TRANSFORMING DISCOVERIES INTO PRODUCTS: MAXIMIZING LEVERS TO CATALYZE TECHNOLOGY TRANSFER

Summary of NIH Workshop Proceedings

July 31, 2023

National Institutes of Health
Office of Science Policy

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1. INTRODUCTION

The National Institutes of Health (NIH) supports new knowledge and discoveries that drive innovation across sectors, and the agency is committed to thinking carefully about its role in making the fruits of that work accessible to the public. As part of this commitment, on July 31, 2023, NIH convened a workshop on *Transforming Discoveries into Products: Maximizing Levers to Catalyze Technology Transfer*.

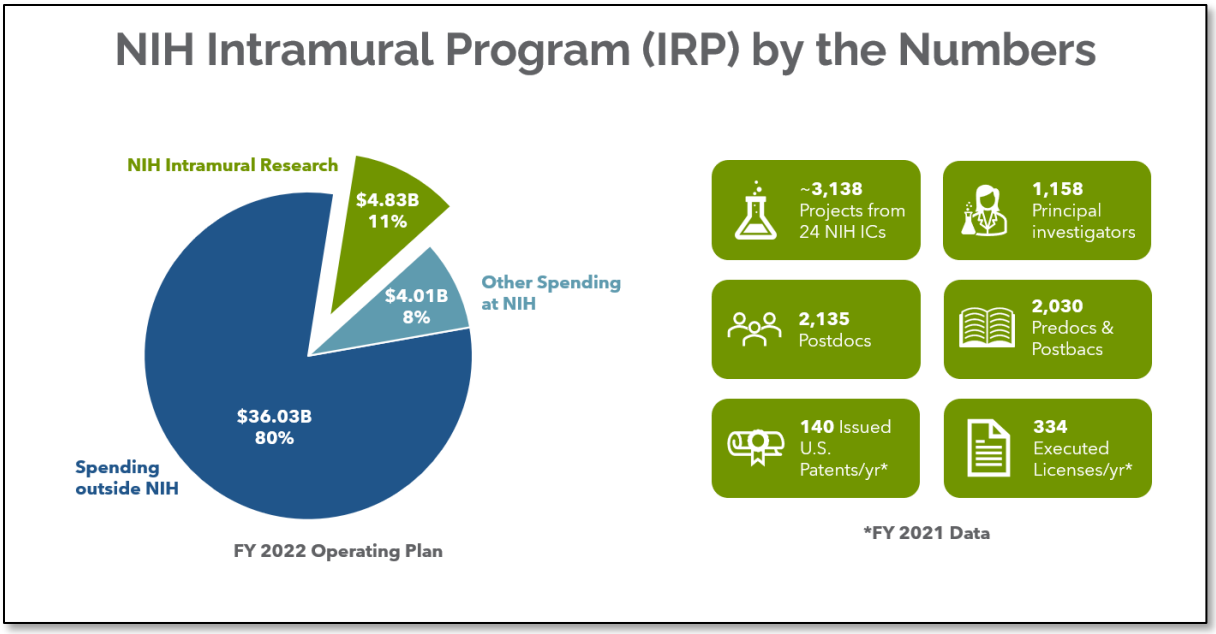
This workshop focused on how NIH approaches patenting and licensing inventions from its intramural research program. Throughout the day panelists, presenters, and the public explored how NIH decides what to patent and license, who NIH partners with, and how NIH negotiates those agreements.[1] Workshop participants shared perspectives on how NIH can best approach these questions to fulfill public health goals.

NIH's current mission statement includes seeking "fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health . . . ."[2] NIH built this workshop around a recognition that fulfilling its mission involves several components, including that:

- The results of NIH's work need to reach people in ways that can improve their lives—including in the form of new products and services for disease prevention, diagnosis, or treatment; and
- People only realize such benefits if they have access to the products and services that are built on NIH's work.

The scope of this workshop—NIH's intramural research program (IRP) and its approach to patenting and licensing—reflects a small but noteworthy slice of the overall agency. Most of NIH's budget goes to fund extramural research and training, largely through competitive grants to researchers at universities, medical schools, and research institutions. Approximately 11 percent of NIH's budget supports the IRP—where nearly 6,000 scientists conduct basic, translational, and clinical research in agency laboratories.[3]

[1] A copy of the workshop agenda is available at Appendix B.
[2] *Mission and Goals*, NIH (July 27, 2017), https://www.nih.gov/about-nih/what-we-do/mission-goals. NIH is reevaluating its mission statement, particularly the inclusion of the phrase "reduce . . . disability," to better reflect the current and future vision for the agency. *See, e.g.*, *Request for Information (RFI): Inviting Comments and Suggestions on Updating the NIH Mission Statement*, Notice No. NOT-OD-23-163 (Aug. 25, 2023), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-163.html.
[3] *Budget*, NIH (Oct. 24, 2023), https://www.nih.gov/about-nih/what-we-do/budget; *What is the IRP?*, NIH INTRAMURAL RESEARCH PROGRAM (Jan. 10, 2022), https://irp.nih.gov/about-us/what-is-the-irp.



The IRP constitutes a fraction of the NIH budget, and patent licensing is only a portion of the IRP's work. However, the technology patented and licensed by the NIH IRP has generated substantial positive impacts on public health and biomedical research.[4] Merely by way of example:

- Intellectual property licensed by NIH has been utilized in over 1,200 clinical trials.
- More than 1,000 products have been brought to market based on NIH licenses, including 39 vaccines and therapeutics approved by the Food and Drug Administration (FDA).
- Examples of the vaccines and therapeutics developed based on technology licensed from the IRP include: Comirnaty®, a COVID-19 mRNA vaccine; Ebanga®, a treatment for ebolavirus; Arexvy®, an RSV vaccine; Zokinvy®, a treatment which helps prevent the buildup of defective progerin or progerin-like protein in Progeria; and Abecma®, a CAR T-cell therapy for multiple myeloma.[5]

[4] Tara L. Kirby, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer, How NIH Negotiates License Terms* 2 (July 31, 2023), https://osp.od.nih.gov/wp-content/uploads/2024/02/Innovation_Policy_Workshop-Kirby.pdf.
[5] *HHS License-Based Vaccines & Therapeutics*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/reportsstats/hhs-license-based-vaccines-therapeutics (last visited Mar. 1, 2024).

Public Health & Economic Impact Study

A recent report on NIH intramural licensing found that IRP-licensed technologies contribute to improved public health, economic growth, and substantial follow-on research and development (R&D). For example:

- Technology developed by the National Cancer Institute (NCI) was licensed to two companies that developed vaccines to prevent the human papillomavirus (HPV). This report estimated that one of those HPV vaccines will avert over 26,500 deaths from cervical cancer and more than 80,000 cancer cases, based on vaccines administered between 2008 to 2019.
- Technologies licensed from the IRP between 1980 and 2021 contributed to products with over $130 billion in U.S. sales and supported an average of 74,500 employment positions each year from 2001 to 2021.
- Over 60 percent of NIH licenses are for research tools that are used to support other research and innovation. These research tools spread quickly throughout the biomedical innovation ecosystem and provide the foundation for research at institutions worldwide.

Source: RTI International, *Public Health & Economic Impact Study: Technology Transfer and Licensing at the U.S. National Institutes of Health* (May 2023).

The July 31, 2023, workshop was structured with an eye toward identifying best practices and potential new approaches in NIH's patent licensing program. The goal of this work is to sustain and build on the agency's historic successes and allow it to further boost innovation, competition, and equitable access to new products and services for disease prevention, diagnosis, or treatment.

This report summarizes proceedings of the workshop and identifies potential areas for further exploration. This report is not intended to provide a comprehensive picture of how NIH approaches patenting and licensing, nor does it offer a complete exploration of how public sector institutions like NIH can optimize their patent licensing programs.[6] Rather, this is a summary of relevant information that emerged from one day of workshop presentations, panel discussions, and public comments.

Ideas and perspectives shared during the workshop provide an encouraging foundation for future efforts. NIH can amplify and expand on what is working well and consider experimenting with promising new approaches that advance the collective goal of improving public health.

[6] This report also does not delve into all the complex scenarios or unique circumstances that can emerge in the course of NIH's patent and licensing efforts. For example, the agency's licensing extends beyond just patents and includes, e.g., unpatented inventions—though this report focuses on patent licensing. And the report does not address what happens when NIH IRP investigators jointly invent technology with academic or industry partners. Considerations around other licenses and managing joint inventions, and the varied issues and opportunities that can emerge, are outside the scope of this report.

2. BACKGROUND

NIH Organization.
NIH is made of up of 27 different Institutes and Centers (ICs), and each has its own research agenda and administers its own budget. Twenty-three ICs have intramural research programs, which are supported by the Office of Intramural Research.[7]

Individual technology transfer offices within the ICs and the NIH Office of Technology Transfer (OTT) serve as a bridge to connect the discoveries made in IRP with external partners who can use these technologies and develop them into products and services that benefit public health.[8] Technology transfer offices across the ICs are responsible for managing the patenting of NIH scientists' inventions and negotiating and executing licenses to those inventions and other types of collaboration agreements.[9] OTT plays a strategic role supporting the patenting and licensing work of the ICs including: providing management and oversight of the collection and disbursement of royalties, monitoring and enforcing patent rights and licensing agreements, marketing available technology, providing support and expertise for technology development systems, and performing other functions.[10]

What is a patent?
A U.S. patent gives an inventor the right to "exclude others from making, using, offering for sale, or selling" an invention or "importing" it into the U.S. A patent does not give its owner the right to make, use, or sell an invention; instead, it gives the owner the right to stop others from doing so. If someone infringes a patent, the owner may initiate legal action.[11] U.S. patents are effective only within the U.S. and its territories and possessions.[12] When a patent owner grants a license to another entity, that means the licensed entity has permission to use the patented invention.

What can be patented?
There are three types of U.S. patents: utility, design, and plant. This workshop focused on utility patents—which may cover "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" —as NIH does not typically pursue the other two types of patents. A patent application and the invention it describes must meet four conditions before a patent can be issued:

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[7] *Our Programs*, NIH INTRAMURAL RESEARCH PROGRAM (May 11, 2022), https://irp.nih.gov/about-us/our-programs. All but three ICs receive their funding directly from Congress. And IRP has components in all the ICs except the National Institute of General Medical Sciences (NIGMS), the Center for Information Technology (CIT), Center for Scientific Review (CSR), and Fogarty International Center (FIC).
[8] *Commercializing Inventions*, NIH INTRAMURAL RESEARCH PROGRAM (Jan. 26, 2023), https://irp.nih.gov/our-research/commercializing-inventions.
[9] For more information about HHS technology transfer offices, see *HHS Tech Transfer Offices & Contacts*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/tdcs (last visited Feb. 27, 2024).
[10] *The NIH and Its Role in Technology Transfer*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer (last visited Feb. 27, 2024).
[11] This material is adapted from *Patent Essentials*, U.S. PATENT AND TRADEMARK OFFICE (May 2, 2023), https://www.uspto.gov/patents/basics/essentials#questions; *Applying for Patents*, U.S. PATENT AND TRADEMARK OFFICE (Feb. 15, 2024), https://www.uspto.gov/patents/basics/apply; *Patent Process Overview*, U.S. PATENT AND TRADEMARK OFFICE (Feb. 9, 2024), https://www.uspto.gov/patents/basics/patent-process-overview#step4.
[12] In general, patents are only applicable in the country where the patent has been filed and granted, as governed by the laws of that country. *See, e.g.*, *Patents*, WIPO, https://www.wipo.int/patents/en/ (last visited Feb. 27, 2024).

- Able to be used (the invention must work and cannot just be a theory);
- Include a clear description of how to make and use the invention;
- New, or "novel" (something not done before); and
- "Not obvious" (compared to things that were already invented).

Patent law defines the limits of what can be patented. For example, the laws of nature, physical phenomena, and abstract ideas cannot be patented, nor can a mere idea or suggestion. However, the subject matter that can be protected by patents is vast and varied.[13]

What is a patent license?
A patent license is a legal agreement by which a patent owner promises not to take action to exclude the licensed party from making, using, or selling a potential invention.[14] Such a license may be for patented or patent pending technology.[15]

NIH technology transfer legal framework.
NIH technology transfer operates within a specific legal and regulatory framework that authorizes patent licensing and other technology transfer activities. And, as with all the agency's work, NIH's technology transfer activities occur under Congressional oversight and public scrutiny. The Stevenson-Wydler Technology Innovation Act of 1980 mandates that federal agencies transfer government-owned technologies to non-federal parties. The Bayh-Dole Act, which permits patenting and licensing by extramural grantees, also authorizes the government to exclusively license its own inventions. And the Federal Technology Transfer Act of 1986 decentralized government technology transfer responsibility to individual agencies and allowed agencies to keep the royalties received from licensing rather than sending the money to the Treasury Department.[16] This legal structure gives rise to other unique features of NIH technology transfer.

General process for patenting at NIH.[17]
Upon receiving an invention report from an intramural researcher, NIH staff evaluate the invention to assess public health need, patentability, and probability of commercial interest, as well as the need for patent protection to serve as an incentive for timely and effective commercial development of the invention. If indicated, NIH will typically seek patent protection by filing an application for a patent with the U.S. Patent and Trademark Office (USPTO). Typically, NIH re-evaluates its patent strategy at multiple time points in its interactions with the USPTO and foreign patent offices and will decide if patent protection continues to be the best intellectual property strategy for a given invention.

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[13] *Supra* note 11.
[14] If a company would like to acquire unpatented biological materials, a biological materials license is available. A biological materials license grants the right to make, use, and/or sell commercially useful biological materials for which patent protection will not be obtained. This type of license typically is non-exclusive and facilitates the commercial development of biological materials without requiring that patent protection be obtained for every material.
[15] This material is adapted from *Licensing FAQs*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/faqs/licensing-faqs (last visited Feb. 27, 2024); *Licensing*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/licensing (last visited Feb. 27, 2024).
[16] Kirby, *supra* note 4, at 4 (citing 35 U.S.C. §§ 207-209; 37 CFR Part 404).
[17] For more information about these processes, refer to case studies in Appendix A.

