

Clients & Friends Memo

COVID-19 Update: Patent Rights in the COVID-19 Pandemic: How will Industries and Governments Respond?

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As the world scrambles to address an ever-expanding wave of COVID-19 infections, new and urgent needs for medical supplies, diagnostics and treatments arise. Shortages of such supplies are plaguing hospitals and care-givers, while doctors and nurses put their lives at risk in their desperate efforts to save COVID-19 patients. Many of these vital supplies, however, are protected by valuable patent rights. The essence behind patents rights is to exclude others from making, using, or selling a patented invention, except by authorization of the patent holder in carefully negotiated license agreements to ensure proper compensation for the efforts and costs invested in developing the patented invention.¹ On the other hand, the U.S. government has rights to forcibly license a patented invention during times of need, in particular when there is a threat to public safety.² Will the government resort to use of these available, yet rarely used, compulsory licensing provisions? How patent owners are responding to the current COVID-19 pandemic is revealing that benevolence may, in some cases, have a place in commercial business without the government needing to exercise its compulsory licensing rights.

In the face of the COVID-19 pandemic, several large companies have come forward with offers to manufacture medical supplies such as masks and respirators. Manufacturers, such as the auto makers General Motors, Ford and Tesla, are offering to repurpose production lines to help manufacture and increase the supply of ventilators and other much needed medical equipment.³ Fashion and cosmetic companies, such as Louis Vuitton, L'Oréal and Coty, are also pitching in and offering to re-allocate their resources to produce hand sanitizers, while fashion designers, like Christian Siriano and Brandon Maxwell, are offering to mobilize their teams to produce masks and

¹ See 35 U.S.C. § § 154, 271.

² See, e.g., 28 U.S.C. § 1498(a), 35 U.S.C. § 203.

³ See <https://www.usatoday.com/story/money/cars/2020/03/22/coronavirus-ventilator-shortage-gm-tesla-covid-19/2895190001/>.

hospital gowns.⁴ Even the beer company giant, ABInBev will use its facilities to manufacture and distribute hand sanitizer.⁵

On the patent front, the drug manufacturer AbbVie has taken a bold public health stance by suspending enforcement of its global patent rights on all formulations of the HIV medication, Kaletra (Aluvia) while the drug is being evaluated as a candidate to treat COVID-19 in several clinical trials. AbbVie's bold stance would allow generic versions of Kaletra to be made by others without fear of repercussion based on patent infringement. This would allow countries to purchase generic versions of Kaletra, if it is found effective in treating COVID-19, and would help alleviate possible drug supply shortages. AbbVie is the first drug-maker to take such a strong public health stance amid the COVID-19 pandemic. However, whether AbbVie's decision to suspend its patent rights to Kaletra is an act of pure benevolence, mounting public pressures, or because at least one clinical trial already suggested Kaletra may not be effective in treating COVID-19, AbbVie's strong public health stance is at the very least a comforting thought and may hopefully sway other drug-makers, like Gilead Sciences Inc. ("Gilead"), to do the same.

On the other end is the drug-maker Gilead who recently halted emergency access to its COVID-19 candidate drug, Remdesivir, except for pregnant women and children with severe symptoms.⁶ In suspending access to Remdesivir, Gilead issued a company statement⁷ on March 22, 2020 citing "overwhelming demand" and "exponential increase" in requests which "flooded [its] emergency treatment access system." However, Gilead's restrictions to Remdesivir come on the heels of it being granted "orphan" drug status⁸ by the U.S. Food and Drug Administration ("FDA") on February 23, 2020 and on the heels of a Chinese drug-maker, BrightGene Bio-Medical Technology ("BrightGene"),⁹ filing for patent protection in China for a combination drug therapy to treat COVID-19 using the active ingredients of Remdesivir. The 1983 Orphan Drug Act¹⁰ allows a seven-year market exclusivity period for pharmaceutical companies developing treatments for a "rare disease"

⁴ See <https://wwd.com/fashion-news/fashion-scoops/fashion-designers-make-masks-hospital-gown-hand-sanitizer-to-fight-coronavirus-1203545006/>.

⁵ See <http://longisland.news12.com/story/41926769/anheuserbusch-to-make-hand-sanitizer-in-response-to-coronavirus-pandemic>

⁶ See *Id.*

⁷ <https://www.gilead.com/purpose/advancing-global-health/covid-19/emergency-access-to-remdesivir-outside-of-clinical-trials>.

⁸ See <https://www.ibtimes.com/coronavirus-treatment-gileads-potential-covid-19-treatment-labeled-orphan-drug-could-2945353>.

⁹ See <https://time.com/5782633/covid-19-drug-remdesivir-china/>.

¹⁰ Orphan Drug Act of 1983. Pub L. No. 97-414, 96 Stat. 2049.

and also provides tax credits. Gilead's strategic move to obtain orphan drug status for Remdesivir blocks generic drug manufacturers from supplying the drug and thus further limiting access.

