JACC: BASIC TO TRANSLATIONAL SCIENCE
VOL. 2, NO. 1, 2017
ISSN 2452-302X
http://dx.doi.org/10.1016/j.jacbts.2017.01.003

TRANSLATIONAL TOOLBOX

Technology Transfer: From the Research Bench to Commercialization

Part 1: Intellectual Property Rights—Basics of Patents and Copyrights

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SUMMARY

Progress in medicine hinges on the successful translation of basic science discoveries into new medical devices, diagnostics, and therapeutics. "Technology transfer" is the process by which new innovations flow from the basic research bench to commercial entities and then to public use. In academic institutions, intellectual property rights do not usually fall automatically to the individual inventor per se, but most often are the property of the institution. Technology transfer offices are tasked with seeing to it that such intellectual property rights are properly managed and commercialized. This 2-part series explores the technology transfer process from invention to commercialization. Part 1 reviews basic aspects of intellectual property rights, primarily patents and copyrights. Part 2 will discuss the ways in which inventions become commercialized through startup companies and licensing arrangements with industry players. (J Am Coll Cardiol Basic Trans Science 2017;2:85–97) © 2017 The Authors. 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/).

Curiosity and hope of reward spur innovation. Both are satisfied when inventions and innovations realize market potential in the form of new products or services. The inventor reaps rewards by being able either to bring the invention to life through personal engagement, or by granting another entity the permission, or license, to do so. These simple concepts are so important for fostering the technological and industrial development of a nation, that the Founding Fathers codified them into the first article of the United States Constitution, which gives Congress the power "to promote the progress of science and the useful arts by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries (1)." Such "intellectual property (IP) rights" are secured mainly through patents, trademarks, copyrights, and trade secrets.

The exploitation of basic science discoveries in order to produce commercially viable technological and therapeutic innovations is critical for medical progress. Academic centers have increasingly been a major source of inventions and innovations (**Figure 1**), with 1 report indicating that the number of commercial licenses and startups launched out of academic centers nearly doubled over a 10-year period (2). With the exception of the years of economic recession between 2008 and 2013, annual growth in total research and development (R&D) in the United States has routinely exceeded growth in the gross domestic product, and in

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All authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC: Basic to Translational Science* author instructions page.

Manuscript received January 9, 2017; accepted January 9, 2017.

JACC: BASIC TO TRANSLATIONAL SCIENCE VOL. 2, NO. 1, 2017
FEBRUARY 2017:85–97

ABBREVIATIONS AND ACRONYMS

AUTM = Association of University Technology Managers

FDA = U.S. Food and Drug Administration

IP = intellectual property

R&D = research and development

TC = technology center

TTO = technology transfer office

USPTO = United States Patent and Trademark Office

2013 was recovering to pre-recession levels (3.2% vs. 2.2% for R&D and gross domestic product, respectively). In 2013, total U.S. R&D expenditures exceeded $456.1 billion (3). Five sectors in the United States are responsible for most R&D performance: chemical manufacturing (including pharmaceuticals), computer and electronics manufacturing, transportation manufacturing, information technology, and professional, scientific, and technical services (including scientific R&D services). Health care innovations include chemical manufacturing, information technology, and scientific R&D, and occupy a prominent place in total U.S. R&D (3).

This 2-part series will review steps that take an invention, process, or innovation to commercialization. Part 1 will discuss the evolving relationship between academic R&D efforts and federal law, and describe important concepts in ownership and protection of intellectual property. Part 2 will describe "technology transfer" from nonprofit research institutes such as universities, that is, practical ways by which innovations then become commercialized, in more detail, through startup companies and license deals with incumbent, mostly for-profit, market players.

TRADE SECRETS AND PATENT LAW

IP rights developed historically via 2 significant routes: trade secret law and patent law. "Trade secrets" are innovations, processes, and specialized knowledge developed within a business and kept confidential (e.g., Google's search algorithms). Although trade secrets are not generally considered "property," trade secrets are nevertheless part of a business's armamentarium in achieving competitive—and oftentimes critical—advantages in the marketplace (4), and employees are held to an obligation to not divulge trade secrets. Of note, the 1851 English case of Morrison and Moat that confirmed this obligation and heavily influenced U.S. law involved a medical product (5). Morrison and Moat were sons of the founders of a company that developed and marketed medicines created around a secret recipe. When Moat left the company, Morrison was able to obtain a legal injunction to prevent Moat from selling a medicine that was made using the company's secret recipe (6,7).

Patent law, on the other hand, grew out of ancient systems that granted exclusive privileges or monopolies for enterprises. Monopoly grants are at least as old as ancient Egypt. In contrast with trade secret laws, which applied to knowledge, monopolies applied to trade and manufacturing, and were often owned by the government (e.g., the "king"). Licenses developed as means of extending monopoly rights to exclusive groups, either as a reward for service (a "royal favor") or in return for compensation to the crown ("royalties"). Patents evolved as a way for an inventor to deny others the right to take advantage of their invention, by denying them the right to manufacture the invention or to license it. This motivated the inventor to share his or her invention with society without fear.

Before World War II, almost all R&D in the United States was conducted in federal facilities by federal employees. Government policy generally made all patents from such work available to the general public in order to encourage product development (8) because the public had paid for the research through taxes. Following the war, the United States federal government remained the single largest source of funding for R&D in all market sectors in the country (8). In the face of a rapid growth in technological advancements, the government increasingly relied on contractors in the form of private companies, universities, and nonprofit organizations for such R&D work, particularly in the areas of defense and health care (9). The use of government facilities to carry out R&D dramatically declined, but the government nevertheless remained a huge contributor to R&D through federal research grants, salaries, and other contributions.