A patent application must be filed prior to any public disclosure of an invention to preserve international patent rights and must be filed within one year of the official publication date or public use to preserve U.S. patent rights.

In general, where international filing is possible and commercial interest is reasonably anticipated, NIH staff may recommend filing under the Patent Cooperation Treaty within 12 months after the U.S. filing date, to preserve international rights for an additional 18 months. Upon NIH determination to exercise international patent rights, National Phase patent applications are filed.[18] The NIH typically focuses on patent protection in countries that have substantial markets or manufacturing infrastructure for biomedical products, such as some or all of the following: the U.S., Australia, Canada, some European countries, India, Japan, China, and the Republic of Korea.[19]

General process for licensing at NIH.[20]

NIH staff review an invention and its commercial potential, develop a licensing approach, and identify potential companies to commercialize the invention. This is a collaborative process requiring input from the inventors and other stakeholders. The invention is also advertised as available for licensing on NIH and other websites, and it may be promoted technology to potential partners.[21]

When the NIH receives an application for a license, for example, an exclusive license or a non-exclusive license for commercial development of a product, the agency gathers as much information as possible—from within the agency, from the inventors, through reviewing market research and comparable technology, and from the license applicant. Applicants submit detailed development and marketing plans that allow NIH to assess whether a license is warranted; and if so, this information helps the agency identify the appropriate field of use and territory (e.g., individual countries or regions or worldwide),[22] and develop potential benchmarks and other specialized terms. NIH's goal is to provide sufficient flexibility and scope to a licensee while still maximizing the availability of other uses of the technology.

NIH considers multiple factors when setting financial terms in a license—including the stage of technology development, type of product, potential market value, scope of patent coverage, and regulatory environment. Financial terms are typically structured as a combination of upfront fees, earned royalties on sales, milestone payments, sublicensing payments, and reimbursement for patent costs. Where a technology is higher risk or the license is going to a small company that needs to conserve cash for technology development, payment obligations may be shifted toward the "back end," i.e., received later in development or even after commercialization rather than as an upfront payment. Finally, financial terms should not hinder public benefit or the ability of new biomedical technology to reach the market.[23]

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[18] National Phase refers to the point where applicants start to pursue the grant of patents directly before national (or regional) patent offices in countries in which the applicant wants to obtain patent protection. *PCT FAQs*, WIPO (July 2022), https://www.wipo.int/pct/en/faqs/faqs.html.
[19] *Id.*
[20] For more information about these processes, refer to case studies in Appendix A.
[21] *Id*.
[22] Given the territorial nature of the patent, a "worldwide license" refers to licenses that would allow the licensee to use the patented invention anywhere in the world—including all the countries where NIH owns patent rights and the regions where it does not have patents. However, anyone would be free to, for example, both manufacture and sell the patented invention (with or without a license) in countries where NIH does not have a patent.
[23] Kirby, *supra* note 4, at 9-12.

Exclusive or partially exclusive licenses.
Government regulations reflect a preference for non-exclusive licenses, but exclusive licenses are available when needed to promote successful commercial development of a licensed invention. Upon receipt of an exclusive license application, NIH evaluates it using several criteria to determine if the company has provided an appropriate plan of development and if an exclusive license is warranted.[24] If NIH determines such a license is warranted, it publishes a notice in the Federal Register for a period of time, generally 15 days.[25] During this time the public may comment on NIH's proposal to negotiate an exclusive license and companies and organizations may submit competing license applications. After the notice and comment period closes, NIH considers comments and makes a final decision regarding the grant of an exclusive license(s).

NIH evaluates an exclusive license application based on the requirements set forth in 37 CFR Part 404.7. In addition to favoring small, U.S. businesses, NIH considers whether:

- "The public will be served by the granting of the license, as indicated by the applicant's intentions, plans and ability to bring the invention to the point of practical application or otherwise promote the invention's utilization by the public;"
- "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;"
- "Exclusive, co-exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public;"
- "[T]he grant of such a license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws;" and
- "In the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced."[26]

A single patented technology may have multiple fields of use, each of which have the potential to be developed into a product or service. NIH identifies potential uses and may decide to license each to different companies. The purpose is to expand the number of products for public use and foster competition. For example, a potential technology to treat cancer might be licensed to one company exclusively for blood cancers and to another company for solid tumors. Often, however, only one company shows interest in licensing an IRP patent to develop an FDA-approved therapeutic due to the early-stage nature of most IRP technologies.

NIH licensing principles. During the workshop, the Director of the Office of Technology Transfer at NIH summarized these principles that guide the agency:[27]

- Grant only the appropriate scope of rights;
- Specified fields of use;

[24] *See* 37 CFR Part 404.7.
[25] This does not apply in the case of an application for an invention developed under a Cooperative Research and Development Agreement (CRADA).
[26] *Supra* note 24.
[27] Kirby, *supra* note 4, at 7.

- Preference for non- or partial exclusivity;
- Permit research uses;
- Enforceable milestones and benchmarks;
- Maximize development of products for the public health;
- Ensure appropriate return on public investment.

3. DEFINING AND DRIVING SUCCESS

Before anyone can meaningfully identify best practices or the most promising approaches for NIH patent licensing, it is critical to consider what constitutes successful technology transfer, particularly in the context of government-owned inventions. And beyond that, to contemplate interim indicators of success and what features of a system drive or promote that success. While the workshop was not intended to pinpoint a definition of success, participants explored these questions from several angles.

A. Defining Success in Patent Licensing

Workshop participants generally identified public health benefit as a central guiding principle for NIH patenting and licensing, consistent with the agency's mission. Participants also offered additional, interrelated goals, including:

- Leveraging patent licenses to incentivize commercial development of products and services for disease prevention, diagnosis, or treatment;
- Spurring follow-on innovation and attracting additional resources to R&D;
- Promoting sustainable public access to emerging biomedical technologies;
- Fostering utilization or uptake of products or services based on NIH research;
- Stimulating economic development, including through job creation and the launch of new companies;
- Creating a pipeline of diverse investigators, innovators, and entrepreneurs; and
- Fostering competition.

Similarly, participants explored how success may look different for different types of technology. If an NIH lab develops a specialized compound with the potential to treat chronic pain, successful technology transfer might involve a company launching an FDA-approved drug and promoting patient access. But if an NIH lab develops a drug delivery platform that could support the development of products for multiple indications, success could include several entities working on different parts of the technology and others using the platform to develop their own proprietary materials into FDA-approved products. Relatedly, many NIH patents claim underlying technologies or components that inform can inform the development of products or services, but not the products or services themselves. These differences further reflect the value of different lenses for viewing success.

Relatedly, workshop participants discussed how difficult it can be to predict the trajectory or ultimate purpose of a given biomedical technology. This is particularly apparent with the type of early-stage research and discovery NIH often supports. While this uncertainty can lend itself to flexibility in many cases, some participants also made the case that NIH should approach certain patenting and licensing decisions deliberately when it does have a clear sense of a technology's purpose.

Triple A Strategy

During the keynote address, Dr. Maria Freire shared this "triple A" strategy driving successful technology transfer—and her view of what it means for technology to be available, accessible, and affordable.

Availability. This refers to a discovery or an invention becoming an actual product or service. Even great ideas can die on the vine if no one is willing to shape the discovery into a useful product. Achieving availability requires, for example, understanding how a given technology can contribute to a final product, where that technology fits in the product development continuum, whether additional investments are needed, and whether the technology is truly innovative or just an incremental improvement. This is where technology transfer professionals with expertise in the technology, relevant industries and markets, and product development and commercialization processes are key drivers of success.

Accessibility. This refers to the ability of patients and society to obtain and use a product or service. A drug, vaccine, diagnostic technology, or piece of equipment may be available—in that it exists—but it may not be accessible. For example, there must be distribution channels to deliver vaccines to patients; manufacturing facilities that can accommodate products which require complicated synthesis; and manufacturers able to keep up with demand. Although these challenges can be unpredictable, technology transfer professionals attempt to anticipate hurdles in accessibility, seek to identify partners who can commercialize the technology, and craft license provisions that address the gap between availability and accessibility.

Affordability. Price is one aspect of affordability, but affordability also implicates things like covering the costs of a product or service through, e.g., government structures, third-party payers, donations, or other mechanisms. Although healthcare prices have been, and will continue to be, an enormous societal challenge, letting patients die or go untreated simply due to cost is not acceptable. Some ways forward on price include streamlining the movement of innovation to market, thereby lowering the resources required, and rethinking reimbursement structures.

Finally, some workshop participants reflected on the challenge of developing metrics for success in patent licensing. By any account, this is hard to measure; the lack of agreement on what success "looks like" and how it is applied to different technologies complicates things. Revenue and financial returns may be one measure, and counting numbers of licenses may be another easily calculated metric. At the other end of the spectrum are less quantitative factors like transforming patients' lives, understanding mechanisms of disease, and influencing the practice of medicine.

B. Unique Considerations for NIH

NIH is in a unique position to prioritize R&D, licensing, exclusivity, and partnerships in areas that would not otherwise receive sufficient support in the commercial market, such as neglected and tropical diseases and rare diseases. Some participants urged NIH to monitor if (or when) industry retreats from certain

areas, like gene therapy, as that creates areas of opportunity for NIH. Not only can NIH's own research and funding help fill gaps, but the agency can leverage IRP patent licenses, where feasible, to incentivize more commercial development or spur follow-on innovation by both academia and industry to address unmet needs.

Relatedly, as NIH pursues research in areas that lack industry interest, some participants also emphasized the value of novel public-private partnerships and urged the agency to be assertive in taking credit for its accomplishments. Patent licenses are not the only tool in the agency's toolkit, and innovation in some areas will require new models to maneuver scientific and economic challenges.

C. Value of Studying and Understanding Impediments to Success

Not all product development or technology commercialization is successful. Some products might fail for technical reasons like a lack of safety or efficacy. Some products will be brought to market but the people who want or need access may not be able to get them. And there are other business-related reasons a product might not make it to market. For example, a company could stop development because of reimbursement or competition reasons, or one firm might acquire another and decide to shut down certain product lines.

But even when NIH and its commercial partners set out to bring a product closer to patients, if that product never makes it to market or is later removed, those experiences are still instructive. They can teach us more about human biology, patient safety, or the risks involved in treating or preventing a given disease. Those experiences can also shed light on approaches to patenting and licensing that align with successful technology transfer. To that end, some participants encouraged NIH to consider what types of arrangements and partnerships allow promising opportunities to learn from failure.

D. Potential Areas for Further Exploration

Explore impact of business risk. NIH could investigate the impact that business risk—or business-related reasons products do not make it to market—has on the successful development of NIH IRP inventions.

Data collection across agencies. NIH could engage with other government agencies to assess utilization of products and services developed based on inventions licensed from IRP. That data could help the agency identify best practices associated with downstream uptake and utilization.

4. ROLES & INCENTIVES

Different individuals and institutions bring varied expertise to the table when it comes to NIH's patenting and licensing decisions and associated policies. These individuals and organizations also have different goals, needs, and views about how to achieve a shared goal of improving public health. Workshop participants explored ways NIH already leverages diverse expertise in its patent licensing program and how the agency can best involve a broad range of perspectives.

A. Who Gets a Seat at the Table

Patent licensing is a process that unfolds and can shift over time. Often, deciding whether to file a patent necessarily starts with the investigators who develop potential inventions. At NIH, the process begins when an investigator submits an Employee Invention Report (EIR).[28]

Inventors are most familiar with their inventions, they have expertise in the relevant fields, and they may have a direct sense of an invention's public health or commercial potential. They are well suited to help educate technology transfer professionals and patent lawyers (in NIH's case, typically contract legal counsel) and help evaluate patentability—e.g., what about the invention is truly new and non-obvious. And their knowledge can contribute to downstream efforts to move patented technology closer to patients. However, while NIH consults investigators on scientific aspects of patenting and licensing, investigators have a limited role in all other aspects of licensing and negotiations, and no role in negotiating financial terms, to avoid possible conflicts of interest.

Other investigators and program staff further equip the agency with a range of expertise. NIH ICs have various mechanisms to consult with scientific advisory or review committees and subject matter experts in a disease area—to inform everything from patenting strategies to commercialization potential and understanding the relevant industry.[29]

Other experts help create a bridge between the public and private sector. NIH does not launch new commercial technology itself, instead relying on partners to turn inventions into products and services for disease prevention, diagnosis, or treatment. When it comes to patent licensing, if there is no interested licensee willing to develop a technology, the invention is unlikely to become a product.

Technology transfer experts bring knowledge about how to move an invention forward in the commercialization process. Legal experts can determine whether something is patentable and opine on the best intellectual property strategy for a technology. At NIH, technology transfer teams and patent attorneys actively advance the patenting and licensing process, and they continue to monitor a technology's progress after licenses are executed.[30] NIH also leverages internal experts with experience in business development, industry, and regulatory approvals to fill the space between public and private sector.

