

Intellectual Property Rights and Research Disclosure in the University Environment: Preserving the Commercialization Option and Optimizing Market Interest

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Clinical and basic scientists at academic medical and biomedical research institutions often form ideas that could have both monetary and human health benefits if developed and applied to improvement of human wellbeing. However, such ideas lose much of their potential value in both regards if they are disclosed in traditional knowledge-sharing forums such as abstracts, posters, and oral presentations at research meetings. Learning the basics about intellectual property protection and obtaining professional guidance in the management of intellectual property from a knowledgeable technology management professional or intellectual property attorney can avoid such losses yet pose a minimal burden of confidentiality on the investigator. Knowing how to successfully navigate the early stages of intellectual property protection can greatly increase the likelihood that discoveries and knowledge will become available for the public good without diminishing the important mandate of disseminating knowledge through traditional knowledge-sharing forums.

Abbreviation: PCT, Patent Cooperation Treaty.

Intellectual property protection guards ownership and use rights for concepts and ideas through mechanisms such as patents, trademarks, copyrights, trade secrets, and know-how agreements (Figure 1). These various forms of intellectual property protection (for example, patents) preserve monopoly-like rights for the technology for specified periods of time. Some, like trade secrets, represent information that is withheld from the public by the developer or owner to provide an entity within an industry sector with a technical advantage over rivals.

From some perspectives, maintaining intellectual property protections may appear to slow the advancement or use of new technologies because some type of financial consideration must be provided to the owner in exchange for legal permission to access and practice the necessary technology rights. That consideration is typically provided as a liquid asset such as cash; however, trading technology rights and providing equity in a company are becoming popular alternative forms of consideration. Some scientists believe that pure science should have no financial agenda and that science can or should be advanced only through open knowledge-sharing forums and peer-reviewed publications. Moreover, industry support of research raises concern of bias if findings reveal greater benefits or fewer risks associated with the use of specific products. Therefore, phrases such as *intellectual property protection* and *industry support* may be red flags of impropriety to some.

However, the likelihood of scientific discoveries or ideas becoming available for public benefit is low without appropriate intellectual property protection. This reality is particularly true in the life sciences and biotechnology arenas relative to other

areas of science because of the high cost of obtaining approval for drugs or devices through the regulations promulgated by the Food and Drug Administration. In addition, companies must assume a considerable liability risk in producing a product for human use. These costs and risks generally are undertaken based on the likelihood of a significant return on investment if the company successfully navigates those challenges, taking a product to market. Other costs associated with bringing a drug to market include advertising and marketing, manufacturing, distribution, and support for other research and development products in the company's pipeline. The return on investment can be supported, justified, and quantified only for products that are well protected as intellectual property.

Scientists typically maintain standing at their academic institutions and in their professional arenas by conducting research and disseminating the new information in a manner that meets the peer review standards of publication and grantsmanship. These considerations create a situation in which the need to produce and publish new discoveries quickly may cause researchers to discount or overlook the intellectual property aspects of their discoveries. To develop recognition in their field or secure promotion or tenure, young researchers and new faculty often are driven to publish their research promptly and to speculate on or explain its potential application in their writings and presentations. In doing so, they may be unaware of or fail to consider the benefits that may be derived from intellectual property protection. Furthermore, the security of a faculty position may be based on the amount of public or private funding the scientist is able to acquire. Therefore, maintaining employment can require laser-like focus on submitting grant applications. However, grant submissions can adversely affect intellectual property opportunities if those submissions become publicly available.

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Term	Definition	Duration of protection
Patent	A property right granted by the US Government to an inventor “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited time in exchange for public disclosure of the invention when the patent is granted.	Utility patents: 20 y from filing
Trademark	A property right used to protect words, names, symbols, sounds, or colors that distinguish goods and services from those manufactured or sold by others and to indicate the source of the goods. Trademarks, unlike patents, can be renewed forever as long as they are being used in commerce.	Continuous
Copyright	A property right used to protect works of authorship, such as writings, music, and works of art that have been tangibly expressed.	Life + 70 y
Creative Commons	A not-for-profit company based in Massachusetts that allows an author to reserve “some rights” through the use of 1 of its license agreements.	Life + 70 y
Trade Secret	A property right that consists of information that companies keep secret to give them an advantage over their competitors.	Continuous
Know-how	Similar to trade secrets but may also be defined as closely held knowledge in a given field created by skills or experience.	Continuous

Figure 1. Forms of intellectual property protection. The definitions of patent, trademark, copyright, and trade secret were obtained from the United States Patent and Trademark Office and are a copyright work of the US Government (17 U.S.C. § 403).

