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Catalyzing Technology Development Through University Research

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1 Introduction

Research universities have traditionally been catalysts for technological innovation, particularly in new and emerging industries. A recent report on the management of university intellectual property confirms this historical role, stating that universities "have a lengthy track record of providing dynamic environments for generating new ideas and spurring innovation, and for moving advances in knowledge and technology into the commercial stream where they can be put to work for the public good."[1] Products ranging from the Gatorade® sports drink to the polymerase chain reaction (PCR) gene sequencing technology have emerged from university laboratories. University-based research played a major role in the growth of the early biotechnology industry and has made notable contributions to industries such as computer software, medical devices and the Internet.[2] In the United States, universities and other research institutions spent over $53 billion on research in 2009[3] and, of the top fifty holders of U.S. patents in the "biotech and pharma" field, in 2009 seven were U.S. universities and eight more were U.S. and non-U.S. governmental or quasi-governmental research institutions.[4]

Against this backdrop, it is not surprising that some of the most promising new technologies relating to climate change are being developed at research universities.[5] A growing number of universities, both in the U.S. and internationally, have established patent positions in climate change technologies such as solar energy, wind power and biofuels.[6] Several U.S. universities have initiated ambitious "clean tech" programs that combine academic research with industrial partnerships, business formation and policy analysis.[7] The Global Climate & Energy Project at Stanford University, for example, supports 66 different research programs at 27 institutions worldwide.[8] The Massachusetts Institute of Technology sponsors an annual competition that awards $200,000 to the most promising clean energy venture in the country and has fostered the creation of numerous spin-out companies in the climate change technologies space.[9] And Washington University in St. Louis has partnered with twenty-five leading academic institutions across the world to form the McDonnell Academy Global Energy and Environmental Partnership (MAGEEP) to fund collaborative research projects in clean tech fields as diverse as aerosol science, solar energy, bioenergy, water quality and building energy consumption. It is likely that university initiatives such as these will proliferate as the need for viable renewable energy sources and climate change technologies continues to escalate.

In this chapter, we first summarize several modes of university technology development and licensing. Next we describe the evolution of university technology commercialization and the Bayh-Dole Act of 1980, which is widely credited with establishing the intellectual property structure of current university licensing and technology transfer. We then discuss some important legal and intellectual property considerations relevant to the development, commercialization and licensing of university technology. While this treatment is necessarily brief, we hope that it may serve as a useful tool both to those who are considering collaborating with, or licensing technology from, a research university, and to university researchers who are contemplating the path to commercializing their climate change technology innovations.

2 Modes of University Research and Technology Transfer

University-based research in climate change technologies takes place in a variety of funding and collaboration structures. The particular structure governing a research project will have a significant impact on the intellectual property rights and technology transfer procedures applicable to that project. In this Section we outline several common modes of university research funding and technology transfer that are prevalent in the United States today. Funding organizations should be aware of the norms and structures of university research as described in this and subsequent Sections when deciding if funding university research will adequately promote their policy and intellectual property goals. Additionally, those interested in licensing climate change technologies should also be aware of the norms and structures of university research as these will effect the licensing terms under which the licensor can utilize the technology.

2.1 *Grant Funding*. The U.S. federal government funds between 62% and 68% of university research in the United States, primarily through grant mechanisms.[10] Federal grants are typically awarded and administered by executive branch agencies such as the National Institutes of Health (NIH), Department of Energy (DOE), Department of Defense (DOD), National Air and Space Administration (NASA), National Science Foundation (NSF) and Department of Agriculture (USDA). As there is currently no single agency responsible for overseeing climate change technology in the U.S., funding is distributed among these and other agencies, with the majority contributed by DOE and NASA. Between 1998 and 2009, federal appropriations for climate change research totaled approximately $99 billion, more than $35 billion of which was appropriated in 2009 alone.[11] While this funding is not directed exclusively to universities, university researchers are the beneficiaries of substantial grant funding relating to climate change.

