

Academic Technology Transfer

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There are approximately 200 research universities operating in the United States today. These universities, with aggregate annual research budgets in excess of \$70 billion,¹ are responsible for many of the most important scientific and technological discoveries of the last century. As recounted by Jonathan Cole, “[t]he laser, magnetic-resonance imaging, FM radio, the algorithm for Google searches, global-positioning systems, DNA fingerprinting, fetal monitoring, bar codes, transistors, improved weather forecasting, mainframe computers, scientific cattle breeding, advanced methods of surveying public opinion, even Viagra had their origins in America’s research universities.”²

Universities actively seek patents and other intellectual property (IP) protection for their innovations. From 1996 to 2015, American universities obtained more than 80,000 US patents, and more than 7,600 in 2018 alone.³ Many of these patents are licensed to start-up and mature companies. The Association for University Technology Managers (AUTM) reports that in 2018 US universities entered into 9,350 new technology license and option agreements.⁴ Accordingly, any discussion of technology licensing and transactions would be incomplete without a brief stop in the world of university technology transfer.⁵

¹ Natl. Sci. Fnd., Rankings by Total R&D Expenditures, <https://ncesdata.nsf.gov/profiles/site?method=rankingBy-Source&ds=herd> (data through 2017).

² Jonathan Cole, *Can American Research Universities Remain the Best in the World?* Chron. Higher Ed., January 3, 2010.

³ See Assn. Univ. Tech. Managers, US Licensing Activity Survey: 2018, <https://autm.net/surveys-and-tools/surveys/licensing-survey/2018-licensing-activity-survey> (hereinafter AUTM 2018 Survey), and Assn. Univ. Tech. Managers, Driving the Innovation Economy Academic Technology Transfer in Numbers, https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_2017_Infographic.pdf.

⁴ AUTM 2018 Survey, *supra* note 3.

⁵ Academic technology transfer is a large subject, and this chapter covers only a portion of it. Given the nature of this book, we will focus largely on agreements relating to IP licensing. For a discussion of topics including government research grants, sponsored research funding and university spinout companies, see, e.g., Jennifer Carter-Johnson, University Technology Transfer Structure and Intellectual Property Policies in Research Handbook on Intellectual Property and Technology Transfer 4 (Jacob H. Rooksby, ed., Edward Elgar, 2020).

14.1 ACADEMIC RESEARCH AND THE BAYH–DOLE ACT

Before World War II, US academic research was confined largely to the laboratory and scientific conferences.⁶ But with the advent of war against technologically formidable adversaries, President Franklin D. Roosevelt placed Vannevar Bush, the Dean of MIT's School of Engineering and the founder of Raytheon, in charge of the government's new Office of Scientific Research and Development. Bush drew on his longstanding ties to MIT as he oversaw key wartime initiatives like the Manhattan Project and the development of radar. During America's post-war boom, Bush continued to shape US research policy, convinced that American academic institutions could serve the national interest through research and development. As a result, the federal government began to pour money into academic labs. In 1953, federal nondefense R&D funding was \$2.2 billion. By 1980 it had reached \$41.5 billion.

But although an increasing share of each year's Nobel prizes went to US scientists, relatively little academic research was finding its way into the commercial sector. Unlike Japan, where the government directly funded industrial research programs in fields like semiconductors and consumer electronics, US research had a hard time finding its way into commercial applications. It has been estimated that of the 30,000 federally owned patents in existence prior to 1980, only 5 percent were ever licensed to industry, and even fewer made their way into commercial products or services.⁷ The problem, many felt, had to do with the way that patents were awarded for federally funded research.

Under prevailing federal regulations prior to 1980, IP rights in federally funded discoveries were murky. Some agencies claimed ownership over inventions that they funded, others gave rights to their grantees, others didn't specify one way or the other. A result of this lack of clarity was that few federally funded inventions were being used by the private sector. A solution to this problem was proposed by Senators Birch Bayh, a Democrat from Indiana, and Bob Dole, a Republican from Kansas. The resulting Bayh–Dole Act of 1980 made a number of tweaks to the patent system focused on federally funded research.⁸

BAYH–DOLE ACT OF 1980

35 U.S.C. § 200: Policy and Objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition

⁶ For a more detailed history of university technology transfer in the USA, see Carter-Johnson, *supra* note 5, at 6–12; Natl. Res. Council, *Research Universities and the Future of America* 37–39 (Natl. Acad. Press, 2012).

⁷ Committee on Management of University Intellectual Property, *Managing University Intellectual Property in the Public Interest* 24 (Stephen A. Merrill & Anne-Marie Mazza eds., Natl. Res. Council, 2010); Daniel S. Greenberg, *Science for Sale: The Perils, Rewards, and Delusions of Campus Capitalism* 52 (Univ. Chicago Press, 2007).

⁸ The Bayh–Dole Act applies to a range of nonprofit institutions and small businesses that receive federal research funding. For purposes of this chapter, however, I focus on academic institutions.

and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

14.1.1 *Ownership of Federally Funded Intellectual Property*

The principal feature of the Bayh–Dole Act was to allow research institutions receiving federal funding to retain ownership of the discoveries and inventions that they made using this funding.⁹ The Act requires these institutions to disclose each such federally funded invention to the government, and to elect whether or not it wishes to retain rights to that invention. If the institution fails to make this disclosure within a reasonable time or to make this election within two years after the disclosure, then the government may take title to the invention (35 U.S.C. § 201(c)(1)-(2)). Then, if the institution elects to take title to the invention, it must file patent applications in the United States and any other countries where it wishes to retain rights (35 U.S.C. § 201(c)(3)). Again, if the institution fails to file such patent applications in a country, the government may take title to the invention in that country.

Despite these provisions, universities typically do not file patent applications covering every invention that is disclosed by their researchers. In many cases the potential commercial value of an invention may be small compared to the cost of filing and prosecuting a patent application, and the university’s educational and research missions may better be served 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 (37 C.F.R. § 401.14(f)(3)). While such a notification technically gives the agency the right to claim ownership of the invention, governmental agencies seldom exercise this right.

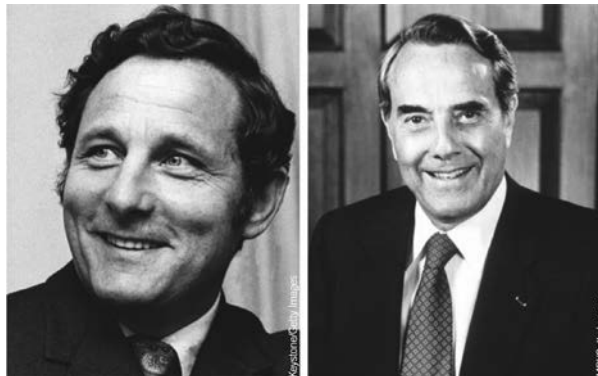


FIGURE 14.1 Senators Birch Bayh and Bob Dole.

⁹ Almost all US universities require their faculty and other personnel to assign patent rights in inventions made using university resources and facilities to the university. See [Section 2.3](#).

A related issue concerns a university's ownership of an invention when a researcher assigns the rights in that invention to a commercial research sponsor. This issue was considered in the following case.

Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.

563 U.S. 776 (2011)

ROBERTS, CHIEF JUSTICE

Since 1790, the patent law has operated on the premise that rights in an invention belong to the inventor. The question here is whether the Bayh–Dole Act displaces that norm and automatically vests title to federally funded inventions in federal contractors. We hold that it does not.

I

In 1985, a small California research company called Cetus began to develop methods for quantifying blood-borne levels of human immunodeficiency virus (HIV), the virus that causes AIDS. A Nobel Prize winning technique developed at Cetus—polymerase chain reaction, or PCR—was an integral part of these efforts. PCR allows billions of copies of DNA sequences to be made from a small initial blood sample.

In 1988, Cetus began to collaborate with scientists at Stanford University's Department of Infectious Diseases to test the efficacy of new AIDS drugs. Dr. Mark Holodniy joined Stanford as a research fellow in the department around that time. When he did so, he signed a Copyright and Patent Agreement (CPA) stating that he “agree[d] to assign” to Stanford his “right, title and interest in” inventions resulting from his employment at the University.

At Stanford Holodniy undertook to develop an improved method for quantifying HIV levels in patient blood samples, using PCR. Because Holodniy was largely unfamiliar with PCR, his supervisor arranged for him to conduct research at Cetus. As a condition of gaining access to Cetus, Holodniy signed a Visitor's Confidentiality Agreement (VCA). That agreement stated that Holodniy “will assign and do[es] hereby assign” to Cetus his “right, title and interest in each of the ideas, inventions and improvements” made “as a consequence of [his] access” to Cetus.

For the next nine months, Holodniy conducted research at Cetus. Working with Cetus employees, Holodniy devised a PCR-based procedure for calculating the amount of HIV in a patient's blood. That technique allowed doctors to determine whether a patient was benefiting from HIV therapy.

Holodniy then returned to Stanford where he and other University employees tested the HIV measurement technique. Over the next few years, Stanford obtained written assignments of rights from the Stanford employees involved in refinement of the technique, including Holodniy, and filed several patent applications related to the procedure. Stanford secured three patents to the HIV measurement process.

In 1991, Roche Molecular Systems, a company that specializes in diagnostic blood screening, acquired Cetus's PCR-related assets, including all rights Cetus had obtained through agreements like the VCA signed by Holodniy. After conducting clinical trials on

the HIV quantification method developed at Cetus, Roche commercialized the procedure. Today, Roche's HIV test "kits are used in hospitals and AIDS clinics worldwide."

Some of Stanford's research related to the HIV measurement technique was funded by the National Institutes of Health (NIH), thereby subjecting the invention to the Bayh–Dole Act. Accordingly, Stanford disclosed the invention, conferred on the Government a nonexclusive, nontransferable, paid-up license to use the patented procedure, and formally notified NIH that it elected to retain title to the invention.

In 2005, the Board of Trustees of Stanford University filed suit against Roche, contending that Roche's HIV test kits infringed Stanford's patents. As relevant here, Roche responded by asserting that it was a co-owner of the HIV quantification procedure, based on Holodniy's assignment of his rights in the Visitor's Confidentiality Agreement. As a result, Roche argued, Stanford lacked standing to sue it for patent infringement. Stanford claimed that Holodniy had no rights to assign because the University's HIV research was federally funded, giving the school superior rights in the invention under the Bayh–Dole Act.

II

Although much in intellectual property law has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not. Under the law in its current form, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter ... may obtain a patent therefor." 35 U.S.C. § 101.

Our precedents confirm the general rule that rights in an invention belong to the inventor. It is equally well established that an inventor can assign his rights in an invention to a third party. Thus, although others may acquire an interest in an invention, any such interest—as a general rule—must trace back to the inventor.

In accordance with these principles, we have recognized that unless there is an agreement to the contrary, an employer does not have rights in an invention "which is the original conception of the employee alone." Such an invention "remains the property of him who conceived it." *Ibid.* In most circumstances, an inventor must expressly grant his rights in an invention to his employer if the employer is to obtain those rights.

Stanford and the United States as *amicus curiae* contend that the Bayh–Dole Act reorders the normal priority of rights in an invention when the invention is conceived or first reduced to practice with the support of federal funds. In their view, the Act moves inventors from the front of the line to the back by vesting title to federally funded inventions in the inventor's employer—the federal contractor.

