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POOLING PATENTS FOR PANDEMIC PROGRESS: MRNA VACCINES AND THE BROADER CONTEXT OF MODERNATX INC V. PFIZER INC.

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*Francis Brefo**

I. INTRODUCTION

The Covid-19 pandemic is among the gravest global health and economic crises in history. In less than a year, the disease took the lives of more than a million people and infected at least another 38 million, leaving many severely ill and some with long-term effects. Its social and economic consequences have been widespread and devastating. Amidst the crisis, people all over the world were pinning their hopes on a potential Covid-19 vaccine. Hundreds of companies answered the call and began allocating resources to prioritize Covid-19 vaccine development. On December 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine became available under emergency use authorization for individuals 16 and older.[1] According to official reports of COVID-19 deaths, vaccinations reduced global deaths by an estimated 63% during the first year of COVID-19 vaccine availability.[2]

Now, imagine a different disease arises five years after the first reported Covid-19 case. This virus has shown itself to be deadlier and more contagious than Covid-19, and a pandemic ensues. Subsequently, scientists declare that mRNA technology is

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[1] U.S. Food & Drug Administration, *FDA Approves First COVID-19 Vaccine*, FDA.gov (Aug 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-firstcovid19vaccine#:~:text=Since%20Dec.,age%20on%20May%2010%2C%202021.

[2] Oliver J Watson et al., Global impact of the first year of COVID-19 vaccination: A mathematical modelling study, 22 The Lancet Infectious Diseases 1293–1302 (2022).

deemed to be the answer yet again. Worry ensues as it is likely that loved ones will contract this virus, but there is anticipation of a vaccine coming soon. After all, scientists previously developed the Covid-19 vaccine in under 12 months when it normally would have taken 10-15 years. However, the rate of producing this new vaccine comes slower than anticipated. One may be puzzled as to why the previous vaccine was developed quickly, since innovation coupled with prior knowledge should have allowed for a faster response. What could be different now? Research on the matter unveils that a year prior, Moderna sued Pfizer for patent infringement over key mRNA technology and prevailed. Moderna was able to secure these rights, creating a high bar for others to innovate upon their patented technology. Amidst this new international health emergency, the company loosened patent enforcement to gain assistance in developing a vaccine. However, the damage had already been done, as numerous companies had not had access to build upon the technology to prepare for the potential of a new virus. With the rush to push out another vaccine to lower the death toll, it is likely this vaccine will come with complications and only partial protections to the virus.

Central to the development of the Covid-19 vaccine is messenger ribonucleic acid (mRNA) technology. Traditionally, to trigger an immune response, many vaccines use a weakened or inactivated germ.[3] This is contrary to how mRNA vaccines operate. Instead, mRNA vaccines use mRNA created in a laboratory to teach our cells how to make a protein that triggers an immune response inside our bodies.[4] This immune response, which produces antibodies, is what helps protect us from getting sick from that germ in the future.[5]

The function of contemporary patent law is vital in fostering such innovations, as it encourages the long-term advancement of inventive concepts by temporarily limiting their dissemination in

[3] Centers for Disease Control and Prevention, *Understanding how vaccines work*, CDC.gov, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html. (last updated May 23, 2022).
[4] *Id*.
[5] *Id*.

the short term.[6] The second aspect of the agreement involves the imposition of costs on society through the granting of temporary exclusive rights or monopoly privileges to the patent holder. Under U.S. patent law, a patent holder can prevent others from manufacturing or selling their patented product without their permission for 20 years.[7] This allows the patent holder to block competitors from the market or extract exorbitant licensing fees before allowing them to enter, ultimately falling on the shoulders of consumers who are charged above-market prices as a result. Thus, patent rights slow the diffusion of a new invention by restricting output and raising prices.

For pandemics and other public health emergencies, the mix of costs and benefits of patents are misaligned with what is needed for an effective policy response. Here, the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Part I of this note argues that current patent law gives drug companies the power to stunt innovation upon technologies that are critical to societal welfare by blocking competitors and raising prices.

Litigation for *Moderna v. Pfizer*[8] is still pending, although it has the potential to foreshadow a future where mRNA technology, which will impact vaccines for influenza, Ebola, and other health risks, is "more monopolistic."[9] The above hypothetical emphasizes a need for lessened barriers of access to the next generation of technology. Innovators, whether large or small, need this opportunity because the process of innovation often requires a significant investment of time, resources, and expertise. From a financial aspect, innovators need the assurance that their investment will result in a meaningful return, and the

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[6] Brink Lindsey, *Why intellectual property and pandemics don't mix*, Brookings.edu (June 3, 2021), https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/.

[7] 35 U.S.C. § 154 (2019).

[8] *Modernatx, Inc. And Moderna Us, Inc.,* Plaintiffs, v. Pfizer Inc., Biontech Se, Bion-Tech Manufacturing Gmbh, and Biontech US Inc., Defendants., 2022 WL 3701751.

[9] Ian Lopez and Lawrence Gostin, *Moderna patent strike on Pfizer sets up post-covid vaccine feuds*, Bloomberg Law (Aug. 29, 2022), https://news.bloomberglaw.com/health-law-and-business/moderna-patent-strike-on-pfizer-sets-up-post-covid-vaccine-feuds.

ability to build upon existing technology provides a foundation for their efforts.[10] By building upon existing technology, innovators can leverage existing knowledge and resources, streamline their development process, and focus on areas that need further improvement.[11] This, in turn, speeds up the process of innovation and enables innovators to bring new solutions to market more quickly.[12]

The lawsuit "sets the stage for patent gamesmanship for the next generation of Covid vaccines, for influenza and all the future health scourges we're going to face."[13] "And there will be many, mRNA should be our savior, it should be the penicillin of the 21st century."[14]

Part II of this study traces the spectrum of litigation within the mRNA field, and dives into relevant litigation concerning technology germane to *Moderna v. Pfizer*. It is important to note, litigation for this case is still pending, and it is still in its early stages. Therefore, this section elaborates on Moderna's filed complaint. Such an analysis is necessary to determine how litigation may proceed and their outcomes.

Part III anticipates how the litigation between the two parties could materialize, and does so in two subsections: Part A analyzes patent pledge Moderna publicly announced in the middle of the pandemic, and whether they professed to not enforce its patents to allow the uninfringed innovation towards Covid-19 vaccines; Part B then analyzes how a direct patent infringement suit between the two parties may play out by referencing the basis from which the courts will operate, the Patent Act, which states Moderna must show by the preponderance of the evidence that all of the elements of their asserted claims are present in Pfizer's and BioNtech's vaccine.

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[10] International Bureau of WIPO, *Wipo National Workshop on Industrial Property and Innovation for Small and Medium-Sized Enterprises*, (SMEs) (July 10,1999), https://www.wipo.int/edocs/mdocs/innovation/en/wipo_inn_cm_99/wipo_inn_cm_99_5.doc.

