International Pharmaceutical Copyright Law: How COVID-19 changed the game

By Rachel Henley

Introduction:

While the United States and other developed countries offer a very high level of protection to intellectual property holders, particularly pharmaceutical companies, there is very little incentive for a pharmaceutical company that has expended significantly on the research and development of a treatment to enter it into an international market with minimal intellectual property protections for said treatment.[1] This is an international trade issue because many developing countries do not provide strong protections for intellectual property, and many do not enforce their existing protections stringently.[2] For these reasons, the World Trade Organization (WTO) adopted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

TRIPS was signed on April 15, 1994. TRIPS was intended to encourage the flow of innovation and technology between World Trade Organization member countries by creating a set of intellectual property rights that are respected in all member countries. TRIPS benefits

pharmaceutical manufacturers and, in some ways, consumers.[3] However, a uniform set of intellectual property rights for pharmaceutical products poses issues for public health in developing countries. Often, these countries lack the infrastructure to enforce stringent intellectual property laws and have populations that cannot afford the high prices that large pharmaceutical companies demand for patented treatments. Prior to TRIPS, developing countries were able to maintain low prices for essential medicines by purchasing or manufacturing comparable generic products for a fraction of the market price.[4] After the signing of TRIPS, these countries are required to enforce similarly high levels of intellectual property protections as those in the United States and other developed countries. This created a tension between the need for affordable medicine within some of the world's poorest communities and the implementation of internationally-acceptable pharmaceutical patent laws.[5]

TRIPS did leave open two opportunities for mitigating the negative impact uniform intellectual property laws for pharmaceuticals has on public health in developing countries. First, governments have the ability to grant "compulsory licenses." This means a government can grant a license to use the patented intellectual property without the rights holder's consent.[6] However, before a compulsory license may be granted, the requesting party must attempt to obtain a voluntary license from the patent holder on reasonable commercial terms.[7] This requirement can be bypassed if a country declares a state of emergency, but the patent holder is still entitled to "adequate remuneration" under the circumstances.[8] Second, TRIPS leaves open the option for parallel importation of pharmaceuticals. This is when goods are sold into a parallel market at a much cheaper price than they would be through the patent owner.[9]

The impact of COVID-19:

In October 2020, India and South Africa proposed a waiver of TRIPS' copyright, patent, industrial design, and undisclosed information sections.[10] The intention of this proposal was to ensure that intellectual property rights would not interfere with "timely access to affordable medical products … or to [the] scaling-up of research, development, manufacturing and supply of medical products essential to combat[ing] COVID-19."[11] The waiver was intended to apply to all COVID-19 related health products and technologies.[12]

In June 2022, almost two years after the initial proposal of the waiver and over two years into the COVID-19 pandemic, the WTO agreed to a modified version of the waiver that only applied to vaccines and is only applicable for 5 years. The modifications also restricted the waiver's applicability to only developing countries in the WTO and obliged countries to prevent the re-exportation of products made under the waiver.[13]

The waiver was criticized as "too little too late."[14] Its failure to cover COVID-19 diagnostics and therapeutics as well as its exclusion of developed countries as eligible manufacturers and exporters of vaccines severely limit the impact the waiver can have.[15] The waiver also only limits patent rights, and not other intellectual property rights such as trademarks and industrial designs.[16] This is inadequate to address the entirety of the intellectual property law, and thus cannot ensure global access to COVID-19 medical products.[17]

According to one study, approximately 48.5% of pharmaceutical companies expressed opposition to the proposed TRIPS waiver during the two-year period before its approval.[18] Many characterized the waiver as "an unprecedented step that will undermine [the] global response to the pandemic."[19] Almost all of the pharmaceutical companies surveyed refuted the assertion that intellectual property protections limited access to COVID-19 health technologies, citing trade restrictions, distribution issues, and scarcity of materials instead.[20] It is worth noting, however, that

WTO's 1994 Agreement on Trade in Pharmaceutical Products (Pharma Agreement) eliminates tariffs and other duties and charges on a large number of pharmaceutical products as well as the substances used to produce them.[21] In addition, the federal government provides significant funding to pharmaceutical research, with one study finding a contribution of $230 billion in federal money going to drug discovery and development from 2010 to 2019.[22] Significantly, many of the rationales offered by those who opposed the TRIPS waiver reflect the same arguments raised during the 2000s HIV/AIDS crisis, which primarily focused on the use and inefficiencies of the compulsory license exception, an option that is still very rarely exercised.[23]

What is Happening Now:

Since the adoption of the 2022 TRIPS waiver, members of the WTO have hotly debated the extension and expansion of the waiver to include COVID-19 therapeutics.[24] The original waiver set a December 17, 2022, deadline for deciding whether or not to expand the waiver.[25] However, this deadline was postponed in December 2022 to March 2023, after difficulty coming to a consensus on the issue.[26] The discussion was continued at the March meeting, but there still failed to be a consensus and the deadline was delayed indefinitely. In a June 2023 meeting of the TRIPS council, some members argued that no evidence indicates intellectual property protections constitute a barrier to COVID-19 technologies, while other members, particularly those from middle- to low-income countries, renewed their interest in expansion of the waiver.[27]

Although negotiations surrounding the expansion of the 2022 TRIPS waiver have stalled, the fact of its implementation is a big departure from previously settled international copyright law. As global public health crises become more common due to climate change and globalization, awareness of TRIPS, and its flaws, may spread. Criticism of large pharmaceutical companies has increased in the United States and the United Kingdom.[28] The passing of the 2022 TRIPS waiver

may be the beginning of a larger change in how we treat intellectual property related to life saving and essential medicines.

In the future, human rights advocates hope to see a prioritization of the population's welfare over the large pharmaceutical companies' profits.[29] The COVID-19 Trips waiver, and potential expansion, is only the first step in addressing international intellectual property law's impact on global health inequality. Further policy must be written allowing for the production of life saving medicines in developing countries that are members of the WTO.

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[2] *Id.*
[3] Naomi A. Bass*, Implications of the TRIPs Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191 (2002).
[4] *Id.*
[5] *Id.*
[6] *See* Mellino, *supra* note 1.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] Council for Trade-Related Aspects of Intellectual property Rights, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19,* IP/C/W/669 (October 2, 2020), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True [https://perma.cc/QFJ8-8U7X].
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[13] *Id.*
[14] Prabhash Ranjan & Praharsh Gour, *The Trips Waiver Decision at the World Trade Organization: Too Little Too Late!*, 13 ASIAN J. OF INT'L LAW 10, 21 (2023).
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[16] *Id.*
[17] *Id.*
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[20] *Id.*
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