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Moving Research to Patient Applications through Commercialization: Understanding and Evaluating the Role of Intellectual Property

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The advancement of research from discovery to the delivery of medical care can be limited without the support of industry to sponsor its continued development. Federal government financial support is generally crucial in early-stage development through funding from the NIH, National Science Foundation, and other federal agencies; however, government support generally stops shortly after basic research discoveries have been reported. Much of the cessation of financial support derives from the government's regulatory responsibilities, as sponsoring the commercialization of a product conflicts with regulation of the approval for clinical use of a drug or device. Furthermore, differences in goals, resources, and flexibility render government, as compared with private industry, inefficient and less responsive to market demands with regard to stream-lining the development of and enhancing the quality of products and services offered. Thus, industry and private investment provide the bridge that converts new discoveries into healthcare products that are available to consumers and patients. This conversion occurs through commercialization, which involves both high risks and high rewards. Taking advantage of the commercialization option for research development requires an understanding of the technology transfer process. This article reviews 5 topics: 1) industry motivation to invest in academic research; 2) institutional considerations in partnering with industry; 3) academia's interactions with inventors in the commercialization process; 4) the research institution's route to commercialization, and 5) the role of intellectual property and commercialization in the advancement of healthcare.

Abbreviation: FDA, Food and Drug Administration.

Moving research from the laboratory to the patient typically requires the use of intellectual property rights to achieve the goal of improving the quality of healthcare. Industry often looks to universities to help fill its development pipelines with new products. When engaging in partnerships with industry, universities should understand their role as the creator and transferor of ideas to maximize their return potential within such relationships. Sound management of the commercialization process can avoid pitfalls and reduce problems that might arise within an institution itself or with its industry partners. However, the use of intellectual property rights by universities can be viewed as limiting access to information for a profit motive and is therefore controversial. However, these concerns should be assessed in concert with the advantages of intellectual property protection in promoting the development and delivery of healthcare advancements. Understanding the commercialization process and the issues that surround intellectual property rights allows universities to enhance industry relationships, establish better policies, avoid inventor conflicts, and advocate effectively when proposed legislation attempts to modify existing laws. This article reviews 5 topics: 1) industry motivation to invest in academic research; 2) institutional considerations in partnering with industry; 3) academia's interactions with inventors in the commercialization process; 4) the research institution's route to commercialization; and 5) the role of intellectual property and commercialization in the advancement of healthcare.

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Industry Investment in Academic Research

Industry is relying increasingly on academia as a leading source of new drug and medical device discoveries that develop through basic research or cross-disciplinary collaborations.[11] This phenomenon can be attributed to a multitude of factors, including the high cost of gaining approval from the Food and Drug Administration (FDA), the need to add more products to pipelines as existing patents for drugs and devices expire, the desire to minimize out-of-pocket costs for failed internal research, and academia's ability to bring multiple resources together from disciplines outside of the medical field to develop novel solutions to various health problems. If the cost of failed drugs is included in the equation, the total research and development cost estimate of taking a single drug from phase I clinical trials to approval exceeds $800 million.[24] Reflecting these hurdles, only 17 new chemical entities were approved by the FDA in 2007.[10] The number of annual drug approvals has been in general decline over the past 13 y; although generally more than 30 drugs were approved annually between 1996 to 1998, no more than 20 were approved annually between 2005 to 2007.[27] Drug discovery and early-stage development are relegated increasingly to smaller drug and biotechnology companies that have little to no revenue stream relative to their operating costs, with legacy pharmaceutical companies that have achieved a sustainable profitability record focusing on later stages of the process.

