

September 2, 2020

Gary L. Disbrow, Ph.D.
Acting Director
Biomedical Advanced Research and Development Authority
U.S. Department of Health and Human Services
Via Email: Gary.Disbrow@hhs.gov

Dear Dr. Disbrow:

Knowledge Ecology International (KEI) requests information regarding the measures that the Biomedical Advanced Research and Development Authority (BARDA) is taking to ensure that Moderna, Inc. discloses BARDA funding of inventions in its patent applications.

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

Moderna (also known as “Moderna Therapeutics” and “ModernaTX”) has entered into multiple contracts with BARDA. These contracts involve an obligation to acknowledge U.S. government support in patents and patent applications.

We believe Moderna has failed to meet similar disclosure obligations in the past, with respect to funding from the Defense Advanced Research Projects Agency (DARPA). KEI sent a letter to DARPA on August 27, 2020 regarding the DARPA funding issue. A copy is available [here](#).

KEI has examined 127 USPTO-granted patents and 154 USPTO patent applications to Moderna or ModernaTX, and found no disclosures of funding for the inventions from any agency of the federal government, including BARDA (we are aware of one WIPO PCT application filed with Vanderbilt University that does disclose National Institutes of Health (NIH) and DARPA funding).

- Granted Patents, as of September 1, 2020:
 - Results of search in US Patent Collection database for: (AN/"moderna therapeutics" OR AN/modernatx): 127 patents.
 - Results of search in US Patents Text Collection database for: ((AN/"moderna therapeutics" OR AN/modernatx) AND GOVT/government): 0 patents.
- Patent applications, as of September 1, 2020:
 - Results of search in AppFT Database for: (AN/moderna OR AN/modernatx) and acn/US: 154 applications.
 - Results of search in PGPUB Full-Text Database for: ((AN/moderna OR AN/modernatx) AND GOVT/government): 0 applications.

One possible source of funding that may be related to inventions concerns BARDA support for Moderna efforts to develop a vaccine for the Zika virus. The BARDA/Moderna collaboration on a Zika vaccine is described in Moderna's 2018 SEC S-1 filing:

<https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473ds1.htm>

Zika vaccine (mRNA-1325 and mRNA-1893): Summary

In collaboration with BARDA, we brought a Zika vaccine from mRNA sequence design to the clinic in twelve months

Zika is an infectious disease caused by the Zika virus, in which infection during pregnancy has been linked to severe brain damage in infants with congenital infection and Guillain-Barré Syndrome in adults. To date, no vaccine to prevent Zika infection has been approved. In September 2016, we were awarded a contract with se to be reimbursed up to approximately \$125 million for the development of a Zika mRNA vaccine. In order to rapidly respond to a potential epidemic, we developed mRNA-1325, which went from mRNA sequence design to first-in-human clinical testing in twelve months. In addition, we also developed a second Zika vaccine, mRNA-1893. mRNA-1893, at 1/20 of the dose, demonstrated better protection in non-human primates, as compared to mRNA-1325. mRNA-1325 is in a Phase 1 clinical trial in the United States and we are planning for a Phase 1 clinical trial of mRNA-1893. Based on the preclinical and clinical data, in collaboration with BARDA, we will determine which mRNA investigational medicine will be advanced for further clinical development.

Another possible source of funding is BARDA's extensive funding of a vaccine for COVID-19, including, for example, the funding described in this Moderna press release:

<https://www.sec.gov/Archives/edgar/data/1682852/000119312520199192/d13301dex991.htm>

CAMBRIDGE, Mass.—July 26, 2020— Moderna, Inc. (Nasdaq: MRNA), a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines for patients, today announced a modification to its contract with the Biomedical Advanced Research and Development Authority (BARDA) for an additional commitment of up to \$472 million to support late stage clinical development including the expanded Phase 3 study of the Company's mRNA vaccine candidate (mRNA-1273) against COVID-19.

An earlier award from BARDA for up to \$483 million was entered into to support the scale up of mRNA-1273 and clinical development, originally with a smaller anticipated number of participants in the Phase 3 clinical trial. Following discussions with the U.S. Food and Drug Administration (FDA) and consultations with Operation Warp Speed over the past several months, the Company has decided to conduct a significantly larger

Phase 3 clinical trial, leaving a gap in BARDA funding that will be closed by this contract modification. Under the terms of the revised contract, BARDA is expanding their support of the Company's late stage clinical development of mRNA-1273, including the execution of a 30,000 participant Phase 3 study in the U.S. The total value of the award is now approximately \$955 million.

"We thank BARDA for this continued commitment to mRNA-1273, our vaccine candidate against COVID-19." said Stéphane Bancel, Moderna's Chief Executive Officer. "Encouraged by the Phase 1 data, we believe that our mRNA vaccine may aid in addressing the COVID-19 pandemic and preventing future outbreaks."

KEI has prepared a spreadsheet that describes published USPTO patent applications and grants assigned to Moderna (as of August 24, 2020). This data is available [here](#). The priority dates for the patents and applications are given below:

Calendar Year	Priority Dates for Patents Granted	Priority Dates for Published Patent Applications
2016	12	13
2017	3	16
2018	0	2
2019	0	2

The following are the results of a search in the AppFT Database for patent applications from 2017 to the present that cite Zika.

Search query: (an/moderna or an/modernatx) and zika and APD/1/1/2017->8/31/2020

PUB. APP. NO.	Title
1	20200254086 EFFICACIOUS MRNA VACCINES
2	20190211065 HIGH POTENCY IMMUNOGENIC COMPOSITIONS
3	20190099481 ZIKA VIRUS MRNA VACCINES
4	20190008947 CHIKUNGUNYA VIRUS RNA VACCINES
5	20190008946 ZIKA VIRUS RNA VACCINES
6	20180344839 CHIKV RNA VACCINES
7	20180344838 DENV RNA VACCINES
8	20180312549 HIGH POTENCY IMMUNOGENIC COMPOSITIONS
9	20180280496 ZIKA RNA VACCINES
10	20180008694 CHIKAGUNYA VIRUS RNA VACCINES
11	20170340724 ZIKA VIRUS RNA VACCINES

It seems unlikely that none of these patent applications benefited from BARDA funding, and there are undoubtedly more relevant USPTO patent applications that have yet to be published, as well as USPTO provisional applications that are not published.

If Moderna has failed to disclose BARDA funding, we expect Moderna to at a minimum publish corrections to the patents with the USPTO. However, KEI believes that BARDA needs to send a signal to the companies it funds that failures to disclose have consequences, by exercising its legal remedies and taking title to the patents.

Sincerely,



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