AdvaMed Accel

University Technology Transfer

Best Practices Guide

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About AdvaMed Accel

AdvaMed Accel is the division within AdvaMed dedicated to addressing the unique needs and challenges of smaller medical device and diagnostics manufacturers – the lifeblood of the medical technology industry. The only organization of its kind focusing specifically on the needs of the medtech industry's emerging growth companies, AdvaMed Accel works to create a policy environment more conducive to capital formation and innovation. For more information, visit **www.AdvaMedAccel.org**.

About AdvaMed

AdvaMed is the world's largest trade association representing manufacturers of medical devices and diagnostics—the medical technology industry. Its membership includes approximately 400 companies, two-thirds of them small companies with annual U.S. sales of less than $100 million. AdvaMed member companies produce medical technology ranging from simple tongue depressors and blood pressure cuffs to the most complex imaging machines and cardiac and orthopedic implants and account for nearly 90 percent of the health care technology purchased annually in the United States and more than 40 percent purchased annually around the world.

About Wilson Sonsini Goodrich & Rosati (WSGR)

Wilson Sonsini Goodrich & Rosati (WSGR) is a legal firm providing services to technology, life sciences and growth enterprises, as well as venture firms, private equity firms and investment banks. The firm extends several services which include joint ventures and strategic alliances, technology licensing and other intellectual property transactions among other areas. WSGR focuses on representing entrepreneurial start-ups to multibillion-dollar global corporations at every stage of development.

About AUTM

AUTM is an association focused on educating, promoting and inspiring academic professionals in the development of academic research and innovation. The association advocates and supports corporate engagement, intellectual property protection, professional practices and the advancement of current and future members in the field of technology transfer.

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Executive Summary

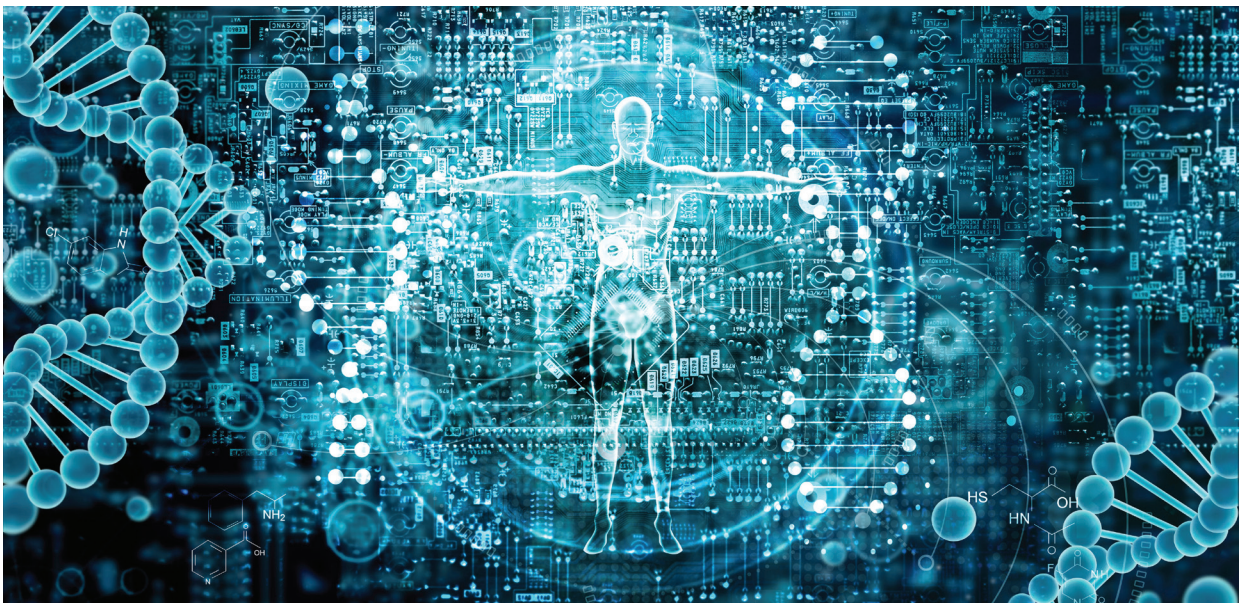
Executive Summary

The relationship between medical technology companies and university technology transfer offices play an integral role in the medical technology innovation ecosystem and impacts the lives of patients. Universities are filled with enthusiastic faculty members conducting cutting-edge research on the most challenging conditions and latest therapies in healthcare, while medical technology companies are equipped with the knowledge and resources to bring transformational devices, diagnostic tests and digital health solutions to the market. When the two groups collaborate on novel approaches to medical technology, the results include stronger research and development pipelines with potential to improve treatment options for patients.

Given the importance of these relationships between universities and medical technology companies, AdvaMed Accel, in conjunction with Farah Gerdes and Jacki Lin of Wilson Sonsini Goodrich & Rosati, has developed the **AdvaMed Accel University Technology Transfer Best Practices Guide** to examine the history of technology transfer and the dynamics of collaboration between universities and medical technology companies. Over the past two years, AdvaMed has employed strategic analysis tools and qualitative research methods to explore and identify the characteristics, culture, and approach of successful academic and industry collaborators in medical technology. Additionally, a formal fireside chat and group discussion with over 40 university representatives was conducted to gain a deeper understanding on this topic from the academic perspective. Further interviews with early-stage companies, medtech investors, large medical device companies, and representatives of incubator/accelerator organizations were also held to inform the drafting of this guide.

With the introduction of the Bayh-Doyle Act in 1980, technology transfer for universities, non-profit entities, and small businesses receiving federal funding was fundamentally changed and entities were given greater flexibility and authority to commercialize federally-funded innovations and technology.

By applying best practices in these key areas, universities and medical technology companies will develop productive relationships and more effectively translate academic innovation to commercial products that positively impact patients' lives.



The Bayh-Dole Act led to a remarkable growth in university patenting and licensing activity. There has also been significant growth in the number of start-up companies forming to develop and commercialize these technologies, pursuant to licenses from the universities, since the enactment of Bayh-Dole.

However, based on a recent AUTM survey (312 responding institutions), 2017 marked the first-ever decrease in reported university invention disclosures (down 3.2%) from the previous year and there was a 7% decrease in new patent application filings in 2017 as compared to 2016.1 In parallel, access to capital for emerging medical technology companies has declined over the past decade, and "financial pressures generated by health care reform, the transition to value-based care, and tougher insurance coverage and regulatory requirements for medtech innovations have deterred some corporate and VC investors."2 Given current trends, it is more important than ever for industry and academia to establish long-standing cooperative relationships.

We examined the strategies employed by both universities and industry partners and conducted further research on the most effective relationships in the field. The result is a best practices guide that discusses the following key factors critical to developing and sustaining effective relationships between university technology transfer offices and medical device companies:

1. **University Strategies** for Engaging with Companies
2. **Industry Strategies** for Engaging with Universities
3. **Points of Contacts** – Gaining Access to Points of Contacts, Scientific Champions
4. **Business Agreements** – Licensing Terms

By applying best practices in these key areas, universities and medical technology companies will develop productive relationships and more effectively translate academic innovation to commercial products that positively impact patients' lives.

Introduction

to the AdvaMed Accel University Technology Transfer Project

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The medical technology industry consists of thousands of companies committed to providing patients and healthcare providers with the best technologies and tools to diagnose and treat patients, and their innovations help patients worldwide live longer, healthier and more productive lives. Medical technology companies continue to invest in the discovery and development of new devices and diagnostic tests, thereby playing a key role in making lifesaving technologies available to patients. According to the International Trade Administration, spending on research and development (R&D) represents a relatively high percentage of medical device companies' overall revenue – roughly 7% percent.[3] Collaborations between universities and medical device companies represent a portion of this spend and have helped to drive advancements in medical technology. These collaborations have also proven to be beneficial in creating an avenue for licensing technologies out of universities and translating them into products, as well as being a method for companies to maximize the value of their R&D spending and to contribute to local economies.

