

PRESENTATION:

**THE UNIVERSITY OFFICE
OF TECHNOLOGY TRANSFER:
A REVIEW OF THE CURRENT U.S. SYSTEM**

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It is a great honor for me to be here today to address this very distinguished audience. My work focuses on the role of intellectual property rights at the public/private divide in research science, with a focus on biomedical research. I am delighted that you have chosen to highlight this important topic at this conference.

Since 1980, U.S. policy has encouraged patenting the results of government-sponsored research. This policy began with passage of the Bayh-Dole Act and the Stevenson-Wydler Act in 1980, and has steadily expanded since that time. I have written about the origins of this policy, which began as an initiative of patent law professionals within federal government funding agencies. Universities had only minimal involvement in developing this policy, although the original Bayh-Dole Act offered special benefits for nonprofit institutions and small businesses. The focus on these particular research performers reflected an eleventh-hour compromise in order to get the legislation passed over objections that it amounted to a giveaway of valuable rights to large corporations. More important at the time than ownership of patents by universities was the ownership of patents by private government contractors whose work was more likely to have commercial implications. These contractors correctly figured that if they went along with the more limited statutory provision for ownership of patent rights by universities and small businesses, the policy would soon be expanded to permit all government contractors to retain ownership of discoveries made with public funds.

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But however small the role of universities may have been in motivating the original passage of the Bayh-Dole Act, universities have been a particularly interesting place to view the consequences of that Act. Some of these consequences were part of the original game plan; others were quite unintended. Prior to passage of the Bayh-Dole Act, the argument for university ownership of patents was that universities don't really care about patents. They just want to publish their research results. But publication without patents dooms new technologies to oblivion. In this analysis, the public domain was pictured as a treacherous quicksand pit in which new discoveries sink beyond reach of the private sector. Patents on university-based discoveries would be necessary in order to get these discoveries commercially developed, as well as to leverage U.S. taxpayer investments in research into an advantage for U.S. firms. But universities, according to the argument, would not bother to file patent applications unless they had an incentive to do so. The promise of patent ownership would provide that incentive.

Universities have responded to the incentives of the Bayh-Dole Act with enthusiasm. The past twenty years have witnessed a tremendous increase in patent filings by universities as universities have created new technology transfer offices and hired a new breed of professionals to staff them. Most of these offices are not making much money, although some have brought in millions of dollars of revenue to their institutions. Even for the most successful technology transfer offices, patent revenues are trivial in proportion to other university revenues. The reason for this is that it is hard to make money off most university inventions, which typically have their primary use as inputs into further research.

An interesting unintended consequence of the Bayh-Dole Act has been an increasing propensity to treat discoveries that are primarily inputs into future research as proprietary inventions. This is happening not only in universities, but also in the private sector. This phenomenon raises a new problem, not contemplated by those who put the Bayh-Dole Act in place: what is the role of intellectual property in exchanges of research tools? This is a growing concern in the biomedical research community, where the tools of discovery – materials, methods, data, DNA sequences, cell lines, clones – are increasingly likely to come with proprietary constraints that limit access, limit use, limit dissemination of results, and compromise stewardship over future discoveries.

Concerned about these issues, the Director of the National Institutes of Health asked me to chair the NIH Working Group on Research Tools two years ago to investigate the perception that researchers were having

difficulty gaining access to proprietary research tools. The Working Group conducted a one-year investigation in which we gathered information from research scientists, university technology transfer professionals, and representatives of pharmaceutical and biotechnology firms. This investigation offered a rare opportunity to talk to people about a problem that they might not otherwise be inclined to speak freely about.

We found that, across the biomedical research community, there is a widespread perception that there is indeed a problem in gaining access to proprietary research tools, and that the problem is getting worse, not better, as more research inputs that would have been freely available in an earlier era are increasingly subject to Material Transfer Agreements, license agreements, and database access agreements that have to be negotiated. Research gets stalled and sometimes derailed as each of these agreements is reviewed and renegotiated. But although everyone agrees that there is a problem, people in different quarters of the research community characterize the problem differently and disagree about what should be done.

An example gives a flavor of some of the stories we heard – stylized and anonymized to protect the innocent – or perhaps to protect the guilty.

