

Failures to disclose government interests in patents

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Global Congress on Intellectual Property and the Public Interest
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Bayh-Dole Section 202(c) requires contractors to disclose government interest in patents

- these disclosures are an important policy tool:
 - inform about the role of the U.S. government in R&D investments towards a particular invention or inventions;
 - provide federal agencies and the public in general with a better understanding of rights they may have in patents.
- contractors often fail to disclose government interest:
 - GAO (1999, 2003), Rai and Sampat (2013);
 - KEI has filed several requests relating to failures to disclose.
- late disclosures via certificate of corrections are also a problem.

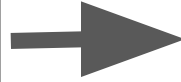
Years between priority date and correction in a sample of patents that originally failed to disclose

priority date	years between priority and correction			sample size
	average	median	max	
1980-1989	8.9	8	29	269
1990-1999	8.1	7	26	774
2000-2009	10.0	10	19	706
total	9.0	8	29	1749

data collection: search for all patents in the NIH RePORTER database that initially failed to make government interest statements, but eventually did it via certificates of corrections. These counts are based on 1749 out of approximately 2200 patents in RePORTER that disclosed via corrections. This is an ongoing analysis. The current dataset, which includes all patent numbers, is [available in this link](#).

How we typically research failures to disclose government interest in patents

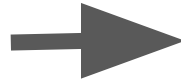
identify U.S. patents that lack government interest statements in the text or certificate of corrections



review priority dates, inventors, claims, abstract, title, and any other relevant bibliographic information



review papers, NIH RePORTER, SEC forms, and other disclosures of U.S. government support



compare the contracts or grants with the patents that lack government interest statements

None of the published U.S. patents assigned to Moderna acknowledge government support

U.S. patents and applications assigned to Moderna as of August 24, 2020			
priority year	N applications	N patents	N with GOVT
2010	3	8	0
2011	24	12	0
2012	40	41	0
2013	10	9	0
2014	7	7	0
2015	38	34	0
2016	13	12	0
2017	16	3	0
2018	2	0	0
2019	1	0	0
total	154	126	0

data collection: we used USPTO databases to search for all patents and applications assigned to “Moderna” or “ModernaTx.” A total of sixteen patents and seven applications were dropped from the dataset, and are not reflected above, because they were assigned to companies other than Moderna.

DARPA backed mRNA research early on



"The first coronavirus vaccine to start human testing is from DARPA investment in the Moderna company."

First vaccine trials

The first coronavirus vaccine to start human testing is from DARPA investment in the Moderna company. The vaccine is made via a new genetic method that does not depend on an overseas supply chain, or massive supplies of eggs as in traditional manufacturing. These features allow U.S. production of vaccine doses to be rapidly increased.

source: www.darpa.mil

Moderna acknowledges DARPA support for their mRNA platform technology in SEC disclosures

	W31P4Q-13-1-0007	W911NF-13-1-0417
start	March 22, 2013	October 2, 2013
award	“approximately \$1.4 million”	“up to \$25 million”, and as of December 31, 2019, \$19.7 million had been funded
summary	“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.”

source: www.sec.gov

At least two academic papers co-authored by Moderna scientists acknowledge DARPA funding

Science Immunology

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RESEARCH ARTICLE | EMERGING INFECTIONS



A lipid-encapsulated mRNA encoding a potentially neutralizing human monoclonal antibody protects against chikungunya infection

Nurgun Kose¹, Julie M. Fox², Gopal Sappapapu^{1,3}, Robin Bombardi¹, Rashika N. Tennekoon⁴, A. Dharshan de Silva^{4,5}, Sayda M. Elbashi⁶, Matthew A. Theisen⁶, Elisabeth Humphris-Narayanan⁶, Giuseppe Ciarrella⁶, Sunny Himansu⁶, Michael S. Diamond^{2,7} and James E. Crowe Jr.^{1,3,8,*}

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²Department of Medicine, Washington University School of Medicine, St. Louis, MO, USA.

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⁴Genetech Research Institute, Colombo, Sri Lanka.

⁵Department of Paraclinical Sciences, Faculty of Medicine, Kotelawala Defence University, Sri Lanka.

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⁷Department of Molecular Microbiology, Pathology & Immunology, Washington University School of Medicine, St. Louis, MO, USA.

⁸Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, TN, USA.