In recent years, the healthcare industry has implemented innovative models for interacting with universities and research institutions to foster the translation of academic research into products and services that can impact patients' lives. One prominent example can be found in Johnson & Johnson's efforts to partner with early-stage companies through Johnson & Johnson Innovation, JLABS, a life science incubator with multiple locations around the world. JLABS focuses on removing hurdles to developing and commercializing healthcare products and empowering life science innovators through access to infrastructure, community, and specialized expertise. At the JLABS location at Texas Medical Center in Houston, alone, numerous companies have spun out of universities, including:

CorInnova

Commercializing technology from Texas A&M University, CorInnova is developing a non-blood contacting cardiac assist device for heart failure patients.

INSTAPATH

A microscopy system developed at Tulane University, which addresses the need for accurate biopsy images using simple florescent stains.

BioLum SCIENCES

A solution that analyzes airway inflammation in real time for streamlined management of chronic respiratory diseases, developed by a founding team from Southern Methodist University.

PATHEX purifying life

An early-stage company emerging from Vanderbilt University focused on providing patients with a new approach to treating sepsis.

These are just a few examples of technology transfers occurring in the medtech ecosystem. Through these and other collaborative initiatives discussed in this guide, medical technology companies and universities have seen the value in developing long-standing relationships. As these relationships develop and mature, both sides are working to identify optimal methods and establish industry standards in cultivating relationships with one another. Although a variety of methods are currently being used, universities and medical technology companies are still evolving their understanding and implementation of the essential elements needed to cultivate long-standing, mutually beneficial relationships.

One advocate working on behalf of the lives of patients and industry is AdvaMed. AdvaMed is a medical technology trade association representing over 400 medical technology company members and advocating on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation. AdvaMed's small-company division, AdvaMed Accel, is committed to fostering future growth and innovation in medical technology and is devoted to the needs of smaller medical device and diagnostics manufacturers. AdvaMed Accel understands these smaller companies are the lifeblood of the medical technology industry and are often the result of technologies being translated out of an academic setting. Therefore, AdvaMed embarked on an initiative to promote effective linkages between medical device companies and university technology transfer offices, through the identification and use of best practices.

Universities and medical technology companies are still evolving their understanding and implementation of the essential elements to cultivate long-standing, mutually beneficial relationships.

Over the past two years, AdvaMed has employed strategic analysis tools and qualitative research methods to explore the areas crucial to the development of this guide. This included a three-part approach towards gathering the necessary data to understand academic and medical technology company relations. The initial step included a dialogue with members associated with innovation in the early stages to identify the strengths and weaknesses in this area. Secondly, a formal fireside chat and group discussion with over 40 university representatives was conducted to gain the academic perspective on technology development and industry relations. Finally, in-depth interviews with early-stage companies, medtech investors, large medical device companies, and representatives of incubator/accelerator organizations were also held to complete this guide.

AdvaMed Accel, in collaboration with Wilson Sonsini Goodrich & Rosati, focused on these factors in the generation of this practical guide for the benefit of industry and academic research institutions. This guide presents the analysis of these discussions and offers certain solutions for all stakeholders to consider as they embark on continued long-standing relationships of mutual benefit.

AdvaMed
Advanced Medical Technology Association

WSGR Wilson Sonsini Goodrich & Rosati
PROFESSIONAL CORPORATION

AdvaMed Accel

A Brief History & Current Trends

A Brief History and Current Trends in Technology Transfer

Pre-Bayh-Dole Act

After World War II, the U.S. federal government moved from focusing on dedicated government-run research facilities to having a greater role in funding academic research, particularly at universities. The funding of university research by the federal government increased from less than 25% of all academic research and development in 1935 to about 70% of the total amount spent on all academic research and development in 1980.[4]

However, despite the increased federal funding of academic research during this time period, the transfer of federally-funded innovations and technologies from universities to the market was typically slow and often unsuccessful. The inability to commercialize much of the federally-funded innovations and technologies from universities was due, in part, to the prevailing policy among federal funding agencies that the federal agency (i.e., the U.S. government) held all ownership rights in federally-funded inventions and to the practice of only issuing non-exclusive licenses to federally-funded inventions by federal agencies.

To further complicate matters, there was not a uniform technology transfer policy governing all the federal agencies. Some federal agencies would provide royalty-free licenses, while others would require royalty payments in consideration for the licenses they granted. In some cases, the lack of consistency within an agency gave the appearance that their technology transfer policy was decided on by somewhat of an *ad hoc* basis.

In view of the aforementioned factors, there simply was not much incentive for private companies to pursue the commercialization of federally-funded inventions produced by universities. In fact, prior to 1980, only about 5% of government-owned patents were used in commercial industry.[5]

The Bayh-Dole Act

During the 1970's, the United States economy was entering a period of stagnant growth due to a combination of high unemployment, high inflation, and an oil crisis. Congress recognized during this time that the U.S.'s competitive technology was falling behind that of other countries (such as Japan, Germany, and the Soviet Union) and that the government was receiving minimal returns on its substantial investment in university-based research. A group in Congress believed that giving stronger intellectual property rights to universities receiving government funding would increase the propensity of universities to patent and license innovations and technologies discovered using federal funding. The group believed that a new technology licensing policy that incentivized the commercialization of federally funded innovations would help promote economic growth in the U.S.

Also, during the 1970's, many universities began to take a greater interest in improving technology licensing procedures in federally funded innovations. These universities recognized that the inefficiencies and uncertainty in technology transfer policies by and between federal agencies were an impediment to their patenting and licensing activities. As a result, these universities increased their efforts to press the federal government to create a more effective, uniform technology transfer policy. The Bayh-Dole Act was passed in 1980 with the intention to incentivize and accelerate the commercial exploitation of federally funded research results.

The Bayh-Dole Act laid out the following key policies:

1. Institutions and entities were allowed to elect to retain ownership of any federally funded invention(s).
2. In electing to retain ownership, the institution or entity must commit to commercialization of the federally funded invention(s).
3. The government maintains a non-exclusive, non-transferable, irrevocable, paid-up, worldwide license to any federally funded invention(s).
4. The government has the right to "march-in" and require a license to be granted if the institution or entity is not taking effective steps to commercialize the elected federally funded invention(s).
5. The institution or entity must share any royalties with the inventors.

The Bayh-Dole Act fundamentally changed technology transfer for universities, non-profit entities, and small businesses receiving federal funding by providing a uniform technology transfer policy in which federally funded entities were given greater flexibility and authority to commercialize federally-funded innovations and technology.

The Bayh-Dole Act fundamentally changed technology transfer for universities, non-profit entities, and small businesses receiving federal funding by providing a uniform technology transfer policy in which federally funded entities were given greater flexibility and authority to commercialize federally-funded innovations and technology. The Bayh-Dole Act led to a remarkable growth in university patenting and licensing activity. Until 1980, fewer than 250 patents a year were issued to university and colleges.[6] In 2003, 3,933 patents were issued to universities and colleges[6] and from 2013 to 2017, patents issued to research institutions (based on 312 responding institutions) increased from 5,714 to 7,459 per year.[7]

Between 1991 and 2002, annual invention disclosures by universities and colleges increased from 6,087 to 15,5104 and from 2013 to 2017, the annual invention disclosures by research institutions increased from about 24,000 to 25,800.[7] Also, between 1991 and 2002, patent applications filed by universities and colleges increased from 1,584 to 7,791 per year[6], and from 2013 to 2017, new patent applications filed by research institutions ranged from about 13,900 to about 16,400 per year.[7]

With regard to licensing, from 1991 to 2003, the number of new licenses and options executed annually increased from 1,229 to 4,516.4 Between 2013 and 2017, the number of executed licenses (exclusive and non-exclusive) and options held by research institutions (based on 312 responding institutions) ranged from about 6,500 to about 7,800 per year.[7]

There has also been significant growth in the number of start-up companies forming to develop and commercialize these technologies, pursuant to licenses from the universities, since the enactment of Bayh-Dole. Between 1980 and 1993, 1,013 start-ups were formed as compared to the 3,104 start-ups formed between 1994 and 2003 (based on 136 responding institutions).[6] Between 2013 and 2017, the number of new start-up companies based on foundational university technology increased from about 800 per year to about 1100 per year for a total of 4843 new start-ups over the four-year span.[7]

Current Trends in Technology Transfer

Based on a recent AUTM survey (312 responding institutions), 2017 marked the first-ever decrease in reported university invention disclosures (down 3.2%) from the previous year and there was a 7% decrease in new patent application filings in 2017 as compared to 2016.[7] The survey also notes that provisional applications were down 5.7% in 2017 as compared to 2016 and that both provisional and U.S. utility applications have essentially remained flat for the past five years.[7] The year-over-year decrease in filings between 2016 and 2017 and the plateau filings over the past five years may be part of a great shift in patenting and licensing strategies in response to recent changes in patent law, the increase in patent challenges (e.g., *inter partes* review), and/or potential changes to federal technology transfer policies.[7] For example, new case law regarding patentable subject matter has led to difficulties in obtaining patents to certain subject matter, in particular software, medical diagnostics, and DNA (or fragments thereof). The difficulty in obtaining such patents could be causing universities to carefully review the likelihood of patentability of the new inventions, thus leading to a reduction in their patent application filings.

