1621 Connecticut Avenue NW
Suite 500
Washington, DC 20009
www.keionline.org

September 13, 2019

Andrew Burke, Ph.D.
Senior Technology Transfer Manager
NCI Technology Transfer Center
9609 Medical Center Drive
RM 1E530, MSC 9702
Bethesda, MD 20892-9702
Via email to andy.burke@nih.gov

Re: "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy," 84 FR 45503

Dear Dr. Burke:

Knowledge Ecology International (KEI), Union for Affordable Cancer Treatment (UACT), Public Citizen (PC), Social Security Works (SSW), LWC Health, Ruth Lopert, Manon Ress, and Terry Love write to oppose the National Institutes of Health (NIH)'s prospective grant of an exclusive license in "Genetically-Modified Lymphocytes for Cancer Therapy" to Intima Bioscience, Inc. The licensed inventions expand upon existing gene therapies, which have mostly been limited to hematological malignancies, to treat solid tumors in diseases such as breast cancer, gastrointestinal epithelial cancer, and lung cancer. The decision to grant an exclusive license and the duration of exclusivity are thus matters of great importance to public health outcomes and should not be treated lightly. As always, any license the NIH negotiates must comply with the criteria set forth at 35 U.S.C. § 209 and 37 C.F.R. § 404.7.

We object to the prospective license on five grounds:

1. The NIH has not demonstrated that it properly analyzed whether an exclusive license is "a reasonable and necessary incentive" under 35 U.S.C. § 209(a)(1);
2. We object to any license that is broader than necessary to induce the investment needed to bring the technology to market, in violation of 35 U.S.C. § 209(a)(2);
3. The NIH has not been fully transparent about the license, impeding the public's right to comment under 35 U.S.C. § 209(e), because it has refused to disclose the government

funding that supported the inventions and identify the principals of the licensee - matters that are both relevant and nonconfidential; and

4. The NIH apparently has not sought the advice advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. § 559.

In the event that the NIH grants the license over our objections, we request that the license agreement incorporates a series of provisions designed to safeguard the public interest and ensure that the license implements the governing principles of the Bayh-Dole Act and Public Health Service (PHS) Technology Transfer Policy Manual.

Background

The Inventions

The Federal Register 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.

The covered inventions build upon existing gene therapies to treat cancer, which are currently limited to treating hematological malignancies, to target solid tumors. The "Background" section of many of the patents state how "significant advances in genetic engineering . . . . have been limited largely to hematological tumors, and more broad application to solid tumors is limited by the lack of an identifiable molecule that is expressed by cells in a particular tumor[.]" The patents go on to state that the "disclosed compositions and methods herein . . . are innovative approaches that open[] new opportunities for extending immunotherapy to many cancer types."

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

The 33 patents or patent applications covered by the prospective license are co-owned by three entities: the United States of America, the University of Minnesota, and Intima Bioscience. For more information about the patent estate, please refer to Appendix, Table 1.

The Prospective Licensee

The Federal Register notice describes the prospective licensee as "Intima Bioscience, Inc. ('Intima'), headquartered in New York, NY." A search for "Intima Bioscience" in the New York Division of Corporations search engine returned no results, and Intima Bioscience does not maintain a website.

Several of the patent applications list "Intima Bioscience, Inc." with an address of 3 Columbus Circle, New York, New York, as an applicant. A company known as Intima Capital, LLC, with an address of 3 Columbus Circle, New York, New York, is registered in New York.

KEI's Correspondence with the NIH regarding the Licenses

On September 9, 2019, KEI emailed you, as the NIH Technology Transfer Officer assigned to answer questions about the licenses, with a list of questions[1] related to whether the license would satisfy 35 U.S.C. § 209 and 37 C.F.R. § 404.7, the federal statute and regulation governing exclusive licenses of federally-owned technology.

You declined to answer some of the questions that we asked, and that were relevant to the criteria for exclusive licenses.[2] You stated that the development stage of the technology is "preclinical" and that the NIH determined Intima Bioscience to be an appropriate licensee based on its "commercial development plan and supporting information submitted by the company in their application for license." You would not, however, disclose which NIH grants have supported the inventions, identify Intima's principals, or indicate whether the NIH had sought the antitrust advice of the Attorney General regarding the licenses.

When asked why the NIH is proposing to grant an exclusive license to intellectual property already co-owned by Intima, you responded: "Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public."

Argument

1. The NIH has not demonstrated that it properly evaluated the necessity of granting an exclusive license.

Section 209 of the Bayh-Dole Act allows a federal agency to grant an exclusive license only if "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).

[1] *See* Attachment A.
[2] *See* Attachment B.

It is our understanding that the NIH has not undertaken a serious evaluation of the adequacy of existing incentives and subsidies, relating to practical application of the inventions, in order to evaluate whether or not an exclusive license was a "reasonable and necessary incentive."