By seeking peer-reviewed, emerging discoveries that are reported in journal articles, conference presentations, and academic centers, biotech companies mitigate the investment risks associated with technology discovery and early-stage development. However, as a result of taking this approach,

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pharmaceutical companies must pay more to acquire commercialization rights for technologies that have already progressed through conception and into early-stage development. Selling the rights to products at this stage can provide an attractive return on investment for small biotech companies that lack the resources or are unwilling to take the financial risk of advancing a new drug into the realm of clinical trials. The pharmaceutical company Pfizer is one example of how legacy pharmaceutical companies are adjusting to the new economic challenges. In January 2009, Pfizer announced its plans to eliminate as much as 8% of its research jobs worldwide and raise productivity by relying on partnerships, licensing, and mergers and acquisitions to efficiently bring late-stage pipeline drugs to market.[25] These actions allow Pfizer to focus on strategic therapeutic areas such as cancer, Alzheimer disease, and pain by managing the later phases of drug to market activities rather than earlier stage, high-risk discovery endeavors. Academic and healthcare administrators should be knowledgeable regarding the complexities that surround such interactions with industry.

Most technology-leveraged companies that rely on their intellectual assets to define their financial net worth seek intellectual property rights to gain control of and protect their investment interests in technologies acquired from academic institutions and other research arenas. Intellectual property rights consist of patents, copyrights, know-how, trade secrets, trademarks, trade dress, and service marks (Figure 1). The value of intellectual property rights is tremendous. For example, in the United States, intellectual property assets are estimated to underlie about 45% of the gross domestic product.[26]

Appropriate management of technology transfer is essential to ensuring that research conducted at universities and similar institutions advances to become useable products or service. Without sufficient attention to securing and negotiating intellectual property rights, the inventor institution may be outmaneuvered in a technology-transfer negotiation, inadvertently giving away valuable information or missing opportunities entirely. For example, a few decades ago, Sutter Health hospital in northern California employed a dermatologist who formulated the idea of using botulinum toxin to plump thin lips and smooth out wrinkles, but the hospital did not file a patent.[21] In 2007, Allergan grossed $1.2 billion in sales from Botox based on the same idea.[21] With appropriate management of intellectual property, Sutter Health hospital could have secured a royalty share on those sales.

Institutional Considerations Related to Partnering with Industry

Generally, the first goal of university licensing agreements is to recover the costs of having secured intellectual property rights. Such expenses can easily amount to thousands of dollars, even if only United States domestic protection has been sought. The end objective for most biomedical research institutions is to make their technologies commercially available to enhance patient care. Achieving these objectives may require partnerships with industry that appear to force more monetary or equity concessions than might seem reasonable or justified. The nature of these agreements will vary depending on the stage of development of the potential product. If the technology requires extensive additional testing and validation to prove efficacy and safety, then gaining a development partner may require the inventor institution to make fewer upfront demands and accept lower royalty rates. For example, if a researcher invents a compound with anticancer activity in vitro and promising in vivo results in mice, the intellectual property agreement for therapeutic use for that compound will likely command a lower royalty rate and lower milestone payments than could be negotiated if the compound had already undergone phase I and phase II clinical trials without adverse affects. If the product has been developed to an advanced stage, a premium may be added to some of the upfront cost considerations. Royalty rates are often decided as a function of exclusive versus nonexclusive rights, volume of product (or service) being sold, market place disruption potential of the intellectual property, and the cost of that product.

In negotiating with potential partners for the commercialization of intellectual property, institutions should consider the risk associated with accepting sponsorship and licensing from a startup biotechnology company in generating acceptable terms. For example, if the startup company is not well capitalized, has little experience with FDA submissions, or generally appears to have inadequate infrastructure that would be necessary to advance the compound, the institution should negotiate for higher royalty rates or milestone payments to help compensate for the risk of losing irreplaceable development time if it becomes necessary to recoup its intangible assets from a bankrupt company. In addition, university licensing agreements should consider requiring payment of a maintenance fee, such that the investor company will have an incentive to advance the technology rather than neglect it. Institutions may also consider taking equity positions in a startup company based on the anticipated product, perhaps making concessions in order to promote local economic development.