Additionally, the number of executed university licenses and options has been flat over the last three years. The number of executed licenses (exclusive and non-exclusive) and options granted by research institutions from 2015, 2016, and 2017 were 7,769, 7702, and 7,798, respectively.[7]

Based on the responses received by the universities surveyed, while the amount of federal research funding significantly increased between 2007 and 2012 (from about $31.6 billion to about $40.2 billion per year), the growth of federal research funding between 2013 and 2017 (ranging between about $38.0 to $39.9 billion per year) was stagnant and reduced as compared to the peak amount in 2012.[7] However, the reduction of federal funding has created the potential for industry or private dollars to increase and fill the gap in available research dollars through sponsored research agreement and/or other collaborations. These funding opportunities may ultimately provide a more efficient pathway to providing patients with access to new technologies.

Areas of Consideration

Areas of Consideration

The Impact of Relationships between Medical Technology Companies and Universities on the Innovation Ecosystem

Relationships between medical device companies and universities can take a variety of forms, from grants to services agreements to licensing arrangements. This best practice guide focuses on arrangements that either begin or end with a license to new technologies, which are generated by or with the university, being granted to a company. The most typical forms of those arrangements are sponsored research agreements, option agreements, and license agreements.

- A **sponsored research agreement** is a contract between a university and an industry sponsor for the purpose of funding and conducting research at the university, pursuant to which the sponsor typically receives an option to obtain a license to develop and commercialize the resulting technology or inventions.
- An **option agreement** is an agreement that grants a company an option to obtain a license to existing technology or intellectual property developed by a university, at a later date. These agreements allow companies to continue to evaluate a technology of interest and gauge the interest of investors. This also results in companies having the confidence that the technology will be available to them to license if the results of those activities are positive.
- A **license agreement** is an agreement that actually grants the company the right to develop and commercialize the subject matter covered by a particular set of patents or technology owned by the university.

A handful of scenarios typically lead to licensing arrangements between companies and universities. The university may identify a technology with commercial potential and market such technology to companies with the capabilities and resources to develop and commercialize such technology. Companies are increasingly looking for models to outsource their research and development functions, or to otherwise drive innovation, and are engaging in relatively open-ended sponsored research arrangements as one way to generate new ideas and technologies. Similarly, companies may seek to work with specific technologies or investigators at a university, and a sponsored research agreement provides an avenue to pay for that research and receive certain rights to resulting inventions or data. Companies may simply identify existing university technologies that they desire to pursue, in which case they may obtain an option or a license to commercialize such technology. Finally, professors, students, and post-doctoral fellows often desire to drive their technologies to market, through companies that they form or advise, and they license the seminal intellectual property for such companies from their university or institution.

Licensing technologies out of a university is often how early-stage life science companies are started. The impact of university licenses on the medical device industry ecosystem, however, is apparent at all stages of the company lifecycle. While the majority of university licenses go to small companies, a significant portion (approximately one-third) of these licenses add technologies to the product portfolios of large companies. Initiation of discussions regarding licenses granted to small companies is typically driven by the company, whereas the initiation of licenses to larger companies may more often be solicited by the university with respect to technologies that the university or investigator is interested in partnering with industry. Each scenario brings its own challenges and considerations when looking to create a productive relationship between industry and academia, and best practices applicable to each are offered below.

Broad Collaborations with Research Institutions and Universities

Several large sponsored research or collaboration arrangements that create a clear path to move technologies out of universities on consistent terms to particular companies have been executed in recent years. For example, the NeuroTechnology Innovations Translator, a translational research center in Ohio focused on providing advisory services and the initial capital needed to assist technologies on their path to achieving commercialization, developed an arrangement with The Ohio State University that provided rights to access certain neurotechnology inventions coming out of the university.[8] The Broad Institute of MIT and Harvard, an institute working in collaboration with Boston's leading educational establishments to advance effective diagnosis prevention and treatment, and Calico, a research and development company comprised of scientists in the areas of medicine, drug development, molecular biology genetics and computational biology, entered into an extensive collaboration focused on the biology of aging and therapeutic approach to diseases of aging.[9] Recently, Deerfield Management, a venture capital firm specializing in diverse financing challenges, entered into a first-of-its-kind research partnership with the Broad Institute to support early-stage research followed by support to create new entities to develop the results of promising projects.[10] The range of entities on the industry or investment side of these relationships has reflected an expansion in the type of arrangements being developed to partner with academic and research institutions to spark and support innovation. These collaborations represent only a small handful of the many broad research collaborations between research institutions and industry. But, they also reflect the importance of continuity and partnership in realizing the potential synergies between these two groups.

Clearing the Hurdles to Successful Relationships between Academia and Industry – a Matter of Perspective

In preparing this guide, a number of publications from the past twenty years that discuss interactions between industry and universities were reviewed. Many of the obstacles to successful relationships between industry and a university that were noted in earlier publications continue to remain the same today. However, changes in perspective or approach to licensing arrangements have resulted in some modest improvements in the relations between the two groups. Some of these changes are reflected in the trends among the forms of license agreements employed by universities. The increased consistency across those forms and adjustments to their terms stem, at least in part, from increased interactions among university licensing professionals, including through groups like AUTM. Some institutions have also solicited input from companies, law firms and other stakeholders on their agreements, in efforts to increase efficiencies in the negotiation process. More regular and substantive interaction among the groups involved in, or impacted by, university licenses can be a powerful tool in improving outcomes and efficiencies in the licensing processes, by helping to bridge the gap between the differing expectations of academia and industry.

Other changes in the interactions between university licensors and licensees are more specific to individual institutions or even individual transactions. For example, certain institutions, such as MIT, Stanford, the University of California system and others, espouse a philosophy that is focused on being industry-friendly and ensuring that technologies reach patients. Lesley Millar-Nicholson, Director, Office of Technology, MIT noted in a February panel session held at the 2018 AUTM Annual meeting,

> *"It is important to understand the main objective - which is to focus on finalizing and solidifying an acceptable agreement - not just focusing on the financial outcome of the technology."*
>
> **Lesley Millar-Nicholson**
> Director, Office of Technology, MIT

As is reflected in the mission statements of many leading institutions, their goal is to have the technologies generated by the universities available to the public and as Nicholson explains, "to have IP move from being unused to being available in the marketplace, with entrepreneurs and inventors who can bring the IP into commercialization." (Lesley Millar-Nicholson, Director, Office of Technology Transfer, MIT). Interactions with institutions that are more outward looking and business-friendly still involve many of the same challenges as negotiations with institutions that do not have a similar focus, such as long negotiations and seemingly onerous financial terms. However, a technology transfer office espousing a philosophy that is focused on entrepreneurs can be instrumental in driving the parties to consensus around license agreements that include terms that support investment in the technologies and subsequent partnering arrangements and acquisitions, all of which may be necessary to ultimately get these technologies to patients.

