21 Questions Paper

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As discussed in recent COGR meeting reports, the COGR Contracts and Intellectual Property (CIP) Committee has updated the COGR *Questions about University Technology Transfer* document. The document, now titled *21 Questions and Answers About University Technology Transfer*, discusses issues such as the relationship of technology transfer to universities' primary missions, the role of universities in economic development, why universities may sue companies to enforce patent rights, the distinction between universities and patent "trolls," whether patent "thickets" are hindering research and innovation, challenges in university—industry research collaborations, and university use of licensing revenues and whether they have any connection to the high cost of drugs. The document also describes the nature and accomplishments of university technology transfer, the Bayh-Dole Act, strategies for promoting dissemination of university technologies, and discusses the relationship between patents and publishing.

We hope that this update will be helpful to COGR member institutions both in explaining the nature of university technology transfer and understanding some of the challenges and issues that may arise. It seeks to reflect the increased visibility of technology transfer issues and to respond to concerns that have arisen since the last version of this document.

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21 Questions and Answers About University Technology Transfer

1. What is technology transfer?

For the purpose of this Q&A, technology transfer refers to the formal licensing of inventions, software, research tools, and other technologies developed within a university's research programs and usually protected under United States intellectual property laws.

In a broader sense, technology transfer may also include the dissemination of knowledge and discoveries to students, other academics, industry, scientists, and the general public. In that respect, technology transfer is another way for a university to teach and thereby disseminate knowledge for public utilization. Traditional routes for such dissemination to occur, for example, include: (i) classroom discussions, (ii) attendance and presentation at conferences, (iii) publications in the scientific literature; and (iv) the employment of students by companies. Technology transfer also can involve a number of different forms of "intellectual property" such as original works of authorship copyrighted by university faculty, trademarks, individual know-how, and tangible research materials. This Q/A discusses university technology transfer that occurs when innovations are licensed by a university to an organization, usually a for-profit organization, that commits to further develop these early-stage technologies into commercial products. The objective of this technology transfer is to create goods and services that will benefit and be generally available to the public.

2. What have been the accomplishments and results of the technology transfer activities of universities?

One measure of the accomplishments of university technology transfer programs is the number of new commercial products that are available to the general public as a result of university technology transfer. In FY 2005 alone, the Association of University Technology Transfer Managers (AUTM) reported that 527 new commercial products were introduced that were a result of a university technology transfer.

Over the past nine years, approximately 3,641 new products have been introduced that are the direct result of university technology transfer in a broad array of fields including medicine, public safety, food and agriculture, new materials, semiconductor devices, education and communications.

Recent examples of these new products are:
(1) *Erbitux*®, a chemotherapeutic for various types of cancers including colorectal cancer, developed by scientists at the University of California, San Diego;
(2) *Restasis*®, a product developed from technology licensed from the University of Georgia that relieves the pain associated with inflammation of the tear ducts in patients with dry eye;
(3) *LegSim*®, an award-winning multimedia, interactive website created at the University of Washington that contains political simulation games now being integrated into a new simulation

called *Desktop Democracy* (http://www.desktop-democracy.org) for high school political science, government, and civic courses;
(4) *Omnibalm*®, a skin cream formulated from tea tree oil and licensed by the University of Arkansas to Balm Innovations LLC;
(5) S*tep-and-Flash Imprint Lithography*®, a technique developed by the University of Texas at Austin and licensed to Molecular Imprints, Inc. that may lead to a nano-printingpress for mass producing nano-devices on a scale previously unimaginable; and
(6) *Fast-Act*® A nannomaterial invented at Kansas State University and licensed to NanoScale Materials, Inc. This nanoparticle material absorbs, immobilizes, and detoxifies hazardous and toxic material spills.

The AUTM licensing survey and AUTM's publication, "The Better World Report" (available at www.autm.net) provide additional examples of how the general public has benefited from university licensing programs.

3. Is the engagement of educational institutions in technology transfer central to their primary missions of education, research and public service?