2.2 *Industry Sponsorship*. In addition to federal grant funding, a significant portion of university research is supported by private industry. In 2008, private industry provided over $2.5 billion in funding for academic scientific research.[12] Such support can take two basic forms: general support and sponsored research. General support consists of unrestricted or earmarked contributions by industry to particular universities or research programs. Under such a model, the corporate donor, while likely obtaining public relations and other intangible benefits, typically does not gain the right to direct or commercially exploit the results of the university's research. ExxonMobil Corporation's $100 million contribution to Stanford's Global Climate & Energy Project falls into this general category.[13]

Sponsored research, on the other hand, is more akin to a contracted research arrangement between the university and the corporate sponsor. The sponsor funds the university's conduct of a specific research project, sometimes in collaboration with the sponsor's own scientists, and typically obtains the right, or an option to license the right, to commercialize the resulting technology. Sponsored research arrangements are not uncommon, particularly in the life sciences. One study found that in 2000, 28% of university faculty in the life sciences received funding from private sponsors.[14] These arrangements, however, must be structured carefully to avoid disputes regarding inventorship and ownership of discoveries. In one recent case, Vanderbilt University scientists were held not to be co-inventors on a patent covering the blockbuster drug Cialis, which they helped to develop under a sponsored research agreement with Glaxo.[15]

2.3 *Licensing and Technology Transfer*. Though significant research activity is undertaken at universities, their educational and research missions do not typically permit them to engage actively in commercial activity. Thus, in order to put university research to commercial use, universities must license or transfer technology to the private sector. To do this, most universities have established technology licensing offices (TLOs) responsible for evaluating the commercial promise of each new university invention, making decisions regarding patenting, identifying appropriate commercial partners, negotiating suitable license and option agreements, and then distributing the resulting royalties and other economic gains within the university.[16] After deducting the TLO's overhead, patenting costs, and the like, most universities allocate royalties in varying percentages among the responsible inventors, their academic departments, and the university at large.

In recent years, TLOs have displayed considerable activity. Data from a survey conducted by the Association of University Technology Managers (AUTM) indicates that, in fiscal year 2009, 4,374 licenses were executed by responding university TLOs.[17] During this period, 8,364 new U.S. patent applications were filed by these TLOs.[18] Evidence indicates that 50% to 75% of TLO patenting and licensing activity falls within the biosciences and pharmaceutical fields, as opposed to fields such as software and electronics which account for less than 10% each.[19] It is unclear whether TLOs will respond to climate change technologies with aggressive patenting and licensing as is observed in the biosciences field.

While most universities, including research powerhouses such as Stanford, MIT and Harvard, operate their TLOs as internal groups, sometimes falling under the jurisdiction of the university counsel or the office of the provost and sometimes operating semi-autonomously, others have elected to establish independent entities to manage intellectual property emerging from university labs.[20] The most notable of these is the University of Wisconsin-Madison, whose Wisconsin Alumni Research Foundation (WARF) was established in 1925.[21] WARF granted its first commercial license to the Quaker Oats Company in 1928 for a Vitamin D supplement developed to combat the childhood disease rickets.[22] Today, WARF enters into approximately one hundred commercial licensing agreements per year and has contributed nearly $1 billion in net revenue to the university.[23]

2.4 *Spin-Outs*. In many cases, the most likely industrial licensee of a university invention is an established enterprise actively pursuing the development of products in the relevant field. Sometimes, however, established industrial partners may not exist, particularly when technologies are in new and emerging fields. In these cases, university researchers, working with external advisors and funders, may form start-up companies to commercialize the discoveries generated by their labs. According to AUTM survey data, 596 start-up companies were formed based on university-owned intellectual property in 2009, up from 241 start-up companies in 1994.[24] These companies are referred to as university "spin-outs", and AUTM reports that in 2008, more than 16% of university technology licenses were granted to such start-up companies.[25] In addition to licenses of university intellectual property, such spin-outs often make use of university-owned facilities and equipment, as well as the services of academics, technicians and graduate students. University spin-outs have attracted significant public attention in recent years, both due to the phenomenal success of a handful of such ventures[26] and the potential conflicts of interest that plague academic investigators who actively participate in corporate research.[27] Spin-out activity has been particularly notable in the field of climate change technology, with the emergence of high-profile companies such as A123 Systems (MIT – lithium ion batteries), SunPower (Stanford – solar energy) and Verenium (Univ. Fla – cellulosic ethanol), as well as a myriad of smaller ventures.[28]