Shaping Relationships to Overcome Historically Divergent Perspectives/Missions Between Universities and Industry

There is often an apparent disconnect, or even a palpable tension, when negotiating agreements between universities and industry. When negotiating these licenses, the first guiding principle is that,

> *"a successful university-industry collaboration should support the mission of each partner. Any effort in conflict with the mission of either partner will ultimately fail. The challenge then lies in understanding how the missions and objectives of both sides differ, and to shape relationships that allow both sides to achieve their desired objectives."* [11]

Recognizing that there are differences in the missions of industry and academia, it is also helpful to identify and articulate the goals that are common between the two sides to provide a focus that unites the parties, and those common goals are ultimately based in the desire to benefit the public and help patients.

UNIVERSITY MISSION

To support this guiding principle, a first and critical step is for universities and industry to understand each other's missions. As you can see from the sample of mission statements on page 21, "The core mission of the university has three major components: the education of students, the creation of knowledge, and the dissemination of knowledge."[11] The missions of technology transfer offices of these institutions are focused on this dissemination of knowledge and transfer of the technologies generated by the universities for the benefit of, and use by, the public.

And, as noted in the Stanford OTL (Office of Technology Licensing) mission statement, revenue generation is also a component of the mission of some university technology licensing offices. Table 1 provides a comparison of select universities and their revenue generation as compared to research expenditure. This revenue supports further research and education within the institution but also is an attractive element for one of the university's primary constituencies, its faculty. Revenues from university licenses are shared with the inventors of the licensed technologies. For innovative faculty, and the students and post-doctoral fellows in their lab, an institution that can efficiently license their inventions into companies that will develop them, coupled with the potential for income generated by the commercialization of those technologies, can be a compelling factor in selecting their institutions. Attracting driven, innovative faculty, students and fellows is critical for top research and academic institutions.

Table 1. Revenue Generation of Select Universities as Compared to Research Expenditure

	Research Expenditures	Income Received
California Institute of Technology	$366,098,909	$10,034,315
Harvard University	$868,100,000	$35,445,437
Massachusetts Institute of Technology (MIT)	$1,734,510,000	$32,980,000
Stanford University	$1,032,395,311	$45,391,705
University of California System	$4,557,000,000	$124,462,132
University of Texas System	$2,872,770,451	$60,259,197
University of Washington Wash. Res. Fdn.	$1,289,000,000	$16,750,848

Source: AUTM 2017 Licensing Activity Survey - A Survey of Technology Licensing and Related Activity for US Academic and Non-profit Research Institutions – Data Appendix pgs. 16 -20.

Carnegie Mellon University

Carnegie Mellon University's Mission:
To create and disseminate knowledge and art through research and creative inquiry, teaching, and learning, and to transfer our intellectual and artistic product to enhance society in meaningful and sustainable ways. To serve our students by teaching them problem solving, leadership and teamwork skills, and the value of a commitment to quality, ethical behavior, and respect for others. To achieve these ends by pursuing the advantages of a diverse and relatively small university community, open to the exchange of ideas, where discovery, creativity, and personal and professional development can flourish.

Harvard University

Harvard's Mission:
The mission of Harvard College is to **educate** the citizens and citizen-leaders for our society.

Harvard Office of Technology Development's Mission:
OTD's mission is to make the fruits of Harvard research more accessible outside the University, including underserved communities, and ensure that society benefits from Harvard innovations by fostering their swift, professional and effective development and commercialization.

Massachusetts Institute of Technology (MIT)

MIT's Mission:
The mission of MIT is to advance knowledge and **educate** students in science, technology, and other areas of scholarship that will best serve the nation and the world in the 21st century.

MIT Technology Licensing Office's Mission:
The MIT Technology Licensing Office mission is to move innovations and discoveries from the lab to the marketplace for the benefit of the public and to amplify MIT's global impact.effective development and commercialization.

Stanford University

Stanford Office of Technology Licensing Mission:
The Office of Technology Licensing (OTL) was established in 1970 to manage the intellectual property assets developed at Stanford University. Our mission is to promote the transfer of Stanford technology for society's use and benefit while generating unrestricted income to support research and education.

Stanford University Founding Grant Principles on Nature, Object, and Purposes of the Institution:
Its nature, that of a university with such seminaries of learning as shall make it of the highest grade, including mechanical institutes, museums, galleries of art, laboratories, and conservatories, together with all things necessary for the study of agriculture in all its branches, and for mechanical training, and the studies and exercises directed to the cultivation and enlargement of the mind;

Its object, to qualify its students for personal success, and direct usefulness in life;

And its purposes, to promote the public welfare by exercising an influence in behalf of humanity and civilization, teaching the blessings of liberty regulated by law, and inculcating love and reverence for the great principles of government as derived from the inalienable rights of man to life, liberty, and the pursuit of happiness.

COMPANY MISSION

The mission of medical device companies, on the other hand, is typically focused on human welfare and providing patients and healthcare providers access to treatments that improve lives. Companies must also have the ability to make a fair profit in order to continue innovating and to create value for their shareholders. While different in emphasis, industry missions do share common elements with those of their university counterparts. Industry's need to consider revenue generation and profit can be a source of distrust on the part of the university, but as noted previously, the university also has an interest in this revenue generation. In fact, how that revenue is shared is often the primary point of contention in negotiating a license agreement between a university and an industry partner. Ideally, the financial terms of a university license agreement should reflect the relative contributions provided by, and risks assumed by, each party in furthering the common goal of both parties, which is the availability of technologies to patients. Financial terms should also support the company's ability to raise the funds, and enter into collaborations and other arrangements, that are necessary to complete development of, and commercialize, the technologies they license.

Better communication and deeper relationships between universities and industry may help to bridge the non-profit/for-profit mission divide. Accessibility to the key players in the relationship is helpful to facilitate that communication and maintain focus on the common goals of the organizations.

Better communication and deeper relationships between universities and industry may help to bridge the non-profit/for-profit mission divide. Accessibility to the key players in the relationship is helpful to facilitate that communication and maintain focus on the common goals of the organizations. Leaders in medical device, biotech, and pharmaceutical companies are driven by the prospect of helping patients. This goal should resonate with universities and investigators if communicated effectively. The potential for financial success is certainly a motivating factor, but absent those financial incentives, moving these technologies beyond the academic lab would be stifled to a degree that would be detrimental for industry and academia alike. Further, while federal funding for research is recently on the rise, this is not always the case and maintaining strong relationships between universities and industry can help to fill gaps in funding for academic research. One example of an entity formed to fill that gap is Cambridge Science Corporation. The corporation was formed in 2017 with a focus on creating companies to fund and house technologies affiliated with Boston universities and its research facilities.

RETAINED RIGHTS

In negotiating with universities, companies will often hear concerns about avoiding limitations on the ability of the university (or similar institutions) to conduct research, freedom to publish, conflicts of interest and receiving a fair share of the revenues generated from the technologies that they produce. While the parties' perspectives on the financial terms of a license can diverge dramatically, acceptance by the industry partner that the university will require certain retained rights (on behalf of itself, other non-profit institutions and, if government funding has been used) for non-commercial research and educational purposes will help to eliminate one issue from the list of points to negotiate. These retained rights are both critical to the university's mission and, to some extent, required by law. While sponsored research agreements typically will include rights for the industry partner to review publications covering the results of the sponsored research, a straight license agreement often will not.

The resistance to provisions limiting publication is, in part, a product of the university's need to protect its investigators' lifeblood, publication, and the scientific integrity of those publications. This resistance also reflects an administrative reality that the technology transfer offices will often not have the ability to police these publications. Companies looking to license university technologies should approach the negotiating table with the understanding that these provisions are unlikely to change much, in principle, from what is included in the university's form agreement. Universities, on the other hand, need to understand that it is challenging for companies to expressly agree that the technology that they are paying to license exclusively can be used in research sponsored by a competing company to potentially develop a competing technology, and licensing officers should come equipped with language or limitations to address that valid concern.

