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U.S. 10,960,070: The U.S. Government's Important New Coronavirus Vaccine Patent

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Abstract

This report presents an analysis of U.S. Patent No. 10,960,070 (the "'070 patent"), an important and new coronavirus vaccine patent owned by the U.S. government, along with two of the government's academic partners. The report concludes that the '070 patent appears to be valid, enforceable by the U.S. government, and infringed by Moderna, Inc. (Moderna), because Moderna is currently making and selling a COVID-19 vaccine—mRNA-1273—that incorporates and relies on technology described and claimed by the '070 patent. Moderna does not appear to have the U.S. government's permission to use this patented technology.

Because Moderna lacks permission to use the technology, because the technology is essential to mRNA-1273's function and value as a vaccine, and because mRNA-1273 has been a financial blockbuster for Moderna, the '070 patent provides the U.S. government significant leverage over Moderna. The U.S. government could assert the '070 patent against Moderna in court and could (assuming Moderna's continued financial success) demand hundreds of millions or even over a billion dollars in compensation. The U.S. government could alternatively use the threat of litigation of the '070 patent to bring Moderna back to the negotiation table and convince Moderna to share its own patents, trade secrets, and other intellectual property on mRNA-1273 with the U.S. government and with vaccine manufacturers around the world. The latter option is the better one, to accelerate scale-up of global mRNA vaccine manufacturing, vaccinate the world, and bring the COVID-19 pandemic to a conclusive end.

I. Executive Summary

U.S. Patent No. 10,960,070 (the "'070 patent") is a U.S. patent on coronavirus vaccine technology. The '070 patent is jointly owned by the U.S. government, Dartmouth College, and the Scripps Research Institute. The '070 patent emerged from important work that scientists at the National Institutes of Health (NIH) and their academic collaborators at Dartmouth and Scripps did on coronavirus vaccines in the mid-2010s. While the roots of the '070 patent date back years, the patent issued—that is, took legal force—on March 30, 2021. The '070 patent broadly covers a technology for modifying and stabilizing the spike proteins that occur on the surface of coronaviruses. When these modified, stabilized spike proteins are delivered to or made within the human body, they generate an immune response. These patented proteins are linchpins of many effective coronavirus vaccines today.

The ’070 patent’s coronavirus vaccine technology was widely recognized as important even before COVID-19 and SARS-CoV-2 (the specific coronavirus that causes COVID-19) emerged. In 2017, NIH scientists and academic colleagues published a paper that presciently described the patent’s technology as “a foundation for the structure-based design of vaccine antigens for highly pathogenic coronaviruses, including those expected to emerge in the future.”[1]

Today, the technology described and claimed in the ’070 patent is fundamental to the design of many of the world’s leading COVID-19 vaccines.[2] One such vaccine is mRNA-1273, which is manufactured by the U.S.-based pharmaceutical company Moderna, Inc. (Moderna). The mRNA-1273 vaccine is widely described as “Moderna’s” vaccine, although some have challenged this characterization, pointing to the enormous public investment made in its research, development, manufacture, and distribution—by the U.S. government first and foremost.[3]

As a vaccine, mRNA-1273 has uniquely valuable properties, including stability during storage, scalability, and suitability to serve as a platform for development of vaccines effective against new variants.[4] These properties of mRNA-1273, along with the U.S. government’s unprecedented investment in its development, have led many civil society groups, including PrEP4All and Public Citizen, to call on Moderna to share its intellectual property covering mRNA-1273—Moderna’s patents, trade secrets, samples of intermediates used in its manufacturing process, and so on—with the world.[5] Moderna has thus far resisted those calls.[6] In

[1] Jesper Pallesen et al., *Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen*, PNAS (Aug. 29, 2017), https://www.pnas.org/content/114/35/E7348.long.

[2] News media and experts in civil society have variously concluded that many of the leading COVID-19 vaccines in use and in trials today—including those manufactured and sold by Moderna, Pfizer-BioNTech, Johnson & Johnson, Novavax, and CureVac—rely on NIH’s patented technology. *See* Selam Gebrekidan & Matt Apuzzo, *Rich Countries Signed Away a Chance to Vaccinate the World*, NEW YORK TIMES (updated Mar. 25, 2021), https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html?smid=tw-share; Bob Herman, *The NIH claims joint ownership of Moderna's coronavirus vaccine*, AXIOS (Jun. 25, 2020), https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html; Zain Rizvi, *Leading COVID-19 Vaccine Candidates Depend on NIH Technology*, Public Citizen (Nov. 10, 2020), https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/.

[3] Public Citizen, *Statement: Moderna Vaccine Belongs to the People* (Nov. 16, 2020), https://www.citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/; PrEP4All, *Hit Hard, Hit Fast, Hit Globally: A Model for Global Vaccine Access* (2021), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/6054fdd855fb270753f4b0c9/1616182745295/P4A+-+Hit+Hard+Hit+Fast+Hit+Globally+Report.pdf.

[4] *See* PrEP4All, *Hit Hard*, *supra* note 3.

[5] The NYU Technology Law & Policy Clinic, with which all of this report’s authors are affiliated, has provided legal representation to PrEP4All. Author Christopher Morten has also represented PrEP4All in his personal capacity.

[6] In October 2020, Moderna made headlines around the world by publicly pledging not to enforce its patents while the COVID-19 pandemic continues. *See, e.g.*, Peter Loftus, *Moderna Vows to Not Enforce Covid-19 Vaccine Patents During Pandemic*, WALL STREET JOURNAL (Oct. 8, 2020), https://www.wsj.com/articles/moderna-vows-to-not-enforce-covid-19-vaccine-patents-during-pandemic-11602154805. Moderna made the following pledge:

fact, Moderna announced in early 2021 that it may raise prices on its vaccine as early as this year, putting mRNA-1273 even farther out of reach for many people worldwide.[7]

This report highlights an important new tool the U.S. government could use to promote wider global access to the mRNA-1273 vaccine: the threat of patent infringement litigation. The key conclusions of this report are twofold:

1. **Moderna appears to be infringing the U.S. government's '070 patent by making and selling its blockbuster COVID-19 vaccine, mRNA-1273**, and

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> Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period.

Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic, Press Release, (Oct. 8, 2020), https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19. Moderna's pledge is unusual among major pharmaceutical companies. However, many experts have concluded that Moderna's pledge, while laudable, is insufficient to spur significant manufacturing of mRNA-based COVID-19 vaccines among its competitors, either in the U.S. or overseas. For one, Moderna's pledge lasts only "while the pandemic continues," and, as Olivia Webb has noted, Moderna "appears to have reserved the right to decide when" the pandemic ends. *A Shot in the Arm: How government succeeded in coronavirus vaccine development, and failed in distribution*, THE AMERICAN PROSPECT (January 21, 2021), https://prospect.org/coronavirus/shot-in-the-arm-coronavirus-vaccine-development/. That may leave competitor manufacturers exposed to liability for using Moderna's patents, if and when Moderna unilaterally determines that the pandemic has ended. *See* MSF (Médecins Sans Frontières/Doctors Without Borders), *Moderna's decision to not enforce COVID-19 vaccine patents during the pandemic isn't enough*, (Oct. 8, 2020), https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-modernas-decision-not-enforce-covid-19-vaccine-patents-during. In addition, while the pandemic continues, Moderna's nonenforcement pledge is limited to patents and does not touch other, critical varieties of intellectual property Moderna possesses: Moderna has not pledged to share its trade secrets or know-how vital to developing and manufacturing mRNA-based COVID-19 vaccines at scale. As Jorge Contreras has written,

> Unlike a replacement valve for a hospital ventilator, which can often be fabricated by anyone with a 3D printer and a design file, a vaccine is difficult and expensive to manufacture, especially in large quantities. Thus, without access to Moderna's proprietary (trade secret) manufacturing data, techniques, and materials, even a rival vaccine manufacturer would have difficulty reproducing the precise processes used by Moderna in making its vaccine safely and effectively.

Deconstructing Moderna's COVID-19 Patent Pledge, *BILL OF HEALTH*, Petrie-Flom Center at Harvard Law School (Oct. 21, 2020), https://blog.petrieflom.law.harvard.edu/2020/10/21/moderna-covid19-patent-pledge/. For these reasons, and others, many experts have concluded that Moderna's pledge to "not enforce patents on its COVID-19 vaccine throughout the duration of the pandemic will not ensure broad access for everyone who needs it." MSF (Médecins Sans Frontières /Doctors Without Borders), *Moderna's decision to not enforce COVID-19 vaccine patents during the pandemic isn't enough*, (Oct. 8, 2020), https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-modernas-decision-not-enforce-covid-19-vaccine-patents-during.

[7] Lee Fang, *Drugmakers Promise Investors They'll Soon Hike Covid-19 Vaccine Prices*, THE INTERCEPT (Mar. 18, 2021), https://theintercept.com/2021/03/18/covid-vaccine-price-pfizer-moderna/ (Moderna has "quietly touted plans to raise prices on coronavirus vaccines in the near future and to capitalize on the virus's lasting presence" and "indicated to investors that they plan to return to more 'commercial' pricing as early as later this year.").

2. As a result of Moderna's apparent infringement of the '070 patent, the U.S. government has significant leverage to negotiate with Moderna to make the mRNA-1273 vaccine more accessible and affordable, in the United States and globally.

The mRNA-1273 vaccine manufactured and sold by Moderna embodies the technology described and claimed in the '070 patent. As a result, the '070 patent covers mRNA-1273. Moderna does not appear to have the U.S. government's permission to use the technology described and claimed in the '070 patent. Without such permission, Moderna's manufacture and sale of mRNA-1273 would constitute acts of patent infringement.

Moderna's apparent infringement of the '070 patent provides the U.S. government significant leverage over Moderna: Based on our analysis, the U.S. government could assert the '070 patent against Moderna in court and (assuming Moderna's continued financial success) demand hundreds of millions or even over a billion dollars in compensation, based on Moderna's U.S. sales in 2021 alone. The U.S. government's leverage seems likely to persist for the foreseeable future, as Moderna projects expanding its manufacturing of mRNA-1273 in 2022 and beyond. Additional revenues from sales of mRNA-1273 after 2021 create additional potential liability for Moderna and additional leverage for the U.S. government. A counterpart patent application to the '070 patent that the U.S. government has pending before the European Patent Office provides more leverage still.

In our view, the U.S. government should use its leverage over Moderna. The goal, however, should not be to litigate nor to maximize the U.S. government's financial returns on the '070 patent. Instead, **the U.S. government could—and, we think, should—use the threat of litigation over the '070 patent to bring Moderna back to the negotiation table and convince Moderna to share its own patents, trade secrets, samples, clinical trial data, and other information on mRNA-1273 with the U.S. government and vaccine manufacturers around the world, so as to expand supplies of mRNA-1273 in the U.S. and globally**. In this regard, the threat of litigation over the '070 patent can be viewed as a new and potent public policy tool at the Biden Administration's disposal to effectuate the plans outlined by Public Citizen,[8] PrEP4All,[9] and other civil society groups to rapidly scale up global manufacturing and distribution of mRNA vaccines, to bring the COVID-19 pandemic to a conclusive end.

The remainder of this report proceeds as follows:

Part II—"What a Patent Is"—briefly explains what a patent is and the legal rights it confers.

[8] Public Citizen, *$25 Billion to Vaccinate the World: The U.S. Government Must Ramp up Vaccine Production and End the Global Pandemic* (Feb. 18, 2021), https://www.citizen.org/article/25-billion-to-vaccinate-the-world/.

[9] *See* PrEP4All, *Hit Hard*, *supra* note 3.

Part III—"The '070 Patent"—describes and analyzes the '070 patent in detail. Part III explains who owns and invented the '070 patent; when it will expire; what the patent describes and protects; how it made its way to issuance by the U.S. Patent & Trademark Office; and why it is presumed to be valid and enforceable by its owners.

Part IV—"Moderna Appears To Be Infringing the '070 Patent"—analyzes the COVID-19 vaccine manufactured and sold by Moderna, mRNA-1273, and considers whether Moderna's manufacture and sale infringes the '070 patent. Part IV shows that Moderna does not appear to have NIH's permission to use the '070 patent. Part IV also shows that mRNA-1273 meets each and every limitation of multiple claims of the '070 patent, leading to the conclusion that Moderna is likely infringing the patent.

Part V—"The '070 Patent Provides NIH Significant Leverage over Moderna"—describes the potential financial liability Moderna faces should a court find that Moderna's manufacture and sale of mRNA-1273 infringes the '070 patent. Based on Moderna's projected U.S. revenues and relevant legal precedent, Part V concludes that the court-ordered compensation Moderna would owe the U.S. government could run in the hundreds of millions or even over a billion dollars based on Moderna's 2021 revenues alone. This gives NIH significant leverage to negotiate a licensing agreement with Moderna that ensures global access to mRNA-1273.

Part VI—"NIH's Pending European Patent Application Could Eventually Provide NIH Additional Leverage"—describes a foreign "counterpart" to the '070 patent: a patent application currently pending before the European Patent Office. If and when this European patent application matures into a patent, it would give the U.S. government additional legal rights and additional leverage against Moderna.

Part VII is a brief conclusion. Part VII presents three provisions that should, in our view, be included in any agreement between the U.S. government and Moderna that extends Moderna a license to the '070 patent. These provisions would

1. empower the U.S. government to authorize manufacturing of mRNA-1273 itself, including in government-owned production facilities;
2. require Moderna to share mRNA-1273 technology, including manufacturing information currently protected as trade secrets, with the World Health Organization, to help ramp up global production; and
3. impose on Moderna requirements for accessible pricing, especially in low- and middle-income countries.

Part VIII provides the authors' biographies, affiliations, and acknowledgments.

II. What a Patent Is

A patent is a government-granted exclusive legal right in a technological "invention."[10] U.S. patents are granted or "issued" by the United States Patent & Trademark Office (USPTO),[11] upon application by the inventors. Before issuing a patent, a patent examiner at the USPTO examines the patent application to determine whether the patent application complies with all the conditions and requirements for patentability. This process typically takes years.[12]

Once issued, U.S. patents grant their holders the legal right to exclude others from making, using, and selling the invention within the United States, and importing the invention into the United States, throughout the life of the patent.[13] Patents are territorial in scope—the holder of a U.S. patent can restrict others' ability to use and profit from the patented invention within the United States. Foreign countries have their own patent offices and grant their own patents that give inventors similar rights within those countries. Patents are important in the pharmaceutical industry and other research-intensive industries because they permit inventors to block "free-riding" competitors from using their inventive technologies without permission.

In general, U.S. utility patents[14] filed after Jun. 8, 1995, have a term of 20 years from their effective U.S. filing date, subject to any terminal disclaimers (which can decrease the patent term) or adjustments or extensions (which can increase the patent term).[15]

III. The '070 Patent

This Part of the report explains the basics of the '070 patent: who owns and invented it; when it will expire; what the patent describes and protects; how it made its way through the USPTO, from filing of the first patent application in 2016 to patent issuance in 2021; and why the patent is presumed to be valid and enforceable.[16]

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[10] 35 U.S.C. § 101.

[11] 35 U.S.C. § 151.

[12] US Patent and Trademark Office, *Patents Pendency Data February 2021*, https://www.uspto.gov/dashboard/patents/pendency.html (accessed Apr. 8, 2021).