Let us consider the example of a scientist, anonymous Scientist A, who is doing research at University A, let's say with NIH funds. He seeks access to a research tool, let's say a mammalian expression vector for high yield production of proteins. The expression system was developed by Scientist B at University B. Scientist A wants to use the vector in order to produce large quantities of a protein that she is studying. Here is how Scientist A might tell the story. Scientist A read about the system, sent Scientist B a letter asking for access to the system, got no response, and followed up with a phone call. Scientist B on the phone tells Scientist A that the vector is the subject of a pending patent application that has been licensed exclusively by her university to Company C. However, Scientist A can still get the vector for research purposes only if she, as an authorized representative of her university, will sign a material transfer agreement that Scientist B will send in the mail. Scientist A gets the material transfer agreement, eagerly forwards it to the technology transfer office within University A expecting that they will promptly take care of the paperwork, and she will soon have the vector in hand. Months pass while the technology transfer office at University A tries to renegotiate the terms of the agreement. Scientist A becomes increasingly frustrated with what she sees as pointless bureaucratic obstacles, and may eventually give up and start looking for another expression system.

Now we call up the technology transfer office at University A saying, "Boy did we hear an earful. What do you have to say for yourselves?" Well they will tell the story a little differently. They will say that the material transfer agreement sent by University B is completely outrageous, and there is no way that they could sign it in the form presented. Scientist A may see their office as simply bureaucrats who are blocking her research, but they see themselves as protecting their interests, and protecting the interests of the university. In particular, when pressed about what is wrong with the agreement, they say that they object to the following provisions: The agreement requires Scientist A to submit her publications to University B, or maybe even Company C, and to delay publication for 180 days pending review for patentability and/or disclosure of confidential information. The agreement prohibits Scientist A from transferring any materials derived from use of the vector to any other institution and from using the vector in research that is subject to a licensing obligation to another institution.

University A fears that this is going to unduly interfere with Scientist A's future research opportunities. Moreover, University A's technology transfer professionals doubt that they can monitor Scientist A's activities to ensure that she is complying with these provisions. The agreement grants University B, or perhaps Company C, an automatic, royalty-free, non-exclusive license to any improvements in the system, or any new uses of the system discovered by Scientist A, plus an option to acquire an exclusive license to any discoveries made by Scientist A using the vector. University A sees these provisions as unduly interfering with its stewardship over discoveries made by its scientists and as potentially undermining future funding opportunities, future opportunities to transfer valuable discoveries as it sees fit once it knows what they are and has an opportunity to evaluate them. Finally – and this is something that is particularly galling to university technology transfer people – the agreement requires University A to indemnify University B and hold them harmless from liability for any injuries arising from the use of the vector by Scientist A. University A is balking at this term because they do not see why they should put their endowments at risk to acquire a mere research tool.

Well those all sound like legitimate concerns. Now we turn to University B and say, "Why did you send this outrageous material transfer agreement?" University B says, "This is no mere research tool, this is a commercial valuable production technology that Company C is developing under an exclusive license from us." Why did they give an exclusive license to Company C? Maybe Company C sponsored the research in Scientist B's lab and acquired the exclusive license under the terms of the sponsored

research agreement. Maybe University B made a judgment call that this was an appropriate technology to license exclusively because it could eventually be scaled up for use in commercial production if they could find a licensee that was willing to make the investment. Maybe, and this is increasingly common, Company C was willing to take over patent costs and pay royalties, but only if they were to receive an exclusive license. However, says University B, "We are good guys, we see the problems, we recognize that this could also be used as a research tool, so we bargained with Company C to retain the right to distribute this system to academic scientists for research purposes only, and Company C agreed, on the condition that we use their MTA. So we did not draft this agreement. If you do not like the terms of this agreement do not complain to us, complain to company C."

So now we give Company C a call, and what do they have to say for themselves? Once again, as you might expect, they tell the story a little bit differently. Company C says, "We paid good money for the research that yielded this system, or for the exclusive license to use it. So, although we are happy to do what we can to accommodate purely academic uses that are of no commercial value to us, we cannot allow academic scientists to use this system in ways that dissipate the competitive advantage that we gained through our exclusive license. The terms of our MTA give us protection from risks of competitive harm while allowing academic research to go forward. We need these provisions that they are objecting to. We need pre-publication review to be sure that we do not lose the opportunity to obtain patent rights through publication prior to filing. We also need to monitor what it is that academic scientists are doing with the system. We are perfectly willing to let Scientist A do the work that she has told us that she wants to do, which we expect to be of no commercial interest to us. However, you can never trust academic scientists to do what they say that they will do and nothing else. Once the material is in her hands, we are afraid that Scientist A might end up using it in research that is closer to what we are doing ourselves, perhaps in competition with us. Pre-publication review gives us a heads up if that happens, so that we can get patent applications on file if she has wandered onto our turf and is getting ready to publish something that will undermine our patent position.

