2020:3 KEI Research Note: Moderna failures to disclose DARPA funding in patented inventions

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1. Introduction

This research note examines apparent failures to disclose U.S. federal government funding of the inventions claimed in several patents assigned to Moderna Therapeutics ("Moderna"). It focuses on awards from the Defense Advanced Research Projects Agency (DARPA).

While similar issues can be raised regarding funding of Moderna from other agencies, including the Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH), this note focuses on the role of DARPA. KEI will publish a different research note examining the reporting of R&D funding by BARDA and the NIH.

The obligation to disclose U.S. federal government support in patent applications is a requirement of the Bayh-Dole Act and regulations issued by the U.S. Patent and Trademark Office.

Moderna was one of the awardees under the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program and performed research related to mRNA vaccines with funds granted by DARPA. Moderna used the ADEPT funding in their Chikungunya and Zika vaccines programs. It is likely that the DARPA awards more generally supported the establishment of their mRNA platform, which can be used against other viral infections, including COVID-19. This support is acknowledged by DARPA itself, for instance on the DARPA website it currently has a statement stating "[t]he first coronavirus vaccine to start human testing is from DARPA investment in the Moderna company."[1]

Several of the patents filed by Moderna since March 22, 2013 (when their first grant from DARPA was awarded), claim inventions related to methods and compositions for inducing an immune response by administering an mRNA vaccine. Some of these patents are specifically related to their Chikungunya and Zika vaccines programs, some are directed to vaccines

[1] https://www.darpa.mil/ddm_gallery/ModernaAntibodybasedVaccine.JPG

against other viral infections, and others are generally relevant to the mRNA platform Moderna has developed.

KEI examined the 126 patents assigned to "Moderna" or "ModernaTx" as well as 154 patent applications. Despite the evidence that multiple inventions were conceived in the course of research supported by the DARPA awards, not a single one of the patents or applications assigned to Moderna disclose U.S. federal government funding.

2. DARPA backed mRNA vaccines research early on

Messenger RNA (mRNA) is a ribonucleic acid (RNA) molecule complementary to one of the deoxyribonucleic acid (DNA) strands of a gene.[2] mRNA serves as an intermediary that carries the genetic information of a DNA molecule to the cell machinery responsible for protein synthesis.[3] Due to this role as an intermediary, mRNA has been considered for years as a candidate for prophylactic and therapeutic applications. One of the potential mRNA applications is in vaccine development. Conventional vaccines usually contain inactivated pathogens that mimic the infectious agent. When administered, they stimulate an immune response. In mRNA-based vaccines, however, no pathogens are introduced. Rather, the instructions on how to produce an immune response are encoded in mRNA and provided to a subject.
Some scientists have been advocating for the use of mRNA as a vaccine platform for years.[4] One of the key benefits of mRNA in vaccine development is flexibility. In principle, any protein can be encoded and expressed by mRNA; this, in theory, enables the development of a wide range of therapeutic and prophylactic applications. Another key feature is safety. Because mRNA is non-infectious, there is no potential risk of infection or insertional mutagenesis.[5]

Successful use of mRNA *in vivo* to elicit a physiological response has been reported since the early 1990s.[6] However, despite promising results, these findings did not lead to substantial private investment towards developing mRNA therapeutics largely due to concerns associated with mRNA instability, high innate immunogenicity and inefficient *in vivo* delivery.[7] It took decades before using mRNA as a vaccine platform became an attractive approach for private investors. Nevertheless, at a time when private investors were still skeptical about mRNA, DARPA made an early push in support of this approach to vaccine development. Starting in 2011, the agency allocated millions of dollars towards developing mRNA platform technologies.

DARPA initially pioneered the research into mRNA vaccines through their *Autonomous Diagnostics to Enable Prevention and Therapeutics: Prophylactic Options to Environmental and*

[2] https://www.genome.gov/genetics-glossary/messenger-rna
[3] http://sitn.hms.harvard.edu/flash/2015/rna-vaccines-a-novel-technology-to-prevent-and-treat-disease/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3597572/
[5] https://www.nature.com/articles/nrd.2017.243
[6] *See* https://pubmed.ncbi.nlm.nih.gov/1690918/ and https://pubmed.ncbi.nlm.nih.gov/1546298/
[7] https://www.nature.com/articles/nrd.2017.243

Contagious Threats (ADEPT-PROTECT) program.[8] One of the goals of this program was to "develop methods to transiently deliver nucleic acids for vaccines and therapeutics, and kinetically control the timing and levels of gene expression so that these drugs will be safe and effective for use in healthy subjects."[9] In 2017 the agency launched the Pandemic Prevention Platform (P3) to continue its work on "rapid discovery, characterization, production, testing, and delivery of efficacious DNA- and RNA-encoded medical countermeasures,"[10] such as the mRNA vaccines. All together, DARPA has awarded millions of dollars to de-risk early research in this field, including awards to pharmaceutical companies focused on the mRNA approach. Moderna is one of the beneficiaries of this funding, as the next section further explains.

3. DARPA was one of the first funders to support mRNA research at Moderna

Moderna was created in 2010 by Harvard University biologist Derrick Rossi and other academic co-founders.[11] Moderna launched their initial public offering (IPO) on December 6, 2018, selling approximately 26.3 million shares at $23 dollars each.[12] Since inception they have had several candidates in their pipeline, at different stages of development, but none have been approved or launched in the market. In January 2020 Moderna started their mRNA-1273 program, a potential COVID-19 vaccine that is based on the mRNA approach. Moderna has been awarded nearly a billion dollars by the Biomedical Advanced Research and Development Authority (BARDA), an agency of the U.S. federal government, to develop mRNA-1273.[13]

Long before the COVID-19 pandemic, however, Moderna had already received awards from federal agencies. DARPA, in particular, backed this company early on. On March 22, 2013, DARPA awarded Moderna "approximately $1.4 million" under the agreement *W31P4Q-13-1-0007*.[14] This award was titled "[m]odified RNA technology for production of antibodies for immune prophylaxis."[15] Next, on October 2, 2013, DARPA awarded Moderna "up to $25 million to research and develop its messenger RNA therapeutics platform as a rapid and reliable way to make antibody-producing drugs to protect against a wide range of known and unknown emerging infectious diseases and engineered biological threats."[16] The award was

