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October 26, 2019

Karen Rogers
Acting Director
NIH Office of Technology Transfer
6011 Executive Blvd, Suite 325
Rockville, MD 20852
Via Email: rogersk@mail.nih.gov

Re: Administrative Appeal, Exclusive Patent License in "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc.

Dear Ms. Rogers:

Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen, Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love (collectively, "Appellants"), write to appeal the decision of the National Institutes of Health (NIH) to grant an exclusive license in **"**Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc. as described in the Federal Register at 84 FR 45503[1] ("the Notice").

The licensed inventions are T-cell therapies with potential indications in diseases such as breast cancer, gastrointestinal epithelial cancer, lung cancer, and B cell lymphoma. Given the broad reach of the inventions and their potential importance to public health outcomes, it is concerning that almost no information is publicly-available about the prospective licensee. Intima Bioscience is not registered to conduct business in New York, the state where it is headquartered according to the Notice, and it does not maintain a website. With a prospective licensee as obscure as Intima Bioscience, the NIH should be particularly transparent about the license. As always, any license that the NIH negotiates must comply with the criteria located at 35 U.S.C. § 209(a).

Unfortunately, the cursory statements contained in the NIH's response to our comments indicate that the NIH has not engaged in the analysis mandated by 35 U.S.C. § 209(a), nor has it given

[1] 84 Fed. Reg. 45503 (Aug. 29, 2019), available at https://www.federalregister.gov/documents/2019/08/29/2019-18648/prospective-grant-of-an-exclusive-patent-license-genetically-modified-lymphocytes-for-cancer-therapy.

any serious consideration to our objections. Moreover, the NIH cannot demonstrate that an exclusive license was necessary in this instance because it did not publicly announce the subject inventions as available for licensing.

Finally, the NIH's lack of transparency regarding information relevant to the license and how it performed the requisite analysis continues a concerning trend in which the NIH is exhibiting an increasing lack of respect for the public's right to comment on its licensing decisions.

This appeal addresses five issues:

1. Did the NIH properly evaluate the necessity of granting an exclusive license in the subject inventions, as it is required to do under 35 U.S.C. § 209(a)(1)?

2. Assuming that the NIH can establish that an exclusive license was necessary in this case, did the NIH meet its statutory responsibility to limit the scope of rights to that which is "reasonably necessary" to induce the investment required to bring the invention to practical application, as required by 35 U.S.C. § 209(a)(2)?

3. Has the NIH withheld relevant, nonconfidential information about the license from the public, impeding its right to comment under 35 U.S.C. § 209(e)?

4. Did the NIH request the antitrust advice of the Attorney General, pursuant to 40 U.S.C. § 559?

5. Has the NIH implemented the objectives in the Public Health Service (PHS) Technology Transfer Policy Manual regarding promoting access in developing countries?

We request a hearing on this appeal.

A. BACKGROUND AND PROCEDURAL HISTORY

The Inventions and Prospective Licensee

The Notice associated with the license, 84 FR 45503, lists 33 patents/patent applications, which are grouped into four categories:

- Group A: Intracellular Genomic Transplant and Methods of Therapy;
- Group B: Modified Cells and Methods of Therapy;
- Group C: Viral Methods of T Cell Therapy; and
- Group D: CAS9 Modified TIL for Treatment of Gastrointestinal Cancer.

According to the patent documents, the inventions seek to overcome a major limitation in cancer immunotherapies: the fact that their "successes have been limited largely to hematological

tumors, and more broad application to solid tumors is limited by the lack of an identifiable molecule . . . that can be used to specifically bind to the tumor target in order to mediate tumor destruction."[2] The patents/patent applications claim a variety of methods to overcome that limitation using cancer-specific T-cell receptors (TCRs) that can identify and target immunogenic mutations in solid tumors, in order to extend immunotherapy to many cancer types.[3]

The Notice refers to the prospective licensee as "Intima Bioscience, Inc. ('Intima'), headquartered in New York, NY."

No corporation with the name "Intima Bioscience, Inc." is registered to conduct business in New York. We are aware of an entity known as Intima Capital, LLC, which appears to be related to Intima Bioscience and is registered to conduct business in New York. Intima Capital's official business address, according to its New York business registration, is 3 Columbus Circle, NY, NY 10019—the same address that is listed for Intima Bioscience in many of the patent documents. Intima Capital maintains a one-page website located at http://intimacapital.com/.[4]

The statements[5] on the one page website for Intima Capital should also remind the NIH that nowhere is there an expectation that the inventions will be made "available to the public on reasonable terms."

