



Claire Cassedy <clairepcassedy@gmail.com>

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## Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

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**Claire Cassedy** <claire.cassedy@keionline.org>  
To: "Burke, Andy (NIH/NCI) [E]" <andy.burke@nih.gov>

Mon, Jun 24, 2019 at 4:17 PM

Dear Mr. Burke,

Thank you very much for your prompt reply. I have one more question regarding this proposed license:

-In working towards executing this license, has the NIH sought advice from the Attorney General (as is required under [40 USC § 559](#)) to determine if the "disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law"?

I appreciate all your assistance on these inquiries.

Best Regards,  
Claire Cassedy

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Claire Cassedy  
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1621 Connecticut Avenue NW  
Suite 500  
Washington, DC 20009  
Tel.: 1.202.332.2670

On Mon, Jun 24, 2019 at 3:42 PM Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov> wrote:

Dear Claire,

Thank you for your email. Answers to your questions are embedded below.

Regards,

Andy

**Andrew R. Burke, Ph.D.**

Senior Technology Transfer Manager

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**From:** Claire Cassedy <[claire.cassedy@keionline.org](mailto:claire.cassedy@keionline.org)>

**Sent:** Monday, June 24, 2019 12:33 PM

**To:** Burke, Andy (NIH/NCI) [E] <[andy.burke@nih.gov](mailto:andy.burke@nih.gov)>

**Subject:** Inquiry regarding 84 FR 28063 Doc 2019-12707 - Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer

Dear Mr. Burke,

I am writing in reference to the Federal Register notice (84 FR 28063 Doc 2019-12707) regarding, "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?

**Answer:** With respect to the advertised fields of use, the technologies are at a "pre-clinical" stage of development.

2. Has the government funded any clinical trials relevant to these technologies?

**Answer:** I am not aware of any US government-funded clinical trials utilizing the referenced technologies within the advertised fields of use.

3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?

**Answer:** NA

4. How many years of exclusivity have been offered in this agreement, and what will the royalty rate be?

Answer: These terms will be the subject of negotiation and are not known at this time.

5. Regarding the company to receive the licenses, Tailored Therapeutics, LLC are any former NIH employees associated with the company?

Answer: Questions regarding employees or associates of the company should be directed to the company.

Thank you in advance for your assistance in this matter.

Best Regards,  
Claire Cassedy

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