or containment of Covid-19.

And while it is well-established that private property may be taken by the government for “public use,” the Fifth Amendment's Takings Clause requires that “just compensation” be paid to the owners of such property—including the owners of intellectual property. Otherwise, IP owners—including pharmaceutical companies and suppliers affected by the waiver—would have to “bear public burdens which, in all fairness and justice, should be borne by the public as a whole,” in contravention of the Fifth Amendment.

If, in implementing any Covid-19 IP waiver, the U.S. does not proactively provide IP owners with appropriate due process and just compensation, the government may face significant legal challenges. Individual aggrieved IP owners or trade associations might seek injunctive relief in federal courts prohibiting the enforcement of the Covid-19 IP waiver, along with a declaration that the waiver is unconstitutional as a violation of due process or of the Takings Clause.

And even if injunctive relief is not granted IP owners may bring suit under the Tucker Act, 28 U.S. Code § 1491, in the U.S. Court of Federal Claims, seeking monetary damages adequate to compensate them for the loss of IP rights. The Supreme Court has noted that an award of monetary damages generally satisfies the Fifth Amendment's requirement of just compensation. But any such constitutional claims in the U.S., whether seeking injunctive relief or damages, are likely to be limited to remedying domestic actions taken by the U.S. government—the U.S. Constitution does not protect against action taken by foreign governments abroad.

What Can History Teach Us?

This is not the first time that Congress has sought to abrogate IP rights in perceived furtherance of the public good. Through the Atomic Energy Act of 1946, Congress created a “triple regime”: limiting or preventing patentability; allowing government acquisition through condemnation; and providing compulsory licensing for inventions concerning fissionable material and atomic weapons.

Essentially, to encourage innovation and ensure that the U.S. was at the forefront of atomic technology, both for its own defense and security and for social and economic benefit, the U.S. abrogated certain patent protections and required the disclosure of atomic inventions. This statute and its implementation provides some guidance for how Congress might approach implementing a Covid-19 IP waiver and compensate IP owners for any rights they have sacrificed.

By limiting and prohibiting the patentability of certain inventions, the Atomic Energy Act went farther than the current proposals. Here, the waiver of patent rights would not fully abrogate patent protection for certain inventions, but rather provide a temporary reprieve from enforcement related to Covid-19. Additionally, under the Atomic Energy Act, Congress

also required the timely and complete disclosure of nuclear inventions either through a patent application or otherwise to the Atomic Energy Commission.

This Commission was an important part of the Act's legislative regime. It had the power of eminent domain over inventions concerning fissionable material and atomic weapons, whether or not they were subject of a patent or patent application. The Atomic Energy Commission had the authority to designate a Patent Compensation Board, to provide just compensation for inventions precluded from patentability. The Commission could also grant compulsory licenses to the relevant patents and inventions, provided the Commission determined it was in the public interest to do so.

Thus, the Atomic Energy Act provided a process for limiting intellectual property protections, granting licenses if necessary, and determining appropriate compensation for the affected IP owners. A potential Covid-19 IP Commission could likewise determine whether particular IP rights are related to the prevention, treatment or containment of Covid-19 such that they fall within any future Covid-19 IP waiver, if a license to that IP would be in the public interest, and the amount of compensation appropriate under the circumstances.

Whether these procedures would pass constitutional muster would be an open question, but they would at least provide a starting point toward ensuring that the implementation of any Covid-19 IP waiver does not violate the constitutional rights of American IP owners.