> "Intima Capital, LLC is a New York-based global alternative asset management firm that seeks to capture superior, uncorrelated, risk-adjusted returns in healthcare.
>
> The investment strategy is predicated on the understanding that healthcare is an investible sector that is fundamentally non-discretionary, uniquely inefficient, and disproportionately requires specific scientific and clinical domain expertise.

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[2] https://patentscope.wipo.int/search/docs2/pct/WO2017023801/pdf/otEXYE0EXzL0pVTJt7ArsQZPscUsR2DLyORQkK7nw_inqGqO6w03ckc7hFpaFj7OKAeSrYtiwSFsN-avMcy30aP3AOcTkgpsjg4TgRfRcSDcd9T212hBQS3yssP1AKiz?docId=id00000036661214 (Group A); http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=10,166,255.PN.&OS=PN/10,166,255&RS=PN/10,166,255 (Group B); https://patentscope.wipo.int/search/docs2/pct/WO2018081476/pdf/xaJoSNF1fS1Chw9zzs3BME7YWoG3S-LhdiHCv9-SSgKMP8N-UmGJNxuioPblJ3rUa6CSfpXCvhkOI7ul8-GN24QehnDy_B1Qaje4RaPbMIHnQawTB-MabL-q-E8r1Jpf?docId=id00000043307594 (Group C); http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=/netahtml/PTO/srchnum.html&r=1&f=G&l=50&s1=20190008899.PGNR.&OS=DN/20190008899&RS=DN/20190008899 (Group D).

[3] *Id.*

[4] https://web.archive.org/web/20190912202840/http://intimacapital.com/.

[5] https://web.archive.org/web/20190912202840/http://intimacapital.com/.

> The firm is focused on identifying long-term secular, economic, and scientific trends and then estabishing [sic] discrete long/short public equity, derivative, and opportunistic private equity investments to express a proprietary understanding of the field."[6]

The inventions are co-owned by the United States of America, Regents of the University of Minnesota, and Intima Bioscience, Inc. The inventors listed on the U.S. patents/patent applications correspond to the co-owners of the inventions: Steven Rosenberg, Douglas Palmer, and Nicholas Restifo are scientists with the National Cancer Institute (NCI). Branden Moriarity, Beau Webber, and R. Scott McIvor are researchers with the University of Minnesota's Masonic Cancer Center. Modassir Choudhry appears to be the founder of Intima Capital.[7]

Proposed Scope of the License

The Notice states that "prospective exclusive license territory may be worldwide[.]"

Four fields of use for the prospective license are listed, all of which involve autologous or allogeneic administration of T-cells that were genetically engineered using methods such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) or Adeno-Associated Viral (AAV) vectors to treat diseases such as gastrointestinal epithelial cancer, lung cancer, breast cancer, and B-cell lymphoma in humans.

The Notice does not state the proposed duration of the license.

Correspondence about the License

On September 9, 2019, KEI emailed a list of questions about the license to Andrew Burke, Ph.D., a Senior Technology Transfer Manager with the NCI and the point of contact for the license. He responded by email dated September 10, 2019, in which he answered some, but not all, of KEI's questions.[8]

KEI and Dr. Burke later corresponded further about the NIH's refusal to disclose the identity of Intima Bioscience's principals or officers and the duration of the license.[9]

Joint Comments

On September 13, 2019, KEI, UACT, Public Citizen, SSW, LWC Health, Ruth Lopert, Manon Ress, and Terry Love (collectively, "the joint commenters") timely submitted comments on the license, via PDF attachment, in an email to Dr. Burke. The joint comments objected to the license on the grounds that the NIH failed to conduct the analysis for granting an exclusive

[6] https://web.archive.org/web/20190912202840/http://intimacapital.com/.
[7] https://www.hfalert.com/search.pl?ARTICLE=161015&SEARCH=&PAGE=350&PROPERTY=.
[8] *See* Attachment A.
[9] *See* Attachments B - J.

license under 35 U.S.C. §§ 209(a)(1)&(2), withheld relevant, non-confidential information about the license, impeding the public's right to comment under 35 U.S.C. § 209(e), and failed to seek the antitrust advice of the U.S. Attorney General concerning the disposition of the government's rights in the intellectual property, as required under 40 U.S.C. § 559.

The comments argued further that in the event that the NIH executes the license over the objections stated therein, the license agreement should incorporate a series of provisions designed to implement the policy objectives of the Bayh-Dole Act and the governing principles of the PHS Technology Transfer Manual.