Some workshop participants also highlighted the unique and important perspective of early-stage entrepreneurs. Especially for an organization like NIH, where startups are often the first private sector partner developing an NIH invention, those participants urged NIH to think about the startup experience and factor that perspective in during the technology transfer process. For example, startups and NIH may have different perceptions about the speed with which a license gets put into place—where NIH has to proceed with a particular, deliberate pace to comply with law and policy while startups are operating on a clock tied to development milestones and fundraising needs—so listening to startups can help the agency

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[28] *Resources: Forms and Model Agreements*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/resources#EIR (last visited Feb. 27, 2024) (links to download, e.g., a blank Employee Discovery and Invention Report form); *see also, e.g.*, Appendix A (case study); *NIH Employee Invention Report (EIR)*, NATIONAL CANCER INSTITUTE TECHNOLOGY TRANSFER CENTER, https://techtransfer.cancer.gov/investigators/inventions/employee-invention-report (last visited Feb. 27, 2024).
[29] *See, e.g.*, Appendix A.
[30] *Supra* Section 2.

attend to the impact of any delays in the process. Indeed, NIH already has startup-focused programs, models, and support services that it could build on.[31]

Another workshop participant emphasized how public health experts, epidemiologists, and affected communities can help shape access strategies during the patent licensing process. He encouraged NIH to bring these voices in early and often, as it would strengthen NIH's ability to truly work in the public's interest. Bringing in public perspectives can also help the agency generate awareness about the technology it develops and foster public support.

Patient voices add value before and after the patent licensing process, as well. The path from biomedical discovery to product launch is about more than getting a product on the market—to enhance public health, those products need to meet patient needs. An investigator might think they are developing something patients want, and they might think patients would be happy to add one more drug on top of the ones they already take to manage a disease. But patients might be unwilling or unable to add that additional drug. Listening to patient voices throughout the R&D process is critical for investigators and institutions to learn what patients and the public value and prioritize.

Finally, workshop participants recognized challenges in bringing many voices to the table. For one, if the agency publicly discloses an invention before filing a patent application, then a patent will not be available (in most jurisdictions). Subsequent patenting decisions also happen on a clock. If NIH files a provisional (or preliminary) patent application, it has a set amount of time to file non-provisional (or full) applications in each relevant jurisdiction. And the agency might need to be nimble negotiating licenses in a timeframe that works for all interested parties. These factors can limit how many people NIH can engage regarding individual patenting and licensing decisions.

B. Aligning Incentives

NIH must also align these varied individuals and institutions toward decisions that promote social benefit. Having a breadth of knowledge at the table is helpful, but effectively orienting everyone around shared public health goals also requires understanding the incentives at play.

Overall, workshop participants generally agreed that licensing biomedical technology is not—or should not be—a zero-sum game. The best partnerships emerge when parties work to deliver value to each other. Participants variously discussed how licenses can act as governing mechanisms NIH can use to elicit interest from companies that have consistent objectives, are willing to work on the agency's time horizons, and prioritize public health. Licensing likewise presents the opportunity to gather information and then structure agreements in a way that aligns the parties. And licenses can be structured in a way that allows teams to work flexibly, solve problems, overcome hurdles, and deliver products to patients.

Aligning individual actors also requires understanding what motivates them. Investigators, for example, want to see their ideas out there in the world—that can mean publishing, sharing research results, and/or paving the way for product development. And paving the way for product development can include patenting and licensing, further developing a technology to de-risk it and attract commercial partners, and

[31] *See, e.g.*, *Start-Up Program 2.0: An Evaluation Option License Program*, NATIONAL CANCER INSTITUTE TECHNOLOGY TRANSFER CENTER (Aug. 30, 2023), https://techtransfer.cancer.gov/partnering/licensing-agreements/start-up; *Innovator Support Resources*, NIH SEED, https://seed.nih.gov/NIH_innovator_support_resources (last visited Feb. 27, 2024).

even transitioning out of academic research to pursue product development full time. One workshop participant reflected on his personal experience moving from an academic lab to launching a company—as he continued his research and learned more about the process of product development, he realized that to make the biggest impact for patients he would need to make the leap to the private sector.

Organizational incentives are also at play, as organizational priorities drive policies and dictate the metrics different institutions use to measure success. NIH's priorities revolve around advancing biomedical science in the service of public health. For public companies, the launch of a new product provides profits that yield shareholder value and can be reinvested in product development. Early-stage biotech companies need to focus on the critical path and meeting timelines, to show investors and patients progress toward development goals.

Organizational policies also shape individual behavior. For example, many institutions offer financial incentives, like royalty payments to inventors, to encourage investigators to pursue innovation that benefits public health. Institutions can also craft policies to guide productive decision-making, as investigators may not have a strong sense for when (and which) patents are useful to advance product development and public health goals.

Relatedly, moving biomedical technology from bench to bedside requires teamwork. In seeking promising partners and looking to optimize chances of translational success, some participants emphasized that NIH should evaluate the strength of the teams applying for licenses and their ability to demonstrate repeated success, as part of the overall decision-making process.

C. Unique Considerations for NIH

Supporting basic research and training.
Many workshop participants emphasized NIH's critical and unique role in supporting basic, fundamental biomedical research and training at a level that is beyond the ability of other institutions. And they encouraged NIH and other policymakers not to lose sight of that fact as they examine the agency's role in innovation, competition, and equitable access to new products and services for disease prevention, diagnosis, or treatment.

Some workshop participants also highlighted the connection between NIH's basic research portfolio and the nation's economic goals. From extramural funding and partnerships with the IRP to seeding startup creation, the agency supports job creation and financial returns which can be reinvested in more R&D. One participant also emphasized how many licensees working with NIH-funded or NIH-generated inventions are startups led by students or young investigators, as opposed to big, established companies. Another noted that approximately one-third of NIH's most successful technologies were licensed by early-stage companies.[32] NIH was encouraged to keep these benefits in mind as it strives for balanced return on taxpayer investment.

Role on price.
The workshop reflected differing views about NIH's role in dictating or shaping the prices patients pay for products and services for disease prevention, diagnosis, or treatment. Overall, the workshop included limited direct discussion of such prices. But, considering the comments made by both public commenters

[32] Kirby, *supra* note 4, at 3.

and panelists, the weight of perspectives signaled concern that calls for NIH to bring down high healthcare costs are misplaced.

On one hand, some urged that NIH must be allowed to focus on its core job of supporting research and advancing biomedical innovation. They suggested that if the agency were to start building price constraints into patent licenses for early-stage technologies, that would discourage innovation, which would, in turn, mean new products would not get made and patients would not realize the benefits of NIH innovation. Several public commenters referred to NIH's use of so-called "reasonable pricing clauses" between 1989-1995,[33] as evidence that these sorts of approaches chill science and public health progress without providing the benefit of lower prices to the public. Another participant offered that asking NIH to fix drug pricing problems is a red herring, instead calling for other government agencies and government functions, like negotiating the prices when purchasing FDA-approved products, to bring down expenses.

By contrast, some argued NIH has a role to shape product price by addressing it in upstream patent licenses. Some participants offered that such an approach makes most sense when NIH is licensing patents that are incorporated into a product that is in the later stages of development at the time of the license or when NIH has, itself, de-risked the product. One participant suggested that the agency reconsider whether its experiment with "reasonable pricing clauses," from the 1990s, was a failure and emphasized that the agency would need to ensure any pricing terms in its licenses give companies clarity and certainty about the obligation they would be taking on.[34]

On a related note, the workshop also touched on the fact that NIH inventions often pass through multiple hands before any product makes it to market, so NIH licensees may have a limited, if any, say in final product pricing. For example, when NIH licenses an invention to an early-stage company, those initial licensees are less likely to sell drugs directly to patients; they instead often hand off their technology to more established companies for subsequent development, clinical trials, regulatory approval, and/or manufacturing.

D. Reducing Barriers to Entry

Workshop participants also explored the need to bring more people into the biomedical innovation ecosystem, especially from communities that have been historically underrepresented. And they discussed how patenting and licensing policies and practices can play a role.

Patenting decisions usually start when an investigator submits an invention disclosure,[35] yet as one participant noted, data indicate that women and underrepresented minorities do not file invention disclosures at the same rate as White men.[36] As she explained, this disparity does not reflect people who

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[33] *See generally The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995* (Nov. 15, 2021), https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.
[34] *See* Ameet Sarpatwari et al., *Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed With Government Support*, 173 ANNALS OF INTERNAL MED. 348 (2020), https://www.acpjournals.org/doi/10.7326/m19-2576.
[35] *E.g.*, *supra* Section 2.
[36] *See, e.g.*, Serena Hanes et al., *Gender Analysis of Invention Disclosures and Companies Founded by Stanford University Faculty from 2000-2014*, 53 LES NOUVELLES 83 (2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3103214; Colleen Chien, *Redefining Progress and the Case for Diversity in Innovation and Inventing* (2022), https://digitalcommons.law.scu.edu/facpubs/1000/.

are not inventing, but rather this data reveal barriers in the system—barriers that could be reduced, including through training and outreach.

NIH offers programs to educate scientific staff about inventing and patenting and to expose them to technology transfer.[37] This equips investigators, at all stages of their career, to identify when they have a new invention and understand how to set the technology on the path to commercialization. Workshop participants noted these programs could be expanded and acknowledged that NIH needs to continue collecting demographic data to understand where there are gaps in the pipeline that could be addressed by tailored training and outreach.

Participants suggested other ways to increase the number of inventions being brought forward, including from underrepresented innovators. Some investigators may not see themselves as innovators or they may have had an initial, negative experience with the patent system. One idea to address that challenge would be shifting from the current opt-in policy to an opt-out policy: instead of asking investigators to identify and disclose potential inventions, create policies that assume anything an investigator comes up with should be disclosed. Another participant suggested NIH's private sector partners also help bring more diversity and equity to the innovator talent pipeline.

Finally, on a related note, participants recognized the impact patenting decisions have on other researchers in a field, and some discussed how this can be particularly salient for early-stage investigators and trainees. For example, participants suggested that if NIH decides to patent an invention, one obvious impact would be that the patent might prevent others from using that technology in their own work, absent a license. But a patent is also a public disclosure that becomes prior art for later patent applications. If several people in one lab are working on related projects, and a patent application is filed for an invention arising from one project, it could make seeking patent protection for other inventions developed in the same lab more challenging—because the earlier-filed patent applications might be used to argue that later patent applications are obvious (and therefore unpatentable). Bringing students and trainees into conversations about what to patent is a chance to hear their perspectives and weigh the impact that patenting and licensing may have on their later innovation.

E. Potential Areas for Further Exploration

Consider pilots to increase engagement in innovation by underrepresented groups. NIH could pilot policies or strategies to bring more underrepresented voices to the table in patenting and licensing. This could include strategies to increase engagement by underrepresented innovators. The agency should also continue to capture data necessary to monitor and evaluate progress.

Sustain and/or expand training. NIH already offers innovation-focused training for its investigators, but it can explore expanding or improving those opportunities. The agency could also consider its role in training and strengthening the pipeline of technology transfer professionals.

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[37] *See, e.g.*, *I-Corps at NIH*, NIH SEED, https://seed.nih.gov/I-Corps-at-NIH (last visited Mar. 1, 2024); Larisa Gearhart-Serna, *Training Opportunities in Tech Transfer*, THE NIH CATALYST (May 17, 2022), https://irp.nih.gov/catalyst/30/3/the-training-page; *NCI Advancing Innovations through Mentorship (AIM)*, NATIONAL CANCER INSTITUTE TECHNOLOGY TRANSFER CENTER (July 25, 2023), https://techtransfer.cancer.gov/fellowships-training/training/advancing-innovations-through-mentorship.

5. EXCLUSIVITY

Exclusivity comes in a variety of forms. A U.S. patent, by definition, gives the patent owner the right to exclude (or stop) others from using an invention. And patent licenses—another source of exclusivity—can be exclusive, non-exclusive, co-exclusive, where a license is granted to a limited number of partners, or partially-exclusive, where the exclusive scope is limited, for example, by field of use, geography, or duration.[38]

Laws and regulations governing NIH reflect a preference for non-exclusive licenses, but NIH may grant an exclusive, co-exclusive, or partially exclusive license when appropriate to promote successful commercial development of a licensed invention, if certain criteria are met.[39] Most of the agency's licenses are non-exclusive.[40]

A. Justifications and Tradeoffs Around Exclusivity

For NIH, deciding whether to patent and license a given technology—exclusively or non-exclusively—is a fact-dependent matter. Throughout the workshop, participants explored the variety of roles patents, exclusive licenses, and non-exclusive licenses play in biomedical innovation. This illustrates how complex and varied situations can be—especially when it comes to early-stage biomedical technology. There is no one-size-fits-all approach.

While the workshop's discussions revealed different views about whether and when exclusivity is justified, there was a general sense of agreement that incentivizing commercialization is one of the reasons for NIH to seek exclusivity. And in that way, patents are one tool to help turn inventions into products that have health, economic, and social impacts. In that same vein, some participants discussed how NIH can use patenting and licensing as a carrot to prompt partners to invest in R&D in priority areas.

Patent licenses can also be a tool for NIH to monitor and enforce progress toward public health goals. NIH asks license applicants for commercial development plans describing how they will turn the agency's inventions into products, and NIH incorporates benchmarks and diligence provisions into its licenses that are monitored during the course of the license. One participant added that licensing allows NIH to "have a finger in the pie," giving the agency some say in how licensees utilize inventions. The agency could use this to encourage broader utilization of technology, for example structuring licenses in a way that encourages sub-licensing of the final product to manufacturers in several countries to meet global demand.

On the flip side, participants offered views about when NIH should skip patenting. For example, one participant suggested that most NIH-developed technology should be available to the public without patents. So, while commercialization makes sense as a guiding principle for patenting, when patents are not needed for commercialization, they argued that should pull the agency toward a different result.

This is consistent with how NIH assesses the best way to disseminate an invention. For example, NIH does not usually file patents on research tools—like mouse models—because those patents could create

[38] *Supra* Section 2.
[39] *Id.* (citing 37 CFR Part 404.7).
[40] *See, e.g.*, Kirby, *supra* note 4, at 2.

barriers for others who want to use those tools in their own research and the exclusivity of a patent is often not needed to realize the public benefits of that technology.[41]

Another participant urged that NIH also consider what ultimate product(s) might incorporate the patented technology and factor that into initial patenting decisions. If the NIH invention can be "used as-is," without other contributions like additional IP, or if the invention reflects the whole product, as could be the case with research tools, then in his view releasing that to the public domain is appropriate. But he argued that if NIH invented something that is a part of a product—for example, one component of a drug—then companies may subsequently file patents on other parts of the drug and block access to the ultimate product through their own patents. In that case, he would prefer NIH patent its invention, issue non-exclusive licenses, and use those licenses as leverage to promote public health and patient access.