[8] https://www.darpa.mil/attachments/ADEPTVignetteFINAL.pdf
[9] https://www.darpa.mil/attachments/DARPAFY19PresidentsBudgetRequest.pdf
[10] https://www.darpa.mil/program/pandemic-prevention-platform
[11] https://www.bostonmagazine.com/health/2013/02/26/moderna-therapeutics-new-medical-technology/
[12] https://www.wsj.com/articles/highly-anticipated-moderna-listing-is-seen-as-test-of-new-ipos-1544092200
[13] https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million
[14] https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473ds1.htm
[15] https://govtribe.com/award/federal-grant-award?searchId=5e60cd79448f914c9b10c15e
[16] https://web.archive.org/web/20200727061854/https://investors.modernatx.com/news-releases/news-release-details/darpa-awards-moderna-therapeutics-grant-25-million-develop/

identified under the number *W911NF-13-1-0417*, and was part of the ADEPT-PROTECT program. Moderna has stated in SEC disclosures that, as of December 31, 2019, $19.7 million of the amount committed under the *W911NF-13-1-0417* award had been funded.[17]

	W31P4Q-13-1-0007	**W911NF-13-1-0417**
Start date	March 22, 2013	October 2, 2013
Award amount	"approximately $1.4 million"	"up to $25 million", and as of December 31, 2019, $19.7 million had been funded
Summary of the research	"modified RNA technology for production of antibodies for immune prophylaxis."	"messenger RNA therapeutics platform as a rapid and reliable way to make antibody-producing drugs to protect against a wide range of known and unknown emerging infectious diseases and engineered biological threats."

At the time of the DARPA awards, Moderna was still a relatively small company. Although the company was created in 2010, the oldest press release currently in company archives dates back to December 6, 2012. On that day Moderna announced $40 million in venture funding from Flagship Pioneering.[18] The Flagship Pioneering venture capital appears to be one of the first significant investments in Moderna. The DARPA awards came shortly after, and it appears that they represented an important share of the total funding Moderna had raised at the time. As explained in the sections below, the DARPA awards in 2013 supported several aspects of their mRNA research and likely led to a number of patented inventions assigned to Moderna.

4. Moderna funded their Chikungunya vaccine program with DARPA awards

There is clear evidence establishing that Moderna funded their Chikungunya vaccine and antibody programs with the DARPA awards. The company has acknowledged the DARPA role in disclosures filed with the Securities and Exchange Commission (SEC), press releases, a scientific paper reporting some of the relevant findings, and a ClinicalTrials.gov entry.

In their SEC registration statement Moderna said that "[t]he DARPA awards have been deployed primarily in support of [their] vaccine and antibody programs to protect against Chikungunya infection."[19] On their website Moderna acknowledges that the DARPA awards

[17] https://www.sec.gov/Archives/edgar/data/1682852/000168285220000006/moderna10-k12312019.htm

[18] https://www.biocentury.com/article/304691/darpa-jump-started-technologies-behind-some-of-the-leading-covid-19-vaccine-and-antibody-hopes

[19] https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473ds1.htm

have been used for their Chikungunya vaccine candidate, called the *mRNA-1388* program.[20] Moderna also has acknowledged DARPA's role in funding their Chikungunya antibody candidate called the *mRNA-1944* program. Indeed, "[t]he research and development of mRNA-1944 was financially supported by [DARPA]," according to a press release in Moderna's website.[21]

Further, an academic paper co-authored by five Moderna scientists that reports findings relating to their Chikungunya antibody candidate acknowledges one of the DARPA awards. The paper, which was published in *Science immunology* in 2019, reports that "mRNA-encoded Ab with virus neutralizing activity has potency at equivalent levels as observed with the corresponding purified IgG form of the mAb."[22] Moreover, "infusion of mRNA encoding a potent virus neutralizing antibody can induce concentrations of human IgG in the serum of treated mice that protect immunocompromised and immunocompetent mice against lethal challenge and arthritis, respectively."[23] The paper was co-authored by Sayda Elbashir, Matthew Theisen, Elisabeth Humphris-Narayanan, Giuseppe Ciaramella, and Sunny Himansu, who were all working for Moderna at the time the research was performed. According to the acknowledgements, the reported research was funded in part with the *W911NF-13–1-0417* award from DARPA.[24]

On August 15, 2017, Moderna launched a phase 1 clinical trial of "VAL-181388."[25] "VAL-181388" was the name Moderna formerly used to refer to their mRNA-1388 vaccine program.[26] This study assessed safety, tolerability, and immunogenicity of the mRNA-1388 candidate in 60 healthy subjects. DARPA is named as the "collaborator" for this study in ClinicalTrials.gov. The *W911NF-13-1-0417* award is listed in the "Other Study ID" section, which

[20] https://www.modernatx.com/pipeline/mrna-1388

[21] https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-dosing-first-monoclonal-antibody-encoded-mrna also see https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-phase-1-results-first-systemic "mRNA-1944 is being developed with financial support from the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense."

[22] Kose, Nurgun et al. "A lipid-encapsulated mRNA encoding a potently neutralizing human monoclonal antibody protects against chikungunya infection." Science immunology vol. 4,35 (2019): eaaw6647. doi:10.1126/sciimmunol.aaw6647

[23] Kose, Nurgun et al. "A lipid-encapsulated mRNA encoding a potently neutralizing human monoclonal antibody protects against chikungunya infection." Science immunology vol. 4,35 (2019): eaaw6647. doi:10.1126/sciimmunol.aaw6647

[24] "The work was supported by Defense Advanced Research Projects Agency (DARPA) grant W911NF-13–1-0417, NIH grant R01 AI114816, and by Moderna Therapeutics. The views, opinions and/or findings expressed are those of the author and should not be interpreted as representing the official views or policies of the Department of Defense or the U.S. Government."