Yes– technology transfer actually is an important component of universities' efforts to fulfill these missions. The primary goal of technology transfer is to ensure that university innovations are diligently developed into goods and services that are ultimately made available to the public, which is entirely consistent with a university's mission of public service.

Research programs that are jointly-funded and supported by the federal government and industry support the development of basic research and science and its application to the resolution of real life problems, such as the discovery and development of valuable therapies, medical devices, new plants, and new technologies that will benefit society. Carefully managed university-industry-government research partnerships therefore provide universities with new research and educational opportunities that encourage scholarship and a spirit of inquiry that generates new knowledge. The development of commercial products from promising university research translates an early-stage scientific advancement into tangible goods and services that benefit the public as a whole. There is general agreement that faculty and students benefit from participating in research programs that involve an examination or development of new technologies to resolve technological problems that may lead to the development of new commercial products. Indeed, interaction with industry through undergraduate research programs and internships has emerged as a key indicator of future career success for students in many disciplines.

4. Universities should be examples of objectivity. Does involvement in technology transfer create conflicts of interest that bias research and might harm patients?

Universities are deeply committed to preserving the integrity of their research and the public's confidence. While true conflicts and bias are rare, the academic community nonetheless recognizes the importance of addressing them in a responsible manner. As a result, most institutions require disclosure of all financial conflicts, active management of most and, in some cases, such as where human subjects are involved, prohibition of the conflicted activity.

Fundamental university research is predominantly discovery driven, or what is commonly known as "basic research" and is largely funded by the federal government. However, new innovations of interest to companies can and do occur. Therefore, universities are increasingly involved in the transfer of technology into the private sector, and there is a small but real risk that academic research may be compromised through a conflict of interest.

Recent studies have examined the relationships between academic scientists and companies, and the effect of these relationships on the reporting of the results of research. These studies confirm that there are increasing ties between academic scientists and companies, and suggest that these relationships may influence the way that academic scientists report on products made by these companies. Universities, professional societies of researchers, and organizations that support academic institutions are concerned about both real and perceived conflicts, because they have the potential to undermine the integrity of the institution and the public's confidence in academic research (See http://www.cogr.edu/files/publications_Conflicts.cfm). As universities become increasingly involved in the transfer of technology into the private sector, they must seek to maintain a climate in which their mission can be conducted in a responsible manner by establishing appropriate policies and processes and striving for a culture of openness and accountability.

Most universities have adopted policies that are designed to ensure objectivity in research projects in which the investigator has a financial interest. Such policies usually start with disclosure by the investigator of relationships in which the investigator has a significant financial interest that would pose a potential conflict of interest. The majority of cases are then addressed through active management, such as by an independent committee. However, in some cases activities may be severely curtailed or prohibited altogether if the complexity of the relationship makes it unlikely that the research can be conducted without the appearance of bias, or if the risks of engaging in the activity outweigh the perceived benefits. The latter instance may occur in studies designed to test new therapies on human subjects if the investigator or the institution has a financial interest in the outcome of the study.

In addition to internal measures implemented by academic institutions, other stakeholders in the academic research enterprise are affected by possible conflicts of interest. For example, scientific journals are taking steps to address potential conflicts by requiring that scientists disclose their financial interests as a condition of publication. The Federation of American Societies for Experimental Biology (FASEB) has developed a white paper on the role of the investigator in the identification and management of potential conflicts (http://opa.faseb.org/pages/Advocacy/coi.htm). Moreover, many funding agencies (NIH, NSF) are requiring similar disclosures.

5. Does seeking a patent on a discovery interfere with the ability of faculty members to publish the results of their research?

No. Universities and their researchers typically do not choose between patents and publications – both are feasible. But if there is a choice, the faculty's need to publish always comes first.

It should be noted that a patent is itself a form of publication. In fact, the very premise of the U.S. patent system is that an inventor is granted a period of exclusivity in return for fully teaching the public about a new and useful invention. In that sense, a patent actually *ensures* publication.