[13] 35 U.S.C. §§ 154(a), 271.

[14] The USPTO grants three kinds of patents: utility patents (on technical and scientific inventions), design patents (on ornamental designs), and plant patents (on plants). US Patent and Trademark Office, *General information concerning patents* (Oct. 2015), https://www.uspto.gov/patents/basics. The '070 patent is a utility patent.

[15] *See, e.g.*, Manual of Patent Examining Procedure § 2701 (R-10.2019) ("Patent Term").

[16] Important caveats apply to this report, and to this Part in particular. This report is not a formal opinion of counsel and cannot and should not be relied upon as such. Among other things, we have not undertaken an in-depth analysis of the construction of the claims of the '070 patent. Claim construction is a question of law that must ultimately be decided by a court. Validity and enforceability of the claims of the '070 patent ultimately depend on the construction of the claims. (The same is true of infringement.) Questions of enforceability are specific to a particular accused

A. Name, Owners, and Inventors of the '070 Patent

U.S. Patent No. 10,960,070 (the "'070 patent") is a U.S. utility patent entitled "Prefusion Coronavirus Spike Proteins and Their Use." The '070 patent is jointly owned by three owners:[17]

- The United States of America, as represented by the Secretary of the Department of Health and Human Services;
- The Scripps Research Institute of La Jolla, California; and
- Trustees of Dartmouth College of Hanover, New Hampshire.

The '070 patent identifies twelve patent inventors:

- Barney Graham
- Jason McLellan
- Andrew Ward
- Robert Kirchdoerfer
- Christopher Cottrell
- Michael Gordon Joyce
- Masaru Kanekiyo
- Nianshuang Wang
- Jesper Pallesen
- Hadi Yassine
- Hannah Turner
- Kizzmekia Corbett

Five of the patent's inventors were affiliated with the Viral Pathogenesis Laboratory of the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases (NIAID), which is one of the institutes of NIH: Graham, Corbett, Kanekiyo, Joyce, and Yassine.[18] Another five of the patent's inventors were affiliated with Scripps: Ward,

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infringer; a patent claim enforceable against one accused infringer may not be enforceable against another. We also have not reviewed all of the prior art references cited during prosecution of the '070 patent. New information relevant to the validity and/or enforceability of the '070 patent could come to light. In addition, the claims of the '070 patent could be cancelled or rendered or determined invalid and/or unenforceable in various ways, e.g., through statutory disclaimer, failure to pay maintenance fees, reexamination, post-grant proceeding at the Patent Trial and Appeal Board, or litigation in federal court.

[17] *See* the front page of the '070 patent and USPTO, *Patent Assignment Search* https://assignment.uspto.gov/patent/index.html#/patent/search (accessed Apr. 8, 2021).

[18] Scientific papers published around the time the '070 patent was filed confirm the institutional affiliations of the patent's inventors. *See* Pallesen et al. *supra* note 1; Masaru Kanekiyo et al., *Rational Design of an Epstein-Barr Virus Vaccine Targeting the Receptor-Binding Site*, CELL 162, 1090-1100 (Aug. 13, 2015), https://www.sciencedirect.com/science/article/pii/S0092867415009599; Robert N. Kirchdoerfer et al., *Pre-fusion structure of a human coronavirus spike protein*, NATURE Vol. 531, p. 118 (Mar. 2, 2016), https://www.nature.com/articles/nature17200.

Kirchdoerfer, Cottrell, Pallesen, and Turner. The remaining two inventors were affiliated with Dartmouth: McLellan and Wang.

B. Filing, Issuance, and Expected Expiration Dates of the '070 Patent

On October 25, 2016, the U.S. government filed the first patent application that ultimately matured into the '070 patent.[19] This first application was a U.S. provisional patent application, Application No. 62/412,703.[20] One year later, on October 25, 2017, the U.S. government filed a Patent Cooperation Treaty (PCT) application, bearing Application No. PCT/US2017/058370.[21] On April 24, 2019, the PCT application entered the U.S. "national stage" and became U.S. Patent Application No. 16/344,774.[22] On February 27, 2020, U.S. Patent Application No. 16/344,774 was published as U.S. Patent Application Publication No. US 2020/0061185.[23]

On March 30, 2021, the USPTO issued the '070 patent from U.S. Patent Application No. 16/344,774.[24] Immediately upon issuance, as of March 30, 2021, the U.S. government has a legal right to assert the '070 patent against any parties using the technology claimed by the patent—the claimed "invention"—without permission, anywhere within the United States.[25]

The '070 patent application has received no patent term adjustment or extension, and it is not subject to any terminal disclaimers. As such, the default 20-year term should apply to the '070 patent. Because the effective filing date of the '070 patent is October 25, 2017, the patent's expected expiration date is October 25, 2037.

C. Content and Claims of the '070 Patent

1. Context and Content of the '070 Patent

The earliest patent application that led to the '070 patent was filed in 2016, years before SARS-CoV-2 and COVID-19 emerged. Today the patent sounds remarkably prescient:

[19] *See* the front page of the '070 patent.

[20] *Id.*

[21] *Id.* PCT applications are international and permit an applicant to obtain multiple patents in multiple countries. Under U.S. patent law, the effective filing date of a U.S. patent derived from a PCT application is the filing date of the PCT application, which makes October 25, 2017 the effective filing date of the '070 patent. *See* 35 U.S.C. § 363.

[22] *See* the front page of the '070 patent.

[23] *Id.*

[24] *Id.*

[25] *See* 35 U.S.C. § 154(a)(1) ("Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . .").

> The high pathogenicity and airborne transmissibility of SARS-CoV and MERS-CoV have raised concern about the potential for another coronavirus pandemic. The high case-fatality rate, vaguely defined epidemiology, and absence of prophylactic or therapeutic measures against coronaviruses have created an urgent need for an effective vaccine and related therapeutic agents.[26]

The inventors of the '070 patent set out to solve this urgent problem—the need to develop effective vaccines and related therapeutic agents to combat deadly coronaviruses.

The solution the scientists invented—and described and claimed in the '070 patent—was a new technology that "produce[d] a superior immune response" when tested against a wide range of different coronaviruses.[27] When administered as a vaccine, the technology described and claimed in the '070 patent can create "a protective immune response" and "inhibit[] subsequent infection with the corresponding coronavirus."[28]

The key to the '070 patent inventors' solution was to use coronaviruses' primary weapon—the "spike proteins" ("S" proteins) that the viruses use to invade human cells—against the viruses. Coronavirus spike proteins—more precisely coronavirus "S ectodomain trimers"[29]—are the parts of a coronavirus that attach onto human host cells.[30] Once attached, the spike protein fuses with the human host cell, changing the structure of the spike protein—and permitting the virus to invade.[31] After fusion of the virus and host cell has occurred, the coronavirus's genes begin instructing the human host cell to make more copies of the virus. This replication is what produces the potentially deadly COVID-19 infection.

The inventors of the '070 patent realized that the prefusion conformation (shape) of coronavirus spike proteins is key. (The "prefusion" conformation of a spike protein is simply the

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[26] '070 Patent 1:53-59.

[27] *Id.* 2:7; 80:40-47; 83:7-12.

[28] *Id.* 74:18-21.

[29] In this context, "S" is simply an abbreviation for "spike." *See* '070 patent 1:16. "Ectodomain" simply refers to the portion of the spike protein that extends outside the viral membrane (and thus is able to contact, and fuse with, a target human host cell).

[30] *See* Ryan Cross, *The Tiny Tweak Behind COVID-19 Vaccines*, C&EN (Sept. 29, 2020), https://cen.acs.org/pharmaceuticals/vaccines/tiny-tweak-behind-COVID-19/98/i38 ("Viruses multiply by dumping their genes into our cells and hijacking our cellular machinery to crank out new virus particles. But first, they need a doorway into our cells. Coronaviruses are studded with spikes, which grab hold of proteins decorating our own cells like doorknobs.").

[31] *See id.* ("Once attached, the spike undergoes a dramatic transformation, stretching before partially turning inside out to forcefully fuse with our cells.").

specific shape of the protein before it fuses with a host cell.[32]) Stabilizing coronavirus spike proteins in the prefusion conformation and then exposing them to the immune system "produce[d] a superior immune response in an animal model compared to corresponding coronavirus S ectodomain trimers that are not stabilized in the prefusion conformation."[33] In other words, the inventors recognized that stabilized spike proteins are more immunogenic—better vaccine candidates—than naturally occurring (so-called "wild type"), unstabilized spike proteins, which do not remain in the prefusion conformation for long.[34]

The inventors developed a generally applicable solution for stabilizing coronavirus spike proteins in their highly immunogenic prefusion conformation. Their solution was to substitute a particular amino acid—proline—for other amino acids at key positions within the chemical sequence of the spike protein. When the inventors introduced one or two proline residues at the right positions within the chemical sequence of a spike protein, the spike protein was stabilized in its prefusion conformation:

> One class of mutation, comprising one or more (such as two) proline substitutions at or near the boundary between a Heptad Repeat 1 (HR1) and a central helix of the protomers of the coronavirus S ectodomain trimer was found to be surprisingly effective for stabilization of coronavirus S protein trimers in the prefusion conformation.[35]

The key positions for the proline substitutions within the chemical sequence of the spike protein are "at or near the boundary between a Heptad Repeat 1 (HR1) and a central helix." These substitutions "provide for increased retention of the prefusion conformation" when compared to the spike protein in its "native coronavirus S sequence."[36]

The '070 patent is broad in scope: it describes not only the modified coronavirus spike protein itself[37] but also various ways of coding for and using the protein, including "[m]ethods of inducing an immune response in a subject" and of "inhibiting or preventing a coronavirus infection in a subject, by administering to the subject an effective amount of a disclosed

[32] '070 Patent 9:45-56.

[33] *Id.* 2:5-9.

[34] *Id.* 18:38-41; *see also* Cross, *supra* note 30 ("Scientists believe that for COVID-19 vaccines to be effective, our immune systems must develop antibodies that prevent this fusion. Such antibodies must target the spike protein in its aptly named prefusion conformation.").

[35] '070 Patent 1:66-2:5.

[36] *Id.* 9:60-63.

[37] Including various locations of the proline substitutions. *Id.* 2:24-55.

recombinant coronavirus S ectodomain trimer, nucleic acid molecule, or vector."[38] The '070 patent specifically contemplates the use of an "mRNA-based immunization protocol" utilizing a nucleic acid that "encodes" the stabilized spike protein.[39] ("mRNA" is "messenger" RNA—RNA that delivers a genetic "message" to cells and thereby instructs those cells to make a particular protein. The precise genetic code of the mRNA "encodes" the precise chemical sequence of the protein.) In other words, the '070 patent inventors anticipated the possibility of creating an effective coronavirus vaccine by delivering to patients mRNA that, once inside a patient's body, begins instructing the patient's body to start making the stabilized spike protein—rather than delivering the stabilized spike protein itself.[40] The patent notes the safety and manufacturing benefits of an mRNA-based vaccine over vaccines that contain the protein.[41]

The '070 patent describes its technology—coronavirus spike proteins stabilized in their prefusion conformation via the proline substitution trick devised by the '070 patent inventors—as applicable to *all* coronaviruses, including those not known at the time of filing. The patent defines a coronavirus as "[a] family of positive-sense, single-stranded RNA viruses that are known to cause severe respiratory illness"[42] and discusses the emergence of new MERS-CoV and SARS-CoV coronaviruses in human populations.[43] The patent also expressly contemplates "the potential for another coronavirus pandemic."[44] The patent includes references to "a coronavirus infection, *such as*"[45] and gives "*[n]on-limiting* examples of betacoronaviruses,"[46] reinforcing the broad definition of coronavirus.

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[38] *Id.* 2:20-25.

[39] *See id.* 78:3-29:

> In another embodiment, an mRNA-based immunization protocol can be used to deliver a nucleic acid encoding a disclosed recombinant coronavirus S ectodomain or coronavirus S ectodomain trimer directly into cells. … mRNA vaccines preclude safety concerns about DNA integration into the host genome and can be directly translated in the host cell cytoplasm. Moreover, the simple cell-free, in vitro synthesis of RNA avoids the manufacturing complications associated with viral vectors.

See also id. 17:30-47.

[40] The mRNA "encodes" the stabilized spike protein because it is genetic code that specifies the specific chemical sequence of the stabilized spike protein.

[41] *Id.* 78:9-11.

[42] *Id.* 9:1-2.

[43] *Id.* at 1:36-42 ("[T]he Middle East respiratory syndrome coronavirus (MERS-CoV) and the severe acute respiratory syndrome coronavirus (SARS-CoV) … emerged into the human population from animal reservoirs within the last 15 years and caused outbreaks with high case-fatality rates.").

[44] *Id.* 1:55-56.

[45] *See id.* 8:45-55 (defining "control" as "a positive control sample obtained from a patient diagnosed with a coronavirus infection, such as MERS-CoV or SARS-CoV").

[46] *Id.* 9:8-14 (defining "coronavirus" and noting listing "[n]on-limiting examples of betacoronaviruses"); *see also id.* 17:40-47 (defining "vaccine" and stating "[i]n a non-limiting example, a vaccine induces an immune response that

Later publications from NIH—published after the patent was filed but long before COVID-19 emerged—confirm NIH's view of the breadth and importance of the '070 patent. In 2017, NIH scientists and academic colleagues published a paper that disclosed the key technology they had described and claimed in the patent application that ultimately became the '070 patent: "an engineering strategy for stabilization of soluble S proteins in the prefusion conformation, which results in greatly increased expression, conformational homogeneity, and elicitation of potent antibody responses."[47] The paper proudly and presciently described the '070 patent's technology as "a foundation for the structure-based design of vaccine antigens for highly pathogenic coronaviruses, including those expected to emerge in the future."[48]

Separately, on April 16, 2018, NIH published in the Federal Register a description of the patent application that would become the '070 patent.[49] NIH invited interested companies to approach NIH for a license.[50] NIH described the patent's stabilized coronavirus spike protein technology as follows:[51]

> Inventors at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases have developed a novel CoV S protein vaccine antigen. This technology employs protein engineering to stabilize S [protein] in its prefusion conformation, preventing structural rearrangement, and exposing antigenically preferable surfaces. . . . Particularly for MERS-COV, stabilized S proteins have been shown to elicit superior neutralizing antibody responses up to 10-fold higher in animal models and protect mice against lethal MERS-CoV infection. This technology is applicable for delivery via other platforms, such as mRNA.

NIH went on to describe "Potential Commercial Applications" of the '070 patent's parent application: "The stabilized prefusion coronavirus spike protein can be used as a vaccine antigen to elicit robust neutralizing antibody responses."[52] It also described "Competitive Advantages"

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reduces the severity of the symptoms associated with a coronavirus infection (such as a SARS-CoV or MERS-CoV infection) and/or decreases the viral load compared to a control.").

[47] *See* Pallesen et al., *supra* note 1, at E7348.

[48] *Id.* at E7349. Nine of the '070 patent's twelve inventors—Corbett, Cottrell, Graham, Kirchdoerfer, McLellan, Pallesen, Turner, Wang, and Ward—co-authored the Pallesen et al. paper (*supra* note 1), and the paper identifies one of the '070 patent's predecessor applications, U.S. provisional patent application no. 62/412,703, as a "conflict of interest." These connections confirm the relationship between the paper and the '070 patent.