[But] nowhere in the Act is title expressly vested in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions. Instead, the Act provides that contractors may "elect to retain title to any subject invention." 35 U.S.C. § 202(a). A "subject invention" is defined as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." § 201(e).

Stanford asserts that the phrase "invention of the contractor" in this provision "is naturally read to include all inventions made by the contractor's employees with the aid of federal funding." That reading assumes that Congress subtly set aside two centuries of patent law in a statutory definition. It also renders the phrase "of the contractor" superfluous. If

the phrase “of the contractor” were deleted from the definition of “subject invention,” the definition would cover “any invention ... conceived or first actually reduced to practice in the performance of work under a funding agreement.” Reading “of the contractor” to mean “all inventions made by the contractor’s employees with the aid of federal funding,” as Stanford would, adds nothing that is not already in the definition, since the definition already covers inventions made under the funding agreement. That is contrary to our general “reluctan[ce] to treat statutory terms as surplusage.”

Construing the phrase to refer instead to a particular category of inventions conceived or reduced to practice under a funding agreement—inventions “of the contractor,” that is, those owned by or belonging to the contractor—makes the phrase meaningful in the statutory definition. And “invention owned by the contractor” or “invention belonging to the contractor” are natural readings of the phrase “invention of the contractor.”

Stanford’s reading of the phrase “invention of the contractor” to mean “all inventions made by the contractor’s employees” is plausible enough in the abstract; it is often the case that whatever an employee produces in the course of his employment belongs to his employer. No one would claim that an autoworker who builds a car while working in a factory owns that car. But, as noted, patent law has always been different: We have rejected the idea that mere employment is sufficient to vest title to an employee’s invention in the employer. Against this background, a contractor’s invention—an “invention of the contractor”—does not automatically include inventions made by the contractor’s employees.

The Bayh–Dole Act’s provision stating that contractors may “elect to retain title” confirms that the Act does not vest title. Stanford reaches the opposite conclusion, but only because it reads “retain” to mean “acquire” and “receive.” That is certainly not the common meaning of “retain.” “[R]etain” means “to hold or continue to hold in possession or use.” You cannot retain something unless you already have it. The Bayh–Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have. Such a provision makes sense in a statute specifying the respective rights and responsibilities of federal contractors and the Government.

The Bayh–Dole Act applies to subject inventions “conceived or first actually reduced to practice in the performance of work” “funded in whole or in part by the Federal Government.” Under Stanford’s construction of the Act, title to one of its employee’s inventions could vest in the University even if the invention was conceived before the inventor became a University employee, so long as the invention’s reduction to practice was supported by federal funding. What is more, Stanford’s reading suggests that the school would obtain title to one of its employee’s inventions even if only one dollar of federal funding was applied toward the invention’s conception or reduction to practice.

Stanford contends that reading the Bayh–Dole Act as not vesting title to federally funded inventions in federal contractors “fundamentally undermin[es]” the Act’s framework and severely threatens its continued “successful application.” We do not agree. Universities typically enter into agreements with their employees requiring the assignment to the university of rights in inventions. With an effective assignment, those inventions—if federally funded—become “subject inventions” under the Act, and the statute as a practical matter works pretty much the way Stanford says it should. The only significant difference is that it does so without violence to the basic principle of patent law that inventors own their inventions.



FIGURE 14.2 Stanford University failed to acquire rights in one of its researchers' inventions due to the future-looking language of its IP assignment policy. The Bayh–Dole Act did not remedy this failure.

Notes and Questions

1. *University ownership.* Why does the Bayh–Dole Act allow universities to patent federally funded inventions? Why doesn't the act award such patents to the federal funding agency? Section 105(a) of the Copyright Act provides that copyright protection is not available for any work of the US government, meaning that works of authorship made by federal personnel are largely in the public domain. Why wasn't a similar rule adopted for patents?
2. *The importance of words.* The Supreme Court, in ruling for Cetus, merely confirmed that the Bayh–Dole Act did not rescue Stanford from the results of its unfortunate drafting choices, discussed in Section 2.3, Notes 3–4. Is this fair? Should a mere contractual slip override the public policy goals of the Bayh–Dole Act?

14.1.2 Royalty Sharing with Researchers

Academic institutions, while excellent sources for basic research, are seldom equipped to bring their inventions to the marketplace. Accordingly, most universities seek to license their patents and other IP to the private sector (see Section 14.2). In most cases these licenses are royalty-bearing, meaning that the university will collect a royalty based on some percentage of its licensees' sales of products covered by the patents (see Section 8.2). The Bayh–Dole Act requires that universities share these royalties with individual inventors, and that the balance of the proceeds (after payment of expenses) “be utilized for the support of scientific research or education” (35 U.S.C. § 202(c)(7)(B)-(C)). Royalty-sharing arrangements vary widely among institutions. For example, Stanford University allocates the first 15 percent of net license revenue (after patenting

costs) to its technology transfer office (TTO), then splits the remaining 85 percent in three equal parts among the inventors (in equal shares), their departments and the university; Washington University in St. Louis allocates 25 percent to its TTO, 35 percent to the inventors and 40 percent to the university; and Rice University allocates 37.5 percent to the inventors, 14 percent to their departments, 18.5 percent to the graduate education function, and 30 percent to the university.¹⁰

14.1.3 Preference for United States Industry

Section 204 of the Bayh–Dole Act embodies a specific preference for US manufacturing in its terms.

35 U.S.C. § 204: PREFERENCE FOR UNITED STATES INDUSTRY

Notwithstanding any other provision of this chapter, no [entity] which receives title to any subject invention ... shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the [entity] that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

An exclusive licensee of a federally funded invention should thus be vigilant – if a US manufacturing provision is included in the license agreement proffered by an academic institution, the licensee should evaluate whether US manufacturing will be practical under the circumstances. For example, does the licensee intend to offshore manufacturing to another country? Will its costs increase substantially if required to manufacture in the United States? Although the US manufacturing requirement is often waived by the funding agency, such waiver must be requested specifically.

Notes and Questions

1. *Bayh–Dole as an engine of global innovation?* In 2002 *The Economist* lauded the Bayh–Dole Act as “Possibly the most inspired piece of legislation to be enacted in America over the past half-century.” The Act, the editors proclaimed, “unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers’ money [and] helped to reverse America’s precipitous slide into industrial irrelevance.”¹¹ An

¹⁰ For a detailed analysis of these revenue splits, see Lisa Larrimore Ouellette & Andrew Tutt, *How Do Patent Incentives Affect University Researchers?*, 61 *Intl. Rev. L. & Econ.* 105883 at 9–10 (2020).

¹¹ *Economist*, “Innovation’s golden goose”, December 14, 2002.

industry coalition celebrating the fortieth anniversary of the Act in 2020 proudly announced that “Bayh–Dole made the United States the engine of global innovation ... Thanks to Bayh–Dole, over 200 new therapies – including drugs and vaccines – have been created since 1980. The legislation has also bolstered U.S. economic output by \$1.3 trillion, supported 4.2 million jobs, and led to more than 11,000 start-up companies.”¹² Why would university patenting be responsible for economic growth on this scale? What is your impression of these figures?

2. *Bayh–Dole, oncomouse, and the Republic of Science.* Beginning in the 1990s, critics began to fear that the promise of licensing revenue may have caused universities to stray from their core educational and public missions. Members of the public, including a number of students, began to protest prominent academic–industry ties. One of the most heated of these incidents involved Harvard’s genetically engineered “oncomouse,” which the university licensed exclusively to DuPont Corporation. The arrangement led to student protests, newspaper op-eds and two rounds of Congressional hearings.¹³ Eventually, in response to this flurry of negative publicity, Harvard and DuPont rescinded some of the more controversial aspects of their arrangement. In response to episodes like this, science journalist Dan Greenberg, in his influential book *Science for Sale: The Perils, Rewards, and Delusions of Campus Capitalism* (2007), asks whether “today’s commercial values [have] contaminated academic research, diverting it from socially beneficial goals to mercenary service on behalf of profit-seeking corporate interests?” (p. 2).¹⁴ What do you think of these critiques? Do they detract from the economic benefits that seem to have flowed from the Bayh–Dole Act?
3. *Royalty sharing.* As noted above, the Bayh–Dole Act requires that universities share royalties that they earn from patent licensing with individual inventors. Why? Private companies that license their patents have no such requirements. Should they? And which “inventors” should be entitled to a share of the university’s royalties? In most cases, inventors for patent purposes must make a meaningful original contribution to the discovery or reduction of an invention to practice – a far higher standard than that required for authorship of a scientific paper. Should other members of the scientific team or lab that made a major breakthrough receive any compensation?¹⁵
4. *US manufacturing.* As noted above, the Bayh–Dole Act requires that an exclusive licensee of a federally funded invention substantially manufacture the resulting product in the United States. Why do you think this preference was included in the Act? Why does it apply only to exclusive licenses? Given the shift of manufacturing capacity overseas, how relevant do you think this preference is today? How often do you think the preference is waived by the relevant federal funding agency?

In *Ciba-Geigy Corp. v. Alza Corp.*, 804 F. Supp. 614 (1992), Ciba-Geigy obtained an exclusive license under the University of California’s patents claiming a nicotine patch. Ciba-Geigy then sued Alza, claiming that Alza’s Nicoderm product infringed the patent. Alza counterclaimed that Ciba-Geigy’s exclusive license from the university was not valid because Ciba-Geigy had been manufacturing its own product in Germany, in violation of the US manufacturing requirement under Bayh–Dole. The court held that Alza could not

¹² BayhDole40, <https://bayhdole40.org/new-coalition-launches-to-celebrate-and-protect-the-bayh-dole-act>.

¹³ See Daniel J. Kevles, *Of Mice and Money: The Story of the World’s First Animal Patent*, 131 *Daedalus* 78 (2002).

¹⁴ For a more recent critique, see Rebecca S. Eisenberg and Robert Cook-Deegan, *Universities: The Fallen Angels of Bayh–Dole?* 147 *Daedalus* 76 (2018).

¹⁵ See Carter-Johnson, *supra* note 5, at 26–27 and 33–37 (discussing revenue-sharing issues).

defend against an infringement claim based on the failure of a university licensee to comply with US manufacturing requirements. Specifically, the court ruled that failing to manufacture in the United States does not automatically invalidate an exclusive license nor convert it to a nonexclusive license, so long as the government agency that funded the invention does not invoke its march-in rights (see [Section 14.2](#)). Unless and until the funding agency chose to exercise those rights (which it had shown no interest in doing), the license was unaffected. Do you agree with this result? If so, what purpose, if any, do US manufacturing rights serve today?

5. *Bayh–Dole around the world.* The apparent success of the Bayh–Dole Act in the United States has led a number of other countries to adopt legislation that seeks, in whole or in part, to replicate the benefits of the Act in their own economies. These include both developed countries such as China, Japan, France, Germany and the United Kingdom, as well as a range of mid-tier and developing countries, including Argentina, Brazil, Ethiopia, India, Indonesia, Malaysia, Nigeria, Poland, Russia and Vietnam. Do you think that local versions of the Bayh–Dole Act will be successful in each of these countries? Are there factors that would make a statutory structure such as that provided under Bayh–Dole less or more attractive in developing countries?