The right of individual faculty members to make independent judgments regarding the timing and venue for the publication of data generated in their research in journals, other written media, and/or through oral presentation at public meetings, is one of the fundamental principles of academic research. At the same time, publication of the details of an invention prior to filing a patent application can result in the loss of patent rights in most countries. The U.S. is an exception since it permits an inventor to obtain a patent if a patent application is filed within one year of the date of publication which first disclosed the invention. [1] In addition, the U.S. permits "provisional" patent applications which allow the extremely quick and inexpensive filing of a patent application as a one-year "place holder" for a subsequent non-provisional patent application.

Nevertheless, some scientists are concerned that the desire to obtain patent protection may cause publication to be delayed for long periods, slowing the exchange of scientific information and thus scientific progress. However, with good advance communication between the researcher and the technology transfer office, it is possible to publish promptly *and* file a patent application, if desired. Moreover, as mentioned above, a provisional filing can be made on short notice to preserve most, if not all of the potential patent rights in an invention.

6. What is the U.S. Bayh-Dole Act?

[1] Currently patent reform proposals are pending in Congress that would change the U.S. system from a "first to invent" to "first inventor to file" standard. However, these proposals preserve a one year "grace period" for publication.

The U.S. Bayh-Dole Act (P.L. 96-517; 35 USC 200-212), the "Patent and Trademark Act Amendments of 1980" (hereinafter the "Act") created a uniform policy that applies to all U.S. federal agencies for the management and licensing of inventions developed by non-profit organizations that are the recipients of federal research funding.

Fundamentally, the Act was economic development legislation which created incentives for a more effective translation of research into products. In passing the Act, the Congress recognized that the best way to bring more university-developed technologies to the marketplace for public benefit was to loosen federal control, and incentivize the creator of the advancement to do something useful with it. Prior to the Act the federal government retained ownership of all inventions developed with federal funds. Therefore, only the federal government had the authority to transfer or license these inventions to third parties to enable the development of products. However, the Congress realized that federally funded inventions were not being effectively and timely licensed to industry for the development of products that would benefit the public (see The Bayh-Dole Act: A Guide to the Law and Implementing Regulations; available at www.cogr.edu).

The Act enables small businesses and nonprofit organizations, including universities, to retain title to inventions that are developed with federal funding in exchange for certain obligations intended to ensure the public's interests are met (see www.cogr.edu/docs/Tutorial). The Act and its amendments provided the basis for the formation of university technology transfer programs. Amendments to the Act further refined the guidelines established by the original legislation (P.L.98-620).

As intended, the Act and its clear implementing regulations (37 CFR 401) have allowed universities and faculty researchers to become more actively involved in the transfer of technology from their laboratories to the marketplace. The ability of universities to take action on behalf of their researchers to patent and license inventions has encouraged the transfer of inventions to third parties for commercial development and motivated universities to expend the resources necessary to engage in technology transfer. As a result, the number of federally-funded innovations that have been developed into commercial products and services has increased sharply since the Act was passed.

7. Why is the Act still relevant? While it may have worked well in the past, aren't the concepts dated and ill-suited to the new "knowledge" economy?

The Act establishes clear rights and obligations regarding inventions that are developed in whole or in part with federal funding. Importantly, Bayh-Dole created certainty of ownership for parties wishing to license inventions made with federal support, and it created a framework for developing a systematic approach to the identification, review, protection, and licensing of inventions made at universities and non-profit institutions. While the Act may not have specifically anticipated new uses and new technologies (e.g. research tools and materials, biotechnologies), it remains the cornerstone of university licensing practices. The results

show the tremendous impact of the creation of that system, with its reliance on government commitment to continued funding of fundamental university research, strong protection of resulting intellectual property, and market forces to drive innovation and commercialization. (For more information see Bayh-Dole Talking Points at http://www.autm.net/about/BayhDoleAct.cfm).

Bayh-Dole supports and is compatible with broad access to technology through a number of different technology transfer scenarios. The Act did not cover all types of intellectual property nor did it anticipate issues relating to research materials. It did not, for example, cover the management of copyrighted material, including software, developed with federal funding. While use of copyright in university technology transfer activities is increasing, FY2005 AUTM survey data confirm that patentable invention disclosures substantially exceed copyrightable works and other types (i.e. biological materials) of disclosures.