CONFLICT OF INTEREST POLICIES

When considering relationships between the company and the faculty member employed by the university, conflict of interest concerns may arise which limit the extent of the faculty member's involvement in the company and/or the compensation he or she can receive from the company. Becoming familiar with the invention assignment and conflict of interest policies of the university with which they are working is, therefore, an important threshold matter for companies to address in entering an arrangement with that university, particularly if the company intends to employ or contract with individuals employed by the university.[13] Conflict of interest policies may also limit an individual physician's or the university's ability to conduct clinical trials for companies in which he/she/it holds an equity interest or has other financial ties.[14] Companies need to be aware of those limitations as they often impact their development plans for the technologies that they license from a university.[15]

Recent news has put the spotlight on conflicts of interest. The *New York Times*, in particular, has run a series of articles describing various failures by physicians to disclose their financial relationships with industry in connection with publications of their work related to those companies' products. One very public case of failure to disclose these relationships encompassed a physician's failure to disclose compensation of over $1.5 million dollars by companies in connection with research articles.[16]

Companies should expect that universities are keenly aware of their conflict of interest policies and how those overlay on relationships with industry. These policies are typically available on the institutions' websites and, therefore, are readily available for companies to read and understand. In particular, physicians involved in the companies to which universities license their technologies should discuss with the universities the options available to him or her for industry involvement and the limitations on that involvement that apply based on title, compensation, and equity ownership.

Under the Physician Payments Sunshine Law, medical technology companies must also publicly disclose financial arrangements with physicians and other healthcare providers. AdvaMed supports appropriate disclosure of these relationships and recognizes that strong ethical standards are critical to ensuring appropriate collaboration between the medical device industry and health care professionals to produce the world's most advanced medical technologies.

SUCCESSFUL UNIVERSITY/COMPANY RELATIONSHIPS PERPETUATE THE INNOVATION ECOSYSTEM

One other way that relationships between universities and industry can support the missions of both entities relates to human resources. The creation and success of companies to develop and commercialize technologies generated at a university provides opportunities for students to continue to pursue their passions, in the form of jobs. Connecting students with jobs is a primary value that universities can provide, and working with companies (through licensing arrangements or otherwise) can add to that value. Universities with incubator space, such as Harvard with its LifeLab and iLab, have created support structures to facilitate the success of their students' companies. Efforts such as these, as well as other shared spaces and resources, can greatly reduce the initial costs that otherwise may be unmanageable for startups and create an ecosystem for the licensee. These sorts of ecosystems were cited by interview participants as structures that would facilitate the licensing process. In addition to physical space and assets, elements to be included in these ecosystems include access to legal advice, investors, regulatory strategies, and industry. Making these resources readily available can help universities and licensees alike.

> *"We seek cooperative research relationships with industry not simply to generate royalty revenue and stimulate economic growth, but to create relationships with industry that will help faculty in pursuing their own research and in training graduate students."*
>
> **Richard Atkinson**
> President, University of California[17]

Best Practices

How can universities and industry develop and support productive and synergistic relationships?

One approach is to follow the lead of the university's mission and focus on education, the creation of knowledge, dissemination of knowledge, in this case of the players involved in the licensing process.[19] At some level, the two sides of licensing negotiations are coming from very different backgrounds and perspectives. Demonstrating knowledge and experience on both sides is critical to designing agreements with mutually beneficial outcomes and developing trust between the parties. (Lesley Millar-Nicholson, Director, Office of Technology Transfer, MIT). Ideally, the relationships between industry and academia are longstanding and can maximize the benefit that each side has to offer: the university brings the ability to do groundbreaking research in a manner that is unconstrained by an economic return to investors, and companies bring the resources and incentives necessary to take the resulting technologies to market. Clearly, there are synergies to be realized between the two groups. A clearer understanding of the other side's business may make the relationships more productive and efficient.

UNIVERSITY PREPARATION

First, let's consider the licensing officers negotiating these agreements on behalf of the universities, and how they can be better equipped to understand the needs of the companies with which they work. Many universities hire licensing professionals who have the scientific background necessary to understand the technologies they are licensing, which is invaluable in facilitating the conversation between the university and the company. For example, MIT employs this approach and has a large office with individuals trained in areas related to the inventions they license out, such as engineering graduates working with a company on licenses that fall within that area of expertise. Stanford is surrounded by people who are innovative and willing to take risks, which helps to make the university a bit less risk-averse (Dr. Christian Eusemann, VP Collaborations, North America, Siemens Healthineers). University licensing officers should be familiar with the technologies they are licensing and the work that has been done by the university to develop related products and de-risk their commercialization profile, particularly if the university is not licensing the technology to the inventor. This ability for the two parties to speak the same language with respect to the technology being licensed is beneficial in terms of describing the technology appropriately and considering appropriate milestones and applicable risks or complementary technologies, but perhaps most importantly to build trust between the university and the company representatives.

With some notable and appreciated exceptions, the gap in the university representative's knowledge base is typically in understanding the development pathways for the technologies being licensed and the business models for exploiting those technologies, due to lack of industry experience. Understanding a company's business requires having an appreciation for the perspectives of the company, as well as its actual and potential investors and strategic partners, as those constituencies will be of primary importance to the success of the company and each will need to review the resulting license agreement.

Educating university representatives with respect to a particular licensee's business necessarily happens on a per deal basis, through conversations with the licensee, at some level within the company. However, as part of their licensing ecosystems, universities can also provide their employees with training on an ongoing basis to understand the development and commercialization process of medical technology companies and other companies, with which they work regularly, noting that models in medtech are often different from those in biotech or high tech (or represent some hybrid of the two). Law firms are good candidates to provide this training because they work with all of these groups and see the impact of university licenses on later transactions for the company. Industry representatives would also provide valuable perspectives that could drive training sessions. In turn, universities should strive to implement systems that can respond to this information by adjusting their forms or their agreements in individual negotiations, to accommodate the various industries and business models of their licensees. Taking the time to understand the company and its goals will facilitate being open and understanding and flexible in the terms of agreement.

In addition to understanding the company's industry and business model, understanding the importance and role of the patents or other intellectual property being licensed to an industry partner, in the context of the development of the product or a larger patent portfolio, is something that often receives insufficient focus in university licensing discussions. Companies should consider the character and quality of the IP to be licensed when seeking rights to university technologies and should discuss it with the universities. For example, a database that is used to identify biomarkers that are relevant to future product development may have a significantly different value to a company than a patent that covers the exact embodiment of a device that is largely developed. The scope of products enabled by those two types of products need to be described differently in the agreement, as does the value of the university's technology over time. Those differences in value should be captured in the agreement in a number of ways, including the economic provisions. Universities tend to be well-versed in licensing out patents that cover a composition of matter and, as a result, their form agreements are geared toward those type of licenses.

As medical device development becomes increasingly reliant on assets like data and software, in addition to patents, institutions need to evolve to allow their industry relationships to accomodate new technologies.

COMPANY PREPARATION

Companies often are uncertain regarding the right time to engage with university licensing offices. Typically, an early start will pay dividends in the long-term relationship with the universty. One of the primary challenges to licensing technologies out of a university is that the process is slow. As a previous publication noted, "Universities and industry should focus on the benefits of each party that will result from collaborations by streamlining negotiations to ensure timely conduct of the research and the development of the research findings."[19] However, companies have a long-standing grievance regarding the length of the negotiation process, which results in delays in financings, research or subsequent deals.

While there are approaches and strategies that can facilitate the licensing process, companies should give themselves the benefit of time by approaching universities early. Option agreements can help because they give companies the security that another licensee will not license the technology for a period of six to twelve months, while negotiations are ongoing or initial funding is being sought. Offering to draft term sheets to start the earnest discussion of terms is well-received by many, but not all, institutions. The license agreement will, almost always, be on the university's form, although occasional exceptions to that rule exist, particularly when licensing from universities or institutions that grant licenses to their technologies regularly. The other advantage of starting the discussion early is to establish relationships with the licensing office and educate them with respect to the company's plans for the technology of interest.[19] Creating a schedule on which to complete the negotiation can also be very effective, especially when there is a consequence to each side to missing the agreed timeline.