[49] 83 FR 16376 (Apr. 16, 2018) (describing "U.S. Provisional Patent Application Number 62/412,703, filed October 25, 2016" and "PCT Patent Application PCT/US2017/058370 filed October 25, 2017").

[50] 83 FR 16376.

[51] National Institutes of Health, HHS, *Government-Owned Inventions; Availability for Licensing*, 83 F.R. 16376, 16376–7 (2018).

[52] *Id.* at 16377.

that the patented technology confers: "[i]mproved immunogenicity compared to other coronavirus S vaccine formulations" and "[i]ncreased protein expression, stability, and manufacturability compared to wild-type CoV S."[53]

2. Claims of the '070 Patent

The '070 patent contains 23 claims. The claims are generally directed to—that is, they describe and claim—immunogens that elicit immunity to coronavirus infections and to methods of making and using these immunogens. The claimed immunogens are modified, stabilized versions of coronavirus spike ("S") proteins, stabilized via substitution of one or more prolines for other amino acids at key positions within the chemical sequence of spike proteins. Some claims of the '070 patent are directed to synthetic nucleic acids, including RNA, that encode (that is, contain the genetic instructions for) those modified, stabilized spike proteins.

What follows are five of the most relevant claims of the '070 patent, claims 1, 2, 4, 13, and 15:

> 1. An immunogen, comprising:
> a recombinant coronavirus S ectodomain trimer comprising protomers comprising one or two proline substitutions at a junction between a heptad repeat 1 (HR1) and a central helix that stabilize the S ectodomain trimer in a prefusion conformation.
>
> 2. The immunogen of claim 1, wherein the recombinant coronavirus S ectodomain trimer comprises two consecutive proline substitutions at the junction between the HR1 and the central helix.
>
> 4. The immunogen of claim 1, wherein the coronavirus is a betacoronavirus.
>
> 13. An isolated nucleic acid molecule encoding a protomer of the recombinant coronavirus S ectodomain trimer of claim 1.
>
> 15. The nucleic acid molecule of claim 13, wherein the nucleic acid molecule is an RNA molecule.[54]

[53] *Id.*

[54] '070 Patent 323:2-11, 323:16-7, 324:8-9, 324:10-11.

D. Prosecution History of the ’070 Patent

As a patent application makes its way through the USPTO, it is reviewed by a patent examiner for compliance with the conditions and requirements of patentability. The patent examiner may reject the application’s claims as not allowable for various reasons, and the patent applicant may respond to the examiner’s rejections by arguing against them and/or by amending the application’s claims. The record of communications between the patent examiner and patent applicant is known as the “prosecution history.” The prosecution history is a public record, made freely available on the USPTO’s website.

The ’070 patent had a relatively smooth prosecution history. The most important events in the prosecution history were as follows: In October 2020, the patent examiner concluded that a 2006 article, “Functional Characterization of Heptad Repeat 1 and 2 Mutants of the Spike Protein of Severe Acute Respiratory Syndrome Coronavirus,” by Chan et al., was a prior art reference[55] that rendered some of the NIH applicants’ then-pending claims invalid. Chan et al. disclosed a chemically modified spike protein of SARS-CoV with a proline residue replacing the naturally occurring amino acid residue at some positions *near but not at* the junction between the central helix and the heptad repeat 1 portions of the spike protein.[56] NIH then amended the claims, narrowing them to specify that in the claimed invention, the chemically modified spike protein stabilized in its prefusion conformation must have at least one proline substitution *at* the central helix/heptad repeat 1 junction, not just near it.[57] By making this narrowing amendment, NIH distinguished the technology claimed in the ’070 patent from what had been disclosed in the Chan et al. reference. Shortly thereafter, in January 2021, the USPTO examiner issued a “Notice of Allowability,” concluding that the claimed “immunogen as recited in claim 1 is free of the prior art of record,” including Chan et al.[58] NIH then paid the issue fee, and the USPTO issued the patent several weeks later, on March 30, 2021.

[55] Black’s Law Dictionary defines prior art as follows: “Knowledge that is publicly known, used by others, or available on the date of invention to a person of ordinary skill in an art, including what would be obvious from that knowledge. Prior art includes (1) information in applications for previously patented inventions; (2) information that was published more than one year before a patent application is filed; and (3) information in other patent applications and inventor's certificates filed more than a year before the application is filed. The U.S. Patent and Trademark Office and courts analyze prior art before deciding the patentability of a comparable invention.” ART, Black's Law Dictionary (11th ed. 2019)

[56] ’070 Patent prosecution history, Office Action of October 29, 2020.

[57] ’070 Patent prosecution history, Amendment of October 30, 2020.

[58] ’070 Patent prosecution history, Office Action of January 7, 2021.

E. Validity and Enforceability of the '070 Patent

Under U.S. patent law, patents are presumed valid once issued by the USPTO.[59] We have no reason to believe that the '070 patent is invalid or unenforceable by NIH.

While not conclusive proof of validity or enforceability, anecdotal evidence suggests that at least 17 companies making or developing COVID-19 vaccines have paid NIH for licenses to the patent and therefore likely believe the '070 patent to be valid and enforceable. *The New York Times* has reported that BioNTech—developer of the leading COVID-19 vaccine sold by Pfizer—has paid the U.S. government for a license to the '070 patent.[60] Public Securities & Exchange Commission (SEC) records show that at least two other vaccine developers—GeoVax, a startup that is developing a COVID-19 vaccine,[61] and Noachis Terra, a subsidiary of Oragenics that is also developing a COVID-19 vaccine[62]—have also paid for a license to the '070 patent.[63] Kathryn Adrizzone of Knowledge Ecology International has reported that 14 additional companies—Medigen Vaccine Biologics Corp.; OncoSec Medical Incorporated; N4 Pharm UK Limited; Dynavax Technologies; RNAceuticals, Inc.; Sanofi Pasteur; GlaxoSmithKline Biologicals SA; Adimmune Corporation; Vaxess Technologies; Meso Scale Diagnostics, LLC; The Binding Site Group Ltd.; ReiThera Srl; ExcellGene SA; and Thermo Fisher Scientific Inc.—have also taken licenses to the '070 patent.[64] The fact that each of these companies has paid for licenses to the '070 patent suggests that the patent is valid and enforceable.

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[59] 35 U.S.C. § 282(a).

[60] *See* Gebrekidan & Apuzzo, *supra* note 2 ("BioNTech has paid the U.S. government to license the technology").

[61] GeoVax, Inc., *GeoVax Awarded NIH Grant to Advance COVID-19 Vaccine Development*, Intrado GlobalNewswire (Jan. 11 2021), https://www.globenewswire.com/news-release/2021/01/11/2156349/0/en/GeoVax-Awarded-NIH-Grant-to-Advance-COVID-19-Vaccine-Development.html.

[62] *Oragenics Issues Letters to Stockholders*, BIOSPACE (Jan. 14 2021), https://www.biospace.com/article/releases/oragenics-issues-letter-to-stockholders/.

[63] *See Patent License—Non-Exclusive and Biological Materials License—Non-Exclusive from NIAID to Noachis Terra Inc.*, https://www.sec.gov/Archives/edgar/data/1174940/000149315220015841/ex10-2.htm, at Appendix A (identifying "US Patent Application 16/344,774 filed 24 April 2019 entitled 'Prefusion coronavirus spike proteins and their use'") *and* GeoVax Labs, Inc. *Form 8-K*, http://archive.fast-edgar.com/20210211/ARZ2B22CZ222KJZ2222I2ZZZG4MR66S8Q232/ ("The MVA backbone that the Company [GeoVax] uses in its vaccines was provided by the laboratory of Dr. Bernard Moss of the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The Company has a non-exclusive commercial license to the NIH MVA backbone for our SARS CoV-2 vaccine with the NIH, which includes the use of the patents and patent applications listed below," including "U.S. App. No. 16/344,774.").

[64] Kathryn Ardizzone, *License to NIH Spike Protein Technology Needed in COVID-19 Vaccines Demonstrates 'Available to the Public on Reasonable Terms' Requirement*, KNOWLEDGE ECOLOGY INTERNATIONAL (Mar. 30, 2021), https://www.keionline.org/35746.

IV. Moderna Appears To Be Infringing the '070 Patent.

This Part demonstrates that Moderna appears to be infringing the '070 patent by making and selling its blockbuster COVID-19 vaccine, mRNA-1273. This Part proceeds in three subparts: Part IV.A provides an overview of both Moderna, the company, and the mRNA-1273 vaccine it makes and sells. Part IV.B establishes that Moderna does not appear to have NIH's permission to use the '070 patent. Part IV.C concludes that multiple claims of the '070 patent appear to cover mRNA-1273 and that, as a result, Moderna is likely infringing the '070 patent by making and selling the vaccine.

A. Moderna and the mRNA-1273 COVID-19 Vaccine It Makes and Sells

This subpart provides a brief factual introduction to Moderna and to the COVID-19 vaccine, mRNA-1273, that Moderna makes and sells.

mRNA-1273 is a COVID-19 vaccine manufactured by Moderna.[65] On December 18, 2020, the Food & Drug Administration (FDA) granted mRNA-1273 emergency use authorization (EUA), based on clinical trial evidence that the vaccine is safe and effective at preventing COVID-19.[66]

As the FDA's EUA materials for mRNA-1273 explain, mRNA-1273 "contains a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles."[67] "Each 0.5 mL dose of Moderna COVID-19 Vaccine [mRNA-1273] contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus."[68] mRNA-1273 contains no protein; only the mRNA that *encodes* spike protein, along with some additional ingredients to help stabilize and deliver the mRNA.[69] When injected into a human's body, the mRNA in mRNA-1273 instructs the human body to produce the SARS-CoV-2 spike protein (in modified

[65] "mRNA-1273" was apparently the internal codename Moderna used for the vaccine while it was in development, and it has stuck. Moderna, the FDA, and the public at large all commonly use the name. *See generally* FDA, *Vaccines and Related Biological Products Advisory Committee Meeting: FDA Briefing Document, Moderna COVID-19 Vaccine* (Dec. 17, 2020), https://www.fda.gov/media/144434/download, *and see* NIH, *Press Release: Phase 3 Clinical Trial of Investigational Vaccine for COVID-19 Begins*, (Jul. 27, 2020), https://www.nih.gov/news-events/news-releases/phase-3-clinical-trial-investigational-vaccine-covid-19-begins.

[66] Letter from FDA Informing Moderna of EUA for mRNA-1273, 1 (Feb. 25, 2021), https://www.fda.gov/media/144636/download.

[67] *Id.*

[68] Moderna, *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)*, at 20 (Mar. 31, 2021), https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

[69] *See id.*

form, stabilized in its prefusion conformation). It is this spike protein that generates the body's immunity to COVID-19: "The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine [mRNA-1273] is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."[70]

As a COVID-19 vaccine, mRNA-1273 appears to have uniquely valuable chemical and medicinal properties, including improved storage characteristics as compared to Pfizer-BioNTech's competitor mRNA-based COVID-19 vaccine.[71] Among existing COVID-19 vaccines, mRNA-1273 and other mRNA vaccines are reportedly also uniquely suitable to serve as platforms for development of new "booster" vaccines effective against newly emergent variants.[72]

mRNA-1273 is manufactured and sold by Moderna but was jointly developed by Moderna and NIAID. As Moderna's press releases attest, "[t]he Moderna COVID-19 Vaccine (previously referred to as mRNA-1273) is an mRNA vaccine against COVID-19 encoding for a prefusion stabilized form of the Spike (S) protein, which was co-developed by Moderna and investigators from NIAID's Vaccine Research Center."[73] The U.S. government not only contributed NIH's and NIAID's scientific acumen; it funded essentially 100% of mRNA-1273's R&D, including nearly $1 billion in grants from the Biomedical Advanced Research and Development Authority (BARDA)[74] and over $400 million from the Department of Health & Human Services (HHS) for the large clinical trial that supported mRNA-1273 authorization by the FDA.[75] (While the U.S. government appears to have covered essentially all of the costs associated with development of mRNA-1273, Moderna did make important earlier investments in mRNA vaccine technology more broadly, including techniques for keeping mRNA molecules

[70] *Id.* at 21.

[71] *See* PrEP4All, *Hit Hard*, *supra* note 3, at 5.

[72] *See id.* at 17.

[73] Moderna Press Release, *Moderna Announces FDA Authorization of Moderna COVID-19 Vaccine in US* (Dec. 18, 2020), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-fda-authorization-moderna-covid-19-vaccine-us.

[74] *See* Bob Herman, *Moderna Skirts Disclosures of Coronavirus Vaccine Costs*, AXIOS (Aug. 5, 2020), https://www.axios.com/moderna-barda-coronavirus-funding-disclosure-2775a517-a775-485a-a509-b6906c8535a9.html.

[75] David Heath and Gus Garcia-Roberts, *Luck, Foresight and Science: How an Unheralded Team Developed a COVID-19 Vaccine in Record Time*, USA TODAY (Jan. 26, 2021), https://www.usatoday.com/in-depth/news/investigations/2021/01/26/moderna-covid-vaccine-science-fast/6555783002/; *see also* Allie Clouse, *Fact Check: Moderna Vaccine Funded by Government Spending, With Notable Private Donation*, USA TODAY (Nov. 24, 2020), https://www.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002/ (acknowledging that while the U.S. government funded almost all R&D on mRNA-1273, Dolly Parton funded a small fraction).

stable enough to use as vaccines.[76]) As a result of the public funding and contributions of U.S. government scientists that led to mRNA-1273, Peter Maybarduk, director of Public Citizen's Access to Medicines program, has characterized mRNA-1273 as "not merely Moderna's" but instead "the people's vaccine."[77]

Moderna is a public company based in the United States, incorporated in Delaware and headquartered in Cambridge, Massachusetts.[78] Moderna conducts and directs extensive manufacturing activities within the United States. Moderna manufactures mRNA-1273 itself at a facility in Norwood, Massachusetts.[79] Moderna's contractor, Lonza, manufactures additional quantities of mRNA-1273 in Portsmouth, New Hampshire.[80] Two Moderna contractors, Catalent and Baxter BioPharma Solutions, perform vial filling and packaging of the vaccine in Bloomington, Indiana.[81] Moderna appears to manufacture mRNA-1273 within the United States in order to sell it within the United States; in January 2021, Moderna stated in a press release that "[a]ll U.S. supply comes from Moderna's dedicated supply chain in the U.S."[82]

Moderna has sold millions of doses in the U.S. and around the world, and it has told investors that it expects to sell much more. Pursuant to advance purchase agreements already executed between Moderna and the U.S. government, Moderna expected to sell 100 million doses to the U.S. government by the end of March 2021 and expected to sell an additional 200 million doses between April and July 2021.[83] In addition, Moderna disclosed that the U.S.

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[76] Ryan Cross, *Without These Lipid Shells, There Would Be No mRNA Vaccines for COVID-19*, C&EN (Mar. 6, 2021), https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8.

[77] Public Citizen, *Statement*, *supra* note 3.

