

# COVID-19 EPIDEMIC: CAN THE COVID-19 VIRUS BE PATENTED?

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Just last week, the outbreak of a novel coronavirus that originated in China, has been characterized as a pandemic, having spread to over 100 countries and affecting a large percentage of the population. This virus has been named “SARS-CoV-2” and the disease that it causes is known as “coronavirus disease 2019,” abbreviated as COVID-19. In general, coronaviruses are a large family of viruses that can occur in both people and animals such as camels, cattle, cats, and bats.[1]

The clinical presentation of those infected with COVID-19 is varied, with some patients presenting very mild symptoms and others presenting severe illness that results in death. Individuals with underlying medical conditions such as heart disease, lung disease, diabetes, and hypertension are at higher risk for complications from COVID-19. Currently, there is no treatment for the virus. As previously reported, Gilead has initiated two Phase 3 clinical studies to evaluate the safety and efficacy of remdesivir in adults diagnosed with COVID-19. This comes after the U.S. Food and Drug Administration’s (FDA) approval of Gilead’s investigational new drug (IND) filing for remdesivir.[2]

## I. Overview of Coronavirus Related Issued Patents in the United States

To date, the United States Patent and Trademark Office (USPTO) has issued 5,578 patents that relate to coronaviruses. The first of such patents issued by the USPTO was filed and assigned to Eli Lilly and Company on June 4, 1975. This patent, entitled “Anti-viral method in animals”, matured into an issued patent on November 30, 1976.[3] The most recent issued patent relating to coronaviruses, entitled “Multigenome retroviral vector preparations and methods and systems for producing and using same” issued on March 10, 2020. This patent was filed by and assigned to Immune Design Corporation of Seattle, Washington.[4]

A review of all patents issued by the USPTO over the last five years indicates that there has been a steady trend of patents issuing in this space. The USPTO issued 443 patents relating to coronaviruses in 2015, 474 patents in 2016, 493 patents in 2017, 471 patents in 2018, 541 patents in 2019, and 103 patents so far in 2020.[5] It is anticipated, that numbers for 2020 will be upwards of 480 patents by end of year 2020

## II. Overview of Coronavirus Related Issued Patents Across the Globe

On a global scale, 24 patent offices worldwide have issued a total of 9,217 patents regarding coronaviruses. The first ever patent relating to coronaviruses was filed in

France in 1974 by researchers at the University of Nebraska-Lincoln. The number of patent applications published each year relating to coronaviruses spikes in years when outbreaks have become prevalent. For example, in 2005 during the height of the severe acute respiratory syndrome (SARS) outbreak, 538 patent applications were published globally relating to coronaviruses. By comparison, in 2001 when the SARS outbreak was only starting, 114 patent applications were published relating to coronaviruses.[6]

Reviewing worldwide patent filings indicates that most patents relating to coronaviruses are filed under the Patent Cooperation Treaty (PCT) through the World Intellectual Property Organization (WIPO), headquartered in Geneva, Switzerland. Further, this review indicates that patents relating to coronaviruses are also often filed in the United States, China, Japan, Canada, South Korea, Australia, European Patent Office (EPO), and India.[7]

Globally, trends have recently indicated an uptick in the number of coronavirus related patents issuing from patent offices across the globe. Additionally, the number of applications relating to nanotechnology in conjunction with coronaviruses have recently increased. Nanotechnology involves the study and application of science on a nanoscale, ranging between about 1 to 100 nanometers. Patents in this space focus on diagnostics, vaccines, and treatment methods of diseases caused by coronaviruses, with some utilizing clustered regularly interspaced palindromic repeats (CRISPR) technology. Patents in this area are often assigned to universities such as Harvard College, The Regents of the University of California, Massachusetts Institute of Technology, and California Institute of Technology.[8]

### **III. Is COVID-19 Patentable?**

Questions surrounding patent filings concerning COVID-19 stem from a fundamental issue—can the current COVID-19 virus be patented? The answer to this question varies based on national and local laws that govern the patentability of biologics.

In the United States, a virus, such as the wild-type COVID-19 virus that is found in nature and has not been genetically modified, is not eligible for patent protection. For example, Under 35 U.S.C. § 101, “laws of nature and natural phenomena” are not patent eligible. These laws of nature and natural phenomena include, for example, products found in nature that are naturally occurring.

Conversely, patent protection is available in the United States for viruses that are structurally different from wild-type viruses, such as a virus created from the wild-type COVID-19 virus using recombinant DNA technology. As one example, a live attenuated

vaccine that contains a genetic mutation to decrease the virulence may be eligible for patent protection in the United States.

Virus-like particles (VLPS) can also be eligible for patent protection in the United States. VLPS are molecules that resemble viruses but are non-infectious because they do not contain any viral genetic material. Frequently, VLPS are used as vaccines as they contain repetitive and high density displays of viral surface proteins that elicit strong T cell and B cell immune responses. In the past, VLPS have been used to develop vaccines for Hepatitis B and human papillomavirus (HPV).

In Europe, patent eligibility of the wild-type COVID-19 virus differs from that of the United States. The EPO considers biological materials which are isolated from their natural environment to be patentable, even if the biological material previously occurred in nature.

In China, the wild-type COVID-19 virus would not be patent eligible. Chinese patent law follows American patent law in this regard in that a gene that is merely found in nature and existing in its natural state is not patentable. However, China does allow for a patent directed to a gene and the process of obtaining that gene, if it is isolated from nature for the first time. For example, a fragment of DNA that is synthesized and isolated from an entire strand of DNA and aimed at detecting a case of disease can be patented in China.

During the upcoming months as scientists race around the clock to develop an effective treatment and vaccine to protect against the COVID-19 virus, intellectual property plays a crucial piece in the viral puzzle. This is why the previously discussed patent dispute between Gilead and BrightGene as well as the faceoff to seek patent coverage of remdesivir as a treatment for COVID-19 remains highly contested. We will all stay tuned to see how intellectual property surrounding this pandemic plays out in the upcoming months

[1]Source: <https://www.cdc.gov/coronavirus/2019-ncov/casesupdates/summary.html>

[2]Source: <https://www.cdc.gov/coronavirus/2019-ncov/casesupdates/summary.html>

[3]Source: <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnethtml%2FPTO%2Fsearch-adv.htm&r=5591&f=G&l=50&d=PTXT&s1=%22coronavirus%22&p=112&OS=%22coronavirus%22&RS=%22coronavirus%22>

[4]Source: <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnethtml%2FPTO%2Fsearch-adv.htm&r=14&f=G&l=50&d=PTXT&s1=%22coronavirus%22&p=1&OS=%22coronavirus%22&RS=%22coronavirus%22>

[5]S o u r c e : <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnethtml%2FPTO%2Fsearch-adv.htm&r=0&f=S&l=50&d=PTXT&RS=%22coronavirus%22&Query=%22coronavirus%22&TD=5591&Srch1=%22coronavirus%22&StartAt=Jump+To&StartNum=1>

[6]Source: <https://patentscope.wipo.int/search/en/search.jsf>

[7]Source: <https://patentscope.wipo.int/search/en/search.jsf>

[8]Source: <https://patentscope.wipo.int/search/en/search.jsf>