14.2 MARCH-IN RIGHTS UNDER THE BAYH–DOLE ACT

Because inventions subject to the Bayh–Dole Act were made using federal funding, the federal government retains some rights to these inventions even when title is held by a research institution. Under Section 202(c)(4), the funding agency has “a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.” This is a “government use” license, which ensures that the government is able to make use of inventions that it funds, even if they are otherwise commercialized.

A more controversial right exists under Section 203 of the Act. This section permits the funding agency to require an academic institution to license an invention to one or more third parties if necessary to “achieve practical application” of the invention or “to alleviate health or safety needs” that are “not reasonably satisfied” by the institution or its existing licensees. This right has significant implications both for the academic institution and its licensees. That is, if a university has granted an exclusive license to a private company, but that company cannot supply the licensed invention in sufficient quantities to meet health or safety needs, then the funding agency can require the university to license other manufacturers to produce the product, notwithstanding the original licensee’s exclusivity.

Petition to Use Authority Under the Bayh–Dole Act to Promote Access to Fabryzyme (Agalsidase Beta), an Invention Supported By and Licensed By the National Institutes of Health under Grant No. DK-34045

August 2, 2010

Joseph M. Carik, Anita Hochendoner, and Anita Bova seek an open license under the Bayh–Dole Act that would allow supply of agalsidase beta [Fabrazyme] in the U.S. and abroad to treat Fabry patients. Specifically, this petition requests that NIH authorize

responsible entities and individuals to use U.S. Patent No. 5,356,804 and U.S. Patent No. 5,580,757 in order to manufacture, import, export or sell agalsidase beta.

Background on Fabry Disease

Fabry disease is an X-linked recessive (inherited) lysosomal storage disease, which can cause [renal, heart, dermatological, ocular and other symptoms]. Fabry disease significantly shortens the life of its sufferers.

Government Role in Funding Research and Development

NIH is one of the largest funding entities for Fabry research, and is heavily invested in securing the well-being of Fabry patients. A July 22, 2010 search of the NIH Research Portfolio Online Reporting Tools (RePORT) database using the keyword “Fabry” identified 372 NIH grants. A July 23, 2010 search of clinicaltrials.gov using the key words “Fabry’s Disease” identified 54 clinical trials, including 14 that were funded by the NIH, 16 identified as having received funding from Universities or other non-profit organizations, and 27 trials that received funding from industry.

Invention of Agalsidase Beta Treatment

While no cure is yet available, one of the greatest breakthroughs in scientific research on Fabry disease has been the discovery that enzyme replacement therapy with agalsidase beta (Fabrazyme) can effectively treat Fabry patients. The breakthrough was a direct result of NIH funding of grant no. DK 34045 awarded to Dr. Robert J. Desnick at the Mount



FIGURE 14.3 Genzyme’s Fabrazyme.

Sinai School of Medicine of New York University. The adoption of Fabrazyme treatment has been widespread and is currently the gold standard of care for patients in the U.S. exhibiting symptoms.

Ownership and Licensing of Fabrazyme

Currently, Fabrazyme treatment is the only FDA approved enzyme replacement therapy in the United States. Genzyme, Inc. is the exclusive licensee to produce Fabrazyme.

The initial production of Fabrazyme was sufficient to meet the needs of all patients in the United States. However, in mid-2009, Genzyme decreased production as a result of a viral infection of their Allston, MA manufacturing plant. Further, in November 2009, Fabrazyme was produced which contained contaminants. The FDA initiated action against Genzyme which resulted in a consent decree including \$175 million dollars in fines as profit disgorgement and oversight of the manufacture of Fabrazyme for at least 7 years.

Genzyme is only producing 30% of Fabrazyme estimated to meet the needs of patients. Current patients cannot have dosage increases, and no new patients being diagnosed are eligible to receive therapy. Although the most recent communication from Genzyme indicates that it expects to increase production by late 2011, there is no substantial guarantee that the projected date will be met.

Health Impact of Genzyme's Rationing of Fabrazyme

No cumulative data on the impact of Fabrazyme rationing is yet available; however, anecdotal data indicate that patients are struggling and at least one patient may have died due to reduced dosage (Genzyme disputes that the death was due to rationing). In addition, the petitioners have suffered immediate and significant harm due to the rationing. Specifically, Mr. Carik, Ms. Hochendoner, and Ms. Bova have had their dosage cut by 70%. They have had a return of symptoms and are now at far greater risk for cardiac disease and renal failure than before rationing began.

Genzyme Has Not Satisfied and Cannot Reasonably Satisfy the Health and Safety Needs of Fabry Patients by Rationing Drugs While Preventing Additional Sources of Manufacture

Rationing drugs does not satisfy the health and safety needs of individuals because there is no alternative treatment, and absent rationing all patients would receive their recommended treatment. The Bayh–Dole Act requires that Genzyme reasonably satisfy the health and safety needs of patients, which it has not done.

- 1) It is ... unreasonable, improper, and even catastrophic to limit patient access to a drug where such a limitation causes morbidity and death. The idea that drug access should be limited where there is a way to mitigate or prevent that limitation is anathema to virtually all ethical and scientific principles. Currently, 100% of Fabry patients have either limited access, or no access at all to Fabrazyme or any alternative treatment. Limiting access instead of encouraging others to make up the shortfall in manufacturing is the worst conceivable public health solution to supply shortages of publicly funded inventions.
- 2) It is further unreasonable and unfair to limit patient access to drug where the only impediment to its full production is a patent monopoly that was paid for in part from

the tax dollars of the patients themselves. In fact, the exception regarding health and safety concerns in Bayh–Dole Act ensures that patent laws do not trump health and safety concerns. Thus, absent an overwhelming argument that patent exclusivity is more important than drug access (e.g., critical national security concerns), there is no medically or ethically justifiable reason to limit access to Fabrazyme where a statutory remedy to the rationing exists.

- 3) To the extent that economic policy is to be balanced against the public need, it is further unreasonable to deny march-in rights where the petitioners or other licensees will not compete against the patentee. Specifically, granting march-in rights will not discourage industry investment in drug development, because licensees will normally not ration drug thus avoiding the instant situation altogether. Further, by granting march-in rights, Genzyme's revenues will actually increase since Genzyme sells every dose of Fabrazyme that it currently manufactures, but only meets 30% of the demand. By being granted march-in rights, the licensee will pay a reasonable 5% royalty rate to Genzyme to sell drug that Genzyme cannot otherwise produce.
- 4) Further it is unwise economic policy (and further unreasonable) to protect, or otherwise favor the licensee where the licensee caused the health crisis in the first place. While there is no specific remedy in the Bayh–Dole Act for licensees with “unclean hands,” the drafters never anticipated that a licensee would breach the public trust by limiting access to drug that could otherwise be manufactured. Specifically, the Bayh–Dole Act has operated seamlessly and successfully for the invention of Fabrazyme until the drug was produced. The only dysfunction in the process has been Genzyme's negligent manufacture of drug and the failure to obey FDA regulations. Thus, where the licensee actually caused the crisis (whether willfully or not), it is inconsistent with the objectives of Bayh–Dole to continue to reward the patentee with further patent exclusivity as it attempts to fix its own mistakes, especially while patients are suffering without a remedy.
- 5) It is unreasonable to deny march-in-rights where it is likely that manufacturers are motivated and encouraged to use the publicly funded patent monopoly to shift the economic costs of its errors directly to patients who, in part, funded the invention. The balance struck in the Bayh–Dole Act between public funding and private development is completely eviscerated where publicly funded pharmaceutical/biological inventions can be rationed due to negligence but, ironically, prices can be increased beyond the FDA disgorgement fees to thereby avoid the economic damages caused by that negligence. Thus, the grant of march-in rights assures that Genzyme will not increase prices in response to the FDA fines further vitiating an already grave health crisis to recover lost profits.
- 6) It is unreasonable to deny march-in rights where granting the license would harmonize with FDA actions. Specifically, the FDA has fined Genzyme \$175 million dollars in disgorgement fees for its negligent manufacturing practices. If Genzyme is allowed to use its patent monopoly to shift the cost of the FDA fine to Fabry patients, then the FDA fines have no effect other than increasing the price of already limited drug. Even worse, failure to grant march-in rights after an FDA fine has the net effect of punishing the victims, not the manufacturer. While there is no provision in the Bayh–Dole Act for regulating prices directly, the remedy of march-in rights assures that the patent monopoly from a publicly funded invention cannot be misused to undermine FDA

punishments for regulatory violations. Specifically, if Genzyme attempts to profiteer from the situation, patients will turn to the march-in licensees for drug. Absent the grant of march-in rights, the FDA fines will have no deterrent effect and, worse, force the victims pay for the manufacturer's breach of regulations.

- 7) In addition, it is reasonable, prudent, and necessary to allow second sourcing where initial demands cannot be met and/or where market disruptions are likely to continue.
- 8) Finally, it unreasonable to argue that inaction is preferable to action where a remedy is available. Specifically, two possible future developments could ameliorate the crisis, the return of normal production of Fabrazyme (projected in late 2011) and/or the FDA approval of Replagal (projected date unknown) by Shire pharmaceuticals. Either development could restore access to effective enzyme replacement treatment for Fabry patients. Despite the fact that both results are hoped for by the petitioners, there is no guarantee that full access will be restored in the near future. In fact, both developments could be delayed by any number of factors. Absent an ironclad guarantee of success in the very near term for these developments, exercising march-in rights is the only immediate solution to the current problem. Because human health is at stake, it is critical for the Government act immediately to ensure that another alternative exists, even if the need for such an alternative may be hopefully mooted in longer term.

Grant of March-in Rights Is Consistent with Prior March-in Determinations

NIH has reviewed three previous petitions for march-in rights and denied exercise of the rights in each case. However, unlike previous petitions, the current petition is distinguishable for the following reasons.

Regarding interpretation of 35 U.S.C. § 203(a)(2) with regard to *In re Cellpro*, the NIH stated that reasonably satisfying a health need included "First, refraining from enforcing patent rights" and a pledge "to ensure that the product is as widely available as possible ... and to ensure patient access to the fullest extent possible." Genzyme has failed to do either.

With regard to *In re Norvir* and *In re Xalatan*, the NIH refrained from acting based on pricing concerns. In both instances, the NIH determined that patients had reasonable physical access to drug, whether or not they could pay the price charged. In contrast, the instant case involves drastic drug rationing and profoundly limited physical access. There is simply not enough of the drug manufactured to treat everyone who needs it. While economic concerns are involved in the instant case and weigh heavily in favor of granting march-in rights, additional facts distinguish the instant case because physical access to the drug is the primary limiting factor preventing access.

Remedy Requested

The Bayh–Dole Act authorizes the Secretary of the Department of Health and Human Services to require that Genzyme issue licenses under terms that are reasonable under the circumstances and, if Genzyme refuses the request, to grant such licenses itself. The petitioners request that NIH use this authority to require Genzyme to issue an open license for use of the Fabrazyme patents subject to this petition. [An open license is a nonexclusive license that is available to any petitioner willing to meet standard nondiscriminatory terms.]