8. Shouldn't information and ideas that are developed at universities with public funds be available to everyone without patents?

The paradox of technology transfer is that often, in order to achieve the noble and quite reasonable goal of making technologies available to everyone, the period of exclusivity provided by the patent system may be required for companies to be willing to invest the significant resources necessary to develop early stage university innovations into marketable products. The patenting of university innovations and subsequent development into products and services that would otherwise not exist is entirely consistent with an institution's mission of public service.

The primary objective of university technology transfer is to benefit the public. In fact, the overwhelming majority of university research results is transferred to the public through publications and the open sharing of information. It is often argued that inventions resulting from federally funded research should be dedicated to the public and not patented. The basis of this argument is that since taxpayers paid for the invention, they should have free access to it. This view largely dominated federal patent policy prior to Bayh-Dole. In most cases, however, taxpayers can only realize the benefit of university inventions if they have sophisticated technical skills, large financial resources and a strong personal interest in practicing the invention. (For more discussion of these issues see http://www.autm.net/about/BayhDoleAct.cfm).

The broadest benefit to taxpayers from federally-funded inventions is to have access to products developed in a highly competitive market place – products that would otherwise not have existed. However, since universities are not in a position to develop, mass produce, and market products, they must rely on industry partners and market forces. A new drug is an excellent example. If such an invention is dedicated to the public through publication, it is extremely unlikely that a company will devote the extensive resources required to develop the first commercial application, knowing that any of their competitors could then step in and reap the profits of commercial exploitation once the invention has been proven and has received FDA approval. A patent, and the limited period of exclusivity it provides the licensee, is therefore necessary for successful commercial development of inventions.

9. How do universities provide incentives to companies to develop university technologies into commercial products?

The exclusivity available through a patent often is the most powerful method to provide incentives to industry to further develop a university-licensed technology. This is a basic concept embodied in the Bayh-Dole Act, which requires patenting of federally-supported inventions as a condition for universities to obtain title

In pursuit of this objective, university licensing programs have the following primary goals:

- to disseminate new and useful knowledge resulting from university research through the use of the patent system for those technologies and research results that could not be further developed and made available to the public without patent protection;
- to disseminate new and useful knowledge, tools, and scholarly works resulting from university research that may be protected by copyright, including software, using licenses to entities capable of bringing such technologies that would otherwise be inaccessible to the marketplace;
- to license patents to industry in order to promote the development of inventions toward practical application for use by the general public *(*with appropriate milestones included in licensing terms to assure due diligence*);*
- to provide income for use in supporting further research and education, with a share of the income going to the inventor (this is a requirement of the Bayh-Dole Act for federally-supported inventions);
- to assure that patent-related obligations to sponsors of research including the federal government are met; and
- to aid states and geographic regions in economic development.

Universities generally apply the same policies and procedures to all inventions made at the institution, regardless of sponsorship. In the case of an industrially-supported invention, the sponsoring company may be granted the first opportunity to obtain a license to commercialize the invention. If joint government and industry funding is involved, the company's rights are subject to the institution's obligations to the federal government. In some newer government programs involving active industry collaboration, such as those for "translational research," the government funding instrument may specify the company's rights in resulting inventions and related intellectual property. These terms are sometimes problematic for institutions. For example, universities cannot grant to a single industry sponsor rights to "background" intellectual property developed elsewhere in the institution as is sometimes requested. The result has been difficult and at times unsuccessful negotiations over such terms. See the COGR *Guide to University Industry Research Relationships* for more discussion of these issues.

10. What factors determine the strategies universities utilize to promote the dissemination and utilization of discoveries made in research on campus?

There are several key points with regard to dissemination and utilization of university discoveries: 1) the vast majority of university discoveries are disseminated through publication in the open scientific literature; 2) a basic principle of the Bayh-Dole Act is to promote the public utilization of products resulting from inventions made in performing federally-supported research; and 3) the basic premise behind the right to patent is "to promote the progress of science and useful arts."