[25] https://clinicaltrials.gov/ct2/show/NCT03325075

[26] https://www.sec.gov/Archives/edgar/data/1682852/000168285219000009/moderna10-k12312018.htm "The Phase 1 trial was conducted with the investigational medicine named VAL-181388, in accordance with our legacy naming convention. We have since changed our naming convention and have adopted mRNA-1388 in place of VAL-181388."

is where U.S. federal grants are normally acknowledged. This study concluded on November 1, 2019.

In summary, there is clear evidence showing that DARPA supported the research and development for Moderna's Chikungunya vaccine and antibodies programs. This evidence consists of acknowledgements made by Moderna or its scientists in SEC disclosures and academic papers. The DARPA awards starting in 2013 came several years before the clinical trial was launched in 2017 or the paper was published in 2019. As we explain in more detail in the sections below, the DARPA-supported research likely led to patented inventions that should have disclosed funding from the U.S. federal government as required under the Bayh-Dole Act and U.S. Patent and Trademark Office regulations.

5. Moderna funded their Zika vaccine program with DARPA awards

In statements filed with the SEC, Moderna says that the DARPA awards have been deployed "primarily" to advance their Chikungunya programs. However, it is clear that the DARPA awards also supported other candidates in their pipeline beyond their Chikungunya programs. In this section we provide evidence establishing that Moderna also used the DARPA awards to fund their Zika vaccine program, and in the next section we explain why these awards likely supported more general discoveries related to the mRNA platform.

There is clear evidence establishing that Moderna used the DARPA awards towards pre-clinical work related to their Zika vaccine program. Their first Zika vaccine candidate was called *mRNA-1325*.[27] This program sought to deliver "mRNA encoding for viral antigenic proteins associated with the Zika virus" from initial discovery concept to first-in-human dosing in 12 months.[28] For this program Moderna was using a formulation licensed in and started a phase 1 clinical trial that began enrolling subjects on December 21, 2016.[29] The trial concluded in July 2019. According to their website, "Moderna's preclinical work for mRNA-1325 was funded through a grant from the Defense Advanced Research Projects Agency (DARPA)."[30]

In July 2017 the *Cell* journal published a paper co-authored by two Moderna employees, Sunny Himansu and Giuseppe Ciaramella, along with other scientists. The paper described research related to a modified mRNA Zika vaccine and reported that "mRNA LNP vaccines can protect against maternal, placental, and fetal infection, with the majority of animals showing no virological evidence of transmission."[31] The study also suggested that "[w]here safety concerns are greatest (e.g., females during childbearing years, immunocompromised, and those with certain comorbidities), the non-replicating prM-E mRNA LNP subunit-based vaccine may have

[27] https://www.modernatx.com/pipeline/mrna-1325
[28] https://www.modernatx.com/pipeline/mrna-1325
[29] https://clinicaltrials.gov/ct2/show/NCT03014089
[30] https://www.modernatx.com/pipeline/mrna-1325
[31] Richner, Justin M et al. "Vaccine Mediated Protection Against Zika Virus-Induced Congenital Disease." *Cell* vol. 170,2 (2017): 273-283.e12. doi:10.1016/j.cell.2017.06.040

greatest utility and shortest pathway to licensure."[32] The paper published in *Cell* acknowledges several sources of funding, including the *W911NF-13-1-0417* award from DARPA.

Based on these acknowledgements, it is evident that Moderna used the DARPA awards to support their Zika vaccines programs. Moderna states that "preclinical work for mRNA-1325 was funded through a grant from [DARPA]." They also acknowledge this in a scientific paper that reports findings related to the Zika virus.

As discussed below, DARPA-funded research has led to patented inventions that should have been disclosed funding from the U.S. government.

6. DARPA supported other discoveries related to the mRNA platform

In addition to their Chikungunya and Zika programs, the DARPA awards supported more general discoveries related to the mRNA platform. Moderna often refers to the mRNA technology as a "platform."[33] For an illustration, the mRNA delivery mechanism is comparable to the operating system on a computer. As Moderna explains, "[i]t is designed so that it can plug and play interchangeably with different programs."[34] As such, the platform is generally the same for each potential therapeutic or prophylactic application. "[T]he only thing that changes from one potential mRNA medicine to another is the coding region – the actual genetic code that instructs ribosomes to make protein."[35] This flexibility is one of the reasons why some have advocated for mRNA as a vaccine approach and funders like DARPA are interested in the technology. As DARPA itself explains, the mRNA technology "needs to work on any viral disease, whether it's one humans have faced before or not."[36] Therefore, it is possible that the research Moderna performed in the context of their DARPA-funded Chikungunya and Zika programs led to discoveries that are more generally applicable to their mRNA platform.

It is evident that Moderna used their mRNA platform to develop their COVID-19 vaccine candidate, *mRNA-1273*. According to Moderna, "[f]or mRNA-1273, we were able to leverage our experience in vaccines to move rapidly on design and manufacture of material for the Phase 1 clinical trial. This included our broad understanding of the safety of our platform to date across more than 1,000 subjects."[37] The use of the mRNA platform in their COVID-19 program has also been mentioned, for instance, by BARDA[38] and the National Institutes of Health (NIH).[39]

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[32] Richner, Justin M et al. "Vaccine Mediated Protection Against Zika Virus-Induced Congenital Disease." *Cell* vol. 170,2 (2017): 273-283.e12. doi:10.1016/j.cell.2017.06.040
[33] https://www.modernatx.com/mrna-technology/mrna-platform-enabling-drug-discovery-development
[34] https://www.modernatx.com/mrna-technology/mrna-platform-enabling-drug-discovery-development
[35] https://www.modernatx.com/mrna-technology/mrna-platform-enabling-drug-discovery-development
[36] https://www.darpa.mil/news-events/2017-02-06a
[37] https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19
[38] https://www.medicalcountermeasures.gov/newsroom/2020/moderna-covid-19-mrna/
[39] https://www.nih.gov/news-events/news-releases/phase-3-clinical-trial-investigational-vaccine-covid-19-begins

