

REPAIRING THE BAYH-DOLE ACT: A PROPOSAL FOR RESTORING NON-PROFIT ACCESS TO UNIVERSITY SCIENCE

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The Wide Scope of Federal Research Spending

The United States government invests billions of dollars every year in scientific research. Government agencies such as the Department of Energy, NASA and the Pentagon directly employ legions of scientists and engineers. The National Institutes of Health (NIH) funds a tremendous amount of biomedical research. Besides running its own labs, the NIH gives generous grants to hundreds of universities and medical schools, and to the thousands of research professors who fill them. The federal government today provides about 60% of the total research funding for America's many prestigious research universities.¹ In addition, the government pays private, for-profit contractors vast amounts of money to complete science-intensive projects on its behalf.

Though some government-funded research is theoretical "science for science's sake," even this "basic research" often leads directly or indirectly to practical developments. Research at American universities has facilitated products ranging from Gatorade to synthetic insulin.² The fact that 71.6% of citations to papers in U.S. biotechnology patents are to government-funded research³ demonstrates the practical value of government research to the private sector.

The Bad Old Days? Government Science Before Bayh-Dole

Before 1980, most inventions made with government funding were never patented.⁴ The U.S. government generally held title to those few inventions that were actually patented, whether created at federal labs or in academia.⁵ Non-exclusive licenses were usually available at a reasonable rate, though these were never very popular.⁶

This system had at least one major advantage: it greatly enriched the "public domain" of science. Government and university science was freely available to all scientists, both non-profit and corporate. This large "scientific commons" meshed particularly well with the idealistic practices and attitudes common among academic researchers. Academic and other non-profit scientists traditionally shared data and discoveries freely among themselves (excepting perhaps direct competitors),⁷ brothers and sisters in their lofty pursuit of the mysteries of nature and the betterment of all mankind.⁸ The private sector was in those days more willing to share information and materials with academics because they valued academia's enrichment of the public domain, particularly in areas that could aid their own commercial research.⁹

Though private contractors before Bayh-Dole could not patent things they discovered under government contracts, they seemed quite willing to accept the lucrative government contracts in any case. Government contracts provide income up-front, so there was no need for the added incentives of eventual patents and licensing revenue.

The old system was also good because public-domain science helps non-profit researchers worldwide: the true "public domain" knows no borders. However, the free flow of information to non-U.S. corporations became a cause for concern in America.

One problem with the pre-1980 system - at least from a U.S. perspective - was that foreign corporations were sometimes cashing-in by developing commercial products based on research funded by American taxpayers.¹⁰ Many people, including politicians, felt that American government science should primarily benefit American companies that would create jobs in the U.S., and provide a greater tax base for the U.S. government.¹¹

At the same time, there was serious concern that the "public domain" system was actually an obstacle to turning government-funded science into commercially available, practical products. To use the classic example, developing, testing, and getting approval for a new pharmaceutical product in the U.S. costs literally hundreds of millions of dollars.¹² If a pharmaceutical company wants to develop a drug based on, say, a new gene target recently discovered in a university lab, it still has massive expenses ahead before it can sell even a single pill.¹³ Worse still, the majority of "candidate" drugs never make it to market at all. If competitors will be free to copy any resulting marketable drug

a company develops, it will usually be impossible to raise, and foolish to provide, that massive initial investment required to go from the newly discovered gene target to an FDA-approved pharmaceutical.¹⁴ If you don't have the exclusive right to use a potential drug target, why not let somebody else invest the money to see if the target actually has therapeutic value? It would often be wiser to sit back and see which public-domain genes or molecules pan out, than to yourself invest in developing public-domain science that may or may not yield something profitable.

Thus, it is widely believed that patents on "upstream" discoveries - such as genes and useful chemical molecules - and the corresponding potential for exclusive licenses, are essential to induce private investment in developing applications for the fruits of "basic" government science. This need is especially strong in the case of biotechnology and pharmaceuticals. As explained by John Golden,

... patent law facilitates innovation not so much by "*spurring*" invention as by "*enabling*" it, by providing small biotechnology firms, which are the heart of the American biotechnology industry, with an immediate product - patents - that they can use to attract investment.¹⁵ (emphasis added)

At this point it is worth stressing that the sort of scientists who work at universities and government labs, especially graduate students, would almost always be happy to pursue their research and "invent" without the extra incentive of possible patents. They invent because they love science, for the benefit of their fellow man, and so they can receive their PhD's, gain tenure, and otherwise advance their research careers.¹⁶ Patent law is simply not what drives their day-to-day work; getting papers accepted by prestigious journals is the surest sign of success.¹⁷ Academic researchers primarily rely on grant money to operate, not licensing revenues. Grants, both government and private, are bestowed and renewed based on what each lab manages to discover and publish, not what it happens to patent.

It is the private-sector science, with a focus on turning a profit from either marketable products or marketable patents, which actually depends on patents. The guarantee of a monopoly on the fruits of research that a patent represents is frequently necessary to raise the private funds that "facilitate" private "invention." This is because without a monopoly, the eventual financial returns (if any) on privately financed inventions will be vastly smaller. Before Bayh-Dole, "upstream" inventions funded by the government were mostly going unpatented. This meant that it was often a good strategy for companies to sit back and "cherry-pick" the public domain science that other companies had shown to be useful. Because nobody wanted to be the first to risk investment in unpatented, "upstream" science when the investment would largely benefit their competitors, some potentially valuable government discoveries were not being used by anybody at all.¹⁸

The Bayh-Dole Act: Rescuing Science from the public Domain?