The 1980 Bayh–Dole Act¹⁴ allows universities and other nonprofit organizations to take an ownership interest of patents that are developed using federal grant money. Through this legislation, universities that are positioned to protect and promote emerging technologies have reaped important dividends for both the institutions and the faculty inventors in the forms of cash revenue, industry collaborations and partnerships, recognized leadership in research, and even the advancement of human health. Some universities may struggle to justify intellectual property investment because the cost–benefit ratio can be hard to estimate. However, the undeniable consequence of the Bayh–Dole Act is that intellectual property activity has accelerated in United States universities. Since 1991, annual university invention disclosures and patents received have risen by nearly 300% and licenses and options by more than 500%.⁷ Most universities provide some form of revenue-sharing incentive to encourage researchers to disclose ideas to the institutional Technology Transfer Office, thereby making such disclosures potentially economically rewarding for those researchers that invest the time and effort needed to obtain patent protection.

Patent Law 101

The most common form of intellectual property protection for drugs and devices is the patent. Under 35USC§101, any person who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of [the United States patent laws.]”²² That is, an invention must be useful, novel, and not obvious to be eligible for patent protection. This law does not require that an invention be reduced to practice such that a working prototype be developed and proven to obtain patent protection, but rather that the idea has been developed fully. Furthermore, an invention is not defined as limited to a composition of matter, plant, device, or mechanical or manufactured item but also includes the use of an existing object if such use of the existing object is novel and nonobvious. The US Supreme Court defines a patentable invention as “anything under the sun that is made by man.”³

The value of a patent is based in its claims and scope. Although a patent might disclose various embodiments and discuss fully how an invention might be constructed or used, the protection afforded boils down to the claims and how broadly those claims might be interpreted. For example, if an inventor has a device whose patent narrowly claims that the invention requires elements A, B, and C, then a similar device that contains elements A, B, and D does not infringe on the inventor’s patent rights. However, if the inventor’s patent claim requires only A and B, then the similar device would be an infringement based on containing the base elements A and B, with element D viewed as irrelevant. The scope of patent protection can be defined as the breadth of the various issued claims combined with the various territories and foreign countries in which foreign patent protection is secured (Figure 2). Scope is an important element when determining the value that a particular patent(s) might hold for an investor if developed.

The scope of claim protection that the Federal Patent Office will allow in a patent application depends on the amount of prior art that is relevant to a proposed invention. Prior art may include previously published journal articles, issued patents, published patent applications, abstracts, and publicly available grant information, just to name a few examples. Therefore, the scope of claim protection for a patent depends on how extensively a particular technology has been studied and reported to the public. The Federal Patent Office uses prior art to argue against the novelty²⁰ and nonobviousness¹⁹ of a claimed invention. A rejection based on lack of novelty is evaluated from an anticipation criterion and may be found if a prior art reference teaches every aspect of the claimed invention either explicitly or impliedly. If a feature is not directly taught, it must be inherently present. A rejection based on obviousness may be found from 1 or multiple prior art references when, from teachings disclosed within those references, modifications could be made that would have been obvious to one of ordinary skill in the art at the time the invention was made that are covered by the claimed invention.¹⁰ Mere suggestions of useful applications of a known device, compound, or moiety in prior art can be detrimental to securing patent protection, even if those suggestions have not been scientifically proven or reduced to

Term	Definition
Patent prosecution	A technical term for the patent requirement that a patent application be scrutinized by an examiner in the Patent Office. The examiner is charged with ensuring that the patent application meets all the patent requirements. This examination process is requirement for authorizing the application to become an issued patent.
Scope of patent protection	This term refers to the breadth of the various issued claims, combined with the various territories and foreign countries in which foreign patent protection is secured.
Best-mode requirement	This term refers to a codified rule that requires an applicant to include the best mode of the invention as it is conceived at the time of filing the patent application. Therefore, the specification in the application must show an enabled invention and also disclose the optimal embodiment of the invention. This US law differs from many foreign jurisdictions, which may not require disclosure of the best mode. If best mode disclosure is not required, the inventor can obtain a patent yet retain an optimized embodiment of the invention as a trade secret.
PCT patent application	PCT is an acronym for the Patent Cooperation Treaty. This treaty allows an applicant to use a single application to obtain international protection in selected member countries and to delay the foreign prosecutions in each selected country for as long as 30 mo.
Prior art	This term refers to any publication or publicly available information that may be used to argue against the allowability of a patent application.
Office Action	An Office Action is a report generated by the US Patent and Trademark Office that requests additional information, modifications, or arguments to overcome rejections or objections raised by the examiner that prevent approval of a patent application.
Priority date (or claiming priority)	A priority date is the date of the first filing of any given patent application. That date establishes a mark in time, such that an inventor can claim conception of the idea at least as early as that filing date. Continuation patent applications often reference back to the first priority date to avoid prior art objections or rejections.