B. Temporal Aspects of Patenting and Licensing Decisions

Throughout the day, participants addressed the timing of patenting and licensing decisions, and they discussed how those decisions are not immutable and can evolve over time. This was on display, for example, as NIH IRP staff presented case studies (appendix A) showing how the agency structures decision-making processes and license agreements to revisit and respond as a given technology proceeds through development. Workshop participants shared various perspectives on how NIH could continue or augment these practices—following along with an invention as it advances and using patenting and licensing decisions to influence optimal product development.

As alluded to above, NIH often has to start making patent-related decisions before it knows how development of a technology may unfold. But this is a process, not just a single decision—the agency decides whether to file a provisional patent application, whether to file a non-provisional application, which countries to file patent applications in, whether to file more patent applications on closely-related technology (applications "in the same family"), and whether to abandon applications or issued patents. Each of those subsequent decisions is a chance to revisit whether a patent on a given technology advances the agency's mission.

Participants also explored how questions about exclusivity may continue to emerge until the termination of any licenses. For example, NIH crafts licenses that allow it to monitor licensee progress—including through examination of progress reports, benchmarks, payment history, and public information. If the licensee is not performing according to the agreed-to plan, with justification, NIH can amend the license to account for changes and ensure the licensee has tools to succeed. NIH can also add terms to an active license to adapt to changing circumstances, and it may revisit the scope of the license (e.g., field of use or exclusivity). If problems emerge and licensees are not keeping up with their obligations, the agency may also terminate a license—although the agency approaches all these issues carefully, to avoid the risk that a technology will not be developed.[42]

Here again, participants acknowledged the challenge of striking the right balance. For example, one participant noted that if NIH patents an early-stage technology and grants an exclusive license, that can tie the agency's hands and make it harder to revisit later. Put another way, once NIH knows more about a technology, it might think a different patenting or licensing strategy makes most sense, but existing

[41] Appendix A.
[42] *See, e.g.*, Kirby, *supra* note 4, at 13-14.

licenses can limit options for changing course. On the other hand, another participant noted that as NIH learns more about a technology and its commercial potential, others also learn more, which might mean NIH has the most leverage earlier in the process when there is more uncertainty. She suggested NIH and its partners set out the framework of what should be included or addressed over the course of an agreement early in the negotiating process, because issues that are not identified early on can become harder to negotiate closer to commercialization.

C. Unique Considerations for NIH

Balancing product development and public disclosure goals.
While most technology developed by NIH is made available to the public without securing patent protection (e.g., through scientific publications, presentations, and online resources),[43] NIH, like academic institutions, often needs to make patenting decisions earlier than other companies and organizations. NIH investigators are looking to share their research and publish papers, and that key factor drives the timing of patent applications. By contrast, a company might choose to more thoroughly develop an invention internally before sharing anything publicly, deferring both a patent application and publications until they have a stronger sense of how the technology may unfold.

D. Non-Exclusive Licenses

Workshop participants also discussed non-exclusive licenses extensively. Some participants offered that, if NIH patents something and then broadly issues non-exclusive licenses, that might indicate it should have skipped patenting in the first place. And they argued that if NIH does file patents when it anticipates a very open approach to non-exclusive licensing, then the agency should be able to explain that choice (and why it serves the public's interest more than merely publishing the research). This could promote broader utilization without the requirements of exclusivity.

This prompted reactions from several other participants. Importantly, non-exclusive licenses are the statutory default for NIH, and the agency must meet a higher burden to justify an exclusive license.[44]

Participants explored a range of justifications for non-exclusive licensing, for example:

- As above, a patent license—even a non-exclusive one—might give NIH some leverage over how an invention is used by licensees. And non-exclusive licenses can encourage companies to conduct research in a certain area.[45]
- Non-exclusive licenses can be a way for the agency to recoup costs. For example, one participant, who had formerly worked at NIH's Office of Technology Transfer, noted that the agency first started issuing Biological Materials Licenses as a means of covering the costs of packing and shipping material, as NIH cannot do that under a Material Transfer Agreement.

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[43] *See, e.g.*, *HHS Technology Transfer Policies and Procedures Manual Ch. 200*, NIH TECHNOLOGY TRANSFER (June 17, 2010), https://www.techtransfer.nih.gov/policy/hhs-technology-transfer-policies (addressing Policy on the Filing of Patent Applications for PHS Inventions); *NIH Public Access Policy*, NIH (Aug. 29, 2022), https://publicaccess.nih.gov/.
[44] *E.g.*, 35 U.S.C. § 209(a).
[45] *Supra* Section 3.A.

- Multiple entities may need to work on different parts of a technology to develop a final product. For example, if the agency has invented a new platform technology and one entity cannot bring it to commercial development alone, non-exclusive licenses can bring several partners together.
- Licenses can allow companies to show their funders and partners that they have a clear path to market without being accused of infringement later.

Overall, several participants encouraged the agency to explain the various roles non-exclusive licenses play—to help the public see the various justifications and help them understand why NIH chose patenting and non-exclusive licensing to promote commercialization of a technology.

Some participants also suggested NIH explore ways to make non-exclusive licensing and negotiations less complicated and time consuming. For example, one participant referred to an IBM policy from the early 2000s, where IBM adopted an open approach to licensing some of its patents and indicated general willingness to grant non-exclusive licenses under certain conditions at a one percent royalty rate.[46]

E. Potential Areas for Further Exploration

Deeper exploration of exclusivity. NIH could hold further discussions and continue to examine the varied roles public sector patenting does, and should, play in biomedical innovation.

Public information about non-exclusive licenses. NIH could explore how the agency currently uses non-exclusive patent licenses, revisit when that approach is warranted, and explain it to the broader public.

6. PARTNERS

Partnering with NIH presents a unique and promising opportunity, and the agency seeks out partners that share in its mission. Furthermore, companies licensing NIH inventions must be comfortable with some unique and challenging aspects of these partnerships, due to NIH's status as a federal agency. For example, while other entities might be willing to grant companies a broad license to further develop technology, in exchange for the company paying a larger sum, NIH is more limited in the scope of licenses it can grant, and licensees need to be comfortable with that. Throughout the workshop, participants explored the critical role of NIH's commercial partnerships and how to optimize those opportunities.

A. NIH's Position in the Innovation and Healthcare Ecosystems

NIH does not bring products or services to the market. Instead, a network of partners must invest in continued development, regulatory approval, manufacturing, and distribution of new biomedical products based on NIH IRP inventions. And each technology that got its start at NIH takes a unique path toward market.

For example, NIH may initially license a patent to an early-stage startup that is well-suited to take risks, and that licensee can develop additional data or establish human proof-of-concept for an early-stage

[46] *IBM Worldwide Patent Licensing Practices*, IBM (June 20, 2002), retrieved from Internet Archive, https://web.archive.org/web/20020620100327/http://www.ibm.com/ibm/licensing/patents/practices.shtml.

technology. Then, a more established company might acquire the technology and invest in later development that a startup could not support, like large clinical trials and regulatory approval. And that company may, in turn, work with a network of manufacturers to scale-up and distribute products to patients worldwide. Several workshop participants discussed NIH's patent licenses through this broader lens, and they encouraged NIH to think about the diligence involved in those later transactions, with an eye toward structuring the agency's deals to increase the likelihood of success down the line.

Relatedly, some participants discussed why early-stage startups may be in the best position to move early-stage technology forward. Indeed, as noted, about one-third of NIH's most successful technologies were licensed by early-stage companies.[47] Compared to established incumbents, startups may be nimbler and able to react rapidly to evolving data about unproven biomedical technology. And they can take smaller amounts of capital to de-risk technologies before handing them off to larger partners.

NIH's relationships and partnership networks also vary depending on the complexity of a given technology. A more complex or unproven technology can mean more complicated and expensive development or manufacturing. That can, in turn, lend itself to novel partnerships that tap global capacity and expertise. For example, some panelists cautioned against making it more difficult for NIH's licensees and partners to make full use of global supply chains. Those sorts of restrictions might drive away licensees and other downstream collaborators, ultimately suppressing the development of new products to meet global needs.

Finally, NIH does not just work on technology that could underpin FDA-approved therapeutics like drugs or biologics. The agency's research includes things like diagnostics, devices, and applications for artificial intelligence. The potential applications for IRP research include med tech, wearables, digital health, and more. The path those technologies take to market will also vary, implicating different networks and creating new and different opportunities for partnerships.

B. Challenge of Finding Interested Licensees

NIH is always interested in finding partners to move IRP technologies closer to patients. Yet, one point emphasized during the workshop—particularly by NIH participants with experience in technology transfer—is that there are often no potential licensees or only one potential licensee interested in working with a given NIH-funded technology, despite the potential for long-term development. Similar sentiments were expressed by university technology transfer professionals, who noted there are often not many licensees waiting to commercialize early-stage technology from university researchers. Others added that this challenge is not unique to NIH, because, in addition to the high risk associated with early-stage technologies, interest in each technology is a snapshot of scientific, healthcare, and market conditions at that moment—and there will always be emerging technologies from every sector for which there is little or no interest at any given time.

Likewise, the level of interest from potential licensees evolves over time. As the circumstances around a technology—and what we know about its potential and associated risks—evolve, the appetite for licensing can also evolve. Technology transfer professionals take this into account as they revisit patenting and licensing decisions. For example, when NIH first started working with a few other institutions to stabilize coronavirus spike proteins, no private sector licensees expressed interest in

[47] Kirby, *supra* note 4, at 3.

working with that technology. But then, when the COVID-19 pandemic hit, there was substantial commercial interest and NIH pursued non-exclusive licensing that allowed multiple vaccine developers to simultaneously use the agency's inventions to meet public health needs.[48]

Workshop participants explored other factors that impact demand for licenses. For one, many potential industry partners are not aware that the NIH IRP offers licensing opportunities. Demand can also hinge on available financing levels and the readiness of relevant parties—basic researchers, clinicians, startups, strategic partners, etc.—to jump in to work on the target, disease, or modality in question. And different types of partners may be interested at different times. One workshop participant suggested NIH compare its experience attracting licensees at the beginning of a wave of technology versus interest from licensees that follow trends as they develop. From that the agency might discern the different visions licensees have for technology and how to approach outreach and partnerships with that in mind.

C. Benefits of Engaging Multiple Licensees for a Given Technology

NIH would prefer to issue as many licenses as possible for each technology. If more licensees are working with a given technology, that improves prospects for innovation, competition, and patient access—increasing the odds that the right products will get into the hands of all patients who need them. However, the agency is admittedly limited in this regard, as it can only issue multiple licenses to an invention if there are multiple interested licensees. So there remains the hurdle of attracting more promising commercial partners; or, as one participant put it, borrowing a term from the VC sector, NIH needs "deal flow."

The agency has several tools at its disposal to disseminate inventions to multiple licensees. Here again, non-exclusive licenses are the statutory default for NIH. But even when an exclusive license is warranted, the agency focuses on making the scope of exclusivity no greater than reasonably necessary; and to that end, the agency may leverage options like co-exclusive licensing, geographic limits, and field of use limitations, which can also create space for more companies to work with a given invention—all with an eye toward expanding the number of products for public use and fostering competition. For example, in some areas there may be substantial commercial interest in an early-stage invention, such that several companies want to do the work but also need some degree of exclusivity. NIH may be able to grant narrow, exclusive fields of use while retaining the ability to grant additional licenses in the future.[49]

While NIH may identify multiple potential applications for a technology and try to license each to different companies, the opportunity to grant multiple licenses can also emerge when NIH publishes a notice in the Federal Register that it is contemplating the grant of an exclusive license to a particular company.[50] If one or more additional companies apply for a license to the same invention, then NIH has an opportunity, based on the companies' interests, to negotiate co-exclusive licenses or separate exclusive licenses with differing fields of use. For example, when NIH announced it was considering the grant of an exclusive license for the development of anti-Tac antibodies to treat multiple sclerosis, it received a second license application and ultimately granted two co-exclusive licenses.[51]

[48] Appendix A.
[49] Appendix A.
[50] *Supra* Section 2.
[51] Appendix A.

Workshop participants encouraged NIH to explore further opportunities like this, to get "more shots on goal," where possible. And some participants urged the agency to try and broaden the approach, to see if there are ways it could attract or incentivize more co-exclusive licenses where two different types of companies get the chance to develop a technology within the same field of use.

D. Outreach

Workshop participants also discussed NIH outreach to prospective licensees and collaborative partners—for example large and small companies, economic development groups, trade associations, foundations, philanthropic organizations, and others. NIH already takes several approaches to advertise licensing opportunities and attract potential licensees, some of which are summarized below. Participants acknowledged there is room to explore expanding these practices across NIH ICs.

- Posting available technologies, collaborations, model agreements, and technology transfer policies on the OTT and IC websites;[52]
- Publicizing available technologies in the Federal Register and on relevant online databases;
- Marketing opportunities at key scientific conferences;
- Establishing relationships with incubators and accelerators, whether non-profit or for-profit, which are often focused on bringing together collections of technologies and knowledge relevant to advancing certain products to market;
- Attending events like industry conventions, investor events focused on particular biomedical technology, and trade association events;
- Connecting with regional life sciences associations;
- Convening dedicated events to showcase technologies that are ripe to be licensed; and
- Conducting individual and smaller virtual meetings to spread the word about general licensing opportunities.[53]
- NIH also looks to introduce its value to potential licensees when they are involved in other NIH programs like the Small Business Innovation Research (SBIR) program. Once a company grows past that SBIR stage, they may still see opportunities for other relationships with NIH.