An institution should use competent legal support to avoid costly consequences when discussing contract terms. Such consequences include accepting less-than-ideal terms or inadvertently making a false warranty in a contract that increases its liability exposure. For example, a standard clause found in most licensing agreements stipulates that the University is the 'sole owner' in a group of patents. If other inventors, named or unnamed on the patents, are employed by a different institution, the University may inadvertently be making a false representation and possibly nullifying its license agreement.

Goals set by universities when establishing and using a technology transfer program may be summarized as follows: 1) facilitate the commercialization of university discoveries for the public good; 2) reward, retain, and recruit faculty; 3) forge partnerships with industry; 4) promote economic growth; and 5) generate income.[2] In an attempt to harmonize university objectives and the public interest, several leading universities have signed on to a document titled *In the Public Interest: Nine Points to Consider in Licensing University Technology*.[4] This document lists principles to consider when licensing technology to third parties. Such principles include preserving the right to practice licensed inventions, encouraging technology development and use, excluding the licensure of future improvements, ensuring broad access to research tools, and supporting neglected patient populations. University technology transfer offices can attempt to adhere to these principals to balance financial interests with positive social outcomes. Securing and marketing intellectual property through principled technology transfer has generated substantial revenue for universities and return-on-investment for industry partners by helping preserve rights for guiding the application of those technologies.[13]

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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).

Academia's Interactions with Inventors in the Commercialization Process

Innovation and marketable ideas start with the researcher in the lab, the medical professional giving care to patients, the engineer putting together a new device, and even the patient or consumer identifying and solving a service or product need. Academic researchers publish approximately 700,000 new research papers every year.[17] However, many are not aware of potential loss of intellectual property protection that results from their publications. Because of this, technology transfer offices should proactively educate their faculty on various intellectual property practices and policies. Employees at research institutions are generally obligated to assign their interest in discoveries created within the scope of their employment back to their institution. With the assistance of the Bayh–Dole Act in 1980, academic research institutions can retain close to ownership-type rights in patented technologies that were developed using federal grant funds.[30] One measure of the effect and success of this law is reflected by the development of new startup companies. Since 1980, more than 4000 new companies have formed based on technologies originating out of university research. In 2003 alone, 470 new commercial products based on university technologies were introduced to the market.[3] These results suggest that the Bayh–Dole Act has promoted keeping the United States competitive, if not the leader, in new-product innovation.

Most research institutions offer some type of financial compensation in the form of profit sharing to reward those innovative scientists whose discoveries or ideas result in commercial success. This type of incentive is controversial to some in the research and academic arena due to their belief that ideas should be freely shared, without a financial agenda. Furthermore, an inherent risk of a conflict of interest occurs if the principal investigator is directly involved in obtaining data that may or may not advance the value of that intellectual property. However, considerations of promoting public benefit through economic development and better healthcare counter these valid concerns. Moreover, academic institutions are becoming more experienced at appropriately managing potential conflicts of interests internally by using established and tested policies. Academic research and inventive activity are reported to accelerate in response to monetary incentives, leading to the conclusion that higher royalty shares for faculty inventors tend to generate higher levels of licensing income.[14]

Providing the faculty inventor with an economic interest in the success of a technology can blur the lines of intellectual property ownership, and disputes over property interests in these assets can result in legal action. In 2003, for example, Washington University initiated legal action against Dr William Catalona, a faculty member in cancer research, to prevent him from taking tissue samples to Northwestern University to continue his research at his new place of employment. The federal court of appeals upheld Washington University's rights to the "highly prized biological materials" in June 2007, even though several thousand of the research participants had been patients of Dr Catalona, and many patients had signed consent forms he created to assign their interests in their tissue to him.[6] In a case at the University of California, the university was sued by 2 researchers who had invented a new MRI technology. The researchers had been assured, based on the university's patent policy, that they would receive 50% minus a 15% administrative fee of net royalties and fees recovered by the university. However, as a result of a license agreement negotiated by the university with a third party, the royalty rate was set at only 0.56%. However, the university also received $20 million from the licensee as sponsored research funds. Therefore, the researchers received far less compensation than they had anticipated. From the university's perspective, the sponsored research was used to help support the researchers' salaries and overhead costs. However, the researchers were successful in securing a $4 million verdict from the university in their favor.[22]

