TECHNOLOGY TRANSFER IN U.S. RESEARCH UNIVERSITIES: DISPELLING COMMON MYTHS

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Preamble

During the past several decades universities have achieved notable success in licensing their research results for commercial Through "technology transfer" they application. provide commercial sector companies with access to new discoveries and innovations resulting from research. Industrial partners develop these inventions and manufacture products that help to improve the lives of Americans. However, there have been persistent criticisms, including that university technology transfer activities detract from the fundamental missions of universities, that universities engage in these activities primarily for financial gain, and that the result is unmanageable conflicts of interest both for institutions and researchers. There also are intense public concerns about the high costs of drugs and therapeutics and possible connections with university patenting and licensing activities.

This document addresses a number of commonly held myths about university technology transfer. Some of them are explained by the

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provisions of the underlying legislation, which not only provides incentives, but also imposes controls to guard the public taxpayer's interests. Some of them are explained by statistics, which deflate the perception that universities derive a steady income stream from technology transfer. Perhaps the biggest myth to dispel is that universities engage in technology transfer "for the money."

Several factors explain why universities are currently so active in partnering with industry. First, under the Bayh-Dole Act, universities have a mandate to ensure, to the extent possible, that inventions arising from federally funded research are commercialized. It is an obligation they have increasingly embraced since 1980 when the law was enacted. Secondly, universities need to make sure they have adequate resources to enable faculty to continue to do research and to provide learning opportunities for students. Universities also must consider their obligation to respond to the needs of local and state economies and the nation as a whole. Policymakers at all levels of government are increasingly focusing on commercialization of university research findings and discoveries as key to economic development at local, regional, and national levels.

This document, first released in 2000, seeks to dispel some of the common myths related to university technology transfer and to provide better understanding of the actual purpose and nature of these activities.

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Myths & Responses:

Myth #1: Technology transfer activities have been detrimental to a university's fundamental missions of education, research, and public service. As a result, universities have been transformed into commercial-minded entities.

Response: Teaching, research and public service are mutually supportive core missions of the U.S. research university. The transfer of new knowledge and innovative discoveries to those who can make use of them for the benefit of society is fundamental to each of these missions. Knowledge transfer and technology transfer occur through various means, such as scientific publications, conference presentations, the training and education of students, and the conveyance of intellectual property rights to entities best situated to further develop the innovation into a product or service that can be used by the general public. While publications in peer-reviewed journals and matriculation of students have a longer history among U.S. universities, the transfer of intellectual property rights has enhanced the beneficial relationship among academia, the private sector and society as a whole. According to a study by the National Research Councilⁱ:

- Commercially oriented faculty are prolific producers of scientific publications (more so even than those who do not pursue commercialization);
- There has not been a significant shift away from fundamental research in favor of more applied research;
- Commercialization of IP rights does not result in meaningful delays to the publication of research results; and
- Scholarly output and its quality remain the principal criteria for academic employment and advancement.

Myth #2: *Neither the U.S. government nor the taxpayer benefits from university patents resulting from federally funded research.*

Response: In 1980, the Patent and Trademark Law Amendments Act, commonly known as the Bayh-Dole Act, was passed to encourage public-private partnerships that would allow inventions created using federal funding to be developed and made available to the public. A study by the Information Technology & Innovation Foundation (ITIF) concluded that the Bayh Dole Act "has proven to be a critical enabler" of the life-sciences research and development system in the United States and "has significantly amplified the utilization of federally funded researchⁱⁱ."

Data from 1996-2020 show that academic-industry partnerships contributed upwards of \$1.9 trillion to the U.S. industry gross output, as well as \$1 trillion to the gross domestic product (GDP) while supporting 6,499,000 jobsⁱⁱⁱ. During FY2020, U.S. research institutions created 1,117 startups, averaging more than three new companies each day of the year^{iv}. This substantive

economic impact generates tremendous value to the U.S. economy and workforce that also supports U.S. competition in the global marketplace. In addition, the public benefits from the 933 new products that were introduced to the market during 2020 and the more than 200 new drugs and vaccines that have been commercialized since passage of the Bayh-Dole Act^v. For example, previous sponsorship of groundbreaking research facilitated the rapid development of COVID vaccines when it was critically necessary for public health and safety.