Right to Manufacture and Export World-Wide

The open license should include the rights to use the patents to make, sell, use, import or export Fabrazyme as either a standalone product or as a component. Additionally, the license should include access to the cell line producing Fabrazyme and any technical know-how developed in conjunction with producing the drug in order to expedite production and reduce duplication of efforts. The license should include the right to export Fabrazyme to overseas markets. These rights are necessary to restore access not only in the U.S. but also meet global treatment needs.

Royalty to the Patent Owner

The petitioners propose that the open license provide to the owners of the Fabrazyme patents a combined royalty of 5 percent of the net sales of the Fabrazyme. The five percent royalty is roughly equal to the average US pharmaceutical royalty payment, as reported by the pharmaceutical manufacturing sector to the US Internal Revenue Service. This is more than adequate given that each of the patents in question were invented through a government funding agreement, and that Genzyme has earned approximately \$431 million from the sale of Fabrazyme in 2009 alone.

Conclusion

The Bayh–Dole Act provides the Federal Government with the tools it needs to address the current public health crisis caused by Genzyme’s drug rationing. Petitioners request that the march-in provisions of the Bayh–Dole Act be immediately implemented in order to restore access to critical treatment for Fabry disease victims.

National Institutes of Health Office of the Director

Determination in the Case of Fabrazyme® Manufactured by Genzyme Corporation
December 1, 2010

Based upon the information currently available, NIH has determined that a march-in proceeding under 35 U.S.C. § 203(a)(2) is not warranted at the present time because any licensing plan that might result from such a proceeding would not, in our judgment, address the problem identified by the Requestors. A march-in proceeding resulting in the grant of patent use rights to a third party will not increase the supply of Fabrazyme in the short term because years of clinical studies and regulatory approval would be required before another manufacturer’s product could become available to meet patients’ needs in the United States. NIH has no information that a company is expecting imminent FDA approval of a competing version of an agalsidase beta product. Secondly, the ’804 patent is not an obstacle for a company to conduct clinical trials in the United States in furtherance of regulatory approval for a competing drug, because such clinical trials are exempt from infringement under the Hatch–Waxman statutory safe harbor provision (35 U.S.C. § 271(e)). Finally, Genzyme has indicated that it expects the production of Fabrazyme to be back to full supply levels in the first half of 2011. Genzyme, appears to be working diligently and in good faith to address the Fabrazyme shortage.

Notwithstanding the foregoing, NIH will continue to carefully monitor the shortage of Fabrazyme and will re-evaluate this determination immediately upon receiving any information that suggests progress toward restoring the supply of Fabrazyme to meet patient demand is not proceeding as represented.

Further, in the unlikely event that NIH receives information that a third party has a viable plan to obtain FDA approval to market agalsidase beta during the period in which Genzyme is not able to meet patient demand for Fabrazyme, and, that third party requires commercial rights to the '804 patent in order to proceed with its plan, NIH will immediately re-consider its decision to exercise its march-in authority. Toward this end, NIH has asked Mount Sinai to: (1) provide monthly reports on the status of Genzyme's progress toward addressing the supply shortage of Fabrazyme until such time as U.S. Fabry patients' needs have been met; (2) provide a copy of Genzyme's reports on the allotment of Fabrazyme to Fabry patients; and, (3) notify NIH within two business days after receiving any request from a third party for a license to the '804 patent to market agalsidase beta during the Fabrazyme shortage.

Francis S. Collins, M.D., Ph.D.
Director National Institutes of Health

Notes and Questions

1. *The Fabrazyme dispute.* Which of the petitioners' arguments for march-in rights do you feel was the strongest? Why did NIH decline to exercise its march-in rights with respect to Fabrazyme? Did NIH address all of the petitioners' concerns? Based on the petitioners' description, do you think that the Fabrazyme case was similar to or different than the previous cases in which NIH declined to exercise march-in rights?¹⁶
2. *March-in and royalties.* The petitioners requested that NIH require Genzyme to license other manufacturers to make and sell Fabrazyme. The requested license was royalty-bearing. That is, any other manufacturer who operated under the march-in license would be required to pay a royalty to Genzyme. Why did the petitioners request a royalty-bearing license? Wouldn't a royalty-free license have been more likely to induce other manufacturers to begin production of Fabrazyme? How did the petitioners arrive at a proposed royalty rate of 5 percent? Were they required to propose a particular royalty rate under the Bayh-Dole Act? Do you think that NIH would have been more likely to exercise its march-in rights had the petitioners proposed a 10 percent royalty rate? Would Genzyme have been less likely to object?
3. *March-in and the market.* In a 1997 petition, CellPro, the manufacturer of a stem cell separation device, asked that NIH exercise its march-in rights against patents licensed by Johns Hopkins University to the drug company Baxter, which CellPro allegedly infringed. NIH offered some insights into its reluctance to exercise those rights:

We are wary ... of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many

¹⁶ A concise summary of march-in cases brought through 2016 can be found in John R. Thomas, *March In Rights Under the Bayh Dole Act*, Congressional Research Service, August 22, 2016. Links to many of the primary documents in these cases are available at www.keionline.org/cl/march-in-royalty-free.

companies' and investors' future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh–Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.

To what degree should a federal agency take market factors into account when deciding whether or not to exercise march-in rights? Does it matter whether all of the statutory conditions for exercising those rights are met?

4. *March-in rights and drug pricing.* In 2016, 51 members of Congress asked the NIH to use its march-in rights under the Bayh–Dole Act to rein in the cost of prescription drugs. As explained by Rep. Lloyd Doggett (D-TX), “When drugs are developed with taxpayer funds, the government can and should act to bring relief from out-of-control drug pricing ... There is a difference between earning a profit and profiteering. The Administration should use every tool it has to rein in the practice of pricing a drug at whatever the sick, suffering, or dying will pay.” How could NIH’s exercise of march-in rights influence drug pricing? Not surprisingly, NIH declined to act on this request. Do you agree?
5. *What’s a licensee to do?* Suppose that your company is negotiating an exclusive license for an experimental new drug candidate with a major research university. Assuming that the university received at least some federal funding in support of its research, should you be concerned about march-in rights? What steps might you take in order to address those concerns?
6. *Are march-in rights illusory?* To date, no federal agency has exercised its march-in rights under the Bayh–Dole Act. Moreover, there is no practical legal or administrative mechanism available to challenge or appeal an agency determination not to exercise those rights. Should there be? What mechanism(s) might you suggest to give greater force to the prospect of march-in rights?
7. *Compulsory licensing.* If exercised by a government agency, march-in rights under the Bayh–Dole Act can require a patent licensee to grant sublicenses to third-party manufacturers, or require a patent holder to license additional manufacturers to operate under that patent. These actions are broadly classified as types of “compulsory licensing” – governmental acts that mandate the licensing of IP to others. There are many types of compulsory licenses in addition to Bayh–Dole march-in rights. In [Section 16.1](#) we discuss various statutory compulsory licenses for musical copyrights. But perhaps the most controversial form of compulsory licensing arises when governments in the developing world have authorized local manufacturers to practice under patents held by foreign companies, usually to create an inexpensive version of a drug for local use. To date, the governments of Thailand, Brazil, South Africa and India, among others, have issued compulsory licenses under drug patents held by companies in the United States and Europe. Such compulsory licenses are generally not granted gratis, however, and a royalty is often paid to the foreign patent holder. How should the level of such a royalty be determined? What arguments for and against such compulsory licenses can be made?

TECHNOLOGY TRANSFER FROM US FEDERAL LABORATORIES

The US federal government operates approximately 300 different scientific laboratories across the country. These federal laboratories conduct research across a broad range of civilian and military disciplines, including nuclear physics, materials science, astronomy, meteorology, geology, oceanography and biomedicine. Like universities, federal labs patent many of their inventions and seek to license them to the commercial sector.

Federal statutes, including portions of the Bayh–Dole Act, place limitations on the ability of federal labs to license their technology on an exclusive basis. In particular, 35 U.S.C. § 209(a) requires that: (1) any such exclusive license must be a “reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application; or otherwise promote the invention’s utilization by the public”; (2) the public must be served by granting the license, “as indicated by the applicant’s intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention’s utilization by the public”; and (3) the scope of exclusivity is no greater than reasonably necessary to achieve these goals. The exclusive licensee must commit “to achieve practical application of the invention within a reasonable time.” The agency must also ensure that “granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws.”



FIGURE 14.4 Federal laboratories like Sandia National Laboratory in New Mexico have active technology licensing and commercialization programs.

14.3 LICENSING UNIVERSITY TECHNOLOGY

14.3.1 *The Role of the TTO*

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 transfer offices (TTOs) responsible for evaluating the commercial potential 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.¹⁷ The TTO typically employs individuals

¹⁷ Some universities refer to their TTO as a technology licensing office (TLO), a technology commercialization office (TCO), an office of technology ventures and commercialization (TVC) or, in the case of the University of Utah, the “Partners for Innovation, Ventures, Outreach & Technology (PIVOT) Center.”

with backgrounds in business, law and technology. While most universities, including research powerhouses such as Stanford, MIT and Harvard, operate their TTOs as internal units, 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 IP emerging from university labs. The most notable of these is the University of Wisconsin-Madison, whose Wisconsin Alumni Research Foundation (WARF) was established in 1925 and today enters into approximately 100 commercial licensing agreements per year. It is likely that any company seeking to negotiate a license agreement with a university will deal with its TTO.¹⁸

14.3.2 *Nine Points for University Licensing*

In many ways, academic license agreements are no different than the ordinary business-to-business license agreements discussed elsewhere in this book. Likewise, the contractual terms of academic license agreements are largely those that are described in [Part II](#). However, the public and educational missions of universities, the traditional role of universities as centers for open, scholarly interaction, and pressures from internal constituencies including students, researchers and alumni have led universities to observe a range of special considerations when licensing their IP.

In 2007, eleven 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”).¹⁹ This nonbinding set of principles relates not only to the terms of academic–industry licensing agreements, but also to issues surrounding enforcement of IP, export controls and conflicts of interest. The Nine Points document has been adopted by more than one hundred academic and research funding institutions around the world and has influenced norms and practices around university technology licensing more broadly. The Nine Points are summarized below and those that impact transactional agreements are discussed in greater detail in the [following section](#).

IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY

MARCH 6, 2007

1. Universities should reserve the right to practice licensed inventions and to allow other nonprofit and governmental organizations to do so.
2. Exclusive licenses should be structured in a manner that encourages technology development and use.
3. Strive to minimize the licensing of “future improvements.”
4. Universities should anticipate and help to manage technology transfer-related conflicts of interest.
5. Ensure broad access to research tools.

¹⁸ For a discussion of the structure and role of university TTOs, see Carter-Johnson, *supra* note 5, at 12–19.

¹⁹ The Nine Points document can be found at www.autm.net/AUTMMain/media/Advocacy/Documents/Points_to_Consider.pdf.

6. Enforcement action should be carefully considered.
7. Be mindful of export regulations.
8. Be mindful of the implications of working with patent aggregators.
9. Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.

14.3.3 *University Reserved Rights*

Point 1 of the Nine Points emphasizes one of the most important issues for universities when licensing their IP – the university must retain the right to use the licensed IP for its own internal research and educational purposes. Thus, whether the IP covers a small molecule drug target or an online safety training module, the university will retain the right for its faculty to continue to use and modify that IP in their own research and teaching activities.