Participants also acknowledged that part of successful outreach includes identifying the right people to connect with at a given institution. For example, at a conference, NIH representatives might meet industry colleagues who are focused on science and less involved with business development. But ultimately, to form partnerships, the agency needs to connect with individuals who make decisions about licensing. While this is something NIH is attuned to, it requires extra diligence during outreach, and some participants urged NIH to keep the importance of that diligence in mind as it expands outreach efforts and tries to reach new communities. It is not just a matter of finding more institutions to talk to, but also the right institutions and individuals at those institutions.

Finally, participants discussed the challenge of doing this outreach at scale. One noted that NIH's in-house technology transfer apparatus is larger than the technology transfer offices at most universities and other public sector research institutions—those are often small teams working under resource constraints.

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[52] NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/ (last visited Feb. 28, 2024) (search abstracts function on home page).

[53] This is not a comprehensive discussion of how NIH approaches outreach to potential licensees and advertising licensing opportunities.

She suggested the agency and recipient institutions explore opportunities to work together, perhaps through intermediaries, to pull together different technologies and aggregate information about potential licensees—and perhaps even leverage AI or other tools to get more information about technology to the institutions who might want to partner.

E. Potential Areas for Further Exploration

Focus on a "warm" partnership ecosystem. Consider how the agency already builds out a larger and more diverse pool of potential licensees and evaluate opportunities to strategically approach developing an ecosystem of promising partners that have already demonstrated they share the agency's goals. This could smooth the path of attracting licensees for a specific technology and negotiating individual agreements that best align with public health goals.

7. LEVERAGING PATIENT COMMUNITIES

Workshop participants underscored the invaluable role of patient advocacy organizations. There is history here to build from. For example, AIDS activists were involved in advancing the science and technology, funding, commercial partnerships, and clinical trials behind early HIV drugs.[54] Workshop participants recognized patient organizations play similar key roles today; and patients, their families, and advocates are increasingly starting companies or serving as investors. At the same time, some participants advised caution in how to approach patients and families in work that requires objectivity, like interpreting data: parents fighting for their children are an asset but not objective. There are critically valuable roles that patients can, and do, play in moving technology closer to market, and NIH should seek ways to leverage that expertise, commitment, and energy in the most positive directions.

A. Connecting with Commercialization Partners

Many workshop participants noted that patient advocacy organizations can play a valuable part connecting NIH with promising commercialization partners—such as biopharmaceutical companies, other for-profit institutions, and non-profits that advance product development. Multiple participants suggested the agency try to leverage its relationships with patient advocates to find successful partnerships, and they encouraged NIH to include patient organizations when it engages in licensing outreach.

Relatedly, another participant suggested NIH consider the role of payors—both public sector payors like the Centers for Medicare & Medicaid Services (CMS) and private sector payors like insurance companies. He offered that those organizations are also interested in seeing emerging technologies brought to market and they might be able to finance things like clinical trials and regulatory approval in exchange for concessionary prices on products. This model could work for products that are lower risk, later stage, and less speculative; and attracting those organizations to fund development might require NIH taking technology further along the developmental pipeline.

[54] *See, e.g.*, SARAH SCHULMAN, A POLITICAL HISTORY OF ACT UP IN NEW YORK, 1987-1993: LET THE RECORD SHOW 169-226 (2021).

B. Diverse Roles Patient Communities Play

Patient communities and public advocates can play varied and sometimes unexpected roles in translation and the development of new products and services for disease prevention, diagnosis, or treatment.

Clinical trial networks.
Workshop participants discussed how patient communities help build and maintain clinical trial networks. One participant noted the facioscapulohumeral muscular dystrophy (FSHD) community as an example,[55] and another referenced a program maintained by the National Organization for Rare Disorders (NORD), that allows patients to inform and shape medical research through registries that can ultimately help advance product development.[56]

Engagement with government.
One workshop participant noted how patient advocates can help a regulatory body like FDA understand a disease, for example clarifying why placebo-controlled trials may not work for some rare diseases. Patient advocates can also talk to government entities that have a direct say in product access or pricing, to help inform those decisions.

The government should always play an active role here, equipping patient advocates and the broader public with the tools and opportunities needed to engage with the government—and seeking ways to meaningfully meet patients where they are at. On this note, it is also important that patient advocates be equipped with the tools to effectively engage with the government. This might mean the government ensuring advocates have a clear sense of which government bodies are responsible for what or finding ways to speak terminology that works for all communities (including in compliance with various laws and regulations).

Fundraising.
Patients and patient advocates raise money for research and development. Going back to the concern about objectivity, some participants also noted the value of organizations, like NIH, in funding meritorious and promising research by instituting controls and guardrails with its organizational structure and policies. One workshop participant spoke about her organization's work, where patient groups can help fund and co-fund projects, but as an organization her institution sits between sectors to make funding decisions based on the most promising opportunities to help de-risk technology development.

C. Potential Area for Further Exploration

Explore leveraging NIH's existing patient relationships and building new ones. Evaluate how NIH currently engages with the public and patient advocacy communities, and consider where to build new relationships, to help further develop and commercialize technology. This could include working with patients to find promising commercial partners, engaging with the full translational pipeline, building clinical trial networks, and more. It can also include expanding the type of education offered to patient

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[55] *See, e.g.*, *About the Facioscapulohumeral Muscular Dystrophy Clinical Trial Research Network (FSHD CTRN)*, KU MEDICAL CENTER, https://www.kumc.edu/fshd-clinical-trial-research-network/about.html (last visited Feb. 29, 2024).
[56] *IAMRARE® Program Powered by NORD*, NORD, https://rarediseases.org/advancing-research/patient-registry-program/ (last visited Feb. 29, 2024).

advocates and developing outreach and communications strategies that are more accessible to a wide variety of audiences.

8. FLEXIBILITY

Throughout the workshop, participants generally agreed there is no one-size-fits-all approach for patenting and licensing NIH inventions. Participants variously spoke to how flexibility is one driver of successful technology transfer. It is part of what allows teams to work together to reach win-win solutions, and the mechanism of licensing itself is an opportunity to negotiate tailored agreements to achieve innovation goals for a given invention. Likewise, while participants noted that NIH faces statutory and regulatory mandates that can limit some options, the agency does have flexibility to operate within the statute.

By way of example, one participant spoke about how some technologies will result in products that affect small populations, so the product and its commercialization will not fit the same economic model as a product to treat more common diseases. Likewise, one technology might be able to help many people, but when different geographies come into play, reaching those patient populations becomes complicated—such that different partnership structures are still needed to deliver the right product to patients globally. These scenarios illustrate the value of flexibility and may call for different types of agreements with various small and large companies working in partnership to move technologies from the bench to the bedside.

Another participant discussed how biomedical researchers and companies may need to pivot midstream, during product development, to adapt to changing scientific or medical circumstances. She spoke of her experience with vaccine clinical trials where disease incidence was intermittent, and infections may be prevalent in different regions of the world at different times. The unpredictability of infectious disease, for example, can impact and re-shape how we understand patient needs, the market, and even the ability to carry out clinical trials.

As far as what this means for NIH, some participants maintained that proscriptive provisions in license agreements can stall efforts to advance products to patients or prevent technology commercialization from moving forward altogether. And others spoke about the value of adopting different, tailored licensing approaches depending on factors such as whether something is a platform technology, the stage of development, etc.

Finally, on a related note, one participant raised NIH's license application process. In her experience, NIH is one of the only entities that asks license applicants to propose full financial terms and provide detailed plans at the initial application stage. Other licensors take a more general, and perhaps more flexible, approach to discussing financials in the early stages. She offered that NIH's process is not required under the statute or regulations and encouraged the agency to explore flexibility and consider revising the application process. That could improve transparency, speed-up negotiations, and lower the barrier to entry for potential license applicants.

9. STAGE OF DEVELOPMENT

Throughout the workshop, participants discussed how the stage of a technology's development impacts patenting and licensing. While the agency most often licenses early-stage technology where there is a lot of uncertainty about what product (if any) may make it to market, the agency also licenses technology that is further along, for example, licensing an invention after preliminary safety or efficacy studies in humans have been completed. But when NIH licenses early-stage inventions, the goal is still to move those inventions along the developmental pipeline to be incorporated into products or services. And the workshop further addressed how NIH structures licenses and makes patenting decisions tailored to stage of development.

A. Importance of Staying Connected with Technology Over Time

Patenting and licensing decisions are not one-time, one-off decisions. The agency periodically revisits whether and how to patent a given technology and it structures license agreements with milestones and benchmarks to monitor development progress.[57] These and other mechanisms allow the agency to tailor patenting and licensing approaches depending on a technology's stage of development and this allows NIH to adjust its approach as inventions advance.

Workshop participants shared how NIH might stretch its current practices further. For example, one suggested NIH explore ways to influence not just how an invention is developed but how any products based on that invention are ultimately utilized. NIH could engage with other U.S. government agencies who interact with products and services for disease prevention, diagnosis, or treatment at the point of approval or adoption, like CMS, FDA, the United States Agency for International Development, or the Veterans Health Administration. There may be collaborative engagements across the government that could promote broader utilization. He also suggested NIH examine the experience of Advanced Research Projects Agency for Health (ARPA-H), as it is adding access-related focus areas that funding applicants may address.[58]

At the same time, several workshop participants urged NIH to carefully consider obligations that will run with an invention over its lifetime. As noted, when NIH licenses an invention to an early-stage startup, that technology could be handed off more than once for later stage development, manufacturing, distribution, etc. The terms NIH negotiates with the initial licensee need to be understandable, clear,

[57] *Supra* Sections 2, 3.B.
[58] *E.g.*, *Our Research*, ARPA-H, https://arpa-h.gov/research-and-funding#scalable-solutions (last visited Feb. 29, 2024) (scalable solutions focus area); *Advanced Research Projects Agency for Health (ARPA-H) Open-Office Broad Agency Announcement (BAA)*, SAM.GOV (Mar. 31, 2023), https://sam.gov/opp/caf109b75a0449418ead3630cef1915e/view (Open Office BAA Amendment No. 2 addressing scalable solutions focus area).

achievable, and definite for those later actors. Otherwise, terms in these licenses could ultimately suppress subsequent development and patient access.

B. Opportunities to Bring Technology Further Along

Several panelists variously addressed whether NIH might be able to further de-risk projects by carrying its own development work further or leveraging partnerships and other public sector institutions. This could fill gaps that are emerging (e.g., in gene therapy) and/or position the agency to attract more commercialization partners. And bringing certain technologies a bit further in development could increase the odds of successful commercialization of new, accessible products.

NIH already supports clinical trials, and one participant noted there may be certain technology areas where it is preferable for NIH to invest more in this later-stage development. That could position the agency to intentionally decide the "right time" to hand off a technology to the private sector, attracting more promising licensees. She mentioned university examples, like the Drug Innovation Ventures at Emory (DRIVE) program affiliated with Emory University,[59] where the university has invested in infrastructure to move therapeutics out of the university and further down the development continuum. This would, of course, require resources.

Other participants added that NIH could continue its work with creative public-private partnerships and incubators, to stay more directly involved with the development of its own technology over time. These avenues also help the agency move technology along to where more investors and licensees are interested.

Finally, one participant suggested that some types of inventions may better lend themselves to non-traditional approaches, while the traditional principles that have worked to develop and deliver new products to market will continue to be appropriate for other technologies.

C. Tiered Approaches

Recognizing that some technologies are further along when NIH licenses them, and that stage of development influences the risk and cost of bringing any product to market, NIH tailors license features—like scope and financial terms—depending on stage.[60] Some workshop participants urged NIH to explore other ways to tier its approach to licensing along a sliding scale.

D. Potential Areas for Further Exploration

Consider other sliding-scale or tiered approaches to licensing. Survey the existing NIH licensing portfolio, taking stage of development into consideration, and explore where additional tailored approaches to licensing could advance innovation, competition, and equitable access goals.

Explore promising opportunities to move certain technology further along. Review NIH programs to assess whether there are trailblazing technologies or unmet needs that could be more easily adopted if an early concept were proven further along the pipeline. If so, evaluate how NIH might continue its own research or engage in other novel partnerships to move those technologies further along before licensing.

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[59] DRIVE, https://driveinnovations.org/ (last visited Feb. 29, 2024).
[60] *Supra* Section 2.

10. ACCESS-ORIENTED TERMS

Workshop participants acknowledged that as R&D on a given technology progresses, and everyone learns more about what products might emerge, this may reveal access challenges that patients face and ways to optimize access and public health benefit. Several participants mentioned access planning clauses as a promising tool, among other contractual terms focused on public benefits. While these types of plans have been used, for example at some universities and public health foundations, participants generally noted that they have not yet been widely adopted.

A. Access Plans

Participants variously described these access plans as a means to proactively approach patient access concerns, as opposed to trying to solve any problems after-the-fact. The general concept can take various forms.[61] The basic idea is to identify commitments around issues like product availability and accessibility in a license—at a high level—with the parties agreeing to revisit those issues with more specificity as the product moves closer towards market.

One participant analogized these access plans to development plans that are also included in biomedical R&D licenses, in that both start out as a set of access-oriented principles the parties agree to and include an outline with milestones for how access planning will evolve over time. As research progresses through development milestones, the parties would also be expected to progress through access planning milestones.

For example, a license might require the licensee to submit a patient access plan to the patent owner when the licensee's product receives regulatory approval. The parties might designate a time to decide, jointly, where to seek regulatory approval once they know where the likely patient population(s) will be. They might sublicense to other manufacturers for markets that the licensee may not wish to pursue. Or the parties might agree to adopt pricing models, like cost-plus or tiered costs for different parts of the world, once there is more information about the likely patient populations and the cost of goods.

This participant also emphasized the need for enforcement provisions that would be triggered if a licensee failed to deliver on access-oriented milestones, as they would for development milestones. This could include consequences as severe as terminating a license, but there are many alternatives and also ways to proactively address gaps in access planning. For example, the licensor could pull-back the scope of a license, if the licensee does not plan to manufacture in certain markets, and start lining-up other developers or manufacturers for those markets.