Because Intima co-owns the relevant intellectual property, along with the United States and the University of Minnesota, Intima already holds a partially-exclusive right to market and sell the inventions and can exclude anyone other than the United States and University of Minnesota from doing so.

When asked why the NIH was proposing to grant an exclusive license to Intima, when the company already co-owns the intellectual property rights associated with the inventions, you responded: "Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public."

Your answer seems to suggest that anything that will "improve the chances" of development would permit an exclusive license, but that is not the statutory standard. Strictly speaking, an exclusive license can easily 'improve" the odds of success, whenever the odds of success are less than 100 percent, but that is a bad faith and tortured interpretation of the statute, which refers to a "reasonable and necessary incentive."

The NIH can perhaps make the case that some type of exclusivity is "reasonable and necessary" for development, but before reaching this conclusion, some analysis should be undertaken, including, for example, consideration of the other types of incentives provided by law, such as test data protection, Orphan Drug exclusivity, etc., and the likely case that the developer can bring other patented inventions into the project, for which exclusivity exists.

The NIH seems to believe that no company will agree to commercialize a government-owned invention without first obtaining fully-exclusive rights. It bears mentioning that there are many non-exclusive licenses associated with the development of cell and gene therapies, including, for example, many in the AAV area, and several of the fundamental CAR T patents. Indeed, Kite, which Gilead owns, lists several non-exclusive patent licenses in its SEC files. These are a few examples:

- https://www.sec.gov/Archives/edgar/data/1510580/000156459016013699/kite-ex1030_304.htm (non-exclusive license to Alpine Immune Sciences related to T-cell receptors);
- https://www.sec.gov/Archives/edgar/data/1510580/000156459015001985/kite-ex1022_20141231312.htm (non-exclusive license to Amgen in CAR T therapies); and
- https://www.sec.gov/Archives/edgar/data/1510580/000156459016023260/kite-ex103_429.htm (non-exclusive license to Cell Design Labs, Inc. in cellular therapies to treat hematological malignancies).

Why must the NIH patents be exclusive, when Kite licenses-in and licenses-out patents on a non-exclusive basis for other technologies?

Before it may license a federally-owned invention on an exclusive basis, the NIH must analyze whether exclusivity is a necessary incentive, and ***not*** whether it is merely helpful.

You confirmed that no Licensing Opportunity notice was posted by the NIH on its Office of Technology Transfer website with regards to the licensed inventions.

The NIH typically posts Licensing Opportunity notices on the OTT website as part of its licensing process.[3]

It is unknown whether the NIH received any license applications from applicants who would agree to develop the technology without an exclusive license. However, without having publicly-disclosed this licensing opportunity (prior to the 15-day notice and comment period, arguably far too short a period of time for a company to prepare and submit a competing bid), the NIH cannot claim that exclusivity was necessary on the grounds that no other company indicated its willingness to commercialize the technology on a non-exclusive basis.

2. The scope of rights will be broader than reasonably necessary to induce the investment needed to commercialize the subject technology.

Before granting an exclusive license in federally-owned technology, the agency proposing the license must find "that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" 35 U.S.C. § 209(a)(2).

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

- The period 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).

Duration of exclusivity

The NIH refused to disclose the duration of the license, stating that it "has not yet been determined." If past practice is any indication, the negotiated duration term will be "life of patent."

[3] https://www.ott.nih.gov/licensing/licensing-process. *See also* Attachment C.

Given the government's investment in the technology and the potential profitability of the inventions (explored below), a shorter duration term appears to be required by 35 U.S.C. § 209(a)(2).

Field of Use

The fields of use listed in the license notice are broad. The license covers at least three separate inventions with four fields of use, all related to immunotherapies involving genetically-modified T-cells to treat breast cancer, gastrointestinal epithelial cancer, lung cancer, and B-cell lymphoma.

Excluding non-melanoma skin cancer, the three most common types of cancer in the United States (and in the world) are lung cancer, breast cancer and prostate cancer. Worldwide, lung and breast cancer are the most common. The potential market for treatments for all of the diseases in the fields of use are thus huge.

Territorial Reach

The Federal Register notice states that "the prospective exclusive license territory may be worldwide" -- the broadest possible territorial reach.

Analysis to Determine the Duration of Exclusivity

The term of exclusivity for the license must not exceed the incentive needed to induce a company to bring a government-owned invention to market. 35 U.S.C. § 209(a)(2).

There are at least seven factors that should be considered when determining the necessary incentive:

1. The costs of financing research and development and bringing the invention to market, including obtaining FDA approval;
2. The government's investment in R&D and the development stage of the technology;
3. Any expected additional subsidies from governments or charities, including, for example, the Orphan Drug Tax Credit or additional grants or continued or new collaborations with the NIH or other government agencies;
4. The existence of other incentives, including, for example, test data protection, Orphan Drug exclusivity and awards of priority review vouchers;
5. The anticipated cost to manufacture the resultant invention; and
6. The expected post-market entry profitability of the invention, by year.