[11] *Id*.

[12] *Id*.

[13] Gostin, *supra* note 8.

[14] *Id*.

Overall, this note argues that entities are able to exploit certain biomedical technology under the gaze of traditional patent law. For example, the compilation of technology that went into the Covid-19 vaccine would fall under this purview, as its development was critical to stopping an international pandemic. Such technologies are critical to societal welfare and without their exposure, can result in public detriment, especially in the case of an international emergency. Part IV proposes patent pools as a potential solution as they allow for two or more patent owners to license one or more of their patents to one another or to third parties.[15] For the pool to be effective, it must only consist of patents that are crucial for implementing the standard in question, in this case, mRNA vaccine development. This allows for increased transparency, reduced coordination costs and avoids costly infringement litigation amongst pool members. This theory tackles the common issue of ownership by allowing creators to financially gain from their inventions whilst addressing the need for immediate innovation by instituting a framework that would allow multiple entities access to the already established technology.

II. BACKGROUND

A. mRNA and its current litigation environment

Covid-19 has triggered the rapid advancement of therapies based on mRNA technology, however, there are numerous individualized technologies that comprise this technology, and much of that technology isn't exactly brand new. In fact, there is prior litigation involving the exact technology in the current *Moderna v. Pfizer* suit. The first claim involves the method to get the cell to start producing the protein by administering the

[15] Monica Armillotta, Comparative Analysis: US Legal Treatment of Patent Pools – Delineating the Modern Archetype, Technology Pooling Licensing Agreements: Promoting Patent Access Through Collaborative IP Mechanisms 73–88 (last visited Feb. 13, 2023).

mRNA.[16] While the second is directed to a pharmaceutical composition of "lipid nanoparticles" that encase the mRNA.[17]

To understand the innovation required to properly deliver mRNA into the body, it is best to expand on the technology of mRNA vaccines as a whole. Our cells naturally produce mRNA to facilitate the production of proteins.[18] During the "transcription" process, enzymes within our cells use segments of DNA as templates to form mRNA in cell nuclei. Then, during the "translation" process, different enzymes use the produced mRNA as templates to form proteins in the cell cytoplasm. The primary structure of each protein produced by our cells corresponds to the primary structure of the mRNA molecules from which the protein was derived.

Pioneers have developed therapies where the applicable mRNA sequences are synthesized in the lab and introduced into the cytoplasm of cells for translation into proteins. Importantly, in these therapies, the synthesized mRNA sequence can encode proteins not derived from a recipient's genome, which may facilitate cells' production of specific proteins.

In the case of the COVID-19 vaccines, companies like BioNTech and Moderna developed specific mRNA configured to encode for the characteristic spike protein appearing on the surface of the COVID-19 virus. This mRNA is then introduced into the recipient's cells, and copies of the spike protein are created and expressed. This allows the recipient's immune system to identify the spike protein as an antigen without exposure to the COVID-19 virus and build its defenses against it, in preparation for potential actual exposure.[19]

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[16] Complaint at 30 ¶ 104, *Modernatx, Inc. And Moderna Us, Inc.*, Plaintiffs, v. Pfizer Inc., Biontech Se, Bion-Tech Manufacturing Gmbh, and Biontech US Inc., Defendants., 2022 WL 3701751 (D.Mass.) (1:2022cv11378).

[17] *Id*. at 34 ¶ 121.

[18] Thomas Schlake, *Developing mrna-vaccine technologies*, Landes Bioscience (Nov. 1, 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3597572/.

[19] Centers for Disease Control and Prevention, Understanding How Covid-19 Vaccines Work, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html (last updated Feb 3, 2023).

Introducing this spike protein into cells is no easy task. These molecules are inherently unstable; if introduced into the recipient's body without a protective layer, they may degrade or otherwise be destroyed by the recipient's biochemistry, rather than being taken into cells for translation into the desired proteins.[20] To address this problem, these vaccines utilize certain lipid nanoparticle (LNP) delivery systems, which surround mRNA molecules with a combination of lipid molecules to prevent the mRNA molecules from being destroyed following injection and to facilitate effective uptake into cells.[21]

B. Arbutus v. Moderna

In February 2022, Arbutus Biopharma Corp. sued Moderna Inc. in the U.S. District Court for the District of Delaware, alleging that Moderna infringed several Arbutus patents (U.S. Patent No. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378) directed to LNP delivery systems through, for example, its manufacture and sale of Moderna's Covid-19 vaccine, Spikevax.[22] The complaint seeks monetary damages but does not seek an injunction, which would demand Moderna to cease operations relating to the production and research of this particular patent.[23]

This is not the first time these two parties clashed, however the history between the two hasn't always been hostile. Previously, Moderna had sublicensed certain Arbutus LNP delivery technology several years ago. Their right to use such technology was undercut following a 2018 settlement involving Arbutus and Moderna's sublicensor, and, according to the complaint, Moderna does not currently have any rights to use Arbutus's LNP technology in connection with COVID-19.[24]

Following this settlement, Moderna challenged three of Arbutus's LNP-based patents through *inter partes review* (IPR)

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[20] *Id*.
[21] *Id*.
[22] *Arbutus Biopharma Corp. v. Moderna, Inc.*, No. CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022).
[23] *Id*.
[24] *Id*. at *2.

proceedings before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, a process that allows petitioners to challenge claims of issued patents.[25] The Moderna IPRs had varying outcomes, with one Moderna win (canceling all claims of U.S. Patent No. 9,404,127), one mixed result (canceling some claims of the '435 patent but not all), and one Moderna loss (all claims of the '069 patent survived). Moderna appealed the ruling on the '069 patent, but it was upheld by the U.S. Court of Appeals for the Federal Circuit in late 2021.[26] The '069 patents survival opened the door for the suit in *Arbutus v. Moderna*, *Moderna v. Pfizer*, and more.