Basic research currently accounts for about 18% of all U.S. R&D performance, with universities and colleges accounting for about 51% of all U.S. basic research. The federal government is still the single largest funder of basic research in the United States, accounting for about 47% of all such funding in 2013. By contrast, the business sector performs the lion's share of applied research in the United States, accounting for 56% of the research and supplying 51% of the funding. In addition, the business sector performed 88% of all technology development in the United States in 2013, and supplied 81% of the funding (3).

Until the latter half of the 20th century, the government had few policies to encourage the public use of the huge reservoir of R&D it had amassed. No overall established polices or methods moved ownership of inventions or ideas arising from government contractors or grantees to private or commercial entities who were better equipped to develop some useful purpose or product from the research; there was also no consistent method to license government-owned inventions or patents to private enterprise for development. Methods that evolved for obtaining such ownerships or licenses thus varied widely, in some cases being governed by federal law

(such as with the Department of Energy), and in others governed by the policies of local agencies (such as with the Department of Defense).

Efforts to bring uniformity to the federal patent system and to promote the more robust transfer of government R&D to private entities were initiated in 1963, when President Kennedy issued a memorandum acknowledging the federal government's responsibility to see that inventions created under government sponsorship were developed for the public good (10). Memoranda from Presidents Kennedy and Nixon, later codified in federal law, established that many private contractors would retain exclusive rights to inventions and developments made during their partnership with the government in all but a few situations (11). These memoranda required the private contractor to bring the invention to the point of practical application within 3 years or risk losing the exclusive license from the government, and they also broadened the authority of agency heads to grant greater rights to contractors (12).

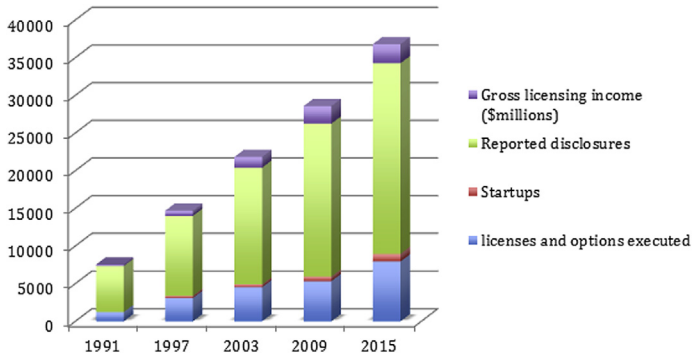
Despite these actions, the number of unlicensed (and therefore unused) government patents continued to grow. To further encourage commercialization of government-partnered innovations, Congress passed the Bayh-Dole Act of 1980 (13) that with a few exceptions allowed the funded entity to retain title to any invention created as a result of government contracts and grants. The scope of the act was extended in 1983 under President Reagan, although the government retained so-called "march-in rights" to reclaim the titles to inventions if the contractor did not take effective steps to commercialize the invention within a reasonable period of time (14). One concrete effect of the enactment of Bayh-Dole in 1980 is that the U.S. government currently takes title to virtually no inventions created by government contractors and grantees (8), although it continues to be the single largest sponsor of all R&D in the nation (3).

If the government does not hold the patent on ideas and inventions developed under government-partnership funding, who does? There is a distinction between ownership of an innovation and having access rights to it (i.e., permission, or license, to exploit it). The Bayh-Dole Act gave research institutes ownership of patents resulting from federally funded research. But since research institutes' core "business" is teaching and conducting research, they generally commercialize such IP assets by granting access rights to (mostly) for-profit commercial entities by way of a license—while in most cases retaining ownership of the underlying IP.

A critical element of product development begins with patent protection and ownership. The development of a drug or device is both risky and expensive. Achieving marketing approval for drugs requires an average of 12 years (15), and for medical devices about 7 years (16). Fewer than 1 in 10 putative drugs that survive preclinical testing make it all the way through to U.S. Food and Drug Administration (FDA) approval, at direct costs that are estimated at $1 billion per drug, and growing (15). Forbes estimates that the total cost of bringing the drug to market is about $5 billion if total drug-approval failure rates and development costs of failed drug candidates are taken into account (17).

Once approved, it is relatively easy for other manufacturers to recreate a drug or device and generate profits without having undergone the expense of the development and regulatory approval steps. Without the protection of exclusive rights to the product and the ability to recoup development costs, there is little incentive for commercial manufacturers to pursue new therapeutics. IP rights, principally in the form of patents, protect a developer's rights to prevent or stop another enterprise from copying the product, or else allow the developer to command fair compensation for the permission—or license—for others to do so. Such licenses are especially critical to academic institutions. Universities and colleges generally do not commercially develop nor do they manufacture or sell such products. Rather, they must attract private manufacturers or investment bodies such as venture capital enterprises. The main attractions for such private entities

FIGURE 1 Growth in Disclosures, Startups, Executed Licenses and Options, and Reported Gross Licensing Incomes 1991–2015



Statistics are from the Association of University Technology Managers FY2015 Licensing Survey, available at: http://www.autm.net/resources-surveys/research-reports-databases/licensing-surveys/fy2015-licensing-survey/. The survey represents 169 universities, 31 hospitals and research institutes, 1 third-party technology investment firm, and 1 national laboratory.

are the strength of an academic institution's IP protection and the reputation of the researchers behind the relevant innovation: most critically it is the quality of research and the commercial opportunity the innovation addresses.

