

# THE GLOBAL CORONAVIRUS PANDEMIC: THE RACE FOR PATENT RIGHTS

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All over the news, there are stories about the new coronavirus (Covid-19). Coronavirus belongs to a family of viruses that cause disease in animals, with some of the viruses having made the jump from animals to humans. To date, the majority of cases originated in China, with there being over 80,000 cases of coronavirus infections reported just in mainland China. However, the virus is continuing to spread internationally.

As the public health crisis continues, a controversy surrounding licensing and patent rights lies underneath. The controversy begins with Gilead, who holds patent rights to remdesivir—an investigational nucleotide analog with broad-spectrum antiviral activity originally developed to fight Ebola. Remdesivir works by blocking a particular enzyme that is required for viral replication.

Presently, remdesivir is not approved for use anywhere on the globe. However, remdesivir has been shown to exhibit activity in animal models against viral pathogens that include Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Current clinical data collected by Gilead indicates that remdesivir may have potential activity against Covid-19. In one case, remdesivir has been administered to a patient in the United States, leading to a dramatic and sudden improvement in the patient's medical condition.

Gilead owns a substantial global patent portfolio surrounding remdesivir, a portfolio which contains over 133 patent applications related to remdesivir with filings in 43 countries. In the portfolio, Gilead has filed patent applications that cover the structure of remdesivir compounds, methods of manufacturing remdesivir, and the use of remdesivir for the treatment of Coronaviridae infections.

In January this year, the Wuhan Institute of Virology applied for a patent covering the combination of remdesivir with an anti-malarial drug, Chloroquine, for the treatment of Covid-19. In addition, the Chinese pharmaceutical company BrightGene recently began to manufacture remdesivir's active ingredients. In an interview with a Chinese news publication, BrightGene claimed they were not infringing Gilead's patent because they have not started to sell any of remdesivir's active ingredients.

This unfolding news story highlights the issues of patent protection on a global scale. Earlier this year, the U.S. and China entered into a trade deal that creates stronger patent protection and enforcement in China and allows for China to implement American-style enforcement of drug-patent rights. For example, under the trade deal, a patent holder may file a preliminary injunction against a generic drug maker. This practice commonly occurs in the U.S. when a brand drug maker seeks to prohibit a generic drug product being produced before the expiration of a patent.

The Covid-19 outbreak has caused Gilead to initiate two Phase 3 clinical trials to evaluate the safety and efficacy of remdesivir in adults diagnosed with Covid-19 at medical centers primarily across Asian countries. Gilead seeks to enroll over 1000 patients in these studies and will utilize both 5-day and 10-day dosing regimens of remdesivir. Gilead has maintained that it owns all patents covering remdesivir, including the use of remdesivir to treat Covid-19.

Further complicating this situation, Chinese law provisions for compulsory licenses have continued to become murky over the past decade, mainly due in part to several amendments to general compulsory license practice. Under such provisions, a compulsory license could allow a company or individual to use or make a patented product without seeking the patent owner's consent. In such a case, a compulsory license is an exception to the general rule of patents that allow for a patent owner to enjoy exclusive rights.

In the U.S., use of compulsory license provisions are rare as such provisions essentially allow for potential patent infringers to be shielded by the U.S. Department of Defense at government expense. However, during the anthrax outbreak in early 2000, the U.S. government did threaten to issue a compulsory license for the antibiotic ciprofloxacin as ciprofloxacin could be used for the treatment of anthrax poisoning.

Compulsory licenses of pharmaceuticals may also be granted on an international scale under the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). Under TRIPS, provisions for compulsory licenses have existed since it was enacted in January 1995. Generally, TRIPS allows for a compulsory license to be granted when a generic copy of a drug is produced solely for a domestic market and not for export. Here, a patent owner would still have rights over the patented subject matter including the right to be paid for any copies of a product made under a compulsory license.

Under Article 31 of TRIPS, a person or company applying for a compulsory license must have attempted to negotiate a voluntary license with a patent owner based on reasonable

commercial terms. Only when negotiations fail may a compulsory license be issued. Even when the compulsory license has been issued, the patent owner still retains the right to receive payment for the subject matter covered by the compulsory license. Further, under this article, a compulsory license may be subject to certain restrictions. For example, the compulsory license may be restricted in scope and duration such that it is limited to the purpose for which the license was granted.

Areas of the world that have been paralyzed by the coronavirus epidemic see remdesivir as a silver bullet and silencer of this quickly spreading epidemic. What remains to be seen is not only how effective remdesivir will be at inhibiting viral replication in humans, but also where ownership of the intellectual property assets covering this novel compound will fall.