This right is particularly important because, contrary to the beliefs of many academic faculty members, US law provides no inherent right to use IP for noncommercial research purposes.²⁰ And while limited classroom reproduction of copyrighted materials may be permitted as “fair use” under the Copyright Act (17 U.S.C. § 107(1)), there is no similar exception for patents. As a result, universities are particularly cautious to retain sufficient internal rights when granting third parties exclusive rights to their IP (this is obviously not an issue when the university only grants nonexclusive rights to third parties).

While the general principle of university retained rights is not objectionable to most exclusive licensees, the scope of the contractual exclusion can sometimes cause concern. Thus, it is one thing to permit the licensing university to retain the right to use licensed IP for its own faculty’s research and educational purposes. But what about other academic institutions? The Nine Points document recommends that universities reserve noncommercial research rights not only for themselves, but for all other nonprofit and governmental organizations (p. 2).²¹ Moreover, many university researchers collaborate with the private sector. Should a university’s commercial collaboration partners also be permitted to conduct research using IP that has been exclusively licensed to someone else? Some university license agreements seek to retain rights that are this broad, but potential exclusive licensees may wish to seek limitations, particularly if they are concerned about competitors gaining access to university-generated technology that they have paid to develop and/or license.

14.3.4 *Publication Rights*

Another important right that universities seek to preserve in licensing agreements is the right of their researchers to publish academic papers and articles covering their discoveries. This right to disseminate knowledge is fundamental to the educational missions of universities, and generally cannot be waived.

²⁰ See *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002) (holding that Duke had no right to continue to use a patented experimental laser apparatus developed by a former faculty member because the university, despite its nonprofit, educational mission, had numerous “commercial” goals such as attracting students and grant funding).

²¹ Following the adoption of the Nine Points document in 2007, university licenses have notably increased their reservations of rights for all non-profit and governmental entities. See Jorge L. Contreras, *In the Public Interest: University Technology Transfer and the Nine Points Document – An Empirical Assessment*, U.C. Irvine L. Rev. (2023) (quantifying this shift).

EXAMPLE: PUBLICATION RIGHTS

Licensee acknowledges that Institution is dedicated to free scholarly exchange and to public dissemination of the results of its scholarly activities. Institution and its faculty and employees shall have the right to publish, disseminate or otherwise disclose any information relating to their research activities including, in Institution's sole discretion, information relating to the Inventions, subject to Institution's obligation to preserve the confidentiality of Licensee's Confidential Information [1].

Institution will submit the manuscript of any proposed publication to Licensee at least 30 days before publication, and Licensee shall have the right to review and comment upon such proposed publication in order to protect Licensee's Confidential Information [2]. Upon Licensee's request, publication may be delayed up to 60 additional days to enable Licensee to secure adequate intellectual property protection for the Inventions. [3].

DRAFTING NOTES

- [1] *Confidential information* – in some cases, a corporate partner will provide a university with data that it considers to be confidential. This information should not be disclosed in a published paper.
- [2] *Review and comment* – academics will often object to any review of their scholarly work by corporate partners, but it is increasingly common for corporate researchers to collaborate with academic scientists on research projects and to co-author any resulting papers for publication.
- [3] *Delay for patent filing* – if a discovery is patentable, and if the corporate partner has the responsibility for filing patent applications, then it may seek to delay a publication that would otherwise disclose an invention in a manner that would limit patentability within the United States or elsewhere.²² If the university has responsibility for patent prosecution, then its internal policies likely contain such a delay mechanism as well.

14.3.5 *Limiting Exclusivity*

As discussed in [Section 7.1](#), there are valid commercial justifications for granting exclusive license rights: without exclusive rights to a particular discovery or invention, a commercial partner may not be willing to invest the substantial amounts necessary to conduct product development, complete clinical trials, and otherwise bring a product to market. Universities recognize this need, but, as the Nine Points document reminds them, “[u]niversities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology” (p. 2). The Nine Points document thus urges universities to grant exclusive licenses only when needed in order to ensure the practical application of an invention.

Moreover, the document (in Points 2, 3, 5 and 9) suggests several strategies that universities can use to soften the effect of exclusive rights:

- requiring the exclusive licensee to meet “diligence” or performance milestones toward commercial development (see [Section 8.5](#));

- requiring the exclusive licensee to grant sublicenses to third parties to address unmet market or public health needs;
- reserving a right in the university to grant licenses to third parties to address unmet market or public health needs (akin to a “march-in” right);
- granting a company the exclusive right to *sell* a product, but not to *make* or *use* it (thus freeing others, including other research institutions, to make their own noncommercial, in-house versions of a product);
- excluding from the scope of the exclusive license grant “clinical research, professional education and training, use by public health authorities, independent validation of test results or quality verification and/or control”; and
- limiting exclusive rights to existing patents and patent applications, and not automatically licensing improvement or follow-on inventions.

The Nine Points document also echoes the advice of NIH in urging patent holders to avoid granting exclusive rights with respect to broadly applicable research tools and methods (see [Section 7.1](#)).

14.3.6 Socially Responsible Licensing

Since the 1980s there has been mounting public pressure to expand the availability of patented technologies, particularly so-called “essential medicines,” to those who could not otherwise afford them, especially in the developing world. When the HIV antiretroviral drug Zerit, developed and patented by researchers at Yale University, became a critical part of the 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 patients in Africa.²³ Since the Zerit episode, an increasing number of universities have declared their support for such humanitarian or “socially responsible” licensing. Point 9 of the Nine Points document refers explicitly to a 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. In 2009 a group of six major research universities endorsed an even stronger statement committing that their IP would not “become a barrier to essential health-related technologies needed by patients in developing countries.”²⁴

Potential licensing structures that reflect socially responsible licensing by universities, as suggested by the experience of essential medicines, include

- excluding developing countries from exclusive license grants;
- requiring licensees to grant sublicenses to local producers in developing countries;
- retaining university private march-in rights if products are not made suitably accessible in developing countries;

²² In the USA an inventor may file a patent application up to one year after the first public disclosure of the invention (35 U.S.C. § 102(b)(1)). In other countries, including most European countries, there is no such grace period.

²³ See A. J. Stevens & A. E. Effort, *Using Academic License Agreements to Promote Global Social Responsibility*, 85 *Les Nouvelles* 86 (2008).

²⁴ *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies*, https://otd.harvard.edu/upload/files/Global_Access_Statement_of_Principles.pdf (endorsed by Harvard University, Yale University, Brown University, Boston University, the University of Pennsylvania, Oregon Health & Science University and AUTM).

- prohibiting the filing of corresponding patent applications in developing countries; and
- requiring that products sold in developing countries be priced on a humanitarian basis (i.e., subsidized, at-cost or no cost).

14.3.7 Price Controls

The last of these approaches – controls on downstream pricing – is perhaps the most controversial. Typically, IP licensees retain flexibility to price their products as they wish, based on market and competitive factors.²⁵ Efforts to control the prices of prescription drugs in the United States have taken many forms, though none has yet been successful. Experiments with contractual price control mechanisms were attempted as early as the 1980s, when NIH tried to rein in drug pricing by requiring a “fair pricing” clause in all of its cooperative R&D agreements (“CRADAs”) with private industry.

This mandatory contractual language, widely reviled by the pharmaceutical industry, was adopted by NIH in response to a controversy surrounding the AIDS drug AZT. The drug, which was released in 1987 by Burroughs Wellcome, bore the then-stratospheric price tag of \$8,000 per year.²⁶ Yet, as AIDS activists were quick to point out, Burroughs Wellcome had not been the one to discover the drug nor its effectiveness against AIDS. A failed cancer treatment, AZT’s potential use against AIDS was first suspected by scientists at NIH’s National Cancer Institute. To encourage Burroughs to bring AZT to market, NIH allowed the company to retain full ownership of the resulting patent. But once that happened, there was no way to constrain Burroughs’ pricing of the drug, and it charged what it felt the market would bear.

To prevent further instances of price gouging, in 1989 NIH inserted a new fair pricing clause into all of its CRADAs, requiring that there be a “reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.” But in Varmus’s view, despite its worthy aims, NIH’s fair pricing clause had little impact on drug pricing. Instead, it seemed to make companies reluctant to cooperate with government labs, or at least to sign agreements with them. Which would be preferable, he must have asked, a high-minded pricing policy that resulted in little or no collaboration with the government, or more collaboration without the fair pricing policy? Ever the pragmatist, in 1995, Varmus decided to eliminate the fair pricing clause from NIH’s standard research agreement, reasoning that this would better “promote research that can enhance the health of the American people.”²⁷

Despite the failure of contractual price control mechanisms in the United States, these mechanisms have achieved some success with respect to drug pricing in the developing world. Thus, university license agreements for biomedical discoveries may include provisions requiring that the licensee, if it sells products in less developed countries, charge prices lower than those it charges in the developed world. Some licenses, such as those promulgated by the Medicines Patent Pool (see [Section 6.2.3](#)), are focused entirely on less developed countries, and are thus entirely price constrained.

²⁵ Even in the context of technical standards, well-known FRAND (fair, reasonable and nondiscriminatory) pricing requirements apply to patent *licenses* by SDO participants, not *product* sales by their licensees.

²⁶ Compared to today’s astronomical prices for the latest gene therapy treatments, some of which can exceed \$2 million, the \$8,000 price tag for AZT seems quaint. Yet, at the time, the *New York Times* called AZT “the most expensive prescription drug in history” (“AZT’s Inhuman Cost,” *NY Times*, August 28, 1989).

²⁷ Jorge L. Contreras, *Association for Molecular Pathology v. Myriad Genetics: A Critical Reassessment*, 27 Mich. Tech. L. Rev.1 (2020) (most citations omitted).

Outside of the developing world, attempts to constrain pricing of end products have been less successful, though some efforts have been made. For example, in the context of IP relevant to COVID-19, twenty-two universities and other research institutions around the world have committed to granting royalty-free licenses for technologies that may help to prevent, diagnose or treat COVID-19 under a “COVID-19 Technology Access Framework.”²⁸ As part of the Framework, the universities expect their licensees “to distribute the resulting products as widely as possible and at a low cost that allows broad accessibility.” It remains to be seen whether and to what extent licenses are granted under the Framework and with what effect.

UNIVERSITY SPINOUTS

In many cases the most promising industrial licensee of a university invention is an established enterprise that is actively pursuing the development of products in a related field. Sometimes, however, established industrial partners may not exist, particularly when technologies are in new and emerging fields. In these cases, university researchers, backed by external funders, may form start-up companies to commercialize the discoveries generated by their labs. These companies are referred to as university “spinouts.” According to the AUTM, 1,080 university spinouts were formed in 2018, and were the recipients of approximately 15 percent of university technology licenses granted.²⁹

In addition to licenses of university IP, spinouts often make use of university-owned facilities and equipment, as well as the services of academics, technicians and graduate students. Several universities have established incubators, shared laboratory spaces and entrepreneurship labs to encourage the formation of spinout companies by faculty, staff and students.

University spinouts have attracted significant public attention in recent years, due to both the success of a handful of these ventures and the potential conflicts of interest that plague academic investigators who actively participate in corporate research. Notable university spinouts over the years have included Bose (MIT), Digital Equipment Corporation (MIT), Google (Stanford), Myriad Genetics (U. Utah), Netscape Communications (U. Illinois), Oxford Instruments (Oxford) and RSA Data Security (MIT).

