

Intellectual Property Rights on COVID-19 Vaccines in the U.S.

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Abstract: The global development and distribution of COVID-19 vaccines have raised concerns over intellectual property rights in the United States. In particular, the two pharmaceutical giants, Pfizer/BioNTech and Moderna, have been embroiled in a contentious dispute over the intellectual property rights surrounding their COVID-19 vaccine technology since August 2022. The stakes are high, as the outcome of this legal battle could determine who ultimately controls this newfound and lucrative market. This paper delves into the legal framework of intellectual property rights in the United States as they apply to COVID-19 vaccines. It also raises critical ethical questions about the implications of these rights for public health and access to lifesaving treatments. By examining these issues, this paper sheds light on the ongoing tension between incentivizing innovation and ensuring equitable access to crucial medical breakthroughs.

Introduction

This paper discusses the legal issue of intellectual property rights on COVID-19 vaccines in the U.S. beginning with a description of the industry in the U.S. and the world. From there, I explain intellectual property and patent laws in the U.S. before moving on to a description of new mRNA technology used for COVID-19 vaccines and its patentability through an analysis of an ongoing patent infringement lawsuit filed by Modern against Pfizer/BioNTech.

I. Description of the COVID-19 Vaccine Industry

The U.S. COVID-19 vaccine industry was formed in early 2020 when the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic. To battle the novel coronavirus, pharmaceutical companies like AstraZeneca, Moderna, Pfizer/BioNTech, and Johnson & Johnson were funded by WHO and many other donors to accelerate the research and development of vaccines. In December of 2020, the first COVID-19 vaccine was added to the Emergency Use Listing (EUL), overseen by the WHO, and distributed to healthcare

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workers, those with high-risk medical conditions, and people older than 65. Eventually, the vaccine became available for everyone, including ordinary citizens and children. Currently, 11 vaccines are listed on the EUL and have been mass produced and distributed to countries all over the world. The U.S. alone has approved and authorized four vaccines: Moderna, Pfizer/BioNTech, Johnson & Johnson, and Novavax. As of November 2022, 15.477 billion vaccines were delivered worldwide,¹ and the U.S. had distributed over 905 million doses and administered over 646 million doses. In the U.S., Pfizer/BioNTech makes up 56.2% of the COVID-19 vaccine market while Moderna makes up 37.8% and the remaining 6.0% belongs to Novavax and Johnson&Johnson.² The size of the U.S. COVID-19 vaccine industry has grown dramatically over the past two years, increasing from a value of \$190 million in 2020 to \$10.81 billion in 2021.³

II. Intellectual Property: Patents

Ila. Intellectual Property Rights

Intellectual property (IP) is any product of human intellect that the law protects from unauthorized use by others, which effectively enables original creators to hold a monopoly on their IP.⁴ IP rights are crucial to our society as they encourage individuals and companies to be creative while offering them protection. There are four ways to protect intellectual property: trademarks, copyrights, trade secrets, and patents. Patents are the “exclusive right of its owner to exclude others from making, using, or selling the invention as defined in the claims of the patent for a period of time.”⁵ Trademarks and trade secrets are indefinite as long as they are in use. Copyrights are valid for 70 years plus the author’s lifetime and 95 years after first publication if anonymous. Patents cover the shortest duration, as they span

¹ “Covid-19 Market Dashboard,” UNICEF Supply Division, accessed 15 November 2022, <https://www.unicef.org/supply/covid-19-market-dashboard>.

² “Covid Data Tracker,” Centers for Disease Control and Prevention, accessed 15 November 2022, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop.

³ “COVID-19 Vaccines,” *statista*, accessed 16 November 2022, <https://www.statista.com/outlook/hmo/pharmaceuticals/vaccines/covid-19-vaccines/united-states>.

⁴ “Intellectual Property,” Legal Information Institute, Cornell Law School, accessed 16 November 2022, https://www.law.cornell.edu/wex/intellectual_property#:~:text=Overview,monopoly%20in%20the%20protected%20property.

