19 April 2019

Jim Knabb,
Senior Technology Transfer Manager,
NCI Technology Transfer Center,
Email: jim.knabb@nih.gov.

RE: Senti Bio license, “Prospective Grant of an Exclusive/Co-Exclusive Patent License: Development and Commercialization of Next Generation Chimeric Antigen Receptor (CAR) Therapies for the Treatment of FMS-Like tyrosine kinase 3 (FLT3) Expressing Cancers”

Dear Jim Knabb,

We are writing regarding the proposed exclusive/co-exclusive patent license of several patent applications to Senti Bio, as set out in the Federal Register notice dated April 4, 2019 [84 FR 13305] for:

> “the development of a universal/split chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, for the prophylaxis or treatment of cancers expressing FMS-like tyrosine kinase 3 (FLT3; also known as CD135), wherein the CAR construct binds to the FLT3-binding domain referenced as NC7 in the invention, but NC7 is not included in the CAR construct. “

Conditions on License

It is our understanding, from your email on April 3, 2019, that the technology is in the pre-clinical stage, and that according to your email on April 5, 2019, the national stage patent applications were only filed in the United States, Europe, Canada, Japan, and Australia.

1. **No price discrimination against U.S. residents.**

We ask that an exclusive license including a requirement that any treatment that uses the inventions be available to the public on reasonable terms, and that those terms include a requirement that prices in the United States are not higher than the median price charged in the seven largest economies, with at least 50 percent of U.S. per capita income, as measured by the World Bank GNI per capita, Atlas method.

2. **Years of exclusivity.**

We propose the license reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the exclusivity of the license be reduced when the global

cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the license could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales.

3. **Transparency of R&D outlays.**

The licensee should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We will note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

4. **Technology Transfer**

The "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy", states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries." The geographic scope of the license is "worldwide" accounting to the Federal Register Notice, but apparently involves patents filed in the United States, Europe, Canada, Japan, and Australia. The NIH should include a provision for provide technology transfer, including know how, to companies or other entities that could provide access to the technology in developing countries, in the event that Senti Bio does not serve these markets, or if the prices it charges are not reasonably affordable in developing countries.

Standards

As you know, when the federal government owns a patent, the decision to grant an exclusive license is subject to restrictions and standards set out in 35 USC 209.

https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35-partII-chap18-sec209.htm

These requirements include an obligation for the NIH to determine if an exclusive license is "a reasonable and necessary incentive to . . . call forth the investment capital and expenditures

needed to bring the invention to practical application," and when the agency finds that "finds that the public will be served by the granting of the license" to ensure that:

> "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;" [35 USC 209(a)(2)]

As you know, the term 'practical application' is defined in the Bayh-Dole Act to include the obligation to

> "to establish that the invention is being utilized and that its benefits are to the extent permitted b law or Government regulations available to the public on reasonable terms." [35 USC 201(f)]

Advice of the Attorney General

Prior the granting an exclusive license, we ask the NIH to seek the advice of the Attorney General with respect to antitrust law, as is required by 40 USC 559 for a patent or invention.

> **United States Code, 2015 Edition**
> **40 U.S.C. §559. Advice of Attorney General with respect to antitrust law**
>
> (b) Advice Required.—
>
> (1) In general.—An executive agency shall not dispose of property to a private interest until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law.
>
> (2) Exception.—This section does not apply to disposal of—
>
> (A) real property, if the estimated fair market value is less than $3,000,000; or
>
> (B) personal property (other than a patent, process, technique, or invention), if the estimated fair market value is less than $3,000,000.

We understand that in the past the NIH has take the position that the Bayh-Dole Act somehow provides an exception to 40 USC 559, but that seems to have been a mistake. There are two provisions in the Bayh-Dole Act that are relevant.

In 35 U.S. Code § 211, “Relationship to antitrust laws,” the Act states “Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.”

In 35 U.S. Code § 210, “Precedence of chapter,” mentions 21 separate acts that the Bayh-Dole Act takes precedence over, but does not mention 40 USC 559. The NIH would have to argue that 40 USC 599 is “inconsistent with the Bayh-Dole Act, despite the plain language in 40 U.S.C. §559 regarding government owned patents.

Sincerely,

HealthGap
Knowledge Ecology International
Public Citizen
Social Security Works
Union for Affordable Cancer Treatment