Consider, for example, a new CAR treatment that is expected to generate $400 million per year (Yescarta generated $99 million in the 2nd quarter of 2019), where the costs of trials are

expected to be $30 million (200 patients at $150,000 per patient). Even if the risks associated with the investments in clinical trials are daunting, such as a likelihood of approval of just 10 percent (quite low for Phase 2 or 3 trials), the risk-adjusted costs of the trials would be less than the revenue from a single year of operation. If the net margin for sales in a year were 50 percent, the project would be a good investment even if exclusivity was limited to five years, the same term that the Bayh-Dole Act permitted for federally-funded patents held by non-government patent holders when the Act was passed.

Federal Funding, So Far

While the NIH has refused to disclose which NIH grants supported R&D associated with the inventions, KEI is aware of at least two NIH grants that are disclosed by the licensed intellectual property.

U.S. patent 10,166,255 and U.S. patent applications 16/180867, 16/182146, 16/182189, and 16/182189, all have 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."

Z01BC010985 is an intramural grant. The Principal Investigator is National Cancer Institute (NCI) scientist Steven Rosenberg, one of the inventors listed on the patent applications.

Z01BC010763 is also an intramural grant. The Principal Investigator is NCI scientist Nicholas Restifo, one of the inventors on the patent applications.

It bears noting that other grants besides Z01BC010985 and Z01BC010763 may have supported the licensed technology. University of Minnesota scientists Branden Moriarity, R. Scott McIvor, and Beau Webber, are listed on the patented inventions.

According to RePORTER, Branden Moriarity was the Principal Investigator on seven NIH grants to the University of Minnesota, including CA-216652, titled "Genetically Modified Natural Killer Cells for Cancer Immunotherapy." In addition, Moriarity is the Chief Scientific Officer at B-MoGen Biotechnologies Inc, a company that lists seven grants on its website, including four from the NIH, and three from the Regenerative Medicine Minnesota Funding Board.[4]

[4] https://bmogen.com/our-science/rd-grant-awards/.

3. The NIH has not been fully transparent about the license, 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 licenses.

The NIH has refused to answer a question that relates directly to Section 209 and is not confidential business information: How much government funding supported the licensed technology? The NIH refused even to confirm whether CA-216652 is associated with the licensed inventions, instead referring KEI to RePORTER and Moriarity himself.

KEI reached out to Moriarity to discuss the license, and he did not respond before the close of the comment period. While we believe that recipients of government funds to conduct biomedical R&D should disclose such funding to the public, we see no valid reason why the NIH itself, as the source of the public funds, may refuse to state how much taxpayer funding contributed to a government-owned invention. And, while RePORTER is a useful research tool, it often does not definitively link NIH grants with federally-sponsored inventions.

The NIH has also been non-transparent about the identity of the licensee, preventing the public from evaluating whether Intima has the qualifications and capacity to bring the inventions to market.

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.

The website for Intima Capital is just one paragraph long,[5] and contains a rather blunt description of its mission, which is not exactly about treating patients, but rather extracting as much "superior . . . risk-adjusted returns in health care" as possible and benefiting from investments in healthcare, as a sector that is "fundamentally non-discretionary" and "uniquely inefficient." The company says it wants "opportunistic private equity investments."

> *"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.*

[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 discrete long/short public equity, derivative, and opportunistic private equity investments to express a proprietary understanding of the field."

With such a mission statement, the NIH should assume extremely aggressive pricing strategies for licensing cancer treatments, which, for the patient, are definitely "non-discretionary" goods. A cancer patient will spend everything he or she has for a life-saving treatment, as well as everything he or she does not have. Cancer treatments are thus susceptible to price gouging.

The NIH would not identify the principals of Intima Bioscience, claiming weakly that 37 C.F.R. § 404.14, Confidentiality of Information, prevents the NIH from explaining who is behind an otherwise highly secretive group that is seeking exclusive rights for a life saving invention that might be worth billions of dollars, negotiated largely in secret with NIH employees.[6]

The NIH's interpretation of 37 C.F.R. § 404.14 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 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 nonconfidential.

We request that the NIH provide us, from the license application, the items described at 37 C.F.R. 404.8(a)(1)-(7),(9)-(11), and the public provisions of any related CRADA (which, we are told, does not exist in this case.)

4. The NIH apparently has not sought the antitrust advice of the U.S. Attorney General regarding the license, as required by 40 U.S.C. 559.

We object to the license unless the NIH first obtains the antitrust advice of the United States Attorney General, who confirms that the license would not be anticompetitive.