Myth #3: U.S. taxpayers, through NIH, provide significant support to find new therapies. These drugs should be free to the public.

Response: The National Institutes of Health (NIH) funds significant extramural research at universities with a goal to "foster fundamental creative discoveries ... and their applications as a basis for ultimately protecting and improving health^{vi}." Universities conduct NIH-funded research to gain greater understanding of medical and scientific knowledge and discover innovative approaches to address medical ailments. Universities are not equipped to turn a basic scientific discovery into a commercial product that can be used by the general public. Universities must transfer these innovative discoveries to an industry partner to further develop the invention, ensure proper safety and efficacy for human use, navigate the time-consuming process of clinical trials to secure regulatory approval, and scale up manufacturing to produce sufficient quantities to meet consumer demands. Universities seek patent protection to provide an incentive for industry partners to invest the significant time and resources required to develop and commercialize the invention into a product. Industry investment in the development and commercialization of drugs far exceeds the initial NIH funding to find new therapies. A 2020 study by the London School of Economics estimates the mean investment by industry to bring a drug to market is upwards of \$1.34 billion^{vii}. In addition, industry seeks a return on this investment so that it can infuse resources into the development of additional drugs.

Myth #4: Technology transfer is a major source of revenue for most universities, creating unmanageable institutional conflicts of interest.

Response: Most university technology licensing offices struggle to make enough in licensing revenue to cover their operating expenses. Lucrative inventions are exceedingly rare. Based on data from the <u>2020 AUTM Survey</u>, the top 5% of U.S. technology licensing operations (9 universities) accounted for 51% of the total licensing revenue reported. In the same year, the top 10% of the reporting U.S. universities realized 70% of the licensing income. Furthermore, licensing revenue is a very small portion of a university's operating budget. In 2020, monies received from commercialization activities was equivalent to less than 4% of U.S. universities' total research expenditures. Despite the lack of revenue in most cases, universities continue to engage in technology transfer as an integral part of their public service mission.



It is important, however, to acknowledge any collaboration with industry can create at least the appearance of a conflict of interest. Any institutional conflict of interest, or potential conflict of interest, should be handled in a transparent manner by the university, typically through a management plan.

Myth #5: University technology transfer offices over-value intellectual property thereby hampering successful commercialization while prospering from high royalties.

Response: The royalty rate is only one variable in determining the overall value of a license agreement and is only paid by the licensee when it is selling products and generating revenue. Moreover, the royalty rate, on its own, is an insufficient indicator of both the value of the intellectual property and the potential success of the commercialization of the technology. Because technology transfer is about impact, additional factors to consider are the possibility of scientists extending their research, graduate students refining their research skills, and undergraduates having the opportunity to be introduced to research.

Data shows that nearly 60% of the licenses that academia execute do not generate licensing revenue for the university, and as little as one percent of the licenses generate licensing revenue of more than \$1M over their lifetime. In 2020, five universities accounted for one-third of all licenses generating more than \$1M in licensing revenue (calculated from the <u>2020 AUTM survey data</u>).

Myth #6: When universities receive royalties, it doesn't help students or keep tuition down.

Response: The majority of the revenue received by universities from licensing activities directly funds further university research and education. The Bayh-Dole Act requires that universities distribute the net proceeds from licensing federally funded inventions, after subtracting the costs of patenting and licensing, to the inventors and to support research and education. While the specific percentages vary from institution to institution, the typical royalty sharing policy distributes, after expenses, about 30-40% of net income to the inventor(s), with the rest going to the inventor's department and/or college, or to the university to support research and education. For example, revenue has been used to support graduate students, postdoctoral fellows, or faculty members, and to enhance research facilities.

Technology transfer is about impact, not income. At most universities, the primary objective of technology transfer is not to generate a profit, but to create opportunities for professors, graduate students, and undergraduates to engage in research. Technology transfer is an integral part of the institution in support of research, student development, faculty recruitment and retention, career opportunities for post-docs, enhanced corporate engagement opportunities, new sources of



research funding through start-up creation and industry collaborations, the dissemination of knowledge, and reputation enhancement.

