

TRANSLATIONAL TOOLBOX

Technology Transfer: From the Research Bench to Commercialization



Part 2: The Commercialization Process

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SUMMARY

Technology transfer (TT) encompasses a variety of activities that move academic discoveries into the public sector. Part 1 of this 2-part series explored steps in acquisition of intellectual property (IP) rights (e.g., patents and copyrights). Part 2 focuses on processes of commercialization, including the technology transfer office, project development toward commercialization, and licensing either through the establishment of startup companies (venture capital-backed or otherwise) or directly to industry. In private industry, TT often occurs through the sale of IP, products, or services, but in universities, the majority of TT occurs through the licensing of IP. (J Am Coll Cardiol Basic Trans Science 2017;2:197-208) Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Part 1 of this 2-part series explored steps in acquisition of intellectual property (IP) rights (e.g., patents and copyrights) (1). Part 2 focuses on technology transfer (TT), which encompasses a variety of activities that move academic discoveries into the public sector. Universities have a mission to ensure that their discoveries, inventions, and new science applications lead to useful products and services for the public. A university that is successful in TT has more opportunities for new research collaborations and funding and for the exchange of materials, information, and personnel with private industry, thus enhancing research opportunities for their faculty and students (2). In fact, faculty candidates are increasingly “interviewing” the technology transfer office (TTO) as part of their diligence process prior to choosing a home institution. Successful TT improves a university’s competitiveness with other academic institutions and the private sector to attract and retain top faculty and researchers. TT may produce income from

royalties and licenses that can be reinvested in new research and teaching programs, although a recent study by the Brookings Institution indicates that 84% to 87% of universities will not realize enough income to cover the costs of a TTO (3,4). In 2003, it was estimated that the average income per license was \$66,645, and that 43% of licenses earned no royalties at all (5).

Acceptance of federal research funding obligates the recipient institution to: 1) obtain written agreements from employees to report inventions and discoveries and assign them to the institution; 2) disclose inventions to the federal agency supporting the grant; 3) elect title (if they are going to) to the invention within 2 years; and 4) file a patent application within 1 year of election of title. Institutional obligations are summarized in **Table 1** (6,7). The U.S. government retains some rights to all federally funded inventions from universities and other nonprofit organizations, as summarized in **Table 2** (6,8,9).

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**ABBREVIATIONS
AND ACRONYMS****COI** = conflict of interest**CRADA** = cooperative research
and development agreement**IP** = intellectual property**MTA** = materials transfer
agreement**NIH** = National Institutes of
Health**SBIR** = small business
innovation research (grant)**SRA** = sponsored research
agreement**STTR** = small business
technology transfer research
(grant)**TT** = technology transfer**TTO** = technology transfer
office**VC** = venture capital

A successful TTO manages IP assets through knowledge of IP, licensing, and contract law; an understanding of business management and practicalities; and connections to outside industrial and investment communities (10). Table 3 lists the top 10 U.S. universities according to number of patents (11). The TTO must furthermore carry out its tasks within the overall institutional context in which it operates—resolving conflicts between its internal activities and the academic and public missions of the university.

THE TT PROCESS

DISCLOSURE AND PATENTS. TT begins when the inventor discloses an invention to the university (although proactive TTO engagement may start even earlier). Initial steps in the TTO are to determine whether the invention is patentable; whether to take

title to the invention and file a patent application; and the practical aspects of the patent application, such as whether funds are available for the application and how quickly the patent application must be filed. Figure 1 shows a simplified overview of the commercialization process.

Considerations regarding whether to file a patent application include whether the discovery is patentable; what the likely uses of a discovery are; whether a discovery has “sufficient” commercial potential; whether significant additional investment (research, development, regulatory approval steps, marketing, and so on) is needed; and (in some institutions) whether the discovery is something without significant commercial value, but nevertheless has potential for social impact through noncommercial channels.

The decision that an invention has “sufficient” potential commercial value for a patent application varies from university to university and depends on many factors. One consideration is the anticipated future royalty revenue of the license. Stanford’s Office of Technology Licensing, for example, reportedly often refuses to patent inventions that are not anticipated to eventually generate at least \$100,000/year in royalties (7). Another factor is whether a commercial entity is already interested in the discovery and is capable of developing it. Inventions arising under sponsored research agreements (SRAs) (i.e., grants associated with commercial companies) are often subsequently developed by the sponsoring company. In other cases, the inventor may know of commercial entities that are engaged in similar research or that have related or complementary products. A third

factor is how broad or enforceable the resulting patent is likely to be, and whether copyright is a more suitable IP tool. For instance, if the invention’s patentability is doubtful but includes copyrightable subject matter and is otherwise very marketable, it may be best for the institution financially and for the scientific community in general to immediately license the invention without patent protection. The National Institutes of Health (NIH) developed streamlined processes by which TTOs may license nonpatented inventions created with NIH funds to ensure that the scientific community will have expedited access to needed research tools (Table 4) (7,12).

Discoveries relating to materials that do not have significant commercial value but may be useful in noncommercial research are sometimes nonexclusively transferred to other parties via materials transfer agreements (MTAs) (13-15); NIH guidelines for MTAs are listed in Table 5 (12). Examples of discoveries that generally fall under MTAs include cell lines, monoclonal antibodies, reagents, animal models, growth factors, deoxyribonucleic acid (DNA) libraries, clones, laboratory methods, and some computer software. A historical example of such nonexclusive licensing is the recombinant DNA—or gene splicing—technology of Cohen and Boyer, for which Stanford University and University of California applied for joint patent in 1974. They then licensed this technology nonexclusively for a \$10,000 1-time payment per license. This technology is so widely used that the 2 universities became the leading earners of licensing income in the United States, with the license generating \$250 million in revenue between 1981 and 1997 (7,14).

FINDING A LICENSEE. Assuming a patent will be sought, the TTO will then partner with the inventor to market the patent to find a licensee (or even establish a new commercial entity to be the licensee) and, as is necessary in most cases, provide resources for technology derisking to increase its marketability. This process often begins as soon as a patent application is submitted, because patent application can take 2 to 5 years. It is generally in the university’s interest to involve commercial entities as early as possible in the development process to be able to recoup the costs of obtaining a patent as well as to support any additional research that is required before product development can proceed. For example, the research necessary to obtain market approval for new drugs typically takes about 12 years (16); thus, the right investor must have a long product-planning horizon to even consider investing in a university-based drug patent. Investing companies with appropriate planning horizons

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