Claim 1 of the '069 patent, which is representative of some of the claims being asserted in *Moderna v. Pfizer*, requires a combination of four types of lipid molecules (i.e., a cationic lipid, phospholipid, cholesterol, and conjugated lipid) and is recited as follows:

> A nucleic acid-lipid particle comprising:
>
> (a) a nucleic acid;
> (b) a cationic lipid comprising from *50 mol % to 65 mol %* of the total lipid present in the particle;
> (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from *4 mol % to 10 mol %* of the total lipid present in the particle and the cholesterol or derivative thereof comprises from *30 mol % to 40 mol %* of the total lipid present in the particle; and
> (d) a conjugated lipid that inhibits aggregation of particles comprising from *0.5 mol % to 2 mol %* of the total lipid present in the particle.[27]

Under US patent law, for the plaintiffs to win their infringement claim of the'069 patent, they would have to show that Spikevax contains an LNP delivery system that has all of the

[25] *Id.*
[26] *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1352 (Fed. Cir. 2021).
[27] U.S. Patent No. 8,058,069 B2 (issued Nov. 15, 2015).

claimed lipids above in amounts that fall within the claimed ranges. During the development process, companies usually anticipate these potential types of claims and try to steer clear of infringing the patent by "designing around" it, meaning that they make sure the product does not have any of the limitations listed in the claim. This might seem simple, but actually creating an effective LNP system that can deliver mRNA as a therapy can be a complicated engineering task.[28] For example, commentators have indicated that a desired LNP should (1) maintain stability while being stored prior to use, (2) encapsulate the mRNA payload and protect both the payload and itself from the recipient's biochemistry post-injection, (3) be configured such that the entire LNP can be taken up into the cell's cytoplasm, and (4) allow the mRNA payload to release from the surrounding lipids once in the cytoplasm while avoiding attack by intracellular endosomes.[29]

There is great instability when lipids and mRNA molecules combine, which affect the overall characteristics of a given nanoparticle. This instability limits the amount of potential particles that would meet the above design criteria, and requires additional engineering efforts to achieve.

As of today, Moderna has attempted to dismiss claims made against them for sales to the U.S. government, citing 28 U.S.C. § 1498(a), which requires plaintiffs to seek compensation from the federal government in the Court of Federal Claims rather than from the company itself.[30] Arbutus has taken a stance against this request. Most notably, Arbutus is not seeking an injunction to prevent Moderna from further producing their vaccine.[31] It is

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[28] Daniel Shores, *COVID-19 Patent Wars: mRNA and Lipid NanoparticlePioneers Clash over Vaccine Delivery Patents*, Americanbar.org (Sept. 28, 2022), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2022-23/september-october/covid-19-patent-wars-mrna-lipid-nanoparticle-pioneers-clash-over-vaccine-delivery-patents/.

[29] Xucheng Hou, *Lipid Nanoparticles for mRNA Delivery*, Nature Revs. Materials (Dec. 2021), https://www.nature.com/articles/s41578-021-00358-0.

[30] Vandana Singh, *Moderna Files Motion to Dismiss COVID-19 Vaccine Related Patent Claims: WSJ*, Yahoo (May 9, 2022), https://www.yahoo.com/video/moderna-files-motion-dismiss-covid-121644408.html.

[31] *Id*.

likely, given the current pandemic atmosphere, a judge would likely rule against such a motion on the grounds of public welfare.

C. Moderna Inc. v. Pfizer Inc, and BioNTech Inc. Complaint

Moderna's complaint alleging that Pfizer and BioNTech infringed on their mRNA technology can be summarized in two key parts. The first is a lengthy expository section that details the extensive history of the technology that Moderna used to create their Spike mRNA Covid vaccine and the particular patents at issue.[32] The patents in question claim:

> U.S. Patent No. 10,898,574
> Claim 2. A pharmaceutical composition comprising:
> a plurality of lipid nanoparticles comprising a cationic lipid, a sterol, and a PEG-lipid,
> wherein the lipid nanoparticles comprise a mRNA encoding a polypeptide,
> wherein the mRNA comprises one or more uridines, one or more cytidines, one or more adenosines, and one or more guanosines and wherein substantially all uridines are modified uridines.[33]
> Claim 9. The pharmaceutical composition of claim 2, wherein the modified uridine is 1-methyl-pseudouridine.[34]
>
> U.S. Patent No. 10,702,600
> Claim 1. A composition, comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.[35]
>
> U.S. Patent No. 10,933,127
> Claim 1. A method comprising administering to a subject a messenger ribonucleic acid (mRNA) comprising an open

[32] *See supra* note 16 at ¶16-38.
[33] *Id*. at 27 ¶ 89.
[34] *Id*. at 27 ¶ 93.
[35] *Id*. at 32 ¶ 110.

> reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle in an effective amount to induce in the subject an immune response to the BetaCoV S protein or S protein subunit wherein the lipid nanoparticle comprises 20-60 mol% ionizable cationic lipid, 5-25 mol% neutral lipid, 25-55 mol% cholesterol, and 0.5-15 mol% PEG-modified lipid.[36]

Of these three asserted patents, the '574 patent has the broadest claims, because LNP delivery is not limited to a particular virus, while the '600 and '127 patents expressly recite mRNAs encoding a b-coronavirus Spike protein; this would encompass the most recent Covid-19 vaccine. These claims form a basis for Moderna's allegations of infringement by Pfizer/BioNTech vaccine, Comirnaty. Moderna alleges that Comirnaty was a direct copy of their vaccine, and even cite public statements made by Pfizer CEO Albert Bourla on June 9, 2020, at Goldman Sachs Virtual 41st Annual Global Healthcare Conference.[37]

Furthermore, this portion of the complaint includes a history of Moderna's development of the underlying mRNA technology as well as its efforts to develop its vaccine during the pandemic. The complaint also makes the case that the company's Intellectual Property was both the technical foundation for its successful and rapid development of the COVID vaccine and provided protection against the significant financial and investment risk occasioned by Moderna's development of its vaccine.

The second feature of the complaint, and Moderna's strategy in bringing suit, is in the Prayer for Relief which explains the limitations of the remedy Moderna asks the Court to grant. In addition to a judgment that Pfizer and BioNTech infringe by sales of its Comirnaty vaccine, Moderna seeks monetary damages that expressly exclude damages it would be entitled to from "sales to the U.S. government that are subject to 28 U.S.C. § 1498 or to the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC)."[38] Moderna has expressly

[36] *Id*. at 35-36 ¶ 128.
[37] *See supra* note 16 at 6 ¶ 20.
[38] *Id*. at 16 ¶ 38.

excluded in its prayer for relief, an injunction from "such other relief the Court may deem just and proper." Deigning to forego compensation for sales to the government under 28 U.S.C. § 1498 is likely done in an effort to avoid any attempt by Pfizer or BioNTech to have the case adjudicated under the statute in the Court of Federal Claims; disclaiming any interest in sales outside the U.S. to countries falling within the scope of the COMAX AMC attempts to avoid allegations that Moderna is putting its profits and patent rights over the health and lives of the citizens of those countries.

Moderna realizes the overwhelming financial benefit of the patents in question, as these are patents that can be and will be used for the next vaccine, and the one after that. Bringing a successful suit might result in a substantial damage award, but this pales in comparison to the potential loss of innovation opportunities during the remaining 10-15 years of patent protection. Of course, any suit brings risks, and is likely that Pfizer/BioNTech will petition for *inter partes review*, and challenge Moderna's patents similarly to how Moderna challenged Arbutus's patents.

The outcome of these litigations could have a major impact on how other mRNA market players approach which delivery technology to use in products even outside the Covid-19 vaccine. It will also remain to be seen how companies design around each other's inventions to facilitate the production of the spike protein in therapies for years to come. If claims for patents are invalidated or canceled during litigation, then other market players could be free to use such technology without licensing costs. Alternatively, if such patents survive these challenges, market players may need to license surviving patents (which could be a significant barrier to entry) or design around them by developing new mRNA delivery technologies.