The Research Institution's Route to the Commercialization of Ideas

The movement of a technology or product from research to patient application requires an understanding of the commercialization process, which can be considered in 2 parts: how a

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technology develops from the perspective of the inventor, and how a secured idea gets developed into a product.

Whether the inventor is a doctor who scribbles down an idea for a new medical device idea on a napkin after lunch or a researcher contemplating a new use for an existing drug while reading an article on nutrition, ideas come at unforeseen times to those seeking solutions to perceived problems in their respective field. The evolution of the idea may develop in any form, but in the research environment, most travel down a similar pipeline (Figure 2). As an investigator proceeds to further explore, develop, and test an idea, the first step is to create a set of experiments to generate valid data and test the hypothesis. Patent attorneys generally advise that researchers maintain well-documented, permanently bound laboratory books with dated entries and preferably have a second individual sign as a witness to those dates to provide evidence that a researcher has diligently been pursuing their invention. The history is important because in the world of patent law, the United States is a 'first to invent' jurisdiction, giving the inventors who 'invent first' priority over a claimed invention in a patent application, as well as in an issued patent that was filed with the US Patent and Trademark Office before the first true inventor had filed.[29] Most other countries use a first-to-file system, whereby the only relevant issue is who filed the patent application first, rather than who invented the invention first.

As the second step in the process, investigators who produce data with a prospective novel utility should consult their office of technology transfer. The technology transfer manager would examine the information and attempt to answer important questions, including whether the data are sufficient to support a patent application, whether existing public disclosures might impede the patentability of the idea, whether specific grant or funding obligations require consideration, and what potential commercial applications the idea might have. If the office of technology transfer determines that the technology has merit for intellectual property investment, the office of technology transfer generally will engage a patent attorney or agent to draft and file a patent application. The office of technology transfer may begin to market the technology before the patent application has been filed; however, various legal and business considerations tend to favor delaying marketing activities until the patent application has been filed. Although presentations and posters by the inventor at specialty-specific conferences generate interest from industry technology hunters who attend these events, generating opportunities for both licensing and sponsored research, some form of intellectual property protection should often be obtained before making a public disclosure of this nature.[18]

Once an industry partner becomes interested in licensing a technology, the industry representative will perform due diligence to evaluate the risks to the investment and to determine whether they are minimal and acceptable or can be mitigated. This due diligence may include: 1) reviewing the scope of protection found in the intellectual property disclosure; 2) examining weaknesses in validity of any patents in the intellectual property portfolio; 3) determining the market readiness for the technology; 4) assessing the costs of bringing the technology to market; and 5) analyzing the competition and market for the product if it came to market. If the industry partner's due diligence is favorable, licensing terms are negotiated. From the researcher's perspective, this step creates a critical opportunity for industry-sponsored development and perhaps clinical trials. For example, further development may include optimizing dosages and delivery systems for drugs and perfecting medical device designs. These investigations can also provide new avenues for intellectual property development. At this stage, translational research typically begins as the drug or device is prepared for clinical trials. The sponsoring industry partner typically will bear the costs and liabilities of conducting clinical trials. This undertaking can engender a considerable financial risk for the company if the drug does not move to marketable status or if an unforeseen side effect develops.