Image source: https://www.darpa.mil/ddm_gallery/ModernaAntibodybasedVaccine.JPG

To the extent that the DARPA awards in fact supported the establishment of the mRNA platform, the COVID-19 vaccine candidate that Moderna is developing therefore involves federally-funded technologies. This seems to be acknowledged by DARPA itself, for example on their website. A statement contained in an image currently available on the DARPA website clearly states that "[t]he first coronavirus vaccine to start human testing is from DARPA investment in the Moderna company."[40] There does not seem to be additional context for this image, but the statement is straightforward and the file is uploaded on the DARPA website. Similarly, DARPA recently published an online pamphlet summarizing the role of the ADEPT-PROTECT program in the development of mRNA technologies.[41] The pamphlet cites the awards granted to Moderna for research related to mRNA and highlights the potential application of this approach against the COVID-19 virus.[42] Here DARPA again seems to suggest that their awards to Moderna played a role in the development of their mRNA platform used to develop a COVID-19 vaccine.

There are additional sources linking the DARPA awards to the mRNA platform that Moderna developed. For example, a report by the Congressional Research Service (CRS) titled *DARPA's*

[40] https://www.darpa.mil/ddm_gallery/ModernaAntibodybasedVaccine.JPG
[41] https://www.darpa.mil/attachments/ADEPTVignetteFINAL.pdf
[42] "In 2012 with the ADEPT:PROTECT program, DARPA began investing in the development of gene-encoded vaccines, a new category of preventive measures based on DNA or RNA. In this approach, genes that encode immune-stimulating antigens, such as the spike proteins on the surfaces of viruses like the one (SARS-CoV-2) that causes COVID-19, are delivered directly to a recipient's body. There, the instructions carried in the DNA or RNA elicit the body's own cells to manufacture the antigenic viral protein, which, in turn, elicits an immune response to the virus."

Pandemic-Related Programs, published on June 30, 2020, states that Moderna used the technology funded by the ADEPT-PROTECT program "to develop its COVID-19 vaccine []."[43]

> "Previous DARPA investments are also showing promise in combating COVID-19. For example, in 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. **The company used that technology to develop its COVID-19 vaccine**, currently undergoing Phase I clinical trials in conjunction with NIH."[44] [emphasis added]

In summary, DARPA itself seems to believe that the funds they awarded to Moderna in 2013 supported the development of their mRNA technology. The same view has been echoed, for example, in a recent report by the CRS. If this is indeed the case, then Moderna was obligated to disclose U.S. government funding in patents directed to inventions conceived in the course of this research. As we explain below, Moderna apparently failed to meet this obligation.

7. Bayh-Dole requires Moderna to disclose U.S. government support in patents

The Bayh-Dole Act and federal regulations and guidelines make clear several obligations for contractors in the disclosure of government rights in subject inventions, including: (1) a requirement to disclose that federal funding contributed to an invention; (2) NIH contractual requirements for disclosure; and (3) required language to be inserted in patent applications and patents, stating the role of federal funding and the government's rights.

Under 35 U.S.C. § 202(c)(1), any contractor that receives funding from the U.S. government is required to "disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters."

Under 37 C.F.R. § 401.3(a), each federal funding agreement shall contain the "standard patent rights clause" found at 37 C.F.R. § 401.14, barring specific circumstances and exceptions. Subsection (c)(1) of the patent rights clause outlines the disclosure requirements.

37 C.F.R. § 401.14(c)(1)

(c) Invention Disclosure, Election of Title and Filing of Patent Application by Contractor

(1) The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify

[43] https://crsreports.congress.gov/product/pdf/IN/IN11446
[44] https://crsreports.congress.gov/product/pdf/IN/IN11446

the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

Under 35 U.S.C. § 202(c)(6) and 37 C.F.R. § 1.77(b)(3), contractors are required to state within the patent application or patent that the federal government contributed funding to support the discovery of the invention and that the government retains certain rights.

35 U.S.C. § 202(c)(6)

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

37 CFR Chapter I - UNITED STATES PATENT AND TRADEMARK OFFICE, DEPARTMENT OF COMMERCE

PART 401—RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANI-ZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND CO-OPERATIVE AGREEMENTS

37 CFR 401.14 - Standard patent rights clauses.

(f) Contractor Action to Protect the Government's Interest

(1) The contractor agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title,

and (ii) convey title to the Federal agency when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The contractor shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

. . .

(4) The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, “This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention.”

The United States Patent and Trademark Office (USPTO) requires that applicants for patents provide a statement regarding federally sponsored research or development..

37 CFR Chapter I - UNITED STATES PATENT AND TRADEMARK OFFICE, DEPARTMENT OF COMMERCE

37 CFR 1.77 Arrangement of application elements.

(b) The specification should include the following sections in order:

(3) Statement regarding federally sponsored research or development.

See also ANNEX: Presidential Executive Order No. 9424. Establishment of a Register of Government Interests in Patents

8. None of the Moderna patents or applications disclose the DARPA awards

On August 18, 2020, KEI searched the United States Patent and Trademark Office (USPTO) Patent Full-Text and Image Database (PatFT) database for patents assigned to “Moderna” or

"ModernaTx." The search returned 126 patents.[45] There were also 154 applications located by searching the Patent Application Full-Text and Image Database (AppFT) with the same criteria.[46]

KEI then reviewed whether any of these patents or applications disclosed funding from the U.S. federal government as required by the Bayh-Dole Act. KEI examined the text of these patents and applications, including their certificates of corrections if any were present. Not a single one of these patents and applications disclosed grants or contracts from the U.S. federal government. Considering the history of DARPA support for this company, which likely led to at least some of their inventions, we believe that Moderna likely failed to meet their disclosure obligations.