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▬ Hide authors and affiliations

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Vol. 4, Issue 35, eaaw6647
DOI: 10.1126/sciimmunol.aaw6647

Article

Cell

Vaccine Mediated Protection Against Zika Virus-Induced Congenital Disease

Justin M. Richner^{1,18,19}, Brett W. Jagger^{1,18}, Chao Shan^{2,18}, Camila R. Fontes^{2,18}, Kimberly A. Dowd^{3,18}, Bin Cao⁴, Sunny Himansu⁵, Elizabeth A. Caine¹, Bruno T.D. Nunes^{7,6}, Daniele B.A. Medeiros^{2,6}, Antonio E. Murato^{2,7}, Bryant M. Foreman³, Huanle Luo⁷, Tian Wang^{6,11}, Alan D. Barrett^{7,11}, Scott C. Weaver^{6,10,11}, Pedro F.C. Vasconcelos^{6,15}, Shannan L. Rossi^{7,10}, Giuseppe Ciarrella², Indira U. Mysorekar^{6,12}, Theodore C. Pierson^{3,4}, Pei-Yong Shi^{2,9,10,16,17,*} and Michael S. Diamond^{1,2,13,14,20,*}

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³Viral Pathogenesis Section, Laboratory of Viral Diseases, National Institutes of Health, Bethesda, MD USA

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¹¹Sealy Center for Vaccine Development, University of Texas Medical Branch, Galveston, TX, USA

¹²Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, MO, USA

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¹⁴The Andrew M. and Jane M. Bursky Center for Human Immunology and Immunotherapy Programs, Washington University School of Medicine, St. Louis, MO, USA

¹⁵Department of Pathology, Pará State University, Belém, Brazil

¹⁶Department of Pharmacology & Toxicology, University of Texas Medical Branch, Galveston, TX, USA

¹⁷Sealy Center for Structural Biology & Molecular Biophysics, University of Texas Medical Branch, Galveston, TX, USA

¹⁸These authors contributed equally

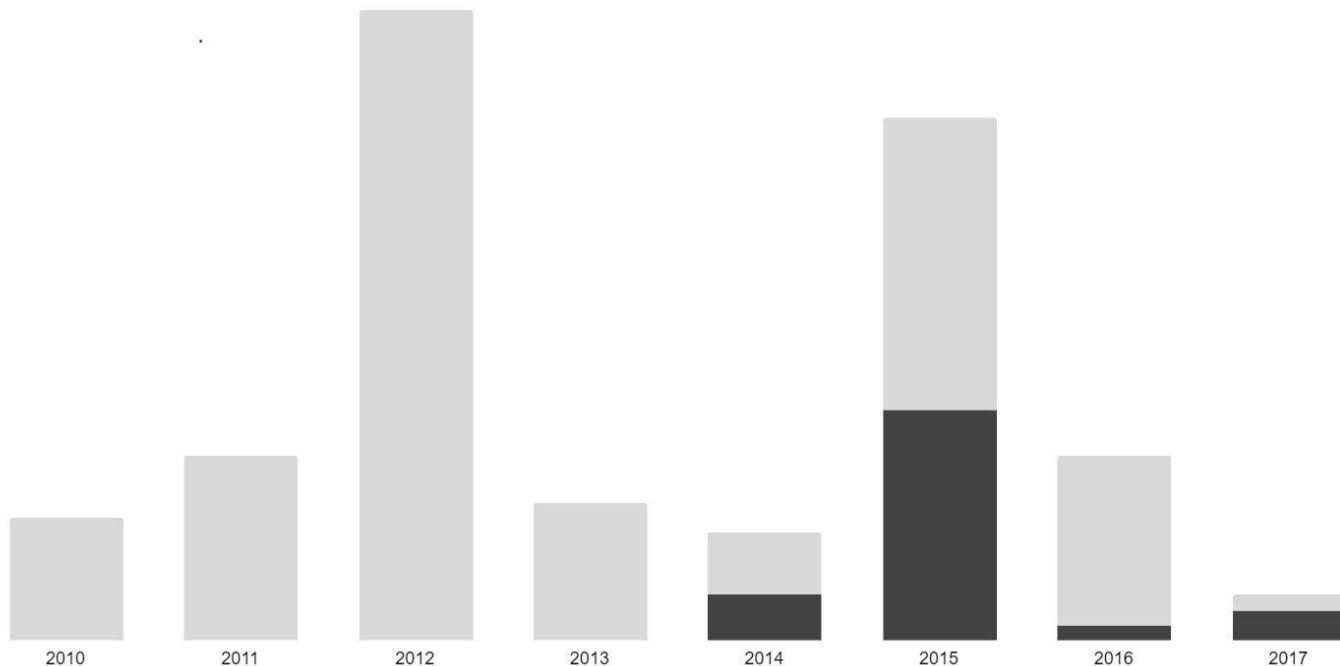
¹⁹Present address: IIT Research Institute, Chicago, IL, USA

