The Emerging Imperative to Patent Academic Discoveries

The major goal of a basic medical scientist in academia is to make novel discoveries that advance his or her field. Importantly, our underlying objective is that these discoveries have a tangible impact on healthcare and the progress of medicine. This epitomizes "translational medicine." One way for scientists in the U.S. to help achieve that objective is to protect their discoveries by filing a patent with the United States Patent and Trademark Office (USPTO).

Leslie R. Gold

Many scientists do not patent their discoveries because they are unaware both of the advantages of doing so and of the process for filing. The purpose of this article is to provide a brief overview of the field of intellectual property (IP) law as it pertains to inventions. IP is defined as an "intangible" that can be bought, sold, or licensed. An invention is one type of IP: a new, previously undiscovered compound, method (e.g., to treat a disease), device, composition of matter, machine, manufacture, process, algorithm, or material that can be used for a specific purpose. It can include a novel use or improvement of another invention or solve a problem. An invention may be protected by a patent, which excludes others from making, using, or selling the property without authorization for 20 years from the date of filing within the U.S. (The length of time the invention is protected varies outside the U.S.)

Why Should Discoveries Be Patented?

There are two major reasons why discoveries should be considered patentable inventions. First, as stated above, since the purpose of medical research is to benefit humanity, we have a moral obligation to ensure that any clinical benefits from our discoveries are fully realized. Second, we can help to support our institutions through licensing fees after a patent is allowed and by royalty revenue streams once an invention is commercialized.

For an academic scientist to realize the clinical and commercial value of an invention, he or she must acknowledge that commercial development, including production of the product, pharmacokinetic and toxicity studies, and clinical trials, costs millions of dollars. These expenses usually can be borne only by the pharmaceutical industry. Without patent protection, any entity is allowed to exploit your discovery for commercial advantage. Importantly, pharmaceutical companies are interested in long-term commercialization through patent protection, since this limits the ability of others within their industry to compete directly with their products.

There is no reason not to protect your inventions, since doing so could reap benefits for you and your institution and promote clinical application of your discovery. There is absolutely no downside, but you must be aware of the rules, resources, and mechanisms of patent protection.

When Is an Invention Patentable?

Not all inventions are patentable. To be patentable, an invention must be novel, non-obvious to a person of ordinary skill, and practicable (useful for a particular purpose; not frivolous). Moreover, the inventor must be able to describe the invention in a way that would enable a person of ordinary skill in the art to make and use the invention without extensive research or experimentation.

One rule that scientists might find disturbing is that either written or oral disclosure of the details of an invention, even in a university newsletter, can cause it to be considered "prior art" and preclude the right to patent protection. However, although it is not the case in most countries, in the U.S., one can file a patent within one year of public disclosure. To ensure that exchange of scientific information can occur without compromising the patentability of an invention, confidentiality agreements should be in place among parties who, for example, transmit information or reagents for experimental purposes.

To obtain patent protection in different countries, one has to file separately in each

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country. The priority date in each subsequent country of filing of the same invention will be the same as the first filed application, but the subsequent filing has to occur within a year.

How Do I File a Patent?

Most universities have a technology transfer office (TTO) or industrial liaison office (ILO) that evaluates a discovery and determines whether it constitutes a marketable invention. The TTO or ILO subsequently guides the scientist through the filing process, including absorbing legal and filing costs. Generally, for consideration of whether the discovery is a patentable invention, the scientist submits a confidential disclosure, which consists of a description of the invention and the problem it solves. It is important to discuss advantages of the invention over others that have been described, and to reference those descriptions. It is also important to be diligent about keeping detailed, dated, and signed bound laboratory notebooks.

If the university TTO or ILO agrees that a discovery is patentable, it may initiate filing of a provisional U.S. patent application, to be followed within one year by a U.S. "utility patent" application. There is also the option of bypassing the provisional patent application and filing the utility patent immediately. The best strategy should be devised in consultation with the institution's attorneys. The university will also file a provisional patent application seeking foreign rights under the international Patent Cooperation Treaty (PCT). These filings contain the "claims" of the invention. Eighteen months from the effective filing date (EFD), the PCT patent is published in Europe. At this point, the invention is public knowledge. An examiner from the USPTO will accept or reject some or all of the claims usually within 19 months of the EFD. Rejections necessitate a rebuttal in which the claims are defended by the scientist and legal counsel.