III. ANTICIPATED LITIGATION

A. Patent Pledge

While Moderna's complaint does not explicitly seek an injunction, if Moderna can prove that Pfizer's vaccine infringes on their patent, they would have the right to receive compensation in the form of royalties on for sales of Pfizer's vaccine. However, Moderna would only be able to receive the royalties of sales Pfizer made after March 2022. This is because Moderna issued a patent pledge on October of 2020 publicly promising that "while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic."[39] Moderna subsequently reneged on this promise in its March 7, 2022 update stating that they will not "enforce patents for COVID-19 vaccines against companies manufacturing in or for the 92 low- and middle-income countries in the Gavi COVAX Advance Market Commitment (AMC), provided that the manufactured vaccines are solely for use in the AMC 92 countries."[40] To avoid criticism that Moderna is attempting to profit during a global health crisis, their complaint is carefully crafted by indicating they only are seeking royalties after March 2022. This approach is designed to demonstrate their dedication to Covid-19 innovation while conveying that they do not seek to capitalize on the public's hardship experienced during the pandemic's peak.

Upon closer look, Moderna's initial pledge included provisions that foreshadowed their subsequent amendment by initially expressing that the pledge is valid only "while the pandemic continues" and "upon request we are also willing to license our intellectual property for COVID-19 vaccines to others

[39] *See*, e.g. *Moderna's updated patent pledge, Moderna's Updated Patent Pledge* (October 8, 2020), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx, *archived at* https://perma.cc/EMU7-9JAT (states that during the pandemic, Moderna will not enforce COVID-19 related patents against those making vaccines intended to combat the pandemic, this was later updated on March 7th 2022 to state they will not enforce COIVD-19 patents against those making vaccines against companies manufacturing in or for the 92 low- and middle-income countries).

[40] *Id*.

for the post pandemic period."[41] These terms were implemented so Moderna could potentially set up a two-stage approach, where during the pandemic everyone has access to their patents, but after they will offer paid licenses. The issue is that there is debate as to whether the pandemic has ended, and at this time many reckon that the pandemic is far from over. The number of COVID cases remain steady around the world, and a combination of factors play a part in its ability to linger such as, the highly transmissible Omicron variant; Omicron's sub-variant; BA.2; and the lifting of public health and social measures.[42]

Patent Pledges are "[public] commitments voluntarily made by patent holders to limit the enforcement or other exploitation of their patents."[43] Individuals and others who take advantage of these commitments or covenants to facilitate innovation do so in reliance on the legal doctrines such as public or implied licenses, and equitable estoppel to protect themselves against a claim of patent infringement by the pledgors and promisors.[44] Moderna's pledge should be classified as a public license, these licenses are not specifically negotiated between copyright owners and users but are publicly posted and can be "accepted" by anyone who wishes to use the licenses content.[45] This concept is appropriately applied in *Jacobsen v. Katzer*, where the owner of a publicly licensed software alleged infringement by an organization that used the owner's program in their product

[41] Dan Shores, *Breaking down Moderna's covid-19 patent pledge: Why did they do it?*, IPWatchdog.com (2021), https://ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/.
[42] Emma Farge, *Covid-19 pandemic is 'far from over' - WHO official*, Reuters (March 18, 2022), https://www.reuters.com/world/covid-19-pandemic-is-far-over-who-official-2022-03-18/.
[43] Jorge L. Contreras, Public Licenses: Open Source, Creative Commons and IP Pledges, in Intellectual Property Licensing and Transactions: Theory and Practice 592–636 (last visited Feb. 14, 2023).
[44] Diane Peters, *Understanding Patent Pledges: An Overview of Legal Considerations*, PATENTCOMMONS, https://patentcommons.org/publications/OSDL_Whitepaper_Final_final_4-12-06.pdf (last visited Feb. 13, 2023).
[45] Contreras, *supra* note 43.

without adhering to the terms of the license.[46] The plaintiff's program was a free to download program that allowed model train enthusiasts to program decoder chips and was subject to the terms of the artistic license, which included conditions for use, distribution, and modification. If users did not agree to the terms, they could negotiate alternative arrangements with *Jacobsen*. The court determined that that the use of the license without complying with its conditions constituted infringement.[47]

Here, Moderna's patent pledge is legally similar to the public licenses in *Jacobsen*, as it was not made to a specific contractual counterparty or business partner, but rather to the general public. Additionally, both pledges act as a public license, which is legally binding. The enforceability of open-source licenses has been validated by courts in the US, and patent pledges are similar to Creative Commons copyright licenses.

The motivation for making pledges or open sourcing software is important as well because they can impact the legal interpretation and enforceability of the pledge or license. For example, if it is deemed that Moderna's initial October 2020 pledge not to enforce its patents simply to avoid negative public relations or to gain publicity, rather than out of a genuine desire to promote innovation and collaboration, a court may be less likely to view the pledge as a binding legal obligation. On the other hand, Moderna can demonstrate that it made the pledge or license in order to advance a particular goal or promote a particular public interest, this may strengthen the legal enforceability of the pledge or license.

Even if it determined that this was not a public license, and a license was not granted, Pfizer will likely allege that Moderna's public promise induced Pfizer to rely on this statement, and Moderna is thus prevented from retracting that promise under the doctrine of "promissory estoppel." This common law doctrine holds that someone who makes a promise is bound by that promise if others reasonably and detrimentally rely on it.[48] A claim of promissory estoppel requires a showing that the promisee actually

[46] *Jacobsen v. Katzer*, 609 F. Supp. 2d 925 (N.D. Cal. 2009), dismissed, 449 F. App'x 8 (Fed. Cir. 2010).
[47] *Id*.
[48] *See* Restatement (Second) of Contract § 90 (1981); infra-Part IV.B.1.).

and justifiably relied on the patent holder's promise.[49] This is the crux of the doctrine that Pfizer will have the most trouble with, because actual reliance can be difficult to prove. The key will be for Pfizer to tie actual reliance to a particular promise. For example, Moderna's October 2022 pledge publicly promised not to assert its patents during the pandemic against anyone who used them to make a COVID-19 vaccine. Pfizer then made such a vaccine, but Moderna may respond by indicating that Pfizer & BioNTech would have made an mRNA vaccine anyway given the huge government payments that were available, and that Pfizer began development of these vaccines before Moderna made its pledge. Despite this, Pfizer doesn't need to show that Moderna's pledge was the only reason it made an mRNA vaccine, this isn't required for promissory estoppel. The promise need not be the only reason, but simply a reason for the action taken.