Remdesivir has been previously used to treat the Ebola virus, Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), but these infections did not cause a sustained global crisis to earn Gilead a sizable or continued financial revenue stream and other more successful experimental therapies existed.¹¹ If Remdesivir is found to be effective for combating COVID-19, a patent protecting such a use may stand to earn a high and continued stream of global revenue for the patent owner. As new combination drug patents or method patents for new uses of known drugs may be separately patentable, repurposing Remdesivir as a combination drug patent or for treating COVID-19 may prove to be a blockbuster hit for its patent owner. Thus, while Gilead has cited overwhelming demand as the reason to restrict access to Remdesivir, one can't help but wonder whether patent rights and the associated commercial revenue are Gilead's underlying concern.

Gilead is not the only patent holder invoking a protectionist stance and seemingly attempting to profit from the global pandemic through the patent system's exclusionary principle. Labrador Diagnostics LLC ("Labrador")—a company backed by its major investor SoftBank and who bought patents from a failed blood-testing start-up called Theranos—recently filed a patent infringement lawsuit against BioFire Diagnostics ("BioFire"), a health start-up who launched three COVID-19 tests.¹² Labrador also requested an injunction demanding BioFire to stop using the technology covered by the Theranos patents.¹³ However, since filing the lawsuit and seemingly after public backlash, Labrador issued a press release¹⁴ stating it would allow third parties to use its Theranos patents to develop COVID-19 tests with a royalty-free license, but that it is continuing its lawsuit against BioFire for activities over the past six years not related to COVID-19 testing.

Similarly, in Italy, a patent holder of a special respirator valve used in respiratory machines allegedly threatened a patent infringement lawsuit against two engineers who volunteered to use their 3-D printing technology to manufacture the patented valves for a hospital in Brescia, Italy without obtaining permission or a license from the patent holder.¹⁵ However, in a follow-up statement, both the patent holder and the two engineers stopped short of calling the communications a threat, and

¹¹ See <https://www.statnews.com/2020/03/16/remdesivir-surges-ahead-against-coronavirus/>.

¹² See <https://www.theverge.com/2020/3/18/21185006/softbank-theranos-coronavirus-covid-lawsuit-patent-testing>; see also, <https://www.businessinsider.com/theranos-patents-fortress-labrador-diagnostics-lawsuit-biofire-coronavirus-tests-2020-3>.

¹³ See *Id.*

¹⁴ See <https://www.businesswire.com/news/home/20200316005955/en/>.

¹⁵ See <https://www.law360.com/articles/1255547/3d-printing-as-indirect-patent-infringement-amid-covid-19>.

instead characterized them as merely a refusal of the patent holder to assist or collaborate with the engineers.¹⁶

While some patent owners are choosing to suspend their global patent rights and others are taking a more protectionist stance, the U.S. government also has the right to take action by forcing patent owners to grant compulsory licenses when there is a threat to public safety. A compulsory license refers to the government's authority to grant permission to a party seeking use of another's patented invention without the consent of the patent owner, and is provided broadly by 28 U.S.C. § 1498. Several multilateral international agreements also address compulsory patent licenses.¹⁷ Other U.S. laws also allow for compulsory licenses in certain circumstances. For example, march-in rights is a provision of the Bayh-Dole Act of 1980 and is codified in 35 U.S.C. § 203. March-in rights allow the federal government the right to grant patent licenses to other parties or take licenses for themselves if the patented invention was researched and developed with the help of federally funded dollars.¹⁸

March-in rights may be a perfectly poised vehicle for increasing access to COVID-19 related therapeutic drugs and vaccines. To fight the global pandemic, the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services ("HHS"), has partnered with several drug manufacturers, including Johnson & Johnson, Sanofi and Regeneron Pharmaceuticals, to fund the development of treatments and vaccines for COVID-19.¹⁹ However, some members of Congress have expressed concern as to the affordability and access should such drugs be found safe and effective, especially since federal funds are being provided.

No U.S. federal agency has ever exercised its power to march-in and license patent rights to others. For example, advocacy groups have long petitioned the National Institute of Health ("NIH") to exercise march-in rights for HIV/AIDS related drugs, but have been rejected by the NIH contending that high drug prices are an insufficient reason to break a patent. However, in the face of a global pandemic, "health or safety needs" may provide a strong basis for the exercise of march-in rights and grant of a compulsory license if more patent owners, like Gilead, take a protectionist patent stance. On the other hand, if more companies like AbbVie take a more socially conscious approach, there may not be need for government intervention in terms of compulsory patent licenses. Nevertheless, the availability of this measure may at least provide some comfort and may motivate companies to voluntarily suspend their patent rights during this global public health

¹⁶ See <https://www.theverge.com/2020/3/17/21184308/coronavirus-italy-medical-3d-print-valves-treatments>.

¹⁷ See Convention of Paris for the Protection of Industrial Property, 13 I.S.T. 25 (1962), Art. 5(A)(2) ("Paris Convention"); See Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Art. 31. ("TRIPS Agreement").

¹⁸ See 35 U.S.C. § 203.

¹⁹ See <https://crsreports.congress.gov/product/pdf/LSB/LSB10422>.

emergency in order to avoid government march-in, or maybe as a pure act of benevolence showing that social responsibility has a place in commercial business.

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