"As for the prohibition on transfer of materials to other institutions, we obviously need that because we do not want our proprietary technology getting into the hands of someone who has not signed our agreement. We need to prohibit use that is subject to a licensing obligation to other institutions because it is one thing to give our system away for free for pure academic research, but it is another thing to give our system away for use in research

by another private company. We want to make sure that Scientist A is not working for our competitors. We have been burned in this respect in the past and we do not want it to happen again. We want to be sure that anything commercially valuable that comes out of her research is not going to enhance the position of a competitor.

"As for the grant-back of license rights we have two principal concerns. First, we want to be sure that University A does not take our system and use it to create a patent position that blocks us from fully developing the technology that we paid for. That is why we want a non-exclusive license to improvement and new uses. Second, if Scientist A makes a commercially valuable discovery using our technology, we think that it is only fair that we should be first in line to license that technology on an exclusive basis. We are providing a valuable system, we are not charging the university any money, so we ought to get something in return for that.

"As for the indemnification clause, why should we end up paying damages if something goes wrong in the course of research that we cannot control? This is our proprietary technology, and if we make it available to Scientist A we are doing her a favor. She is one of many scientists making requests for access to this system. We set the terms, and it is not worthwhile for us to hire people to spend a lot of time negotiating each one of these transfers. So University A, take our agreement or leave it."

You hear four different versions of the same story, everybody is angry, everybody is indignant. Some of these problems, maybe even all of these problems, could be worked out in negotiations, if it were worth it to all of the parties. For example, everybody could probably live with a 60-day pre-publication review period rather than the 180-day pre-publication review period. The grant-back provisions might be acceptable if they were confined to Company C's field of use. The option to future discoveries might be acceptable if it were limited to discoveries within a short period of time following the use of the system rather than extending forward indefinitely. However, the problem is compounded by the fact that this agreement is not the most important thing on anyone's desk. No one thinks that it is worth investing a lot of time and resources in haggling over its terms so it gets deferred.

So there are the problems. Why can't the parties just work it out? Is there any reason to think that this is not the ordinary fits and starts of a new market emerging, that there is some sort of enduring market failure going on? These are sophisticated institutions with the staff and resources to work out agreements for major collaborative research among themselves. These are not people who never talk to each other or never enter into agreements.

Surely, if they can work out their differences over major collaborative research agreements, they can also work out their differences over everyday exchanges of research tools, if we just let them at it. Well I surely do hope so, I really do.

I was charged not simply with describing this problem but with solving it. However, based on what I have heard, I have some concerns that there might be a more enduring problem going on here. There are four features of this particular emerging market that cause me some concern that there might be an enduring problem.

The first is that the transaction costs here loom large relative to the gains from exchange, relative to the value of any particular transfer of research tools. If there is enough at stake on both sides, they can and do work it out, usually. However, what is becoming a serious problem is the bottleneck of these low-value exchanges, these material transfer agreements that facilitate research that has a low probability of yielding anything of commercial value. Why does anybody care? Why are they bothering to bargain to impasse over these low value exchanges? Well it is not clear, *ex ante*, whether you are talking about a low-value exchange or a high-value exchange. That is the fundamental problem. So, everybody treats each one of these as if it were a high-value exchange. Otherwise you might find that you have signed over a winning lottery ticket on the cheap, and nobody wants to find themselves in that position. Individually these are low-value exchanges *ex ante*. Some of them, *ex post*, will prove to have been high-value exchanges, and you cannot tell which ones.

So, the parties then routinize the terms of exchange to bring down the transaction costs; this is something that remains puzzling to me, although I have some things to say about it. All commerce would come grinding to a halt if people did not use form agreements to routinize transactions, even very major, high-dollar transactions. We all buy and sell our houses using form agreements so that we are just haggling over the price and the contingencies, but not over every term in there. But here, people are haggling over just about every term, or quite a few terms anyhow. There is no standardization of even the definitions. That creates really high transaction costs.

I think one of the reasons that people are having trouble working out any sort of standardized agreements – there have been some efforts that by and large have been unsuccessful – is that this is a heterogeneous community. There is a lot of evidence in other settings indicating that homogeneous communities have an easier time developing forms of exchange than heterogeneous communities. Here we have different sectors that, as you can get a flavor of from my example, do not trust each other and

do not respect each other particularly. Each sector says, "We can do deals with our own kind with relatively few problems, it is the other guys that are making all of the trouble," and they each tell these stories on each other.