The transfer of technology from the academic to the private sector can happen in several ways: 1) through publication of innovations to the general public without taking further measures of a commercial nature; 2) through sponsored research agreements with private industry; and 3) through the formation of startup companies. The latter 2 routes involve the granting of access rights to IP in the form of licensing or an option to license (where the research institute retains ownership over such IP) or, rarely, assignment of ownership to such IP rights.

The Bayh-Dole Act of 1980 and the Bayh-Dole regulations that flowed from it form the basis of the current framework for technology transfer at academic institutions to this day. The regulations give universities the right to claim ownership of global patents to inventions created under U.S. Government grants and contracts and require that: 1) university employees report to their university the development of any inventions arising out of a government grant or contract, and inform the university of any public disclosures or sales of such inventions; and 2) that the university disclose to the government funding agency whether the university is going to elect to take title to the invention and apply for patents. If a university elects not to take title, the government agency has 60 days after being informed of the invention to determine whether the agency will take title. The National Institutes of Health developed Interagency Edison (iEdison) as a tool to allow government grantees and contractors to report government-funded subject inventions, patents, and utilization data via the web to the government agency that issued the funding award (18).

It should be emphasized that the government does not require that an inventor assign title of their invention to their university. Similar to rules regarding trade secrets, however, most all universities do require such assignment as a condition of employment, although there are some exceptions, and it behooves an inventor to be familiar with the specific requirements of their home institution (**Table 1**). If both the university and the government agency waive title, the inventor may personally claim the patent (19,20).

Clearly, if an academic institution perceives that an invention may be valuable, then it would opt to take title to it. However, they will usually license those rights exclusively and under certain business terms to the startup company or incumbent market player engaged to do product development. In many cases, universities will take equity in a startup company in lieu of upfront license fees (cash) as partial consideration for the license, in order to preserve cash flow for the fledgling startup and also to enjoy equity-related upsides such as dividends or equity payouts. In 2001, the Association of University Technology Managers (AUTM) found that universities had executed at least 3,282 licenses and options, received $852 million in income from licensing fees, and held equity in 70% of the 494 startup companies that were formed in that year around university-licensed technology (21). The 2014 AUTM survey indicates that these numbers continue to grow, with 5,435 licenses executed (representing a 4.5% increase over the previous year), 549 licenses including equity (an increase of 17% over the prior year), 914 startup companies formed (an increase of 11.7%), and 965 new commercial products created (an increase of 34.2%) (**Figure 1**) (22).

The Bayh-Dole Act of 1980 applies only to inventions that arise during the course of government-partnered R&D, which accounts for the majority of university inventions. However, the technology transfer processes developed in response to the Bayh Dole regulations generally inform most university policies and procedures with regard to all inventions created by their employees in the course of their employment. Most universities have created technology transfer offices (TTOs), to source innovations, manage IP protection, provide commercialization-promoting resources (such as gap funding programs, access to business savvy mentors and entrepreneurs as well as regulatory consultants, connections to industry and investment bodies, etc.), and to negotiate and execute licensing deals. In the course of reviewing an invention (and whether the university will claim title to it), the TTO will determine whether an invention can likely be patented or copyrighted.

INTELLECTUAL PROPERTY RIGHTS: TRADE SECRETS, PATENTS, AND COPYRIGHTS

TRADE SECRETS. In the course of a business, information, innovations, or processes may be developed that the owner keeps confidential and that give the business competitive advantage in the marketplace—a "trade secret." The owner is not required to have a patent to acquire property rights over information that is thus deemed to hold "independent economic value" (5). The holding of intellectual rights to such information and processes depends instead on the care the owner takes in protecting the information,

TABLE 1 Possible Exceptions to Automatic Patent Assignment at a University

- The inventor is a student at the university, but not employed by the university, and did not receive any direct support from the university regarding the invention.
- The inventor is an employee, but the invention was developed entirely on the employee's own time, did not involve the use of any university resources, and the invention is not related to university business, or to any actual or demonstrably anticipated research or development.

innovation, or process from unwanted disclosure. The owner can legally disclose the existence of such things to anyone they want, but they are then virtually powerless to prevent others from freely using them to their own advantage. If disclosure of such materials occurs because of a "morally offensive breach"—for example, an employee of the company discloses the secret against the owner's wishes—the owner may have legal recourse against the employee who disclosed the information. However, the owner does not have legal recourse against others who use the material once it is disclosed (**Table 2**). Secrets, once told, are no longer secrets. Trade secret law does not apply to information, innovations, or other materials that are readily deducible or obvious. Furthermore, trade secret law does not protect the owner against independent development or "reverse engineering" by others of a similar or identical innovation (5).

PATENTS. Patents are the instruments by which inventors retain for a limited period of time the exclusive rights to "exclude others from making, using, offering for sale, or selling" the invention in the Unites States, or "importing" the invention into the United States (23). Critically, they do not grant the owner of the patent the right to commercially exploit the invention. It is in fact possible for a patent owner to be prevented from using their invention by another patent.