Intellectual property rights and a public service mission to develop useful products for the benefit of society are mutually complementary concepts. For inventions made with federal funding, Bayh-Dole requires that patent protection must be sought as a condition of the university's ability to retain title. In almost all cases, the university decides on a case-by-case basis the licensing and commercialization strategy that is likely to result in the greatest utilization of the invention. In the case of an invention that has broad applicability over multiple industries, a non-exclusive license is usually preferable. A good example of this is the Cohen-Boyer patent on DNA cloning which Stanford University and the University of California licensed to hundreds of companies. It is credited with enabling the development and growth of the biotechnology industry. Software is another area where non-exclusive licensing or open sourcing distribution is often the most effective dissemination strategy. For other discoveries such as a new therapeutic compound, exclusivity is important because of the significant resources required to bring the discovery through FDA approval. Exclusivity provides assurances that the patent holder or its licensee will be able to recoup this investment. In either case, the licensing strategy is dictated by the question of what route will result in the broadest dissemination and greatest public benefit.

11. Are universities suing companies over patents? If so, why?

In only a small number of cases do universities seek to enforce patents by pursuing legal action to enforce their patent rights.

Although there are instances of universities involved in litigation with companies, the number is small 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 patents are licensed as 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) 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 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.

12. What is the difference between a "patent troll" and a university in terms of technology transfer?

Universities are a leading source of discovery and innovation and require companies to develop products from these discoveries. 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.

"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 under a particular patent, universities typically seek to collaboratively develop technologies with the assistance of corporate partners. 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.

13. Do patents create barriers that hinder innovation and research?

While a small number of academic scholars and theorists have claimed that over-patenting hinders the progress of science, the data do not support these claims.

A number of theorists have speculated that over-patenting in a particular area of technology results in complex interrelationships of ownership that prevent further advancement of this area. This is sometimes referred to as "patent thickets" or the "tragedy of the anti-commons". These theorists surmise that resources will be inefficiently under-used and innovation squelched in the face of too many overlapping patent rights.

However, there is little empirical evidence to support these theories, and the limited data that exist show that patents do not hurt the progress of science. Most recently, the American Association for the Advancement of Science released the results of a survey that showed that scientists are not as constrained by intellectual property rights as some theorists have proposed. (see January 26, 2007 Chronicle of Higher Education, p.A31. See also Walsh et. al., "View from the Bench: Patents and Materials Transfers;" Science Vol. 309 September 23, 2005).

Moreover, there are theorists who have suggested that multiple parties having patents in a technology area is just as likely to reduce the amount of litigation since each patent represents only a small piece of the intellectual property landscape. In such cases, they argue, few patentees would be willing to go through a costly litigation simply to recover such a small slice. This possibility seems even more plausible following the Supreme Court ruling in the eBay v. MercExchange (126 S. Ct. 1837 (2006), where an injunction is no longer automatically granted upon a finding of infringement. See Lichtman, Douglas Gary, "Patent Holdouts and the Standard-Setting Process" (May 16, 2006 U. Chicago Law and Economics;http://www.journals.uchicago.edu/JLE/home.html).

14. Is the patenting of research tools slowing the advancement of basic research?

Despite frequent claims, there is little evidence to support the contention that the alleged proliferation of research tool patents results in adverse effects on research. Standard approaches and principles for sharing of research tools have been developed that are followed by most research institutions. Recent surveys of scientists have demonstrated that research tools are not as constrained by IP protection as often thought (see #13 above).

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. However, there have been concerns that such agreements could interfere with the widespread dissemination of research tools among scientists, either because owners and users are unable to reach agreement on fair terms or because the negotiations are difficult and cause protracted delays. While the concerns are understandable, they are not supported by the survey results discussed above.