Final Determination Letter

On September 26, 2019, Dr. Burke emailed KEI the NIH's final response letter regarding the joint comments, which KEI then forwarded to the other commenters.

The body of the letter states in its entirety:

> Thank you for providing us with your comments regarding the above-referenced notice ('Notice'). As you indicated your comments were submitted on behalf of several organizations and individuals, we kindly request that you share your response with these same parties.
>
> Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified fields of use. 37 C.F.R. § 404.7(a)(1)(i) provides an opportunity for public comment and possible objection to the proposed license.
>
> NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.[10]

Pursuant to the NIH's OTT's appeals procedures, an administrative appeal regarding the license must be submitted within 30 days of the NIH's transmission of the final response letter[11] (no later than October 26, 2019 for the instant license).

[10] *See* Attachment K.

[11] The URL for NIH's appeals procedures, https://spweb.od.nih.gov/OTT/DTDT/TTPB/US%20PHS%20Technology%20Transfer%20Policy%20Manual/PHS%20TT%20Manual%20Chapters%20-%20Approved%20by%20TTPB/307-Procedure.pdf, is still nonfunctional. KEI brought this issue to the NIH's attention in early 2018.

B. STANDING

A right to appeal an exclusive patent license in federally-owned technology is afforded to: "(1) A person whose license has been denied; (2) A licensee whose license has been modified or terminated, in whole or in part; or (3) A person who timely filed a written objection in response to the notice . . . and who can demonstrate . . . that such person may be damaged by the agency action." 37 C.F.R. § 404.11(a).

Appellants satisfy the third basis for an appeal. We timely submitted our comments to the NIH, and appellants Terry Love and Manon Ress are cancer patients who could be damaged by the license. An overly broad exclusive license that is inconsistent with 35 U.S.C. § 209 not only violates federal law but could harm patients, such as Mr Love and Ms Ress, who may need to access the licensed technology but face unnecessary barriers or financial hardship, due to cost.

Also, KEI has had to divert resources in order to counteract the NIH's unlawful lack of transparency, frustrating KEI's mission, which involves informing the public about the activities of government, particularly as regards administration of taxpayer-funded resources. As explained below, the NIH has withheld information about the license without any valid legal basis for doing so. KEI was thus forced to pursue that information from other avenues, such as requesting it from private entities who did not have an obligation to report the information to the public and did not respond to our inquiries.[12]

C. ARGUMENT

Appellants appeal the NIH's decision to proceed with the license for the following reasons:

1. The NIH did not conduct the analysis required by 35 U.S.C. § 209(a)(1) to conclude that an exclusive license was a reasonable and necessary incentive;
2. Assuming that the NIH can establish that an exclusive license was necessary in this case, the NIH has not properly analyzed whether the scope of rights is limited to that which is "reasonably necessary" to induce the investment required to bring the invention to practical application, as required by 35 U.S.C. § 209(a)(2);
3. The public's right to evaluate and comment on a proposed license under 35 U.S.C. § 209(e) was undermined by the NIH's unjustified lack of transparency, particularly concerning the identity of the prospective licensee and the extent of federal funding of the licensed inventions;

[12] KEI requested information about the covered inventions directly from co-inventors, University of Minnesota scientists Branden Moriarity and R. Scott McIvor. Moriarity and McIvor never responded to KEI's inquiries. Similarly, KEI requested information about Intima Bioscience directly from the company. KEI called a telephone number listed for the company and asked the person who answered the call for the names of Intima Bioscience's principals. The person who responded refused to answer the question himself but promised to call back. As far as KEI is aware, the company never followed up with the requested information.

4. The NIH did not request the advice of the Attorney General regarding whether the license would create or maintain a violation of federal antitrust laws; and
5. The NIH has not done anything to implement to objectives in the PHS Technology Transfer Policy Manual regarding promoting access in developing countries.

This appeal addresses each issue in turn.

1. The NIH lacks authority to execute the license because it did not conduct the analysis required by 35 U.S.C. § 209(a)(1) to conclude that an exclusive license was a reasonable and necessary incentive.

A federal agency may not license federally-owned technology on an exclusive basis without first determining that "(1) granting the license is a reasonable and necessary incentive to— (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or (B) otherwise promote the invention's utilization by the public[.]" 35 U.S.C. § 209 (a)(1).