2.5 *Patent Pools and Commons*. When multiple entities each hold patents necessary to exploit a single technology, a situation referred to as patent "stacking", or a patent "thicket" or anti-commons, may be said to exist.[29] In order for a producer to implement the technology in a product, it must obtain licenses from multiple parties, each acting independently and each seeking to maximize its gains. The sum of these individual demands may be excessive in relation to the overall value of the product being produced. In order to address patent stacking concerns, groups of patent holders sometimes aggregate their essential patents into so-called patent pools, which are licensed and administered on a collective basis. Well-known patent pools exist in the areas of consumer electronics and digital media, and Columbia University is one of the original patent holders in the large pool responsible for licensing use of the ubiquitous MP3 data compression standard. The formation of patent pools is complex and involves the application of antitrust analysis well beyond the scope of this chapter.[30]

A close relative of the patent pool is the patent commons, in which participants voluntarily commit not to assert patents relevant to a specific field, subject to certain conditions. One such effort that is gaining significant attention in the area of climate change is the Eco-Patent Commons, in which a number of global corporations including IBM, Sony, Fuji Xerox, Nokia, Dow Chemical and DuPont have pledged to make environmentally-beneficial inventions available to the public on a royalty-free basis.[31] The Eco-Patent Commons is organized under the auspices of the Geneva-based World Business Council for Sustainable Development (WBCSD).[32]

3 University Research and the Bayh-Dole Act

Due to the dominance of federal funding of university research, inventors and investors interested in climate change technologies must understand the regulations surrounding the dissemination of federally funded research. In this Section we discuss specific practical, legal and intellectual property considerations that arise in the context of the federal funding described in Section 2.1.

3.1 *A Brief History.* Until World War II, university research in the U.S. tended toward the theoretical and received relatively modest governmental support.[33] With the advent of the Manhattan Project, however, federal funding for research, and applied research in particular, increased dramatically.[34] In the decades that followed, numerous federal agencies began to fund university research; today the majority of university research is funded by the federal government, which contributed more than $32 billion to the research budgets of universities and non-profit research institutions in 2008.[35]

Prior to 1980, rights in federally-funded inventions were governed by the rules of individual funding agencies and often inured to the agencies themselves.[36] Yet the federal government rarely put these inventions to commercial use, it being estimated that of the 30,000 federally-owned patents in existence prior to 1980, only five percent were ever licensed to industry and even fewer used in commercial products or services.[37] In response to this perceived underutilization of federally-funded research, the Bayh-Dole Act[38] was enacted in 1980. The purpose of the Act was to provide a consistent patent policy in regards to federally funded research and to promote the commercialization of resultant technologies.[39] The Act effected a major change in U.S. policy by allowing universities, small businesses and other research institutions to retain ownership of inventions resulting from federally funded research. In exchange for this grant of ownership, the Act requires these entities to apply for patent protection in the U.S. and abroad and imposes penalties for failing to take effective steps to achieve "practical application" of the inventions.[40]

3.2 *Requirements of the Bayh-Dole Act*. In exchange for giving universities the right to retain ownership of their federally-funded inventions, the Bayh-Dole Act imposes a number of obligations. Given the pervasiveness and magnitude of federal research funding in the U.S., most universities have incorporated the requirements of the Act into their standard technology development and licensing practices. The principal among these are described below.