They all agree that symmetrical terms of exchange do not really make sense given the different missions and agendas of the public and private sectors, but each side thinks that the asymmetry ought to cut in its favor. So the universities will say "We are academic institutions trying to advance the frontiers of knowledge. Therefore, private groups should make their research tool freely available to us. However, we can charge them when we make our research tool available to them because they are profit making enterprises." You turn to the profit-making enterprises and they say, "Universities are subsidized by taxpayers like us, so they should make their materials freely available to the taxpaying public, including us. However, we are using our shareholder dollars to make our discoveries, and we have a fiduciary duty to return value to our shareholders. They should understand why we need to deploy our research tools in a way that brings something back to our shareholders." They cannot even agree among themselves on what is a research tool because one institution's research tool is another institution's enterprise. This makes the standardization option very difficult because they cannot even figure out what is the zone within which standardized terms would apply.

There is another complicating factor that I put under the heading of "agency problems." That is, even within each of these institutions, apart from the heterogeneity across these institutions, you have heterogeneous populations of people with different interests, different missions, and different agendas. For example, the scientists and the technology transfer professionals have different concerns, different aspirations. The scientists want to do the science, that is their primary concern, and the rest seems like bureaucratic gobbledygook to them. The technology transfer professionals are more focused on protecting the financial interests of the institution. They do not understand each other particularly, and they do not trust each other. The scientists see the technology transfer professional as, in the words of one scientist who spoke to us, "bureaucrats who sit on these agreements and find errors," The technology transfer professionals see the scientists as naive and short-sighted. They have no patience to even read the documents and they cannot trust them to comply with the obligations that they are so willing to incur.

The other side of these transactions inevitably exploits the differences among agents within each institutions. When a company scientist wants to exchange research tools with a university scientist, he will encourage his

counterpart to think that the technology transfer office professionals are the bad guys that are preventing this from happening. Scientists within each of these institutions sometimes have the power to defect, and simply go ahead and do the transaction without going through their offices, and they sometimes do that. I think that leads to a persisting normative expectation of free availability that may be delaying the emergence of a smoother market.

Finally, there are valuation problems that make it very hard to have anything like a smoothly operated market in this setting. It is very hard to assess the value of a research tool, particularly before you use it. The value of a research tool is a function of its capacity to facilitate future discoveries, and that is very difficult to measure *ex ante*. It is complicated even when the user is a wealthy company that is willing to pay up front in dollars. It is more complicated when the user is a less prosperous institution like a university or even a biotechnology company that basically has only future intellectual property to offer. It requires a valuation of both past and future innovations, without knowing what those future innovations are or if they will come into being. Research involves investigation of the unknown, its outcome is inherently uncertain, and the information that might help estimate the likely value of research using a tool is divided between the owner of the tool – who has typically worked with the tool before and may already be considering what are its most promising uses – and the would-be user who may have complementary expertise that brings into view a research plan that might or might not have occurred to the owner. The owner will generally ask the user what is it that he plans to do, but both parties have good reason not to be fully candid with each other, as they may be, or may become, research competitors.

Moreover, the owners and the users of research tools may simply differ in their subjective assessments of the likelihood of a valuable outcome. Those differences can make it difficult to reach agreement. Or they may even be misreading signals from each other's bargaining behavior that lead them away from agreement rather than towards it. For example, a university owner of a research tool may figure that if a major pharmaceutical firm wants to use this tool it is probably pretty valuable and therefore they ought to charged a lot of money. Or an owner might figure that, "If the university is reluctant to promise me a license to future discoveries, they must figure that they are on the verge of making an important discovery, and I ought to hold out for a piece of the action in that future discovery." For research that is remote from enterprise development, it may be some time before the commercial value of any resulting discoveries becomes apparent. Even when the research yields an outcome of manifest value, it may be difficult to agree

on the formula for assessing how that value should be apportioned between prior and subsequent innovators.

I think that this is a really big problem and I do not see any easy solutions. It is not very clear to me what we ought to do, but an up-close look at the struggles and failures in this particular market suggests, I think, at the very least, that we should not be unduly optimistic about contracting as a way of solving all problems arising from a proliferation of intellectual property rights. We should remember that contracting has real costs, and that these costs can sometimes consume the gains from exchange; when that happens the exchange does not occur. It is not like the threat point is litigation that at some cost will resolve these issues. The threat point is that there is no deal, no transfer, no access to the research tool, that the particular research path, at least, does not go forward. When the exchanges that are impeded are exchanges of biomedical research tools, the aggregate costs of so many low-valued exchanges, when measured in human life and health, can be quite high.