

# What Is a ‘Patent Waiver’ Anyway? Zooming Out on the TRIPS COVID-19 IP Waiver Debate

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Scientists, engineers, and everyday people have developed solutions for testing, preventing, and treating the COVID-19 disease. Ordinarily, we wouldn't think twice about granting patents on these inventions. But, today, when COVID-19 is spreading all over the world and killing millions of people, some world leaders are questioning whether we should be granting the exclusionary rights of patent protection on inventions that help respond to the pandemic. Included in that group is the Biden-Harris Administration, which, [in May, announced](#) their support of an “IP waiver” on COVID-19 vaccines.

## Patent Waiver

The “patent waiver” is a [proposal](#) to waive certain provisions of the [Trade-Related Aspects of Intellectual Property \(TRIPS\) Agreement](#) for three years. The TRIPS Agreement requires certain member countries (Members), including the United States, to have certain minimum intellectual property protections. While this proposal is often referred to as a “patent waiver,” the proposal would also waive sections associated with copyright, industrial designs, and undisclosed information.

The proposal seeks to waive Part II, Section 5 Patents of the TRIPS Agreement and the associated enforcement sections only with respect 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” for a period of three years. Article 27 of Section 5 requires that certain Members issue patents to inventions that “are new, involve an inventive step and are capable of industrial application.” However, Members have the option to refuse to grant patents to certain categories of inventions, including, “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” Article 28 explains that an owner of a patent can prevent others from “making, using, offering for sale, selling, or importing” (infringing) the patented inventions. Finally, Part III of the TRIPS Agreement explains the potential consequences of infringing a patent. Among other things, the infringer can be liable for money damages and the judicial authority of the Member may order injunctions.

Therefore, as the TRIPS Agreement currently stands, each Member must have patent laws that give patents to inventions that meet certain requirements, and each must provide avenues for patent holders to enforce its patent rights. As applied to the current situation, Members are required to grant patents to qualifying inventions related to “the prevention, containment and treatment of COVID-19” (with exceptions for pharmaceuticals if the Member

does not allow pharmaceutical patents). Infringers could be liable for money damages and the judicial authority of the Member may order injunctions.

If provisions in Part II, Section 5 and the associated enforcement sections are waived, Members would no longer be required to issue patents or provide avenues for patent holders to enforce patent rights. The proposal does not, however, require Members to waive their own domestic patent rights. In other words, the proposal to waive certain provisions of the TRIPS Agreement, the “patent waiver,” does not directly waive any patent protections. Rather, the patent waiver grants to Members permission to waive their own domestic patent protections.

Patent laws are geographically limited; they only protect an invention in the country that issued the patent. For example, one cannot make, use, offer to sell, sell, or import an invention protected only by a U.S. patent in the United States; however, one may do those things in another country where corresponding patent protection does not exist. Therefore, in order to waive patent protections worldwide, each Member subject the TRIPS Agreement’s requirement to have certain minimum intellectual property protection would have to waive its own domestic patent protections.

The U.S. patent laws are codified in Title 35 to the U.S. Code. It provides that inventors may obtain patents for their new and useful inventions and infringers are liable for making, using, offering to sell, selling, or importing into the U.S. patented inventions without the patent holders consent. Because the power to enact patent laws lies with Congress, Congress would likely have to waive these laws. If Congress chooses not to waive the U.S.’s patent laws, patent holders will continue to be able to enforce their U.S. patent rights in the United States.

### **Will This Solve the Problem? Arguments in Favor and Against**

Proponents argue that patent protections are a barrier to widespread vaccine distribution. Opponents, however, assert that a patent waiver will do little to improve widespread vaccine distribution, particularly in developing countries, and instead will hinder innovation. A patent waiver would not require developed countries, like the United States, to provide the necessary supplies and technical expertise to other countries or mandate transfer of essential know-how. In contrast, the patent waiver would merely prevent the vaccine manufacturers from seeking exclusion rights via intellectual property protection. Accordingly, developing countries might have the right to manufacture and distribute the vaccines without fear of infringement, however, the question of if developing countries would be able to effectuate this right is a concern. For these reasons, many opponents suggest that instead of implementing a patent waiver, developed countries should increase exports of the COVID-19 vaccine to those countries in need.

### **Practical Implications**

Whether a patent waiver would result in widespread vaccine distribution is an issue of debate. What is not an issue of debate is that a patent waiver could be problematic for those companies that invested considerable time and money into developing these vaccines. If a patent waiver is enacted, everyone (including competitors) could reap the rewards of the time and money invested by those companies having developed a vaccine. That is exactly what proponents of the patent waiver want, but it certainly is not “fair” to those companies who invested the time and money developing these vaccines under the promise that it would receive a patent granting them exclusionary rights.

If this proposal is enacted, companies that hold patents for “the prevention, treatment or containment of COVID-19” should closely monitor which, if any, countries waive their domestic patent protections and, if so, what scope the waiver is limited to. In its current form, the patent waiver would waive rights on all inventions “for the prevention, treatment or containment of COVID-19,” but it is unlikely that a waiver would be so broad, at least in the United States. Rather, given that the Biden-Harris Administration has announced its support of patent waivers for COVID-19 vaccines, any patent waiver in the United States would likely be limited to only COVID-19 vaccines only.

## **Have a Backup Plan**

To avoid a patent waiver, companies could do two things: First, they could lobby the U.S. Congress and other countries’ lawmaking bodies to oppose a waiver of domestic patent rights. In doing so, they should point out that TRIPS Agreement already has provisions for national emergencies. Second, they should come up with an alternative solution themselves.

The Biden-Harris Administration is trying to solve a problem — to vaccinate everyone in the world so that people stop getting sick and to prevent the spread of variants of the disease. [One of the possible solutions](#) it has come up with is the patent waiver. If these companies can come up with an alternative way to solve this problem first, the United States and other Member countries will not need to waive patent protections.

If a patent waiver becomes inevitable, companies should consider proactively dedicating their patented or patentable inventions directed 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” to the public. Doing so would at least give them positive publicity.

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