This apparent failure to disclose U.S. government funding in patents contrasts with the disclosures Moderna has made to their investors. In several documents filed with the SEC Moderna has acknowledged that some of the research they have conducted has been funded by the U.S. federal government. The company has explained to their investors that, because of this, they "may not have the right to prohibit the U.S. government from using certain technologies developed by [them], and [they] may not be able to prohibit third-party companies, including [their] competitors, from using those technologies in providing products and services to the U.S. government."[47] Moderna has further told investors in several disclosures filed with the SEC that "[t]he U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts."[48]

This apparent failure to disclose also contrasts with statements made by other DARPA awardees. In November 15, 2011, DARPA awarded $33.1 million to a consortium integrated by CureVac, Sanofi-Pasteur, and In-Cell-Art to develop mRNA vaccines.[49] This award was also part of the ADEPT program that supported the mRNA research performed by Moderna. In contrast with Moderna, however, CureVac has disclosed DARPA funding in several issued patents. For example, this is the case in U.S. patent 10,653,768 (the '768 patent) issued on May 19, 2020.

[45] Sixteen patents that appeared on this search were dropped because they were assigned to other companies that also had the term "Moderna" in their name.
[46] Seven patents applications that appeared on this search were dropped because they were assigned to other companies that also had the term "Moderna" in their name.
[47] https://www.sec.gov/Archives/edgar/data/1682852/000095012318009220/filename1.htm
[48] https://www.sec.gov/Archives/edgar/data/1682852/000095012318009220/filename1.htm
[49] https://web.archive.org/web/20121207123349/http://www.curevac.com/pdf/CureVac_Sanofi%20Pasteur_DARPA_Collaboration_20111012_EN.pdf

9. KEI asks DARPA to investigate whether Moderna failed to disclose their awards

KEI asks DARPA to investigate the apparent failures to disclose government funding in patents and applications assigned to Moderna, and take remedial action.

An investigation on Moderna's failure to disclose should include but not limited to granted patents and pending applications broadly directed to (a) vaccines compositions and methods for inducing an immune response against the Chikungunya virus, (b) vaccines compositions and methods for inducing an immune response against the Zika virus, (c) vaccines compositions and methods for inducing an immune response against coronaviruses, including COVID-19, and (d) methods and compositions generally applicable to their mRNA platform, regardless of the indication for which they are useful. It should include all patents and applications claiming a priority benefit on or after March 22, 2013, the grant date of the first DARPA award. An investigation should also cover pending and unpublished applications, including any mRNA platform technologies that Moderna may be using in their COVID-19 vaccine mRNA-1273 program.

DARPA should conduct a comprehensive investigation of the patent portfolio Moderna has built since the first award supporting their research in 2013. Merely for illustration purposes, below KEI has provided a list of patents that, from our research, should be part of a DARPA investigation since they meet at least one of the three criteria explained above.

The '597, '342, and '731 patents

KEI urges DARPA to investigate failures to disclose government funding in U.S. patents 10,702,597 (the '597 patent), 10,675,342 (the '342 patents) and 10,238,731 (the '731 patent). These three patents all claim a priority date after the start of the DARPA awards in 2013. Most of their claims are directed to Chikungunya vaccine compositions, or methods of inducing an immune response in a subject by administering a Chikungunya vaccine. The inventions claimed in these patents are based on the mRNA vaccine approach. These patents name Sayda Elbashir, Giuseppe Ciaramella, and Sunny Himansu among the co-inventors, scientists that are also listed as co-authors in the *Science immunology* paper that reports research related to Chikungunya and acknowledges one of the DARPA awards.[50]

Since several of the above mentioned inventors have acknowledged performing work under the DARPA awards around the time when their inventions were likely conceived, there is strong evidence suggesting that they should have disclosed U.S. government funding in at least some of these patents. If that is the case, the U.S. government has certain rights over these patents. Despite this, none of these patents disclose contracts or awards from the U.S. government.

[50] Kose, Nurgun et al. "A lipid-encapsulated mRNA encoding a potently neutralizing human monoclonal antibody protects against chikungunya infection." Science immunology vol. 4,35 (2019): eaaw6647. doi:10.1126/sciimmunol.aaw6647

The '767, '940, '244, '269, and '055 patents

KEI urges DARPA to investigate failures to disclose government funding in U.S. patents 10,653,767 (the '767 patent), 10,517,940 (the '940 patent), 10,449,244 (the '244 patent), 10,273,269 (the '269 patent), and 10,124,055 (the '055 patent). These five patents all claim a priority date after the start of the DARPA awards in 2013. Most of their claims are directed to Zika vaccine compositions, or methods of inducing an immune response in a subject by administering a Zika vaccine. The inventions claimed in these patents are based on the mRNA vaccine approach. These patents name Giuseppe Ciaramella and Sunny Himansu among the co-inventors, scientists that are also listed as co-authors in the *Cell* paper describing research related to a mRNA Zika vaccine and acknowledges one of the DARPA awards.[51]

Since these two inventors have acknowledged performing work under the DARPA awards around the time when their inventions were likely conceived, there is strong evidence suggesting that they should have disclosed U.S. government funding in at least some of these patents. If that is the case, the U.S. government has certain rights over these patents. Despite this, none of these patents disclose contracts or awards from the U.S. government.

The '435 and '779 patents

KEI also urges DARPA to investigate apparent failures to disclose U.S. government funding in patents assigned to Moderna that are generally applicable to their mRNA platform. KEI believes this is reasonable considering that DARPA itself seems to believe that the mRNA platform Moderna used for their COVID-19 vaccine candidate was funded with their awards to the company. Of particular interest are the patents broadly directed to the mRNA platform that claimed priority benefits after March 22, 2013, and list as co-inventor any Moderna scientists that have acknowledged performing work under the DARPA awards, namely Sayda Elbashir, Matthew Theisen, Elisabeth Humphris-Narayanan, Giuseppe Ciaramella, or Sunny Himansu. U.S. patents 10,022,435 (the '435 patent) and 10,709,779 ('779 patent), which name Giuseppe Ciaramella as one of the co-inventors and are generally directed to methods of vaccinating a subject by administering an mRNA encoding an antigenic polypeptide, meet this criteria.