Myth #7: Universities are filled with valuable inventions just waiting to be "picked" like low hanging fruit. Technology transfer offices are an unnecessary barrier to effective commercialization.

Response: Effective stewardship of an intellectual property portfolio is a highly complex, costly, and time-consuming process that can require a decade or more of active management for any single invention. University technology transfer offices are staffed with dedicated, trained professionals who work closely with both academic researchers and industry.

Effective technology transfer requires a diverse set of skills. Scientific expertise, technical assessment, market evaluation, intellectual property law, marketing, negotiation skills, contract law, and knowledge of relevant federal laws are all essential in the technology transfer profession. Often these are skills that are developed over years of experience.

In addition to a diverse skill set, technology transfer also requires that the individual carefully balance the academic mission of the institution with the business focus of the technology transfer office. Cultures, goals, and missions may vary from one academic institution to another, as well as from one company to another. Experienced and effective technology transfer professionals understand the differences between the academic culture and the company culture, have the ability to communicate these differences in a meaningful way to all stakeholders in a negotiation, and also have the experience to develop relationships that carefully balance the needs of the parties. At times, this is likely to require close collaboration with colleagues in other units of the university that support research, such as sponsored programs, or regularly interact with companies, such as development. By providing a wide range of expertise, resources, and funding, technology transfer offices can effectively assess, protect, and commercialize research discoveries across the various disciplines of the university. Most faculty are ill equipped to conduct market research, evaluate company capabilities, negotiate license agreements, etc., functions that technology transfer offices perform on a routine basis.

Response: Universities are a leading source of discovery and innovation and *require* companies to diligently develop products from these discoveries. This may include continued research collaboration so that the technology is in a more ready state for the company to further develop the product. So-called "trolls" on the other hand, seek only to profit from discoveries made by others, and have no interest in the ultimate development of a product.

Myth #8: University technology transfer offices function as "patent trolls".

"Troll" is an unfortunate pejorative term that some critics use to lump university licensing practices with those of other entities that neither conduct research nor engage in product development. Whereas a so-called patent "troll" has no research and development capabilities and is only looking to enforce rights it has acquired from others purely for financial gain, universities typically seek to collaboratively develop technologies in collaboration with corporate partners to *ensure* that the technology can be made available to the public. In fact, most university technologies could not be developed by a licensee without the continued assistance of the faculty member/inventor, making cooperation between the parties almost a necessity.

Myth #9: *Most university intellectual property is licensed to large, well-established companies because small businesses cannot afford to license university inventions.*

Response: Large, well-established companies can play an important role in commercializing university innovations. With certain technologies, these large organizations are best suited to further develop and bring those innovations to market. However, most of the time, this has not proven to be the case. For more than two decades, startups and small companies have been shown to license the majority of the technologies from U.S. universities. According to AUTM, between 1996 and 2017, over two thirds of the innovations that were licensed by academia to industry were with startups and small companies. In 2020, over three quarter of the licenses executed by technology transfer offices were with small and startup companies^{ivv}.

Myth #10: Universities are more interested in seeking patent protection, and enforcing patent rights, than publishing findings for the public to use.

Response: Next to the matriculation of students, publishing the results of research is historically one of the most important functions of a university and remains the primary factor in promotion and tenure decisions^{viii}. Moreover, publication remains the primary vehicle for academic professional recognition and is critical in establishing credibility in grant applications. Like the federal government^{ix}, universities have supported open access policies so that the general public will have free access to publications of federally funded research results. These activities exist in harmony with seeking patent protection for specific technologies with the potential to be commercially viable and developed into a product accessible to the public.

Universities take the right to publish very seriously and include language in license agreements specifically stating that the license does not prohibit a researcher from publishing their results. It is also worth noting that patents and patent applications are published and available to the public.