With the dual goals of facilitating private development of public science and of keeping publicly funded science in American hands, Congress passed two separate pieces of legislation in 1980, the Stevenson-Wydler Act and the Bayh-Dole Act.¹⁹ The Stevenson-Wydler Act required that U.S. federal laboratories actively transfer technology to American private industry.²⁰ The Bayh-Dole Act, which is the focus of this article, allowed the recipients of government grants and contracts to patent any resulting inventions.²¹ Both pieces of legislation were the result of an increasing belief that strong patent rights were good for private industry and would help the U.S. science economy.²²

The preamble of the Bayh-Dole Act sets out Congress's objectives:

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 insure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; [and] to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.²³

As mentioned, the main thrust of the Bayh-Dole Act is that it allows recipients of federal funds, regardless of their for-profit or non-profit status, to patent their inventions. These patentees may then sell or grant exclusive or non-exclusive licenses, though there is a preference for licensing to small businesses, and non-profit entities may need federal permission to fully assign their patent rights.²⁴

Those patenting under Bayh-Dole may only grant exclusive licenses to those agreeing that “any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially within the United States.”²⁵ This requirement can be waived upon a showing that no licensee likely to manufacture the product in America could reasonably be found.²⁶

Bayh-Dole patentees are subject to a federal “march-in” right, which may be exercised if the patentee has not taken reasonable steps towards timely, practical application of the invention - such as licensing it out - or if there are health and safety needs not reasonably being met by the patentee.²⁷ In such a case, the federal funding agency has the discretion to require the patent holder to grant licenses on terms “reasonable under the circumstances.”²⁸ The march-in rights function to assure that inventions are not utterly neglected and that glaring public health needs are met, and do not guarantee that the technology will be available cheaply or consistently to cash-strapped researchers.

The federal agency that funds the patented research retains a “nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention.”²⁹ Though it is not quite clear who has the right to use this non-exclusive license “on behalf of” the government, the privilege definitely does not extend to all government-funded researchers. Neither does the government have the right to routinely grant-out U.S. licenses on its own.

Universities Flex their Scientific Muscle

American universities quickly became avid patentees once Bayh-Dole was in place. In the 1970s, American universities were issued a combined total of about 250 patents each year.³⁰ In 1999 the total was 3,079.³¹ In recent years, between 10% and 20% of all biotechnology-related patents have been issued to universities.³² Universities today feel obligated to obtain patents as a potential source of revenue, whether or not individual professors are themselves interested in intellectual property.³³ Nowadays, “the discoveries that enter the public domain ... are those that slip through the net” of university policy, having been either overlooked or not seen as valuable.³⁴

Though Bayh-Dole was enacted to facilitate private-sector research, and not specifically to enrich research institutions, universities have seen things differently.³⁵ A noticeable and growing minority of schools have made headlines by licensing “star” patents to the private sector,³⁶ particularly to life sciences firms.³⁷ For example, Rockefeller University licensed a mouse obesity gene to Amgen for \$20 million plus future payments totaling several times that amount.³⁸ Florida State has received over \$67 million for its patented method for producing the cancer drug Taxol.³⁹ Technology transfer offices have been held up as an academic equivalent to collegiate football teams, bringing recognition, prestige, and sometimes even profits to their home school.⁴⁰

The Trouble With Bayh-Dole

Universities have been eager to patent, and the private sector has often been happy to license and develop the university patents they consider valuable. So far, so good. The trouble with Bayh-Dole is that it keeps the very best and most promising public-sector discoveries from enriching the “scientific commons” that was long at the heart of non-profit science. Non-profit researchers who want to further develop these discoveries, even if they are not concerned with future profits, may be prevented from doing so when university science is patented. The preamble of Bayh-Dole explains that the statute aims to “promote free competition and enterprise without unduly encumbering future research and discovery.”⁴¹ The second half of this clause has sometimes fallen by the wayside.

As mentioned previously, the government right to have Bayh-Dole patents practiced “on behalf of the United States” does not extend very far, and almost certainly does not include everyone receiving United States funding.⁴² Though the extent of this “government license” has not yet been resolved in the courts, it would seem wise to end this ambiguity and head off litigation by amending the statute to define the government’s rights explicitly.

The federal government retains a “march-in” right to force patent exploitation and licensing when a Bayh-Dole patent holder does not take “effective steps to achieve practical application of the subject invention,”⁴³ or when “necessary to alleviate health or safety needs.”⁴⁴ The march-in rights basically “provide a remedy when the federal agency determines that the public would benefit by forcing the contractor to permit wide use of the technology.”⁴⁵ The march-in rights really only apply when a patent is being utterly neglected, and have nothing to do with guaranteeing university scientists access to interesting technology. What is more, these rights have gone essentially unused.⁴⁶ In theory, it might be possible to broadly define “health and safety needs” to include basic medical

research, and then to have funding agencies to force patentees to give cheap licenses to medical researchers. But this already-unlikely course of action would require substantial administrative procedure,⁴⁷ could arguably amount to a constitutional “taking,” and would certainly spend years in the courts.

Experimental Use is Dead

Anyone with even minimal exposure to patent law has heard of the “experimental use” defense to patent infringement. It seems intuitive that non-profit, basic research is an “experimental use” of a patent in the purest sense of the term. This was long a common and reasonable belief. However, recent case law, most famously *Madey v. Duke University*, has defined “experimental use” so narrowly as to render the defense almost nonexistent.

