



Claire Cassedy <clairepcassedy@gmail.com>

Additional inquiry regarding 84 FR 28063, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, to Tailored Therapeutics

Luis Gil Abinader <luis.gil.abinader@keionline.org>

Thu, Jun 27, 2019 at 12:26 PM

To: Jamie Love <james.love@keionline.org>, "claire.cassedy" <claire.cassedy@keionline.org>

Cc: Kathryn Ardizzone <kathryn.ardizzone@keionline.org>, Laurel Boman <laurel.boman@keionline.org>

----- Forwarded message -----

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

Date: Thu, Jun 27, 2019 at 11:57 AM

Subject: RE: Additional inquiry regarding 84 FR 28063, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, to Tailored Therapeutics

To: luis.gil.abinader@keionline.org <luis.gil.abinader@keionline.org>

Dear Luis,

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

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

National Cancer Institute

[9609 Medical Center Drive](#), Rm 1E550

Rockville, MD 20850

Direct: (240) 276-5484

Email: andy.burke@nih.gov

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From: Luis Gil Abinader <luis.gil.abinader@keionline.org>
Sent: Wednesday, June 26, 2019 1:58 PM
To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>
Cc: Jamie Love <james.love@keionline.org>; claire.cassedy <claire.cassedy@keionline.org>
Subject: Additional inquiry regarding 84 FR 28063, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, to Tailored Therapeutics

Dear Andy Burke,

I am writing in reference to the Federal Register notice 84 FR 28063, Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer, to Tailored Therapeutics, LLC, for which you are listed as the contact for inquiries. Thank you for your previous response to my colleague Claire Cassidy. We have additional questions about the proposed license.

1. Our research suggests that none of the four patent documents listed in the Federal Register notice has been published online. Have any of them been published?

Answer: The cited patent applications have not published.

2. Is <https://tailored-therapeutics.com> the website of the prospective licensee?

Answer: This appears to be the company's new website. Please confirm directly with the company.

3. Is the prospective licensee mentioned in the Federal Register notice 84 FR 28063, Tailored Therapeutics, the same company that appeared as prospective licensee in the Federal Register notice 83 FR 49109, published on September 28, 2018?

Answer: Yes, both FR notices concern the same company.

4. Was the license proposed in the Federal Register notice 83 FR 49109 executed?

Answer: Yes, the license was executed.

5. Will the exclusive license proposed in the Federal Register notice 84 FR 28063 amend the previous license described in the Federal Register notice 83 FR 49109? In which ways and to what extent?

Answer: If the proposed license described in 84 FR 28063 is executed, it will be as an amendment to the company's existing license. Should this occur, the existing license would be amended to include the patent rights listed in 84 FR 28063 in the fields of use described in the same.

6. If this is the case, what is the rationale for granting additional exclusive rights to a company that presumably has outstanding obligations under a previous license?

Answer: The company requested a broader scope to their existing license and provided an adequate commercial development plan describing how it will bring the referenced patent rights to practical application within the fields of use described.

7. Does the license proposed in the Federal Register notice 84 FR 28063 has any relation to the license proposed in the Federal Register notice 84 FR 2537, published on February 7, 2019, which describes Ziopharm Oncology as the prospective licensee? We note that there is a least one patent document, 62/749,750, that is cited in both notices.

Answer: As you noted, both FR notices are directed, in part, to a set of common patent applications. Beyond that, I am not aware of a relationship between Tailored Therapeutics and Ziopharm Oncology.

[Quoted text hidden]