It is in the interest of the legal and scientific community that Moderna be held to their pledge. There are intrinsic market-wide benefits that patent pledges have. Patent pledges create an environment in which multiple firms are more likely to adopt particular standards or open-technology platforms, resulting in greater product interoperability and increased network effects.[50] Wi-Fi technology illustrates this concept properly. Any computer, tablet, smart phone, or other device that implements the relevant Wi-Fi standard can communicate with any other device that implements the same standard. The manufacturers of those devices need not interact at all during the development and manufacturing of their respective products. So long as two devices comply with the relevant standard, they can communicate with each other. Patent owners limit their statutory right to enforce their patents in an attempt to induce market participants to adopt *their preferred* standards or technology platforms. These pledges can create a "safe space" in which innovation can flourish with a reduced threat of patent enforcement. Such commitments thus benefit the market broadly, but also guide the market toward the patent holder's own products and technologies, which benefits the patent holder. Patent pledges have the potential to produce a

[49] *Id.*

[50] Contreras, *supra* note 43.

number of beneficial market effects towards the patent holder, however, in this case Moderna is attempting to renege its promise to capture rents associated with those that have adopted their technology under the presumption they would not be sued for it. Moderna, in their October 2020 pledge stated, "upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period."[51] This may seem like a fair warning from Moderna, however, at this time it is a common presumption that we are still in the midst of a pandemic.[52]

Potentially halting innovation upon such technology that directly impacts lives is contrary to public interest. Therefore, Moderna needs to be held to the pledge that they alleged in order to comport with the purpose of patent pledges, which is to further product development and innovation.

Finally, patent pledges should be treated as legally enforceable obligations based on the reliance market actors have on the pledges. Manufacturers who rely on a patent holder's promise not to block the sale of a product will often make costly investments on that basis. These investments could include product design and development, marketing, materials, capital equipment, information technology, employee training, and supply chain management. Once such investments have been made, the manufacturer is said to be "locked-in" and cannot switch to an alternative technology without significant, and potentially prohibitive, cost. It is important to enforce the patent holder's pledge to protect other market actors who have relied on those pledges in making investments, especially when it is likely to have a societally beneficial effect.

B. Patent Infringement

[51] *Moderna's updated patent pledge, Moderna's Updated Patent Pledge*, MODERNA (October 8, 2020), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx.

[52] *COVID-19: Renewal of Determination that a Public Health Emergency Exists*, U.S. Department of Health & Human Services (Jan 11, 2023), https://aspr.hhs.gov/legal/PHE/Pages/covid19-11Jan23.aspx.

The Patent Act specifies that a patent holder can bring an action for 'direct' infringement against anyone who makes, uses, offers to sell, sells, or imports into the United States a patented invention or a product that is made by a patented process.[53]

A patent holder has the burden of proving infringement by a preponderance of the evidence.[54] The determination of patent infringement is a two-step process.[55] First, a court construes the claims of the patent, namely, the court determines the meaning of the claims. Claim construction is a question of law for the court to rule upon.[56] Second, the accused product or process is compared to the properly construed claims.[57] This step is a question of fact and therefore is usually determined by a jury. Infringement will be found when an accused product or process includes every element 'limitation' of a claim, and can occur either through literal infringement or through the doctrine of equivalents.[58] Literal infringement exists when each and every element in a claim reads on, or is found in, an accused product or process.[59] In addition to literal infringement, infringement under the 'doctrine of equivalents' exists even if one or more of the claim limitations are not literally present in the accused product or process, as long as the equivalents of those limitations are present.[60] In other words, to find infringement under the doctrine of equivalents, any differences between the claimed invention and the accused product must be insubstantial.[61]

The burden of proof in infringement cases is placed on the patentee who alleges the complaint.[62] To prove infringement, this patentee must show, by the preponderance of the evidence, that all of the elements of the asserted claims are present in the accused

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[53] 35 U.S.C. § 271.
[54] *Centricut LLC v. Esab Grp., Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004).
[55] *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1340 (Fed. Cir. 2005).
[56] *Id*.
[57] *Id*.
[58] *Id*.
[59] *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002).
[60] *Id.* at 1340.
[61] *VirnetX, Inc. v. Cisco Sys*., 767 F.3d 1308, 1322 (Fed. Cir. 2014).
[62] *Imhaeuser v. Buerk*, 101 U.S. 647, 662 (1879).

product or process.[63] To do so, the patentee may rely on testimonial or other evidence, as well as appropriate inferences and admissions.[64] Once the patentee has proven infringement the burden shifts to the accused infringer to prove non-infringement.[65]

In response to Moderna's first claim, involving patent '574, Pfizer and BioNtech could take the initiative and respond by challenging the validity of Moderna's patent through *inter partes review* (IPR). This is a legal process provided by the United States Patent and Trademark Office (USPTO) for challenging the validity of a granted patent.[66] As outlined before, IPR proceedings are used to challenge the patentability of one or more claims of a patent based on prior art, i.e., previously known inventions or publications. Given the past events involving both Arbutus and Moderna, particularly Arbutus' assertion that Moderna has replicated their LNP delivery system, it can said there is merit to such a move. Here, Pfizer and BioNtech, would allege that Moderna's '574 patent lacks 'novelty', meaning it is anticipated by prior art. Prior art refers to any information or other evidence that was publicly known prior to a certain date.[67] Examples may include published patents, patent application, books, articles, advertisements, or even pre-existing products. In anticipation of such a claim, it is likely Moderna "designed around" prior art to avoid any infringement issues when creating their mRNA delivery system. Inventing around patents involves designing a product or process in a way that avoids infringing on an existing patent by purposefully modifying the original to avoid infringement and legal disputes all whilst producing a similar competitive product.[68]

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[63] *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005).

[64] *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006)

[65] *SRI Intern. v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985).

[66] 35 U.S.C. § 311.

[67] United States Patent and Trademark Office, Detailed Discussion of AIA 35 U.S.C. 102(a) and (b) United States Patent and Trademark Office, https://www.uspto.gov/web/offices/pac/mpep/s2152.html (last updated Nov 2013).

[68] Robert E Yoches, *Designing around patents*, Finnegan (August 2010), https://www.finnegan.com/en/insights/articles/designing-around-patents.html.

Arbutus v. Moderna suggests that Moderna employed this tactic when creating their LNP delivery systems.[69]

This will be Moderna's most difficult patent infringement challenge because this technology is not exclusive to Covid-19, and there are variations of it that have been licensed to Moderna, Pfizer, and BioNTech. Again, the Arbutus litigation displays Moderna has previously relied on technology related to certain Arbutus LNP delivery systems and reports indicate that Moderna's vaccine may have relied on preclinical data generated using technology covered by Arbutus.[70] Moderna continues to posit they have developed their own delivery technology and therefore don't need an Arbutus license to commercialize its products.[71] When asked to disclose their molar ratios (an instrument that is used here to gauge infringement), Moderna stated they did not plan to disclose their proprietary ratios. These ratios may surface as evidence during litigation, and could be an indicator of prior art, invalidating Moderna's infringement claim. Overall, the history of LNP delivery systems is convoluted, and coupled with the lack of undisclosed data it is difficult to determine who has the upper hand. The evidence that arises during litigation will be interesting to see since it could possibly backfire against Moderna's patents as initiating litigation for patent infringement makes one's patents vulnerable to invalidation.