John Madey was a highly regarded physicist at Stanford University, and obtained sole ownership of two patents on laser technology while working there.⁴⁸ Madey accepted a position directing a sizable “free electron laser lab” (“FEL”) at Duke University, and set up shop in his new home in 1988.⁴⁹ An administrative dispute eventually arose between Madey and Duke, and he was removed as director of the FEL in 1997.⁵⁰ The following year Madey left Duke entirely.⁵¹

Scientists in the FEL lab, quite naturally, continued to use the same equipment after Madey left that they had been using for nearly a decade while Madey was director. Madey still had his patents however, and sued Duke for infringement.⁵² As one would expect, Duke invoked the “experimental use” defense.⁵³ The Court of Appeals of the Federal Circuit issued a truly shocking opinion in October of 2002.⁵⁴ First, the court quoted *Embrex, Inc. v. Service Engineering Corp.*, reiterating that the experimental use defense was very narrow, and only applied to actions “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”⁵⁵ The decision went on to say that ALL of the University’s research, both theoretical and applied, “unmistakably further[s] the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects” and seeking research grants.⁵⁶ The Court of Appeals announced the effective death of “experimental use” with this almost brutal holding:

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.⁵⁷

Thus, it seems that experimental use is left mostly to basement tinkerers, or perhaps to scientists replicating the patentee’s experiments for the sole purpose of confirming accuracy of the original experiments.

To be fair, it is worth considering that in the Bayh-Dole era academia has lost some of its “specialness,” delving deep into the patenting business, at least at the institutional level.⁵⁸ Universities today sometimes look very much like commercial actors, patenting their best research advances and then auctioning them off.⁵⁹ Considered in this light, is it really so strange that the *Duke* court decided to treat a wealthy university just like anyone else engaged in commerce?⁶⁰ It is almost certain that Duke would have patented and licensed anything it invented using Madey’s tools. Is it so wrong that they should reap the whirlwind of their IP mercantilism? With unlimited fair-use rights, universities would be allowed to use - and profit from - everybody else’s patents, and not be obligated to share their own patents freely in return.⁶¹

University mercantilism has also reduced the willingness of the private sector to share with and help academia, at least without first getting a “collaboration” contract giving it a stake in any results.⁶² The pre-Bayh-Dole ethos of public-domain scholarship encouraged corporations to help academics without strings attached. This was partly a form of altruism, and partly because the “charitable” corporation would often be in an ideal position to commercially exploit the recipient’s eventual public-domain results.⁶³

It is the bench-level, non-profit scientist, who has probably surrendered his patenting rights to his home institution, that may now pay a heavy price for the research universities’ embrace of Bayh-Dole.⁶⁴

Upstream Patents Compound the Problem

As mentioned above, there are very good reasons to allow “upstream” patents on genes, chemical molecules and lots of other “inventions” that are not in themselves marketable end-products. For the purposes of this article, the validity

and necessity of these patents will be assumed. But upstream patents pose a special problem for universities now that the “experimental use” exception is apparently unavailable to them. Upstream patents can cover not just commercial product markets, but also sizeable, unexplored areas for future scientific inquiry.⁶⁵ For example, since Myriad Pharmaceuticals owns a patent on the BRCA 1 gene, which has an established link to many breast cancers, medical researchers who want to work on this gene must buy a costly license.⁶⁶ Some investigators have abandoned BRCA 1 entirely because they find Myriad’s terms unacceptable.⁶⁷ In light of *Duke*, academic researchers are in no way excepted from the burdens of purchasing patent rights.

Upstream patents are also very difficult to invent around: a scientist can hardly “invent around” a specific gene that he would like to study. Existing drugs targeted about 400 of the estimated 5,000 “druggable targets” (often corresponding to genes) in the human body⁶⁸ as of 2000. Adding to this the patented drug targets that are not yet marketable drugs, and considering the rapid and accelerating rate of protein and gene patenting, it starts to look like patents could eventually stake out the most “interesting” parts of medical science.

Patented research tools can also be particularly sticky obstacles, an especially frustrating situation when the “tool” is an experimental method involving little or no hardware. Research tools can take years to create. Individual labs can thus hardly be expected to invent non-infringing substitute tools to use in conducting their primary research.

All the world’s experimental biologists should be made to understand the power that Stanford University and the University of California wield. Together, they owned patents⁶⁹ on fundamental recombinant DNA techniques that are quite literally indispensable to all manner of molecular biology, genetics, cell biology and genetic engineering research.⁷⁰ Luckily, the licenses for these methods were priced low enough that both private companies and schools could afford them. This was an unusual positive example, serving to illustrate the leverage that one or two key patents can generate. Scientists have not always been so lucky.

Harvard biologists developed a clever and efficient method of genetically engineering mice (also an essential biomedical tool, and patented under Bayh-Dole), and in 1990 sold an exclusive license to DuPont Pharmaceuticals.⁷¹ This method, the Cre-loxP system, was the best method for engineering mice when it was released, and is still widely used in biomedical research. DuPont soon demanded “reach-through” rights in any and all inventions made with the use of these mice, and demanded the right to pre-screen all publications involving research with the Harvard mice.⁷² It should be understood that this “method” patent could extend to ANY mouse altered with ANY gene, and that literally millions of these mice were already in use. Many researchers had invested years in work involving these mice, and could not realistically back out by this point.