The NIH has failed to conduct the analysis required by 35 U.S.C. § 209 (a)(1) and thus lacks the authority to execute the proposed license.

During the comment period, KEI asked Dr. Burke why the NIH was proposing to grant an exclusive license in the subject technologies to Intima Bioscience. He responded: "Because NIH wishes to grant an exclusive license to improve the chances that the technology will be made available to the public."

In its final response letter, the NIH's discussion of exclusivity was limited to the following:

> Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified field of use.

The NIH's analysis of exclusivity with respect to the proposed license thus consisted of the following two considerations:

- Whether an exclusive license would improve the chances that the technology will be made available to the public; and
- Whether the license applicant was qualified, technically and financially, to be granted the license.

Neither consideration tracks the statutory standard, which asks whether exclusivity is both (1) reasonable and (2) necessary to incentivize a company to bring an invention to market.

We interpret the word “necessary” according to its plain meaning. Merriam-Webster defines “necessary” to mean “absolutely needed: required.”[13] In the context of 35 U.S.C. § 209(a)(1), the word “necessary” plainly means that an agency may license a federally-owned invention on an exclusive basis only if no qualified business would agree to undertake the investment needed to bring the technology to market absent exclusive rights. Stated otherwise, if even one qualified firm would agree to commercialize the technology on a non-exclusive or co-exclusive basis, then an exclusive license would not be authorized under Section 209(a)(1).

The NIH’s Office of Technology Transfer (OTT) has expressed the same understanding of the term “necessary.” In a 2006 presentation by the OTT, two of the stated criteria for granting an exclusive license were that “practical application of technology has not been achieved and **may not be achieved under a non-exclusive license**” and that exclusivity is “**[r]equired** to attract investment capital or to justify capital expenditures[.]”[14] Thus, at least at one point in time, the NIH understood that necessary means “required” and not merely “helpful.”

Aside from being inconsistent with Section 209(a)(1), neither standard supplied by the NIH with respect to the instant license is sufficient to protect the public’s investment in biomedical research, which, according to the same OTT document, is part of the agency’s mission.

Granting exclusive rights to a license applicant will always improve the chances that the technology will be made available to the public. It is no secret that for-profit businesses prefer exclusive rights; that is what allows them to maximize revenues by charging the public whatever price the market can bear. But that concept is precisely what makes patients particularly vulnerable to businesses’ profit-maximizing strategies in the context of life-saving cell or gene therapies, and is why it is imperative that the NIH thoughtfully administers the criteria located at 35 U.S.C. § 209 to protect the public’s investment in those technologies. If “improving the chances” were the relevant legal standard for granting an exclusive license - and it is not - the NIH would be free to grant a monopoly in a federally-owned invention 100 percent of the time, guaranteeing American taxpayers the worst possible deal. On the other hand, by granting an exclusive license only where doing so can truly be considered “necessary,” the NIH would be able to promote innovation without compromising access.

Asking whether a license applicant is financially qualified to commercialize a technology likewise misses the mark. There may be any number of businesses interested in licensing federally-owned technology that possess the qualifications to bring an invention to market. The question is whether the NIH can persuasively demonstrate that no qualified firm would be willing to undertake that investment on a non-exclusive or co-exclusive basis.

[13] https://www.merriam-webster.com/dictionary/necessary.
[14] http://www.pfc.org.in/workshop/page50-53.pdf (emphasis added).

The NIH document, *Best Practices for the Licensing of Genomic Inventions*, recognizes the importance of granting non-exclusive licenses in genomic inventions, such as the subject technology, "whenever possible."[15] It states, in pertinent part:

> Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to-operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights.

The NIH cannot demonstrate that exclusivity was necessary in this instance because it failed to advertise the invention to the public as available for licensing.

Typically, a biotech firm interested in licensing NIH-owned technologies can discover what inventions are available for licensing through at least two avenues. First, firms can use the *Find Technologies* search engine at the OTT website to search NIH-owned inventions by "Keywords," "NIH OTT Ref. No. (aka E. no.)," "Inventor Last Name," and other fields.[16] Or, if they click on "Licensing Opportunity" under the "Licensing" tab on the OTT homepage, businesses can find a list of available technologies.[17] Second, interested parties can search NIH inventions available for licensing in the Federal Register. The Department of Health and Human Services recognizes that "publication of a notice that an invention is available for licensing serves to meet one of the requirements of 37 C.F.R. § 404.7 if an exclusive or partially exclusive license is ultimately granted."[18] It is thus the policy of PHS that "all PHS inventions that are available for licensing and for which a patent application has been filed . . . will be described in a notice published in the *Federal Register*."[19] Neither avenue would have disclosed the subject inventions as available for licensing, however.