Courts understand that none of the companies in the present litigation are originators of LNP delivery systems, and a vast web of litigation to this regard precedes them. In addition to Arbutus, Alnylam Pharmaceuticals has ongoing patent infringement suits against both Pfizer and Moderna for the use of LNP technology in their vaccines.[72] This technology is not exclusive to Moderna thus implicating a high burden on them, as "Judges and juries generally don't like people who are trying to

[69] Daniel Shores, *The mrna patent and competitive landscape: Pioneers, litigation outlook and Big Pharma's next moves (part III)*, JD Supra (2021), https://www.jdsupra.com/legalnews/the-mrna-patent-and-competitive-7682620.
[70] *Id*.
[71] *Id*.
[72] *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc.*, C.A. No. 22-cv-00336-CFC, Defendant's Response to Complaint (Pfizer Inc., Sept. 12, 2022).

pull the wool over their eyes, and Moderna nowhere in this complaint actually acknowledges that it was building on a mountain of other science."[73]

The second claim involves patents, '600 and '127, which describe chemical modifications made to mRNA to ensure that upon entrance to the body that the mRNA introduced can enact an immune response to build antibodies. The complaint asserts Pfizer and BioNTech continue to directly infringe these patents, either literally or under the doctrine of equivalents through its use and sale in the United States, which is a direct violation of 35 U.S.C. § 271(a).[74]

Given Moderna's presented patent portfolio, the likelihood of a finding for literal infringement by Pfizer is slim, as it requires a jury to determine that Pfizer's device or method matches every aspect of all the limitations of the patent's claims. In other words, a literal construction of Pfizer's patents would encompass only its disclosed structure and equivalents when compared to Moderna's, without modification. A finding under a doctrine of equivalents would be much more likely because of the clear similarity of the patents in question. To prevail under this doctrine, one must satisfy the following steps: (1) determine whether the accused device or process achieves substantially the same result as the claimed invention; (2) determine whether the accused device or process performs substantially the same function as the claimed invention; (3) and determine whether the accused device or process operates in substantially the same way as the claimed invention.[75] The overall purpose of this test is to determine whether the accused device or process operates in the same way as the claimed invention. This test can be built to identify and catch those who purposely design around patent claims to avoid infringement.

Largely in patent infringement suits, and in the suit in question, experts play a large part for both parties. Juries usually

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[73] Robert Cook-Deegan and Gina Vitale, *Moderna sues Pfizer and BioNTech over COVID-19 vaccine*, Cen.acs.org (Aug. 31, 2022), https://cen.acs.org/policy/intellectual-property/Moderna-sues-Pfizer-BioNTech-over/100/web/2022/08.

[74] *See supra* note 16 at 30 ¶ 105.

[75] *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 41 (1997).

are not composed of technicians or scientists, therefore, an expert is necessary to explain what the technology is and provide testimony on whether the accused products include each element of the assert claims.[76] Additionally, parties can use factual admissions such as the accused infringer's testimony or discovery responses[77]; testing, simulations, or other demonstrations,[78]which are typically conducted by expert witnesses; or surveys.[79]

To further their claim, Moderna professes evidence pointing towards infringement by emphasizing Pfizer and BioNtech's vaccine development procedure. They allege Pfizer and BioNtech took four different vaccine candidates into clinical testing, which included options that would have steered clear of Moderna's innovative path.[80]They then proceeded with a vaccine that has the same exact mRNA chemical modification to Moderna's vaccine, Spikevax. Moderna claims their scientists began developing the technology, designed to avoid provoking an undesirable immune response when mRNA is introduced into the body in 2010, and were the first to validate it in human trials in 2015.[81]

It is uncontested, however, that the idea to modify the chemistry of mRNA to avoid the body's immune response was devised at the University of Pennsylvania, by mRNA pioneers Katalin Karikó and Drew Weissman in the mid 2010's.[82] Moderna initially responded to the patent issue by modifying the technology slightly, but eventually paid $76 million to license the patent

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[76] Practical Law Intellectual Property & Technology, Patent Litigation: Expert Considerations, Westlaw (last visited Feb. 13, 2023).
[77]*Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1362 (Fed. Cir. 2008).
[78] *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1351-52 (Fed. Cir. 2010).
[79] *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1334 (Fed. Cir. 2019).
[80] *See supra* note 16 at 6 ¶ 19.
[81] *Moderna sues Pfizer and BioNTech for Infringing Patents Central to Moderna's innovative mRNA Technology Platform*, MODERNA (Aug, 26 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.
[82]Jason Mast, *Moderna sues Pfizer and BioNTech over Covid-19 vaccine*, Statnews (Aug, 26 2022), https://www.statnews.com/2022/08/26/moderna-sues-pfizer-and-biontech-over-covid-19-vaccine/.

belonging to Kariko and Weissman. Meanwhile, BioNTech also licensed the same patent and even hired Kariko after her stint at Moderna.[83] Moderna alleges that the relationship between Pfizer, BioNTech and Weissman resulted in the exact chemical modification Moderna devised.[84] These pieces of evidence will not determine this case, but it is simply another tool in the Moderna litigation toolbox. It seems Moderna has a documented history and a bit more novelty for these chemical modifications, but there are still many players who contributed to its development. Pfizer and BioNtech will largely lay their hat on the fact that Moderna did not initially license the Kariko and Weisman technology. Instead, Moderna claimed to have their own modification, but licensed the technology down the line. In a patent infringement suit, traditionally, the party who licensed first would be provided deference.[85]

IV. MRNA TECHNOLOGY AND PATENT POOLS

There is a pressing need for continued innovation to effectively combat Covid-19 and other diseases that can be treated through mRNA technology. To ensure the development of effective vaccines in the future, it is in the public's best interest to encourage multiple entities to build upon mRNA technology. Removing financial barriers that hinder progress in this area is essential. Messenger RNA (mRNA) technology is revolutionary and has a wide range of potential applications beyond Covid-19 research. In the field of vaccine development, mRNA represents a paradigm shift from traditional methods that rely on weakened or deactivated forms of a virus.[86] Lawsuits aimed at monopolizing key technologies, particularly in biomedicine, go against the public interest. This became clear during the Covid-19 pandemic, where the ploy of patent rights stunted the production of sufficient remedies to combat the virus.

[83] *Id*.
[84] *Id*.
[85] 35 U.S.C. 271 (2009).
[86] Samagra Jain, Messenger RNA-based vaccines: Past, present, and future directions in the context of the COVID-19 pandemic, (Oct. 9, 2021).