Notes and Questions

1. *Surrogate licensing.* Despite the Nine Points cautionary language concerning exclusive licensing, some universities have recently been criticized for granting exclusive licenses with extremely broad fields of use to their own spinout companies. When a university effectively grants the entire set of rights with respect to an IP portfolio to a single company, Professor Jacob Sherkow and I refer to that company as a “surrogate” because it acts as a stand-in for the university, but without its public mission and charter.

For example, the academic institutions holding the foundational patents to the CRISPR gene editing technology (University of California Berkeley and the Broad Institute, a joint venture of Harvard and MIT) each granted to a single surrogate company broad exclusive

²⁸ See <https://tlo.mit.edu/engage-tlo/covid-19/covid-19-technology-access-framework>.

²⁹ See AUTM US Licensing Activity Survey: 2018.

licenses to use CRISPR in all fields of human therapeutics across all 20,000+ human genes. This broad exclusivity, we point out, could result in serious research bottlenecks:

Because no single company could develop, test, and market therapeutics on the basis of even a fraction of the entire human genome ... it is ... unlikely that any of the surrogate companies could explore a significant fraction of the potential human health applications that CRISPR could enable, even with a range of experienced commercial partners and collaborators. If an unlicensed company has the expertise and wherewithal to develop a novel human therapy using CRISPR—even if that therapy concerns a previously unexplored gene—that company might not be able to obtain the sublicense necessary to undertake this work.³⁰

Why do universities engage in surrogate licensing? Does this practice subvert the public missions of these institutions? What can be done to limit the impact of this practice on research and discovery?

2. *Improvements.* We discussed a licensee's improvements to a licensor's technology in [Section 9.1](#). Why does the Nine Points document suggest that universities not include improvement patents in the scope of exclusive licenses? Why might a licensee feel differently? The Nine Points document (p. 4) suggests that if improvements are included within the scope of an exclusive license, they should be limited to "inventions that are dominated by the original licensed patents, as these could not be meaningfully licensed to a third party, at least within the first licensee's exclusive field." How would this limitation address potential concerns about hold-up?
3. *Ethical licensing and field restrictions.* Some academic institutions have begun to focus on constraining the activities of their licensees based on ethical principles beyond pricing and access to medicines. For example, in the area of CRISPR gene editing, the Broad Institute has limited several of its patent licenses to industrial partners on ethical grounds. In its license of CRISPR technology to Monsanto for agricultural applications, Broad is reported to have prohibited Monsanto from: "(i) performing gene drives that spread altered genes quickly through populations, which can alter ecosystems; (ii) creating sterile 'terminator' seeds, which would impose a serious financial burden on farmers who would be forced to buy them each year; and (iii) conducting research directed to the commercialization of tobacco products, which might increase the public health burden of smoking."³¹ Likewise, in its license of CRISPR technology to Editas Medicines, Broad's surrogate company, Broad excludes the right "to modify human germ cells or embryos for any purpose or to modify animal cells for the creation or commercialization of organs suitable for transplantation into humans." Restrictions like these generally take the form of exclusions from the licensee's permitted field of use (FOU), rather than contractual covenants such as fair pricing requirements. Why might a licensor wish to use FOU restrictions rather than contractual covenants under these circumstances? Would there be a benefit to using both FOU restrictions and covenants?
4. *Other terms of university licensing agreements.* While the contractual issues and terms discussed in this part of the book are among the most controversial ones raised in the area of academic technology transfer, it is worth remembering that academic licensing agreements contain many other terms as well—mostly along the lines discussed in [Part II](#). The licensing attorney, however, should be aware of some prevalent norms in university licensing agreements. For example, technology licensed under university licenses is almost always provided

³⁰ Jorge L. Contreras & Jacob S. Sherkow, *CRISPR, Surrogate Licensing, and Scientific Discovery*, 355 *Science* 698, 699 (2017).

³¹ Christi J. Guerrini, et al., *The Rise of the Ethical License*, 35 *Nature Biotech.* 22, 23 (2017).



FIGURE 14.5 Tobacco plants have been genetically modified to grow larger, faster and more efficiently. The Broad Institute prohibits licensees of its CRISPR gene editing technology from using it in connection with commercialization of the tobacco plant.

as is, without warranties of any kind (except, in some cases, as to ownership). A university will almost never indemnify a licensee. Sublicensing generally requires the consent of the university. Progress reports and milestones will usually be required. The governing law and forum of the agreement are almost always those of the university's home jurisdiction. If challenged, university attorneys will often argue that these terms are nonnegotiable, either due to strict university policy, state law, the Bayh–Dole Act or some combination of these factors. This positioning can sometimes be frustrating, but it is a reality that must be faced when dealing with academic institutions.

5. *Impact of the Nine Points.* One recent study of university licensing agreements executed before and after the Nine Points document reveals that the document had very little impact on actual university licensing practices, and that universities continued to use essentially the same licensing documents both before and after signing the Nine Points document.³² What do you think these findings suggest about university technology transfer?

14.4 SPONSORED RESEARCH: DOLLARS AND OPTIONS

Under the traditional – some would say idealized – model of academic research, researchers select projects to pursue based on some combination of intellectual curiosity, unanswered questions in the field, and the scientific impact of their discoveries. Oftentimes, this research is funded by grants from the federal and state government, as well as private foundations. However, it is largely directed by researchers themselves.

In reality, much research that is conducted on the campuses of modern academic institutions is driven by corporate programs that use universities as outsourced R&D contractors. As Cynthia Cannady explains,

In the United States, research institutions rely increasingly on private research sponsorships, as a number of factors coincide: constraints on public funding, ambitious research agendas and university development, and physical plant expansion. Even with massive public funding of

³² See Jorge L. Contreras and Jessica Maupin, “*In the Public Interest*”: University Technology Transfer and the Nine Points Document – An Empirical Assessment 13 U. Cal. Irvine L. Rev. (2023).

research in the United States, there is a financial codependency between research institutions and private sponsors that increases reliance on the sponsored research model of contract.³³

Sponsored research arrangements are effectively service contracts under which a company pays an academic institution to perform specified research activities and report the results back to the company. The services are almost always led by a particular senior investigator. If the company is a university spinout, the investigator will often have an additional consulting or founding role at the company.

University sponsored research agreements resemble many of the other technology development and service agreements discussed elsewhere in this volume. One significant difference, however, relates to IP ownership. As discussed in [Section 9.2](#), it is typical that when one company (the client) engages a second company (the developer) to conduct R&D, the results of that R&D are owned by the client, not the developer. A university sponsored research agreement is usually different. Whether because of the Bayh–Dole Act or simply because the outcome of basic research is difficult to predict, the company sponsoring research at a university typically does not automatically obtain ownership of the resulting IP.

If the company is a university spinout that already has an exclusive license covering a particular university lab's output, then the IP generated by the sponsored research arrangement will often fall under that existing agreement. Myriad Genetics offers a good illustration of this principle.

THE MYRIAD STORY: PRELUDE TO DISCOVERY

Myriad Genetics was formed in 1991 by Dr. Mark Skolnick, a genetic epidemiologist at the University of Utah, and Peter Meldrum, a local investor. The company's goal was to locate the *BRCA1* gene that was suspected to have a high correlation with certain cases of breast cancer, and then to develop, patent and commercialize a diagnostic test for the gene.

The first thing that the new company did was enter into an exclusive license agreement with the university. Under the agreement, Myriad obtained exclusive rights to any discoveries made by Skolnick's academic lab in the area of breast cancer genetics. Whatever the lab discovered concerning *BRCA1* – or any other breast cancer gene – would be patented by the university, as required by the Bayh–Dole Act. But, practically (and legally) speaking, a university couldn't develop a commercial testing service and offer it to the public. That could only be done by a company, and, in this case, the company would be Myriad. It didn't matter that Skolnick hadn't discovered anything yet, or that his lab hadn't even begun to look for *BRCA1*. The company would simply acquire all future rights to the gene whenever it was discovered.

In exchange for this license, Myriad agreed to pay the university \$250,000 to fund the lab's research, cover all of the university's patenting expenses, pay the university a 1 percent royalty on the company's future *BRCA1* testing revenue and grant the university a 2 percent ownership stake in the company.

Researchers from Myriad, the university and other collaborators isolated and patented the *BRCA1* gene in 1994. Over the lifetime of the *BRCA* patents, which were cut short by a Supreme Court ruling in 2013, Myriad paid the university approximately \$40 million.³⁴

³³ Cynthia Cannady, *Technology Licensing and Development Agreements* 355–56 (Oxford Univ. Press, 2013).

³⁴ For a detailed account of Myriad genetics and its dealings with the University of Utah, see Jorge L. Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA* (Algonquin Books, 2021).

If, however, research at a university is sponsored by an established company without an existing license to the university's technology, then the company may receive an *option* to obtain a license to the results of that research. An example option clause is given here.

EXAMPLE: SPONSORED RESEARCH AGREEMENT

Option Clause

- a) In consideration of Sponsor's funding of the Research Program, Institution hereby grants to Sponsor, and Sponsor accepts, an option to obtain a license to all or any portion of the developed IPR (the "Option"). Sponsor shall have sixty (60) days from the receipt of Institution's notice that it has filed a patent application covering any developed IPR to provide Institution with written notice of its election to exercise the Option with respect to such IPR. Sponsor's failure to so notify Institution within this time period shall be deemed to be an election by Sponsor not to secure a license to such IPR, in which case Institution shall have the unrestricted right to license such IPR to third parties.
- b) Should Sponsor elect to exercise its Option for any IPR, the parties agree promptly to commence negotiations, in good faith, of an exclusive License Agreement to be entered into no later than three (3) months after the date of the exercise of the Option. Such License Agreement shall take into consideration the relative contributions of both parties, including the support provided by Sponsor to the Research Program and shall include at least the following provisions:
 - i. the exclusive license to Sponsor of the right to exploit the IPR in [all fields] for the duration of such IPR;
 - ii. an up-front license fee,
 - iii. ongoing royalty payments,
 - iv. reimbursement by Sponsor of past, present, and future Patent Costs,
 - v. the right to grant sublicenses,
 - vi. a summary of a commercial development plan for the IPR,
 - vii. the right of Institution to terminate the license should Sponsor not meet specified milestones, and
 - viii. indemnity and insurance provisions satisfactory to Institution's insurance carrier.

If the parties do not execute a License Agreement by such date, Institution shall be free to offer the IPR for licensing to third parties, but for a period of one (1) year after failure to reach an agreement Institution shall not license the subject IPR to any third party on terms more favorable than those last offered to Sponsor without first offering such terms to Sponsor.

- c) If Sponsor elects not to exercise its Option for any IPR pursuant to Paragraph (a), Sponsor shall have no further rights to such IPR. Notwithstanding the foregoing, Sponsor's failure to exercise the Option with respect to any particular IPR shall not limit Sponsor's rights with respect to any other IPR developed hereunder.