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 the invention for research and educational purposes, when executing license agreements. NIH addresses this in the NIH *Principles and Guidelines* on the patenting, licensing, and commercialization of research tools (http://www.ott.nih.gov/policy/rt_guide_final.html), now a condition of NIH funding. The foundation for the Principles and Guidelines is that scientific advancement depends on broad access to research tools. NIH expects recipient institutions to develop proactive policies to ensure that this goal is met. COGR has provided guidance to universities on the NIH guidelines (see http://www.cogr.edu/files/publications_intellectual.cfm) As the result of a cooperative project involving the NIH and several universities, NIH also 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 (http://www.autm.net/aboutTT/aboutTT_umbta.cfm). While the UBMTA and Simple Letter Agreement have provided an efficient, standardized mechanism for transfers within the academic community, neither has been accepted or used by industry partners. [see COGR Materials Transfer in Academia; September 2003; http://www.cogr.edu/files/publications_intellectual.cfm).

15. Why are some companies and industries complaining about how hard it is to work with U.S. universities?

Non-profit entities and for-profit entities have largely divergent objectives. However, these differences can be easily overcome when all parties recognize the objectives and limitations of the other parties. Industry sectors differ from one another in their relationships with universities, as do companies within sectors. Similarly, universities differ from one another in many significant ways (e.g. public vs. private, mission, history, culture, etc.).

Because of the divergent objectives and cultures between universities and companies, there are some issues that arise during the negotiation of the legal language covering the proposed collaboration. As a result, there have been several initiatives over the last 15 years to develop template agreements or to agree on a framework for thinking about agreements (e.g., Working Together, Creating Knowledge: The University-Industry Research Collaboration

Initiative(http://www.bhef.com/publications/),University—Industry Demonstration Partnership (see www.uidp.org/)).

However, while much of the research at universities is targeted at the discovery of basic mechanisms, industry wants universities to do targeted research directed at solving specific problems. This schism is one important factor that contributes to the difficulty in these negotiations. For a productive collaboration, it is critical that there is alignment between the research objectives of the faculty collaborator and the company. For a more in depth discussion of this topic, please see the COGR *Guide to University Industry Research Relationships* at http://www.cogr.edu/files/publications_intellectual.cfm).

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" intellectual property issues. 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 and 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 cross-license key discoveries with competitors to ensure freedom to operate. However, with respect to all of these issues, universities have developed approaches to deal with these issues and enable industry-sponsored research projects. The vast majority of university-industry collaborative research arrangements are put in place smoothly.

16. How do technology transfer officers gain the experience and skills necessary to do their jobs effectively?

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 appropriate federal laws are all essential in the technology transfer profession. Often these are skills that are developed over years of experience. Additionally, universities seek new employees for their technology transfer office from fields where they have already developed some of these key skills. Business development or technical marketing are two areas that can produce candidates with many of the skills that are desired.

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 mission of the technology transfer office. Cultures, goals, and missions vary from one academic institution to another, and from one company to another. Experienced and effective technology transfer professionals understand the differences between the academic culture and the business culture, have the ability to communicate these differences in a meaningful way to all stakeholders in a negotiation, and also have the experience to craft 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 either support research, such as sponsored programs, or regularly interact with companies, such as development. The AUTM FY2005 Licensing Survey includes information on the staffing of university technology transfer offices.

Additionally, professional organizations such as AUTM and the Licensing Executive Society (LES) have played a significant role in providing the training and networking opportunities that have contributed to a significant increase in the professionalism of their members. Both organizations view professional development as one of their core missions. These associations sponsor conferences, courses and workshops that bring together licensing professionals from all over the world to share best practices and develop new skills with the goal of gaining expertise.

17. What do universities do with the money that they receive from their licensing activity?

The majority of the revenue received from licensing activities goes directly into further university research and education.

The Bayh-Dole Act requires that universities distribute the proceeds from licensing federally-funded inventions, after subtracting the costs of their patenting and licensing activities, 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 1/3 of net income to the inventor or inventors, 1/3 to the inventor's department and/or college, and the final 1/3 to the university to support research and education. A survey conducted by COGR confirmed that the university share of revenues often funds initiatives that support the research and educational missions of the institution (see University Use of Royalty Returns, http://www.cogr.edu/files/publications_intellectual.cfm).