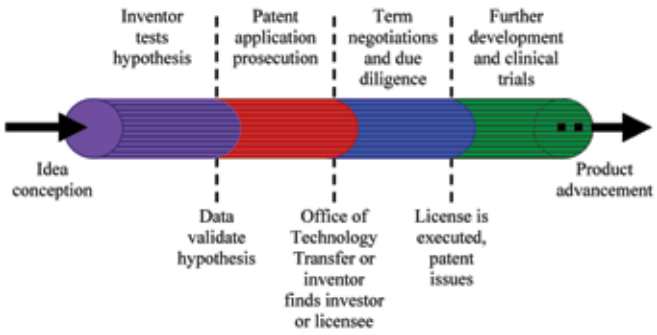

Figure 2. General movement from idea conception in the academic setting to commercialization.

The movement of drug and medical device development from academic and research institutions to industry tends to follow the model illustrated in Figure 3. Direct licensing rarely occurs directly with established legacy pharmaceutical companies. These large companies generally will not consider engaging in negotiations for a licensing agreement unless a drug has been approved through phase II clinical trials of the FDA. Therefore, the faculty entrepreneur or an opportunistic small company typically raises the capital investment necessary to move a project through phase I and phase II clinical trials. Funds to support this development may be raised through various means (Figure 4), including Small Business Innovation Research or Small Business Technology Transfer grants, private capital investment that may request an equity stake in the company, or seed or angel funding that act as loans or grants. Once a company has produced a viable product and substantially greater funds are required to expand the operation of the company, venture capital funds are generally sought. Many companies fail early in this process because of poor management, insufficient capitalization, lost funding, legal issues, or unexpected difficulties with technology development or market challenges. However, many others are successful in advancing their technology to a state at which it becomes attractive for licensing or sale to a third party. Alternatively, the technology may be converted into a useable product or service that will be sold directly to consumers by small, innovative companies.

Another means of creating a working relationship with an established drug or device company is through a sponsored research agreement. Under this scenario, sponsoring companies provide funds that allow the inventor to further develop the technology in the laboratory. In such cases, the sponsor will often ask for the 'right of first refusal.' Under the right of first refusal, the recipient institution agrees to give the sponsoring entity a finite period of time in which to opt to license any technology developed by using funding from the sponsor. In exchange for this research funding, the recipient institution generally will accept a lower royalty interest than might otherwise be requested. If the sponsoring entity exercises its right of first refusal, the intellectual property assets will be licensed to that entity for further commercialization development. At this stage, the inventor is often retained as a scientific advisor to assist in