Notes and Questions

1. *Myriad – sponsored research, version 2.* As noted above, Myriad Genetics sponsored breast cancer genetic research conducted in Mark Skolnick's lab at the University of Utah. But Myriad was also the *recipient* of sponsored research funding, in much larger amounts, from pharmaceutical firms. Its first research sponsor was pharmaceutical giant Eli Lilly, developer of the blockbuster antidepressant Prozac. Like many large drug companies, Lilly had become interested in genetics during the 1980s. It believed that Myriad's foray into breast cancer genetics offered a promising opportunity to explore potential gene-based therapeutics. In 1992 (still two years before the *BRCA1* gene was located) Lilly entered into a sponsored research agreement with Myriad. Lilly agreed to pay Myriad \$1.8 million over three years, invest another \$1 million in Myriad's stock and pay Myriad a royalty of 4 percent on sales of any *BRCA1*-based drugs that Lilly developed. In exchange, Myriad granted Lilly exclusive rights to any *BRCA1*-related discoveries made by Myriad or the university, but solely in the field of breast cancer therapeutics. Myriad thus reserved for itself the sole right to exploit *BRCA1* in the diagnostics market (it sold a third company the right to make test kits – a business that never materialized).
Why did Myriad find it advantageous to split the field into three different subfields? Why didn't the University of Utah, which owned several of the underlying patents, limit Myriad's original license to the diagnostics subfield? In other words, why did the university allow Myriad to control the therapeutic and test kit fields when Myriad had no intention of entering those markets?
2. *Sponsored research variants.* Why do sponsored research agreements look so different depending on whether the sponsor is a university spinout company versus an established company?
3. *Options and incomplete agreements.* The sample option clause shown above commits the parties to negotiate a license agreement, but only outlines a few terms of the license agreement in advance. Why aren't these terms specified in greater detail? Better still, why don't the parties attach a complete license agreement to the option, which could be exercised simply by signing the license agreement and tendering the first payment?

14.5 MATERIAL TRANSFER

Often, scientific research involves the use of unique or novel materials – cell lines, DNA, tissue samples, model organisms, plant specimens, fossilized remains, geologic core and soil samples, lunar minerals, historic artifacts, new polymers, alloys, fibers, chemical compounds and the like. In order to access such materials, researchers must either come to the place where they are stored, or request a sample for use in their own laboratory. If materials are not overly fragile or unique, many researchers are willing to send samples for others to use, but only under certain conditions. Those conditions are often set out in material transfer agreements (MTAs).

These MTAs vary in length and complexity, depending on the type of material in question. Soil samples taken from a large contaminated field might be supplied under relatively minimal terms and conditions, whereas DNA from living human subjects would usually be subject to much more stringent restrictions. The complexity of MTAs also depends on the parties involved. Generally, MTAs between academic institutions are relatively lightweight, but complications can arise when materials come from the private sector. As one National Academies report notes, "private companies often make demands that researchers—or their technology

licensing offices—balk at. A company might, for instance, ask researchers to hold off in publishing their results to give it a head start in applying the results. Or it might insist on rights to an exclusive license on any invention or discovery made using its materials.”³⁵ Do you understand why a university might find provisions like these to be objectionable?

As noted by Dr. Tania Bubela and colleagues, “Researchers commonly express frustration with institutional processes. Surveys and interview-based studies of researchers have come to the conclusion that access to research reagents is hampered by negotiations over MTAs, whose complexity rarely reflects the value to the institution of the materials to be shared.”³⁶

One way to simplify the MTA process is to use a standardized set of MTAs. The NIH was among the first institutions to regularize the use of MTAs in 1995. As Bubela et al. explain:

These policies were, in part, a response to restrictions over access to two transgenic mouse technologies: OncoMouse, a mouse strain with a genetic predisposition to cancer, developed by researchers at Harvard and exclusively licensed by DuPont; and Cre-lox, a technology for generating conditional mouse mutants, developed by DuPont researchers. In both cases, the NIH stepped in to negotiate access and distribution on less restrictive terms than the original MTAs proposed by DuPont.³⁷

Below are excerpts from two of NIH’s standard MTAs, one for general purposes, and one geared toward biological materials. As you read these two documents, consider how they differ and why.

SIMPLE LETTER AGREEMENT (SLA) FOR THE TRANSFER OF MATERIALS

In response to Recipient’s request for the Material, the Provider asks that the Recipient and the Recipient Scientist agree to the following before the Recipient receives the Material:

1. The above Material is the property of the Provider and is made available as a service to the research community.
2. This Material Is Not for Use in Human Subjects.
3. The Material will be used for teaching or not-for-profit research purposes only.
4. The Material will not be further distributed to others without the Provider’s written consent. The Recipient shall refer any request for the Material to the Provider. To the extent supplies are available, the Provider or the Provider Scientist agree to make the Material available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.
5. The Recipient agrees to acknowledge the source of the Material in any publications reporting use of it.
6. Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED

³⁵ National Research Council, *Finding the Path: Issues of Access to Research Resources* 6 (Nat’l Acad. Press, 1999).

³⁶ Tania Bubela, Jenilee Guebert & Amrita Mishra, *Use and Misuse of Material Transfer Agreements: Lessons in Proportionality from Research, Repositories, and Litigation*, 13 PLOS Biology e1002060 at 2 (2015).

³⁷ *Id.* at 3.

WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.

7. The Recipient agrees to use the Material in compliance with all applicable statutes and regulations.
8. The Material is provided at no cost, or with an optional transmittal fee solely to reimburse the Provider for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____.

THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT (UBMTA)

MARCH 8, 1995

1. The Provider retains ownership of the Material, including any Material contained or incorporated in Modifications.
2. The Recipient retains ownership of: (a) Modifications (except that, the Provider retains ownership rights to the Material included therein), and (b) those substances created through the use of the Material or Modifications, but which are not Progeny,³⁸ Unmodified Derivatives or Modifications (i.e., do not contain the original Material, Progeny, Unmodified Derivatives). If either 2(a) or 2(b) results from the collaborative efforts of the Provider and the Recipient, joint ownership may be negotiated.
3. The Recipient and the Recipient Scientist agree that the Material:
 - a) is to be used solely for teaching and academic research purposes;
 - b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider;
 - c) is to be used only at the Recipient organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision; and
 - d) will not be transferred to anyone else within the Recipient organization without the prior written consent of the Provider.
4. The Recipient and the Recipient Scientist agree to refer to the Provider any request for the Material from anyone other than those persons working under the Recipient Scientist's direct supervision. To the extent supplies are available, the Provider or the Provider Scientist agrees to make the Material available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this

³⁸ "Progeny" means unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism.

- Agreement, to other scientists (at least those at Nonprofit Organization(s)) who wish to replicate the Recipient Scientist's research; provided that such other scientists reimburse the Provider for any costs relating to the preparation and distribution of the Material.
5. a) The Recipient and/or the Recipient Scientist shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Original Material only if those substances are not Progeny, Unmodified Derivatives, or Modifications.
 - b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the Provider's rights), the Recipient may distribute Modifications to Nonprofit Organization(s) for research and teaching purposes only.
 - c) Without written consent from the Provider, the Recipient and/or the Recipient Scientist may NOT provide Modifications for Commercial Purposes.³⁹ It is recognized by the Recipient that such Commercial Purposes may require a commercial license from the Provider and the Provider has no obligation to grant a commercial license to its ownership interest in the Material incorporated in the Modifications. Nothing in this paragraph, however, shall prevent the Recipient from granting commercial licenses under the Recipient's intellectual property rights claiming such Modifications, or methods of their manufacture or their use.
 6. The Recipient acknowledges that the Material is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the Material made by the Provider. In particular, no express or implied licenses or other rights are provided to use the Material, Modifications, or any related patents of the Provider for Commercial Purposes.
 7. If the Recipient desires to use or license the Material or Modifications for Commercial Purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with the Provider to establish the terms of a commercial license. It is understood by the Recipient that the Provider shall have no obligation to grant such a license to the Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the Material to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.
 8. The Recipient is free to file patent application(s) claiming inventions made by the Recipient through the use of the Material but agrees to notify the Provider upon filing a patent application claiming Modifications or method(s) of manufacture or use(s) of the Material.
 9. Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO

³⁹ "Commercial Purposes" means the sale, lease, license, or other transfer of the Material or Modifications to a for-profit organization. Commercial Purposes shall also include uses of the Material or Modifications by any organization, including Recipient, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the Material or Modifications for Commercial Purposes *per se*, unless any of the above conditions of this definition are met.

REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.
11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the Material or the Modifications. The Recipient Scientist agrees to provide appropriate acknowledgement of the source of the Material in all publications.
12. The Recipient agrees to use the Material in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.
13. This Agreement will terminate on the earliest of the following dates: (a) when the Material becomes generally available from third parties, for example, through reagent catalogs or public depositories or (b) on completion of the Recipient's current research with the Material, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:
 - i. if termination should occur under 13(a), the Recipient shall be bound to the Provider by the least restrictive terms applicable to the Material obtained from the then-available sources; and
 - ii. if termination should occur under 13(b) or (d) above, the Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications; and
 - iii. in the event the Provider terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the Provider will defer the effective date of termination for a period of up to one year, upon request from the Recipient, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications.
14. The Material is provided at no cost, or with an optional transmittal fee solely to reimburse the Provider for its preparation and distribution costs. If a fee is requested by the Provider, the amount will be indicated in an implementing letter.

Notes and Questions

1. *Onward distribution.* Both the NIH SLA and UBMTA prohibit the onward transfer of materials by the recipient. Why? What risks may be inherent in a researcher providing such materials to a third party?
2. *Noncommercial research.* Both the NIH SLA and UBMTA require that materials be used for “teaching or not-for-profit research purposes only.” What is the reason for this restriction? Some academic researchers have criticized this restriction. Why?
3. *No liability.* Both the NIH SLA and UBMTA release the provider from all liability for the materials. Why? What if the materials are more dangerous than expected (e.g., infectious, toxic, combustible or inflammable) and cause damage, injury or death at the recipient’s facility?
4. *Ownership.* Both the NIH SLA and UBMTA allow the recipient to own and file for patent protection of any modifications made to the materials or results achieved using the materials. But this approach is not universally followed. Some MTAs give the provider of materials rights not only to modifications of the materials, but to anything developed using the materials (so-called “reach-through” rights [see Section 8.2.3, Note 3]). Thus, if a new drug is discovered using a reagent or cell line provided to the discoverer under such an MTA, ownership of that drug could be challenged. What is the best approach to the ownership of discoveries made using someone else’s materials, that of the NIH or “reach-through” rights?
5. *Human samples.* Bubela et al. describe the additional difficulties that are presented when materials involve human samples or data:

Informed consent given by research participants determines the use of their samples; for example, limiting research to a specific disease. Thus, if each sample in a biobank is collected using a different consent form, the samples may be deposited on different terms. Those terms must then attach to the sample and, in turn, dictate the distribution terms. This adds a layer of complexity to the transactions managed by biobanks, requires significant informatics resources, and may impede the ability of biobanks to accept legacy materials and data from the research community. Additional constraints arise for associated data that may link to patient records or other identifiable information. In this case, MTAs must comply with national or regional privacy laws in setting conditions for storage and use of samples and associated data.⁴⁰

How does the UBMTA address these issues? Should it do more?

14.6 UNIVERSITIES AND COPYRIGHT

While much of the focus of university technology transfer is on patents, university personnel develop a broad range of IP beyond patented inventions. In fact, on a per capita basis, academic faculty produce far more copyrighted works – articles, books, blog posts, teaching materials, software, recordings – than inventions. Yet the Bayh–Dole Act relates only to inventions, and academic faculty generally assume that copyrighted works, even if supported by government funding, are owned by themselves rather than by their employers.