While successful technology transfer activities are often considered to be a source of discretionary revenue for universities, it is important to note that the majority of technology transfer offices struggle to break even and in most cases require a subsidy for their day-to-day operation. One myth that persists is that the revenues from technology transfer have the potential to replace other sources of research support in an institution. Even in the few universities with strong revenue streams this is not correct. Comparison data show that annual gross revenues (before distribution, see paragraph above) generated from a university's technology transfer activities generally total less than three percent of research dollars spent by that university and an even smaller percentage of total university revenues.

18. Do university royalties contribute to the high cost of drugs?

It is a serious misinterpretation of the nature of biomedical research and the role of federally sponsored research to think that all drugs on the market are the direct result of research sponsored exclusively, or in large part, by taxpayers. Research at universities that is sponsored by federal agencies is typically aimed at the discovery of basic biological mechanisms and processes, and the road from a key discovery in a university laboratory to a drug is long and often times indirect. Significant private funds are required to translate and further develop these basic scientific findings into safe and effective drugs.

The research that is sponsored by the federal government is at the earliest stages, and is often considered to be research that companies cannot afford to conduct because of its basic nature and

the inherent uncertainty of financial return. Basic research can contribute an essential understanding of disease mechanisms that can provide important clues about the development of a medical condition which can point to potential targets for drug intervention. After a disease target is identified, or even after a compound is synthesized, there is still a significant investment and risk that must be traversed to bring the drug to market that includes lead optimization, preclinical testing, toxicology, formulation, and then clinical trials. There are varying estimates of the time and cost that this may take, but most suggest that it costs between $200,000,000 and $800,000,000 to bring a new drug to the marketplace. Regardless of the actual dollar figure for a particular drug, it is well understood that the product development costs exceed the costs of the underlying basic research by several orders of magnitude.

Despite the impressive accomplishments of university technology transfer, studies have concluded that only a small number of drugs resulted directly from patents held by universities, and that the university contribution typically was in the method to make the drug and not the drug itself. (for a recent study of FDA-approved drugs developed by public sector institutions including universities see http://www.autm.net/events/dsp.eventItem.cfm?EventItemID=248&eid=91&Mode=past; Poster Presentation #6). Thus, universities generally provide the basic science that allows pharmaceutical scientists to synthesize chemicals that can alter the course of a disease. Only relatively few drugs or lead compounds have been developed by university scientists.

In cases where a university has actually held a patent on a drug, the royalties paid to the university represent a small portion of the sales price from the manufacturer to the wholesaler (not to the customer). This figure is typically less than 5 percent (and less when compared to the final retail price) and does not contribute significantly to the price of the drug to the consumer.

19. Does university research have a role in economic development?

Economic development is an objective of some universities, especially public land grant institutions. Scholars and economic development professionals have identified clusters of economic activity in the vicinity of universities that they attribute to the physical and intellectual assets of the university. These observations and the growth of technology transfer have lead many states to adopt university-based research as an element of their economic development strategy.

Universities increasingly are recognized as playing a key role in regional economic development, although within many universities there is a diversity of opinion about the appropriate scope and magnitude of that role. Many states have implemented multi-tiered strategies to catalyze the development of technologies with commercial potential and foster business creation from university research. In part these programs seek to develop early-stage technologies, but at the same time recognize that many of these technologies will be early-stage and require assistance to overcome what can be substantial hurdles in the high path to the commercialization of a product. These strategies include: i) the use of tobacco settlement funds for applied research, ii) funding programs that partner a university research laboratory with a local company, iii) tax incentives to enhance investment in venture capital, iv) state pension fund investment in venture capital funds, v) business incubators, vi) business assistance programs, and vii) networking and mentoring for entrepreneurs.