Industry licensees should take the time necessary to develop their business plans with respect to the technologies that they desire to license from universities and educate the university with respect to those plans and the role of the technology in those plans. Some of the following questions are relevant in contemplating those plans:

- How much **development work** will be required with respect to the licensed product, and how much funding will be needed to support that development?
- What is the **anticipated product or service** that will result from the licensed technology and how likely is it that the product or service will be covered by the licensed patents?
- Is the **technology unique** in the marketplace or will it face significant competition?
- What is the **size of the market** for the product and what percentage of that market can the company hope to capture if the product is successful?
- What are the **regulatory and reimbursement pathways** for the product? Are they clear or will the company need to tread new ground?
- Is the **planned reimbursement pathway** likely to remain lucrative in light of the changing reimbursement landscapes in the United States and elsewhere?
- What does the **patent landscape** look like for this technology? Are the university's patents strong? Will rights to other patents need to be acquired to have the freedom to operate?

Often patents licensed out of universities cover nascent technologies that will require years of work and millions of dollars to develop and commercialize into a usable and desired product. In many instances, the products will evolve such that these initial patents don't even cover the final product. Both sides need to keep this in mind. If the patents do cover the ultimate product, should the university be compensated? The terms of the license should not be so broad that they encumber products that ultimately are not enabled by the university's intellectual property. Particularly if the university holds an equity stake in the company, it does not ultimately benefit from imposing terms or economic burdens that disadvantage the company relative to others who are not subject to the same restrictions yet have a clear path to market.

Intellectual property diligence is another activity that can improve the quality of the discussions between the university and industry and help the parties reach consensus on appropriate licensing terms. Due to resource constraints of universities, this diligence typically falls to the industry licensee. The licensee may also have resource constraints, particularly if the licensee is a startup. However, some initial freedom to operate searches can help to frame the discussions around appropriate economic terms in the license agreement, such as royalty rates and anti-stacking provisions, as well as allocations of risk with respect to infringement claims. Patentability searches can provide some insight into the importance of linking economics to patent coverage or later stage events to provide for the appropriate allocation of risk in the case that the patents have potential challenges to issuance.

Importance of Due Diligence

If the company has conducted due diligence, is equipped with the necessary information regarding the university's technologies, and has created a business plan when it approaches the university, the company is likely to be received favorably by the university as a potential licensee. This initial work will also support the crafting of an agreement that addresses both sides' concerns because the company will know and be able to articulate the terms it needs to support its business. This will, in turn, enable the university to respond to those needs. If the company also understands the university's mission and conflict of interest policies, the company will be able to respond to the university's needs.

Successful Industry-Academia Partnership
Case Studies

Research and Development – Successful Prototyping

Dr. Christian Eusemann, VP Collaborations, North America, Siemens Healthineers

The Massachusetts General Hospital (MGH) and Siemens collaborated on an ultra-high performance Magnetic Resonance Imaging (MRI) grant that had great benefits for both parties. The hospital received multiple NIH grants, and Siemens stepped in to build the prototype for MGH. The prototype not only led to ground-breaking scientific discoveries by MGH scientists, but also the development of clinical MRI systems that are now used around the globe, as the collaboration provided Siemens the opportunity to realize the great clinical benefit of an ultra-high-performance system when designing, building, and conducting research on the custom prototype. Overall, this academic-industrial partnership not only had a significant impact in understanding the human brain but it also greatly strengthened an already successful scientific partnership between MGH and Siemens.

The Importance of a Scientific Champion

Dr. Eric Agdeppa, Executive Director, Innovation and General Manager, Hill-Rom

One of Carnegie Mellon's successful tech transfer stories is related to a professor who was enthusiastic to out-license a university technology and passionate to see it commercialized by industry. A key component to this success story was the university's decision to take a business-friendly approach to its licensing deals, including from an economic perspective, instead of an overly aggressive approach.

Another example of a successful university technology transfer arrangement involved an artificial intelligence technology coming out of a Canadian university, which assigned full rights in the technology to the company for a nominal fee. In Dr. Agdeppa's opinion, assignment is a valuable option to intellectual property transfer out of a university, when possible. Full ownership of the technology was granted to the acquiring company, allowing for further development, unfettered by ongoing obligations to the university.

The Importance of a Scientific Champion

Jamie Kemler, VP, Intellectual Property Business Strategy, Stryker

The University of Colorado (CU) Denver and Stryker collaborated on a successful acquisition due in large part to the relationship and interaction with the Bioengineering Chair and engineer at CU and the inventing orthopedic surgeon responsible for the research activities. The relationship between the bioengineering department and its location on the medical campus also contributed to the synergy between all members. According to Mr. Kemler, "Typically, successful deals are a result of relationships already established through clinicians." Additionally, another contributor to the outcome was a result of the biomedical engineers having partners who were able to "quickly understand the clinical need, assemble a business-savvy technical team and iterate though multiple prototypes efficiently."[18] The overall outcome was a result of the bioengineering members being proactive and acting as facilitators - not so much as drivers of the agreement.

Fundraising Support

M. Jason Brooke, Co-Founder & General Counsel, Vasoptic Medical Inc.

Johns Hopkins University has created pitch books to support their students and faculty seeking to commercialize their technologies. The pitch books include detailed information regarding the companies that have licensed technologies generated by the university. Johns Hopkins prioritizes attending industry gatherings, such as the J.P. Morgan Healthcare Conference, to conduct meetings and share these materials with potential investors. The university also hosts its own "investor days" to provide an avenue for investors to find these technologies. This engagement has been invaluable to startup companies, including Vasoptic Medical, Inc. Vasoptic has maintained a positive relationship with the lab associated with Johns Hopkins, which has proven to be instrumental as the company continues to develop its products and seek grant funding to support further development activities. This type of relationship with the university, which may be facilitated through its technology transfer office, is invaluable to a startup. University technology transfer offices recognizing the value that startups provide in terms of further development of university technology can also support the companies by providing licenses with reasonable financial terms. This in turn will support the company's financing prospects and long-term success.

POINTS OF CONTACT

One repeated concern raised by universities was the lack of visibility into the appropriate contact within companies to discuss technologies available to license. Participants in our fireside chats and interviews recommended that universities utilize resources such as LinkedIn or the company contact page to identify individuals tasked with identifying early-stage assets that may be of interest to the company. However, if these resources are not updated to reflect changes in the organization, maintaining up to date contact information on individuals within the company may be challenging for universities. A solution to this concern may come in the form of identifying a primary contact within the company who can provide insight on organizational changes, as well as maintaining consistent contact with a secondary executive who is primarily responsible for academic relations within the organization. In addition to identifying a primary and secondary contact within the company, it may also be helpful to take advantage of events attended by both academic and industry professionals for the purpose of creating a large network of members within a specific company and throughout the industry.

Mark Boden, Senior Fellow, Corporate Research, Boston Scientific, shared how "AUTM meetings provide a good opportunity for industry and academic licensing offices to connect." Industry conferences such as The MedTech Conference powered by AdvaMed, Wilson Sonsini Goodrich & Rosati's Medical Device Conference, and the BIO International Convention offer other opportunities for industry and technology transfer offices to network. When discussing this topic with industry representatives, one executive shared that "engaging with industry outside of licensing will keep relationships alive and allow universities to remain apprised of current contacts for potential licensing deals." Similarly, companies can help address this gap by including on their contacts page a partnering contact or even a specific university partnering contact if one exists. Allocating this responsibility to a member of its business development team and providing timely responses to university queries may also facilitate university-industry relationships. Employing some or all of the aforementioned methods may help university and industry members to maintain open lines of communication between the correct points of contact within both groups.

Universities also have an obligation to conduct due diligence: Understanding each company's business will also help universities to find the right homes for their technologies. According to Matthew Brown, Director, Business Development & Licensing General Management, BD, "It is important for universities to perform an analysis on which companies have products in the space related to the technologies being presented. Oftentimes, the technologies being presented are not related to the current technologies in the company's portfolio and are also unrelated to the area of expertise for the company. Conducting due diligence on the space, players, and portfolio is key. It would be helpful for universities to also utilize tools that can help to identify the right company to approach with technologies." When approaching companies to discuss licensing opportunities, it is beneficial for universities to consider the following two questions:

- Would the patents that the university is looking to license represent a new product line for the company or an improvement to an existing product line?
- How do the products fit into the company's existing patent portfolio?