3.2.1 *Invention Disclosure*. The Act and its implementing regulations require that each federally-funded institution disclose to the relevant funding agency each invention reduced to practice within two months after it becomes known to the institution's patent administration personnel.[41] In order to support this obligation, each institution is also required to implement written agreements with its technical personnel (including faculty, technicians and students) requiring them to disclose all such inventions to the TLO.[42] Typically such agreements, which may be implemented in signed contracts or binding policy documents, also include an explicit assignment of intellectual property rights from the inventor to the university.[43]

Each university TLO submits invention disclosures to the applicable funding agencies, typically through the federal government's iEdison interagency web-based system, which accepts submissions for eighteen different federal agencies.[44] Invention disclosures and other information submitted to a federal agency pursuant to the Bayh-Dole Act are treated as privileged and confidential and are not disclosed outside of the agency.[45]

A university's failure to comply with the disclosure requirements of the Act can result in the government's receiving title to the relevant invention.[46] In at least two litigated cases, courts have prohibited institutions from enforcing patents following a failure to comply with the disclosure requirements of the Bayh-Dole Act on the basis that the plaintiffs never acquired title to the patents in suit.[47] However, even in cases in which the government receives title to a federally-funded invention, the university retains a non-exclusive, royalty-free, worldwide license to exploit such invention.[48]

3.2.2 *Patent Election*. A university may elect to retain title to any invention disclosed to the federal government within two years of making such disclosure.[49] If the university elects to retain title, it must file a patent application covering that invention in the U.S. prior to the expiration of any statutory bar date, and in any other countries in which it elects to retain title.[50] If it fails to make such filings, the government may receive title to the relevant invention.[51]

This is not to say, however, that universities file patent applications covering every invention that is disclosed by their researchers. In fact, according to AUTM, over 20,000 invention disclosures were filed across all U.S. research universities in 2009, whereas less than 8,400 new U.S. patent applications were filed in the same year.[52] In many cases, the potential commercial value of an invention may be small and the university's educational and research missions may better be achieved by permitting the researcher to publish the relevant findings and/or to release the invention, for example, on an "open source" basis. If a university wishes to discontinue prosecuting a patent application or maintaining a patent that was developed using federal funding, it must so notify the federal agency.[53] While such a notification technically gives the government the right to receive ownership of the invention, in practice governmental agencies rarely exercise this right.

A related issue concerns a university's right to an invention under the Bayh-Dole Act when an investigator purports to assign the rights in that invention to a commercial research sponsor. The issue recently arose when a Stanford University researcher, Mark Holodny, entered into a sponsored research agreement with Cetus Corporation (now part of Roche).[54] Under the agreement, the researcher assigned his rights in an invention pertaining to AIDS therapy to Cetus in violation of Stanford's intellectual property policy and his agreement with Stanford. When Stanford subsequently sued Cetus for infringement of the resulting patent, the Federal Circuit held that Stanford lacked standing to sue, as the invention had previously been assigned to Cetus.[55] The Supreme

Court recently granted *certiorari* to consider the question of whether the patent ownership provisions of the Bayh-Dole Act pre-empt private assignments such as that effected by Dr. Holodny.[56]

3.2.3 *Government Rights*. In addition to the right to receive ownership of inventions as described above, the federal government retains several additional rights in federally-funded inventions. First, it retains a non-exclusive, paid-up license to practice, or have practiced, any such invention for or on behalf of the United States anywhere in the world.[57] Second, the government may exercise so-called "march in" rights under which it may compel a university to license an invention to one or more third parties if necessary to alleviate health or safety needs, if the university has not taken effective steps toward the commercialization of the invention, or if the U.S. manufacturing requirements described below are violated.[58]