The '600 patent

KEI urges DARPA to investigate apparent failures to disclose U.S. government funding in patents assigned to Moderna that are directed to methods and compositions specifically against coronaviruses, including COVID-19. DARPA itself reports to shareholders that the mRNA-1273 program involves technology that they funded. Of particular interest is U.S. patent 10,702,600 (the '600 patent), which claimed "[a] composition, comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or

[51] Richner, Justin M et al. "Vaccine Mediated Protection Against Zika Virus-Induced Congenital Disease." *Cell* vol. 170,2 (2017): 273-283.e12. doi:10.1016/j.cell.2017.06.040

S protein subunit formulated in a lipid nanoparticle." The '600 patent was disclosed in the conflict of interest section of an academic paper relating to COVID-19, published by the New England Journal of Medicine (NEJM) - which suggests that it is relevant to the mRNA-1273 program.[52] The patent names Giuseppe Ciaramella and Sunny Himansu as inventors, both of which acknowledged performing work under the DARPA awards in two academic papers.

Other patents

DARPA is also asked to investigate apparent failures to disclose U.S. government funding in patents assigned to Moderna that are generally applicable to their mRNA platform, even if none of the scientists that have acknowledged DARPA funding in academic papers are listed as co-inventors. Acknowledging funding from the U.S. government in an academic paper surely constitutes strong evidence indicating that the equivalent patents should have disclosed those grants or contracts. Nevertheless, the opposite is not necessarily true. Work supported under federal grants or contracts might have not yielded an academic paper making such disclosure, but this does not mean that the work was not funded by the U.S. government.

10. Remedies for Non-Disclosure

Failure to disclose subject inventions pursuant to 35 U.S.C. § 202(c)(1) permits the federal government to "receive title to any subject invention not disclosed to it within such time[.]"

> 35 U.S.C. 202 Disposition of rights.
> (c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:
>
> (1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

The funding agencies should remedy a failure to disclose by at a minimum requiring a correction to the patent and more appropriately by taking title to the patents themselves, as the sanction for the failure to disclose.

[52] https://www.nejm.org/doi/suppl/10.1056/NEJMoa2024671/suppl_file/nejmoa2024671_disclosures.pdf

Selected quotes from Moderna SEC filings, 2019 or earlier

Moderna SEC Form 10-Q, for quarterly period ending March 31, 2019.

We have contracts with the U.S. government's Defense Advanced Research Projects Agency (DARPA), Biomedical Advanced Research (BARDA), and the Bill & Melinda Gates Foundation (Gates Foundation).

4. Grants

Biomedical Advanced Research and Development Authority (BARDA)

In September 2016, we received an award of up to $125.8 million under Agreement No. HHSO100201600029C from BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response, or ASPR within the U.S. Department of Health and Human Services, or HHS, to help fund our Zika vaccine program. Under the terms of the agreement with BARDA, an initial base award of $8.2 million supported toxicology studies, a Phase 1 clinical trial, and associated manufacturing activities. Contract options were available, for $117.6 million to support an additional Phase 1 study of an improved Zika vaccine candidate, Phase 2 and Phase 3 clinical studies, as well as large-scale manufacturing for the Zika vaccine.

As of March 31, 2019, three of the four contract options had been exercised resulting in $117.3 million of available funding with an additional $8.5 million available if the final contract option is exercised. For the three months ended March 31, 2019 and 2018, we recognized revenue of $1.5 million and $1.0 million, respectively, relating to the BARDA Agreement.

The Bill & Melinda Gates Foundation (Gates Foundation)

In January 2016, we entered a global health project framework agreement with the Gates Foundation to advance mRNA-based development projects for various infectious diseases. The Gates Foundation has committed up to $20.0 million in grant funding to support our initial project related to the evaluation of antibody combinations in a preclinical setting as well as the conduct of a first-in-human Phase 1 clinical trial of a potential mRNA medicine to help prevent human immunodeficiency virus, or HIV, infections. Follow-on projects which could bring total potential funding under the framework agreement up to $100.0 million (including the HIV antibody project) to support the development of additional mRNA-based projects for various infectious diseases can be proposed and approved until the sixth anniversary of the framework agreement,

subject to the terms of the framework agreement, including our obligation to grant to the Gates Foundation certain non-exclusive licenses. In March 2019, the Gates Foundation provided an additional funding commitment up to $1.1 million to support a follow-on project.
As of March 31, 2019, up to $21.1 million has been committed for funding with up to an additional $80 million available, if additional follow-on projects are approved. For the three months ended March 31, 2019 and 2018, we recognized $0.3 million for each period, relating to the Gates Foundation agreement. Deferred revenue of $0.6 million and $0.8 million was recorded for both March 31, 2019, and December 31, 2018, respectively, related to the Gates Foundation agreement.

Defense Advanced Research Projects Agency (DARPA)

In October 2013, DARPA awarded us up to $24.6 million under Agreement No. W911NF-13-1-0417, which was subsequently adjusted to $19.7 million, to research and develop potential mRNA medicines as a part of DARPA's Autonomous Diagnostics to Enable Prevention and Therapeutics, or ADEPT, program, which is focused on assisting with the development of technologies to rapidly identify and respond to threats posed by natural and engineered diseases and toxins. The DARPA awards have been deployed primarily in support of our vaccine and antibody programs to protect against chikungunya infection.
As of March 31, 2019 and December 31, 2018, $19.7 million has been committed by DARPA. There was no revenue recognized for the three months ended March 31, 2019, related to the DARPA agreement. We recognized revenue of $0.2 million for the three months ended March 31, 2018, related to the DARPA agreement.

. . .

Aspects of our pipeline have been supported through strategic alliances, including with AstraZeneca, Merck, and Vertex, and government-sponsored organizations and private foundations focused on global health initiatives, including BARDA, DARPA, and the Bill & Melinda Gates Foundation.

. . .

Our revenue has been primarily derived from strategic alliances with Merck, Vertex and AstraZeneca, and from contracts with government-sponsored and private organizations including DARPA, BARDA, and the Bill & Melinda Gates Foundation, to discover, develop, and commercialize potential mRNA medicines.

