



IP NEWS QUARTERLY



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INTELLECTUAL PROPERTY RIGHTS DURING PANDEMICS

Introduction

While the world grapples with the effects of the SARS-CoV-2 (COVID-19) outbreak, including economic shutdowns, isolation, and extensive loss of human life, many have their eyes on the pharmaceutical industry's attempt to develop a vaccine or treatment for the disease. However, questions arise regarding the Intellectual Property rights of a company or companies which develop such a highly demanded product. This issue of IP News Quarterly will look at the dynamics of Intellectual Property rights (with a focus on patent rights) during a pandemic and other similarly drastic times. First, legal statutes will be examined, followed by a discussion of the optics of IP, including some examples from the current pandemic, and finally a look at how the IP landscape may be affected.

Legal Statutes

In the United States, Intellectual Property is guaranteed by the United States Constitution, which gives Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries" (Article I, Section 8). This right has been described by U.S. law, most notably for patents in United States Code Title 35, for trademarks in U.S.C. Title 15 Chapter 22, for copyrights in U.S.C. Title 17, and for all three in the Code of Federal Regulations Title 37. For patents, these laws give the owner of the patent "the right to exclude others from making, using, offering for sale, or selling the invention" in the United States (35 U.S.C. § 154(a)(1)). However, under certain circumstances, these rights can be limited or revoked by the United States government.

28 U.S.C. § 1498(a) states that an "invention described in and covered by a patent of the United States [can be] used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same," provided the government provides "reasonable and entire compensation for such use and manufacture." This statute has been used several times in the past by the Department of Defense and other United States agencies. In 2001, during the anthrax attacks, Health and Human Services threatened the use of this statute as a means of obtaining a stockpile of the antibiotic ciprofloxacin after Bayer AG refused to reduce the price of the drug. This threat caused Bayer AG to produce and sell the antibiotic to the US government at a reduced cost. If the patent owner of a COVID-19 therapy refuses to sell their product at a price deemed reasonable by the US government, a similar threat may be used.

Similar to the statute described above, 35 U.S.C. § 203 gives the government the ability to require the patent owner of any invention which was discovered using federal funds to "grant a nonexclusive, partially exclusive, or exclusive license . . . upon terms that are reasonable under the circumstances." This includes drugs initially discovered at a university funded by an N.I.H. grant, or at a small business funded in part by the Small Business Innovation Research or Small Business Technology Transfer programs. Although requested a number of times, the United States government has so far never invoked this statute.

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Did You Know?

While many point out similarities between the 1918 Flu Pandemic and the COVID-19 Pandemic, there is another pandemic which caused wide-spread panic and economic instability in the U.S., The Great Epizootic of 1872. This disease only affected animals such as horses and mules, but as they were a main source of transportation and hauling essentials such as firemen, coal for steam engines, and food, U.S. industry and life was forced to a crawl as the disease spread throughout the country. With their horses and mules ill or dead, humans were suddenly required to cart their own supplies, pull their own plows, and walk rather than ride wherever they were headed.

Public Relation Optics

In general, companies want the public to have a positive view of their brand. Especially during a pandemic, balancing one's Intellectual Property rights with the optics of hoarding or profiteering on suffering can be a difficult path to navigate. For example, in March the drug company Gilead Sciences submitted an application to the Federal Drug Administration for the anti-viral drug remdesivir as a COVID-19 therapy under the "orphan drug status." Orphan drugs are designed for patient populations under 200,000, reduces some of the regulations around the drug development, and importantly gives tax credits to help alleviate some of the costs associated with the research and development. When Gilead applied, the number of people confirmed to have COVID-19 was under the 200,000 mark, but that number has obviously increased significantly since the application date. The FDA approved the orphan drug status, but in response to public outcry, Gilead refused the designation and the drug is now being treated as a normal non-orphan drug. This is important as the FDA approved the emergency use of remdesivir as a COVID-19 treatment on May 1, 2020. Similarly, *Time Magazine* published a July 7, 2020 interview with Pfizer's CEO Albert Bourla who stated that their m-RNA COVID-19 vaccines, which recently received "fast-track" designations from the FDA, "should be free to all people" and that would be charging governments only a "very nominal value." This interview was followed by a purchase agreement between Pfizer and the US government, announced in July 22, 2020, of at least 100 million vaccine doses, provided these vaccines are given to the public for free. Many other companies are promising to offer their drugs "at-cost" should they be found to be effective COVID-19 therapies. While the discussion above focuses on the pharmaceutical industry, similar struggles were seen for companies with patents on the manufacture or composition of face masks, ventilators, and other essential equipment.

Future Outlook

Many questions surround the future in the wake of the COVID-19 pandemic, and Intellectual Property is no exception. In recent years, the ability to patent diagnostic tools have waned due to claims of ineligibility under 35 U.S.C. § 101. For example, in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019), the Federal Circuit ruled that Athena's diagnostic tests attempted to patent laws of nature and thus were patent ineligible. This ruling mainly was drawn from *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), where the Supreme Court stated that the Mayo diagnostic tests lacked inventive concept and that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws." The importance of diagnostic tests has been on display, especially in the early parts of the pandemic, and having a system which values and protects diagnostic inventions is crucial. Because of this, encouraging innovation through strengthening patent protection, as opposed to the erosion of it, should be a major focus coming out of the COVID-19 pandemic. It is unlikely that the U.S. will use the legal statutes discussed above against any company that does discover a COVID-19 cure, as public pressure and other factors will certainly be reasons enough to spread the cure to as many people as quickly as possible. This is especially true considering the significant restraint the government has shown in the past as a means of upholding and supporting patent rights. However, the best way to support patent owners is to better define the conditions of 35 U.S.C. §101. As discussed in previous Quarterly News articles, §101 rejections have become increasingly common, especially for software and other computational patent applications, and the USPTO has released several changing guidelines in their attempt to fall in line with the Supreme Court's numerous decisions. Better definitions of the conditions of 35 U.S.C. § 101 have been attempted in the past, such as the proposed bill released by Senator Tillis et. al. in May of 2019, but unfortunately, these reforms have not received much traction. Perhaps the pandemic, as it has already changed much of our lives, will be the right wake-up call.



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