⁵ Rachel Spooner, “Intro+F22+IP,” PowerPoint presentation, Boston College, Chestnut Hill, MA. Accessed Fall 2022.

from 14 to 20 years depending on the patent type. Once the patent is expired, the invention enters the public domain and anyone can make, use, or sell the product.

Iib. Patent Law Under the Constitution

Under Article I, Section 8, of the U.S. Constitution, Congress has the power to promote scientific progress by allowing inventors to secure exclusive rights to their discoveries for a limited amount of time.⁶ This law is important because it fosters innovation and incentivizes individuals and companies to make new scientific discoveries and advancements that may be helpful to the world. Moreover, inventors can gain profit due to the exclusive rights that protect their inventions.

Iib(i). Patent Act of 1952

The Patent Act of 1952 requires that a patent must be novel, non-obvious, useful, and a valid subject matter. “Novel” means the patent should propose something new, like an innovative technology or a scientific discovery. It must be non-obvious “to a person of ordinary skill and knowledge in the art or technology to which the invention is related.”⁷ The usefulness of the invention is determined by its intended purpose. A valid subject matter must not be abstract, the product of nature, or within the laws of nature. A patent can be found invalid if it does not fulfill all four requirements.

Iic. Patent Infringement

Patent infringement occurs when the owner of the patent files a suit for infringement for unauthorized use of their patent, and obtains appropriate monetary damages and injunctive relief.

III. IP and COVID-19 Vaccines

IIIa. mRNA and Patentability

There are three main types of COVID-19 vaccines approved in the United States: “messenger RNA (mRNA), viral vector, and protein subunit.”⁸ While mRNA technology is new to the field, viral vector and protein subunit vaccine technologies have long been used

⁶ Twomey, David P., “Chapter 9,” in *Business Law: Principles for Today's Commercial Environment* (Australia: Cengage Learning, 2017).

⁷ Twomey, *Business Law*, Chapter 9.

⁸ “Overview of COVID-19 Vaccines,” Centers for Disease Control and Prevention, updated 1 November 2022, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/overview-COVID-19-vaccines.html?s_cid=11758:types%20of%20covid%20vaccines:sem.ga:p:RG:GM:gen:PTN:FY22.

and are considered the “traditional” methods. “mRNA vaccines use mRNA created in a laboratory to teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. This immune response, which produces antibodies, is what helps protect us from getting sick from that germ in the future.”⁹ While mRNA technology has been researched for decades, it was not implemented in vaccines until the COVID-19 pandemic. Similar to how viral vector and protein subunit vaccine methods have been used for effective vaccines in the past, the mRNA method can be a new way of making more effective vaccines in the future. Pfizer/BioNTech and Moderna were the first pharmaceutical companies to make effective mRNA vaccines for humans. With an expanding global vaccine industry, patenting this new technology will be profitable in the long run and allow patent holders to eventually shape the future of mRNA vaccines.

IIIb. Association for Molecular Pathology v. Myriad Genetics Case

The Association for Molecular Pathology and other medical associations sued the United States Trademark and Patent Office (USTPO) and Myriad Genetics to challenge its human- gene-related patents. Myriad Genetics discovered specific mutations in human genetics, called BRCA1 and BRCA2, that marked a high risk of breast and ovarian cancer. To test whether a person is at high risk, it is necessary to isolate their genes. Therefore, Myriad patented the process that isolates BRCA1 and BRCA2, which would give them the exclusive right to breast and ovarian cancer testing as well as gene isolation. However, the U.S. Supreme Court ruled that Myriad’s patents are invalid because human genes are found in nature and merely isolating them is unpatentable.

Unlike this case, the technology of mRNA in vaccines is novel. mRNA can be found in nature as it is “genetic material that tells your body how to make proteins,”¹⁰ but for COVID-19 mRNA vaccines, the mRNA is laboratory-made. Moreover, it is nonobvious to an ordinary person without any knowledge of mRNA and it is useful because it triggers the immune system against a virus. It is also a valid subject matter, fulfilling all four criteria and rendering the mRNA technology patentable.