Though usually a peaceful lot, scientists revolted. Nobel Laureate Harold Varmus, acting on behalf the entire NIH, refused to agree to a license under such harsh terms.⁷³ This refusal inconvenienced many NIH labs, but also drew attention to the issue, and publicly embarrassed DuPont. After taking a beating in the press, and absorbing untold venom from the world’s biologists, DuPont relaxed most of its demands.⁷⁴ But the point was again made: research tool patents can have truly extraordinary reach.

What is to be Done?

This is hardly the first article to discuss the shortcomings of the Bayh-Dole Act, and the burdens that patent law can place on non-profit scientists. At this point it is worth considering some of the many interesting proposals that others have made as to how to approach these issues.

Change the Patentability Requirements?

There have been calls from a wide variety of sources to prohibit upstream patents in general, particularly for genes. Many laypeople, often skeptical of and/or unversed in patent law, want to do away entirely with patents on genes and living organisms. Many of these objections are for ethical reasons that are beyond the scope of this paper. It will suffice to point out that a patent monopoly is only 20 years, making the more apocalyptic “corporations-owning-people” predictions doubtful in my mind. For reasons discussed earlier in this paper, I believe that at least some gene patents are necessary to encourage companies to invest the massive sums necessary to go from a gene target to an FDA-approved drug. As applied to Bayh-Dole, a total end to gene patenting⁷⁵ is over-inclusive because it would also prevent private researchers from patenting genetic discoveries, and would probably mean the end of most private research in the area. Prohibiting all gene patents would also be under-inclusive as applied to Bayh-Dole

because it would only expand access to one thing: genes.

In 2001 the U.S. Patent and Trademark Office actually issued new guidelines for granting gene patents that include a heightened “utility” requirement:

An isolated and purified DNA may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not per se unpatentable for lack of utility, and each application must be examined on its own facts.⁷⁶

This seems like a sensible compromise decision, given the increasing ease with which raw DNA can be isolated and sequenced today. There is a strong argument that the progress of “science and the useful arts” will be best advanced if the reward of a patent requires that a “gene discovery” comes packaged with at least one use that is likely to benefit society. Granting a monopoly on a gene lacking any known application could actually hinder the search for a beneficial use. It is better that researchers, public and private, should race to be first to find a potential *use* for a gene, than to let someone patent the “raw” gene and find a use at their leisure.

A Broader Experimental Use Exception?

In the wake of *Madey v. Duke*, the experimental use rule is of no help to most non-profit researchers. The defense could, of course, be resurrected by a federal statute. Experimental use might, for example, be expanded to cover any and all use by non-profit researchers,⁷⁷ or could be limited to “upstream” patents. As mentioned earlier, allowing unfettered academic access to any and all patents seems rather unfair when universities will usually patent the resulting discoveries. An unlimited non-profit exception might also chill the private development of laboratory research tools,⁷⁸ or of any essential product where non-profit scientists are themselves the primary customers. Allowing academia free use of only “upstream” patents begs the question: how will the system actually *define* “upstream” patents, especially when science inevitably takes unforeseeable turns? While an ambiguous rule applying to “upstream” patents could be the best thing that ever happened to IP attorneys, it is probably unwise to create this extra uncertainty, and the litigation that would spring from it.

Allowing more academic “experimental use” may still be a good idea, and is certainly compatible with my proposals.⁷⁹ Still, experimental use would probably remain a vague doctrine that might spread uncertainly. Any statute broadening the experimental use defense should be meticulous in specifying precisely who is covered, and what uses it applies to.⁸⁰

Try Some Copyright Law?

Maureen O’ Rourke has proposed that a “fair use” doctrine be added to patent law by statute, including this four-factor test:

1. The nature of the advance represented by the infringement;
2. The purpose of the infringing use;
3. The nature and the strength of the market failure that prevents a license from being concluded; and
4. The nature of the patented work.⁸¹

This is certainly a very interesting proposal, and could provide ideas for any new experimental use statute that might one day emerge. Such an unorthodox - and unlikely - move would also be compatible with my proposal.⁸² But again, the application of this sort of test is always unpredictable, ensuring universal employment for patent litigators, and confusing law students who would have to learn two different “fair use” tests in introductory IP courses. Like experimental use, fair use would often have to be established in a costly infringement suit when the “use” is already underway. It is far more efficient to clearly establish a scientist’s rights before she begins her project, such as with a license.

A Waiver System?

Rochelle Dreyfus has proposed a system where non-profit researchers can use absolutely any patented technology if they agree to sign a waiver.⁸³ The waiver would require that the non-profit institution promptly publish anything it found, and that it refrain from patenting discoveries made in the course of the “infringing” work.⁸⁴ I have

incorporated much of Dreyfus's idea into my proposal. This plan recognizes the financial differences between public and the private sector science. The waivers also eliminate the incongruity of a university first getting special treatment as a "non-profit", and then patenting their result and selling licenses.⁸⁵ Waivers would provide certainty for researchers who would have an actual government permit, and thus would not have to hope that a court later recognizes their "fair use" or "experimental use" infringement defense.⁸⁶

The trouble with Dreyfuss's proposal is that all discoveries made using the patent waiver enter the public domain.⁸⁷ The actual patent holders will be certainly be unhappy when discoveries based on their patent become forever unpatentable because of work done under a waiver. Clearly, such legislation would encounter heavy industry resistance.⁸⁸ Allowing this university research to go completely unpatented also seems to conflict with Congress's aims under Bayh-Dole. Lastly, the "waiver" plan would require modifying basic patent law (a complication in itself), seriously limiting the "right to exclude" that a patent conveys, and could be a constitutional "taking" if applied retroactively.⁸⁹

Considering Foreign Models

In the UK, the government retains a right to grant compulsory licenses on all patents issued, not just those created using government funds.⁹⁰ Though the licenses may be granted whenever "demand ... for that product is not being met" or if "the establishment or development of commercial activities ... is unfairly prejudiced," they are only granted rarely, to meet urgent health, defense or emergency needs.⁹¹ Licenses to use UK patents are not generally granted to non-profit scientists under normal non-emergency conditions.⁹² Like the Bayh-Dole "march-in" rights, this exception seems only to apply to patents that are being ignored or dangerously underutilized.

