



The TRIPS Waiver

If you work in an industry that uses Intellectual Property of any kind, it's probable that you have heard of the TRIPS waiver proposals. If you read newspapers or news websites, it's probable that you have heard of the TRIPS waiver proposals. If you are generally interested in the COVID-19 response and concerned about global access to vaccinations and when the pandemic may be brought under control then it's also probable that you have heard of the TRIPS waiver proposals! This article aims to explain what TRIPS is, what the waiver proposals are, and the likely timelines for discussion and implementation. It can be a deeply divisive topic and so we will refrain from opinion and restrict ourselves to the facts.

The IP Federation is a cross industry body representing companies from many sectors, including pharmaceuticals, telecoms, engineering and data management. The common thread between all members is that they are innovative, and rely on a cost effective, high quality IP framework to succeed in their industry, a view shared by many nations. As part of harmonisation of IP rights across the world, in 1994 the TRIPS agreement was signed. This is a WTO agreement on the Trade Related aspects of Intellectual Property Rights that introduced intellectual property law into the treaty framework of the global trading system for the first time.

The TRIPS agreement establishes minimum international guarantees for the availability, protection and enforcement of IP rights. It includes such "basics" as the availability of patents for inventions in all areas of technology (subject to other patentability requirements) and that the term of a patent must be at least 20 years. It also provides that a patent should be exclusive, and any exceptions to this exclusivity should be narrowly limited. Although TRIPS provides a minimum set of standards, provided that these standards are met the mechanics of how IP is protected remains a matter for domestic legislation – leading to many jurisdictional differences in how patents are granted and enforced. As TRIPS is a WTO treaty, non-compliance with any of the minimum standards, such as a reduction in copyright term below 50 years by one Member, would enable another Member to use the WTO's dispute settlement system.

A waiver to TRIPS would enable countries to legislate their individual domestic IP regimes to below these minimum standards with no violation of International Law. For example a Member country could choose not to grant monopoly rights to patentable inventions, or to allow copying of registered design rights without infringement. Provided this was in line with the boundaries of the waiver it would be acceptable.

The currently proposed waiver was submitted by India and South Africa in October 2020, asking for a waiver from TRIPS for "all health products and technologies including diagnostics, therapeutics, vaccines, medical devices and personal protective equipment for the prevention, treatment or containment of COVID-19"... WTO members would, under the proposal, have the discretion to forego "implementation, application and enforcement of the provisions of the TRIPS agreement relating to copyright, industrial design, patents and protection of undisclosed information (including regulatory test data and trade secrets)."

Any decision on whether a waiver is implemented is taken at the Ministerial Conference, the highest decision making body of the WTO. It is customary for a full consensus of all 164 Member countries to be required for decisions on waivers, however a vote could be forced if there is no agreement and a three quarters majority would be sufficient to pass.

The debate around the potential waiver exploded in May 2021 when the Office of the U.S. Trade Representative announced U.S. government support for waiving IP protection for COVID-19 vaccines, and indicating that the U.S. government would actively participate in text-based negotiations at the WTO. As a result Members agreed to enter into text based negotiations in June, discussing a slightly revised waiver proposal and a separate proposal submitted by the EU which calls for limiting export restrictions, supporting the expansion of vaccine production, and facilitating the use of current compulsory licensing provisions already in TRIPS. Updates on discussions can be found on the WTO website, from which it appears that positions are still divergent. The 12th Ministerial Conference is taking place at the end of November 2021, and advocates for the waiver are hopeful that a decision will be taken there.

Even if this were to happen, that won't be the end of the story. Should a waiver be passed there is no obligation for any individual country to implement changes in their IP law – this will be determined by each Member and is likely to result in an array of different IP provisions in jurisdictions around the world. This is of course already the case to some extent, but with the requirement for a minimum level of protection and standardisation removed one could speculate that some countries will seize the opportunity to legislate in a way that drives the removal of IP protections; particularly the disclosure of valuable know-how and trade secrets. Even if a waiver is limited temporally, once disclosed this protection is lost permanently.

The outcome of the discussions will depend in large part whether vaccine access becomes more balanced across the world regardless of whether a country is designated low, middle or high income. This will require manufacturers and governments to work together to facilitate the smoothing of supply chains and ensure equitable access to vaccine supply. It remains to be seen whether next year's *IP Federation Review* article is talking about the impact of the introduction of a waiver or not – watch this space!

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