Samuel Kim

A COVID-19 Vaccine: To Patent or Not

Given the current situation the world is experiencing with coronavirus disease 2019 ("COVID-19") — in which over 600,000 people have died worldwide, including about 150,000 deaths in the United States alone — corporations and universities race to develop a vaccine to slow the spread of the virus. Patents play a vital role in the research to develop the vaccine. Patents provide a safeguard to patent holders to exclude others from exploiting their innovations. With respect to vaccine-related patents, patent holders can exclude others from practicing various vaccine-related aspects concerning, for example, micro-organisms in a living but recombinant state, antigens and antibodies, and processes relating to methods for producing the vaccine.

This paper discusses aspects of patenting vaccine-related innovations in the United States in three sections. Section I describes patents and their purpose. Section II surveys patent requirements and whether a COVID-19 vaccine can be patentable. Finally, section III discusses the possible moral and ethical dilemmas that vaccine developer may face in view of deciding whether to obtain a vaccine-related patent.

I. What Is a Patent?

A patent is a government-issued grant conferring the right to exclude others from making, using, or selling the invention throughout the United States or importing into the United States for 20 years beginning from the date of patent application. 35 U.S.C. §154. This right of exclusion is provided by the U.S. Constitution, which grants Congress the enumerated 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." U.S. Const., art. I, § 8, cl. 8. Accordingly, the primary goal of the U.S. patent system is to advance technological and economic development by stimulating innovation and investment.

The U.S. patent system serves two policy objectives: 1) by requiring disclosure of the manner and processes of manufacturing an invention, the system encourages public disclosure of otherwise confidential information so that others may utilize it, and 2) by rewarding successful endeavors, the system provides inventors with incentives to invest time and resources in research

and development. To this end, whoever invents or discovers any new and useful process, machines, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent. 35 U.S.C. §101.

II. Patent Requirements

The basic requirements for obtaining a patent on a claimed invention are adequate disclosure of enablement or written description, subject matter eligibility, usefulness or utility, novelty, and non-obviousness. Each of these requirements is discussed below.

A. Adequate Disclosure of Enablement

To satisfy the enablement requirement, the patent specification must enable a person having ordinary skill in the art to practice the claimed invention without undue experimentation. Some or even a considerable amount of experimentation is not undue if it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed.

For a vaccine-related patent, the patent application must adequately describe the manner and process of making and using it. It should include guidance on how to isolate and weaken particular viruses or bacteria, inactivate them to change their genetic blueprint, and purify the antigen extracted from the virus. It should specify which procedure is used for each step of the vaccine development. The patent application's disclosure must be sufficient to inform a person having ordinary skills in the art, such as a scientist or a researcher in the same technology field, on how to make and use the vaccine.

B. Patentable Subject Matter

Section 101 of the Patent Act defines the four categories of inventions that Congress deemed to be appropriate subject matter of a patent: processes, machines, articles of manufacture, and composition of matter. However, certain types of patent applications are more likely to be challenged as to whether they fall within Section 101. Because abstract ideas, laws of nature, and natural phenomenon are the basic tools of scientific and technological work, granting patent rights for these concepts may impede innovation rather than promote it. In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Court held that patents cannot issue for discovering that

certain strains of bacteria can be mixed without harmful effects. 333 U.S. 127, 131. (1948). The Court reasoned that this phenomenon of nature is a part of the storehouse of knowledge to all men, free to all and reserved exclusively to none. *Id*. at 130. In *Diamond v. Chakrabarty*, on the other hand, the Court held that the creation of a bacterium that is not found anywhere in nature constitutes a patentable "manufacture" or "composition of matter" under Section 101. 447 U.S. 303, 310. (1980). Similarly, the Court in *Parke-Davis & Co. v. H. K. Mulford & Co.*, upheld a patent for adrenaline, an isolated and purified form of a DNA compound from an animal's suprarenal gland. 196 F. 496, 500. (1912).

While a vaccine derived from nature through live bacteria or viruses can be viewed as falling under the laws of nature or a natural phenomenon, it is nonetheless a complex biological product with a production process that is equally as complex and difficult. Scientific knowledge of the virus's genetic material being composed of RNAs with a higher likelihood to mutate quicker than DNA, rendering vaccine development for that specific RNA useless, indicates the complexities of vaccine development. The process of producing a vaccines involves years of research and development, typically on small animals, to determine the efficacy of the vaccine. This research and development can also include identifying and isolating protective antigens of a specific pathogen, cloning DNA or RNA, and new vector systems. In sum, vaccine development is the product of years of researching, creating, modifying and improving, with testing at every step in between.

C. Usefulness or Utility

An invention must have a useful purpose or utility and meet three types of utility categories: operational, beneficial or moral, and practical. This requirement is even more important when attempting to patent a pharmaceutical or chemical compound, as it is necessary to specify a practical or specific utility for the compound. With respect to the operational category, the invention does not need to be commercially feasible as long as it is functional. The invention must actually work. If a vaccine is proven to build immunity to the virus, then it is operational.