Japan only enacted Bayh-Dole-like legislation in 1998. Before this time it was common for professors to quietly pass their inventions off to corporations who would file a patent, with tacit understanding that the corporation would support the inventor's future work.⁹³ Universities were not allowed to file for a patent on their own behalf, and often took so long in deciding whether to let the state or the inventor file the patent that technology either became obsolete, it or entered the public domain due to publishing.⁹⁴ Today Japanese universities have their own technology transfer offices to license employee inventions, and usually have systems where professors receive some financial benefit.⁹⁵ Japan does not seem to have any special program giving academics special access to use patented matter, although it seems that professors, especially those with industry relationships, are not generally pursued for infringement.⁹⁶

My Proposal: A Government Right to Grant Licenses for Bayh-Dole Patents

I am proposing the following modifications to the Bayh-Dole Act, and to the terms under which the U.S. government issues scientific grants:

The federal government will retain a right to *grant* non-exclusive licenses to use any technology that is patented under Bayh-Dole.

- This new government right to grant non-exclusive licenses would be included in the terms of all future funding agreements with grant recipients, and would be added to the Bayh-Dole statute. The right would not apply retroactively to patents that have already been granted.

- These non-exclusive licenses would be available only to non-profit researchers. Non-U.S. researchers are potentially eligible.

- The government will have the final say as to who receives these licenses, but patent holders and the owners of exclusive licenses are invited to object on a case-by-case basis.

- The terms of the government-granted licenses would require the licensee to *cede all patent rights* to discoveries made under the license to the holder of the Bayh-Dole patent or their exclusive licensee.

Academic scientists working under these new licenses would be free to publish their results, but would be required to give the patent owner reasonable warning so that they have the opportunity file preliminary patent applications. The scope of my proposal is admittedly narrow: it only allows non-profit access to future Bayh-Dole patents, and would not increase access to future private discoveries or to past Bayh-Dole patents.⁹⁷

A License is a Better Defense Than a Doctrine

As the *Duke II* opinion⁹⁸ shows, it is unclear what rights the non-exclusive license the government currently retains under Bayh-Dole actually conveys. Allowing the government to actually *grant* non-exclusive licenses avoids any wrangling over what constitutes a “government use,” or over who can use a patent “on behalf of” the government. Researchers would enjoy the certainty of actually holding their own licenses, and would not be left hoping that their use will fit into a judge’s conception of “experimental” or “fair” use in the event of an infringement suit.

Acceptable to Private Enterprise

The central goal of the Bayh-Dole Act was to facilitate the transfer of useful, exclusive technology rights to companies who would turn them into commercial products. Unlike the other proposals I have outlined, my plan should be quite acceptable to private companies, both those that already license or own Bayh-Dole technology, and those that might do so in the future. Corporate acquiescence would be important in getting Congress to enact new legislation, in light of the considerable power wielded by industrial lobbyists. My plan would not affect the rights of parties that already own or license Bayh-Dole technology because it is not retroactive. This approach also avoids stepping on the toes of private corporations whose current right to exclude would be reduced if experimental use were broadened, and who would be prevented from patenting many of their own inventions if upstream patents were categorically restricted.

I am confident that private entrepreneurs will not hesitate to license future Bayh-Dole patents that are subject to the new non-exclusive government licenses because those entrepreneurs would get to patent any inventions made under those licenses. The value of Bayh-Dole patents would not be reduced, and would sometimes actually be increased under such an arrangement. Academics would find new uses for the original patents, and would potentially allow the patent holders to obtain even more patents. Since most patents on genes and other upstream subjects end up being worth little or nothing,⁹⁹ the holders of Bayh-Dole patents would stand to gain quite a bit by having non-profits working to find uses for their technology under government licenses.

Corporations need not worry that government licenses will give their competitors an advantage because the licenses will be strictly limited to non-profit entities. Patent holders also have the right to object when unusual circumstances would make it unfair for the government to grant the license, even given their strict terms.

American Science for American Business?