Finally, here again, participants urged NIH to carefully consider obligations that will run with a license over its lifetime, and craft license terms—including access planning language—that are clear, feasible, and flexible. One participant mentioned the Coalition for Epidemic Preparedness Innovations (CEPI) as an organization that has tried to structure access planning obligations in an achievable way.[62]

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[61] One participant referred to her organization's work cataloging relevant agreements. *See Master Alliance Provisions Guide (MAPGuide®)*, GLOBAL HEALTHCARE INNOVATION ALLIANCE ACCELERATOR, https://ghiaa.org/mapguide-home/ (last visited Feb. 29, 2024) ("The MAPGuide® platform is a tool for accessing and exploring analysis of global health agreements, particularly those that seek to ensure equitable access to medical products.").

[62] *See* CEPI, https://cepi.net/ (last visited Feb. 29, 2024).

Socially Responsible Licensing at Berkeley

Dr. Laleh Shayesteh shared the experience of the University of California, Berkeley, which has included socially responsible licensing clauses in all its license agreements since 2010. Those agreements include humanitarian provisions that provide: if there is a humanitarian use for a licensed technology developed at Berkeley, and someone is interested in using the technology for that humanitarian purpose in a low- or middle-income country, the university will ask its licensee to issue a sub-license for that use or the university will issue such licenses itself. This applies to all types of technology, and Dr. Shayesteh reported it has been a successful approach and licensees have been receptive.

More recently, Berkley has started working with Universities Allied for Essential Medicines (UAEM) and the Medicines Patent Pool (MPP) on a program for affordable medicines plans. The university has a new template agreement for therapeutics, diagnostics, and chemicals patent licenses. If a licensee develops a product, once the licensee has FDA clearance, it will make a plan in coordination with Berkely to provide the product for people who cannot afford it, including U.S. and global populations.

Berkeley has taken this approach in several licenses already, and Dr. Shayesteh explained licensees have willingly accepted it. It is too soon to say exactly what impact this approach will have, because the university just started implementing it, and it takes many, many years from a patent license to a product being launched on the market. But Dr. Shayesteh expressed optimism that she would be able to report back in several years that these licenses have had a positive effect.

Sources: *Socially Responsible Licensing at Berkeley*; *Sample Exclusive License with Equity Template for Therapeutics and Diagnostic Fields*.

B. Other Patient Access and Public Benefit Terms

Patent licensing is a tool NIH uses so that the benefits of its work can reach people in the form of new products and services that improve their lives. But workshop participants also discussed other terms NIH uses to achieve public benefits beyond the launch of those products and services. These terms can include supplying back products or services developed during the license for use in further research, or terms can provide for indigent patient access programs, health education programs, or developing country access.[63]

There are other strategies for facilitating access to technologies, such as licensing to patent pools and special license models that are designed to increase the availability of NIH's technologies to licensees who might not fit the traditional model but who nonetheless can provide value by developing technologies. These include nonprofit licenses targeted to products related to neglected and tropical

[63] Kirby, *supra* note 4, at 11.

diseases, and startup licenses for companies that are less than 5 years old, have less than $5 million in capital, and have fewer than 50 employees.[64]

C. Potential Area for Further Exploration

Explore access plans for NIH patent licenses. Review how access plans are currently used in licensing and product development and the range of approaches that have been adopted by other public sector institutions, and consider whether there are similar approaches that might make sense for certain NIH IRP programs. Include consideration of monitoring and evaluation to understand the short- and long-term impact of these approaches.

11. TRANSPARENCY & DATA

A. Role of Transparency and Information Sharing

The NIH IRP publishes substantial information about technology transfer policies and practices, technology transfer statistics, active licenses, and broad impacts.[65] Workshop panelists offered perspectives about the role of transparency and this information sharing—from the importance of NIH taking credit for its contributions to providing the public and potential partners with information about the agency's technology and its approach to licensing. Conversations during the workshop also explored the utility of this information sharing and addressed where disclosure of other information could lead to improvements in public health.

Participants also acknowledged the need for balance, recognizing that when it comes to biomedical patent licenses and commercial development of products and services for disease prevention, diagnosis, or treatment—there are legitimate needs to maintain some information confidential. Relatedly, there are legal limits on what information the government can share.

As far as the values transparency can help deliver, participants variously discussed:

- ***Public awareness and support for NIH.*** Several participants argued that a motivated public with awareness of the technology NIH has developed can help the agency get ideas out into the world in a way that truly improves human health. And some participants connected the theme of transparency to that goal, suggesting the agency focus additional energy on taking credit for its contributions and ensuring the public can access information they need to push forward NIH's

[64] Kirby, *supra* note 4, at 15.
[65] *E.g.*, *Policy*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/policy (last visited Feb. 29, 2024); *Technology Transfer Statistics*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/reportsstats/technology-transfer-statistics (last visited Feb. 29, 2024); *Technology Transfer Metrics*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/technology-transfer-metrics, (last visited Feb. 29, 2024); *Active NIH Licenses and U.S. Patents*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/reportsstats/active-nih-licenses-and-us-patents (last visited Feb. 29, 2024); *HHS License-Based Vaccines & Therapeutics*, NIH TECHNOLOGY TRANSFER https://www.techtransfer.nih.gov/reportsstats/hhs-license-based-vaccines-therapeutics (last visited Feb. 29, 2024); *Top 20 Commercially Successful Inventions*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/reportsstats/top-20-commercially-successful-inventions (last visited Feb. 29, 2024).

ultimate goal of improving health.

- ***Accountability, building public trust.***
    - Participants likewise emphasized the value of demonstrating for the public that NIH is approaching patent licensing in a thoughtful way. One noted, for example, that the NIH Strategic Plan only makes brief, passing mention of technology transfer. But this is an important area of the agency's work, and they argued it is an area where NIH might articulate its technology transfer goals more prominently. They likewise urged NIH to be more data-driven in its approach to licensing agreements, encouraging the agency to let the public see efficacy in the agency's patent licensing. That also includes letting the public see that the agency adjusts if there's an approach to licensing that is not working well, or if there is something that could work better.
    - On a related note, some participants discussed the value of NIH making model forms and template agreements publicly available—which the agency already does.[66] However, participants also acknowledged limitations are necessary to preserve flexibility in negotiating agreements.

- ***Identifying best practices or those that should be avoided.*** Some participants flagged how information sharing can help the government and others identify best practices.

- ***Giving other institutions information to inform their own negotiations.*** Some participants spoke about how organizations—including research funders and small businesses—may consult NIH precedent or experience as a model in their own work.

- ***Helping match-up people who are working on similar technology.*** One participant noted transparency can also help people know the status of various technologies and which investigators and companies are working on related products. This information can be used to establish connections between those organizations and experts. She also noted that this information is often available to companies that are willing to purchase it, emphasizing value for the government and non-profit sector to collect and share where possible.

B. Data-Driven Decision-Making

Several participants also explored how NIH leverages data it has (or could collect) to study the downstream impacts of its patent licensing and inform specific approaches for the future. Gems of wisdom in the data may suggest specific approaches to optimize NIH's success. Here again, success can be measured a variety of ways—from product launches to meeting public utilization goals to supporting other economic growth like job creation.[67]

One participant encouraged NIH to look both internally and externally as it considers data-driven decision-making. First, he urged NIH to internally assess which technology transfer programs and approaches are most successful, and then allocate resources (including staff time and attention) to increasing those activities. For example, if the agency finds that collaborative research agreements like

[66] *See, e.g.*, *Resources*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/resources (last visited Feb. 29, 2024).
[67] *Supra* Section 3.

Cooperative Research and Development Agreements (CRADAs) are most likely to lead to FDA-approved products, the agency could devote more of its energy to finding CRADA partners and cut back on activities less correlated with success.

Second, looking outside the agency's walls, this participant also urged NIH to try and make technology transfer-related data available—in an aggregate or anonymized fashion—to, e.g., academics, non-profits, public sector organizations, and law firms. Alternatively, if appropriate anonymization is not possible, the agency might find ways to use an internal task force or other mechanisms to enable more data analyses. This way, NIH might leverage more expertise to, for example, assess what technology transfer approaches make the most positive impact on public health. This information and data could also help other organizations that conduct or fund R&D, themselves, know what works for the agency so that they have the opportunity to leverage that knowledge for themselves.

Some of this may require NIH to draw on or tap into other data sources. For example, one participant suggested the agency may need to partner with other parts of the government to get a sense of whether the products that emerge from NIH patent licenses enjoy broad uptake and utilization, and if so, where patients have (or may lack) access.

Finally, and on a related note, one participant argued for a trusted, neutral source to provide data about the costs and risks of pharmaceutical R&D and regulatory approval. One justification that is sometimes offered for high drug prices is that the costs of pharmaceutical development are high and there is a high risk of failure. However, to factor those costs and risks into broader conversations about drug prices, he argued it is important to work from accurate, relevant numbers and to put them in context.

C. Potential Areas for Further Exploration

Revisit how NIH shares relevant information and investigate what other information might improve public health. Review how the agency currently shares information, e.g., data, licensing terms, product development outcomes, success stories, and licensing opportunities; investigate how it currently advances successful technology transfer, increases patient access to biomedical technology, and/or improves public health; and explore areas to expand.

Explore new opportunities for data-driven decision-making to identify best practices.

12. LOOKING BEYOND PATENT LICENSING

While the workshop's main topic was patenting and licensing, many participants emphasized that NIH has many tools in its toolkit to promote dissemination of knowledge and innovation goals. Likewise, participants acknowledged that licensing is not the thing, by itself, that will deliver products to market and into the hands of patients. Technology transfer and biomedical product development are complicated, intertwined, iterative efforts. And workshop participants offered a range of other perspectives and ideas for supporting such efforts.[68] They also recognized that NIH may be limited in what is has the authority to

[68] Since several of the ideas discussed in this section were outside the formal scope of the workshop, there was not time for extensive exploration of these topics. As such, this reflects a brief summary. Complete consideration of these ideas and future directions is outside the scope of this report.

do, or to try. It may fall to other agencies or Congress to take certain steps, enabling novel arrangements to bring products closer to patients in a way that optimizes successful development and patient access.

A. Public-Private Partnerships

NIH participates in public-private partnerships (PPPs) focused on key biological problems or product development tasks that cannot be tackled by one group alone. These PPPs address unique challenges, and partners share expertise and resources, often in a precompetitive space, with the goal of reducing the time and cost to develop new medical interventions. PPPs often have joint governance, clear goals, and preestablished decision points. When those goals are met, the partnerships end; but the improved communication and understanding gained across organizations can also create the foundation for more partnerships and further innovation. Examples mentioned during the workshop include the Accelerating Medicines Partnership (AMP)—a collaboration involving NIH, FDA, not-for-profit organizations, and private-sector companies "to improve understanding of disease pathways, facilitate better selection of targets for treatment and identify platforms and processes to accelerate new and effective therapies to patients"[69]—and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership that was rapidly put in place to address the global COVID-19 pandemic.[70]

One participant offered that PPPs led by patient advocates can be very powerful. Some are exploring hybrid models where patient advocates raise money that can fund R&D in a specific area—creating opportunities for new therapies that change the lives of many patients but would never make enough money for industry stakeholders to make it worth their while. This is an area NIH could continue to build on.

[69] *See, e.g.*, *Accelerating Medicines Partnership (AMP)*, FNIH, https://fnih.org/our-programs/accelerating-medicines-partnership-amp/ (last visited Feb. 29, 2024); *Accelerating Medicines Partnership® (AMP®)*, NIH, https://www.nih.gov/research-training/accelerating-medicines-partnership-amp (last visited Feb. 29, 2024).
[70] *Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)*, NIH, https://www.nih.gov/research-training/medical-research-initiatives/activ (last visited Feb. 29, 2024).

Venture Philanthropy

Dr. Maryann Feldman gave a presentation about venture philanthropy, a new organizational hybrid blending the logic of both venture capital (VC) and traditional philanthropy. She explained how traditional philanthropy logic focuses on contributions and deploying funds to serve the greater public good. And the VC model involves features like a funder closely involved in managing the R&D process investing tranches of funding. Venture philanthropy bridges those worlds by pairing philanthropic funds with more active management of the bench-to-bedside translational process. It is a mission-driven and results-driven way to invest.

Dr. Feldman noted that a growing group of organizations dedicated to specific diseases are adopting this model; perhaps thanks to motivated patients and caregivers shepherding resources towards disease-focused research. Venture philanthropy brings together funds for specific R&D, critical time frames, and patient populations committed to progress by, e.g., volunteering as clinical trial participants.

As far as how venture philanthropy agreements are structured, Dr. Feldman highlighted a few unique elements. (1) Information sharing: She noted an emerging problem where academic scientists do not want to share their results or their reagents, explaining that venture philanthropy agreements may redirect that with sharing requirements. (2) Progress, oversight, and monitoring: These agreements often contain language against shelving technology, give the funder opportunities to intervene if a recipient is not moving fast enough, provide for site visits, and build in accountability through milestones. (3) Building teams: She also noted that venture philanthropists often do more than evaluate funding proposals, as they often actively review literature in an area with an eye toward building teams of experts that they think can solve a given problem.

Finally, Dr. Feldman noted academic scientists have reflected positively on this model, and they like being part of a community working towards a targeted cure. She suggested this as a model for NIH to consider, as well.

B. Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

NIH devotes $1.3 billion per year (3.65 percent of its extramural research & development budget) to supporting small businesses through the SBIR and STTR programs.[71] Workshop participants spoke about the value of the SBIR/STTR programs and some highlighted other NIH efforts that leverage the small business community. For example, the agency reaches out to SBIR/STTR recipients when it markets opportunities to license IRP technology, and workshop participants generally encouraged the agency to continue to expand that outreach.