With respect to the beneficial or moral category, while rarely raised, an invention must not be socially harmful, immoral, or injurious. It must not purposefully deceive society and those who use the product.

With respect to the practical category, the invention must have a specific, non-trivial, substantial use. Issues often arise when inventors do not sufficiently know or demonstrate their invention. In *Brenner v. Manson*, an inventor sought to patent a chemical process for synthesizing certain steroidal compound but failed to state the specific, practical use of the known steroid other than to aid in research. 383 U.S. 519, 531. (1966). There, the Court held that an invention must not only be harmless, but it must also not be frivolous or insignificant. *Id*. at 533.

A vaccine, especially for the current COVID-19, should meet the three types of utility categories. First, the vaccine will be beneficial to society by slowing the spread of the virus and possibly preventing future outbreaks. Second, a vaccine for a spreadable disease is neither frivolous nor insignificant. Third, with approximately 150,000 deaths in the United States alone, the development of a COVID-19 vaccine will not only prove to have moral utility but would also be extremely beneficial and practical in current times.

D. Novelty

Section 102 of the Patent Act has three requirements: 1) the invention must have novelty, 2) the invention must not be subject to a statutory bar, and 3) the inventor must have derived the invention. For an invention to be patentable, it must be considered to be new or novel. An invention cannot be patented if it is subject to a statutory bar, meaning if the invention has been known to the public, described in a printed publication, or already been filed, it is no longer novel and therefore cannot be patented. An exception to the statutory bar is made for inventor disclosures less than one year before patent application filing, meaning there is a one-year grace period after an initial public disclosure or offer for sale on the invention. This statutory bar is unforgiving, so if an inventor does not file for patent protection within a year of initial disclosure of his or her invention, he or she loses all right to obtain a patent protection for that invention. Lastly, the inventor must have derived the invention, meaning he or she is responsible for the original conception and not merely created an obvious variant of a previous invention.

There will likely not be an issue as to whether a vaccine related to build immunity to COVID-19 has been developed in the past. Coronaviruses are a large family of viruses that can cause illness ranging from the common cold to more severe diseases. COVID-19 is a “novel” respiratory disease, meaning the virus that causes the illness is a new strain of virus that has not

been previously identified in humans. Because this virus is new and little is known about how the virus acts, no vaccines have been developed.

What may potentially raise a novelty issue is the one-year statutory bar, which starts at the time of initial public disclosure. COVID-19 was first identified in December 2019 and scientists and researchers have been working around the clock to develop a vaccine for it ever since. Per the Patent Act, this one-year grace period may start with something as innocuous as showing the invention to other scientists and researchers without any confidentiality obligations. Hypothetically, if someone has created a potential vaccine and publicly shared it with colleagues or other organizations as early as December 2019, that development could be well over the halfway point into the statutory grace period. Once the one-year period passes, the inventor would have lost all rights to obtain patent protection.

E. Non-Obviousness

For an invention to be patentable, it is required to be a non-obvious improvement over the prior art. Whether or not the invention is non-obvious is determined by whether the claimed invention would have been obvious to a person having ordinary skill in the art. In *KSR International Co. v. Teleflex, Inc.*, KSR attempted to patent an adjustable gas-pedal system that included an adjustable accelerator pedal and an electronic throttle control, in which both components were previously patented by Teleflex. 550 U.S. 398, 399. (2007). The Supreme Court held that even though no one had combined the pre-existing adjustable gas pedal and electronic sensor technology in the precise way, the existence of the technology would have caused a person having ordinary skill in the art to see the obvious benefit of combining the two. *Id*. at 404.

At the U.S. Patent and Trademark Office, to determine whether a patent application is "obvious" over the prior art, an examiner reviews prior publications to find prior art closest to the invention for which patent protection is being sought. If all the features of the invention can be found in a single piece of prior art, the patent application can be rejected for lacking novelty. If a single piece of prior art is not applied, the examiner can consider combining two or more prior art to reject the patent application. If the examiner succeeds in finding such combination, the patent application can be rejected as an obvious combination of features known in the prior art.

While COVID-19 is a novel respiratory illness caused by SARS-CoV-2, a specific strain of coronavirus, coronaviruses have caused various diseases in mammals and birds for almost a century. Coronaviruses were first discovered in the 1930s as an acute respiratory infection of domesticated chickens. The infection of new-born chicks was characterized by gasping and listlessness, and the mortality rate for infected chicks was 40-90%. In the 1940s, two more animal coronaviruses were discovered. And in the 1960s, the first human coronavirus was discovered. In recent history, an outbreak of severe acute respiratory syndrome (SARS) occurred in 2003 and another outbreak of Middle East respiratory syndrome (MERS) occurred in 2012. These outbreaks were caused by different strains of the coronavirus. While a vaccine or a treatment for COVID-19 would likely be new given that the disease itself is caused by a different strain of the coronavirus, if the COVID-19 vaccine or treatment share similarities or are obvious combinations of prior treatments — such as those for either SARS or MERS — obviousness issues may arise.