Congress intended to put the fruits of federally funded research into the hands of U.S. businesses via Bayh-Dole. For better or for worse, any new legislation will have to respect this goal if it is to actually become law. My plan takes no important rights away from U.S. companies. Conversely, making upstream subjects categorically unpatentable would put more federal science in the public domain, and thus in the hands of foreign corporations. In addition, I would make the non-exclusive government licenses available to foreign academics that were willing to assign any patent rights to the (usually American) owners of Bayh-Dole patents.¹⁰⁰

Terms Academics Can Live With

My plan guarantees that future academic discoveries - those that would have entered the “scientific commons” in the days before Bayh-Dole - will always be available to non-profit scientists. In exchange for free access to patented science, academics would agree to *automatically* “transfer” their inventions to the patent holder. It is worth remembering that non-profit scientists receive external funding, and do not rely on licensing revenues or investment capital in the same way many private companies do.¹⁰¹ In a sense, my proposal merely allows academics the option of electing to work under pre-Bayh-Dole conditions, when they would have had free access to non-profit science, but would also have been prevented from seeking their own patents.¹⁰²

My plan guarantees academics the crucial right to publish their work if they cede patent rights to gain a government license.¹⁰³ When this trade is unacceptable, researchers always have the option not to participate in this new scheme, and can seek a license directly from the patent holder as they would today. Many academics will indeed be willing to trade patenting opportunities for access to technology, however, because they are usually more interested in publishing new work than in patenting. University professors, along with their postdoctoral fellows and graduate students, were quite content to research and publish without the promise of patents in the decades prior to Bayh-

Dole. As Dr. Hilda Ye of the Albert Einstein College of Medicine recently explained, “Since all MTAs¹⁰⁴ will say that the reagents being transferred are not to be used for commercial purposes, it’s my understanding that you can’t patent a discovery based on such material[s].”¹⁰⁵ Because Dr. Ye says she has acquired reagents under such conditions on several occasions, “if the study is really important,”¹⁰⁶ the similar terms of my proposed government licenses should also be acceptable in many situations.

Academics might often prefer the terms of my proposed licenses to those included in some institutions’ MTAs because the licenses guarantee the recipient’s right to publish their findings.¹⁰⁷ According to Dr. Matthew Scharff,¹⁰⁸ “The nastiest MTAs make you feel like you are signing your life away.” As a condition of sharing proprietary materials, some researchers will insist on screening any resulting articles several months before they are submitted for consideration by journals. If the material supplier deems the new data to be in competition with their own work (or, worse still, contradicting their work), they can sometimes prevent publication altogether.¹⁰⁹ Some MTAs will require that the supplier get co-authorship on publications of results made with their materials, which is no small request in the academic “culture of credit.” In some cases, my proposed government licenses will let non-profit researchers get materials otherwise obtainable only by submitting to highly burdensome material transfer agreements.

Consistency With the Goals of Bayh-Dole

The preamble of the Bayh-Dole Act explains that Congress aimed to “promote free competition and enterprise without unduly encumbering future research and discovery.”¹¹⁰ By allowing the government to grant non-exclusive licenses to researchers, while at the same time channeling any resulting patents - and thus profits - back to the patent holder, my proposal brings Bayh-Dole closer to achieving its original goals. Not only would the burden on future research be reduced, but the private sector might actually see a greater financial return than they do today.

Consistency With Current Patent Law

The proposed government licensing system could be implemented merely by altering the Bayh-Dole statute, and by changing the terms of the contracts that accompany federal research grants. §202(c)(4) of Bayh-Dole already specifies that the “funding agreement may provide for ... additional rights [for the funding agency], such as the right to assign or have assigned foreign patents.”¹¹¹ Since the government-funding agency already retains the ability to assign foreign patent rights in certain situations, there is no reason the government cannot also retain the right to grant non-profit research licenses. There should be no need to alter the general requirements for patentable subject matter, or to limit the “right to exclude” in non-Bayh-Dole patents.

Some Shortcomings of the Government License Plan

Though the proposed licensing plan should do significant good and little to no harm, its scope is limited, and the plan leaves some problems unaddressed. To begin with, only future Bayh-Dole patents would be covered; there is no retroactivity. Non-profit scientists will have to negotiate normal licenses for all patents that are granted before the new rules take effect. This plan would also do nothing to reduce the total number of patents granted, and might do little to enrich the true public domain. Thus, private companies will still be completely prohibited from using some technology that would not have been patented at all before Bayh-Dole.

The licenses would entitle the patent holder to all discoveries made “under the licenses.” This would seem to invite conflict and litigation over precisely which of a non-profit institution’s many activities are “using” the patented technology, when specific projects begin and end, and endless other likely gray areas. Would any research receiving any benefit or direction from data discovered with the help of the patented technology be covered? Or just those inventions that obviously and directly required the license? It is also easy to imagine a situation where a patentable discovery will have connections to more than one government license, with the two Bayh-Dole patent holders each claiming the new find for itself.

Like the Bayh-Dole Act in general, my proposed plan would still favor Americans. From its inception and by its own terms, Bayh-Dole has always operated to divert science away from the public domain - which is free to all the world - and into the hands of American universities and corporations. Although I would make the new government licenses available to non-U.S. researchers, foreign researchers would probably resent having their discoveries patented by American corporations even more than American researchers would. It would not be surprising if some

foreign researchers using these licenses, faraway overseas and potentially hostile, were less than cooperative in helping the American Bayh-Dole patent holders obtain yet more patents.¹¹² Though recognizing what is arguably selfishness and unfairness, I think the continued preferences for American industry will be necessary to get any new legislation through the U.S. Congress.