The basic progression of milestones that apply to drug development is to obtain proof of principle through preclinical data (which may be contained in the patent) and then to generate interest of angel investors to license and finance development of the invention. This includes conducting the pharmacokinetic, toxicology, and stability studies to obtain approval of an Investigative New Drug (IND) application from the U.S. Food and Drug Administration (FDA). IND status is required for testing in humans through clinical trials (phase I–III). Once efficacy in humans is established, venture capitalists or pharmaceutical companies may be interested in licensing the technology. The length of time an invention has exclusive protection for commercialization is a key component of the value of the licensing agreement between the university/inventor and the licensor. Following FDA approval of a New Drug Application, the drug can be commercialized. The revenues (royalties and licensing fees) generated from commercialization of the technology, generally shared between inventors and the university, are subject to varied university technology transfer policies.

Interestingly, the Bayh-Dole Act, adopted in 1980, created a new IP management policy for federal agencies that is in part responsible for the increase in inventions and revenue streams in universities. This policy has enabled academic institutions to pursue ownership of inventions that resulted from federally funded research. This law has greatly contributed to the rise in commercialization of discoveries made in universities, at the same time spurring the economy.

University Patent Applications and Licensing Revenues Are Rising Rapidly

Patent applications and licensing revenues are increasing at a rapid pace and have become a critically essential university enterprise. The total revenue for licensing and royalties for all universities in the U.S. in 2009 was $1,782,113,228.[1] Many universities are reaping significant benefits from licensing fees and royalties.[1,2] This may seem surprising in light of the past disinclination of academic scientists to patent their discoveries and become entrepreneurial with their inventions.

In one example of this trend, the annual number of inventions by faculty at my institution, the New York University (NYU) School of Medicine, has doubled since 2000. In the same period, the number of new license agreements signed with companies per year has more than tripled, and over 24 products that are derived from NYU technology that benefit patients have reached the market. Moreover, the Association of University Technology Managers (AUTM) has reported that academic technology commercialization has flourished despite the global financial crisis. An AUTM licensing activity survey for FY09 showed that there were 658 new commercial products; 5,328 total licenses and options executed; 596 new companies formed; and 3,423 startup companies in operation.[3] I hope that this brief article has generated newfound interest,

inspiration, encouragement, and realization of the necessity for academic scientists to think in terms of patenting their discoveries for commercialization. There is no reason not to patent a discovery, and the rewards can be huge! To enable this process, universities have allocated funds to their TTOs and ILOs, which often have informative websites. Moreover, a wealth of information is available through workshops, seminars, and pharmaceutical company–sponsored collaborations. ■

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Notes and Resources

The information contained in this article was largely derived from the *Inventor's Handbook* published by the New York University School of Medicine's Office of Industrial Liaison: http://oil.med.nyu.edu/faqs-inventors-handbook. Further information can be found at:

- The National Institutes of Health website (http://intramural.nimh.nih.gov/techtran/ott_patent.htm) and glossary of terms (http://ttc.nci.nih.gov/glossary.php)
- The USPTO website (for searching issued and published patents): http://patft.uspto.gov
- The AUTM website: www.autm.net ■

References and Footnotes

[1]Anonymous. (2010). Licensing and Patent Activity, 2009 Fiscal Year. *The Chronicle of Higher Education* [Administration], Dec 17, 2010 (http://chronicle.com/article/Table-Licensing-Revenue-and/125729).

[2]Examples of universities with high licensing and royalty revenue in 2009 include Northwestern, with $161,591,544 in revenue (168 new patent applications); Columbia, $154,257,579 (202); New York University, $113,110,437 (50); Stanford, $65,054,187 (221); Massachusetts Institute of Technology, $66,450,00 (509); Harvard, $12,308,207 (175); and University of Pennsylvania, $11,658,000 (517).

[3]Association of University Technology Managers. (2010). *AUTM U.S. Licensing Activity Survey: FY2009.* Deerfield, IL

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