[78] Moderna, *Form 10-K* (2020), https://investors.modernatx.com/static-files/6c67452f-6a27-47a2-8ee7-48d18c54ea4c.

[79] Dan Stanton, *Inhouse Manufacturing Helping Speedy Progression of mRNA COVID Vaccine, Says Moderna*, BIOPROCESS INTERNATIONAL (May 19, 2020), https://bioprocessintl.com/bioprocess-insider/facilities-capacity/inhouse-manufacturing-helping-speedy-progression-of-mrna-covid-vaccine-says-moderna/.

[80] Paul Briand, *Lonza on Target Producing Moderna COVID Vaccine in Portsmouth*, SEACOASTLINE (Dec. 18, 2020) https://www.seacoastonline.com/story/news/local/2020/12/18/lonza-moderna-covid-vaccine-portsmouth/3912244001/.

[81] Catalent Press Release, *Moderna and Catalent Announce Collaboration for Fill-Finish Manufacturing of Moderna's COVID-19 Vaccine Candidate* (June 25, 2020), https://www.catalent.com/catalent-news/moderna-and-catalent-announce-collaboration-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-candidate/; Baxter Press Release, *Baxter BioPharma Solutions and Moderna Announce Agreement for Fill/Finish Manufacturing of the Moderna COVID-19 Vaccine in the U.S.* (Mar. 8, 2021), https://www.baxter.com/baxter-newsroom/baxter-biopharma-solutions-and-moderna-announce-agreement-fillfinish-manufacturing.

[82] Moderna Press Release, *Moderna Provides U.S. COVID-19 Vaccine Supply Update* (Jan. 26, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-provides-us-covid-19-vaccine-supply-update.

[83] Moderna Press Release, *Moderna Announces Additional Capital Investments to Increase Global Manufacturing Capacity for COVID-19 Vaccine* (Feb. 24, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-additional-capital-investments-increase-global ("Moderna expects to complete delivery

government has an option of purchasing 200 million more doses before the end of 2021,[84] suggesting Moderna may sell as many as 400 million doses of mRNA-1273 to the U.S. government alone between April and December 2021. Moderna has also said it expects to continue to scale up its global manufacturing and distribution of mRNA-1273 in the months to come, projecting a global total of 700 million doses made and shipped in 2021 and 1.4 billion doses in 2022.[85]

Moderna's astounding commercial success[86] is driven by the medical value of mRNA-1273. mRNA-1273 is widely considered to be one of the leading COVID-19 vaccines, with an excellent safety and efficacy profile.[87] It was authorized by the FDA in December 2020 after FDA regulators found the vaccine to be 94% effective at preventing symptomatic disease.[88]

B. Moderna Does Not Appear To Have NIH's Permission To Use the '070 Patent.

Moderna does not appear to have NIH's permission to use the stabilized spike protein technology described and claimed in the '070 patent.

A March 21, 2021 story in *The New York Times* by Selam Gebrekidan and Matt Apuzzo discussed the '070 patent[89] and stated that "it is clear now that several of today's vaccines—including those from Moderna, Johnson & Johnson, Novavax, CureVac and Pfizer-BioNTech—

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of the first 100 million doses to the U.S. Government by the end of the first quarter 2021, the second 100 million doses by the end of May 2021 and the third 100 million doses by the end of July 2021.").

[84] *Moderna Inc. Q4 2020 Earnings Call Transcript* (Dec. 31, 2020), https://www.fool.com/earnings/call-transcripts/2021/02/25/moderna-inc-mrna-q4-2020-earnings-call-transcript/ ("We have disclosed advanced purchase agreements to supply our COVID-19 vaccine to 40 countries through the end of 2021, including the U.S. government for 300 million doses with options for an additional 200 million doses . . . .").

[85] Holly Ellyatt, *$100 Billion Market Cap is the Blue-Sky Scenario for Moderna, Analyst Says*, CNBC (Feb. 25, 2021), https://www.cnbc.com/2021/02/25/100-billion-market-cap-is-the-blue-sky-scenario-for-moderna-analyst.html.

[86] Shares of Moderna rose by 700% in 2020 alone. Matt Egan, *Pfizer and Moderna Could Score $32 Billion in Covid-19 Vaccine Sales – in 2021 Alone*, CNN BUSINESS (Dec. 11, 2020), https://www.cnn.com/2020/12/11/business/pfizer-vaccine-covid-moderna-revenue/index.html.

[87] *See* PrEP4All, *supra* note 3, at 17.

[88] Carolyn Johnson, *FDA Review Clears Path for Second Coronavirus Vaccine, This One Developed by Moderna*, WASHINGTON POST (Dec. 15, 2020), https://www.washingtonpost.com/health/2020/12/15/moderna-vaccine-found-safe-effective/; *see also* Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, (Dec. 17, 2020), 8 https://www.fda.gov/media/144452/download.

[89] While the *Times* story does not identify the '070 patent by its name or number, the story refers to a patent that is clearly the '070 patent. The *Times* describes the patent in question as having an issue date of March 30 and as having been filed by the U.S. government "along with its partners at Dartmouth College and the Scripps Research Institute." A search of the USPTO website established that the '070 patent is the only patent owned by the U.S. government, Dartmouth, and Scripps that issued on March 30, 2021, confirming that the *Times* story is referring to the '070 patent.

rely on" the technology described and claimed in the patent.[90] The *Times* story revealed that, among those several vaccine developers, "only BioNTech has paid the U.S. government to license the technology."[91] Moderna declined to comment when asked outright by the *Times* whether it has authorization to use the '070 patent.[92] As such, Moderna seems not to have paid the U.S. government for a license to the '070 patent.

Even if Moderna has not paid the U.S. government for a license to the '070 patent, is it possible that Moderna nonetheless has secured by some other means legal authorization to use the patent? In the context of the close collaboration between Moderna and NIH to develop mRNA-1273, the U.S. government could perhaps have extended Moderna a royalty-free (gratis) license to the '070 patent (and perhaps to other U.S. government-owned patents). (Under the leadership of then-President Trump and HHS Secretary Alex Azar, BARDA provided Moderna with almost a billion dollars in support for the development of mRNA-1273 as part of Operation Warp Speed,[93] and NIH spent over $400 million in additional public money funding and conducting clinical trials of mRNA-1273.[94] A gratis license to the '070 patent could plausibly have been included in these agreements, as an additional incentive to induce Moderna to join Operation Warp Speed.) However, we have reviewed the set of confidential contracts between NIH and Moderna that were obtained by Bob Herman of *Axios*.[95] None of these contracts appears to provide Moderna with a license to the '070 patent, gratis or otherwise.[96]

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[90] *See* Gebrekidan and Apuzzo, *supra* note 2.

[91] *Id.*

[92] *Id.*

[93] *See* Clouse, *supra* note 75.

[94] Sydney Lupkin, *Prices For COVID-19 Vaccines Are Starting To Come Into Focus*, NPR (Aug. 6, 2020), https://www.npr.org/sections/health-shots/2020/08/06/899869278/prices-for-covid-19-vaccines-are-starting-to-come-into-focus.

[95] *See* Bob Herman, *The NIH claims joint ownership of Moderna's coronavirus vaccine*, AXIOS (Jun 25, 2020), https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html. (The NIH-Moderna agreements are linked at https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html.)

[96] In August, 2016, NIAID and Moderna entered a Cooperative Research and Development Agreement (CRADA), the goal of which was to "identify and optimize the next generation of HIV-1 [redacted] antigens by enabling the accelerated expression and characterization of lead molecules through Moderna's mRNA technology … [by] … discover[ing] antigens that can induce broadly neutralizing antibodies ["bNAB"], or stimulate bNAB lineages … as well as to test the preclinical efficacy of an mRNA vaccine encoding for these proteins." *See NIH-Moderna Confidential Agreements* at 35, 38–39, https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html. If research undertaken by NIAID pursuant to this CRADA had resulted in invention of the stabilized spike protein technology described and claimed by the '070 patent, the CRADA could grant Moderna co-ownership of the '070 patent (*id*. at 24, § 6.1), or at minimum an option to license NIAID's rights therein (*id*. at 25–26, § 7.2). However, the August 2016 CRADA does not appear to us to grant Moderna any such rights, for two reasons. First, the August 2016 CRADA concerned research at NIAID on HIV, apparently unrelated to the distinct line of research on coronaviruses undertaken with Dartmouth and Scripps scientists that led to the '070 patent. Second, NIAID filed the provisional application (Application No. 62/412,703) that eventually became the '070 patent on October 25, 2016—two months after executing the 2016 CRADA with Moderna, an improbably

It is also possible that the ’070 patent’s non-governmental co-owners, Dartmouth and Scripps, could have provided Moderna with a license. Under the default rules of patent law, Dartmouth or Scripps could extend Moderna a license to the ’070 patent without NIH’s knowledge or permission: “Each co-owner’s ownership rights carry with them the right to license others, a right that also does not require the consent of any other co-owner.”[97] However, the default rules can be superseded by contract among a patent’s co-owners to give one of the co-owners unilateral and exclusive control of decisions to license the patent.[98] Indeed, from publicly available information, the U.S. government appears to have unilateral and exclusive control of licensing of the ’070 patent. Three lines of evidence support this premise:

- According to *The New York Times*, “the United States government will control” the ’070 patent.[99] The same *Times* story suggests that NIH is undertaking discussions with drug companies unilaterally, without participation of Dartmouth or Scripps; for example, the story states that “[t]he National Institutes of Health declined to comment on its discussions with the drugmakers.”[100]
- NIH’s website lists the ’070 patent as “available for licensing for commercial development” and provides, as “licensing contact,” the name of an NIH official, Amy Petrik.[101] Dartmouth and Scripps each maintain technology transfer offices of their own, but their respective websites make no mention of the ’070 patent.[102]
- The U.S. government appears to have paid for and controlled the process of obtaining the ’070 patent. According to the USPTO website, the law firm officially responsible for the ’070 patent is “Klarquist Sparkman, LLP (OTT-NIH).”[103] “OTT-NIH” appears to be a reference to NIH’s Office of Technology Transfer,[104] and Klarquist Sparkman appears

short period of time in which to invent a technology like that covered by the ‘070 patent. It is, of course, possible that another contract between Moderna and the U.S. government, unknown to us, extends Moderna a license to the ’070 patent.

[97] *Schering Corp. v. Roussel–UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir. 1997).

[98] Arina Gorbatyuk, *The Allocation of Patent Ownership in R&D Partnerships: Default Rules v. Contractual Practices*, 17:1 SCRIPTED 4 (Jan. 31, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3534172.

[99] *See* Gebrekidan & Apuzzo, *supra* note 2.

[100] *Id.*

[101] NIH, Office of Technology Transfer, *NIH Prefusion Coronavirus Spike Proteins and Their Use* (Apr. 8, 2020), https://www.ott.nih.gov/technology/e-234-2016.

[102] *Dartmouth Technology Transfer Homepage*, https://www.tto.dartmouth.edu/ (accessed Apr. 8, 2021); *Scripps Research Technology Development Homepage*, https://www.scripps.edu/technology-development/ (accessed Apr. 8, 2021).

[103] USPTO Public PAIR entry for the ’070 patent, https://portal.uspto.gov/pair/PublicPair (search Patent Number “10,960,070” and navigate to “Address & Attorney/Agent tab).

[104] NIH, *Office of Technology Transfer Home page*, https://www.ott.nih.gov/ (accessed Apr. 8, 2021).

to be the U.S. government's preferred law firm for help with patent matters, and is the largest provider of legal services to the U.S. government.[105]

C. Moderna Appears To Infringe Multiple Claims of the '070 Patent.

The previous subpart concluded that Moderna does not appear to have NIH's permission to use the '070 patent. This subpart considers the question of whether Moderna infringes the '070 patent. It sets forth the legal standard for patent infringement and then explains why Moderna appears to meet that legal standard. This subpart includes detailed claim charts that map in detail how elements of the mRNA-1273 vaccine manufactured and sold by Moderna meet each and every limitation of multiple claims of the '070 patent, establishing that those claims cover mRNA-1273. We conclude with a brief analysis of the recently reported news that BioNTech has paid for a license to the '070 patent; given the apparent chemical similarity between mRNA-1273 and the Pfizer-BioNTech vaccine, it is likely that if the'070 patent covers the Pfizer-BioNTech vaccine, the patent covers mRNA-1273 as well.

1. The Legal Standard for Patent Infringement

Direct infringement of a U.S. patent "consists of the making, using, selling or offering for sale, within the United States, or the importing into the United States, during the term of the patent, the invention defined by a patent's claims, without the patent owner's authority."[106] "To infringe a claim, each claim limitation must be present in the accused product, literally or equivalently."[107] "Literal infringement exists when every limitation recited in the claim is found in the accused device."[108]

A party may also infringe a U.S. patent indirectly. For example, "[w]hoever actively induces infringement of a patent shall be liable as an infringer."[109] "[A] person infringes by actively and knowingly aiding and abetting another's direct infringement of the patent."[110] To induce infringement, "[t]he accused infringer must have knowingly aided and abetted direct infringement."[111] The accused infringer must also know of the patent and know that the induced

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[105] Klarquist News, *Klarquist Recognized as the Largest Provider of Legal Services to the United States Government* (Jan. 13, 2015), https://klarquist.com/news/klarquist-ranked-largest-provider-of-legal-services-to-united-states-government/.

[106] 5 CHISUM ON PATENTS § 16.01 (2021); *see also* 35 U.S.C. § 271(a).

[107] *Dawn Equipment Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998).

[108] *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1341 (Fed. Cir. 2016).

[109] 35 U.S.C. § 271(b).

[110] 5 CHISUM ON PATENTS § 17.04 (2021).

[111] *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (internal quotations omitted).

acts constitute infringement. "To prove inducement of infringement, the patentee must show that the accused inducer took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement."[112]

The question of patent infringement is a complex one, and ultimately one for a judge or jury to decide. In addition, a thorough analysis of infringement of a patent claim requires careful "construction"—interpretation—of the words of the claim,[113] which we have not undertaken here. Accordingly, what follows is merely our preliminary analysis of Moderna's apparent infringement of certain claims of the '070 patent.

2. Moderna Appears To Meet the Legal Standard for Infringement.

As described above, Moderna is currently making and selling mRNA-1273 within the United States. Moderna is doing so during the term of the '070 patent, which began on March 30, 2021. As described above, Moderna does not appear to have a license or other authority from the U.S. government (or from either of the other two owners of the '070 patent, Dartmouth and Scripps) to make, sell, use, or otherwise profit from the invention defined by the claims of the '070 patent.

Direct Infringement of Claims 13 and 15

As is presented in detail in the charts below, mRNA-1273 appears to embody at least two of the inventions defined by the '070 patent's claims. That is, each and every limitation of two claims of the '070 patent can be found in mRNA-1273 itself. Below are claim charts that map, in detail, how various elements of mRNA-1273 match each and every limitation of claims 13 and 15 of the '070 patent. Because mRNA-1273 meets each and every limitation of these claims, Moderna appears to directly infringe these two claims. The U.S. government's claim that Moderna infringes these two patent claims seems to us clear and strong.

All **emphasis** in the claim charts that follow has been added, to highlight how elements and features of mRNA-1273 meet limitations of various claims of the '070 patent.