Take the following example:

Inventor A patents a kind of house paint that not only looks great, but kills carpenter ants. Both properties are mentioned in the patent application claims. Inventor B wants to patent a new use for the paint, to kill hornets. The patent application fails, because it does not meet the requirement for non-obviousness; the paint's ability to kill hornets could reasonably be expected, based on its ability to kill ants. Inventor C accidentally discovers that hair grows wherever the paint contacts human skin. Inventor C is able to patent the use of the paint as a treatment for baldness, because it is an unanticipatable claim that does not rely on the invention's expected properties, either as paint or as an insecticide. However, Inventor A can exclude Inventor C from manufacturing the compound until Inventor A's patent expires and Inventor C can exclude Inventor A from marketing his paint as a baldness cure (which Inventor A would like to do since the baldness market is much stronger and less competitive than the market for house paint). Inventor A could seek a license from Inventor C to market the new use, or Inventor C could seek a license from Inventor A to manufacture the paint. Once each inventor's patent expires, they each can proceed with plans to manufacture and market the paint as a baldness remedy without a license from each other.

Patent laws are nation-specific, and inventors must apply for a separate patent and pay separate fees in each nation in which a patent is desired. Patenting rights can be pursued in multiple countries at once through a single application if filing is done in accordance with applicable international treaties, agreements, or conventions (24). However, a nation-specific application or validation of the patent will always be eventually required. This discussion will focus on U.S. patents.

What innovations qualify for a patent? In the United States, patents can be issued for any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" (25), with the exception that the Atomic Energy Act of 1954 excludes inventions useful solely for the utilization of nuclear material or atomic energy in an atomic weapon (26). In order to qualify for a patent, an innovation must be useful, novel, and non-obvious.

Usefulness. It is key that an invention be "useful," meaning that there is a useful purpose and that the invention is operational. If a machine does not perform its stated and intended purpose, it will not be issued a patent. A patent also cannot be issued for an idea or suggestion, and a complete description of the object or machine for which a patent is sought will be required. A patent is, in fact, a teaching document; in exchange for the government granting exclusive rights to the patent owner(s), they are expected to provide a full description and instruction to the public regarding the purpose of technology and how to build it. The description must be in sufficient detail that a person skilled in the art could build the innovation and produce at least 1 of the results claimed for it. The patent applicant need not have actually built or produced a marketable product, however.

Patent law excludes the issuance of a patent for a law of nature, physical phenomena, and other

TABLE 2 Characteristics of Patents, Trade Secrets, and Copyrights

	Patents	Trade Secrets	Copyrights
Registration and protection of IP rights	Required to protect IP rights	Not required: protection is depending on owner's ability to keep a secret	Not required: the material existence of the item is proof enough of copyright
Owner's recourse for infringement	Can take action to prevent marketing of the invention	Can take action against the entity that disclosed the secret, but cannot prevent others from using it	Can take action against the user after registering copyright
"Fair use" exceptions	Not allowed	N/A	Allowed for limited specified uses without the author's permission. Examples include use to criticized the original work, report the news, to teach, for scholarship, for research, and for other uses that might meet exceptions
Eligible innovations	New process, machine, manufacture, or composition of matter, or new and useful improvement thereof	Information and processes that are kept confidential by the owner and that give the business a competitive edge in the marketplace	Creative expressions including fiction, nonfiction, music, paintings, choreography, architecture, certain computer software
Requirements	Must be novel, useful, and non-obvious	Must be kept confidential by the owner and/or their employees	Must be set down in some tangible medium of expression
Exclusions	Cannot patent laws of nature, physical phenomena, or other abstract concepts, or inventions solely for the utilization of nuclear material or atomic energy in an atomic weapon		Cannot copyright ideas, procedures, processes, methods of operation, concepts, principles, or discoveries
Duration of protection	Generally 20 yrs from time of registration; may be extended in certain circumstances	Until secret is disclosed	Generally 70 yrs beyond the life of the creator; for works copyrighted before 1978, the total term is 95 yrs

IP = intellectual property.

abstract concepts. Furthermore, in order for an invention to be patentable, it must be novel and non-obvious.

Novelty. To meet the novelty requirement, an invention cannot have been previously invented, have a patent application already filed, or be known to others or otherwise available to the public anywhere in the world. This means that the invention cannot have been described in a printed publication, be in public use, be on sale, be on public display, or otherwise be available to the public before the effective application filing date. It is critical for academic researchers to appreciate that, according to the United States Patent and Trademark Office (USPTO), "otherwise available to the public" includes types of disclosures such as "an oral presentation at a scientific meeting, a demonstration at a trade show, a lecture or speech, a statement made on a radio talk show, a YouTube™ video, or a website or other online material" (27). Any of these activities before filing a patent application destroys the "novelty" requirement for an invention and renders it unpatentable. This requirement is specific and far-reaching. For example, merely describing the invention in a grant application, if it is done in sufficient detail such that someone skilled enough could duplicate it, may violate the novelty condition if the grant is disclosable under the Freedom of Information Act (20,28). However, the majority of grants do offer confidentiality so that merely applying to them isn't treated as a novelty-destroying public disclosure by TTOs.

In the United States, a researcher has a 12-month grace period to present a patent application after such a disclosure. Other countries are less generous. In Japan, the grace period is 6 months. In Europe, there is no grace period. Fortunately, if a patent application is filed in any country subject to the 1967 Paris Convention for the Protection of Industrial Property, such publication no longer violates the novelty requirement in any other Convention countries as long as patent applications are pursued individually in the other countries (29).

Non-obviousness. Even if an invention is novel and useful, it may not be patentable if it is not sufficiently different from existing methods or materials to make it nonobvious to someone skilled in the area and viewing the available literature. As a practical matter, usefulness is rarely if ever an issue for patentability because most innovations are useful one way or

another. Novelty issues are much more common, but they are usually easy to identify if properly searched for, because the answer is binary: Does a single prior art source describe the invention? The answer is either yes or no. Non-obviousness, on the other hand, is trickier to identify because judging non-obviousness of an innovation is commonly done against a combination of elements from several different sources. Determining obviousness is more nuanced and perhaps even subjective—and hence more prone to interpretation and increased uncertainty.