Figure 2. The terminology of intellectual property.

practice. For example, suppose a PhD scientist in pharmacology discovered and tried to patent a novel application of an existing chemotherapeutic drug for use in preventing blood clots. In this situation, the US Patent and Trademark Office would examine the submitted patent application against prior art surrounding this drug and treatments for these disorders to determine whether another PhD scientist in pharmacology could have reasonably reached the same conclusion. Therefore, if a paper published on using the drug against cancer suggested that the drug might also have benefit, though not yet proven, in reducing blood clots, the claimed invention could be found novel but would likely be rejected due to obviousness. The US Supreme Court recently broadened the basis of a finding for obviousness as a basis to reject patent applications through its 2007 decision in *KSR Intl versus Teleflex*.⁸ In this case, inventors patented a position-adjustable pedal assembly with a modular sensor. Prior art included modular sensors, position-adjustable pedals, and a sensor location that would prevent wear or damage but did not contain explicit reference to combining those elements into a pedal assembly. The US Supreme Court held that the combination of these elements were obvious and found the patent invalid, reasoning that market pressures and the concept of a finite number of solutions supported a finding of obviousness.

In addition to the scope of claim protection, the territory of protection is another determinant of the value that a particular patent might have to an investor. A patent with international protection is more attractive to investors than one that is protected only in the United States. The territory of patent protection that a technology holds will depend greatly on when the idea or invention was released to the public before establishment of a priority date (that is, the date on which the application for patent protection was filed). In general, if a patent application

covering a specific technology is filed before the technology is released to the public, the inventor's rights to pursue foreign protection are well preserved. Although several approaches can be used to give a technology international patent protection, the most cost effective is to file a Patent Cooperation Treaty (PCT) patent application (Figure 2). Filing a PCT application allows a delay of as long as 30 months for beginning international patent prosecutions in each selected member country. Prosecuting the patent in each member country can be extremely costly, because each member country has its own government processing fees, prosecution procedural rules, and patent laws; many countries require translations of documents; and foreign attorneys must be retained to advance the patent prosecution in the elected country. Therefore, a careful cost-benefit analysis is crucial when considering pursuing foreign protection after the 30-mo expiration of the PCT application. Because of this situation, many Technology Transfer Offices will not seek foreign protection unless a licensee is willing to support those costs. The 30-mo time allowance can be crucial in providing time to convince an investor or licensee to support costly foreign patent prosecution costs.

Provisional and Nonprovisional Patents

Evaluating the effect of prior art and keeping open the potential for international protection are important tasks for Technology Transfer Offices at academic and research institutions. A simple strategy for managing these challenges is the filing of provisional patent applications. Provisional patent applications can be submitted quickly if an investigator has an enabling disclosure meeting the 'best mode'²⁴ requirement (Figure 2) with at least 1 supporting drawing (or table for chemical species). Provisional patent application disclosure

requirements are normally fulfilled by a manuscript that the inventor (often the principal investigator) is submitting for publication. To qualify as an inventor, a person must contribute materially to the concept of an invention, not just work under instructions to produce a prototype or obtain data. Often only minor edits of a research article by a patent attorney or patent agent can provide the disclosure document and thereby be used to preserve the patent priority date prior to publication of the research. Oded Hecht, the Director of Business Development at Harvard University, explains that early filings of provisional patent applications are “very much in concert with the university principle of free academic publication.”⁶

Delays in publishing generally develop when a technology manager elects to file for a non-provisional patent without a prior provisional application. Non-provisional patent applications require that a patent attorney or patent agent prepare the application by drafting claims and ensuring that the application contains the necessary supporting specifications and drawings. This preparation can be very time-consuming. If appropriate time and attention are not permitted for preparing the non-provisional application, the claims as drafted may miss important elements of the invention, and the specification may contain serious defects such as missing the best-mode requirement.