[112] *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1279 (Fed. Cir. 2015) (quoting *Info–Hold, Inc. v. Muzak LLC*, 783 F.3d 1365, 1372 (Fed. Cir. 2015)).

[113] *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) (stating that "[v]ictory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process, which in turn necessitates a determination of what the words in the claim mean" (citations and internal quotation marks omitted)).

Claim 13

Claim limitations:	***Corresponding elements of mRNA-1273, as identified by Moderna:***	***Comments:***
An isolated nucleic acid molecule	"The candidate vaccine mRNA-1273 is a lipid nanoparticle–encapsulated, **nucleoside-modified messenger RNA (mRNA)–based vaccine** that encodes the SARS-CoV-2 spike (S) glycoprotein stabilized in its prefusion conformation."[114]	As the '070 patent explains, an "isolated" nucleic acid or other biomolecule refers to a nucleic acid or other biomolecule that "has been substantially separated or purified away from other biological components." '070 patent 13:6-10. The nucleic acid (mRNA) molecule of mRNA-1273 is "isolated," per this definition, as it has been purified away from other biological components.[115]
encoding a protomer of the recombinant coronavirus S ectodomain trimer of claim 1	"mRNA-1273, an mRNA vaccine that **encodes a SARS-CoV-2 spike protein that is stabilized in the prefusion conformation**."[116] "We report interim findings from this phase 1 clinical trial of the mRNA-1273 **SARS-CoV-2 vaccine encoding a stabilized prefusion spike trimer, S-2P**. . . . The candidate vaccine mRNA-1273 is a lipid nanoparticle–encapsulated, nucleoside-modified messenger RNA (mRNA)–based vaccine that **encodes the SARS-CoV-2 spike (S) glycoprotein stabilized in its prefusion conformation**."[117]	As the '070 patent explains, a "recombinant" protein, nucleic acid, or other biomolecule refers to a biomolecule that has a sequence that is not naturally occurring. '070 patent 15:36-41. The protein encoded by mRNA-1273 is recombinant because it is not the naturally occurring spike protein for SARS-CoV-2; instead, the spike protein associated with mRNA-1273 has been chemically modified by substitution of two proline residues in place of the naturally occurring amino acid residues. An "ectodomain" is the portion of a membrane protein that extends into extracellular space (the space outside a cell or viral membrane). All coronavirus spike proteins contain

[114] Lisa A. Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, 383 NEW ENGL. J. MED. 1920, 1921 (2020), https://www.nejm.org/doi/full/10.1056/nejmoa2022483.

[115] *See, e.g.*, Moderna, *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)*, https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf, *supra* note 68, at 20 (describing the "Moderna COVID-19 Vaccine" (mRNA-1273) as containing "100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus" and no other biological components).

[116] Kizzmekia S. Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, 586 NATURE 567, 567 (2020), https://www.nature.com/articles/s41586-020-2622-0.

[117] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921.

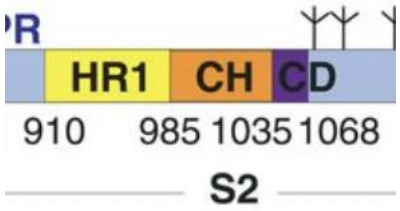
	"Cells are able to uptake mRNA delivered in an LNP, **translate the mRNA into its associated protein**, and then express that protein viral antigen(s) on the cell surface to elicit an immune response. . . . After delivery, **the mRNA utilizes the cell's translational machinery to produce the spike protein**, which after proper assembly and processing is trafficked to the cell membrane for display to the immune system."[118]	ectodomains. It is the ectodomain portion of the spike proteins of SARS-CoV-2 virus particles that permit them to invade and "fuse" with host cells, causing infection.[119] A "trimer" is "a molecular complex having three components or subunits." *See* Oxford Dictionary of Biochemistry and Molecular Biology, 2006. With both the naturally occurring SARS-CoV-2 virus spike protein and the modified, stabilized version produced by mRNA-1273, three identical copies of the individual spike protein "protomer" combine to form the trimer.
[wherein the recombinant coronavirus S ectodomain trimer of claim 1 comprises protomers comprising one or two proline substitutions at a junction between a heptad repeat 1	"S-2P spike (S) protein **modified with 2 proline substitutions within the heptad repeat 1 domain**"[120] "The mRNA-1273 vaccine candidate, manufactured by Moderna, encodes the S-2P antigen . . . S-2P is stabilized in its prefusion conformation by **two consecutive proline substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit**."[121] "Subsequently, we identified **2 proline substitutions (2P) at the apex of the central helix and heptad repeat 1** that effectively stabilized MERS-CoV, SARS-CoV and human	A "protomer" is the building block of a trimer; three copies of a protomer combine to form a trimer. *See* Oxford Dictionary of Biochemistry and Molecular Biology, 2006 (defining "protomer" as "any of the subunits of an oligomeric protein that are identical"). As noted above, with both the naturally occurring SARS-CoV-2 virus spike protein and the modified, stabilized version produced by mRNA-1273, three identical copies of the individual spike protein protomer combine to form the trimer. According to Moderna, in the modified SARS-CoV-2 spike protein protomer encoded by mRNA-1273, two naturally occurring amino acid residues at positions 986 and 987 of

[118] Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, *supra* note 88, https://www.fda.gov/media/144452/download, at 9.

[119] *See*, *e.g.*, Yuan Huang et al., *Structural and functional properties of SARS-CoV-2 spike protein: potential antivirus drug development for COVID-19*, 41 Acta Pharmacologica Sinica 1141, 1144 (2020), https://www.nature.com/articles/s41401-020-0485-4 (the SARS-CoV-2 "S protein consists of an extracellular N-terminus, a transmembrane (TM) domain anchored in the viral membrane, and a short intracellular C-terminal segment. . . . The trimer of the S protein located on the surface of the viral envelope is the basic unit by which the S protein binds to the receptor.").

[120] Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, *supra* note 88, https://www.fda.gov/media/144452/download, at 7.

[121] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921.

(HRl) and a central helix	coronavirus HKU1 S proteins in the prefusion conformation."[122]	the protein sequence are replaced with proline residues.[123] Once these modified spike protein protomers combine to form a trimer, the two proline substitutions stabilize the trimer in its prefusion state.[124] The two proline substitutions occur at one precise place in the sequence of the spike protein protomer: at the junction between the heptad repeat 1 (HR1) portion of the sequence and the central helix (CH) portion of the sequence.[125] 
that stabilize the S ectodomain trimer in a prefusion conformation].	"mRNA-1273 encodes the full length SARS-CoV-2 spike protein **stabilized in a prefusion conformation** with 2 proline mutations."[126]	

[122] Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, *supra* note 116, at 567 (citing the 2017 PNAS paper that is the counterpart publication to the '070 patent, Pallesen et al., *supra* note 1).

[123] *See* Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921 ("S-2P is stabilized in its prefusion conformation by two consecutive proline substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit.").

[124] *Id.*

[125] *See* Yongfei Cai et al., *Distinct conformational states of SARS-CoV-2 spike protein*, 369 SCIENCE 1586, 1587 (2020), https://science.sciencemag.org/content/369/6511/1586/tab-pdf (showing that, in the sequence of the SARS-CoV-2 spike protein, the junction between the heptad repeat 1 portion (ending at amino acid position 985) and the central helix portion (beginning at amino acid position 986) occurs at amino acid positions 985-986).

[126] Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, *supra* note 88, https://www.fda.gov/media/144452/download, at 9.

	"mRNA-1273, an mRNA vaccine that **encodes a SARS-CoV-2 spike protein that is stabilized in the prefusion conformation**."[127] "We report interim findings from this phase 1 clinical trial of the mRNA-1273 **SARS-CoV-2 vaccine encoding a stabilized prefusion spike trimer, S-2P**. . . . The candidate vaccine mRNA-1273 is a lipid nanoparticle–encapsulated, nucleoside-modified messenger RNA (mRNA)–based vaccine that **encodes the SARS-CoV-2 spike (S) glycoprotein stabilized in its prefusion conformation**."[128]	

Claim 15

Claim limitations:	***Corresponding elements of mRNA-1273, as identified by Moderna:***
The nucleic acid molecule of claim 13,	*See supra,* claim 13.
wherein the nucleic acid molecule is an RNA molecule.	"RNA-1273, **an mRNA vaccine** that encodes a SARS-CoV-2 spike protein that is stabilized in the prefusion conformation."[129] "The candidate vaccine mRNA-1273 is **a lipid nanoparticle–encapsulated, nucleoside-modified messenger RNA (mRNA)–based vaccine** that encodes the SARS-CoV-2 spike (S) glycoprotein stabilized in its prefusion conformation."[130]

[127] Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, *supra* note 116, at 567.

[128] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921.

[129] Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, *supra* note 116, at 567.

[130] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921.

Indirect Infringement of Claims 1, 2, and 4

Claims 1, 2, and 4 of the '070 patent cover immunogens that contain spike protein—"a recombinant coronavirus S ectodomain trimer comprising protomers comprising one or two proline substitutions at a junction between a heptad repeat 1 (HR1) and a central helix that stabilize the S ectodomain trimer in a prefusion conformation."[131] mRNA-1273 does not contain any spike protein, only mRNA that *encodes* spike protein. As such, mRNA-1273 cannot meet each and every limitation of any of claims 1, 2, or 4, and Moderna cannot directly infringe those claims by making or selling mRNA-1273.

However, as explained above,[132] once injected into a human patient, the mRNA of mRNA-1273 instructs the patient's body to produce spike protein, which then confers immunity. This fact pattern can constitute *induced* infringement of a claim covering spike protein.[133]

Moderna may be infringing claims 1, 2, and 4 under this theory. To induce infringement of any of claims 1, 2, and 4, Moderna must take "an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement."[134]

There is no question that Moderna is actively encouraging—indeed, instructing—health care providers to inject mRNA-1273 into patients, and is doing so in order to induce those patients' bodies to create immunogenic spike protein that confers immunity to COVID-19. For example, Moderna maintains on its website a "Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)" ("Moderna's Fact Sheet").[135] Moderna's Fact Sheet instructs health care providers to inject mRNA-1273 into patients: "Administer the Moderna COVID-19 Vaccine intramuscularly."[136] Moderna's Fact Sheet also explains to health care providers that, once inside the human body, mRNA-1273 begins instructing the body to produce immunogenic SARS-CoV-2 spike protein, thus conferring immunity: "The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the

[131] '070 patent claim 1.

[132] *See supra* § IV.A.

[133] *See Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997) ("[T]he right to exclude may arise from the fact that when administered, [the alleged infringer's product] metabolizes into another product . . . which [the patent] has claimed."); *Zenith Labs. v. Bristol-Myers Squibb*, 19 F.3d 1418, 1422 (Fed. Cir. 1994) (induced infringement may occur if the administered product is converted *in vivo* into the claimed product).

[134] *Astornet Techs.*, 802 F.3d at 1279.

[135] Moderna, *Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)* (Mar. 31, 2021), https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

[136] *Id.* at 4.

SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."[137] "Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus."[138]

Health care providers have already vaccinated millions of Americans according to Moderna's instructions.[139] In March of 2021, Moderna issued a press release stating "[m]ore than 67 million doses of the Moderna COVID-19 Vaccine have been administered in the U.S., according to the U.S. Centers for Disease Control and Prevention."[140] It is clear, then, that Moderna is inducing health care providers to inject mRNA-1273 into patients so as to spur the creation of immunogenic spike protein and that health care providers are doing just that.

Does Moderna know that the acts it is inducing health care providers to undertake—injection of mRNA-1273 into patients, so as to provoke production of coronavirus spike protein and thus immunity—constitute infringement of the '070 patent? There is overwhelming evidence that Moderna knows of the existence of the '070 patent. Reporters from numerous newspapers, including *The Washington Post*[141] and *STAT*,[142] have asked Moderna to comment on whether it is infringing the '070 patent. (Moderna has consistently declined to comment.) And language in Moderna's recent SEC filings suggests—though does not confirm beyond all doubt—that Moderna is aware it may have a legal obligation to license the '070 patent:

> [T]here may be issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we may need such patents for our mRNA therapeutic candidates. Thus, it is possible that one or more organizations will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. If those organizations refuse to grant us a license to such patent rights on reasonable terms or a court rules that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms, we may be unable to

[137] *Id.* at 21.

[138] *Id.* at 20.

[139] *See supra* § IV.A.

[140] Moderna Press Release, *Moderna Announces Shipment of 100 Millionth Dose of its COVID-19 Vaccine to the U.S. Government* (Mar. 29, 2021), https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-shipment-100-millionth-dose-its-covid-19.

[141] Christopher Rowland, *Advocates want NIH to use its Moderna vaccine patent to push for global access*, WASHINGTON POST (Mar. 25, 2021), https://www.washingtonpost.com/business/2021/03/25/moderna-vaccine-patent-nih/.

[142] Ed Silverman, *HHS is urged to use its patents for the Moderna Covid-19 vaccine to widen global access*, STAT (Mar. 25, 2021), https://www.statnews.com/pharmalot/2021/03/25/covid19-coronavirus-vaccnie-moderna-patents-nih-hhs/.

> perform research and development or other activities or market products, including mRNA-1273, covered by such patents.
>
> * * *
>
> Further, we may be required to obtain licenses under third-party patents to market our proposed products or conduct our research and development or other activities. If licenses are not available to us on favorable terms, we may not be able to market the affected products or conduct the desired activities.[143]

The only remaining question is whether the specific immunogenic spike protein produced by mRNA-1273 upon injection into the human body is the same immunogenic spike protein claimed by claims 1, 2, and 4 of the ’070 patent.

As is presented in detail in the charts below, it is. Below are claim charts that map, in detail, how various elements of the immunogenic spike protein created by mRNA-1273 match each and every limitation of the immunogenic spike protein covered by claims 1, 2, and 4 of the ’070 patent. As a result, Moderna appears to induce infringement of these three claims.

All **emphasis** in the claim charts that follow has been added, to highlight how elements and features of mRNA-1273 meet limitations of various claims of the ’070 patent.

[143] *See* Moderna Inc. (MRNA) Q4 2020 Earnings Call Transcript, *supra* note 84.

Claim 1

Claim limitations:	***Corresponding elements of mRNA-1273, as identified by Moderna:***	***Comments:***
An immunogen, comprising:	"mRNA-1273 is **immunogenic**, efficacious and does not produce evidence of VAERD when given at subprotective doses in mice."[144] "The mRNA-1273 vaccine was **immunogenic**, inducing robust binding antibody responses to both full-length S-2P and receptor-binding domain in all participants after the first vaccination in a time- and dose-dependent fashion."[145] The mRNA-1273 vaccine "encapsulate[s] synthetic mRNA that encodes for the full length SARS-CoV-2 spike protein stabilized in a prefusion conformation with 2 proline mutations. The CoV spike protein mediates attachment and entry of the virus into host cells by attachment followed by membrane fusion, making it a primary target for neutralizing antibodies (nAbs) that prevent infection. . . . The mRNA-1273 vaccine is delivered via intramuscular injection, and mRNA is subsequently delivered into cells, primarily antigen presenting cells at the injection site and draining lymph nodes. After delivery, the mRNA utilizes the cell's translational machinery to produce the spike protein, which after proper assembly and processing is trafficked to the cell membrane for display to the immune system. **mRNA-1273 stimulates innate immune responses** . . . ."[146]	The mRNA-1273 vaccine is immunogenic because it induces a vaccine recipient's body to create a stabilized, modified form of the SARS-CoV-2 spike protein. The spike protein then activates the body's immune system. As Moderna has written, mRNA-1273 "utilizes the cell's translational machinery to produce the spike protein, which after proper assembly and processing is trafficked to the cell membrane for display to the immune system."[147]

[144] Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, *supra* note 116, at 570.