Footnotes

- * B.S., Cornell University; J.D. Candidate, Boston College Law School.
- 1 Joshua A. Newberg and Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 Am. Bus. L.J. 187, 193 (2002).*
- 2 Harry Rubin et al., *From Ivory Tower to Wall Street - University Technology Transfer in the U.S., Britain, China, Japan, Germany and Israel*, 11 Int'l J.L. & Info. Tech 59, 72 (2003).
- 3 John M. Golden, *Biotechnology, Technology Policy and Patentability: Natural Products and Invention in the American System*, 50 Emory L.J. 101, 117 (2001).*
- 4 See Newberg & Dunn, *supra* note 1, at 196 (Only about 250 patents a year were issued to US universities in the 1970s).
- 5 *Id.* at 194.
- 6 *Id.*
- 7 E-mail from Dr. Hilda Ye, Assistant Professor of Cell Biology, Albert Einstein Medical School, to Aaron Miller, Boston College Law School, Class of 2006 (November 14, 2004, 10:15:08 EST) (on file with the author). Dr. Ye explained that while academics are usually mutually helpful, especially with their already-published results and within each institution, many are still reluctant to help their direct scientific competitors. In the academic "Culture of Credit," there is still competition to be the first to discover and publish new science.
- 8 See Golden, *supra* note 3, at 145.
- 9 Rochelle Dreyfus, *Biotechnology Patents Get Special Treatment: Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 Ariz. L. Rev. 457, 463-464 (2004).
- 10 Golden, *supra* note 3, at 120.
- 11 *Id.*
- 12 William A. Haseltine, *The Case for Gene Patents*, Tech. Rev., Sept./ Oct. 2000, at 59.
- 13 *Id.*
- 14 See *id.*; Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1669 (1996).

- 15 *See* Golden, *supra* note 3, at 111.
- 16 *See id.* at 145. (Academic and student researchers are mostly concerned with pure science, bettering medicine, and other lofty goals).
- 17 *See id.*
- 18 Newberg & Dunn, *supra* note 1, at 194-195.
- 19 Golden, *supra* note 3, at 120.
- 20 *Id.*
- 21 *Id.*
- 22 *See id.*
- 23 35 U.S.C.A. §200.
- 24 35 U.S.C.A. §202(c)(7)(A); 35 U.S.C.A. §202 (c)(7)(D).
- 25 35 U.S.C.A. §204.
- 26 *Id.*
- 27 35 U.S.C.A. §203(a).
- 28 *Id.*
- 29 35 U.S.C.A. §202(c)(4).
- 30 *See* Newberg & Dunn, *supra* note 1, at 196.
- 31 *Id.*
- 32 Golden, *supra* note 3, at 117.
- 33 Dreyfus, *supra* note 8, at 464.
- 34 Eisenberg, *supra* note 13, at 1666.

- 35 See Dreyfus, *supra* note 8, at 464.
- 36 Rubin et al., *supra* note 2, at 71-72 (2003).
- 37 See *id.* In 1998, the life sciences accounted for about 70% of university licensing income.
- 38 Eisenberg, *supra* note 13, at 1711.
- 39 Rubin et al., *supra* note 35, at 72.
- 40 Dreyfus, *supra* note 8, at 464.
- 41 35 U.S.C.A. §200.
- 42 See *Madey v. Duke University*, 336 F. Supp. 2d 583, 588 (2004 U.S. Dist LEXIS 19182). Duke University asserted a “Government License” defense to infringement of patents issued under Bayh-Dole. Though this has not been completely resolved, the courts are unlikely to hold that the right has such a far reach. As the court in this case put it, it felt that, “Duke has failed to establish its entitlement to the government license defense at this time.” *Id.* at 594.
- 43 35 U.S.C.A. §203(a)(1).
- 44 35 U.S.C.A. §203(a)(2).
- 45 Scott D. Locke, Esq., *Patent Litigation over Federally Funded Inventions and the Consequences of Failing to Comply with Bayh-Dole*, 8 Va. J.L. & Tech. 3, 23 (2003).
- 46 Informal Interview with Michael A. Albert, Esq., Partner, Wolf, Greenfield & Sacks, P.C., in Boston, Mass. (Dec. 6, 2004) A senior IP litigator and Harvard Law graduate, Mr. Albert claims to know of no occasion when the “march-in” rights have ever been exercised.
- 47 See 35 U.S.C.A. §203.
- 48 See *generally* *Madey v. Duke University*, 307 F.3d 1351, 1352-1353 (Fed. Cir. 2002) (narrating background of case).
- 49 *Id.*
- 50 *Id.*
- 51 *Id.*
- 52 *Id.*

- 53 *Id.*
- 54 *Id.*
- 55 Embrex, Inc. v. Service Engineering Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000). *
- 56 Madey, 307 F.3d at 1362. Again, it's worth remembering that Duke's "government license" defense is still pending, although I seriously doubt they will get the court to say that the "government license" extends absolutely anyone receiving government funds. Doubly bad for Duke, the "government license" provisions of Bayh-Dole were enacted after Madey obtained his patents.
- 57 *Id.*
- 58 Some researchers are interested in getting patents, some are not. Institutions, who juggle massive budgets and who usually receive the lion's share of licensing revenue, are more consistently interested in obtaining patents.
- 59 Dreyfus, *supra* note 8, at 464.
- 60 *Id.*
- 61 My proposal addresses this dilemma, with "infringing" researchers assigning rights to the "infringed" patent owner or exclusive licensee.
- 62 A lot of good has come from academic/corporate partnerships. But the point stands that the corporation today needs to guarantee that the university won't turn around and charge them for their results.
- 63 Dreyfus, *supra* note 8, at 464.
- 64 When I started work as a lab technician at the Albert Einstein Medical School, I signed papers granting the university ownership of anything I invented. This is standard at most schools. Typically the institution, the department, and the individual lab each get assigned percentages of any licensing revenue.
- 65 Dreyfus, *supra* note 8, at 463.
- 66 *Id.* at 459.
- 67 Gary Stix, *The Silent Revolution*, Sci. Am., June 2004, at 46 (reviewing Adam B. Jaffe and Josh Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress and What to Do About It* (2004)).
- 68 Antonio Regaldo, *The Great Gene Grab*, Tech. Rev., Sept. 1, 2000, at 48.
- 69 The patents have expired fairly recently, but the point still stands.