III. Patent: the Right Thing to Do?

Developing a vaccine is a long and arduous process that includes an exploratory stage, a pre-clinical stage, clinical development, regulatory review and approval, and manufacturing and quality control. It can take many years, or even decades, to complete. In fact, there is still research underway for the MERS vaccine from 2012, where the first in-human trial was conducted in April 2020, eight years after the initial outbreak. Vaccine development requires enormous manpower, countless number of hours, and an unmeasurable amount of resources. From an economic point of view, patent protection protects a patent holder's investment in developing new vaccines.

However, with millions of people infected and the number continuing to rise, many believe that it would be unethical to restrict access to a vaccine that could potentially save hundreds of thousands of lives. If development of COVID-19 vaccine takes as long as it has for the MERS vaccine, the death toll can grow significantly. There have been number of instances where inventors did not patent or restrict access to their patents because of moral and ethical reasons.

A famous example is the discovery of penicillin by Alexander Fleming in 1927. Fleming had been studying the properties of staphylococci bacteria when he observed "by accident" that a

mold on a petri dish was breaking down the surrounding bacteria, effectively preventing contamination of the culture. He isolated this mold and identified it as a member of the Penicillium genus. He grew the mold in a pure culture and found the culture broth contained an antibacterial substance. He found this substance in the "mold juice," later named penicillin, to be effective against many Gram-positive pathogens, which are responsible for diseases such as scarlet fever, pneumonia, gonorrhea, meningitis, and diphtheria.

This accidental discovery and isolation of penicillin led to one of the first broadly effective antibiotic drugs. Its impact on the world was immediate and profound. With its development, infections that were once severe and often fatal were able to be treated easily. However, Fleming believed that patenting the process of isolating penicillin would restrict access to penicillin to those who desperately needed it. Howard Florey, who worked with Fleming to isolate the antibacterial substance, believed patenting the process would have been unethical in view of the profound impact of the life-saving drug.

Another example of an unpatented scientific product is the polio vaccine. Polio is an infectious disease that potentially causes muscle weakness that can lead to an inability to move. While rare, this disease has a long history, as shown in ancient paintings and carvings that depict people with withered limbs and young children walking with canes. In the late 19th and early 20th centuries, small localized paralytic polio epidemics began to appear in Europe and in the United States, and eventually spread to other parts of the world including Australia and New Zealand. In the United States, a polio epidemic in 1952 became the worst outbreak in the nation's history at that time. With nearly 58,000 cases reported that year alone, over 3,000 people died and over 21,000 people developed disabling paralysis.

The first effective polio vaccine was developed in 1952 by Jonas Salk. Over the next three years, the vaccine was tested through experiments involving almost 2 million children across the country: some received the actual vaccine, while others received either a placebo or no vaccination at all. The test yielded very high effective rates, and the vaccine was soon declared "safe, effective, and potent." When an interviewer asked Salk who owned the patent, Salk allegedly replied that there is no patent and that it belongs to the people. Salk was reluctant to patent his vaccine, and polio was eliminated in the Americas by 1994. By 2000, it was officially

eliminated in 36 Western Pacific countries including China and Australia. And in 2002, Europe was declared polio-free.

Yet another example, while not scientific, of an unpatented product is the three-point seatbelt developed by Volvo and found in a majority of today's cars. Until the late 1950s, many car seatbelts were a rudimentary two-point waist restraint, which often caused more harm than good in accidents. These two-point seatbelts hinged at the pelvis, leaving the torso and head vulnerable in accidents. Bohlin, a Volvo engineer, recognized that an effective seatbelt must not only absorb force across the body, but also be easy to use for anyone, even children. He combined the idea of a lap belt and a diagonal belt then anchored the straps low beside the seat so the belt would remain in place and not shift around. The new three-point seatbelt proved to significantly reduce injuries by effectively holding both the upper and lower body. In 1962, the U.S. Patent and Trademark Office issued Bohlin a patent for his seatbelt design. However, Volvo quickly released the new seat belt design to other car manufacturers because the invention had more value as a life-saving tool than a product to profit from.

Patenting an invention or a discovery is not a bad thing. Congress's intention behind patent protection was to provide an incentive for inventors "to promote the progress of science and useful arts" by rewarding them the right to exclude others from practicing the invention. Forbes estimates that if Salk had patented his polio vaccine, he would have made billions of dollars. However, given the current unprecedented situation and many research laboratories around the world racing to develop a COVID-19 vaccine, organizations such as the Open COVID Pledge have been established to encourage the free sharing of existing patents and copyrights associated with vaccine research to serve the public good. For now, there are very few pharmaceutical and biotechnology corporations participating, raising questions over whether this initiative would be successful. We'll just have to wait and see.