In practice, the federal government has never exercised its march-in rights under the Act, though there have been several instances in which third parties have petitioned federal granting agencies to exercise those rights. The first instance occurred in 1997 when CellPro, Inc. petitioned the NIH to exercise march-in rights against Johns Hopkins University.[59] CellPro's goal was to obtain a license to four patents that Johns Hopkins had previously licensed exclusively to Baxter Healthcare. The NIH determined that the exercise of march-in rights was not warranted because Baxter Healthcare had used reasonable efforts to make a product manufactured under the patents available.[60] In 2004, two individuals petitioned the NIH to exercise march-in rights against Abbott Laboratories, which had received NIH funding to develop the AIDS drug Norvir, after Abbott increased the retail price of the drug by approximately 400%.[61] Again, the NIH determined that the patentee had used the requisite efforts to achieve practical application of the federally-funded invention, and further commented that the exercise of march-in rights "is not an appropriate means of controlling prices."[62]

Another request for the exercise of march-in rights was made to the Dept. of Health and Human Services with respect to the drug Fabrazyme, which is used to treat the rare disorder Fabry's Disease. Fabryzyme was created in part with NIH grant funding and is currently the only FDA-approved treatment for Fabry's Disease.[63] The manufacturer of Fabryzyme, Genzyme, was forced to shut down its primary Fabryzyme manufacturing line due to contamination, which resulted in shortages of the drug and rationing to patients since June of 2009.[64] Fabry's Disease patients subsequently filed a petition with the Dept. of Health and Human Services petitioning the federal government to exercise its march-in rights to allow an alternative manufacturer to produce the compound.[65] NIH denied the petition, however, reasoning that any alternative manufacturer would face subtantial and time-consuming regulatory hurdles that would not soon result in an increased supply of the drug.[66] It has been reported that the petitioners intend to appeal this decision.[67]

3.2.4 *U.S. Manufacturing*. The Bayh-Dole Act prohibits the owner of an invention made using federal funding from exclusively licensing the use of that invention in the United States unless the licensee agrees that all products embodying the invention, or produced through use of the invention, will be manufactured substantially in the United States.[68] This provision is essentially a "Buy American" initiative intended to promote U.S. industry and has been criticized as outdated in today's global economy.[69] The U.S. manufacturing requirement may be waived by the funding agency if domestic manufacture is not “commercially feasible” or if efforts to identify U.S. manufacturers have been unsuccessful.

3.2.5 *Non-Assignment*. The Act expressly prohibits universities from assigning rights in federally-funded inventions to third parties without the approval of the funding agency.[70] An exception is made only for assignments to patent management entities such as University of Wisconsin-Madison’s WARF. This restriction often causes confusion among inexperienced venture capitalists and angel investors who argue, sometimes vociferously, that university spin-out companies should obtain full ownership, rather than a mere license, of the fundamental patents underlying their business. This perception is also widely shared by non-U.S. investors, who are accustomed to dealing with non-U.S. university spin-outs, which are typically not subject to non-assignment prohibitions under local legislation.

3.2.6 *Royalty-Sharing*. The division of economic returns from university technology is typically handled internally by the university through its TLO. The Bayh-Dole Act requires only that universities share royalties with individual inventors, without specifying the level or form of such sharing, and that the balance of these proceeds (after payment of expenses), “be utilized for the support of scientific research or education.”[71] Royalty sharing arrangements vary widely among institutions. For example, Stanford University allocates the first 15% of net license revenue (after patenting costs) to its TLO, then splits the remaining 85% in three equal parts among the inventors (in equal shares), their departments, and the university; Washington University in St. Louis allocates 25% to its TLO, 35% to the inventors and 40% to the university;

and Rice University allocates 37.5% to the inventors, 14% to their departments, 18.5% to the graduate education function, and 30% to the university.[72]

While these arrangements are typically invisible to licensees, they become particularly important in arrangements involving collaboration by researchers at two or more universities. In such settings, institutions are often sensitive to perceived unequal treatment of collaborating researchers and must adjust their revenue sharing policies to account for differing expectations.