KEI searched the "E. nos." pertaining to the subject inventions (E-171-2018, E-173-2018, and E-174-2018) in the *Find Technologies* search engine. No results were returned. Likewise, a search for the subject inventions in the Federal Register returned no results.

Dr. Burke confirmed that the NIH did not post the inventions as available for licensing using either the *Find Technologies* search engine or posting on the Federal Register. KEI asked Dr. Burke: "Did the NIH previously post this technology in the Federal Register under 'Government

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[15] Best Practices for the Licensing of Genomic Inventions - Final Notice (April 2005), available at https://www.govinfo.gov/content/pkg/FR-2005-04-11/pdf/05-7247.pdf.
[16] https://www.ott.nih.gov/licensing/licensing-process.
[17] https://www.ott.nih.gov/opportunities.
[18] United States Public Health Service Technology Transfer Manual, Chapter No. 302, *PHS Policy for Preparing and Submitting Notices Regarding LIcensing of PHS Inventions to the Federal Register for Publication*, available at https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/302-Policy.pdf.
[19] *Id.*

Inventions available for licensing' or on the NIH's OTT Website's 'Licensing Opportunities'"? He responded: "No." On September 12, 2019, KEI asked Dr. Burke why the NIH did not post the inventions as available for licensing. He did not respond.

Because the NIH has not, and cannot, demonstrate that exclusivity was a reasonable and necessary incentive under 35 U.S.C. § 209(a)(1), it lacks the authority to execute the license.

2. Assuming that the NIH could establish that an exclusive license was necessary in this case, the license violates 35 U.S.C. § 209(a)(2) because the NIH has not met its statutory responsibility to limit the scope of rights to that which is not broader than "reasonably necessary" to induce the investment required to bring the invention to practical application, including, in particular, the number of years of exclusivity.

Even if the NIH properly concluded that exclusivity was both reasonable and necessary, it still lacks the authority to execute the license because it has not properly analyzed whether "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 U.S.C. § 209 (a)(2).

The scope of a license in federally-sponsored technology may vary along the following (non-exhaustive) list of parameters:

- The duration of exclusivity - how long the licensee may claim a monopoly on the right to market and sell the invention (*i.e.*, five years, ten years, life of patent, etc.);
- Territorial reach (worldwide or limited to the U.S. or a particular geographic region); and
- Field of use (*i.e.*, targeted diseases).[20]

The NIH's lack of transparency has made it difficult for Appellants to evaluate how the NIH applied the criteria located at 35 U.S.C. § 209(a)(2) regarding scope - if the NIH engaged in that analysis at all. During the comment period, KEI asked Dr. Burke how the NIH determined that the "scope of exclusivity [is] no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology[.]" He responded as follows:

> [C]onsideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.

The NIH's final response letter, too, failed to answer KEI's question about the scope of the license, although timeliness objections no longer applied by that point. With respect to the scope of the license, the letter stated only:

[20] 37 C.F.R. § 404.5(b).

> NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.

At the outset, the NIH's conclusory statement that it has satisfied the relevant legal standard is unbefitting of a federal agency that receives 40 billion dollars of public funds each year to promote biomedical research and is entrusted with ensuring that the fruits of that investment are available to the public on reasonable terms.

More importantly, KEI's correspondence with Dr. Burke about the duration of the license reveals that the NIH has not engaged in the analysis mandated by 35 U.S.C. § 209(a)(2), because it concluded that the license fulfilled all of the relevant criteria, which include that the scope of the license is not broader than reasonably necessary, without first determining the period of exclusivity.

During the comment period, KEI asked Dr. Burke to "please state the duration of exclusivity" of the license. Dr. Burke stated that he could not answer that question because the period of exclusivity "had not yet been determined." It is unclear why the NIH could not contemplate the period of exclusivity before commencing the notice and comment period; the NIH disclosed the other aspects of the license's proposed scope—such as its fields of use and territorial reach—in the Federal Register notice.

After the comment period had closed and the NIH issued its final determination letter stating that all license criteria were satisfied, KEI again asked Dr. Burke to state the period of exclusivity for the license. He still would not answer, claiming that the duration of the license was yet to be determined and that he could not estimate when that determination would be made. It is thus clear that the NIH's analysis of the relevant criteria did not include consideration of the duration of the license.