Computer software: special considerations. Computer software present special complexities with regard to patents (30). "Software" generally refers to computer source code, object code, procedures, and any documentation that contributes to the operation of a computing device, its performance, or output. Although some computer software (e.g., that which contributes directly to the operation of the computer itself) might be patentable, in general, computer software programs have been considered "creations in the area of thought" (4) or the expression of an abstract idea (31). As such, software can be protected by copyright (see below) but is often not patentable, although the rules of patent eligibility for software are under frequent re-examination by the USPTO.

Patent duration. Patent laws clearly present conflicts with the general principle in the United States that monopolies are bad for a free marketplace. Antitrust legislation in the United States limits monopoly power to preserve market competition. Antitrust laws and patent laws exist in tension with one another: antitrust legislation condemns monopoly power, whereas patent law promotes innovation by granting certain monopoly powers. One way in which conflicting aims of these laws are managed is by limiting the duration of patents.

For patents filed after 1995, the duration of a patent is 20 years after the patent application is filed (32). This poses some challenges for many medical innovations. In the drug industry, for example, the FDA process for marketing approval for a new drug after patenting takes an average of 12 years (15), thus limiting the effective marketing period before patent expiration to 5 to 8 years, after which other companies are allowed to create chemically identical or equivalent "generic" drugs and market them.

Once other companies are allowed to produce competing versions of an innovation, the market value often falls dramatically. Pfizer experienced a 19% decline in total first quarter total company sales revenues after Lipitor (atorvastatin) lost patent in 2011, almost solely due to the decline in sales of Lipitor (33). Similar large-scale declines in total company sales revenues were experienced after patent losses by Eli Lilly: when Prozac (fluoxetine) lost patent in 2002 (9%) (34) and again after Zyprexa (olanzapine) lost patent in 2011 (73%) (35). When Merck lost patent for Pepcid (famotidine) in 2000, company revenues dropped from $775 million annually to $110 million (33).

Patent extensions. Patents can be extended beyond 20 years under certain circumstances, and many examples can be found in the drug patenting process. The Hatch-Waxman Act of 1984 recognized that the FDA approval process held up companies' abilities to market their drugs during the patent period, and allowed patent extensions to compensate for delays in the approval process. However, the entire patent extension is limited to 5 years no matter how long the approval process takes. Furthermore, the maximum total amount of patent protection following FDA approval is capped at 14 years (33).

After drug patent expiration, a 3-year extension in exclusive marketing can be obtained if a new use is found for the drug. One example is the extension of patent on atomoxetine (patented in the early 1980s for treatment of depression). It was later found to be effective for attention deficit disorder. Atomoxetine was then marketed under the name Strattera, under a patent that will expire in 2017 (36). It is common practice for drug developers to assess the patentability of a new use ("drug repurposing") because a new patent could "buy" such a developer an additional 20 years of patent protection.

Drugs can also be purified (e.g., remove inactive isomers) and be repatented as a new chemical compound (e.g., Celexa was repatented as Lexapro), extending protection for an additional 20 years, and new drug combinations can be patented (e.g., Symbyax, a combination of Zyprexa and Prozac) (33).

Occasionally, exceptions in the patent law allow longer extensions: for example, drugs approved under the U.S. Orphan Drug Act allows a 7-year extension on the first approved use to encourage development of drugs that treat diseases affecting fewer than 200,000 people in the United States (37).

Companies producing a generic drug equivalent sometimes "jump the line" and seek FDA approval before original patent expiration, on the grounds that the original patent was invalid, or that the new drug somehow does not infringe on the original patent. The company holding patent can obtain an automatic 30-month stay of FDA approval for generic equivalents by simply filing a lawsuit for copyright infringement (38).

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COPYRIGHTS. The concept of copyrights followed the invention of the printing press in the 15th and 16th centuries and the rapid growth of public literacy in Europe. Printing technology facilitated the dissemination of multiple creative avenues: from scientific and theological thought to authorship of works of fiction. The professional and financial value of authorship increased, and laws were developed to protect the rights of authors to the rewards of their works. As with patent laws, copyright laws in the United States are derived from the first Article of the Constitution (1). The first U.S. copyright laws date to the beginning of the 20th century, but advances in technology as well as pressure for U.S. participation in international efforts to codify copyright protections lead to the first major amendment in 1976, which went into effect in 1978 (39). The act extended the rights of widows and heirs to collect royalties on various published material for another 190 years for certain copyrights, and protected the authors' rights "for life plus 50 years," a term for which Mark Twain fought in his lifetime (40). Under the amended law, copyright protection extends to "original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device" (41). Works that are included in the act are summarized in **Table 3**. Most importantly, before 1976, copyright protection only applied to published work that had a notice of copyright attached. With the new act, these requirements were abolished, and copyright applies to any work that is "fixed in a tangible medium of expression, whether or not they have been published" (41). Thus, any creative work covered by the copyright act is automatically the copyrighted property of its creator unless it was work made for hire.

The copyright act explicitly does not protect ideas, procedures, processes systems, methods of operation, concepts principles, or discoveries, "regardless of the medium in which they are described, explained, illustrated or embodied in such work" (42).