3.3 *Accolades and Criticisms*. The Bayh-Dole Act and the university technology transfer structure it formed has generated numerous accolades and criticisms. Proponents of the Act contend that its encouragement of the patenting and licensing of federally-funded research has provided an effective framework for federal technology transfer, yielding economic benefits not just for universities and private industry, but for the U.S. economy as a whole.[73] A 2002 article in the *Economist* famously referred to the Bayh-Dole Act as "possibly the most inspired piece of legislation to be enacted in America over the past half-century".[74] The Biotechnology Industry Organization reported that, in the period from 1996 to 2007, university licensing to industry created over 279,000 jobs and contributed to over $457 billion in industry output.[75] According to the former president of the Association of University Technology Managers, during the years 2000 to 2008 universities signed 41,598 license and option agreements with industry and filed 83,988 patent applications.[76]

Despite these glowing numbers, critics of the Act argue that the technology transfer system is inefficient and detrimental to the mission and norms of university research.[77] Relatively few of the patent applications filed by universities resulted in licensing agreements with industry, and fewer still resulted in large revenues, with only 0.5% of licensing agreements over the last 20 years exceeding $1 million in royalty income.[78] In 2005, only 25 universities reported more than $10 million in licensing revenue, a small amount in comparison to the research expenditures at many universities.[79] For most universities, revenue from licensing barely covers the cost of staff and legal expenses associated with the process.[80] Furthermore, some critics contend that the race to patent university research, and the revenue generated by university-owned patents, has caused many universities to shift their focus from basic research to commercial development.[81] This shift, they argue, has led to a reduction in non-remunerative basic research, a stifling of the free flow of ideas that previously characterized scientific inquiry, and an inappropriate linkage, if not an outright conflict of interest, that afflicts not only academic institutions but also individual investigators who stand to gain substantial financial rewards from the commercial exploitation of their laboratory research.[82]

To-date, there is little definitive empirical evidence supporting either position.[83] Indisputable, however, is the fact that universities continue to develop innovations across a broad range of technologies, to obtain patent protection for those innovations (approximately 4,000 U.S. patents per year)[84] and to license those patents to the private sector for commercial application.

4 Other University Policy Considerations

Despite the frequent appearance of universities in the modern R&D landscape, universities are fundamentally different than corporate technology developers.

Universities operate on a not-for-profit basis, their missions are directed primarily toward research and education, and they are populated largely by academics, scientists and students. These unique characteristics distinguish university-based climate change technology development and exploitation and result in policies and practices that are significantly different than those found in commercial settings.

4.1 *The Research Exemption.*

4.1.1 *A Narrow(ed) Exemption*. A university's ability to carry on research freely and without impediment is fundamental to its mission. A decade ago it was widely believed that academic research in the U.S. could be conducted without threat of patent infringement on the basis that pure research does not infringe the exclusive rights of a patent holder (i.e., the rights to make, use and sell a patented article and to perform a patented process).[85] This assumption was severely undermined by the Federal Circuit's 2002 decision in *Madey v. Duke University*.[86] In that case Professor Madey, a senior academic researcher, sued Duke, his former employer, for infringing several patents that Madey held in his own name. The alleged infringement involved Duke's continuing use of experimental laser equipment developed by Madey during and before his tenure at Duke. Duke asserted, among other things, that its use of the equipment had no commercial application and was directed solely to its non-profit research mission. The court, while recognizing a limited judicial "experimental use" exemption from patent infringement, held that this exemption should be interpreted narrowly to exclude from infringement only activities that are carried out "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[87] Duke, it held, did not meet this standard, as its research was intended to further institutional business objectives such as educating students, improving its academic standing and attracting research grants, students and faculty.[88] As numerous commentators have observed, the *Madey* court's narrow reading of the experimental use exemption effectively eliminates its use in all but the most extreme cases, and does little to protect the research activities of any modern research university.[89]