During the pandemic, the US government's approach was to finance research and development costs upfront while allowing companies to retain ownership of their intellectual property. This included patent and copyright monopolies, as well as protection of trade secrets. This has limited the availability of vaccines and other essential items needed to control the pandemic, while also driving up the price of vaccines far beyond what would be expected in a free market.[87] Each mRNA vaccine costs less than $1 to manufacture, even by doubling the costs to cover the cost of distribution, the companies are still charging markups close to 2000% above their actual costs.[88] In almost all cases, these would be available at very low prices in a market without patent or related monopolies.

The United States, specifically the USPTO, must recognize that certain inventions play a critical role in promoting social welfare, and therefore, should not receive full protection of exclusive rights under patent law. To ensure the public's access to these vital inventions, the USPTO must refrain from granting patents to companies for such essential inventions. However, the sub-issue of private ownership of fundamental research has also been brought to light, as seen in the Human Genome Project in the 1990s, where publicly funded scientists had to fight against private companies to prevent patent applications that would block access to research. Here, publicly funded scientists worked hard to ensure that all their research would remain in the public domain.[89] This prevented patent applications that would block access to research.[90] Their attempts were not always successful.[91] For example, one day before Mike Stratton was due to publish his paper on cancer genes in the journal *Nature* in 1995, the private

[87] Dean Baker, *Getting ready for the next pandemic: Can we get patent monopolies on the table?*, Center for Economic and Policy Research (Dec. 20 2021), https://cepr.net/getting-ready-for-the-next-pandemic-can-we-get-patent-monopolies-on-the-table/.
[88] *Id*.
[89] Parthasarathy, Shobita. "The Patent Is Political: The Consequences of Patenting the BRCA Genes in Britain." Community Genetics, vol. 8, no. 4, 240 (last visited Feb. 15 2023).
[90] *Id*.
[91] *Id*.

company Myriad Genetics applied for a patent on BRCA1 and BRCA2, which were associated with breast cancer.[92] The patents allowed Myriad to charge for tests that cost $2,500 per patient. Myriad's simpler tests for breast cancer were licensed to other labs for several hundred dollars per patient, which made it unaffordable for many female patients in the USA. As of a result of these high costs, Myriad's value skyrocketed to over $3 billion by 2015.[93]

Private ownership and equity are widely accepted concepts in the United States, despite their limitations in the realm of fundamental research. Nevertheless, discovering a resolution that falls within the structure of private ownership can yield better results. One promising avenue is the incorporation of patent pools into the US patent system. It is crucial to recognize that a standardized patent system may not be suitable for all types of innovations. Rather, it must be tailored to meet the distinct demands of diverse industries, types of knowledge, and inventors. By establishing a patent pool, it could be ensured that numerous scientists could contribute to the continued progress of mRNA technology.

A patent pool is an agreement between two or more patent owners to license one or more of their patents to one another or to third parties.[94] Although this technology is known, these pools traditionally deal with technology that has yet to be fully developed. Allowing the pool to supply itself with the necessary technologies to further innovate and develop compatible products and services.

Traditionally, these pools consist of multiple patent holders. In our scenario, companies such as Pfizer, BioNTech, Moderna, CureVac, Arbutus, and others could all be key players for this proposed pool. The many patents regarding mRNA technology would be made available to members through licenses,

[92] Parthasarathy, *supra* note 95, at 238.
[93] Pollock, R. The Open Revolution: Rewriting the Rules of the Information Age. 2015).
[94] Patent Pools and Antitrust – A Comparative Analysis, World Intellectual Property Organization (WIPO), (March 3, 2014).

and typically a pool would allocate a portion of the licensing fees to each member in proportion to the particular patents value.[95]

The basis of patent pools relies on substitute patents and complementary patents. “Substitutes" refer to technologies that can be utilized in parallel without infringing on another patent, leading to competition between them outside of the patent pool. In contrast, "complementary patents" are required to produce a specific output and must be used together in the production process. Another scenario involves the presence of two "mutually blocking patents," which would also be considered complementary as well. Outside of a patent pool, these patents would legally infringe upon each other due to their coverage of similar of identical technology, with each patent’s claims being interpretable to encompass the other’s subject matter.[96] In this situation, the technologies employed are so alike that using one would constitute infringement against the party that did not initially file the patent. Patent pools provide safe haven for these patent types by enacting an umbrella licensing within the pool to allow for the cumulative innovation to be marketed individually without potential litigation due to the protected patent rights of different companies.

Furthermore, Patent pools are an effective solution to the tragedy of anticommons, where “multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use.”[97] Patent pooling is a method that enables a standard implementer to obtain a single license for all patents in a pool at a single royalty rate. This results in reduced transaction costs, greater control over the cumulative license fee, and improved access to patents.[98]

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[95] Rochelle Cooper Dreyfuss et al., Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society (2001).

[96] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, The National Bureau of Economic Research and the Massachusetts Institute of Technology (2000).

[97] Heller, Michael A. “The Tragedy of the Anticommons: Property in the Transition from Marx to Markets.” 111 Harv. L. Rev. 621–88 (1998).

[98] Bekkers, Emerging ways to address the reemerging conflict between patenting and technological standardization (Nov. 10, 2011).

Without patent pooling, a patent owner has the ability to prevent innovators from manufacturing new products associated with the patented technology. In contrast, patent owners can accelerate the development of new technologies by licensing their pooled patents as a group, which provides innovators with a "one-stop-shop".[99] This approach is highly advantageous for innovators as it eliminates the need for reaching out to multiple entities for a variety of licensing arrangements, thereby saving time and streamlining the development process. The practical application of this theory can be observed in the utilization of patent pools by the United States during periods of national emergency, such as in 1917, when the US entered World War I and faced a significant demand for airplanes. At the time, this technology was then limited and controlled by two firms that essentially blocked the patents necessary for airplane manufacturers. The Wright Company held the fundamental patent, which covered the wing-twisting mechanisms, while Curtiss Aeroplane & Motors Corporation possessed the principal patents for a wing-flap mechanism that improved Wright's patent.[100] The two companies disputed for an extended time where Wright claimed Curtiss infringement on its wing-twisting mechanism and refused to manufacture airplanes as a result. The National Advisory Committee for Aeronautics responded by proposing to form a patent pool encompassing almost all aircraft manufacturers in the US where those involved would pay a royalty to be able to have access to all the patents in the pool.[101]

Such a process may be employed in the case of an international pandemic, patent pooling could expedite the development and production of vaccines or treatments. The current COVID-19 pandemic has displayed that time is of the essence when developing effective vaccines and treatments. If a handful of companies hold patents for different aspects of mRNA technology, it could lead to delays and disputes over licensing arrangements, hindering the development process. A patent pool therefore could make the differing mRNA technologies whole by providing a

[99] *Id*.
[100] *War Business: A Laboratory and Licensing; Committees and Engines*, NASA, https://history.nasa.gov/SP-4103/ch2.htm (last visited March 31, 2023).
[101] *Id*.

single place for innovators to access all necessary patents.[102] This eliminates the need to approach individual entities separately, pay for each patent and go through different procedures, thereby streamlining the development process and accelerating the production of vaccines or treatments.[103] In this way, patent pooling could play a crucial role in responding to future international emergencies where rapid innovation is necessary.