Provisional patent applications offer several advantages over non-provisional applications for initial filings. First, non-provisional applications are far more costly than are provisional applications. Effective 2 October 2008, the United States government charges only USD\$110 for filing fees on provisional patent applications of fewer than 50 pages made by nonprofit organizations. The filing fees for a non-provisional patent application can be as low as \$545 for mailed submissions but can range into many thousands depending on the length of the patent application, the number of claims filed, and whether the applicant is considered a small or large entity (as not-for-profit institutions, universities enjoy a small-entity status unless their patent application is licensed to a large, for-profit company).⁵ Two additional benefits of provisional patent applications are that they are not made publicly available for inspection, and if a non-provisional patent application is not filed within 1 y of the original filing date of the provisional application, the provisional patent application expires and ceases to exist without any public disclosure. In contrast, non-provisional patent applications are automatically published by the US Patent and Trademark Office 18 mo after their filing date and, after that publication, can be used as prior art against any like discoveries attempting to obtain patent protection. To avoid publication of a non-provisional patent application, a Request for Non-Publication must be made at the time of filing, and the applicant must certify that he or she does not intend to seek international patent protection.¹⁷ This action would be taken only rarely by a Technology Transfer Office. If a non-provisional patent application has been submitted without the Request for Non-Publication, an inventor or assignee may request an Express Abandonment to Avoid Publication.¹⁶ This action would result in the loss of a priority date, and additional government fees would apply. Because of the high cost of filing non-provisional patent applications, stopping the patent prosecution is hard to justify once the process has begun, and an application generally is not abandoned before a first Office Action (Figure 2) is issued on the merits of its patentability. Therefore, another advantage of provisional patent applications is that they allow the filer to abandon the prosecution before the expensive non-provisional patent filing is initiated if the market looks poor or prior art is discovered.

Figure 3 illustrates the basic process of patent prosecution. Several points are relevant to this diagram. First, the time periods presented are based on the maximal time periods allowed by law for a given application without additional time extensions (for example, extensions due to undue delays by the Patent and Trademark Office during patent prosecution). By petitioning to make an application deemed ‘special,’¹⁵ an applicant may elect to shorten the life of a patent application. This route usually is taken due to the applicant’s age or health or because of some special social benefit consideration. In addition, the applicant may elect to abandon a patent before its 20-y term expires because of the burden of maintenance fees or may lose patent protection if a third party successfully challenges a patent’s validity. A second point relevant to Figure 3 is that the life of the PCT depends on whether priority is claimed from a provisional patent application. If priority is claimed from the provisional patent application, then the PCT’s maximal life is reduced by the amount of time the provisional patent application has existed (the maximum is 12 mo). After a non-provisional application is filed, several years may pass before the patent is examined and prosecuted (Figure 3). After the patent is issued, it enjoys a presumption of validity²³ and is enforceable for up to 20 y from the filing of the non-provisional patent application. This term can be extended if approval from the Food and Drug Administration is required and obtained.²¹

Despite potential advantages, filing a provisional patent application may not always be the best strategy, especially when sufficient time is available for drafting claims and when considering international protection. If a PCT application is filed without a prior provisional patent application, an applicant can receive a search result and opinion regarding the patentability of an invention from the International Searching Authority within 9 mo (16 mo from a priority claim).¹² An applicant thereby may learn that existing prior art renders the invention unpatentable, giving the applicant the opportunity to abandon the application before costly international prosecutions begin. In addition, PCT application provides the option of amending the application before it enters international prosecutions, based on either the International Searching Authority patentability opinion or the results of a demand for preliminary examination.¹¹ Making amendments at this stage can greatly reduce the cost of international prosecution because they are made at the PCT level of examination rather than at multiple times during the international prosecution.

Market Interest and the Role of the Technology Transfer Office

Although the scope of protection provided in intellectual property rights is a key determinant of the strength and value of intangible assets, companies often seek licenses in the early stages of securing those rights. In the case of patents, license negotiations typically begin before the final claims in a patent application are deemed allowable. The Technology Transfer Office at a university or institute typically manages the transfer of these assets and represents the best interests of the institution. Some Technology Transfer Offices strive to adhere to *Nine Points to Consider in Licensing University Technology*, which identify language considerations that should be employed in licensing provisions.² Endorsed by the Association of University Technology Managers, *Nine Points to Consider in Licensing University Technology* was developed by 11 prominent academic institutions and the Association of American Medical Colleges. However, these 9 points were idealistically crafted, and the real-