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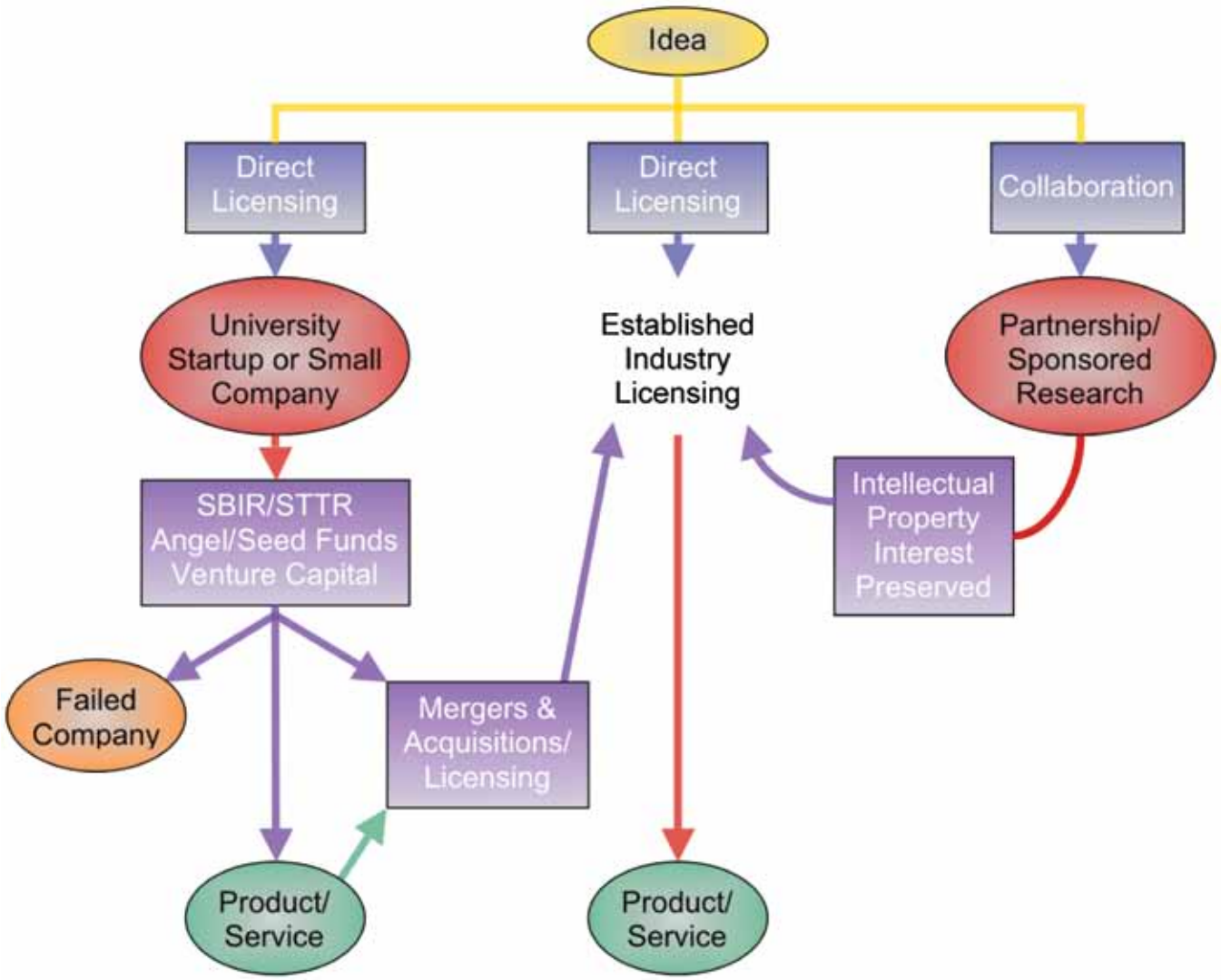

Figure 3. Commercial development pathways most commonly used in moving a product or service to market. This diagram illustrates frequent key steps as funding is sought, buyouts take place, and collaborations progress.

mass production efforts or clinical trial protocol development. Ultimately, the success of the product depends on its efficacy and safety and whether (or not) market demand can support the costs of research, development, and production.

Does Intellectual Property Protection Promote or Inhibit Advancement in Healthcare?

Intellectual property is a tool that can promote the movement of ideas from academia to industry, and eventually to patients. To illustrate this, the Association of University Technology Managers launched a campaign in 2005 called the Better World Project to highlight successes of research and technology and show how our lives and the world have improved as a result of collaborations and industry investment. This professional organization highlighted 25 such achievements in their 2008 publication *The Art of Collaboration: the Relationships that Bring Academic Innovations to the Marketplace*. Featured innovations included a robotic device that assists persons with neurologic injuries, an ultrasonic toothbrush, a nasal spray flu vaccine, and a drug to treat chronic lymphocytic leukemia.[1] Through these and similar examples, the Association of University Technology Managers attempts to demonstrate the important role of intellectual property protection, technology transfer managers, and the process of converting academic ideas into marketable and beneficial realities. Universities have an important role in promoting changes in healthcare through technology. Development of each of the top 10 pharmaceuticals and biologics, which had annual domestic revenues exceeding $200 billion in 2008, relied heavily on academic contributions.[20]