The NIH may not arbitrarily exclude the duration of exclusivity from its purview when analyzing the appropriate scope of an exclusive patent license. 35 U.S.C. § 209(a)(2) conditions the grant of such a license on the federal agency first determining that its scope is not broader than reasonably necessary. It does not specify that the scope of a license is measured only by its territorial reach or field of use. Moreover, technology transfer regulations require that federal agencies ensure that the duration of a proposed license serves the public interest. 37 C.F.R. § 404.5 - Restrictions and conditions on all licenses granted under this part, states as follows:

> Licenses shall contain such terms and conditions as the Federal agency determines are appropriate for the protection of the interests of the Federal Government and the public[.] The following terms and conditions apply to any license: (1) The duration of the license shall be for a period specified in the license agreement, unless sooner terminated in accordance with this part. . . .

37 C.F.R. § 404.5(b)(1).

Duration of exclusivity is arguably the most important licensing parameter, in terms of the public interest, because it most directly impacts price and access by determining the length of time that the licensee can set whatever price the market can bear. This is a particularly sensitive concern where, as here, an invention is directed toward treatment of life-threatening diseases, such as cancer and the demand for a life-extending therapy is especially inelastic.

Because the NIH failed to consider the duration of exclusivity when analyzing 35 U.S.C. § 209(a)(2), it lacks the authority to execute the proposed license.

3. The NIH has withheld relevant, non-confidential information about the license from the public, impeding the public's right to comment under 35 U.S.C. § 209 (e).

A federal agency may not grant an exclusive license in government-owned technology without first notifying the public of the prospective license, allowing a minimum 15-day period for the public to comment, and considering all timely submitted comments. 35 U.S.C. § 209(e).

In order for the public to meaningfully participate in the notice-and-comment process, it must have basic information about the license.

The NIH has refused to answer questions seeking the following information, which relates directly to the criteria listed in Section 209 and is not "confidential business information":

- The amount of federal funding that has supported the licensed inventions;
- The identifying numbers of any NIH grants that are associated with the technology;
- The identity of any officers/directors of the prospective licensee, Intima Bioscience; and
- The period of exclusivity of the license.

Following is a discussion of how Dr. Burke refused to respond to KEI's requests for the information listed above, and why his objections lacked any legitimate legal or factual basis.

Federal Funding

Dr. Burke refused to disclose how much federal funding has supported the licensed inventions, to list which NIH grant numbers financed the inventions, or even to confirm whether a particular grant supported the inventions. Instead, he referred KEI to the inventors of the technology. KEI reached out to Moriarity and McIvor to inquire about funding. They never responded.

Also, in declining to answer KEI's questions about funding, Dr. Burke referred KEI to the NIH's RePORTER database.

While Appellants believe that recipients of government funds to conduct biomedical R&D should disclose information about such funding to the public, we see no valid reason why the NIH itself, as the administrator of the public funds, may refuse to state how much taxpayer funding contributed to a government-owned invention. There is no legitimate private interest involved that would preclude the NIH from providing that information to the public. If the NIH were fulfilling its duty to act as a responsible steward of the public's investment in biomedical research, it would be able to state the amount of public funding attributable to a particular invention.

Also, it is inaccurate to state that KEI can access the requested information using RePORTER. According to the NIH, "RePORTER . . . is an electronic tool that allows users to search a repository of both intramural and extramural NIH-funded research projects from the past 25 years and access publications (since 1985) and patents resulting from NIH funding."[21] Although RePORTER can provide a useful research tool, it did not enable KEI to determine the amount of federal funds that supported the subject inventions.

Many of the relevant patent documents contain the following government interest statement:

> This invention was made with government support under project numbers Z01BC010985 and Z01BC010763 awarded by the National Institutes of Health, National Cancer Institute. The government has certain rights in the invention.[22]

Searching those grant numbers using RePORTER, KEI was unable to identify the portion of those grants that supported the invention. According to RePORTER, BC010985, titled "Gene Therapy of Cancer," is an intramural research grant administered by the NCI that spans fiscal years 2008 - 2018 and has allocated a total of $24,434,060 to cancer research. Because the patents claim a priority date of 2015 and the grant was in effect through 2018, it would be inaccurate to state that all $25 million supported the inventions. Even if we could isolate only the grant years that contributed to the inventions, we could not eliminate the possibility that the award for that year encompassed multiple studies. RePORTER does not isolate the funds that led to discovery of only the relevant inventions. Likewise, BC010763, "Building on the Success of the Adoptive Immunotherapy of Cancer," is an NCI grant project spanning 13 fiscal years and $55,194,006 in total federal funding. As is the case with BC010985, it is impossible to determine which portion of the $55 million supported only the discovery of the licensed technology. We also note that neither grant number links to the relevant patents/patent applications in RePORTER.