[145] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1925.

[146] Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, *supra* note 88, at 19-20.

[147] *Id.* at 19.

a recombinant coronavirus S ectodomain trimer	"Cells are able to uptake mRNA delivered in an LNP, **translate the mRNA into its associated protein**, and then express that protein viral antigen(s) on the cell surface to elicit an immune response. . . . After delivery, **the mRNA utilizes the cell's translational machinery to produce the spike protein**, which after proper assembly and processing is trafficked to the cell membrane for display to the immune system."[148] "We report interim findings from this phase 1 clinical trial of the mRNA-1273 **SARS-CoV-2 vaccine encoding a stabilized prefusion spike trimer, S-2P**."[149]	As the '070 patent explains, a "recombinant" protein, nucleic acid, or other biomolecule refers to a biomolecule that has a sequence that is not naturally occurring. '070 patent 15:36-41. The protein encoded by mRNA-1273 is recombinant because it is not the naturally occurring spike protein for SARS-CoV-2; instead, the spike protein associated with mRNA-1273 has been chemically modified by substitution of two proline residues in place of the naturally occurring amino acid residues. An "ectodomain" is the portion of a membrane protein that extends into extracellular space (the space outside a cell or viral membrane). All coronavirus spike proteins contain ectodomains. It is the ectodomain portion of the spike proteins of SARS-CoV-2 virus particles that permit them to invade and "fuse" with host cells, causing infection.[150] A "trimer" is "a molecular complex having three components or subunits." *See* Oxford Dictionary of Biochemistry and Molecular Biology, 2006. With both the naturally occurring SARS-CoV-2 virus spike protein and the modified, stabilized version produced by mRNA-1273, three identical copies of the individual spike protein "protomer" combine to form the trimer.

[148] *Id.* at 9, 19.

[149] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1925.

[150] *See, e.g.*, Huang et al., *Structural and functional properties of SARS-CoV-2 spike protein: potential antivirus drug development for COVID-19*, *supra* note 119, at 1144 (the SARS-CoV-2 "S protein consists of an extracellular N-terminus, a transmembrane (TM) domain anchored in the viral membrane, and a short intracellular C-terminal segment. . . . The trimer of the S protein located on the surface of the viral envelope is the basic unit by which the S protein binds to the receptor.").

comprising protomers comprising one or two proline substitutions at a junction between a heptad repeat 1 (HRl) and a central helix	"S-2P spike (S) protein **modified with 2 proline substitutions within the heptad repeat 1 domain**"[151] "The mRNA-1273 vaccine candidate, manufactured by Moderna, encodes the S-2P antigen . . . S-2P is stabilized in its prefusion conformation by **two consecutive proline substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit**."[152] "Subsequently, we identified **2 proline substitutions (2P) at the apex of the central helix and heptad repeat 1** that effectively stabilized MERS-CoV, SARS-CoV and human coronavirus HKU1 S proteins in the prefusion conformation."[153]	A "protomer" is the building block of a trimer; three copies of a protomer combine to form a trimer. *See* Oxford Dictionary of Biochemistry and Molecular Biology, 2006 (defining "protomer" as "any of the subunits of an oligomeric protein that are identical"). As noted above, with both the naturally occurring SARS-CoV-2 virus spike protein and the modified, stabilized version produced by mRNA-1273, three identical copies of the individual spike protein protomer combine to form the trimer. According to Moderna, in the modified SARS-CoV-2 spike protein protomer encoded by mRNA-1273, two naturally occurring amino acid residues at positions 986 and 987 of the protein sequence are replaced with proline residues.[154] Once these modified spike protein protomers combine to form a trimer, the two proline substitutions stabilize the trimer in its prefusion state.[155] The two proline substitutions occur at one precise place in the sequence of the spike protein protomer: at the junction between the heptad

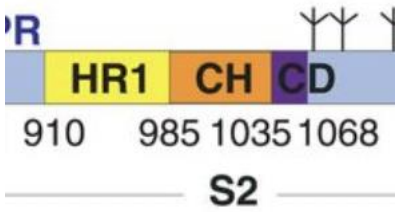
[151] Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, *supra* note 88, at 7.

[152] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921.

[153] Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, *supra* note 116, at 567 (citing the 2017 PNAS paper that is the counterpart publication to the '070 patent, Pallesen et al., *supra* note 1).

[154] *See* Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921. ("S-2P is stabilized in its prefusion conformation by two consecutive proline substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit.").

[155] *Id.*

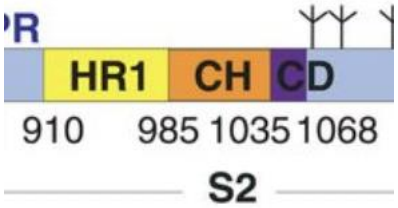
		repeat 1 (HR1) portion of the sequence and the central helix (CH) portion of the sequence.[156] 
that stabilize the S ectodomain trimer in a prefusion conformation.	"mRNA-1273 encodes the full length SARS-CoV-2 spike protein **stabilized in a prefusion conformation** with 2 proline mutations."[157]	

Claim 2

Claim limitations:	***Corresponding elements of mRNA-1273, as identified by Moderna:***	***Comments:***
The immunogen of claim 1,	*See supra*, claim 1.	
wherein the recombinant coronavirus S ectodomain trimer comprises two	"The mRNA-1273 vaccine candidate, manufactured by Moderna, encodes the S-2P antigen . . . S-2P is stabilized in its prefusion conformation by **two consecutive proline**	A "protomer" is the building block of a trimer; three copies of a protomer combine to form a trimer. *See* Oxford Dictionary of Biochemistry and Molecular Biology, 2006 (defining "protomer" as "any of the subunits of an oligomeric protein that are identical").

[156] *See* Cai et al., *Distinct conformational states of SARS-CoV-2 spike protein*, *supra* note 124, at 1587 (showing that, in the sequence of the SARS-CoV-2 spike protein, the junction between the heptad repeat 1 portion (ending at amino acid position 985) and the central helix portion (beginning at amino acid position 986) occurs at amino acid positions 985-986).

[157] Moderna, *Vaccines and Related Biological Products Advisory Committee Meeting Presentation*, *supra* note 88, at 9.

consecutive proline substitutions at the junction between the HR1 and the central helix.	**substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit**."[158]	As noted above, with both the naturally occurring SARS-CoV-2 virus spike protein and the modified, stabilized version produced by mRNA-1273, three identical copies of the individual spike protein protomer combine to form the trimer. According to Moderna, in the modified SARS-CoV-2 spike protein protomer encoded by mRNA-1273, two naturally occurring amino acid residues at positions 986 and 987 of the protein sequence are replaced with proline residues.[159] Once these modified spike protein protomers combine to form a trimer, the two proline substitutions stabilize the trimer in its prefusion state.[160] The two proline substitutions occur at one precise place in the sequence of the spike protein protomer: at the junction between the heptad repeat 1 (HR1) portion of the sequence and the central helix (CH) portion of the sequence.[161] 

[158] Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921.

[159] *See* Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1921. ("S-2P is stabilized in its prefusion conformation by two consecutive proline substitutions at amino acid positions 986 and 987, at the top of the central helix in the S2 subunit.").

[160] *Id.*

[161] *See* Cai et al., *Distinct conformational states of SARS-CoV-2 spike protein*, *supra* note 124, at 1587 (showing that, in the sequence of the SARS-CoV-2 spike protein, the junction between the heptad repeat 1 portion (ending at amino acid position 985) and the central helix portion (beginning at amino acid position 986) occurs at amino acid positions 985-986).

Claim 4

Claim limitations:	***Corresponding elements of mRNA-1273, as identified by Moderna:***
The immunogen of claim 1,	*See supra*, claim 1.
wherein the coronavirus is a betacoronavirus.	"SARS-CoV-2 is the third novel **Betacoronavirus** in the past 20 years to cause substantial human disease . . . ."[162]

[162] Corbett et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, *supra* note 116, at 567.

3. BioNTech's License to the '070 Patent Corroborates the Conclusion That Moderna Likely Infringes.

We close our analysis of Moderna's apparent infringement of the '070 patent with a final observation: BioNTech's license to the '070 patent corroborates the conclusion that Moderna likely infringes the '070 patent.

The fact that BioNTech has paid the U.S. government for a license to the '070 patent[163] suggests that BioNTech believes the patent to be valid and enforceable and that BioNTech believes it would be at risk of patent infringement liability if it did not pay for a license. That, in turn, suggests that BioNTech believes that BNT162b2—the COVID-19 vaccine it is manufacturing and selling through its commercial partner, Pfizer—is covered by the claims of the '070 patent. Indeed, BioNTech has explicitly stated to its investors that BNT162b2 "utilizes" the technology described and claimed in the '070 patent: "We . . . have a non-exclusive license from the National Institutes of Health granting us right to use certain US and European patent filings relating to SARS-COV-2 spike (S) protein variants that lock the S protein in an antigenically preferred prefusion conformation; such a variant is utilized in BNT162b2."

BNT162b2 and mRNA-1273 are widely reported to be very similar in terms of their chemical composition and clinical effectiveness. The active ingredient in both vaccines is a nucleotide-modified messenger RNA (mRNA).[164] Both vaccines elicit immune responses in humans in the same way—like mRNA-1273, BNT162b2 "encodes the RBD [receptor-binding domain] of the spike protein of SARS-CoV-2, a key target of virus-neutralizing antibodies."[165] Like mRNA-1273, BNT162b2 encodes not the naturally occurring (wild type), *un*stabilized form of the SARS-CoV-2 spike protein but instead encodes a "SARS-CoV-2 full-length spike, stabilized in the prefusion conformation."[166] A paper coauthored by scientists at Pfizer and BioNTech indicates that BNT162b2 relies on precisely the same stabilization technology—substitution of two proline residues for the naturally occurring amino acid residues at key positions within the sequence of the spike protein—that is described and claimed in the '070 patent and that Moderna relies on in mRNA-1273.[167]

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[163] *See* Gebrekidan & Apuzzo, *supra* note 2.

[164] *See supra* § IV.A & C.2 (description of mRNA-1273); Edward E. Walsh et al., *Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates*, 383 NEW ENGL. J. MED. 2439-2450 (Dec. 17, 2020), https://www.nejm.org/doi/full/10.1056/NEJMoa2027906 (description of BNT162b2).

[165] Mark J. Mulligan et al., *Phase I/II Study of COVID-19 RNA Vaccine BNT162b1 in Adults*, 586 NATURE 589, 589 (Aug. 12, 2020), https://www.nature.com/articles/s41586-020-2639-4.

[166] Walsh et al., *supra* note 164.

[167] "BNT162b2[] encodes the SARS-CoV-2 full-length spike, modified by two proline mutations to lock it in the prefusion conformation." *Id.*

Given the extensive similarities between BNT162b2 and mRNA-1273, if the claims of the '070 patent cover BNT162b2, they likely cover mRNA-1273 as well. Thus, given that BioNTech believes that manufacture and sale of BNT162b2 without NIH's permission would constitute infringement of the '070 patent, Moderna's manufacture and sale of mRNA-1273 without NIH's permission likely also constitutes infringement of the '070 patent.

D. NIH Seems To Know That Moderna Is Infringing the '070 Patent.

Additional evidence from NIH itself corroborates the premise that Moderna is infringing the '070 patent. Specifically, a spokesperson for NIH recently stated that mRNA-1273 is "an example" of the coronavirus vaccine technology invented and patented by NIH and that mRNA-1273 expresses "the stabilized spike protein developed by NIAID investigators."[168] That stabilized coronavirus spike protein is what NIH (and its academic collaborators) have described and claimed in the '070 patent. As such, the statement appears to confirm NIH is aware of Moderna's infringement.

In April 2021, NIAID Director Dr. Anthony Fauci published a short essay, *The Story Behind COVID-19 Vaccines*, that summarizes the stabilized coronavirus spike protein technology described and claimed in the '070 patent.[169] Dr. Fauci wrote,

> [Barney] Graham's team [at NIAID], including Kizzmekia Corbett, and collaborators in the laboratories of McLellan and Andrew Ward adopted this approach of mutational stabilization of prefusion proteins in their work on the spike protein of the coronaviruses that cause Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS). So, when the genetic sequence of the SARS-CoV-2 became available, **Graham's team lost no time in joining their long-time collaborators at Moderna to develop an RNA vaccine using a stabilized, prefusion spike protein as the immunogen**. Pfizer and BioNTech, where [Katalin] Karikó was working, also used the RNA platform that she and [Drew] Weissman had perfected and the immunogen designed by Graham to develop an RNA vaccine. **Additional companies also used Graham's immunogen in other vaccine platforms that had been evolving for years, to make SARS-CoV-2 vaccines**.
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> * * *
>
> When the stories and recounting of this pandemic are written, it is important that this history not be forgotten, as we are reminded once again of the societal value of a sustained and robust support of our scientific enterprise.[170]

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[168] *NIH Statement to Axios*, provided by Bob Herman, Axios (undated), https://www.documentcloud.org/documents/6956323-NIH-Statement-to-Axios.html.

[169] Anthony S. Fauci, *The story behind COVID-19 vaccines*, 372 SCIENCE 109 (Apr. 9, 2021), https://science.sciencemag.org/content/372/6538/109.

[170] *Id.* (emphasis added).

The editorial seems to reveal that Dr. Fauci believes that Moderna and other COVID-19 makers are using the immunogen described and claimed by the '070 patent—"Graham's immunogen."

Finally, in a November 2020 press release, NIH states that mRNA-1273 "combines Moderna's mRNA (messenger RNA) delivery platform with the stabilized SARS-CoV-2 spike immunogen (S-2P) developed by NIAID scientists."[171] This press release again suggests NIH believes that mRNA-1273 relies on the stabilized coronavirus spike protein technology described and claimed in the '070 patent.

V. The '070 Patent Provides NIH Significant Leverage over Moderna.

The previous Part focused on the question of whether Moderna is infringing the '070 patent and concluded that it probably is. Under U.S. patent law, if the U.S. government can prove to a court that Moderna is infringing the '070 patent, then Moderna will be liable to the U.S. government for compensation—"damages," in legal parlance.

This Part turns to the natural next questions: What, exactly, is Moderna's potential liability? How much might Moderna owe the U.S. government if the U.S. government brought and won a lawsuit against Moderna for patent infringement?

These questions about Moderna's potential liability for infringing the '070 patent are important because they determine the magnitude of the U.S. government's leverage over Moderna. The larger the scope of Moderna's potential liability, the greater the government's leverage. That leverage could be exerted by the government to negotiate with Moderna a deal that avoids litigation and instead extends to Moderna a license to the '070 patent in exchange for concessions from Moderna that expand global access to mRNA-1273 and other mRNA vaccines.