[71] *Understanding SBIR and STTR*, NIH SEED, https://seed.nih.gov/small-business-funding/small-business-program-basics/understanding-sbir-sttr (last visited Feb. 29, 2024).

One participant, whose company has received an NIH SBIR grant, noted the NIH SBIR Technology Transfer (SBIR-TT) program.[72] He indicated the value of this program and referenced the NIH peer review process, which provides strong technical and business valuation of small business projects that are developing technology licensed from NIH. Another participant analogized this program to the so-called "CRADA babies"—which refers to "firms formed around a cooperative agreement with a government laboratory."[73] She discussed the transformative power of seed funding for early-stage companies that license NIH inventions.

NIH SBIR Technology Transfer (SBIR-TT) Program

This program encourages small businesses "to submit applications that further develop available technologies from the NIH Intramural Program and bring them to the commercial market." If selected for SBIR-TT funding, the small business is "granted a royalty-free, non-exclusive patent license agreement for internal research use for the term of and within the field of use of the SBIR award to technologies held by NIH with the intent that the [recipient] will develop the invention into a commercial product to benefit the public." The program also directs potential applicants and interested parties to the Technology Transfer Community website for the complete listing of NIH intramural technologies which are available.

Source: *Notice of Special Interest: SBIR Technology Transfer*, NIH GRANTS & FUNDING (Nov. 12, 2021).

Another workshop participant also noted that a company must be for-profit to apply for Small Business Program funding.[74] However, there are many non-profit companies interested in bringing new therapeutics or health products to market. She encouraged NIH to think about outreach, as those types of businesses may be eligible for other types of NIH funding or product development support, and she also suggested policymakers could loosen the eligibility criteria for Small Business Program funding.

Finally, participants who spoke about the success of the NIH Small Business Program further suggested that directing additional funding to the program could be transformational. Given that 24 NIH ICs provide funding to small businesses, they also noted there could be opportunities for NIH to collectively use some of that funding to strategically target diseases where there could be particular societal benefit.

C. Powering Partnerships with "Something More"

Several participants discussed how NIH and its partners are often looking for more than a bilateral, arms-length transaction that transfers a patented invention from the agency to a licensee. For the agency and

[72] *Notice of Special Interest: SBIR Technology Transfer*, NIH GRANTS & FUNDING (Nov. 12, 2021), https://grants.nih.gov/grants/guide/notice-files/NOT-NS-22-017.html.
[73] Maryann P. Feldman & Johanna L. Francis, *Fortune Favours the Prepared Region: The Case of Entrepreneurship and the Capitol Region Biotechnology Cluster*, 11 EUROPEAN PLANNING STUDIES 765, 781 (2003), https://www.researchgate.net/profile/Johanna-Francis/publication/228270474_Fortune_Favors_the_Prepared_Region_The_Case_of_Entrepreneurship_and_the_Capitol_Region_Biotechnology_Cluster/links/02e7e53aa1e4f96553000000/Fortune-Favors-the-Prepared-Region-The-Case-of-Entrepreneurship-and-the-Capitol-Region-Biotechnology-Cluster.pdf.
[74] *See, e.g.*, *Eligibility Criteria*, NIH SEED, https://seed.nih.gov/small-business-funding/small-business-program-basics/eligibility-criteria (last visited Feb. 29, 2024).

many of its partners—especially early-stage startups—they are often looking to exchange access to innovators, expertise, and other resources like specialized facilities. With the safeguards in place to make sure this is done in a way that serves public health goals, this can help move individual technologies forward and help strengthen the biomedical R&D ecosystem.

Relatedly, while patent licensing addresses some needs, it—alone—will not be the thing that gets a product to patients.

Clinical trial support.
Several participants variously spoke about NIH's support for clinical trials, which can be especially valuable in areas where clinical trials pose unique challenges for the efficient approval of safe, effective products. For example, one participant emphasized how NIH engagement has been critical in in the approval of treatments for rare diseases. The agency has helped fund the collection of natural history data which FDA uses in the approval of gene therapies where a placebo-controlled study would not work.

One participant noted that NIH does small, high-risk clinical trials very well—something that happens almost nowhere else. He also favorably mentioned NCI's Cancer Therapy Evaluation Program (CTEP) program[75]—a clinical trials network—and similar efforts like the Rare Diseases Clinical Research Network.[76] Relatedly, he mentioned the stories of some drugs that exist today because an NIH researcher used a compound off-label and that clinical work, in turn, laid the foundation for a new compound that goes after a more optimal target.

Another participant spoke to her experience with clinical trials for some infectious diseases like tuberculosis and Ebola. It can be challenging to connect with clinical trial participants in certain communities, and, where a disease is intermittent, that can compound the difficulty. Public sector institutions can help by supporting the development of clinical trial sites worldwide, where knowledgeable medical staff can develop trust and confidence in their communities.

Finally, harkening back to the point of transparency, one participant encouraged NIH to continue its efforts to improve the accuracy and completeness of ClinicalTrials.gov reporting.[77]

Working across the government.
In addition to clinical trial support, one participant explored how the whole of government can offer support. With COVID-19 vaccines, demand initially outstripped supply and the government stepped in to support manufacturing in ways that were essential. She noted other government programs, focused on HIV elimination, PrEP access, and Hep-C elimination plans, as other examples. These are tools that the whole government can use to help get a product to market and manufactured or sold at an affordable price.[78]

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[75] *Cancer Therapy Evaluation Program (CTEP)*, NCI DIVISION OF CANCER TREATMENT & DIAGNOSIS, https://ctep.cancer.gov/ (last visited Feb. 29, 2024).
[76] RARE DISEASES CLINICAL RESEARCH NETWORK, https://www.rarediseasesnetwork.org/ (last visited Feb. 29, 2024).
[77] *See, e.g.*, GAO Report GAO-23-105656, *NIH: Better Data Will Improve Understanding of Federal Contributions to Drug Development* (Apr. 4, 2023), https://www.gao.gov/products/gao-23-105656.
[78] *See, e.g.*, *Ending the HIV Epidemic*, CDC.GOV (June 9, 2023), https://www.cdc.gov/endhiv/index.html; Mitch Leslie, *White House Budget Includes Ambitious Push to Eliminate Hepatitis C*, SCIENCE (Mar. 10, 2023), https://www.science.org/content/article/white-house-budget-includes-ambitious-push-eliminate-hepatitis-c.

Capacity building.
Another participant discussed how capacity building and getting new biomedical technology distributed globally often turns on how a range of technologies (not just patent licenses) are transferred. This broader transfer can include things like know-how and human capital. She noted how NIH develops and shares its technology—including with private sector partners—in a way that equips them with additional know-how and further resources. She urged the agency to seek ways to ensure that the agency's immediate partners, including companies with patent licenses, carry forward a similar flow of information, for example setting up expectations for those companies to transfer more of their know-how and resources to build more national and global capacity.

13. CONCLUSION

This workshop grappled with undeniably complex questions at the intersection of science, human health, innovation, commercialization, competition, and public health benefits. Participants drew on their vast range of expertise, sharing ideas and perspectives on what helps NIH best fulfill its mission. And the day's conversations—including concrete ideas for further exploration—will help the agency amplify and expand its work toward ensuring equitable access to new products and services for disease prevention, diagnosis, or treatment.

14. APPENDIX A: CASE STUDIES

Case Study 1: Coronavirus Prefusion Stabilized Spike Proteins: A Mission-Based Patent Application Filing Decision

Amy Petrik, Ph.D., Senior Technology Transfer and Patent Specialist at the National Institute of Allergy and Infectious Diseases (NIAID), presented the case study.

Dr. Petrik offered an overview of how NIAID approaches patenting decisions. The process starts when an inventor submits an Employee Invention Report (EIR). These reports usually describe inventions that are at a very early stage in development. NIH has a responsibility to share the results of its publicly funded research in a timely manner. However, if inventors publicly disclose their inventions before a patent application is filed, a patent will not be available in most jurisdictions. This means that NIH typically makes patent application filing decisions at a much earlier stage of development—when there is significant uncertainty—compared to a private company that might develop an invention more extensively before filing a patent application or making a public disclosure.

Overall, Dr. Petrik noted that for a governmental research entity like NIH that does not itself develop products, the goal of seeking patent protection is to leverage the patent rights to attract commercial entities to develop a product based on an NIH invention. Developing clinical products is time consuming, risky, and expensive. A patent provides some incentive to prospective licensees, to justify investment in developing the product.

NIH's initial considerations, when evaluating an EIR and deciding whether to seek patent protection, include: (1) whether the invention is primarily useful as a research tool, in which case a patent will not be filed but instead the inventors will publish on the invention so that the scientific community can benefit from it ; and (2) whether filing a patent application on the invention is aligned with the Public Health Service's patent policy.

If the EIR meets those two criteria, a more detailed analysis is conducted, including:

- patentability;
- commercialization potential and pathway, including whether the invention is addressing an unmet public health need, whether the invention is superior to an existing technology, whether there is commercial interest in the form of a licensee/license applicant or a commercial collaborator working on a project related to the invention, and what challenges are expected as the invention is developed;
- whether the inventor plans to continue development of the technology, for example additional testing of an invention can de-risk it and make it more attractive to a potential licensee; and
- how the invention relates to NIAID's mission.

Dr. Petrik noted the agency engages a variety of experts in this process, including the inventor, subject matter experts (SMEs), technology transfer professionals, and advisory committees such as NIAID's Technology Evaluation Advisory Committee (TEAC). This committee is made up of NIH employees with relevant expertise, including investigators from the IRP, as well as individuals from various parts of NIH who have experience in product development or intellectual property. Other ICs within NIH have analogous committees that advise on patent filing decisions.

Dr. Petrik also emphasized that there are multiple decision points along the way to seeking patent protection or abandoning patent applications—for example the stages of international patent filing decisions when an invention can be re-evaluated. If NIAID decides to seek patent protection, it typically starts with a provisional patent application in the U.S. From there NIAID decides, in consultation with its TEAC and others, whether to continue to seek patent protection and in which jurisdictions. If there is a licensee at this point, its input is taken into consideration. In the absence of a licensee, NIAID considers where an eventual product might be used and manufactured. If patent applications are filed, technology transfer specialists will monitor and periodically reconsider whether the invention is still of interest to NIAID or relevant in the field.

Dr. Petrik described a case study example of this process: the patenting of stabilized coronavirus pre-fusion spike proteins. The story starts in 2016, following outbreaks of severe acute respiratory syndrome corona virus (SARS) and Middle East respiratory syndrome corona virus (MERS). Barney Graham, M.D., Ph.D., then Deputy Director at the Vaccine Research Center, led a team focused on corona viruses that included investigators at Dartmouth College and The Scripps Research Institute. Dr. Graham submitted an EIR describing the spike proteins stabilized in their pre-fusion conformation. The prefusion stabilized proteins were expressed more efficiently in cell culture. Additionally, animal studies indicated the prefusion stabilized spike protein elicited a better immune response relative to the native or natural spike protein. Dr. Graham and his collaborators wanted to publish a manuscript describing the technology, and the NIAID technology transfer office analyzed the invention to decide whether to seek patent protection. NIAID decided to file a U.S. provisional patent application based on the information that while coronaviruses (CoVs) were not an active threat to public health at the time, CoVs had emerged in the recent past and a vaccine against CoVs was not yet available.

After filing the U.S. provisional patent application, NIAID received no interest in licensing the patent application, which was not surprising, because no coronaviruses were posing a significant threat to public health then. In 2019, NIAID filed patent applications limited to the U.S. and Europe; despite the uncertainty around the invention's commercial potential, it was hoped these patents in these regions would be sufficient to incentivize development of the invention should a CoV become an active threat to public health.

In January 2020, however, when the public health threat of COVID-19 became clear, requests to license the invention poured in. NIAID adopted a nonexclusive licensing approach to allow multiple vaccine developers to use the invention in their proprietary vaccine platforms. The invention is now used in the COVID-19 vaccines authorized in the U.S. and many used abroad. It has had a positive impact on public health that could not have been imagined when the initial decisions about patenting were made.

Case Study 2: Nanomouse: A Camelid Antibody–Expressing Mouse Chimera

Michael Shmilovich, J.D., M.S., Senior Licensing and Patenting Manager at the National Heart, Lung, and Blood Institute (NHLBI), presented the case study.

To illustrate how NIH makes decisions about whether to file a patent application on a particular invention, Mr. Shmilovich introduced a case study: a research tool related to severe acute respiratory syndrome (SARS)-CoV-2. Mr. Shmilovich emphasized that when deciding whether to file a patent application on a particular invention, NIH balances its public health mission with commercial considerations and considers what policies and approaches may be best for disseminating that invention.

First, Mr. Shmilovich raised these overarching inquiries the agency considers when making a patenting determination:

- The agency will consider whether an invention is patentable under U.S. patent law, which includes evaluating:
    - Whether a technology is patent eligible,
    - Whether it is useful, and
    - Whether it is nonobvious.
- Second, the agency turns to policy criteria that are more customized to NIH, with a focus on assessing the best way to disseminate an invention and whether—on balance—NIH should file a patent on a given technology. In making this assessment, the agency will consider questions such as:
    - What is needed to incentivize innovation (including investment in further R&D, clinical trials, and regulatory filings)?
    - What is the best way to promote public access to the technology?
    - What would be the impact of blocking others from using the technology, if NIH does file a patent? What role does, or could, exclusivity play for the prospects of the given technology?