A correctly functioning patent system that rewards innovation also encourages the public disclosure and dissemination of innovations in medicine, whereas in its absence, such disclosure may not occur. For example, in the early 1600s in England, a member of the Chamberlen family invented the first practical obstetrical forceps, allowing the delivery of babies from women who otherwise die in childbirth. The family kept the forceps as a trade secret for the next several generations because, due to the lack of an effective patent system in England at that time, trade secrets were the most practical means of profiting from the invention. Many women who could not see the Chamberlen obstetricians died in childbirth because the device was not made available to other practicing physicians.[7]

The use of intellectual property rights to advance healthcare technologies obviously brings financial returns to the university and inventor, yet several economic realities engender

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Term	Definition
SBIR Grant	The Small Business Innovation Research grant program was established under the Small Business Innovation Development Act of 1982 to assist small companies with research or research and development that has the potential for commercialization and public benefit.
STTR Grant	This grant mechanism was established under Small Business Technology Transfer Act of 1992 and allows researchers employed at nonprofit research institutions to apply for grants where the institution has a formal relationship with a small company.
Private and Angel Capital	Individual or group investors who supply their own money or services in exchange for a defined financial return or equity position in a company.
Seed Funding	Money intended to help launch a startup company and may comprise private investors, venture capital investments, or funds from friends or family pulled from savings or mortgages.
Venture Capital Funding	Money or other forms of consideration that are investments managed by a separate party that often use company growth benchmarks as a condition to receive additional investment funds. Venture capitalists often seek preferred investment privileges that help mitigate potential losses.

Figure 4. Forms of funding available to assist small companies with innovation development.

disadvantages in terms of the use of patent protection for healthcare advances. One of the most prominent arguments is the relationship of patents to the rising cost of healthcare. For example, drug patents cause market inhibition by preventing less-expensive generic formulations from entering the market. The rise in healthcare costs, whether related to patents or other medical service inefficiencies, continues to outpace the growth in inflation and the growth in the gross domestic product of the United States.[5] These soaring healthcare costs create additional burdens on companies trying to retain talent in their workforce. General Motors, for example, which spent $4.8 billion on healthcare for its employees in 2006, was a strong advocate for a bill that promoted the availability of generic drugs.[12]

Large pharmaceutical companies hold a different perspective toward loosening the intellectual property grip on technology or access to information rights, arguing that these protections expedite bringing new treatments into the healthcare market. Their data commonly are protected by trade secret or copyright claims that prevent sharing such information without the agreement of the owner. Industry currently has little incentive to share their data with a competitor or generic pharmaceutical company if those data would enhance the approval process for a competing drug. However, some members of the research community and legal experts believe that public access to scientific information held by the FDA and industry would help curb costly repeat failures of common etiologies.[13]

The Wisconsin Alumni Research Foundation provides another example of market inhibition related to patent protection. This organization owns 2 patents that cover the making, using, selling, offering for sale, and importing of human embryonic stem cells. The research that led to the initial discovery and patent was sponsored by a federal grant, thereby giving the United States government various rights in using the patented technology. However, the Wisconsin Alumni Research Foundation generally requires a license and a fee from entities that want to use human embryonic stem cells for research purposes. Such fees, while perhaps not as prohibitory in amount, nonetheless increase the cost of performing the research. Furthermore, if a therapeutic use is discovered, those rights are controlled by a company (Geron) that helped to fund the patented human embryonic stem cell derivations, and negotiation with this company is necessary for further development of the discovery. Aspiring startup companies must therefore absorb the costs of fees imposed by the Wisconsin Alumni Research Foundation and seek license agreements with Geron to develop and advance technologies related to human embryonic stem cells. Because of these costs, entering the field in the United States is less attractive than doing the research abroad because most countries around the world have not allowed human embryonic stem cells to be claimed as broadly as they are in the United States patents. The patents held by the Wisconsin Alumni Research Foundation do not expire until 2015.[15]

Industry and universities often hold competing perspectives regarding the role of technology transfer at academic and research institutions. Industry representatives may view university monetary demands for intellectual property rights as excessive, arguing that universities should make technologies readily available for development at reasonable prices, especially if public funds supported the research. In contrast, university technology managers are becoming increasingly knowledgeable regarding license negotiations and the true market value of their technologies. In either case, the classical business scenario emerges in that industry as the buyer seeks to minimize its costs in acquiring an intellectual asset while the university as the seller seeks to maximize its return.