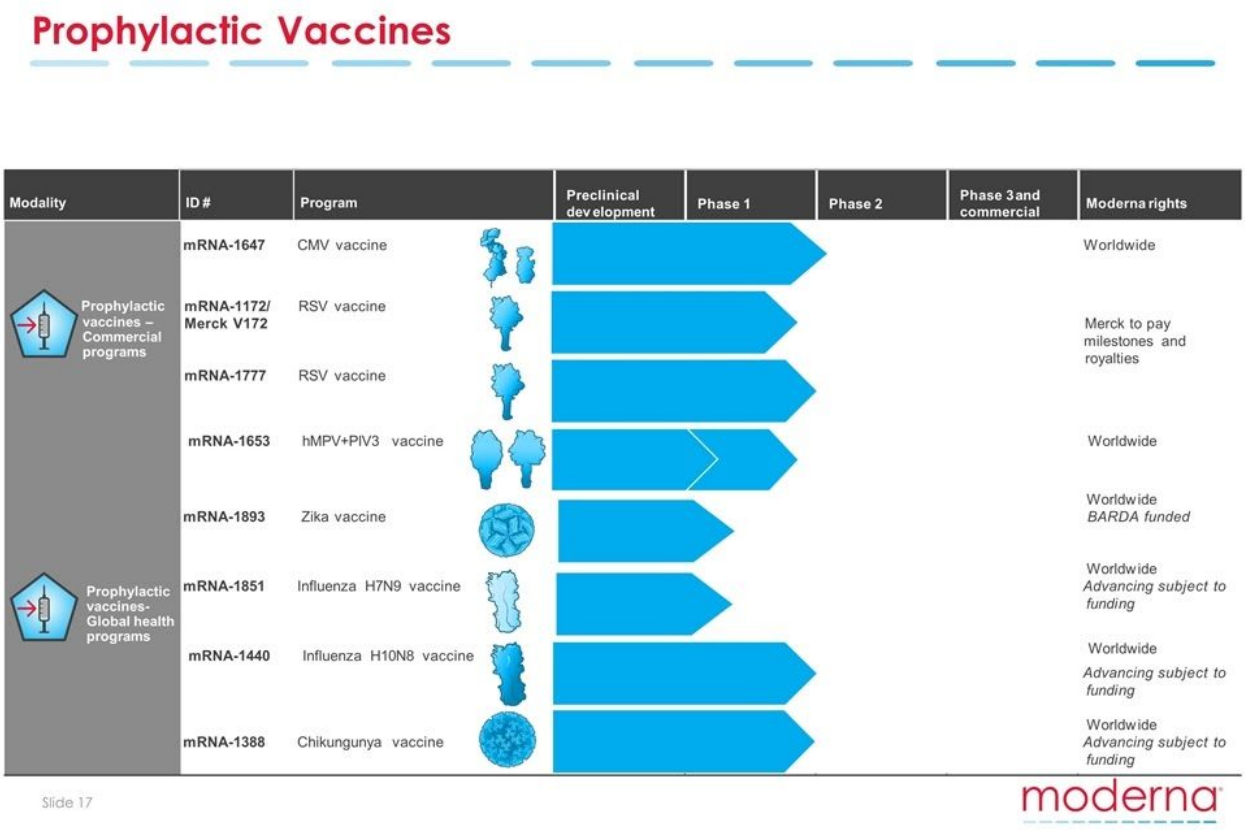
URL:
https://www.sec.gov/Archives/edgar/data/1682852/000168285219000023/moderna10-q3312019.htm

EX-99.1 2 d796420dex991.htm EX-99.1, September 12, 2019 press release.

> Moderna currently has five development candidates for potential commercial uses in this modality, including: respiratory syncytial virus (RSV) vaccine (mRNA-1777 and mRNA-1172 or V172 with Merck), cytomegalovirus (CMV) vaccine (mRNA-1647), human metapneumovirus and parainfluenza virus type 3 (hMPV+PIV3) vaccine (mRNA-1653) and Zika vaccine (mRNA-1893) with the Biomedical Advanced Research and Development Authority (BARDA). Three development candidates in this modality are being explored for potential global health uses including: influenza H10N8 vaccine (mRNA-1440), influenza H7N9 vaccine (mRNA-1851) and chikungunya vaccine (mRNA-1388) with the Defense Advanced Research Projects Agency (DARPA). . . .
>
> Moderna currently has strategic alliances for development programs with AstraZeneca, Plc. and Merck, Inc., as well as the Defense Advanced Research Projects Agency (DARPA), an agency of the U.S. Department of Defense; the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS).

URL:
https://www.sec.gov/Archives/edgar/data/1682852/000119312519243385/d796420dex991.htm

EX-99.3 4 d796420dex993.htm EX-99.3, R&D Day, September 12, 2019.



URL:
https://www.sec.gov/Archives/edgar/data/1682852/000119312519243385/d796420dex993.htm

Moderna 10-K, for year ending December 31, 2019.

> Aspects of our pipeline have been supported through strategic alliances, including with AstraZeneca, Merck, and Vertex Pharmaceuticals, or Vertex, and government-sponsored organizations and private foundations focused on global health initiatives, including BARDA, DARPA, NIH, CEPI and the Bill & Melinda Gates Foundation.
>
> . . . the Chikungunya vaccine being developed in collaboration with DARPA .. .

. . .

Our global health portfolio for prophylactic vaccines seeks to leverage our mRNA technology to address epidemic and pandemic diseases. We are currently working with strategic collaborators such as BARDA, DARPA, and NIH to fund and support our programs within this area.

SARS-CoV-2 vaccine (mRNA-1273): Summary

In collaboration with the NIH and CEPI we are rapidly developing a vaccine to address the SARS-CoV-2 outbreak.