²⁰Lead Contact: Michael S. Diamond

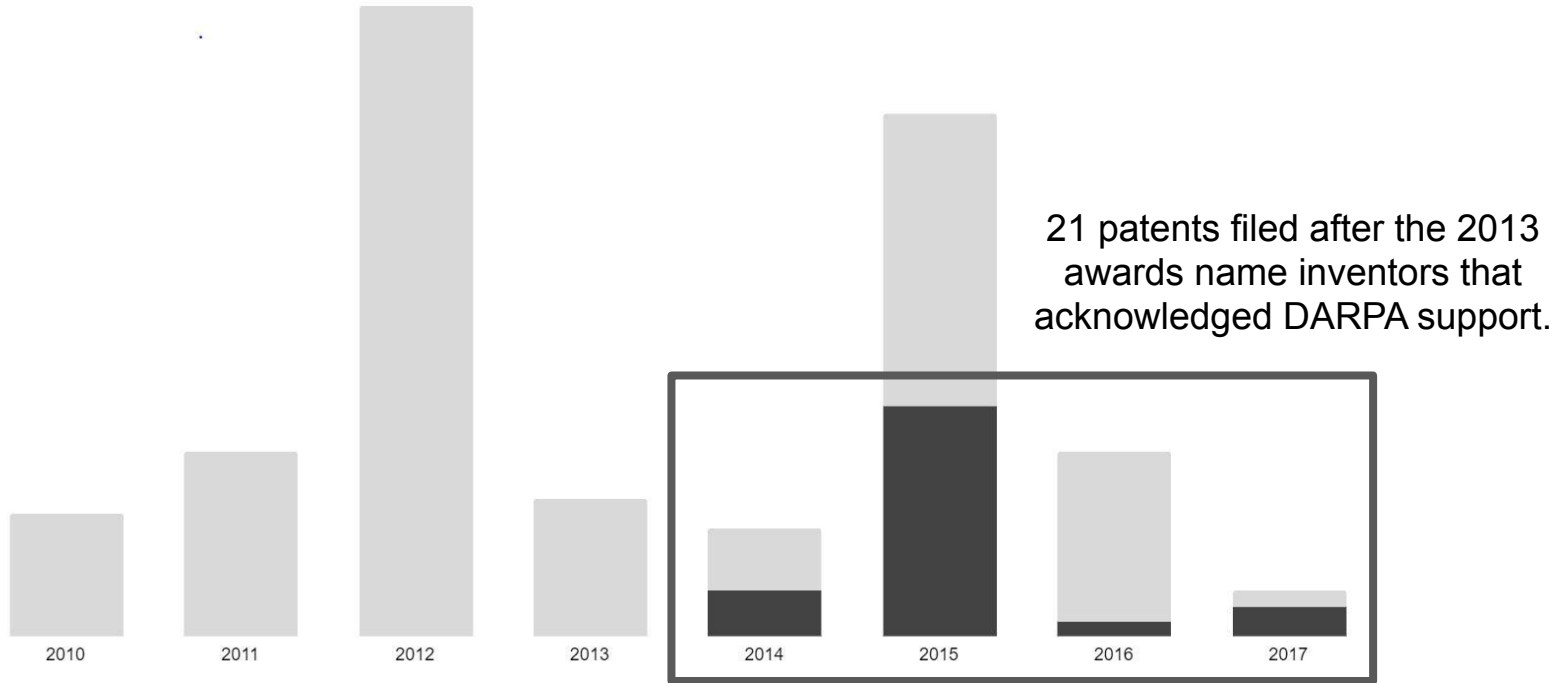
*Correspondence: piersontc@niaid.nih.gov (T.C.P.), peshi@utmb.edu (P.-Y.S.), diamond@wum.wustl.edu (M.S.D.)