4.1.2 *The Limited Reach of Madey*. It is worth noting two significant categories of institutions to which the Federal Circuit's narrow experimental use exemption does not apply. First, due to the territorial nature of patent law, the *Madey* decision only applies in the United States. Other jurisdictions, including the United Kingdom, have recognized infringement exemptions for experimental use that are still believed to protect most non-commercial academic research.[90] In the aftermath of *Madey*, some commentators have called for the U.S. Congress to enact a broad patent immunity for research and experimental activity.[91] To date, Congress has acted only incrementally by exempting from infringement experimentation conducted in furtherance of regulatory submissions for drugs and veterinary products.[92] A more general legislative experimental use exemption does not currently appear to be on the horizon.[93]

In addition to non-U.S. institutions, state-sponsored colleges and universities within the U.S., which are immune from suit in federal court under the Eleventh Amendment of the U.S. Constitution, cannot be sued for patent infringement. Accordingly, state-operated research institutions such as the University of Michigan, the University of Wisconsin-Madison, the University of Florida and the entire University of California system, each of which apply for and are awarded large numbers of patents every year, are themselves immune from patent infringement claims under current Supreme Court interpretation of the Eleventh Amendment.[94] While there have been calls to eliminate this apparent windfall to state universities,[95] such legislative proposals have not yet been successful. It is thus private U.S. universities that bear the brunt of the limited experimental use exemption.

4.1.3 *Preserving Research Use Through Contract*. Given the limited scope of the experimental use exemption, private universities in the U.S. must conduct their research activities in the shadow of potential patent infringement. While there is evidence that many academic scientists ignore or are unaware of potential patent risks,[96] evidence also suggests that potential patent claims may deter research in certain areas.[97] If nothing else, university TLOs and legal offices have become significantly more aware of potential infringement issues. According to one report, the University of Iowa, in attempting to clear the research being conducted at a single laboratory studying rare ocular disorders, unearthed 71 different entities of concern and spent $24,000 on background checks and queries to patent holders.[98]

Absent a change in the judicial interpretation of the experimental use exemption, universities are likely exposed to some level of risk from infringement of third party patents. Such exposure may be unavoidable for the university that wishes to conduct research at the cutting edge of science. What is avoidable, however, is the risk that universities face from the patents on their own inventions. There have been recent examples of universities that, whether through inadvertence or carelessness, licensed inventions for exclusive use by industrial partners, thereby blocking any further use or development by the university laboratory that originated them.[99]

To avoid such situations, most universities now require standard language in all license agreements that reserve the university's right to exploit licensed inventions for their own non-commercial research and educational purposes.[100] In 2007, a group of major research universities together with the Association of American Medical Colleges (AAMC) released a document setting forth nine principles relevant to the licensing of academic technology "in the public interest and for society's benefit" (the "Nine Points Document").[101] The first of these principles calls for universities not only to retain through their licensing agreements the right to practice licensed inventions, but also to extend such rights to any other non-profit or governmental organization.[102] The Nine Points Document goes so far as to suggest that even research sponsored by commercial entities should be permitted, so long as it is conducted by a non-profit entity. Ordinarily, such a reservation of rights would benefit a third party university only if the licensing university granted it a license under the relevant patents. However, the Nine Points Document, which has now been endorsed by over 70 universities, also suggests an approach whereby any industrial licensee would contractually agree not to enforce a licensed patent against any university or other non-profit institution.[103] Additionally, some funding organizations such as the NIH and the California Institute for Regenerative Medicine, are encouraging the creation of contractually-based research exemptions for non-commercial research.[104] Should such contractual language be adopted widely by universities, a broad, contractually-constructed experimental use exemption could emerge where Congress has failed to recognize one.

