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

<table>
<thead>
<tr>
<th>priority date</th>
<th>years between priority and correction</th>
<th>sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>average</td>
<td>median</td>
</tr>
<tr>
<td>1980-1989</td>
<td>8.9</td>
<td>8</td>
</tr>
<tr>
<td>1990-1999</td>
<td>8.1</td>
<td>7</td>
</tr>
<tr>
<td>2000-2009</td>
<td>10.0</td>
<td>10</td>
</tr>
<tr>
<td>total</td>
<td>9.0</td>
<td>8</td>
</tr>
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</table>

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

<table>
<thead>
<tr>
<th>priority year</th>
<th>N applications</th>
<th>N patents</th>
<th>N with GOVT</th>
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</thead>
<tbody>
<tr>
<td>2010</td>
<td>3</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>2011</td>
<td>24</td>
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<tr>
<td>2016</td>
<td>13</td>
<td>12</td>
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</tr>
<tr>
<td>2017</td>
<td>16</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2018</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2019</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>total</td>
<td>154</td>
<td>126</td>
<td>0</td>
</tr>
</tbody>
</table>

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

“...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
Modernia acknowledges DARPA support for their mRNA platform technology in SEC disclosures

<table>
<thead>
<tr>
<th></th>
<th>W31P4Q-13-1-0007</th>
<th>W911NF-13-1-0417</th>
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<tr>
<td>start</td>
<td>March 22, 2013</td>
<td>October 2, 2013</td>
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<tr>
<td>award</td>
<td>“approximately $1.4 million”</td>
<td>“up to $25 million”, and as of December 31, 2019, $19.7 million had been funded</td>
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<tr>
<td>summary</td>
<td>“modified RNA technology for production of antibodies for immune prophylaxis.”</td>
<td>“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.”</td>
</tr>
</tbody>
</table>

source: [www.sec.gov](http://www.sec.gov)
At least two academic papers co-authored by Moderna scientists acknowledge DARPA funding.
Several patents assigned to Moderna name inventors that acknowledged DARPA support
Several patents assigned to Moderna name inventors that acknowledged DARPA support.

21 patents filed after the 2013 awards 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.kelonline.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.
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. (Brien Snyder/Reuters)

By Christopher Rowland
August 26, 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 266 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. 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 300 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.
Moderna failed to disclose federal patents, researchers say

The company with a leading coronavirus vaccine candidate did not adhere to US government's probed Moderna's vaccine patents

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

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

Darpa's probes Moderna's Covid-19 vaccine. In this Research Centers of America in Hollywood, Florida. Image by EPA

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 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 $35m 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.

"Furthermore, 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

The company with a leading coronavirus vaccine candidate did not adhere to government guidelines.

By Christopher Rowland

August 26, 2020, 7:00 a.m. EDT

Moderna, the Massachusetts biotech company leading the global race to develop a coronavirus vaccine, has failed to disclose government funding in any of the 256 patents it has filed, according to a new report by activist group Knowledge Ecology International (KEI).

KEI, a patient advocacy group that Moderna failed to disclose in its vaccine patents that it had received about $575 million in new grants from the Biomedical Advanced Research Projects Agency, or Darpa, to develop its vaccine technology.

It "appears that at least 111 patents Moderna, including the requirement to report the role of government-funding for related inventions," KEI 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.

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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
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 Donaghy  
Contracting Officer-Division Director  
Contracts Management Office
Modernastocks fell 7% amid funding transparency issues

Shares of Moderna Inc. plummeted 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.

Why Moderna Stock Fell Today

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

Joe Tenney
TMQ Guardian
Aug 31, 2020 at 4:00PM

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.
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.