Copyright holders have exclusive rights to reproduce the work, create derivative works, distribute copies of the work, perform the work publicly, display the work publicly, or perform a sound recording by means of digital audio (the last amended in 1995) (41).

Despite otherwise "exclusive" rights, however, "fair use" of copyrighted material is not considered copyright infringement, even if it technically violates the above rules. Fair use allows creative works to be produced by those other than the copyright holder for such purposes as to criticize the original work, to report the news, to teach, for scholarship, for research and for "other purposes" (43,44). Factors that determine whether such unauthorized use constitutes copyright infringement are summarized in **Table 4**. The law covers both published and unpublished work.

The term of copyright protection for authored works has been periodically amended, and is now 70 years beyond the life of the author, and for general copyrights, works made for hire, and those works that had been copyrighted before the 1978 amendments, 95 years. Copyrights can be transferred to others by written instrument (41).

OBTAINING PATENTS AND COPYRIGHTS

THE PATENT APPLICATION. The average time between patent filing and issuance in the United States is 2 to 3 years (20), and for a university technology licensing office, the average cost of obtaining a patent is about $10,000, much of which is spent on attorney's fees (**Figure 2**). Kneller (20) found that about 2% to 50% of all university patent applications are ultimately licensed. Currently, the USPTO issues 3 types of patents: 1) utility patents for processes, machines, articles of manufacture, or composition of matter; 2) design patents for a new original and ornamental design for an item of manufacture; and 3) plant patents to anyone who invents or discovers and asexually reproduces any new and distinct variety of plant (45).

PRELIMINARY PATENT SEARCH. A preliminary patent search, as well as an examination of other materials related to the invention is an important step in preparation for any patent application. Anyone contemplating a patent application, or engaged in an even earlier step in the invention process, should attempt to discover whether "prior art" exists for the invention (be it other patents or any publications in the United States or outside) featuring sufficient similarity that the "novelty" requirement would not be met. Such searches should include, not only the patent office itself, but also internet sites, literature, and other sources that might include information on innovations within the same relative field. The search may allow the inventor to strategically draft his or her patent application to pre-empt detrimental objections that could occur during the patent examination process that are based on such prior art, and can provide defenses of novelty, usefulness, and non-obviousness. The search may also save the inventor futile efforts to pursue development of an unpatentable invention. Such searches are never perfect,

TABLE 3 Works Protectable by Copyright Under U.S. Law

Literature
Musical works, including lyrics
Drama, including musical accompaniment
Choreography and pantomime
Pictorial or graphic work
Sculpture
Motion pictures and other audiovisual works
Sound recordings
Architectural works
Certain computer programs

however. Despite requirements that patents be published, inventors can sometimes prevent publication (46). Patents are published 18 months following filing, thus creating a "window" of 18 months in which their existence may be missed by a search. In particularly competitive fields, in which inventors are racing to file patent applications, it is not uncommon for applications to fall within the 18-month window.

Provisional patent application. Provisional patent applications can be filed quickly and inexpensively by submitting to the USPTO a provisional fee and a manuscript or other document upon which the invention is based. Provisional applications must be converted to full patent application within 1 year, or the provisional protection is considered abandoned. Provisional applications are not examined by the office, but merely filed, and therefore the fee for provisional applications is minimal (as low as $65) (Table 5). The 1-year period for the provisional application does not count against the 20-year term granted on a subsequently filed full (nonprovisional) application. A provisional application represents a simple and inexpensive means of "buying time" while further development of an invention is underway. In contrast with a full patent application, no "claims" are required to be made regarding the type and scope of patent protection being sought. It should be noted that if a competing inventor files a full application for a patent after the filing of a provisional application for the same or similar invention, the original inventor will still have priority for any discoveries or claims that are disclosed in their provisional application, but not for discoveries that are not disclosed. Therefore, an important part of the value of a provisional application, like that of a full patent application, lies in the breadth and specificity of claims made in the application and the extent to which the application materials support the claims.

TABLE 4 Factors Considered in Determining Whether Unauthorized Use Constitutes Copyright Infringement

The purpose and nature of the use (commercial versus educational)
The nature of the copyrighted work (fictional or factual, the degree of creativity involved)
The amount and substantiality of the portion of the work that is used
The effect of such use on the marketplace for the original work

Full (nonprovisional) patent application. The full patent application includes 4 elements: 1) a written document with a description and claims regarding the invention (the "specification") (Table 6); 2) a drawing of the invention (when necessary); 3) an oath or declaration that the applicant believes him or herself to be the original and first inventor and 4) payment of application fees for filing, search, and examination of the patent.