4.2 *Publication and Data Release*. While university administrators and technology transfer officers may be increasingly concerned with maximizing licensing and royalty revenue for their institutions, the currency of academic researchers is, and always has been, publication. The quantity and quality of a scientist's publications has been among the most important factors used in assessing the quality of his or her research, advancing his or her career, and determining his or her stature within the scientific community.[105] It is not surprising, then, that most university licensing and sponsored research agreements expressly reserve the right of university researchers to publish the results of their work in scholarly or scientific journals. If the work is being performed on behalf of a corporate sponsor or is likely to contain trade secrets of an industrial collaborator, it is not unusual for the agreement to require the university to provide a draft of any publication to the sponsor or collaborator in advance of publication, and to allow a period (usually 30-60 days) during which the sponsor or collaborator may suggest changes to preserve the ability to file patent applications and/or to redact trade secrets and confidential information.

A scientific publication typically includes a brief presentation of significant experimental findings, often made in summary or tabular fashion, together with the scientist's analysis and conclusions based upon those findings.[106] While the published data are usually essential to support the scientist's analysis, the data reported in a journal article seldom represent the entirety of the "raw" data collected or observed by the scientist, and are typically only a small fraction of the full data set. Over the past decade, however, an increasing number of scientific journals have required that authors make the data supporting their published claims available to readers upon request.[107] In certain fields such as genomics, government funding agencies routinely require the deposit of raw data sets into public databases,[108] and there are numerous initiatives to encourage the sharing of observational and experimental data in the atmospheric and climatological sciences.[109] It is likely that this trend toward broad sharing of, and public access to, scientific data concerning climate change will continue through a combination of journal requirements, funding obligations and academic agreements.

4.3 *Socially Responsible Licensing*. For the past decade there has been mounting public pressure to expand the availability of patented technologies, particularly so-called "essential medicines", in the developing world. When the HIV anti-retroviral drug Zerit®, developed and patented by researchers at Yale University, became a critical part of the standard AIDS treatment regimen, Yale students and faculty, together with the popular press, exerted sufficient pressure on the university's exclusive licensee Bristol-Myers Squibb (BMS) to persuade the company in 2001 to make the drug available at nominal cost to AIDS sufferers in Africa.[110] Since the Zerit® episode, an increasing number of universities have declared their support for such humanitarian or "socially responsible" licensing.[111] The 2007 Nine Points Document refers explicitly to the university's "social compact with society" and urges universities to structure their licensing arrangements so as to ensure that underprivileged populations have access to medical innovations.[112] In 2009 a group of six major research universities endorsed an even stronger statement committing that their intellectual property would not "become a barrier to essential health-related technologies needed by patients in developing countries."[113]

While current university initiatives have focused on access to essential medicines, commentators have suggested that similar considerations should also apply with respect to climate change technologies, which are also likely to have a profound effect on human health and welfare, both in the developed and the developing world.[114] Certainly the public debate over international intellectual property policy and climate change technology echo the earlier (and ongoing) debate regarding access to essential medicines in developing countries.[115] Thus, it is likely that considerations of socially-responsible licensing will enter into university sponsored research and licensing agreements for climate change technologies in the not-too-distant future.

Potential licensing structures that might emerge, as suggested by the experience of essential medicines, include (a) excluding developing countries from exclusive license grants, (b) requiring licensees to grant sublicenses to local producers in developing countries, (c) retaining university private march-in rights if products are not made suitably accessible in developing countries, and (d) prohibiting the filing of corresponding patent applications in developing countries.[116] Other contractual approaches that may achieve socially-responsible goals include university patent pledges and non-assertion covenants such as those expressed in the Eco-Patent Commons (described in Section 2.6 above), as well as the contribution of patents to socially-oriented patent pools along the lines of the newly-formed UNITAID pool for essential medicines.[117]

5 Conclusion

Research universities have traditionally been catalysts for technological innovation and are likely to generate significant advances in climate change technology for decades to come. However, unlike commercial enterprises, universities are subject to significant limitations and obligations arising from federal funding requirements, statutory regimes such as the Bayh-Dole Act, and the dictates of their non-profit charters. It is important to keep these particular characteristics of universities and university research in mind when considering any collaboration, license or sponsorship arrangement with them. If appropriate consideration is given to these characteristics, however, substantial benefits may be derived for industry, academia and society as a whole.

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