NIH Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

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Background on Patenting and Licensing at NIH

Contents

Patent Overview[1]

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. What is granted is not the right to make, use, offer for sale, sell, or import the invention, but instead the right to stop others from doing so. If someone infringes on a patent, the owner may initiate legal action. U.S. patents are effective only within the U.S. and its territories and possessions.

What can be patented?

There are three types of patents: utility, design, and plant. This document focuses on utility patents, which may cover "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." For a patent to be issued, the patent application and invention it describes must meet four conditions:

- 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)
- "Not obvious," as related to a change to something 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 only an idea or suggestion. However, the subject matter that can be protected by patents is vast and varied.

Licensing Overview[2]

What is a 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. An exclusive license limits the use of the invention to a single group or entity, while a nonexclusive license allows for use by multiple parties. A license may be for patented or patent pending technology.[3]

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[1] 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 (May 2, 2023), https://www.uspto.gov/patents/basics/apply; *Patent Process Overview*, U.S. PATENT AND TRADEMARK OFFICE (Apr. 28, 2023), https://www.uspto.gov/patents/basics/patent-process-overview#step4.

[2] This material is adapted from *Licensing FAQs*, NATIONAL INSTITUTES OF HEALTH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/faqs/licensing-faqs (last visited July 28, 2023); *Licensing*, NATIONAL INSTITUTES OF HEALTH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/licensing (last visited July 28, 2023).

[3] 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 nonexclusive and facilitates the commercial development of biological materials without requiring that patent protection be obtained for every material.

What types of licenses are available?

Generally speaking, these are types of licenses available from NIH's intramural program:

- **Commercial Evaluation License:** Commercial evaluation licenses grant the nonexclusive right to make and use the technology for the purpose of evaluating its commercial potential. The licenses are for a limited number of months, and do not grant the right to sell the technology. Companies are subsequently then required to obtain one of the licenses below for further use and development of a technology.
- **Internal Use:** Internal Use licenses grant the nonexclusive right to make and use, but not sell, the technology for an extended period of time. Typical internal uses include compound screening and use of animal models.
- **Exclusive/Nonexclusive License**: Commercial patent licenses can be exclusive or nonexclusive and allow commercialization of the technology, under appropriate circumstances, pursuant to applicable statutes and regulations.

What general process does the NIH use when approaching patenting and licensing?

Upon receiving an invention report, Technology Transfer Professionals (TTPs) evaluate the invention to assess patentability and probability of commercial success of the invention, as well as the need for patent protection to ensure rapid and effective development of the invention. If indicated, NIH will seek patent protection for commercially valuable inventions and initiate this process by filing an application for a patent in the U.S. Patent and Trademark Office (USPTO). Typically, NIH will re-evaluate the patent strategy at multiple time points and will decide if patent protection continues to be the best intellectual property strategy for the invention.

A U.S. 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. After appropriate Technology Development Coordinator (TDC) reviews of patentability and commercial marketability, a patent application may be filed with the USPTO by one of NIH's contract patent attorneys. The Technology Transfer Professional (TTP) is responsible for the supervision of patent prosecution and for ensuring that all information and material are forwarded to the USPTO to assure that a patent may be awarded. Once the U.S. patent application is filed, the TTP will update the preliminary marketability and patentability analysis to determine potential commercial uses.

In general, where international filing is possible and one can reasonably anticipate commercial interest, the TTP may recommend at least preliminary filing under the Patent Cooperation Treaty 12 months after the U.S. filing date, to preserve international rights for an additional 18 months at modest cost. Upon NIH determination to exercise international patent rights, the contract attorney arranges for international patent prosecution. While patent applicants may check all the boxes to reserve the right to file in any country, the NIH typically focuses on patent protection in countries that have substantial markets or manufacturing infrastructure for biomedical products, such as the U.S., Australia, Canada, some European countries, India, Japan, China, and the Republic of Korea.

In parallel with the filing of a patent application, the TTP reviews the invention and its commercial potential, develops a licensing approach, and identifies potential companies to commercialize the invention. This is coordinated by the TTP and is a collaborative process requiring input from the inventors and the TDC. After formally advertising for potential licensees and promoting the technology to companies, the TTP may receive an application(s) for a license.

What is the process for obtaining an exclusive or partially exclusive license?

While Government regulations reflect a preference for nonexclusive licenses, exclusive licenses are available when appropriate to promote successful commercial development of a licensed invention. To obtain an exclusive license a company must complete a license application and submit the application to the appropriate NIH Institute or Center Technology Transfer Professional (TTP). Upon receipt of an exclusive license application, the TTP evaluates the license application using several criteria to determine if an exclusive license is warranted.[4] If NIH determines an exclusive license is warranted after review of the application, a notice of intent to grant the license is published in the Federal Register for a period of time, generally 15 days.[5] During this time the public may object to the grant of the license. After the notice and comment period closes, the NIH makes a final decision regarding the grant of the exclusive license(s).

What are the criteria considered when the NIH evaluates exclusive license applications?

The criteria the NIH uses when evaluating an exclusive license application are based on the requirements set forth in 37 CFR Part 404.7. In addition to favoring small, U.S. businesses, these criteria include whether:

1. Exclusive licensing serves the best interests of the public.
2. An exclusive or partially exclusive license is a reasonable and necessary incentive to promote the investment of risk capital to bring the invention to practical application.
3. Exclusive license terms and conditions are not broader than necessary.
4. Exclusive licensing will not lessen competition.

What terms are included in a license agreement?

NIH has developed several model license agreements that serve as the basis for license negotiations.[6] The business development plan submitted as part of the license application process serves as the basis for establishing performance benchmarks that are included in the license agreement. The Technology Transfer Professional works closely with licensees to monitor performance and to adjust benchmarks, when appropriate, to ensure successful commercial development of agency inventions. Licensees are required to report at least annually on their utilization of, or efforts to utilize, licensed patent rights. These reports are kept confidential, by law. The license is revocable for specific reasons, such as non-use of the patent or failure to comply with governing regulations or to satisfy public health needs.

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[4] *See* 37 CFR Part 404.7.

[5] This does not apply in the case of an application for an invention developed under a Cooperative Research and Development Agreement (CRADA).

[6] *Resources: Forms and Model Agreements*, NATIONAL INSTITUTES OF HEALTH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/resources (last visited July 28, 2023).

More information on these topics can be found, for example, in 35 U.S.C. §§ 207 and 209, 37 CFR Parts 404 and 501, the HHS Technology Transfer Policies and Procedures Manual,[7] *and the NIH Office of Technology Transfer website*.

[7] *HHS Technology Transfer Policies and Procedures Manual*, NATIONAL INSTITUTES OF HEALTH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/policy/hhs-technology-transfer-policies (last visited July 28, 2023).