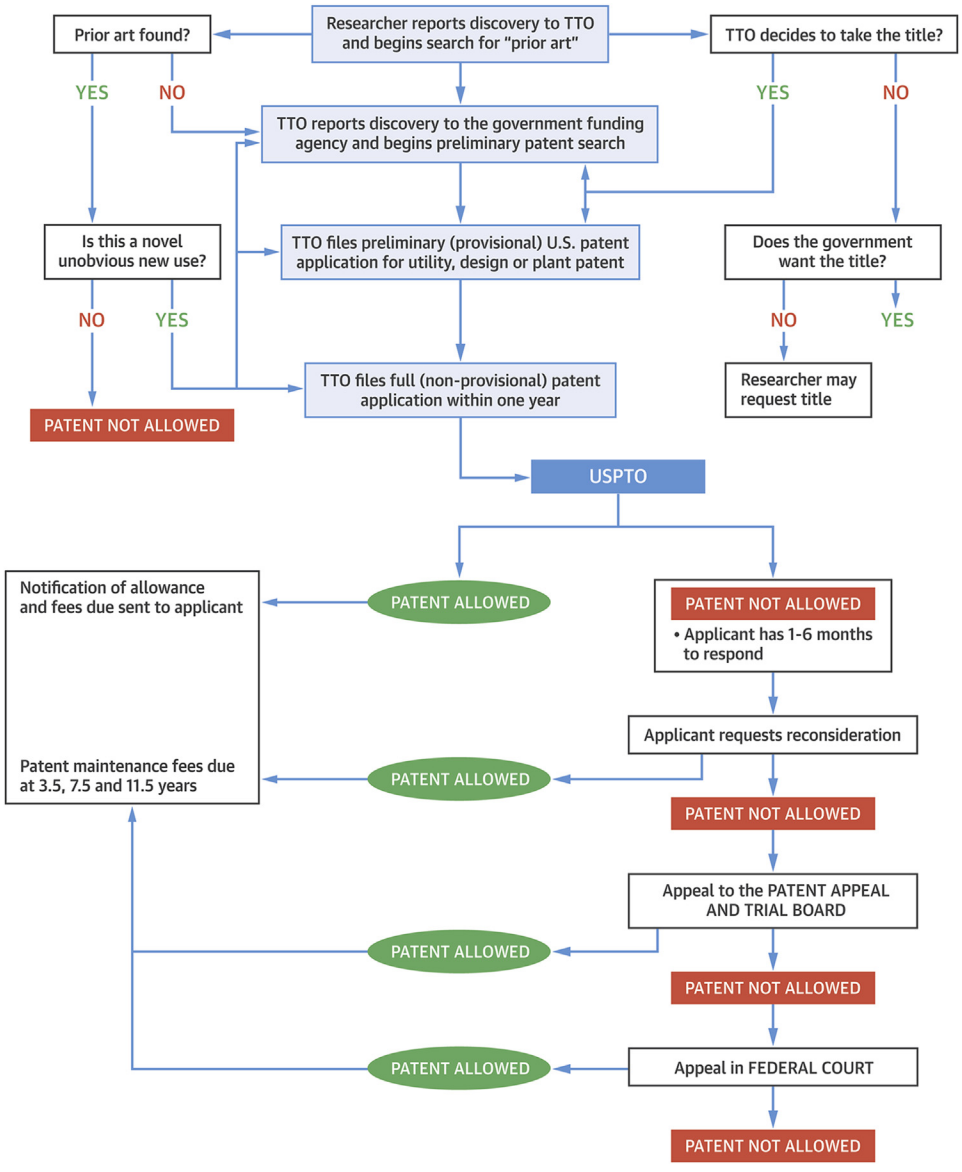
If the application is submitted to the USPTO electronically, it must be in PDF file format. All files must be submitted in English or be accompanied by an English translation.

Filing date. The application is filed and given a filing date by the USPTO once the completely written description of the innovation (the "specification"), the claims (1 or more claims regarding the "subject matter" or invention) and drawings when needed to understand the "subject matter" for which a patent is being sought. The USPTO will notify the applicant of receipt of the required elements and of the assigned application number.

Publication of the patent application. U.S. law requires under the American Inventors Protection Act of 1999 that most plant and utility applications be published (although under certain conditions an inventor can request that an application not be published) (46). Publication of the application occurs after 18 months, and the entire file becomes open to the public. An inventor may assert provisional rights after publication and can seek pre-patent grant infringement damages from third parties before patent issuance.

Examination of the application. Once the application is complete, the USPTO assigns the application to the appropriate technology center (TC) that has charge over the area of technology related to the invention. The TC takes up application examinations in the order in which they were filed unless otherwise directed by the director of the USPTO. The examination reviews the application to ascertain that it is in compliance with U.S. laws, rules, and regulations. The TC then undertakes a search of patent application and foreign patent documents, and reviews the available literature to ascertain that the invention meets the novelty, usefulness, and non-obviousness requirements. The summary of USPTO guidelines for the patent examination (47) is a useful review for the

FIGURE 2 Overview of Common TTO Patent Process



TTO = technology transfer office.

prospective inventor. At this point, a patent may be granted. However, relatively few patents are allowed as filed, and it is common for the office to reject certain claims. The USPTO will notify the applicant in writing of the examiner's decision, normally sent by U.S. mail. This notification will contain specific reasons for any adverse decision, and information and references as may be useful for the inventor to judge the appropriateness of continuing the pursuit of a patent.

If the applicant wants to proceed, they must request reconsideration in writing within the time specified in the Office action, and distinctly and specifically point out errors in the Office's action. The response time the Office will specify will not be >6 months, nor <30 days—the usual period of time is 3 months. The applicant must reply to every ground of objection and rejection in the Office's action, and cannot merely state that they believe the action was in error. The Office will review the applicant's reply

and respond with another notification of action. The applicant's reply should be a bona fide attempt to resolve the patent, since the second action by the Office is usually final.

A final rejection by the Office can be appealed to the Patent Trial and Appeal Board and thereafter to the Federal Court of Appeals.

Allowance and issuance of patent and payment of fees. If the patent is found to be allowable, a Notice of Allowance and Fees Due will be sent to the applicant. A fee for issuing the patent, and if appropriate for publishing, the patent is due within 3 months of notice. If the fees are not paid within 3 months, the application is considered abandoned, unless the director makes an exception. After payment of fees, the patent issues as soon as government printing will permit. Maintenance fees for utility patents are required at 3.5, 7.5, and 11.5 years from the date of granting. Failure to pay the maintenance fees can result in expiration of the patent (48). A summary of common current patent fees can be found in Table 5.