Finally, because neither Moriarity nor McIvor responded to KEI's inquiries, we could not determine whether any extramural grants to the University of Minnesota contributed to development of the technologies.

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[21] https://report.nih.gov/brochure/index.html.

[22] *See* U.S. patent 10,166,255 and U.S. patent applications 16/180867, 16/182146, 16/182189, and 16/182189.

The Identities of Officers of Intima Bioscience, the Prospective Licensee

The NIH has also been non-transparent about the identity of the licensee, preventing the public from evaluating whether Intima Bioscience is qualified to commercialize the patented inventions.

As noted, Intima Bioscience is not registered to conduct business in New York, the state in which it is headquartered, and it maintains no website. Given the significance of the license to public health outcomes, the identity of the licensee that will likely hold a 20+ year monopoly on the subject technology is a compelling concern. It is not encouraging that Intima Bioscience has never issued a press release, does not maintain an online or social media presence, does not appear to ever have successfully brought an invention to market, and apparently is operating illegally in New York without a license to conduct business there.[23]

As noted above, the one-page website for related entity, Intima Capital, reinforces Appellants' concerns about the NIH granting a 20+ year monopoly in life-saving cancer treatments to the company. As our comments note, Intima Capital's website announces an investment strategy that is "predicated on the understanding that healthcare is an investible sector that is fundamentally non-discretionary [and uniquely inefficient]" and describes the company as being focused on "opportunistic private equity investments."[24]

Because KEI was able to learn virtually nothing about the company from internet search engines, it asked Dr. Burke to identify Intima Bioscience's principals/officers.

Dr. Burke refused to answer the question, stating that it was "confidential business information." When asked to identify some authority for that proposition, he cited 37 C.F.R. § 404.14.

The NIH's interpretation of 37 C.F.R. § 404.14 as precluding it from releasing the identity of a license applicant is not sound. 37 C.F.R. § 404.14 refers to "any **plan** submitted pursuant to § 404.8(h)[.]" 37 C.F.R. § 404.14(emphasis added). 37 C.F.R. § 404.8(h) lists 11 different components of a license application, of which only one, 37 C.F.R. § 404.8(a)(8), is a "plan." The other components, listed at 37 C.F.R. § 404.8(a)(1)-(7) and (9)-(11), are not "plans" and thus are not confidential. Since KEI did not ask Dr. Burke to disclose Intima Bioscience's development plan, 37 C.F.R. § 404.14 offered no basis for withholding the requested information.

[23] For-profit corporations incorporated outside of New York may not conduct business in the state without first receiving authorization to do so. N.Y. Bus. Corp. Law § 1301(a). Intima Bioscience, Inc. is a foreign corporation because it was incorporated in Delaware. It is conducting business in NY, and is not registered with the NY Division of Corporations.

[24] https://web.archive.org/web/20190912202840/http://intimacapital.com/.

Duration of the License

Lastly, and most importantly, Dr. Burke refused to disclose the duration of the license. Aside from stating that the period of exclusivity was yet to be determined, Dr. Burke also objected to disclosing the duration of the license on the basis that it was confidential business information. Appellants are not aware of any federal statute or regulation that makes the term of exclusivity for a license in a federally-owned invention "confidential business information." 37 C.F.R. § 404.14 refers to license applicants' development plans and licensee's periodic utilization reports. Similarly, 35 U.S.C. § 209 refers only to commercial development plans and utilization reports as confidential. 35 U.S.C. §§ 209(d)(2)&(f).

Appellants are dismayed by the NIH's habitual resort to citing inapplicable confidentiality provisions as a means to withhold information germane to its licensing decisions from the public. With no statute on point, the licensee's identity and the duration of the license are confidential only if the private interest in nondisclosure outweighs the public's interest in disclosure.[25] When a federal agency expends millions of taxpayers' dollars to develop a life-saving technology, a strong case can be made that the public's interest in knowing the identity of the company that intends to claim a monopoly on that invention outweighs the licensee's interest (if there is one)[26] in shielding the identity of its officers from the public. Moreover, Appellants strongly question the notion that disclosure of the duration of an exclusive patent license might seriously harm the licensee's business interests, threatening the success of NIH's technology transfer program. Publicly-traded companies like Kite Pharma, the business that launched the commercially successful Yescarta, frequently disclose such terms in their SEC filings.[27]

3. As far as Appellants can determine, the NIH did not request the advice of the DOJ regarding whether the license would create or maintain a violation of federal antitrust laws.