However, universities contribute to the economic well being of their region more broadly than just through the creation of spin-off companies. Licensing of new inventions and improvements to existing products fuels the cycle of innovation in local and national industries. Universities, particularly state universities, often have research institutes that work with traditional industries in their regions and provide innovation to maintain the competitiveness of these industries in the global economy. States often include their universities – showcasing the talents and research competencies of faculty and students - in efforts to attract new companies to the state. Universities are drivers of regional economies as they provide an educated workforce for existing and emerging industries and many provide business development outreach for small businesses in the area. Local impacts are also felt through employment opportunities, local procurement, construction projects, and local student spending. Generally, these are byproducts, rather than specific objectives of technology transfer.

20. How are universities helping non-profit organizations that are trying to bring medical care to underdeveloped populations and countries?

The development, approval and ultimate delivery of therapeutics and diagnostics to the developing world is a complex problem that clearly requires more than simply a change in the ways that universities license their inventions. 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.

The emergence of SARS and bird flu as threats to global health have reinforced the need to better understand the ways that highly infectious diseases spread throughout the world, and have heightened the importance of monitoring and treatment of diseases with the potential to cause pandemics. In addition to acute outbreaks, there is a recognition that the developed world has an important role and obligation to provide health solutions to chronic diseases that for the most part are restricted to the developing world, and inflict underserved populations outside of the traditional markets for pharma and biotech.

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. Organizations like MIHR (Center for the Management of Intellectual Property in Health), the TB Alliance, PIPRA (Public Intellectual Property Resource for Agriculture) and others have approached specific segments of global health, but 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 to bring therapeutics or diagnostics to the developing world, many efforts have focused on the earliest stages of the commercialization ecosystem – such as university research and licensing.

The AUTM Better World Project provides numerous examples of university licensing that have an impact on global health. Licensing practices that are already in place in universities also are making an impact.(See AUTM Journal Volume XVIII No. 2 2006
Patenting, Licensing, and Social Responsibility; available at http://www.autm.net/about/dsp.pubDetail2.cfm?pid=10).

Examples of these practices are:

> Patent pooling to aggregate critical intellectual property for the development of minor and subsistence crops – PIPRA
>
> Reduced royalties or no royalty obligations for licensees providing products for the developing world-- University of Washington and Yale University joint license to One World Health for a treatment for Chagas disease.
>
> Licensing strategies that reserve rights for the developing world. 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.

The significant support of the Bill and Melinda Gates Foundation ("BMGF") has placed an intense spotlight on global health research. The BMGF has used its influence to launch initiatives like the Grand Challenge grants and the Collaboration for AIDS Vaccine Discovery (CAVD) to develop technologies or products for the developing world and accelerate research progress through new approaches for data sharing and collaboration. These and other non-traditional approaches and new partnerships will be important elements to provide important solutions to the most pressing global health challenges.

21. Have universities agreed among themselves on the goals and practices in transferring their technologies to assure public interest and societal benefit?

The U.S. university community is diverse, and different institutions employ various strategies and objectives in transferring their technologies. There is no universally accepted statement that covers university goals and practices in technology transfer. Since the best route for broad utilization will vary based on the nature of the discovery, most decisions regarding licensing are made on a case-by-case basis.

However, as the accomplishments and visibility of university technology transfer have increased, universities are increasingly cognizant of and aware of their responsibilities to the public and to society in their practices with regard to developing and licensing technologies. Recently a number of leading universities issues a white paper entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology" (available at http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf.) A number of higher education associations have endorsed or are considering endorsing the statement. The statement addresses reserving rights for non-profit organizations to practice inventions for research and educational purposes; exclusive vs. non-exclusive licensing; minimizing licensing of future improvements; managing technology transfer- related conflicts of interest; ensuring broad access to research tools; considerations with regard to enforcing intellectual property rights; implications of export control regulations; working with patent aggregators; and addressing unmet needs, such as those of neglected patient populations or less developed countries.

These points address a number of concerns raised by critics of university technology licensing practices. The white paper "aims to encourage technology transfer agreements to facilitate broad

development and dissemination of university-generated technologies. A key point is that researchers at universities across the country should be able to continue to work with intellectual property that has been licensed to commercial concerns." Professional groups such as AUTM also are increasingly concerned with these types of issues. It appears that a consensus as to best practices in these areas is beginning to emerge in the university community.

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