Assignment and licenses. A patent is personal property. It can be sold, mortgaged, bequeathed, and licensed or assigned to others in whole or as a part interest.

THE COPYRIGHT APPLICATION. The mere creation of a material copy of an original work that falls under the copyright protection act is all that is required to acquire copyright protection. The work need not ever be published, but merely exist materially. Copyrights, unlike patents, do not require any registration or recording process for legal protection to be afforded to a work, although it is possible to register materials with the Copyright Office if the creator wishes to do so. Reasons to register a work with the Copyright Office include a desire on the part of the author to have a public record of the copyrights that they own, and the fact that registration within 5 years of a work's creation can be used as prima facie evidence of ownership in a court of law (49). Furthermore, if a creator chooses at any time to pursue an action against another for copyright infringement, they will be required to first register the work with the Copyright Office.

It is commonly claimed that by sending themselves a copy of their own work, an author establishes a "poor man's copyright." In fact, the law does not contain any provisions for protection in this way, and such an action is not a legal substitute for registration (49).

For the inventor, it is important to be aware that certain types of works, such as computer programs, may not be patentable, but may qualify for copyright. In such a case, the specific expression of the computer program (the "coding") would become the exclusive property of the copyright owner, although the concept behind the computer program would not necessarily be protected.

TABLE 5 Examples of Common Fees* Incurred in the Basic Application and Issuance of a Utility§ Patent

Description of Fee	Basic Fee	Small Entity Fee	Micro Entity Fee
Provisional application filing fee	$260.00	$130.00	$65.00
Filing fee	$280.00	$140.00	$70.00
Patent search fee	$600.00	$300.00	$150.00
Patent examination fee	$720.00	$360.00	$180.00
Patent maintenance fee			
Due at 3.5 yrs	$1,600.00	$800.00	$400.00
Due at 7.5 yrs	$3,600.00	$1,800.00	$900.00
Due at 11.5 yrs	$7,400.00	$3,700.00	$1,850.00

Small entity = independent inventor, a small business, or a nonprofit organization; micro entity = qualifies as a small entity AND has not been named as an inventor on > 4 previously filed patent applications, did not in the calendar year preceding the calendar year in which the application fee is paid have a gross income exceeding 3 times the median household income, and has not assigned, granted, or conveyed (and is not under obligation to do so) a license or other ownership interest in the application concerned, to an entity that in the calendar year preceding the calendar year in which the application fee is paid, had a gross income exceeding 3 times the median household income. *For a comprehensive list of fees, including international patent issuance, see United States Patent and Trademark Office website: https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule. Accessed November 29, 2016. §There are 3 types of patents: utility, design, and plant patents. See section on "The Patent Application."

Registering a copyright. An application for copyright registration includes 3 elements: a completed application form, a nonrefundable filing fee, and a nonreturnable copy or copies of the work being registered. Once the Copyright Office issues a registration certificate, the effective date is the date on which all of the application elements were received in

TABLE 6 Elements of the "Specification"

Title of the invention
Cross-reference to related applications (e.g., provisional applications, applications of continuation)
Statement regarding federally sponsored research or development
Background of the invention—including reference to "similar art" and explaining/emphasizing differences of the new invention, and pointing out improvements
Brief summary of the invention discussing the claims, advantages, and how the new inventions solves previous problems if it is an improvement on existing technology or art
Brief description of the several drawings of the invention if drawings are included in the application
Detailed description of the invention: the most substantial section, consisting of 2 parts: ○ A general explanation of the invention and how to practice it, and definition of key terms ○ Specific examples of how to practice the invention. "Prophetic" examples demonstrate how the invention would be practiced, if a working model has not been built. "Working" examples present complete undertakings of the invention.
Sequence listing if the invention includes nucleic acid or amino acid sequences
Abstract: a brief summary of the entire specification

The patent application contains a full description of the innovation and claims regarding the invention. Together, these sections of the application are referred to as "the specification."

the office, regardless of how long it took to process the application (50). Applications can be filed via paper or online, although certain types of actions, such as renewal of copyright claims, may only be filed via paper. Fees for filing of standard initial copyright registration applications are $35 to $50, depending on the type of application.

SUMMARY

It is in the public interest to encourage innovation, and to reward inventors with exclusive rights to exclude others from exploiting their creations. Such rights are established by law in the form of patents (for processes, discoveries, and machines) and copyrights (for creative works of authorship), and also to some extent by employer-employee contracts and relationships. The process of technology transfer takes an invention from bench to commercialization, the first step of which is to establish who has IP rights over the creation.

Patents award exclusive rights for approximately 20 years, and may be issued to new and useful processes, machines, manufactures, or compositions of matter, or any new and useful improvement thereof. The inventor is not required to have built the device, but must provide a specific enough description in the patent application such that a person with appropriate expertise and know-how could build the device and produce at least one of the inventor's claimed results. Copyrights award exclusive rights to works of creative authorship, including works of fiction, nonfiction, music, choreography, architecture for up to 95 years beyond the life of the author. Copyrights exist once the authored material is put into some tangible form, and do not require registration with the U.S. Copyright Office. Some innovations, such as that of certain computer programs, may fall variously under patent protection or copyright, depending on the nature and purpose of the program.

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KEY WORDS **copyright, intellectual property, patent, technology transfer**