The truth is not quite so simple. As shown by Professor Shubha Ghosh, universities differ in their treatment of copyrighted material.⁴¹ Under many university policies, computer software is treated as “technology” and subjected to the same rules as patentable inventions. University

⁴⁰ Bubela et al., *supra* note 32, at 5–6.

⁴¹ Shubha Ghosh, Bayh–Dole Beyond Patents in Research Handbook on Intellectual Property and Technology Transfer 69, 71–80 (Jacob H. Rooksby, ed., Edward Elgar, 2020).

TTOs routinely seek to license and commercialize software developed within university labs. According to one 2011 study, software accounted for about 10 percent of both licensing activity and invention disclosures at US research universities.⁴² This being said, an increasing number of university researchers are releasing software on an open source basis.⁴³

The treatment of other forms of copyrighted works is less clear. Most universities appear to allow individual faculty members to retain copyright in traditional scholarly, creative and pedagogical works such as books, articles and artistic creations. An exception sometimes occurs, however, when those works are developed at the behest of the university or under a sponsored research grant. Thus, the university may claim ownership of the copyright in an online course or website that a professor develops if the university wishes to utilize it after the professor retires or departs for another university. An example of a detailed university policy governing copyrights and other forms of IP follows.

UNIVERSITY OF UTAH: POLICY 7-003: OWNERSHIP OF COPYRIGHTABLE WORKS AND RELATED WORKS

I. Purpose and Scope

A. Purpose

The Purpose of this Policy on ownership of copyrightable Works is to outline the respective rights that all members of the University community – faculty, students and staff – have in such Works created during the course of affiliation with the University. This Policy preserves the practice of allowing faculty to own the copyrights to traditional scholarly works, and at the same time seeks to protect the interests of the university in works that are created with the substantial use of university resources (see [section III](#)).

E. Types of Works Covered by this Policy

The following is a list of the types of Works that are covered by this Policy. This list is intended to be illustrative rather than definitive: literary Works, musical Works including accompanying words, dramatic Works including accompanying music, pantomimes and choreographic Works, pictorial, graphic, and sculptural Works, motion pictures and audiovisual Works, sound recordings, multi-media Works, computer programs and documentation, electronic course materials and software used in on-line courses and in the classroom, architectural Works, other Works of authorship, as defined in the U.S. Copyright Act, fixed in a tangible medium of expression, semiconductor mask Works, databases.

II. General Rules of Ownership

A. University Staff and Student-Employees

Works created by University staff and student-employees within the scope of their University employment are considered to be works made for hire, and thus are Works as to which the

⁴² Nat'l Res. Council, *Managing University Intellectual Property in the Public Interest 20* (Stephen A. Merrill and Anne-Marie Mazza, eds., Nat'l Res. Council, 2011).

⁴³ See Daniel Katz, *Open Source Software and University Intellectual Property Policies*, March 4, 2015, <https://danielskatzblog.wordpress.com/2015/03/04/open-source-software-and-university-intellectual-property-policies-2>.

University is the Owner and controls all legal rights in the Work. In contrast, Works created by University staff and student-employees outside the scope of their University employment are not covered by this Policy and are considered to be owned by the Creators, unless such Works are created through “substantial use of University resources” (as described in [Section III](#) of this Policy).

B. Faculty

The principal mission of the University is the creation and dissemination of knowledge. Therefore, the University transfers to the Creators any copyrights that it may own in a traditional scholarly Work created by University faculty members that result from teaching, research, scholarly or artistic endeavors, regardless of the medium in which the Work is expressed, unless the Work was developed with substantial use of university resources and commercial use is made of the Work. If the Creator intends to make commercial use of the Work, then disclosure must be made as required under [section IV.A](#).

C. Students

Notwithstanding [Section III](#) ... students are the Owners of the copyright of Works for which academic credit is received, including theses, dissertations, scholarly publications, texts, pedagogical materials or other materials.

D. Independent Contractors

Any Work created by an independent contractor for the University shall be the subject of a written agreement whereby the contractor may be required to assign all rights in the Work to the University and to acknowledge that such Work constitutes work made for hire, if appropriate.

E. Assignment or Release

The University may, at its sole discretion, determine whether to assign or release to a Creator of a Work any ownership rights of the University in such Work upon such conditions as the University deems beneficial and fair to all parties. Any such release of rights must be in writing and approved by the appropriate dean or equivalent supervisor of the Creator, in consultation with the Technology Transfer Office, and by the cognizant vice president or similar administrator.

III. Substantial Use of University Resources

The following provisions provide guidance in determining whether or not the creation of a Work involved the “substantial use of University resources.”

A. Categories of Substantial Use

“*Substantial use of University resources*” in the creation of a Work, resulting in the University being the Owner of the Work, includes, but is not limited to the following situations:

1. The University and the Creator-employee (whether faculty, staff or student) agree to create the Work, in whole or in part, as part of a specific grant, contract, appointment or assignment, with or without a reduction in other University responsibilities.

The agreement to create the work should include a clear stipulation of the copyright ownership.

2. The Work is produced through the use of University facilities not available to the general public and beyond the level of facilities and services (e.g., office space, libraries, limited secretarial and support staff, ordinary use of computers or other University facilities or equipment) that are customarily used by similarly situated colleagues of the Creator. Such facilities and services the use of which constitutes substantial use include, but are not limited to, laboratories, studios, equipment, production facilities, specialized computing resources, or special expertise of University-employed individuals.
3. The University provides significant University funding in direct support of the Work's creation. However, regular sabbatical and administrative leaves shall not count as a factor in determining substantial use.
4. The Work is significantly based upon material that is proprietary to the University, regardless of whether the Creator produced such proprietary information.
5. The Work is produced under the specific terms of a sponsored research grant or contract administered by the Office of Sponsored Projects.

IV. Commercialization and Revenue

A. Obligation to Disclose and Assign

The Creator shall promptly disclose to the Technology Transfer Office the creation of any Work in which the University has an ownership interest, as provided in [Section II](#) of this Policy. The ... Creator of a Work owned by the University according to the provisions of this Policy shall promptly execute an assignment of all their rights to the University when requested to do so by the administration. The Creator shall cooperate fully with the University and the Technology Transfer Office in further protection, promotion or dissemination of the Work.

B. Revenue Sharing

1. The Creator of a Work that is owned by the University, other than a Creator of a work made for hire, shall receive a share of any royalty income or other revenue realized by the University as Owner, from the sale, licensing or other commercialization of the Work. The Creator of a Work made for hire may receive a share of royalty income or other revenue, provided that an appropriate agreement is entered into between the University and the Creator prior to the inception of the Work.
2. The Creator's share of income shall be based on a percentage of such income or revenue remaining after reimbursement of all the University's direct costs of copyright registration, licensing and other legal protection of the Work ("net revenue"). The Creator's share (which, in the case of co-Creators, shall be divided between them equally or as they shall agree in their sole discretion) shall normally be forty percent (40%) of the first twenty thousand dollars (\$20,000) of net revenue, thirty-five percent (35%) of the next twenty thousand dollars (\$20,000) of net revenue, and thirty percent (30%) of any additional net revenue received by the University from the Work.

C. Creators' Rights in University-Owned Works

1. The University will make reasonable efforts to consult with the Creator of a Work with respect to proposed uses to be made of the Work before it is licensed or sold to a third party. When disputes over use occur, the matter shall be referred to the cognizant vice president or similar administrator for resolution, in consultation with the Vice President for Research.
2. University-owned Works that have not been licensed or sold shall not be altered or revised without making reasonable efforts to provide the Creators an opportunity to assume the responsibility for the revision. If the Creators decline the opportunity to revise such material, the University shall assign responsibility for the revision in consultation with the appropriate department.
3. The Creator may request that University-owned Works that have not been licensed or sold be withdrawn from use when the Creator or the relevant department deems such use obsolete or inappropriate. The cognizant vice president or similar administrator shall decide disputes over the withdrawal of Works.

Notes and Questions

1. *Employment status.* In the sample policy excerpted above, why are staff, faculty, students and contractors treated differently? Do you think that different categories of employees are treated differently under the IP policies of most private companies?
2. *Categories of works.* Does it make sense under this policy to treat such a broad range of works – books, articles, art works, software, semiconductor mask layouts, databases – in the same manner? Would it be preferable to tailor the policy more specifically to each different category of work, or is there a benefit to a more uniform treatment?
3. *Adjudication.* In the policy above, most discretionary questions are left to the judgment of the university TTO. Is this appropriate? Why doesn't the policy leave such judgment questions to individual faculty members, or a committee of the faculty governing body? Are there advantages to giving this discretion to the TTO?
4. *Revenue sharing.* Why do university employees automatically receive a share of university revenue from their works that are owned by the university, but not from works made for hire? What practical reasons might exist for this distinction?
5. *Rights of authors.* Why does [section IV.C](#) give authors any rights with respect to works owned by the university? Do you think that the rights granted are too generous or not generous enough to authors?
6. *Continuing uncertainty.* Not all universities have always had detailed copyright policies. Consider the dispute between Columbia University and the estate of one of its former faculty members, Persian scholar Ehsan Yarshater, who died in 2018.⁴⁴ Yarshater founded Columbia's Center for Iranian Studies in the late 1960s. In 1973, he began to assemble the *Encyclopaedia Iranica*, a comprehensive reference work dedicated to the study of Iranian civilization. Today, the *Encyclopaedia* includes dozens of volumes with contributions from

⁴⁴ See Kyle Jahner, *Columbia Spat Tests Question of When Professors Own Their Work*, Bloomberg Law, November 5, 2019 (edited by the author).

more than 1,300 scholars. The Encyclopaedia Iranica Foundation created by Yarshater claims that it began to list itself as the owner of the copyright in the *Encyclopaedia* in 2003. But after Yarshater's death, Columbia claimed that it never authorized the foundation to list itself as the registered copyright owner and did not become aware of this practice until 2017. Columbia also says that it rejected the foundation's request to transfer ownership of the *Encyclopaedia* to it in 2015 under a policy allowing professors to request rights to their noncommercial work.

Could this dispute have been avoided if Columbia had a policy similar to the one excerpted above? If Columbia did have such a policy, how would the dispute over the *Encyclopaedia Iranica* have turned out?

Problem 14.1

Professor Plum, a historian, is on the faculty of Bigg University, which has adopted the copyright policy excerpted above. Over the past ten years Professor Plum has been working on a definitive biography of US president William Henry Harrison. While conducting research for the book, Plum has traveled multiple times to Harrison's birthplace in Virginia, the battlegrounds at Tippecanoe, Indiana, where he earned the nickname "Old Tippecanoe" and various sites in the former Northwest Territory where Harrison served in the government. All of these trips were funded by a grant that Plum received from Bigg University. Much of the background research for the book was performed by a series of five different undergraduate research assistants provided by the History Department at Bigg University. Recently, Professor Plum signed a publishing contract for the biography with Southern University Press, a reputable academic publisher, which paid him an advance of \$10,000. Then, to Professor Plum's surprise, he received a call from a New York literary agent, who informed him that a famous Broadway producer wished to option the book for a new musical production. What obligations, if any, does Professor Plum have with respect to Bigg University?