Mr. Shmilovich also noted that a patent—by definition—does not confer the right to use a particular technology; instead, a patent gives the patent owner the right to exclude others from using the technology. NIH does not usually file patent applications for research tools, because doing so could prevent others from using a potentially useful tool in creating other inventions. Instead, it has various contractual approaches to permit academic institutions and companies to use the tools on a non-exclusive basis (typically royalty-free or royalty-bearing, respectively).[79]

Mr. Shmilovich then described a case study to illustrate these points. In this case, the research tool was a mouse engineered to express camelid antibodies that was invented by Rafael Casellas, Ph.D., at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Camelid antibodies are a lot smaller than human or mouse antibodies—meaning they can bind epitopes that are not normally accessible and thus are potential therapeutics against hard to target viruses. However, for several reasons, it is difficult to create antibodies with therapeutic value that can be harvested and used from llamas, camels, and alpacas. Dr. Casellas cloned an antibody region from a camelid and inserted it into a mouse genome so that a mouse would express these camelid antibodies against new proteins it was exposed to.

[79] *See, e.g.*, *Research Tools Policy*, NIH SCIENTIFIC DATA SHARING, https://sharing.nih.gov/other-sharing-policies/research-tools-policy (last visited Feb. 28, 2024).

While this technology was deemed patent eligible, novel, and nonobvious, NIH did not file a patent. With such research tools, NIH typically does not seek patents as such protection is not necessary to provide an incentive for use or further R&D.

Although it did not file a patent on the nanomouse, NIH did patent a particular set of antibodies made using these mice that were specific to the SARS-CoV-2 spike protein. NIH is now seeking potential therapeutics and a partner to develop those antibodies into a drug.

Case Study 3: Partnering on the Use of Therapeutic Antibodies as Novel Treatments for Multiple Sclerosis (MS)

Sue Ano, Ph.D., Director, Technology Transfer Office, National Institute of Neurological Disorders and Stroke (NINDS), presented the case study.

Dr. Ano offered a case study about NIH's approach to outreach and encouraging commercialization partnerships for patented technologies developed by NIH intramural researchers. She discussed the use of anti-Tac antibodies, either alone or in combination with interferon beta, for the treatment of multiple sclerosis (MS). At the time of the invention under discussion, which arose out of the labs of Thomas A. Waldmann, M.D. at NCI and Bibiana Bielekova, M.D. at NINDS, the use of anti-Tac antibodies was known; some such antibodies had been developed into products and were already being tested against a wide variety of diseases. For example, a company called Protein Design Labs (PDL) was developing anti-Tac antibodies as a possible treatment for organ transplant rejection.

The NIH researchers reported their invention so that NIH could decide whether to pursue patent protection. After assessing many factors, the agency elected to do so. As Dr. Ano reiterated, the agency pursues patent protection to encourage appropriate partners to commercially develop new products or processes that can benefit global public health.

There are many ways the agency finds potential partners to develop technology, and these have expanded and evolved over the years. In this case, for example, NIH identified and reached out to companies and organizations—like PDL—known to be developing similar or complementary technology, to gauge their interest in pursuing commercialization. The agency also utilized other efforts, like publishing an abstract describing the invention, which lets potential partners know that the invention exists, and that NIH is actively seeking partners. This also provides an opportunity for interested organizations to learn more about the technology in question—and in this case, two parties requested more information based on the abstract.

Dr. Ano described how PDL submitted an application to NIH seeking an exclusive license for the development of these antibodies to treat MS. There is a long development timeline and many uncertainties associated with bringing therapies to market. Therefore, any interested applicants often request exclusive licenses so they will be able to invest in the necessary pre-clinical, clinical, and manufacturing processes required for product development and approval. It is also, often the case that only one applicant applies for a given NIH technology.

In this case, NIH evaluated PDL's license application and made a preliminary determination that PDL met the legal and regulatory requirements for an exclusive license—criteria which apply even if there is only one applicant interested in a license. Then the agency proceeded with the process of exclusive licensing by publishing a public notice of the agency's intent to negotiate an exclusive license. This public notice provides a period of at least 15 days for comments and objections, in advance of NIH granting a license, and it is another opportunity to make potential partners aware of a technology. In this case, a second company, Serono S.A., submitted a license application expressing its interest in an exclusive license to the same invention. This new license application went through the same process and evaluation of the same criteria as the earlier application.

NIH determined that both PDL and Serono would be appropriate licensees for the development of these anti-Tac antibodies. When these circumstances arise, NIH seeks ways to help all interested parties further develop the technology in question and maximize access to the technology for parties capable of translating inventions into FDA-approved products. In this instance, and with PDL's and Serono's agreement, NIH entered into co-exclusive licensing agreements, whereby each company was granted the same rights to develop the invention.

Dr. Ano concluded the case study by noting that, while NIH's partnering and outreach strategy was successful in terms of finding multiple partners for licensing and commercialization, the final outcome of the case was less successful. Serono ended up terminating its license, and only PDL developed the technology. It formed other partnerships to advance development and was eventually acquired. While the anti-Tac antibody made it to market and was approved for sale in the U.S. and Europe as an MS therapeutic, the product was associated with a complex safety profile and was voluntarily removed from the market not long after its launch.

Although the ultimate outcome in this case did not yield a product that stayed on the market for long, the process of identifying and evaluating potential licensees to develop the technology accomplished what was intended—maximizing partnership opportunities towards the development of products that could have a positive impact on global public health.

Case Study 4. Expediting Development of Adoptive Cell Therapy to Address Unmet Medical Need in Oncology

Andrew Burke, Ph.D., Senior Technology Transfer Manager, Technology Transfer Center, National Cancer Institute (NCI), presented the case study.

Dr. Burke first noted the frequent challenge of finding a good commercial partner to advance product development, as there is often a mismatch between the technologies a research institution like NIH has available and the market conditions at a given time. Yet he offered a case study where:

- NIH had the right technology at the right time, and the right market conditions drove strong commercial interest, and
- NIH was able to use the tools of technology transfer to facilitate maximum product development and attempt to address an unmet public health need.

Dr. Burke's case study involved developments in the field of adoptive cell therapy (ACT). With these types of therapies, the treatment process starts when immune cells—particularly T-cells or Natural Killer

cells—are isolated from the body. Those immune cells may then be genetically engineered in a lab to express a receptor that binds to the patient's cancer cells. When these cells are reinfused into the patient, they can bind to the cancer cells and lead to cell death.

Since 2017, FDA has approved six chimeric antigen receptor (CAR)–T cell products, a specific type of ACT, for the treatment of certain blood cancers, particularly leukemias, lymphomas, and myelomas. Given the responses that some patients with blood cancers have had following ACT, there is interest in exploring the use of ACT in more common solid cancers such as those of the breasts, lungs, or pancreas. This has proven particularly challenging for a variety of reasons, and there is significant ongoing research aimed at addressing challenges such as determining what type of receptors these cells should be engineered to express and how to target only cancer cells and not normal, healthy tissue.

NCI supports this research through its intramural and extramural programs, and the lab of Steven A. Rosenberg, M.D., Ph.D., at NCI has created foundational technologies in the field—including a portfolio of isolated T-cell receptors with broad potential application in treating cancer. The lab has worked with NCI's Technology Transfer Center to establish robust patent rights around this portfolio.

With this portfolio in hand, NCI has sought capable commercial partners who can broadly explore the application of NCI's inventions to clinical practice. NCI has used a combination of methods including academic publications; passive web-based marketing; and active marketing at conferences and meetings to make companies aware of what NIH has to offer. Based on this multi-pronged outreach effort, Dr. Burke summarized a series of more than 20 meetings, 15 confidential disclosure agreements, and 7 license applications related to these T-cell receptor inventions. This outreach has already generated 5 active commercial licensees, with another one anticipated in the near future.

However, Dr. Burke qualified this unprecedented level of commercial interest by pivoting the case study to address associated challenges. While in this case there was a significant, unmet medical need and multiple, capable applicants; these companies required a degree of exclusivity to justify the significant research and development and investment capital needed to bring a cancer therapy to market. Dr. Burke then summarized 37 CFR Part 404.7, which NIH must consider when deciding whether an exclusive license is appropriate, and he highlighted that NIH can grant an exclusive license only if it has determined (among other factors) that the "proposed scope of exclusivity is not greater than reasonably necessary."

Dr. Burke explained that while each company working with (or interested in working with) this T-cell receptor technology is addressing a common market need—and the same or similar patient population—the types of products they intend to develop are different. For example, the companies employ different types of cells and/or a different method of gene engineering in their commercial development efforts.

To craft licenses with a reasonable, balanced scope of exclusivity: NIH developed narrower, exclusive fields of use for each licensee, and it tailored the licenses to their specific commercial development approaches. This has also enabled NIH to grant licenses to multiple applicants and support parallel development efforts. Indeed, the agency has already been able to support 5 licensees—at various stages of development—who are exploring multiple, promising approaches to ACT. In this way, NIH also retains the ability to grant additional licenses to others that may develop new approaches in the future.

In closing, Dr. Burke noted this case illustrates how NIH can enhance the likelihood of products securing regulatory approval and ultimately becoming available to the public.

15. APPENDIX B: AGENDA

National Institutes of Health
Office of Science Policy

TRANSFORMING DISCOVERIES INTO PRODUCTS

MAXIMIZING NIH'S LEVERS TO CATALYZE TECHNOLOGY TRANSFER

July 31, 2023 (all times ET) – Webcast
AGENDA

9:00 – 9:10 AM **Welcome**
Lyric Jorgenson, PhD – Acting Associate Director for Science Policy, NIH

9:10 – 9:25 AM **NIH Mission and Workshop Objectives**
Tara Schwetz, PhD – Acting Principal Deputy Director, NIH

9:25 – 9:45 AM **Keynote**
Maria Freire, PhD – Principal, The Freire Group

SESSION 1: TECHNOLOGY TRANSFER PRACTICES AND LESSONS FROM NIH'S INTRAMURAL PROGRAM

9:45 – 11:15 AM **How NIH Chooses What to Patent and License**

Moderator: Daniel Reich, MD, PhD – Senior Investigator, Translational Neuroradiology Section, National Institute of Neurological Disorders and Stroke

Presenters:

- Amy Petrik, PhD – Senior Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases
- Michael Shmilovich, JD – Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute

Panelists:

- Margo Bagley, JD – Vice Dean and Asa Griggs Candler Professor of Law, Emory University School of Law
- Almesha Campbell, PhD – Assistant Vice President for Research and Economic Development, Jackson State University & Chair, Board of Directors, AUTM
- Peter Maybarduk, JD – Access to Medicines Director, Public Citizen
- Lisa Larrimore Ouellette, JD, PhD – Deane F. Johnson Professor of Law, Stanford Law School; Senior Fellow, Stanford Institute for Economic Policy Research
- Surekha Vathyam, PhD – Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases
- Richard Wilder, JD – Professor of Practice, UNH Franklin Pierce School of Law; Senior Scholar, O'Neill Institute for National and Global Health Law, Georgetown University Law Center; Consultant & Strategic Advisor in Law and Global Health, Wilder Consulting LLC

11:15 – 11:30 AM **BREAK**

11:30 – 1:00 PM **How NIH Identifies and Evaluates Licensees**

Moderator: Penny Burgoon, PhD – Director of Policy, Communications and Education, National Center for Advancing Translational Sciences

Presenters:

- Sue Ano, PhD – Director, Technology Transfer Office, National Institute of Neurological Disorders and Stroke
- Andrew Burke, PhD – Senior Technology Transfer Manager, Technology Transfer Center, National Cancer Institute

Panelists:

- Rena Conti, PhD – Associate Professor, Department Of Markets, Public Policy, And Law, Questrom School Of Business, Boston University
- Gillian Fenton, JD – Special Counsel for Innovation and Government Collaborations, GSK
- Matthew Miessau – Senior Associate, Epidarex Capital
- Michael Salgaller, PhD – Supervisory Technology Analysis and Marketing Specialist, National Cancer Institute
- Liza Vertinsky, PhD, JD – Professor of Law, University of Maryland Francis King Carey School of Law

1:00 – 1:45 PM **BREAK**

1:45 – 3:15 PM **How NIH Negotiates License Terms**

Moderator: Matt McMahon, PhD – Director, NIH Small Business Education & Entrepreneurial Development Office

Presenter: Tara Kirby, PhD – Director, Office of Technology Transfer, NIH

Panelists:

- Reid Adler, JD – Chief Corporate Development Officer and General Counsel, Vistagen
- Krishna Balakrishnan, PhD – Director, Office of Strategic Alliances, National Center for Advancing Translational Sciences
- Julia Barnes-Weise, JD – Executive Director, Global Healthcare Innovation Alliance Accelerator; Senior Consultant, Coalition for Epidemic Preparedness Innovations
- James Love – Director, Knowledge Ecology International
- Ameet Sarpatwari, PhD, JD – Assistant Professor of Medicine, Harvard Medical School; Assistant Director of the Program On Regulation, Therapeutics, And Law, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital

3:15 – 4:00 PM **Public Comments**

SESSION II: NIH'S ROLE IN THE BROADER BIOMEDICAL RESEARCH INNOVATION ECOSYSTEM

4:00 – 5:25 PM **Perspectives from the Public and Private Sector**

Moderator: Courtney Silverthorn, PhD – Associate Vice President, Science Partnerships, Foundation for the National Institutes of Health

Panelists:

- Maria Kefalas, PhD – Founder, The Calliope Joy Foundation; Professor, Department of Sociology and Criminal Justice, Saint Joseph's University
- Justin Mendoza, MPH – Executive Director, North America, Universities Allied for Essential Medicine
- Anji Miller, MSc, PhD – LifeArc and Skills Lead for Innovation Hubs for Gene Therapy, Senior Business Manager, LifeArc
- Maryann Feldman, PhD – Watts Endowed Professor of Public Affairs, Arizona State University School of Public Affairs
- Anthony D. Saleh, PhD – CEO, miRecule, Inc.
- Laleh Shayesteh, PhD, JD – Director of Intellectual Property and Administration, Office of Technology Licensing, UC Berkeley

5:25 – 5:30 PM **Closing Remarks and Adjournment**

Lyric Jorgenson, PhD – Acting Associate Director for Science Policy, NIH