- 70 It is difficult to convey to people not versed in biology just how key these methods are. No undergraduate with a life science degree can get their BS without learning about and, if his diploma is worth anything, using several of these methods. As a medical research technician, I used them literally every day. Imagine trying to be an engineer if screws and washers were patented.
- 71 David C. Hoffman, *Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 Cornell L. Rev. 993, 1029 (2004).
- 72 *Id.*
- 73 *Id.*
- 74 *Id.* at 1030.
- 75 The same basic argument can be applied to other “upstream” subjects. It’s all a matter of degree, and what should be patentable will vary based on the area of development, and the economics of related industries. Still, life sciences have been far and away the biggest area of Bayh-Dole patenting, so the specific case of genes is unusually important.
- 76 66 Fed. Reg. 1092, 1094 (January 5, 2001) (status).
- 77 Hoffman, *supra* note 64, at 1036-1037.
- 78 *Id.* at 1036 (quoting Judge Rader).
- 79 My proposal would do nothing to expand academic access to patents granted directly to corporations; an expanded experimental use defense would apply to ALL patents.
- 80 A major advantage of my plan is that it actually distributes licenses, so it will always be clear who is covered and what they may use BEFORE research begins. There is no need to hope that an experimental use defense will actually hold up in an infringement suit, or to speculate and gamble as to where it will apply.
- 81 Hoffman, *supra* note 64, at 1033 (quoting Maureen O’ Rourke).
- 82 As with experimental use, this would apply to private patents, while my proposal only relates to Bayh-Dole patents.
- 83 Dreyfus, *supra* note 8, at 471.
- 84 *Id.*
- 85 *Id.*
- 86 Not to mention inevitable battles over what research is and is not conducted using the patent waiver. When one project ends and another begins is not always cut-and-dry. And what about projects that benefit from “negative”

information gained using the waiver?

- 87 Rochelle Dreyfuss deems this enrichment of the public domain a positive aspect of the plan. Whether or not this is true from a policy perspective, it would be a serious obstacle to enacting such legislation.
- 88 My system assigns any resulting patent rights to the patent holder, and so would probably be welcomed by industry.
- 89 My plan does not require any changes to general patent law, and could be implemented by amending Bayh-Dole, and then changing the content of funding agreements between the government and grant recipients. My plan would not be retroactive.
- 90 Rubin et al., *supra* note 35, at 74.
- 91 *Id.*
- 92 *Id.*
- 93 *Id.* at 78.
- 94 *Id.*
- 95 *Id.*
- 96 *Id.*
- 97 It is not hard to imagine a system allowing non-profit access to ALL patents on roughly these terms. This would be more complicated in that it would limit the “right to exclude” of all patents, and might still raise objections from the private sector.
- 98 *See* Madey, 336 F. Supp. 2d at [page].
- 99 Regaldo, *supra* note 61.
- 100 Yes, this might be hard for them to swallow. See below.
- 101 Golden, *supra* note 3, at 111.
- 102 The main difference is that here the Bayh-Dole patent owner gets any resulting new patents, whereas before Bayh-Dole the discovery would probably have entered the public domain. But from the point of view of the researcher working under the government license, this distinction will usually be unimportant.
- 103 E-mail from Dr. Hilda Ye, Assistant Professor of Cell Biology, Albert Einstein Medical School, to Aaron Miller, Boston College Law School, Class of 2006 (November 14, 2004, 10:15:08 EST) (on file with the author). Dr. Ye

explained that “Unpublishable results are useless for academic people.”

- 104 Material Transfer Agreements: Basically, a contract setting out the conditions for using proprietary materials provided to another researcher. Common subjects for MTAs include pharmaceuticals, genetically engineered mice, cultured cell lines, and antibodies.
- 105 E-mail from Dr. Hilda Ye, Assistant Professor of Cell Biology, Albert Einstein Medical School, to Aaron Miller, Boston College Law School, Class of 2006 (November 14, 2004, 10:15:08 EST) (on file with the author).
- 106 *Id.*
- 107 My plan would require notice to the patent holder when they may need to consider filing a patent application, such as when a paper is published. This should not be a problem given the twelve-month window to file an application in the U.S. after publication. I would not give the patent holder the right to censor any findings, or to delay publishing for unduly long periods.
- 108 E-mail from Dr. Matthew Scharf, Professor of Cell Biology, Albert Einstein Medical School, to Aaron Miller, Boston College Law School, Class of 2006 (November 14, 2004, 10:15:08 EST) (on file with the author).
- 109 E-mail from Dr. Hilda Ye, Assistant Professor of Cell Biology, Albert Einstein Medical School, to Aaron Miller, Boston College Law School, Class of 2006 (November 14, 2004, 10:15:08 EST) (on file with the author).
- 110 35 U.S.C.A. §200.
- 111 35 U.S.C.A. §202(c)(4).
- 112 This might also be a problem with American licensees. Still, it would probably easier to enforce the rules in U.S. institutions that themselves benefit from the Bayh-Dole system, and who are simply easier to keep an eye on.