To lower the hurdle that patents create with regard to the availability of generic drugs, Congress has attempted to protect certain forms of research from patent infringement charges. The Hatch–Waxman Act enacted in 1985 states that "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . a patented invention *solely* for uses *reasonably related* to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[28] This law was intended to construct a safe harbor exemption to patent laws that would assist generic drug companies that were attempting to comply with FDA requirements in better positioning the company to make a generic drug available immediately after patent protection of the drug expired. However, through several years of litigation, the term 'solely' has lost its significance, and the phrase 'reasonably related' has had its meaning extrapolated by the courts. The interpretation of "reasonably related" has been extended to include the use of imported drugs for preclinical development, clinical trials, and device demonstrations.[9] In 2005, the US Supreme Court held in *Merck KGAA v Integra Lifesciences I, Limited* that experimental use of drugs and compounds is permissible even if it does not result in an investigational new drug filing because parties wishing to seek FDA approval could not be sure which specific drug might be the best candidate. However, the Supreme Court did not provide an opinion as

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to whether 'reasonably related' extended to research tools (for example, devices, kits, and gene sequences).[16] In August 2008, the Federal Circuit Court addressed the research tool issue with its decision in *Proveris Scientific Corporation v InnovaSystems*, holding that an optical spray analyzer made by InnovaSystems violated Proveris' patent.[19] InnovaSystems was unsuccessful in arguing the safe harbor defense of 'reasonably related' to FDA requirements in the Hatch–Waxman Act. The court reasoned that the optical spray analyzer itself, which is used to measure the physical parameters of aerosol sprays, did not require FDA approval, and therefore the devices covered under Proveris' patent would not fall under this exception. Kathleen Petrillo, a patent attorney at Senniger Powers in St Louis, states "Research tool companies may be able to attract more venture and seed capital now that investors are assured that the [safe harbor] exemption will not apply to patented inventions that don't require FDA approval."[8]

The patent examination process and its rules are in a constant state of flux due in part to new advancements in science that complicate the broad application of statutory laws to vastly different areas of research (for example, information technology, the biological and chemical arts, and mechanical sciences). Judicial decisions, statutory modifications or additions, rule revisions, and international pressures also add to the constantly changing considerations that impact interpretations and practices relevant to intellectual property. The medical profession is the only entity that has won a policy battle against the intellectual property establishment. This occurred in 1996 when a bill endorsed by the American Medical Association but opposed by the American Intellectual Property Law Association and other interest groups was passed into law to prohibit the enforcements of patents on surgical methods against hospitals or doctors.[17] However, the government continues to reevaluate the effectiveness of its own patent policies. The National Research Council reported in 2006 that significant burdens are rarely imposed on biomedical researchers because of patented biomedical research.[23]

Conclusion

Commercialization of medical discoveries is necessary for bringing new biomedical advancements to market. Drug and medical device companies generally shoulder the financial and legal risks that are involved in obtaining regulatory approval for new products. The basic components of collaborating with industry to advance a drug or device to market include licensing directly to established medical device or pharmaceutical companies, using smaller but riskier startup companies, and accepting industry sponsorship of research. Securing industry interest can be challenging. The inventor often can generate this interest by presenting at conferences and becoming well recognized in his field. Using industry as a vehicle to advance science engenders criticism from some stakeholders, especially when intellectual property rights are used to secure the technology transfer objectives. The role of academia, acting through its office of technology transfer, is to balance the interests of the institution, the inventors, social responsibilities, and market demands.

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