Under the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, "[a]n 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." 40 U.S.C. § 559(b)(1).

This includes when the NIH proposes to grant an exclusive license in federally-owned technology. "Property" is defined at 40 U.S.C. § 102 to mean "any interest in property," with

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[25] *See Pub. Citizen Health Research Grp. v. Nat'l Institutes of Health*, 209 F. Supp. 2d 37, 45 (D.D.C. 2002)(balancing the public interest in disclosure against the private interest in withholding the information when analyzing whether terms of an NIH patent license are exempt as confidential business information under Freedom of Information Act Exemption 4).

[26] We question how Intima Bioscience can raise the capital necessary to bring the covered inventions to market without establishing more of an internet or social media presence and publicizing its business endeavors to investors.

[27] *See, e.g.*, https://www.sec.gov/Archives/edgar/data/1510580/000156459015010571/kite-10q_20150930.htm.

certain exceptions that do not include patents. Similarly, Section 559 creates certain exceptions that do not include patents.

41 C.F.R. § 102-75.270 supports the notion that the term "property" in Section 559 includes intellectual property rights such as patents.

41 C.F.R. § 102-75.270 - Must antitrust laws be considered when disposing of property?

Yes, antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of -

(a) Real and related personal property that has an estimated fair market value of $3 million or more; or

(b) Patents, processes, techniques, or inventions, irrespective of cost.

KEI asked Dr. Burke whether it requested the advice of the U.S. Attorney General concerning the license. Dr. Burke did not answer.

On February 13, 2018, KEI emailed Dr. Lambertson and Karen Rogers, Acting Director of the NIH Office of Technology Transfer, asking whether NIH requests and obtains advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests, as required by Section 559.

Ms. Rogers responded as follows:

> The statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally government by the Bayh-Dole Act and its regulations.

The NIH's statement about the applicability of 40 U.S.C. § 559 is incorrect.

The Bayh-Dole Act expressly incorporates federal antitrust laws. 35 U.S.C. § 209(a)(4) allows a federal agency to grant an exclusive license only if the license "will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws." 35 U.S.C. § 211 provides that "[n]othing 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[.]" The Bayh-Dole Act sets out the areas in which the statute "shall take precedence over any other Act which would require a disposition of rights in subject inventions[,]" 35 U.S.C. § 210, and mentions 21 separate statutes, but not the FPASA.

Second, the term "disposal" is not a defined term under 40 U.S.C. § 102 of the FPASA, and is not limited to "assignment" or "sale." In fact, there are many examples of regulations and laws

that include licensing amongst dispositions, either explicitly or by implication.

Finally, by granting a fully-exclusive license in a federally-owned invention for life of patent, and allowing termination of the license only in narrow, vaguely-defined circumstances, the NIH is effectively disposing of a government property interest so as to trigger 40 U.S.C. § 559.

4. The NIH has not implemented objectives in the PHS Technology Transfer Policy Manual regarding promoting access in developing countries.

The PHS's licensing policy is governed by the following principle, among others:

"PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."[28]

We object to any license that does not satisfy PHS's governing licensing principle of promoting access in developing countries.

It would be quite simple to at least ask the licensee to provide a plan, made public so there is some accountability, as to how access will be extended to countries with per capita incomes less than 30 percent of the United States. Not even making this part of the negotiation is appalling and inconsistent with PHS's own stated licensing policies.

D. CONCLUSION

For all of the reasons stated above, Appellants request that the NIH reverse its decision to proceed with the license at issue and reopen the license to competitive bidding. Any license in the subject inventions may not be executed unless the NIH can demonstrate that it engaged in the necessary analysis. The license agreement should incorporate the public interest safeguards referred to in our submitted comments, and before executing the license, the NIH must seek and obtain the antitrust advice of the U.S. Attorney General, who confirms that the license will not create or maintain a situation inconsistent with federal antitrust laws.

We request a hearing on this appeal.

Sincerely,

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

[28] PHS, *United States Public Health Service Technology Transfer Manual*, Chapter No. 300, PHS Licensing Policy, available at https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/300-policy.pdf.

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Attachments