As for enforcement, in only a small number of cases do universities seek to enforce patents by pursuing legal action. Although there are instances of universities involved in litigation with companies, the number is tiny relative to the total number of intellectual property infringement

cases. Moreover, of the total number of university patents, the number subject to litigation is trivial – in other words, the vast majority of licensed technologies are a result of good-faith negotiations between a university and a corporate partner. The small number of university-initiated patent infringement cases usually result from: i) the university being joined as an indispensable party when its licensee files a lawsuit; or ii) as a last resort when all attempts to license a technology to an infringer have failed. In these cases, the university-plaintiff is faced with the prospect of either initiating a lawsuit to protect its rights or risk losing rights altogether under the legal doctrine of laches. In any case, given the burden and expense of patent litigation, and limited university budgets, universities cannot and do not engage in trivial or frivolous lawsuits to enforce patents^x.

Myth #11: Universities are doing too much patenting. It would be better for economic growth and U.S. competitiveness to put more inventions into the public domain for everyone to use freely.

Response: Universities conduct a broad range of research that can lead to inventions in a variety of fields. The university technology transfer office determines how to best distribute the innovation for the public benefit, whether that is through open-source availability or patenting and licensing. Many innovations need an industry partner to further develop them into commercial products that can be accessed by the general population. Having patent protection for a novel innovation provides an incentive for an industry partner to license the technology and invest the effort and financial resources in development leading to a product. This is particularly true for inventions that will require significant investment, e.g., relating to regulatory approval. As innovations come to the market, this activity spurs regional economic growth. In addition, when local startups develop the technology, new jobs are created.

Before passage of the Bayh-Dole Act in 1980, the federal government owned federally funded inventions and licensed only 5 percent of the 28,000 patents that the government retained^{xi}. Since the Bayh-Dole Act passed, university-industry partnerships have accelerated collaborative research and innovative discoveries to benefit society. More than 200 drugs and vaccines were developed through public-private partnerships since the Bayh-Dole Act was enacted^v. Commercialization of university research results has contributed in important ways to the growth of the U.S. economy. According to AUTM estimates, between 1996 and 2020, academic technology transfer activity contributed \$1 trillion to the U.S. gross domestic product, led to the creation of 18,000+ new companies, and supported 6.499 million jobs.

Response: Biological materials and research tools discovered at universities are helpful to both universities and companies for continued research or the development of products that could

Myth #12: University patenting of biological materials and research tools is harmful to the advancement of science and is hampering the efforts of researchers.

benefit society. When use of an invention does not require significant investment, it is often not patented, but is shared with commercial partners non-exclusively to ensure ethical use of the material and allow for wide dissemination. In those instances where patent protection is sought, it is to provide incentives for industry to develop and commercialize the technology so that the general public can actually use and access the technology. For example, a research tool may need to be carefully and consistently prepared in order to be utilized by scientists in a research laboratory, or an exclusive license may be required to encourage the company to develop those tools on a broad scale to be widely available to many research laboratories. Even when a material is patented, however, universities routinely deposit such materials into public repositories where other researchers can access the materials to either validate the research results or to continue research on the materials in other directions.

A study supported by the National Academy of Sciences and the National Science Foundation evaluated whether the patent system created barriers for those conducting research in biomedical fields, particularly with research tools^{xii}. The study found that neither university research nor drug discovery has been significantly hindered due to patents on research tools. Even the National Institutes of Health (NIH) which remains one of the most important supporters of biomedical research in the United States. promotes the sharing of unique research resources with other researchers, while acknowledging the possibility of patent protection^{xiii}.

,Advances in biomedical science continuously yield new research tools that play a critical role in the advancement of knowledge and innovation in both the public and private sectors. Some of these developments are patented and subsequently require the negotiation of license agreements and material transfer agreements (MTAs) to delineate the terms and conditions under which research tools can be used. These agreements, which have long been standard practice for companies, have also become standard practice for universities and government laboratories. Most institutions use these agreements effectively to disseminate patented or unpatented materials on reasonable terms^{xiv}.