This Part concludes that Moderna's liability could easily run into the hundreds of millions or billions of dollars and that, therefore, the credible threat of infringement litigation over the '070 patent provides the U.S. government significant leverage over Moderna.

A. The Scale of Moderna's Manufacturing and Sales of mRNA-1273

The extent of Moderna's financial liability for infringing the '070 patent depends on the scale of Moderna's infringing activity—that is, the scale of Moderna's manufacture and sale of mRNA-1273.

[171] NIAID, *Promising Interim Results from Clinical Trial of NIH-Moderna COVID-19 Vaccine* (Nov. 16, 2020), https://www.niaid.nih.gov/news-events/promising-interim-results-clinical-trial-nih-moderna-covid-19-vaccine.

That scale is massive. As noted above,[172] Moderna expected to sell 100 million doses to the U.S. government by the end of March 2021, and it expects to sell 200 million more doses to the U.S. government between April and July 2021. Moderna has also stated that the U.S. government may purchase another 200 million doses before the end of the 2021,[173] suggesting Moderna may sell as many as 400 million doses of mRNA-1273 to the U.S. government alone between April and December 2021.

Moderna will collect billions of dollars in revenue from sales of hundreds of millions of doses of mRNA-1273. Moderna charges the U.S. government $15 per dose for mRNA-1273.[174] Assuming it sells 200 million doses to the U.S. government between April and July 2021, it will collect $3 billion. If the U.S. government exercises its option to purchase another 200 million doses before the end of the year, Moderna will sell a total of 400 million doses from April to December 2021, for total revenues of $6 billion.

These revenues from sales of vaccine to the U.S. government will constitute just a fraction of Moderna's projected global revenues for 2021 and beyond. In February, Moderna projected that its global mRNA-1273 vaccine revenues for 2021 alone will exceed $18 billion.[175] Based on its manufacturing projections—1.4 billion doses in 2022—its global revenues in 2022 will likely be higher still.

B. Preliminary Thoughts on Determination of Appropriate Compensation from Moderna to the U.S. Government

Having approximated the scale of Moderna's manufacturing and sales of mRNA-1273, we turn to Moderna's potential liability if the U.S. government were to assert the '070 patent against Moderna and a court were to find Moderna's manufacture and sale of mRNA-1273 to infringe.

[172] *Supra* § IV.A.

[173] *See* Moderna Inc. (MRNA) *Q4 2020 Earnings Call Transcript*, *supra* note 84 ("We have disclosed advanced purchase agreements to supply our COVID-19 vaccine to 40 countries through the end of 2021, including the U.S. government for 300 million doses with options for an additional 200 million doses . . . .").

[174] Jonathan Gardner, *As COVID-19 becomes a business, vaccine makers confront thorny pricing questions*, BIOPHARMA DIVE (Feb. 9, 2021), https://www.biopharmadive.com/news/coronavirus-vaccines-pricing-questions-moderna-pfizer/594762/.

[175] Julia Kollewe, *Moderna forecasts $18bn in sales of Covid vaccine this year*, THE GUARDIAN (Feb. 25, 2021), https://www.theguardian.com/business/2021/feb/25/moderna-forecasts-18bn-in-sales-of-covid-vaccine-this-year.

1. General Legal Principles of Compensation in Patent Infringement Cases

Remedies in patent infringement cases are complex, and we do not attempt a comprehensive analysis here. Instead, we make a few simple, preliminary observations that together suggest that an appropriate court-ordered damages award—that is, Moderna's financial liability to the U.S. government—could reach over a billion dollars.

The typical court-ordered remedies for patent infringement are either an injunction—a court order instructing the infringer to cease its infringing activity—or an award of monetary damages from the infringer to the patent owner. It would be inappropriate for the U.S. government to seek an injunction against Moderna as a remedy for infringement of the '070 patent, for transparently obvious reasons: shutting down Moderna's manufacture and sale of its vaccine while the pandemic continues would be disastrous for public health.[176] That leaves an award of monetary damages as the appropriate remedy for the U.S. government to seek from Moderna for Moderna's unauthorized use of the '070 patent. How would a court calculate those damages?

2. Legal Principles for Determining Appropriate Monetary Compensation in This Instance

In general, in patent infringement cases, the appropriate baseline measure of monetary damages may be (1) the patent owner's lost profits, (2) an established royalty on the infringed patent, or (3) a court-calculated reasonable royalty, depending on the circumstances of the case.[177] Because the U.S. government generally, NIH specifically, and NIH's academic partners Dartmouth and Scripps are not for-profit enterprises, lost profits is an inappropriate measure.

An established royalty is "a uniform one freely negotiated and paid by a sufficient number of licensees."[178] If an established royalty on the '070 patent exists, it may be an appropriate baseline measure. As of writing, we do not know whether an established royalty for the '070 patent exists—i.e., a royalty established by repeated voluntary licensure of the '070 patent by NIH to other vaccine makers at a consistent royalty rate. We know that BioNTech, GeoVax, Noachis Terra, and 14 other companies have paid the U.S. government for licenses to

[176] In the *United States v. Gilead* patent infringement litigation—likewise a lawsuit brought by the U.S. government against a drug company allegedly using government-owned patents without the government's permission—the government's lawyers have likewise refrained from seeking an injunction and are seeking only monetary damages from the drug company. *See* Complaint at 75, *United States v. Gilead Sciences, Inc.*, No. 1:19-cv-02103 (D. Del. Nov. 6, 2019).

[177] 7 CHISUM ON PATENTS § 20.03 (2021).

[178] *Id.* § 20.06 (2021).

the ’070 patent,[179] but we do not know the royalty rates or other terms of these licensing agreements. Should an established royalty exist, it could serve as a minimum for estimating an appropriate court-ordered royalty for Moderna’s use of the ’070 patent. “Although existence of an established royalty usually sets the minimum recovery by a patent owner for infringement, it does not necessarily set the maximum recovery.”[180] Courts can diverge from an established royalty when the economic or technological contexts of the infringer’s use of the patented technology differ from the contexts in which the established royalty was agreed upon.[181] If the established royalty was set before the value of COVID-19 vaccines based on the patent’s technology was known as fully as it is today—i.e., before such COVID-19 vaccines had completed clinical trials and before they were authorized for use by drug regulators around the world—then a court might impose on Moderna a royalty greater than the established royalty previously set.

Absent an established royalty on the ’070 patent, a court will likely determine a reasonable royalty appropriate to compensate the U.S. government for Moderna’s infringement of the ’070 patent. Determination of the reasonable royalty is a complex analysis, but the determination most commonly “attempts to ascertain the royalty upon which the parties would

[179] *See supra* notes 60-64.

[180] 7 CHISUM ON PATENTS § 20.06 (2021).

[181] *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1211 (holding that when established royalties are factored into a reasonable royalty calculation, “use of past patent licenses . . . must account for differences in the technologies and economic circumstances of the contracting parties”). One interesting pair of questions is whether the existing licenses to the ’070 patent were executed prior to NIH’s decision, in October 2020, to narrow the scope of the ’070 patent’s claims—*see supra* § III.D—and, if so, whether a court might award the U.S. government a royalty *lower* than the established royalty to reflect the claims’ reduced scope. *See, e.g.*, 7 CHISUM ON PATENTS § 20.06 (2021) (“Under *Rude* [*v. Westcott*, 130 U.S. 152 (1889)] and . . . *Faulkner v. Gibbs* [, 199 F.2d 635] ([9th Cir.] 1952), prior negotiated royalties, to set an established royalty, must be . . . for comparable rights or activity under the patent”). Recall that NIH narrowed the claims of the ’070 patent to specify that in the claimed invention, the chemically modified spike protein stabilized in its prefusion conformation must have at least one proline substitution at the central helix/heptad repeat 1 junction, not just near it. *See supra* § III.D. NIH’s narrowing amendment diminished the scope of NIH’s claims, but it may not have diminished the commercial importance or value of the ’070 patent at all, as leading COVID-19 vaccines and vaccine candidates appear to rely on the claimed proline substitution at the central helix/heptad repeat 1 junction. *See, e.g.*, BioNTech, *Form 20-F* (Mar. 30, 3021), https://biontechse.gcs-web.com/node/9571/html (stating, “[w]e . . . have a non-exclusive license from the National Institutes of Health granting us right to use certain US and European patent filings relating to SARS-COV-2 spike (S) protein variants that lock the S protein in an antigenically preferred prefusion conformation; such a variant is utilized in BNT162b2.”); Cheryl Keech et al., *Phase 1–2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine*, 383 NEW ENGL. J. MED. 2320 (2020), https://www.nejm.org/doi/full/10.1056/NEJMoa2026920 (Novavax scientists stating that the Novavax vaccine contains the SARS-CoV-2 spike protein modified with “two proline substitutions at residues K986P and V987P at the top of the heptad repeat 1/central helix in the S2 subunit to stabilize the construct in a prefusion conformation”). The BioNTech and Novavax examples underscore that major COVID-19 vaccines are using the technology claimed by the ’070 patent—a spike protein stabilized in its prefusion conformation with at least one proline substitution at the central helix/heptad repeat 1 junction—which, in turn, evinces the enduring commercial significance of the ’070 patent. As such, we see no reason for a court to order Moderna to pay a royalty rate any lower than any established royalty that BioNTech and other existing licensees are paying. And other factors, discussed above the line, suggest a royalty *higher* than the established royalty may be appropriate.

have agreed had they successfully negotiated an agreement just before infringement began."[182] This hypothetical negotiation "assumes that the asserted patent claims are valid and infringed."[183] Courts consider and weigh many factors when predicting the outcome of this hypothetical negotiation,[184] and we address only a few of those factors here.

For one, even in the absence of a clearly established royalty, courts commonly consider a patent owner's pattern of licensing the infringed patent and related patents.[185] Here, we do not know what NIH has charged, by way of royalties, other companies to use the '070 patent, but we do have some high-level evidence of the royalties NIH generally charges drug companies for use of its patents: a recent report of the Government Accountability Office found that NIH charged royalty rates that ranged "from less than 1 percent to over 10 percent of sales" of 34 different FDA-approved drugs covered by NIH-owned patents.[186] Thus, a range of about 1% to 10% of Moderna's mRNA-1273 sales revenues might form an appropriate starting point for a reasonable royalty rate for Moderna's unauthorized use of the '070 patent.

Other factors that courts commonly consider in setting a reasonable royalty are "[t]he nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention" and "[t]he portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer."[187] These factors generally "aim to elucidate how the parties would have valued the patented feature during the hypothetical negotiation."[188] Relatedly, a patent owner may recover damages based on the value of an entire product that contains

[182] *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009).

[183] *Id.* at 1325.

[184] *See id.*; *see also Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

[185] *Georgia-Pacific*, 318 F. Supp. at 1120 (listing "[t]he royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty" and "[t]he licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly" as factors relevant to the reasonable royalty); *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161, 1168 (weighing a patent owner's history of licensing patents on related technology).

[186] U.S. Government Accountability Office, *Biomedical Research: NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property*, GAO21-52 (Oct. 20, 2021), https://www.gao.gov/products/gao-21-52.

[187] *Lucent*, 580 F.3d at 1332 (citing *Georgia-Pacific*, 318 F. Supp. at 1120).

[188] *Id.*

multiple features—both patented and unpatented—when the patented feature at issue "constitutes the basis for customer demand" or "substantially create[s] the value of the component parts."[189]

How do these factors affect the calculation of a reasonable royalty rate for the '070 patent? Here, these factors tend to increase the rate, and they corroborate the notion that the royalty should be based on the full sales price of mRNA-1273 (the vaccine product as a whole), rather than merely the vaccine's active mRNA component. That is so because the patented invention—NIH's coronavirus spike protein stabilization technology—is not incidental to the value of mRNA-1273 but central and essential to it. The value of mRNA-1273 derives primarily from the technology described and claimed in the '070 patent, as Moderna scientists themselves have stated:

> The rapid and robust immunogenicity profile of the mRNA-1273 vaccine **most likely results from an innovative structure-based vaccine antigen design**, coupled with a potent lipid-nanoparticle delivery system, and the use of modified nucleotides that avoid early intracellular activation of interferon-associated genes. These features of the mRNA composition and formulation have been associated with prolonged protein expression, induction of antigen-specific T-follicular helper cells, and activation of germinal center B cells. **Stabilizing coronavirus spike proteins by substituting two prolines at the top of heptad repeat 1 prevents structural rearrangements of the fusion (S2) subunit.**[190]

mRNA-1273 is no outlier; the experiences of two other COVID-19 vaccines developed within the last year or so confirm that the stabilized spike protein described and claimed by the '070 patent is vital to their success, too. As Public Citizen has reported,[191]

> Pfizer[-BioNTech] and J&J actually tried to test other vaccine proteins [for their COVID-19 vaccines], but selected a 2P protein [as described and claimed in the '070 patent] because it showed early superiority in clinical trials. In the Pfizer Phase 2 trial, for example, the 2P protein seemed to produce fewer side effects, particularly in older adults. Pfizer then selected the vaccine candidate based on the 2P protein for Phase 3 trials.

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[189] *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1549-50 (Fed. Cir. 1995) (en banc) (citations and internal quotation marks omitted).

[190] *See* Jackson et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, *supra* note 114, at 1929. (emphasis added).

[191] *See* Rizvi, *supra* note 2 (citing Edward Walsh et al., *Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates*, NEJM (2020) and Noe Marcado et al., *Single-shot Ad26 vaccine protects against SARS-CoV-2 in rhesus macaques*, Nature (2020)).

The scientific literature further corroborates the notion that the stabilized spike protein stabilized and claimed in the '070 patent is central to the success of coronavirus vaccine development generally. Even before the emergence of SARS-CoV-2 and COVID-19, independent scientists in the field of vaccine research identified a high-profile 2017 scientific publication by many of the inventors of the '070 patent[192]—which first disclosed the technology of the '070 patent to the world—as "instrumental to design better immunogens" for coronavirus vaccines[193] and as providing "a basis for the design of structure-based CoV [coronavirus] vaccines."[194]

3. Estimating the Compensation Moderna May Owe the U.S. Government

What, then, might a reasonable royalty be for Moderna to compensate the U.S. government for use of the '070 patent? Again, this is a complex question for a court to decide, but given that NIH's typical royalty rate range is apparently 1 to 10% of licensees' sales revenues,[195] and given that the technology described and claimed in the '070 patent is vital to mRNA-1273's value, a number at the middle or top of that range seems appropriate.[196]

With that range of reasonable royalty rates in mind, we can attempt some back-of-the-envelope calculations to very roughly approximate the total court-ordered compensation Moderna might owe. These calculations suggest that Moderna could conceivably owe the U.S. government over $500 million in royalties for its sales of mRNA-1273 in 2021 alone:

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[192] *See* Pallesen et al., *supra* note 1. This paper identifies, as a related "conflict of interest," the original provisional patent application that ultimately led to the '070 patent (Application No. 62/412,703), confirming the paper's relationship to the '070 patent.

[193] Reham A. Al Kahlout et al., *Comparative Serological Study for the Prevalence of Anti-MERS Coronavirus Antibodies in High- and Low-Risk Groups in Qatar*, 2019 J. IMMUNOLOGY RESEARCH (Feb. 18, 2019), https://www.hindawi.com/journals/jir/2019/1386740/.