⁹ “Understanding How Covid-19 Vaccines Work,” Centers for Disease Control and Prevention, updated 3 February 2023, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html>.

¹⁰ “Understanding How Covid-19 Vaccines Work,” CDC.

IIIc. Moderna v. Pfizer/BioNTech Ongoing Case

In August 2022, nine months after the first mRNA vaccine, Moderna sued Pfizer/BioNTech for three patent infringements related to mRNA technology. The company stated that “Pfizer and BioNTech’s COVID-19 vaccine Comirnaty infringes patents Moderna filed between 2010 and 2016 covering Moderna’s foundational mRNA technology. This groundbreaking technology was critical to the development of Moderna’s own mRNA COVID-19 vaccine, Spikevax. Pfizer and BioNTech copied this technology, without Moderna’s permission, to make Comirnaty.”¹¹ Under the Patent Act of 1952, Moderna has the right to sue Pfizer/BioNTech for patent infringement and seek appropriate monetary damages and injunctive relief. Moderna is seeking damages, including royalties and lost profits incurred since March 2022 and license fees from high-income countries. However, the company chose not to seek damages from Pfizer’s sales of its vaccine to the world’s poorest countries and the U.S. government, which bought Pfizer/BioNTech vaccines.¹²

To Moderna’s claim, Pfizer/BioNTech responds that their “work is original, and [they] will vigorously defend against all allegations of patent infringement.”¹³ The case has important ramifications for the future profitability of both companies. Experts have already started speculating on the matter and believe that it could either come to a relatively quick decision or drag on for years.¹⁴ The ruling of this ongoing lawsuit will likely shape the future of mRNA technology, not only in the COVID-19 vaccine industry, but also in the medical industry.

Conclusion

Intellectual property rights promote and incentivize the COVID-19 vaccine industry to flourish and develop groundbreaking technology. However, patents on COVID-19 vaccines,

¹¹ “Moderna Sues Pfizer and BioNTech for Infringing Patents Central to Moderna’s Innovative mRNA Technology Platform,” Moderna, 26 August 2022, <https://investors.modernatx.com/news/news-details/2022/Moderna-Sues-Pfizer-and-BioNTech-for-Infringing-Patents-Central-to-Modernas-Innovative-mRNA-Technology-Platform/default.aspx>.

¹² Rebecca Robins and Jenny Gross, “Moderna Sues Pfizer and BioNTech Over Covid Vaccine Technology.” *New York Times*, 26 August 2022, <https://www.nytimes.com/2022/08/26/business/moderna-covid-vaccine-lawsuit.html>.

¹³ “Press Release: Statement on Patent Infringement Lawsuit Filed by Moderna,” BioNTech, 26 August 2022, <https://investors.biontech.de/news-releases/news-release-details/statement-patent-infringement-lawsuit-filed-moderna>.

¹⁴ Jon Cohen, “Scientists question Moderna Invention claim in covid-19 vaccine dispute.” *Science*, 29 August 2022, <https://www.science.org/content/article/scientists-question-moderna-invention-claim-covid-19-vaccine-dispute>.

specifically mRNA technology, can be a hindrance to inoculation during the ongoing pandemic as patent license fees can increase the price of vaccines. It is important to remember that the public is still at risk, with 33% of the U.S. and 39% of the world population not fully vaccinated.¹⁵ One might argue that the Moderna lawsuit is justifiable because they are protecting their rights under the U.S. Constitution. In reality, however, the case brings awareness to the ethical dilemma of whether intellectual property rights should be prioritized over life-saving technology.

¹⁵ The Visual and Data Journalism Team, “Covid vaccines: How fast is progress around the world?” *BBC News*, 1 June 2022, <https://www.bbc.com/news/world-56237778>.