<http://dx.doi.org/10.1016/j.cell.2017.06.040>

Several patents assigned to Moderna name inventors that acknowledged DARPA support



Several patents assigned to Moderna name inventors that acknowledged DARPA support



KEI asks DOD to investigate failure to disclose DARPA funding in Moderna patents

Posted on August 28, 2020 by James Love

(More on Moderna here: <https://www.keionline.org/moderna>)

Luis Gil Abinader has taken a deep dive into Moderna's surprising practice of never declaring government funding in its 126 patents and 154 patent applications, despite having had funding from multiple federal agencies.

One outcome of his research is a 25 page report ([RN-2020-3](#)) on Moderna's failure to report funding from DARPA, and a request by KEI to DOD and DARPA to remedy this, including by taking title to patents where disclosures should have been made. (Text of letter below, and PDF version [here](#)).

KEI will also send a letter to BARDA. The letter below was addressed to DOD and DARPA, and focuses on their funding.

Business

Moderna failed to disclose federal support in vaccine patents, researchers say

The company with a leading coronavirus vaccine candidate did not adhere to a law designed to protect public investment



Moderna's headquarters in Cambridge, Mass. (Brian Snyder/Reuters)

By **Christopher Rowland**

August 28, 2020 at 7:00 a.m. EDT

Moderna, the Massachusetts biotech company leading the global race to develop a coronavirus vaccine, has failed to disclose government financial support in any of the 126 patents it has filed in its 10-year history, in apparent violation of federal law, according to a new report by activist researchers.

Moderna was founded in 2010 and has yet to win market approval of a drug. But its vaccine technology, which has been developed with a combination of U.S. taxpayer support and a large share of private investment, allowed it to be the first company to test its SARS-CoV-2 vaccine in humans.

With a boost of nearly \$1 billion in research and development money from the Trump administration, it has initiated Stage 3 clinical trials in tens of thousands of people and is sprinting toward seeking an emergency-use authorization from the Food and Drug Administration before the end of the year. It also has a contract to sell 100 million doses to the United States for another \$1.5 billion. The key protein used in the vaccine was co-invented by the National Institutes of Health.

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Moderna [Add to myFT](#)

US government's Darpa probes Moderna's vaccine patents

Researchers accuse biotech company of failing to disclose federal grants in patents which also cover Covid-19 candidate



Moderna protocol files for Covid-19 vaccinations are kept at the Research Centers of America in Hollywood, Florida. (AP Photo/Chris Wedel)

Donato Paolo Mancini in Rome AUGUST 29 2020

22

The US Department of Defense's research arm is probing patents filed by and awarded to Moderna, a US biotech company developing a Covid-19 vaccine, after researchers accused the company of failing to disclose government funding as it is required to do by federal law.

In a report published this week, researchers at Knowledge Ecology International (KEI), a patient advocacy group, said Moderna failed to disclose in its vaccine patents that it had received about \$25m in grants from the DoD's Defense Advanced Research Projects Agency, or Darpa, to develop its vaccine technology.

"It appears that all past and present Darpa awards to Moderna include the requirement to report the role of government-funding for related inventions," Darpa spokesman Jared Adams said in an emailed response to the Financial Times.

"Further, Darpa is actively researching agency awards to Moderna to identify which patents and pending patents, if any at all, may be associated with Darpa support," he said.

Mr Adams declined to comment further, saying the investigation was continuing. US federal law required government funding to be disclosed in these circumstances, he noted.

Moderna failed to disclose federal patents, researchers say

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Activists Say Moderna Hid Gov't Support For Vaccine Patents

By Kevin Stawicki

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Law360 (August 28, 2020, 10:03 PM EDT) -- The U.S. Department of Defense must investigate whether Moderna Therapeutics — which is developing a closely watched COVID-19 vaccine — disclosed federal funds it received in its patent applications, and seize the biotechnology company's patents if it didn't, a nonprofit has urged the agency.

Knowledge Ecology International asked Defense Secretary Mark Esper in a letter Thursday to probe the Massachusetts-based company's "apparent failures" to tell the U.S. Patent and Trademark Office that the Defense Advanced Research Projects Agency was funding its efforts to develop mRNA vaccines for viral infections, including its COVID-19 vaccine candidate.

If the company's government funding sources are exposed, the DOD can demand ownership of the patents under the Bayh-Dole Act, KEI said.

"To protect taxpayer investments, the funding agency should remedy the 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," the advocacy group said in the letter.

DARPA had been funneling cash into research at Moderna as early as 2013, to help build its mRNA platform to develop vaccines for viral infections like Chikungunya and Zika, according to a KEI report published on Wednesday.