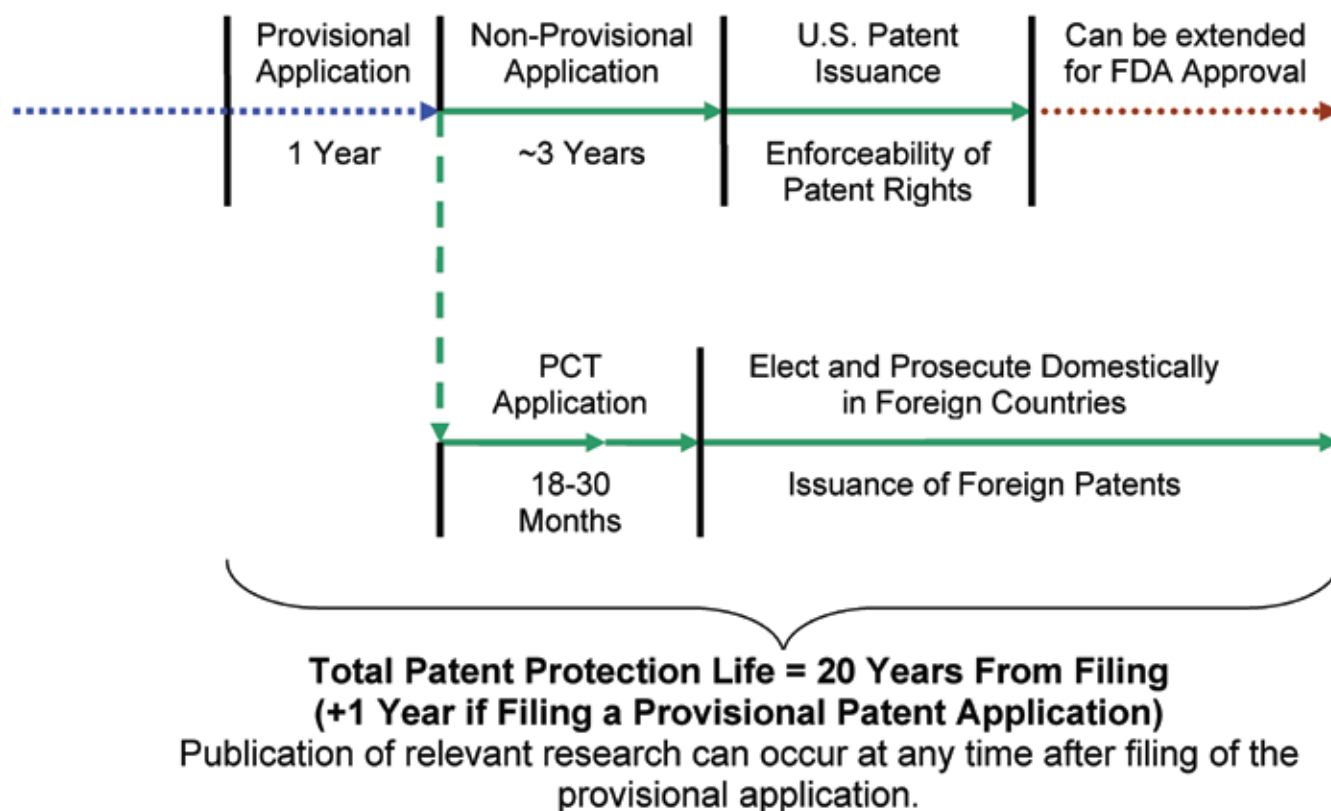


Figure 3. Basic process of patent prosecution and issuance. This diagram summarizes the events that occur with regard to successful prosecution and issuance of a patent. An estimated or average time frame for completing each phase is provided.

ity of negotiating license provisions may require the technology transfer professional to deviate from these points to address market demands and meet internal needs. The underlying goal of the Technology Transfer Offices at not-for-profit institutions generally is to promote the advancement of a technology through business development outside the university. Such development greatly increases the likelihood that the technology eventually will become available to the public to improve the quality of life. The ranking interests of beneficiaries of new technology developed by not-for-profit institutions is ideally the public good first, the good of the institution second, and the good of the inventor third. However, patent protection and licensing are key components of the eventual satisfaction of any of these interests.