Critics have questioned the effectiveness of patent pools in light of a recent international program, the COVID-19 Technology Access Pool (C-TAP), which aimed to encourage the voluntary sharing of knowledge, intellectual property, and data related to COVID-19 health technologies among 30 different countries and international organizations.[104] While the program sought to distribute COVID-19 vaccines and medical technologies to low- and middle-income countries (LMICs) through pooling intellectual property rights and other relevant data, the pharmaceutical industry's overall unwillingness to engage has hindered its success. The voluntary nature of the program is believed to be a key factor, as companies prioritize short-term financial gain over public welfare, leading them to opt out of participating. As the world continues to grapple with the challenges of dealing with an inevitable health crisis, the difficulties encountered by this program provide guidance on how to operate patent pools in the future.

To encourage the adoption of patent pools, the Department of Justice (DOJ) must actively contribute to their development and establish a model that is resistant to antitrust practices. Fortunately, the DOJ is not uninformed on this matter. In fact, there has been an evolution in the regulation of patent pools, which was initiated by the DOJ's business review letters in the late 1990s.[105] As of late, the DOJ has acknowledged that these pools

[102] Josh Lerner and Jean Tirole, *Public Policy toward Patent Pools*, 8 Innovation Policy and the Economy 172 (April 2008), http://www.nber.org/books/jaff08-1.
[103] *Id*.
[104] Health Action International, C-tap has not (yet) lived up to high expectations Health Action International (May 28, 2021), https://haiweb.org/c-tap-has-not-yet-lived-up-to-high-expectations/.
[105] Lerner, *supra* note 104 at 159 – 160.

can provide pro-competitive benefits as long as they only include essential patents, not be used to fix prices or reduce competition, and that pool members retain the right to license their property separately.[106] The DOJ also would monitor royalty rates and grant-back provisions to ensure they do not encompass non-essential patents. This approach has resulted in a cautious revival of patent pools in recent years, with pool designers taking steps to avoid antitrust scrutiny.[107]

Antitrust concerns must be addressed because pool members can create market power by reducing the number of competing patents and firms, through the restriction of entry and limitation of innovation by excluding firms with valuable patents or preventing new entrants from using the pooled technology. This must be weighed against potential efficiency gains from the pooling of complementary patents, such as reducing licensing costs and facilitating technology standardization.[108] By addressing this the DOJ can further the appeal of these patent pools and encourage more companies to participate in order to promote access to healthcare products, reduce research and development costs, and spur innovation.

Specific strategies can be employed to achieve this ideal patent pool model., with the promotion of complementary pools being the most notable one due to its ability to facilitate collaboration among firms while limiting the elimination of competition.[109] Complementary patents are those that are necessary for a single product or technology, and therefore, no one firm can create a complete product or technology without access to all the necessary patents.[110] By creating a patent pool with complementary patents, firms can collaborate and access all necessary patents while still competing on other aspects of their products or technologies.

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[106] *Id*.
[107] *Id*.
[108] Lerner, *supra* note 104 at 162.
[109] The United States Department of Justice, *ANTITRUST ANALYSIS OF PORTFOLIO CROSS-LICENSING AGREEMENTS AND PATENT POOLS*, (April 2007),3 ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 57–85.
[110] *Id*.

Additionally, non-exclusive licenses ought to be granted to these pools, thereby conferring the right to combine technology to licensors and licensees for the purpose of either enhancing or competing with the pooled technology.[111] Allowing independent licensing beyond the pool affords inventors who innovate around one or more pool patents the opportunity to engage in competition outside of the pool. Ultimately, the size of the patent pool will influence the willingness of pool members to support competing standards or participate in other pools.[112] The determination to pursue independent licensing is contingent upon whether such a license is profitable and whether licensees possess an incentive to invest in complementary assets.[113] While exclusive licenses may be advantageous in specific instances, it is advocated that independent licensing outside the pool should also be permitted to obviate potential antitrust concerns and give patent holders market freedom.

Nonetheless, great caution must be exercised to ensure that the formation of complementary patent pools does not result in the suppression of competition to be appealing to companies. The DOJ should evaluate each patent pool on a case-by-case basis to ensure that they are formed under established regulations. In order to do so there would need to be transparency of the pools through the display their formation arrangement including operation agreements, the terms of the licenses, and the distribution of royalties.[114]

V. CONCLUSION

Moderna has achieved the equivalent of the Holy Grail of patenting: true platform patents that can and will be used for the next vaccine and many more to come. Bringing a successful suit may result in a healthy damages award in the short term, but it may pale in comparison to what could happen during the 10-15 years of patent life remaining. A successful verdict would be

[111] *Id*.
[112] *Id*.
[113] Dept. of Justice, *supra* note 112.
[114] Lerner, Josh and Tirole, Jean, Efficient Patent Pools. American Economic Review (2004).

detrimental not only to the dormant power the technology in question holds but would also establish a negative precedent for future litigation. Actors on the side of Moderna would argue that they are not preventing others from building upon the technology and that one can simply purchase the rights through licensing. However, the cost associated with these agreements is often prohibitively high, limiting access to competent scientists who could contribute to further advancements in the field. Given our current knowledge, the possibilities MRNA technology has displayed are endless, especially after its application towards the recent pandemic. The rapid development and success can be attributed to the relationship between inventors and innovators. However, to unlock the full potential of mRNA technology quickly, action must be taken to prevent a barrier of entry to building upon this technology. This technology has distinguished itself from other non-essential products and processes by providing access to treatment for illnesses and lifesaving drugs/vaccines. It is evident from the way that firms use patenting as a strategic tool that access to lifesaving formulae should not be left to the market. Access to research that can affect humankind should not depend on whether a private company is prepared to license its technology. Governments need to recognize that not all technology types should be subject to traditional patent regulation; certain technologies must be exempt because they are too important to the wellbeing of the planet and its inhabitants to be left to the control of private companies. In the interest of social welfare, some areas of biomedicine should be exempt from the reach of the patent system. These include medicines, diagnostic tests, and research tools that should be accessible not only to those who can afford the exorbitant fees required to license these technologies but to as many researchers as possible. Accessibility of these resources to as many researchers as possible can greatly benefit society, particularly in the current fight against Covid-19. Lowering the barriers to entry could make a significant impact, not only in battling the ongoing pandemic but also in preparing for future diseases that may arise.