The DARPA-backed company then started filing patents for inventions related to methods involving the mRNA vaccine, without reporting those funds, the report said. Through an analysis of its U.S. Securities and Exchange Commission filings and academic papers, KEI said there is "clear evidence" that the company proceeded with its Chikungunya vaccine and antibodies programs without disclosing its primary funding source.

The federal money was also secretly used by the company to develop its COVID-19 vaccine candidate, the report said, citing DARPA's own website stating that "[t]he first coronavirus vaccine to start human testing is from DARPA investment in the Moderna company."

Not one of the 126 patents assigned to Moderna or the 154 patent applications it has filed disclosed federal funding even though DARPA was among the first funders to support Moderna's mRNA research, the report said.

Most of those DARPA funds resulted in patented inventions for which their government funding was never disclosed, as required under the Bayh-Dole Act, the report said. The law requires companies to disclose when government-funded research played a role in a patented invention, and any violation of that could lead to the government taking over the patent's rights, KEI said.



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Senator Chris Van Hollen ✓

@ChrisVanHollen



Each year taxpayers invest billions in medical research. Corporations should not turn taxpayer-funded discoveries into a means of price-gouging consumers and patients. We must pass the We PAID Act, which would ensure a fair price after public investments.



Moderna failed to disclose federal support in vaccine patents, researchers say
The company, which has a leading coronavirus vaccine candidate in clinical trials, has not followed a law requiring it to list government financial support in its ...
[washingtonpost.com](https://www.washingtonpost.com)

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675 NORTH RANDOLPH STREET
ARLINGTON, VA 22203-2114

September 18, 2020

Via Electronic Mail

James Love
Knowledge Ecology International
1621 Connecticut Avenue, NW, Suite 500
Washington, D.C. 20009

Dear Mr. Love:

I am responding to your letter of August 27, 2020, to Dr. Amy Jenkins at the Defense Advanced Research Projects Agency (DARPA) requesting the Department of Defense investigate Moderna Therapeutics' (Moderna) alleged failure to disclose DARPA funding support in its patented inventions. DARPA is reviewing agreements it has awarded to Moderna and U.S. patents and published patent applications for Moderna and ModernaTx, since March 2013.

Thank you for bringing this matter to our attention. Should you have any questions, please contact DARPA Deputy General Counsel, Geraldine Chanel, at 571-218-4609 or geraldine.chanel@darpa.mil.

Sincerely,

D. Peter Donaghue
Contracting Officer-Division Director
Contracts Management Office



Moderna sinks 7% amid funding transparency issues

BUSINESS Breaking the News / ND | @ 31 August

1 min read



EPA SEF/CJ GUNTHER

Shares of Moderna Inc. plunged more than 7% on Monday after it was revealed that the United States defense agency Darpa has opened an investigation into the company's patents linked to its development of a coronavirus vaccine.

Knowledge Ecology International (KEI) claimed last week that Moderna didn't report that it had received around \$25 million in grants from Darpa to develop a vaccine used against the coronavirus. Meanwhile, the biotech company from Massachusetts announced its vaccine produces [neutralizing antibodies](#) necessary to build immunity against the disease.

Moderna's stocks sank 7.08% to sell for \$62.80 per share at 10:55 am ET. Additionally, the company's shares have faced a loss of over 15% in the last 30 days.

CORONAVIRUS VACCINE MODERNA DARPA



Why Moderna Stock Fell Today

The coronavirus vaccine maker is being investigated for failing to disclose government



Joe Tenebruso (TMFGuardian)

Aug 31, 2020 at 4:50PM

Author Bio

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What happened

Shares of **Moderna** ([NASDAQ:MRNA](#)) declined by 3.9% on Monday. The [biotech](#) company's vaccine patent portfolio is reportedly being probed by the U.S. Department of Defense for a lack of proper funding disclosures, according to the *Financial Times*.

So what

The Defense Department investigation comes after a report by patient advocacy group Knowledge Ecology International, which claimed that Moderna failed to disclose the grants it received from the Defense Advanced Research Projects Agency (DARPA) in its patent applications -- including those of its coronavirus vaccine candidate -- as required by federal law.



THE U.S. DOD IS SCANNING MODERNA'S PATENT FILINGS. IMAGE SOURCE: GETTY IMAGES.

If funding agencies **never** take title of patents that failed to disclose government funding, regardless of the facts, contractors will have little incentives to comply with the Bayh-Dole Act requirements.