[194] Yan-Hua Li et al., *Molecular Characteristics, Functions, and Related Pathogenicity of MERS-CoV Proteins*, 5 ENGINEERING 940 (July 17, 2019), https://www.sciencedirect.com/science/article/pii/S2095809918307598#bb0025.

[195] These royalty rates are based on the manufacturers' full sales price of the commercial product covered by an NIH-owned patent. *See* U.S. Gov't Accountability Off., GAO-08-751, *Biomedical Research: NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property*, *supra* note 186, at 23 n.58 (2020) ("The sales used to calculate royalties were the manufacturing company's sales of the drugs, not the final costs paid by patients, insurers, or federal programs, according to NIH officials.").

[196] Royalty rates above 10% are possible in patent infringement cases. For example, in a recent case, the Federal Circuit affirmed a jury's verdict that the maker of an injectable biologic drug used to treat hemophilia had infringed a competitor's patent and affirmed the jury's decision to award a reasonable royalty based on a royalty rate of 17.78% of the infringing drug manufacturer's total sales. *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 986-87 (Fed. Cir. 2021).

- *Assuming $3 billion in U.S. revenue between April and December 2021 (200 million doses sold)*
    - Assuming a 5% royalty rate: $150 million total royalty
    - Assuming a 10% royalty rate: $300 million total royalty
- *Assuming $6 billion in U.S. revenue between April and December 2021 (400 million doses sold)*
    - Assuming a 5% royalty rate: $300 million total royalty
    - Assuming a 10% royalty rate: $600 million total royalty

These numbers could easily underestimate rather than overestimate the total compensation Moderna may owe the U.S. government, for four reasons.

First and foremost, these calculations are based on Moderna's projected sales in the United States from April through December 2021 alone. Any additional U.S. sales made by Moderna after 2021 would incur additional liability. For example, if Moderna sells hundreds of millions of booster doses of mRNA-1273 in the United States in 2022 and beyond—as Wall Street analysts and Moderna itself expect[197]—these could create hundreds of millions of dollars in additional liability at a 5% or 10% royalty rate, as long as the booster doses continue to rely on the technology claimed in the '070 patent.

Second, to the extent Moderna and its suppliers are manufacturing additional vials of mRNA-1273 inside the U.S. for sale in other countries, this manufacturing would also appear to infringe the '070 patent and would constitute a basis for the U.S. government to seek additional damages for patent infringement.[198]

Third, if it chooses to assert its patent against Moderna, the U.S. government may also be entitled to seek enhanced damages.[199] If the government proves an entitlement to enhanced

[197] Robert Langreth, *Big Pharma Is Racing to Bolster Its Vaccines Against Variants*, BLOOMBERG BUSINESSWEEK (Feb. 4, 2021), https://www.bloomberg.com/news/articles/2021-02-04/pfizer-pfe-moderna-mrna-race-to-make-vaccines-for-covid-variants ("Morgan Stanley analyst Matthew Harrison estimates the yearly market for Covid vaccine booster shots could range from $5 billion to almost $23 billion."); *see also* Moderna Inc. (MRNA) Q4 2020 Earnings Call Transcript, *supra* note 84 (Moderna CEO Stephane Bancel stating, "I think will be a very important differentiation as we move into '22, as we move more to a traditional commercial market, where it's not governments buying directly, but the traditional kind of retail channel.").

[198] 35 U.S.C. § 271(a) ("Except as otherwise provided in this title, whoever without authority ***makes***, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." (emphasis added)); *see also Railroad Dynamics, Inc. v. A. Stuki Co.*, 727 F.2d 1506, 1519 (Fed. Cir. 1984) ("When [the accused infringer] made the [accused products] in this country, it infringed [the patent claim at issue]. Whether those [accused products] were sold in the U.S. or elsewhere is therefore irrelevant . . . .").

[199] 35 U.S.C. § 284 ("[T]he court may increase the damages up to three times the amount found or assessed.").

damages, the court may increase the reasonable royalty by up to a factor of three.[200] The Supreme Court has held enhanced damages are appropriate when infringement is "willful" or in "bad faith."[201] "The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless."[202] It is clear that Moderna knows of the '070 patent; as noted above,[203] reporters from numerous newspapers, including *The Washington Post*[204] and *STAT*,[205] have asked Moderna to comment on whether it is infringing the '070 patent. And, as noted above, language in Moderna's recent SEC filings suggests Moderna is aware it may have a legal obligation to license the '070 patent.[206]

If a court concludes Moderna's manufacture and sale of mRNA-1273 infringes the '070 patent and further concludes Moderna knowingly and willfully infringed the '070 patent while refusing to take a license from NIH, then the court may conclude enhanced damages are appropriate. In that case, a court could double or even triple its reasonable royalty award.

Enhanced damages are unusual in patent infringement cases, but there is precedent for the U.S. government seeking them from a drug company. In its ongoing litigation against Gilead, the U.S. government currently seeks enhanced damages, on the theory that Gilead has willfully infringed, and continues to willfully infringe, the government's patents.[207] Because of the government's request for enhanced damages, news media and legal experts have estimated that the government could recover as much as $3 or $4 billion from Gilead.[208] In our view, in the event that the U.S. government asserts the '070 patent against Moderna, the court-ordered damages awarded could also conceivably run into the multiple billions if the government seeks and obtains enhanced damages. For example, a reasonable royalty of $600 million—conceivable based on Moderna's 2021 activities alone, assuming 400 million doses sold in the United States

[200] *Id.*

[201] *Halo Elecs., Inc. v. Pulse Elecs.*, 136 S. Ct. 1923, 1932 (2016).

[202] *Id.* at 1933.

[203] *See supra* § IV.C.2.

[204] *See* Rowland, *supra* note 140.

[205] *See* Silverman, *supra* note 141.

[206] *See supra* § IV.C.2 and text surrounding notes 140 & 141.

[207] Christopher J. Morten and Amy Kapczynski, *United States v. Gilead: Can a Lawsuit Yield Better Access To PrEP?*, HEALTH AFFAIRS (Nov. 18, 2019), https://www.healthaffairs.org/do/10.1377/hblog20191118.218552/full/.

[208] Donald G. McNeil Jr. and Apoorva Mandavilli, *Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says*, NY TIMES (Nov. 8, 2019), https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html; Lawrence O. Gostin and Arti K. Rai, *Expanding Access and Reducing Prices for Drugs to Prevent HIV: Should Government Enforce Its Patent Rights Against the Pharmaceutical Industry?*, JAMA 2020;323(9):821-822 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/article-abstract/2762318.

between April and December 2021 and a 10% royalty rate, as shown in our back-of-the-envelope calculations above—could conceivably be trebled to $1.8 billion.

Fourth, if Moderna raises the prices it charges for mRNA-1273 and consequently increases its revenues beyond the projections used in our back-of-the-envelope calculations above, that too would increase Moderna's prospective liability. In March 2021, Moderna's President, Stephen Hoge, stated that Moderna expects to raise its prices "[p]ost-pandemic," to "more normal pricing based on value."[209] For example, should Moderna's U.S. revenues from April 2021 onward exceed $6 billion, the relevant royalty base will increase, and even our largest estimates of the total royalty owed to the U.S. government could be substantially lower than the actual liability.

For all these reasons, it seems that Moderna's ultimate liability to the U.S. government for infringement of the '070 patent could easily run in the hundreds of millions of dollars and could conceivably run into the billions of dollars. Such an award would not be unprecedented. Damages awards in patent infringement cases in excess of $500 million and even $1 billion have become increasingly common in recent years.[210] We reiterate, however, that determination of an appropriate monetary damages award is a complex question that must be decided by a court.

VI. NIH's Pending European Patent Application Could Eventually Provide NIH Additional Leverage.

The main focus of this report is NIH's U.S. patent on stabilized coronavirus spike proteins—the '070 patent—and on Moderna's potential liability for infringement of that patent, based on activities Moderna has undertaken solely within the territory of the United States. As was described in the preceding Part, the '070 patent alone provides NIH significant leverage over Moderna.

This Part briefly considers a further issue: additional liability that Moderna could incur for infringing other patents on the same technology owned by the U.S. government in other countries, based on Moderna's activities in those countries. (Recall that patents are territorial; the inventors of a single invention can and often do apply for and receive patents on the same invention in many different countries all over the world.) This liability would provide NIH and the U.S. government with independent, additional leverage over Moderna.[211]

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[209] *See* Fang, *supra* note 7.

[210] Matthew Bultman, *Investors Eye Patents After 'Extraordinary' Damage Awards Run*, BLOOMBERG LAW (Nov. 6, 2020), https://www.bloomberglaw.com/bloomberglawnews/ip-law/X57MGGOK000000?bna_news_filter=ip-law#jcite.

[211] Foreign patents on the stabilized spike protein could provide the U.S. government with leverage over other vaccine makers, too.

We are aware of one foreign "counterpart" to the '070 patent: a patent application currently pending before the European Patent Office.[212] The European Patent Office website states that NIH has requested, and that the European Patent Office has not yet begun, substantive examination.[213] If and when this European patent application matures into a patent, it would give the U.S. government additional legal rights and additional leverage against Moderna. Moderna has contracted to sell hundreds of millions of doses in the European Union,[214] just as it has in the United States, creating some probability of substantial future liability for Moderna in Europe.

While the U.S. government does not currently own an in-force patents in Europe covering mRNA-1273—there is only a pending patent application—it could nonetheless use the probability of obtaining European patent rights as an additional source of leverage in negotiations with Moderna today. That is so because any agreement that the U.S. government makes with Moderna to extend a license to the '070 patent in the United States could also extend a license to any and all counterpart patents in Europe. Such a license would have value to Moderna, as it would eliminate Moderna's risk of litigation and liability in Europe if and when NIH's patent issues there.

VII. Conclusion

The preceding Parts have shown that the '070 patent describes and claims important coronavirus vaccine technology and is likely infringed by Moderna. As we have shown, Moderna's potential liability for its apparent infringement of the patent could reach hundreds of millions of dollars, or even over a billion dollars, based solely on projected sales of mRNA-1273 through the remainder of 2021. Additional sales of mRNA-1273 in 2022 and beyond will likely incur additional liability for Moderna, unless and until Moderna obtains a license to the '070 patent. As a consequence, the '070 patent provides the U.S. government significant leverage over Moderna.

NIH—and the U.S. government broadly—should see assertion of the '070 patent as an important policy tool to expand vaccine access. In our view, when considering how best to use

[212] The patent application bears patent application no. EP17800655A and was filed October 25, 2017. The application was published as EP3532095A1. The published European application has the priority applications, the same title, the same twelve inventors, and the same three owners as the '070 patent, confirming that this application is the European counterpart of the '070 patent. EP3532095 (A1)—2019-09-04, *Prefusion Coronavirus Spike Proteins and Their Use*, Espacenet Patent Search, https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=3532095A1&KC=A1&FT=D&ND=3&date=20190904&DB=&locale=en_EP# (accessed Apr. 9, 2021).

[213] European Patent Register, Legal status: EP3532095, European Patent Office, https://register.epo.org/application?number=EP17800655&lng=en&tab=legal (accessed Apr. 9, 2021).

[214] Fraiser Kansteiner, *Pfizer, Moderna pledge more mRNA vaccine doses to Europe after AZ supply concerns*, FIERCEPHARMA (Feb. 17, 2021), https://www.fiercepharma.com/manufacturing/pfizer-and-moderna-ramp-up-covid-19-vaccine-orders-europe.

this tool, the government's focus should not be to maximize its own financial position. Nor should the goal be simply to extract the highest possible royalty from Moderna (or from any other vaccine manufacturers who may be infringing the patent). Instead, the goal should be to leverage the '070 patent to scale up production of mRNA-1273 and other vaccines to ensure rapid, equitable global access.

Current best estimates suggest that global supplies of mRNA-1273 and other mRNA vaccines effective against COVID-19 will run far below global demand in 2021 and 2022.[215] The U.S. government could use the '070 patent to address that problem. Specifically, the U.S. government could use the threat of litigation over the '070 patent to bring Moderna to the negotiation table. The U.S. government could use the leverage provided by the '070 patent—alongside the Defense Production Act[216] and other policy tools at its disposal—to convince Moderna to share its own patents, trade secrets, and other intellectual property on mRNA-1273 with the U.S. government and with vaccine manufacturers around the world. Doing so would promote more rapid scale-up of manufacturing and distribution of the vaccine.

In March of 2021, a group of six non-governmental organizations and fifteen leading scientists—including the deans of several prominent schools of public health—sent a letter to HHS Secretary Becerra, NIH Director Dr. Francis Collins, and NIAID Director Dr. Anthony Fauci, calling on the U.S. government to license the '070 patent to Moderna in a manner that promotes wider global access to mRNA-1273.[217] The letter spells out three provisions that the government's licensing agreement with Moderna should include:

1. Empowering the U.S. government to authorize manufacturing of mRNA-1273 on its own initiative, including in government-owned production facilities.
2. Requiring Moderna to share mRNA-1273 technology, including manufacturing information currently protected as trade secrets, with the World Health Organization, to help ramp up global production.
3. Imposing on Moderna requirements for accessible pricing, especially in low- and middle-income countries.

We endorse the letter's call to action. NIH and the U.S. government should leverage every policy tool at their disposal—including the '070 patent—to scale up global vaccine manufacturing, vaccinate the world, and bring the COVID-19 pandemic to a conclusive end.

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[215] *See* PrEP4All, *Hit Hard*, *supra* note 3.

[216] U.S. Department of Health & Human Services Press Release, *Biden Administration Announces Historic Manufacturing Collaboration Between Merck and Johnson & Johnson to Expand Production of COVID-19 Vaccines*, HHS.gov (Mar. 2, 2021), https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html.

[217] *See* Rowland, *supra* note 140. The letter is available at https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/605c7d657cca1206e17b4d87/1616674150606/Moderna+and+the+%27070+Patent+24+March+2021.pdf. One of the authors of this report (CM) signed the letter.

VIII. About the Authors; Acknowledgments; Copyright Notice

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[218] Ariella Barel & Laurel Boman, *Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations*, ENGELBERG CENTER ON INNOVATION LAW & POLICY AND TECHNOLOGY LAW & POLICY CLINIC AT NYU SCHOOL OF LAW (Aug. 2020), https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH.

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About the Technology Law & Policy Clinic at NYU Law:

With technological advances driving greater social, economic, and political change—from access to information, health care, and entertainment to impacts on the environment, education, and commerce to increased surveillance by law-enforcement agencies—issues related to privacy, consumer rights, algorithmic accountability, free speech, and intellectual property are becoming increasingly critical and complex. The Technology Law & Policy Clinic at NYU Law focuses on the representation of individuals, nonprofits, and consumer groups who are engaged with these questions from a public interest point of view. The clinic involves a mixture of fieldwork and seminar discussion ranging from technology law and policy to the ethical challenges of representing public interest organizations. The clinic is taught by Professors Jason Schultz and Brett Max Kaufman and Deputy Director Chris Morten. The clinic's website is https://www.law.nyu.edu/academics/clinics/tech-law-policy.

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All errors are our own.

[219] Rizvi, *supra* note 2.

[220] https://creativecommons.org/licenses/by-sa/4.0/