To facilitate the use of research tools in academic research, many academic institutions reserve the right not only for themselves but also for other academic institutions to practice an invention for research and educational purposes when executing license agreements. As the result of a cooperative project involving the NIH and several universities, NIH has provided two template documents: the Uniform Biological Material Transfer Agreement (UBMTA) and the Simple Letter Agreement, which it suggests be used for most routine transfers^{xv}.

Myth #13: University licensing is harmful to the advancement of science and is hampering the efforts of non-profit organizations that are trying to bring medical care to underdeveloped populations and countries.

Response: The development, approval, and ultimate delivery of therapeutics and diagnostics to developing nations is a complex challenge that clearly requires more than simply a change in the ways that universities license their inventions. In addition to the need for effective regional infrastructure, new models and partnerships ultimately will be required at later stages of the commercialization ecosystem to develop and distribute a product that has an impact.

Non-traditional approaches to develop and distribute therapeutics and diagnostics to the developing world are emerging through novel partnerships that merge philanthropic and humanitarian goals with product development^{xvi}. Organizations like MIHR (Center for the Management of Intellectual Property in Health), <u>PIPRA</u> (Public Intellectual Property Resource for Agriculture, includes MIHR), <u>TB Alliance</u>, and others are addressing specific segments of global health, and the vast resources of the Bill and Melinda Gates Foundation have focused the attention of policy makers and the public on global health research.

While some initiatives have looked broadly at the problems, issues, and needs associated with bringing therapeutics or diagnostics to developing countries, they focus on the earliest stages of the commercialization ecosystem, such as university research and licensing, without taking into account the issues throughout the innovation pipeline up through patient delivery. Many universities already have sublicensing practices that accommodate new markets or unanticipated uses of licensed technologies. Refinement of this language or the use of terms that more clearly articulate the needs for the developing world have been encouraged by groups that advocate these causes and by university technology licensing managers themselves^x.

The AUTM Better World Project provides numerous examples of university licensing that have had an impact on global health. Licensing practices that are already in place in universities also are making an impact.

Myth #14: The recent focus on industrial relationships and entrepreneurial activities in U.S. universities is detrimental to the university's fundamental mission of educating students.

Response: In today's changing world, universities must seek to provide students with experience and training that prepares them for jobs in or associated with contemporary industry. Companies want to hire students who are critical thinkers and can easily assimilate into the industrial environment and often fund university research in anticipation of finding talented future employees. Enabling students to participate in research of interest to industry gives students a window to the industrial world, offering an opportunity to solve real-world problems, providing experience working in cross-disciplinary teams with industrial scientists, and developing the

knowledge to thrive in an industrial workplace or start up a company.

Many universities are seeing an increase in student demand for innovation and entrepreneurship, and as a result, are broadening course and program offerings. This type of education improves upon traditional classroom instruction by actively engaging students in innovative and entrepreneurial activities through workshops, conferences, internships, hands-on experience, and real-world projects. Industry and entrepreneurship courses and programs (i) develop critical thinking, analytical, organizational, interpersonal, and leadership skills, and (ii) broaden life skills, such as budgeting, marketing, networking, professionalism, business-plan development, and connecting with business leaders. Students learn to identify and solve problems, work in teams, calibrate risks, and effectively communicate with others. This encourages students to move beyond current approaches of particular disciplinary perspectives to adopt strategic approaches to experiment and transform good ideas into reality. Fostering an entrepreneurial mindset develops the mental agility to prepare students for an uncertain and unpredictable world. This is part of the change needed to modernize university studies to prepare students for the next generation of jobs and industries of the future. Universities help fulfill their economic and social missions by promoting entrepreneurship and industry collaborations.

Myth #15: University faculty should just educate students and conduct research, but not be encouraged to start companies.

Response: One primary goal of a university is to broadly educate and prepare students to enter the workforce post-graduation. Some graduates pursue traditional jobs in established organizations, and some prefer to pursue entrepreneurial opportunities, for example, in a startup company. For the latter, incorporating entrepreneurial courses or experiences into educational training would better prepare students for a job in a startup. Universities also hear from companies hiring graduates that even in traditional roles, students with entrepreneurial experience were more adept at solving problems, so gaining such experience through their university education provides long term value to the students.