The economic advantages of having intellectual property protection for a technology or discovery cannot be overemphasized. Intellectual property gives institutions a defined instrument that allows them to take formal title to promote an idea to third party investors or industry partners for technology advancement or product development. Politically, institutions of higher education increasingly are relied on as sources of innovation and entrepreneurship to drive economic development.¹³ Meeting such expectations can be challenging for some universities and colleges, given the limited resources and lack of entrepreneurial spirit that are common in various academic and scientific environments. An important means in creating more scientific disclosures in an academic institution, thereby opening more avenues for economic development, is to educate the faculty and staff regarding the benefits of securing intellectual property rights. Inventors with novel ideas may be unaware of the option of obtaining intellectual property protection through their institutions until that intellectual property opportunity

is lost through public disclosure. A helpful tool in delivering that perspective is pairing the utility message of intellectual property protection with an economic incentive to inventors for developing revenue-generating inventions. For example, universities that allow higher royalty shares to their faculty are reported to generate higher inventive output and higher levels of license income.⁹ Therefore, a prudent strategy for institutions is to adopt a fair and attractive monetary incentive for employee inventors and to communicate that incentive to faculty and staff while educating them on the basics of intellectual property protection. For example, a common income-sharing split is a 50–50 distribution between the university and the inventor after costs have been recovered. In addition, many universities will reduce the inventor's interest as the amount of income increases. For example, faculty inventors may retain only a 25% income interest after the income exceeds USD\$1 million annually.

Securing intellectual property protection does not guarantee that a license will be executed or that a product will succeed in the market place. Furthermore, in the case of drugs and medical devices, many fail to meet safety and efficacy requirements during clinical trials. One estimate is that between the years 2000 and 2003, 91% of new drugs failed during clinical trials.¹⁸ The high failure rate, together with the high investment costs needed to advance a new drug, mandates that drug companies have a strong intellectual property portfolio in support of a given drug. Estimates are that more than USD\$800 million in research and development and more than 90 mo from the start of clinical testing are typical for getting a drug to market.⁴ Drug companies will not invest millions of dollars in time, research, and testing without the intellectual property protection that will support postapproval profits sufficient to offset the high investment costs and risk. Strong intellectual property protection directly

correlates to the scope of patent protection secured during the patent prosecution process, which ultimately depends on how and when researchers disclose their ideas to the public.

If a technology does result in a commercially lucrative agreement, the university is faced with the 'good problem' of deciding how to best deal with an influx of money. The first allocation of funds from licensing generally is reserved for recouping the direct costs of patent prosecution, consulting, and licensing fees. The university then will often distribute a proportion of the funds to the inventor, based on the institution's intellectual property policy. The remainder of the money typically is re-invested into the institution to promote other needs, projects, or ongoing technology transfer activities. A recent deal by the University of Georgia Research Foundation illustrates the best and worst outcomes of a technology transfer success story.¹ In its bid to secure an industry partner, the university secured an attractive upfront sum of \$23 million from Allergan in payment for rights to an eyedrop solution (marketed as Restasis). However, in exchange, the university accepted a lower royalty percentage during commercialization. The disgruntled university inventor filed a lawsuit against the university, claiming that the university lost as much as \$230 million in additional cash by opting for the lower royalty percentage. The inventor would have made nearly \$70 million had the university retained its initial negotiating position for a higher royalty percentage. The lower court ruled in favor of the university, citing that the university had a right to act without the inventor's input. This case exemplifies 1 of the many challenges and decisions that technology transfer professionals face when choosing among technology development opportunities.

Conclusion

The patent application process can be costly, difficult, and complicated to navigate. Companies interested in licensing technology protected by patent rights will gravitate toward technologies with broad claims that are protected in multiple foreign jurisdictions. In some situations, other forms of intellectual property protection (for example, trademarks, trade dress, copyrights, trade secrets, or a combination thereof) may offer a more sensible approach for bringing technology to the market. However, products come to market through the investment of industry, and technologies that hold appropriate protection as intellectual property will attract those investment dollars first. Furthermore, gaining industry investment is often essential to bringing new technology to the market in support of both public wellbeing and economic development. A competent technology transfer professional or intellectual property attorney should be consulted to help map out the best strategies for moving forward in obtaining strong protection for new ideas. Being aware of the market potential of an idea early on and knowing where to find advice on intellectual property protection strategies are important early steps in ensuring that discoveries become available for public enjoyment. In most academic and research settings, that step may be as simple as a brief visit to the university's Technology Transfer Office. In other circumstances, outside consultants or legal counsel should be sought. However, to avoid the inadvertent loss of valuable intellectual property opportunities, as well as the associated opportunity to develop new technologies for public benefit, inventors should

seek advice in advance of releasing the findings to the public as presentations or publications.

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