In collaboration with the NIH and CEPI, we are applying our platform for rapid vaccine design and manufacture to produce a vaccine against SARS-CoV-2 virus in response to the currently emerging outbreak of SARS-CoV-2. SARS-CoV-2 is a novel coronavirus that has infected thousands of people since identification on January 7, 2020, spreading to multiple continents. In collaboration with the VRC, we are developing an mRNA-based vaccine designed to express the coronavirus Spike (S) protein based on the genomic sequence of SARS-CoV-2. On January 13, 2020, the NIH and our infectious disease research team finalized the sequence for the SARS-CoV-2 vaccine and we mobilized toward clinical manufacture. As of February 24, 2020, the first clinical batch has been shipped to and received by the NIH for use in their planned Phase 1 clinical trial in the U.S.

Antibody against Chikungunya virus (mRNA-1944): Summary

Systemic mRNA administration to instruct cells to secrete antibodies, in this case for passive immunization to prevent Chikungunya infection

We are using this program to help understand how mRNA can be used to make complex secreted proteins in the human body and to address the potential health threat of Chikungunya virus, particularly for the military and others exposed to this virus. This program highlights a potentially important advancement of our platform and expansion of our modalities.
Chikungunya is a serious health problem with and is estimated to have caused at least three million cases during the 2005-2015 epidemic. There are no vaccines or prophylactic treatments for this disease. This virus can cause severe arthritic-like conditions in approximately 15% of the infected people. This program offers a passive immunization approach using antibodies to prevent infection, to complement our vaccine approach. In this program, we utilize two mRNAs encoding for light chain and heavy chain of an antibody against the envelope glycoprotein E. We plan to administer these

mRNAs encapsulated in our proprietary LNPs intravenously to people to prevent infection by the Chikungunya virus. We are being financially supported for specific activities by DARPA and have an open IND for mRNA-1944.

Strategic alliances with government organizations and foundations

Defense Advanced Research Projects Agency (DARPA)

In October 2013, DARPA awarded Moderna up to approximately $24.6 million under Agreement No. W911NF-13-1-0417 to research and develop potential mRNA medicines as a part of DARPA's Autonomous Diagnostics to Enable Prevention and Therapeutics, or ADEPT, program, which is focused on assisting with the development of technologies to rapidly identify and respond to threats posed by natural and engineered diseases and toxins. As of December 31, 2019, $19.7 million of the award amount has been funded. This award followed an initial award from DARPA of approximately $1.4 million given in March 2013 under Agreement No. W31P4Q-13-1-0007. The DARPA awards have been deployed primarily in support of our vaccine and antibody programs to protect against Chikungunya infection.

Biomedical Advanced Research and Development Authority (BARDA)

In September 2016, we received an award of up to approximately $125.8 million under Agreement No. HHSO100201600029C from BARDA, a component of the Office of the Assistant Secretary for Preparedness and Response, or ASPR, within the U.S. Department of Health and Human Services, or HHS, to help fund our Zika vaccine program. Under the terms of the agreement with BARDA, an initial base award of approximately $8.2 million supported toxicology studies, a Phase 1 clinical trial, and associated manufacturing activities. Additionally, four contract options were awarded under the agreement with BARDA. Three out of four of these options have been exercised, bringing the total current award to approximately $117.6 million to support an additional Phase 1 study of an improved Zika vaccine candidate, Phase 2 and Phase 3 clinical studies, as well as large-scale manufacturing for the Zika vaccine.

Our reliance on government funding and collaboration from government and quasi-governmental entities for certain of our programs adds uncertainty to our research and development efforts with respect to those programs and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.
The development of each of our Zika vaccine (mRNA-1893), our antibody against Chikungunya virus (mRNA-1944), and our Chikungunya vaccine (mRNA-1388) are currently being funded through subcontracts with funding from either the Biomedical Advanced Research and Development Authority ("BARDA") or Defense Advanced

Research Projects Agency ("DARPA"). Our SARS-CoV-2 vaccine (mRNA-1273) is being developed in collaboration with NIAID, and NIAID plans to conduct IND-enabling studies and a Phase 1 clinical study of mRNA-1273 in the United States. CEPI has agreed to fund the manufacture of the preliminary clinical batches of the mRNA-1273. Contracts and grants funded by the U.S. government and its agencies, including our agreements funded by BARDA and DARPA and our collaboration with NIAID, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including IP rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

URL:
https://www.sec.gov/Archives/edgar/data/1682852/000168285220000006/moderna10-k12312019.htm

ANNEX: Presidential Executive Order No. 9424. Establishment of a Register of Government Interests in Patents

1944. President Roosevelt. Executive Order No. 9424, Establishment of a Register of Government Interests in Patents.

Source: The provisions of Executive Order 9424. February 18, 1944, at 9 FR 1959, 3 CFR, 1943-1948 Comp., p. 303, unless otherwise noted. https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title35-section207&num=0&edition=prelim

1. The Secretary of Commerce shall cause to be established in the United States Patent Office [now Patent and Trademark Office] a separate register for the recording of all rights and interests of the Government in or under patents and applications for patents.

2. The several departments and other executive agencies of the Government, including Government-owned or Government-controlled corporations, shall forward promptly to the Commissioner of Patents [now Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office] for recording in the separate register provided for in paragraph 1 hereof all licenses, assignments, or other interests of the Government in or under patents or applications for patents, in accordance with such rules and regulations as may be prescribed pursuant to paragraph 4 hereof; but the lack of recordation in such register of any right or interest of the Government in or under any patent or application therefor shall not prejudice in any way the assertion of such right or interest by the Government.

3. The register shall be open to inspection except as to such entries or documents which, in the opinion of the department or agency submitting them for recording, should be maintained in secrecy: Provided, however, That the right of inspection may be restricted to authorized representatives of the Government pending the final report to the President by the National Patent Planning Commission under Executive Order No. 8977 of December 12, 1941, and action thereon by the President.

4. The Commissioner of Patents [now Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office], with the approval of the Secretary of Commerce, shall prescribe such rules and regulations as he may deem necessary to effectuate the purposes of this order.

ATTACHMENT: Additional data on Moderna patents

See: Moderna patent applications and grants, as of August 24, 2020