Some faculty want to start a company, commercialize a product useful to society, create jobs, and contribute to the local economy, which most universities allow under outside activities policies. Gaining that experience firsthand is enormously valuable for a faculty entrepreneur who is also teaching and training student entrepreneurs. This provides a richer experience for the student, and the faculty mentor becomes a better researcher and teacher. Additionally, university research often generates results that show early promise, but require additional validation before a strategic partner will invest in further development. A startup may be necessary to further develop such a technology to be of interest to a more established company with manufacturing and distribution infrastructure. Startup companies with faculty founders are also an important way to answer commercially relevant questions of lesser academic merit which are not typically funded through

academic research grants. The startup company can seek small business grants and attract earlystage investors to fund the validation and early development of their inventions. These results can be used to attract additional investment or engage strategic partners.

Myth #16: Some companies and industries believe it is hard to work with U.S. universities

Response: Non-profit entities, such as universities, and for-profit entities have largely divergent missions and objectives. These differences can be overcome when all parties recognize the objectives and limitations of the other collaborating parties and work together to find a path forward. Industry sectors differ from one another in their relationships with universities, as do companies within sectors. Similarly, universities can differ from one another in important ways (e.g., public vs. private).

While much of the research at universities is directed toward the discovery and understanding of basic mechanisms, industry wants universities to conduct targeted research focused on solving specific problems. This schism is one important factor that contributes to the difficulty in negotiating industry sponsored agreements. Other common sticking points in negotiations relate to ownership and access to intellectual property that is created during the projects, publication delays, confidentiality, and "freedom to operate" with respect to intellectual property. Access to pre-existing intellectual property that might be used in a project, so-called "background intellectual property," may pose particular challenges. Some corporate proposals for access to and exclusive control of intellectual property can conflict with a university's fundamental missions of disseminating knowledge and ensuring public benefit from research results, as well as the ways that universities manage intellectual property and reward inventors. In part, these differences stem from the ways that some companies view intellectual property, manage innovation, and crosslicense key discoveries with competitors to ensure their own freedom to operate. However, with respect to all of these issues, universities have developed approaches to enable industry-sponsored research projects. For a productive collaboration, it is critical that there is alignment between the research objectives of the faculty collaborator and the company.

The <u>University Industry Demonstration Partnership</u> (UIDP) is a project-oriented organization where university and industry members identify issues impacting university-industry relations and opportunities to develop new approaches to working together. UIDP tackles strategic and tactical challenges impacting the environment for research collaboration to remove barriers and build new networks and opportunities for future collaboration. UIDP has developed many materials on addressing key issues in university-industry collaborations.



Myth #17: Faculty startup companies create financial conflicts of interest for academic researchers.

Response: The creation of startups is an important mechanism for the successful transfer of university-based innovations into the marketplace. Study after study have shown that these newly formed companies create jobs and have a significant impact on the local and regional economies. Conflicts of interest are inherent with respect to any startup in which a university employee has a financial interest. Most conflicts of interest, however, can be managed through a process of disclosure and oversight^{xvii}. Research universities in the United States have conflict of interest policies and experienced staff to evaluate conflicts of interest and administer management plans for university employees.

Myth #18: *Creation of incubators on campuses replaces basic research with commercialization activities.*

Response: Universities conduct basic research to generate knowledge and understanding in various scientific fields. This activity occurs very far upstream from commercialization activities. While discoveries may arise during basic research, such discoveries often are too early stage or insufficiently defined for commercialization potential to attract a company or investor to further develop the discovery. Basic research remains a critical component of the innovation ecosystem and provides a pipeline for discoveries that could one day become an invention that could benefit mankind.

Incubators, on the other hand, operate downstream and are established to offer facilities and services to startup companies that are just trying to get off the ground. Incubators may provide physical location, resources such as mentorship, or networks to connect with experienced professionals who could be part of the management team. Incubators play an important role in encouraging startup companies that further develop university inventions into products and create jobs. They also help manage potential conflicts of interest by providing separate, leased space for entrepreneurs.

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Endnotes

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