This initial effort will help to ensure that universities receive a prompt response to their solicitations. All of this can be facilitated by regular meetings between industry and universities, or perhaps a role (at the university or the company) dedicated to these relationships and understanding the landscape. Certain universities, including Harvard, have robust business development groups that actively maintain industry contacts within companies in their assigned industry areas and facilitate interaction with potential licensees. In addition, universities with a reputation of clinician involvement, clinicians who are regarded in their field, and clear invention disclosures are attractive for companies to work with, as are those with an established reputation within a desired academic arena, established relationships, seed funds and/or mentorship programs.

SCIENTIFIC CHAMPION

Often, the licensee company and the faculty member inventor have an ongoing relationship that aligns the interests of the university and the company and can help to mitigate the company's concerns around license terms, especially with respect to retained rights and publication. This relationship with the inventor may come in the form of sponsored research, which provides funding for the faculty member to continue his or her research related to the licensed technology and the ability for the company to access that individual's expertise in the continued development of its products. The relationship between the company and inventor may also be manifested through consulting arrangements or even employment by the company. Whatever the form, "a key factor in the success of a collaboration also is in the relationships between the persons involved,"[19] which includes the inventor, investigator, and technology transfer staff and management. Regardless of the form of the relationship, a scientific champion can provide the support needed in developing a synergistic relationship between the university and company.

> *"Having a scientific champion can be very influential, and he or she can also help behind the scenes on issues that are challenging to resolve."*
>
> **Eric Agdeppa**
> Executive Director, Innovation and General Manager, Hill-Rom

PERSPECTIVES ON NEGOTIATING AGREEMENTS

The knowledge generation and sharing described herein is beneficial to ensuring that universities and companies understand each other's goals for a license agreement. However, soft skills and institutional support can be equally important to moving a deal forward. Participants involved in a fireside chat discussion surrounding the topic of relationships between university technology transfer offices and medical technology companies identified the following success factors:

(1) **Recognizing** that the technology transfer office is a service organization, and

(2) **Having support** from the administration both in terms of funds and staffing. Directors and other leaders of licensing offices play a key role in setting that tone and motivating their teams to create positive, productive relationships with industry.

Licensees will have a broad range of backgrounds and levels of experience. They can gain insights into the university licensing process by engaging attorneys and other advisors who have experience with these negotiations, but, even with this guidance, approaching a university license for the first time can be a daunting endeavor for a young company. "Involving someone who is experienced in the negotiation and technology transfer process, or engaging an advisor to assist in certain areas, can smooth and expedite the process, as well as help to establish trust between the parties," shared Erik Robinson, Chief Executive Officer, Sintact Medical Systems Inc. Universities can also help guide their students, faculty and post-doctoral fellows through the process by providing access to outside advisors. It is important for any advisors engaged by the company to approach negotiations with the understanding that the agreement is one component of a long-standing cooperative relationship between the company and university. This perspective can be helpful in addressing both parties' interests effectively.

The use of standard form agreements by universities and research institutions can help to create efficiencies and set licensee expectations by identifying broad terms from previous agreements that have been used repeatedly with companies and have yielded positive results, while addressing the university's objectives. If well-crafted, form agreements can be helpful in streamlining negotiations, which in turn decrease transaction costs and maximize the life of the patents being licensed. The use of forms is also necessary to help address financial, volume and personnel constraints on the university.

> *"Involving someone who is experienced in the negotiation and technology transfer process, or engaging an advisor to assist in certain areas, can smooth and expedite the process, as well as help to establish trust between the parties."*
>
> **Erik Robinson**
> Chief Executive Officer
> Sintact Medical Systems Inc.

The challenges inherent in a form-based approach arise, however, when the forms do not accommodate the likely business models of licensees, and licensing officers are not empowered to adjust the forms to accommodate the inevitable variations required specific deals. Provisions that are not necessary to address the university's primary goals and conflict with the terms that will inevitably reside in its licensees' future sublicense arrangement or acquisition agreements should be avoided in creating form agreements. This will facilitate the initial license negotiation and avoid the need for

time-consuming and sometimes costly amendments in the future. It can also be quite powerful for universities to develop their forms in concert with their prospective partners, to build a starting point that addresses common concerns. As discussions with individual licensees proceed, the terms of a form agreement, even one that is thoughtfully constructed, should be adjustable to accommodate the peculiarities of each licensee, technology and business plan. Universities that are able to be nimble in making such adjustments display flexibility that results in a higher level of trust with their partners and often better results for both parties in the terms of the agreements. As noted by a one executive during our discussions, "universities that are desirable to work with are those with top-notch researchers and technology transfer officers that are creative and flexible."

University licensing officers should be prepared with an understanding of the range of perspectives they will face in license negotiations, which will include those of first-time entrepreneur inventors, venture capital investors, and multi-billion-dollar companies expanding their product and patent portfolios, either by directly licensing technologies from universities or acquiring companies that obtain such licenses. Equipping university licensing officers with tools to adapt forms to address competing concerns as efficiently as possible, while still protecting the universities' interests, will facilitate smooth negotiations. Where licensing officers are unable to resolve deviations from the university's form agreements independently, efficient escalation structures are important to provide a path forward and enable completion of the agreement. Responsiveness and creativity help universities to develop long-term relationships with industry partners. During the February 2018 AUTM Fireside Chat, Lesley Millar-Nicholson shared how MIT tries "to bend to every single term received from their partners without compromising the goals and beliefs that stand true to the university." Balancing the need for flexibility and the need to support the university's goals is challenging and regularly manifests itself in different ways that can be confusing to companies because they seem counter to the companies' business strategies. University licensing officers should understand (and be able to articulate to the licensee) the university's goals for each provision in its form and, where possible, be equipped with alternative language or approaches to facilitate negotiations.

Companies, on the other hand should bear the perspective that these negotiations are likely to be different than those they might be used to when entering into agreements with other industry partners. The form of agreement will be the university's form, which the licensing officer may have little independent ability to agree to change. There are terms in those form agreements that will not feel like a business-to-business deal, and approaching the process with this understanding will help to minimize the frustration as certain inevitable sticking points arise.

Companies can help to educate universities with respect to their goals and business plans for the licensed technology. According to Lesley Millar-Nicholson, "MIT focuses on drafting licenses that do not run small companies into the ground within the first two years." This is a positive start to addressing the concerns of small companies; however, it is also helpful to consider that the lifecycle of most medical device companies is longer than two years. Approaching license agreements with a longer outlook may be helpful in creating a mutually beneficial arrangement. Being proactive in explaining its business goals and strategies to its university partner can help a licensee to ensure that those goals and strategies are supported by the terms of its university agreements.

KEY LICENSING TERMS

Much of the foregoing discussion is focused on preparatory activities intended to enable the parties to maximize the value of what matters most to each side in the negotiation of a university license - the terms of the agreement. A separate detailed guide could be written on which provisions are important to universities and their licensees and why. However, we will try to summarize some of the important themes here. Because the majority of university licenses are granted to small companies, it is important for each side to think through the financial burdens placed on these small companies and whether those financial burdens are reasonable and sustainable based on fundraising plans, anticipated development expenses, expected margins on the products once commercialized, and subsequent transactions that involve the licensed product or intellectual property. If those burdens are too high, then the company will not be financed or will otherwise fail under their weight. Remembering that the ultimate goal is to provide patients with access to medical technologies may help each side to remain reasonable in its requests.

Some of the most important elements of a license agreement to company licensees can be summarized with the following **four E's: Exclusivity, Economics, Enforcement, and Exit**.

EXCLUSIVITY

Considerations related to exclusivity include the scope and duration of the license.

- What are the patents and technology being licensed?
- Does the licensee require exclusivity with respect to those patents or is the goal simply to obtain freedom to operate through a non-exclusive license?
- If patents are included in the license, the duration of the license should match the life of the patents. Particularly in an industry where the development pathway can be long, it is critical to maintain the benefit of an exclusive license for as long as the patents have the ability to exclude competitors from the market.
- What are the field and territory of the license? Most typically a licensee will want a worldwide license. Field limitations diminish the power of the license, unless they are crafted in a way that matches the maximum potential market for the licensed technology based on the scope of the subject matter of the license patents or the industry in which the licensee operates.