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

[6] *See* Attachments D & E.

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 you whether the NIH requested the advice of the U.S. Attorney General concerning the licenses. You did not answer. In the past, the NIH has asserted its position with respect to 40 U.S.C. § 559 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."[7]

The NIH's statement about 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.

If NIH grants 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, then it is effectively disposing of a government property interest so as to trigger 40 U.S.C. § 559.

[7] *See* Attachment F.

5. In the event that the NIH decides to grant the license over our objections, we recommend that the NIH includes a series of provisions designed to safeguard the public interest and ensure that the licenses implement the governing principles listed in the Public Health Service (PHS) technology transfer manual.

In the event that the NIH proceeds with the license, KEI requests that it includes the following provisions to protect the public's interest in the NIH-funded technology:

1. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

2. **Low and middle income countries.** The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

3. **Global registration and affordability.** The license should require Intima Bioscience to disclose the steps it will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

4. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

5. **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. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

6. **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.

Conclusion

The licensed technology, if successful, promises an enormous benefit to patients suffering from three of the most common cancers in the United States and worldwide. The NIH's decision concerning the license thus carries great importance for public health outcomes, and should not be taken lightly.

We object to the prospective license on the grounds that (1) the NIH apparently has not engaged in the analysis mandated by 35 U.S.C. § 209(a)(1) to determine whether exclusivity is a necessary incentive; (2) the NIH apparently has not engaged in the analysis mandated by 35 U.S.C. § 209(a)(2) to determine whether the duration of the license is not greater than reasonably necessary; (3) the NIH has, without justification, withheld information that is relevant to Section 209 and nonconfidential; and (4) the NIH has failed to seek the antitrust advice of the United States Attorney General regarding the license. If the NIH decides to execute the license over our objections, we request that, at the very least, it includes the safeguards we have proposed herein, which are designed to implement the Bayh-Dole Act's stated policy objective that government-sponsored inventions are available to the public on reasonable terms and the PHS Technology Transfer Manual's policy of promoting access in developing countries.

Sincerely,

Knowledge Ecology International

Union for Affordable Cancer Treatment
Public Citizen
Social Security Works
LWC Health
Ruth Lopert
Manon Ress
Terry Love

Attachments

Appendix

The Intellectual Property

The Federal Register notice 84 FR 45503 lists 33 patents documents, comprised of: 1 patent issued in the United States, 28 pending applications, and 4 PCT international applications. The pending applications were filed in Australia (2), Canada (3), China (3), Hong Kong (1), Israel (1), Japan (3), the United Kingdom (3), the United States (9), and the European Patent Office (3).

Group	Patent office	Number	Priority date	Type
Group A	PCT	PCT/US2016/044856	July 31, 2015	PCT
Group B	United States	16/180,867	July 31, 2015	Application
Group B	United States	16/182,146	July 31, 2015	Application
Group B	United States	16/182,189	July 31, 2015	Application
Group B	United States	15/224,159	July 31, 2015	Application
Group B	United States	15/250,514	July 31, 2015	Application
Group B	United States	15/256,086	July 31, 2015	Application
Group B	United States	16/513,933	July 31, 2015	Application
Group B	United States	10,166,255	July 31, 2015	Issued patent
Group B	United Kingdom	1803280.5	July 31, 2015	Application
Group B	PCT	PCT/US2016/044858	July 31, 2015	PCT
Group B	Japan	2018-525531	July 31, 2015	Application
Group B	Israel	257105	July 31, 2015	Application
Group B	Hong Kong	18115478.9	July 31, 2015	Application
Group B	EPO	16833645.1	July 31, 2015	Application
Group B	China	201680059181	July 31, 2015	Application
Group B	Canada	2993431	July 31, 2015	Application
Group C	United States	16/389,586	October 26, 2016	Application
Group C	United Kingdom	1906850.1	October 26, 2016	Application
Group C	PCT	PCT/US2017/058615	October 26, 2016	PCT
Group C	Japan	2019-522944	October 26, 2016	Application
Group C	EPO	17865054.5	October 26, 2016	Application
Group C	China	[awaiting application number]	October 26, 2016	Application
Group C	Canada	3,041,835	October 26, 2016	Application
Group C	Australia	2017347854	October 26, 2016	Application

Group D	United States	15/947,688	October 18, 2016	Application
Group D	United Kingdom	1906855	October 18, 2016	Application
Group D	PCT	PCT/US2017/057228	October 18, 2016	PCT
Group D	Japan	2019-520738	October 18, 2016	Application
Group D	EPO	17861792.4	October 18, 2016	Application
Group D	China	2017800784716	October 18, 2016	Application
Group D	Canada	3,041,068	October 18, 2016	Application
Group D	Australia	2017346885	October 18, 2016	Application