

Coronavirus



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Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID- related Medical Products

Companies holding intellectual property in medical products used in the fight against COVID-19 should be aware of formal efforts by a group of nearly 60 developing countries, led by India and South Africa, to obtain a waiver of international intellectual property protection for patents, industrial designs, copyright and undisclosed information, which they imply is needed “for unimpeded and timely access to affordable medical products including **diagnostic kits, vaccines, medicines, personal protective equipment and ventilators** for a rapid and effective response to the COVID-19 pandemic,” according to a proposal submitted to the World Trade Organization (WTO) in October 2020 and considered at the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) most recently on February 23, 2021. The waiver request is gathering momentum and will be discussed again on March 10-11, 2021 at a WTO TRIPS Council meeting in Geneva. Companies with intellectual property related to pharmaceuticals, medical devices, diagnostics, and medical supplies should assess their risk exposure and explore their options for addressing this effort and its potential outcomes.

Existing flexibilities for developing countries. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) protects intellectual property, and recognizes that patents can be licensed either voluntarily on commercial terms, or without the authorization of the rights holder under “compulsory licenses” where “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.” (TRIPS Agreement, Article 31(b).) Countries are not required to request authorization “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” but must notify rights holders “as soon as



reasonably practicable;” and in any case must pay “adequate remuneration” to the right holder.

Notably, intellectual property rights may be protected pursuant to bilateral investment treaties or free trade agreements that protect covered investments in certain circumstances. Some such treaties reference the TRIPS Agreement while others do not.

Less-developed WTO Member countries are now seeking a complete waiver from the TRIPS Agreement for all medical products “in relation to prevention, containment or treatment of COVID-19,” notwithstanding the existing options under the WTO TRIPS Agreement for voluntary, commercial licensing and “compulsory licensing.” Even if limited in time, the waiver as proposed would be sweeping in scope, and purports to bypass both the notice and compensation provisions of TRIPS Article 31. It also ignores the possibility that a waiver of a country’s obligations under the TRIPS Agreement may not be effective as a waiver of that country’s obligations under bilateral investment treaties and/or free trade agreements.

Efforts to develop, produce, and equitably distribute medical products. WTO Members recognize that unprecedented demand for medical products used in the fight against COVID-19 has far outstripped supply of required supplies. Several WTO Members have pointed out that intellectual property protections have not limited production of vaccines and other medical products. Rather, these Members have argued that intellectual property protection has incentivized the research, development and production of the necessary vaccines, treatments and products.

Moreover, the international community is coordinating and funding equitable COVID-19 vaccine distribution globally through COVAX, which is organized by Gavi, the Vaccine Alliance, the World Health Organization and the Coalition for Epidemic Preparedness Innovations. Despite these facts, less developed countries continue to push for a waiver of all intellectual property protection for medical products related to the pandemic.

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19



vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

Intellectual property may be protected under bilateral investment treaties and free trade agreements. Bilateral investment treaties and investment chapters in free trade agreements protect foreign investment by private investors of one State in the territory of another State. In most treaties, the definition of foreign “investment” is very broad and includes intellectual property rights, as well as any right having an economic value. These treaties protect both directly and indirectly owned investments. Among the protections in the treaties are the prohibition against expropriation without fair compensation, and the obligation to provide fair and equitable treatment to foreign investments. These treaties allow foreign investors a direct remedy against a State in violation of the treaty via international arbitration to seek compensation for the State’s breach. There are more than 2000 bilateral investment treaties in force today, and numerous free trade agreements. Some of these investment treaties pre-date the TRIPS Agreement while some do not. As a result, some of these investment treaties have provisions that address the relationship between the investment treaty and the TRIPS Agreement while some do not have such provisions.

Companies holding intellectual property rights relating to COVID-19 medical products should analyze whether their rights are protected under any international investment treaty. Companies should monitor their intellectual property rights in the nearly 60 developing countries currently pushing to obtain a waiver of international intellectual property protection for those products and analyze **the remedies to which they may be entitled** should the efforts to obtain a waiver or a compulsory license ultimately harm their intellectual property rights. These States’ actions may be inconsistent with their obligations under their international investment treaties to protect the companies’ valuable IP rights, which may entitle qualifying companies to compensation, even if these States act in conformity with the TRIPS Agreement.

International arbitral tribunals constituted under international investment treaties have **broad authority to award different forms of relief, including preliminary injunctions aimed at preventing the exacerbation of the dispute.** The arbitral tribunals’ final awards are enforceable under the World Bank’s Convention for Settlement of Investment Disputes or the 1956 New York Convention on Recognition and Enforcement of Foreign Arbitral Awards. This may provide investors with leverage in their negotiations with host States or remedies if host States violate their investment treaty obligations.

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In light of developments at the WTO and potentially in less developed countries, companies that hold intellectual property in medical products related to COVID-19 should seek the advice of counsel to develop legal and policy strategies regarding the TRIPS waiver request, including (1) if they receive requests for licensing authorization, or (2) if they learn of unauthorized use of their intellectual property.



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