An exclusive license typically includes the right to grant and authorize sublicenses. For companies with business models that include the potential for collaborations or partnerships, broad sublicensing rights are critical to support that model. The sublicensing rights should include the ability to grant sublicenses through multiple tiers to enable global development and commercialization of the products and services within the scope of the license. Consent rights to sublicenses can put the university in the position of controlling the business model of the licensee, which is not a core strength of the university and should be avoided to give the technology the best chances to get to patients broadly.

ECONOMICS

As noted previously, the economic terms of the license agreement can determine whether a company will be funded and whether the licensed products and services will ultimately be viable from a financial perspective, so they must be reasonable for the specific technology being licensed and as compared to prevailing market terms.

Considerations related to the economics of a university license include:

- The scope of products that are subject to payment obligations. Most typically these are limited to products that would infringe the licensed patents, but for the license being granted. When patents are not involved, or other materials of significant value are being licensed, however, the university may push for some scope of enabled products to be subject to payment obligations. Ensuring that such an expanded scope of products requiring payments to the university does not disadvantage the licensee as compared to its competitors, who have not taken a license from the university, is critical.
- Royalty rates and milestones should be commensurate with the value that the licensed technology brings to the overall intellectual property portfolio of the company and the products being developed. University technologies are often nascent when they are licensed into companies, and extensive resources are required to complete development and bring products to market. The relative value contributed by the university, as compared to that to be invested by the company, should be kept top of mind in determining the consideration to be paid to the university. Royalties and milestones also need to be supportable based on the size of the market being addressed and the business model of the licensee.
- Sublicense revenue sharing models can result in universities receiving a disproportionate share of the economic value of a company's partnering arrangements if not crafted carefully. These sharing models are typically in addition to the baseline economics that the university would receive if the company exploited the licensed products directly. Again, the relative value of the university technology, as compared to the value contributed by the company and by other technologies provided to a sublicensee, should be accounted for in defining the sublicense revenue to be shared and the percentages to be received by the university.
- Equity provided to, or purchased by, the university can be a good way for the university to participate in the potential upside of a company receiving a licensed to its technology and to align the incentives of the parties. Rights associated with equity that are not commensurate with those of other shareholders can raise red flags for investors and others. Further, equity should be viewed as part of the overall consideration provided to the university, typically as part of the upfront payment being made.

ENFORCEMENT RIGHTS

- Enforcement rights go hand-in-hand with exclusivity. The power of an exclusive patent license is the ability to exclude others from practicing the subject matter of the licensed patents. Accordingly, investors and acquirers of a medical device company will put a premium on the licensee having the first right to enforce the licensed patents against third-party infringers to protect the market being pursued.
- In order to maximize the ability to protect a market, the licensee also should be provided robust rights to have input into the prosecution of the licensed patents.

EXIT

- For many early-stage medtech companies, being acquired by a larger company is often a primary goal and the swiftest path to making their devices broadly available to patients. Accordingly, ensuring that the assignment provision includes the right to assign the agreement to affiliates and acquirers of the licensee, without requiring the consent of, or onerous payments to, the university, is critical to enable different acquisition structures.

Additionally, the following items have been expressed by universities as being important components of licensing terms – **the four P's: Publication, Prosecution, Participation, and Protection**.

PUBLICATION (AND OTHER RETAINED RIGHTS)

- The retained rights described earlier in this guide represent one term that universities typically have little latitude to change. If the licensed technology was funded using government grants, then under Bayh-Dole, the government will retain certain rights to the technology that must be passed through in the licensed agreement. In addition, the university will require the right to continue to use the technology for research and educational purposes, including publication.

PROSECUTION

- The university will typically retain the right to control prosecution of the licensed patents, at the licensee's cost. As noted previously, the licensee will want, and can typically receive, rights to provide input into the prosecution of the license patents, and often company counsel plays a lead role in maximizing the scope of the patents to the benefit of both parties.

PARTICIPATION FROM AN EQUITY AND ECONOMIC PERSPECTIVE

- This is the flip side of the "third E," Economics. A university will want to maximize its potential financial return if a technology that it licenses is successful. As a result, university licenses have come to include multiple layers of payment to the university: equity (including the right to participate in future financing events), license fees, milestone payments, maintenance fees or minimum annual royalties, royalties, sublicense revenue sharing provisions, and/or payments on assignment of the agreement.
- As medical technologies evolve and are not always protected by patent, one of the challenges is to find economic models that make sense for different types of technologies. The economics attached to access to a database or a license to software likely shouldn't be the same as those typically associated with an exclusive patent license. Determining the scope of products that should be subject to payment can be challenging when a license is the result of early-stage research that may not be patentable but still provides value. Particularly in these cases, it is important for the parties to understand the potential business models for the licensee to determine potential economics models that could apply. Equity or annual payments can provide alternative approaches to allowing the university to receive compensation for its technology when the traditional royalty and milestone structures are more challenging to apply.

PROTECTION OF THE UNIVERSITY'S INTEREST

- Universities are risk averse and include robust protective provisions in their agreements that shift risk to their licensees, including warranty disclaimers, liability disclaimers, liability caps, and broad indemnification obligations on their licensees that would not typically be included to the same degree in agreements between two companies.
- Risk-shifting associated with developing an early technology out of a university may be understandable in many regards, given the relative levels of control of the two parties over that development and, ultimately, the commercialization of resulting products. Companies have largely become comfortable that they will receive little in the way of promises from the university regarding the quality or comprehensive nature of the technologies they are licensing. However, they do reasonably expect the university to take responsibility for its own action, including negligence, willful misconduct and breach of the agreement.

These are not the only issues that will be negotiated in agreements between academia and industry, but they do highlight the importance of understanding the different perspectives to be considered in these negotiations. The resulting agreement will nearly always be the subject of due diligence in the context of a financing, a partnering arrangement or an acquisition—frequently all three over the life cycle of a company. Crafting agreements that facilitate those critical junctures for companies will render the technologies in the best position to reach patients, and therefore should be a goal of both parties during negotiations. This can be uncomfortable for universities as this will cede some level of control over these technologies to their licensees. Accordingly, it is also important that the agreements support the mission of the universities.

Throughout the development of this guide, universities frequently expressed their preference to amend licenses in response to requests from investors, sublicensees, and acquirers, rather than deviate from their form agreements in the initial negotiation of the deal. If the university has a clear and efficient path to amending its licenses, companies may be receptive to this approach. Lengthy negotiations of an initial agreement, however, offer little comfort that an amendment will be any more clear cut. Companies, on the other hand, value not having to come back to the university to obtain permission to conduct its business, particularly in the manner that is anticipated from the outset. Accordingly, a forward-looking view of these agreements that anticipates likely challenges, coupled with speed, can add tremendous value in the context of these negotiations.

Conclusion

Conclusion

This guide outlines an approach to creating long-standing, effective relationships between university technology transfer offices and medical technology companies. Based on discussions with both university and industry members, cultivating greater synergy between both groups requires focusing on the suggested groundwork to effectively prepare the respective organizations for partnership. Universities must cultivate relationships with the right industry contacts and have a technology transfer office that is empowered by its administration to be creative and flexible when negotiating with industry. Industry must recognize that technology transfer is a service organization of the university tasked with protecting the university's mission and goals and that license agreements will be different from other business-to-business transactions. The preparatory work described in this guide can drive further collaboration among universities and industry on license agreements and improve the efficiency of negotiations and the quality of the resulting agreement.

The speed of negotiation and quality of license agreements directly impact whether a company will be able to form around the technology, and subsequently develop and commercialize the product. If the agreement subsequently needs an amendment, that can also jeopardize the company's chances of receiving funding or entering a pivotal deal for the company. Each layer of challenge decreases the chances that the technology will reach patients. Accordingly, the parties' interests should be aligned to move these agreements forward quickly and on reasonable terms.

By incorporating the key factors outlined in this guide, universities and industry can develop mutually-beneficial, long-standing relationships that will catapult innovative medical technology solutions from academic research to products that impact patients' lives, as well as drive the medical technology industry into a new dimension of innovative solutions.

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