Testimony of

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Committee on the Judiciary
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"The Role of Federally-Funded University Research in the Patent System"

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Introduction

Good afternoon Mr. Chairman and distinguished members of the committee. Thank you for the opportunity to speak on the subject of "The Role of Federally-Funded University Research in the Patent System."

I am Arti Rai, a law professor at Duke Law School and a faculty associate of the Duke Institute for Genome Sciences and Policy. For the last 10 years, I have conducted research on the interaction of federally funded research and the patent system. Currently, I am funded by the National Institutes of Health to examine intellectual property rights issues that arise in collaborative inter-university and public-private partnerships. I am also funded by the Kauffman Foundation to conduct research on technology transfer issues surrounding university-generated software. I have no consulting relationships with, and have accepted no money from, any for-profit entity.

Background on Federal Efforts in Technology Transfer

I understand that the immediate catalyst for the Committee's interest in federal technology transfer issues is the prospect of changes in the statutory provisions that govern patent royalties earned by government-owned, contractor-operated facilities (GOCOs). Under the existing provisions of the Bayh-Dole and Stevenson-Wydler Acts, GOCOs such as the Ames laboratory operated by Iowa State University must pay back to the U.S. Treasury a percentage of the royalties they earn on any patented invention. Specifically, they must pay back 75% of the net amount they earn in excess of 5% of their annual budget. Iowa State, and presumably most universities that operate government labs, would like the amount of the recoupment to be smaller.

In order to understand whether there should be "more" or "less" royalty recoupment, it is useful to understand the background of Bayh-Dole and Stevenson-Wydler. Both of these statutes aim to commercialize federally funded research through the use of patents. The theory is that if federally funded research is patented, then private sector firms will have a powerful financial incentive to seek exclusive licenses to the research and commercialize it. (Rai & Eisenberg 2003; Rai 1999; Eisenberg 1996).

For certain types of inventions, this commercialization theory makes a lot of sense. Economic research indicates that patents on (for example) promising drugs are quite important for commercialization of such drugs. (Cohen et al. 2000). So if a university comes up with what looks like a promising drug, allowing a patent on that drug is probably necessary for commercialization. Outside of the life sciences, however, the importance of patents for commercialization is not as clear. In general, as recent debates over reform of the patent system have illustrated, patents may play a very different role in the life sciences than they do in other industries.

So commercialization through the "patent and exclusive license" model raises at least three questions. First, are all inventions best commercialized through this model? Or it is possible that one size does not fit all? Second, if one size does not fit all, who should make the decision about whether an approach based on patents and exclusive licenses is the way to go? Currently, Bayh-Dole gives a large amount of discretion to universities. Are universities well-placed to exercise that discretion in the public interest? And, third, in cases where patenting is the way to go, should some percentage of the patent licensing royalties earned by the university be paid back to the federal government?

I address each of these questions in turn.

Does One Size Fit All?

In 1980, when the Bayh-Dole and Stevenson-Wydler Acts were passed, the world of patents looked quite different than it does now. Many inventions that were patentable looked like a lot like drugs - in other words, they needed to be "scaled up" before they would be useful to anyone. Exclusive licenses to patents provide a powerful incentive to do this scaling up. Since that time, however, the scope of what can be patented has expanded a great deal. Software is now patentable. Biomedical inventions that look a lot more like scientific research tools than end product drugs are now patentable.

In the case of some of these patentable inventions, it's not entirely clear how important patents are for commercialization. Consider the case of software. Some scholars have argued have patents might help start-up software firms attract venture capital. (Mann 2005). But even these scholars note than only a minority of start-up software firms appear to have such patents. (Mann 2007). As for biomedical inventions that look like research tools - for example, embryonic stem cells, on which the University of Wisconsin has a broad patent - commercialization might be achieved through the lure of downstream patents on specific applications of these stem cells. (Rai & Eisenberg 2003).

Another argument that is sometimes made for an approach based on exclusive licenses to patents is that the prospect of sharing licensing royalties induces university researchers to work with industry licensees and thereby transfer tacit knowledge necessary for commercialization. (Jensen and Thursby 2001). However, not all inventions involve tacit knowledge. In software, for example, development is often based on principles of modular design that require little tacit knowledge. Even outside software, absorptive capacity in industry can sometimes obviate the need for transfer of university-based tacit knowledge. In the biomedical arena, Columbia's DNA co-transformation technology was taken up by industry without an exclusive license. (Mowery et al. 2004).

In fact, there have been some recent prominent cases in which it appears that the university patent did not aid in technology transfer but instead simply allowed the university or its exclusive licensee to extract money from an entity that had already commercialized. In the recently settled case of Eolas v. Microsoft, for example, Microsoft and various other firms did not need an exclusive license or tacit knowledge in order to commercialize the Web browser software that was the subject of the patent dispute. In this case, and others involving litigation over university software patents (Rai et al. 2007), commercialization by firms other than the university licensee was going forward, and patent rights/exclusive licenses were not necessary to facilitate "technology transfer." Rather, contrary to the spirit of Bayh-Dole, software patents in these cases primarily allowed universities to extract money from, and perhaps even to "hold up," ongoing development efforts.

Who Decides: Tweaking "Exceptional Circumstances" and March-In

Let us next move to the question of who should decide whether a federally funded invention is patented and how it should be licensed. The cases I have just discussed might suggest that the default option under the Bayh-Dole Act - giving universities broad discretion to determine when to patent and how to license - is a bad idea. But one never knows how representative litigated cases are. Universities may generally be doing a good job, with these litigated cases being the exception.

A more troubling indicator emerges from research demonstrating that the most important predictor of how many software patents a university acquires is not how much software-related research it is doing but simply how many other patents it has. (Rai et al. 2007). In other words, at least for patents that issued in the 1980s and 1990s (the

period covered by the research), many universities with large patent operations were simply patenting a substantial percentage of whatever came in the door. They were very much using a "one size fits all" approach to their invention.

So it should come as no surprise that information technology firms are somewhat troubled by what universities are doing. (Bohr 2006). These firms have argued that development opportunities and university-industry collaborations are likely to be spurred through fewer, not more, university assertions of patent rights. (Johnson 2007; Thursby & Thursby 2006).

Even so, I would be reluctant to call for major changes in "who decides." In software, there is some reason to believe that universities are beginning to understand differences in technology and are using models other than the traditional ones that work for end-product biomedical inventions. (Rai et al. 2007). In the life sciences, there have been some individual cases that are troubling but not enough to merit a significant overhaul.

In terms of tweaking, it's worth studying two small changes. First, Bayh-Dole currently requires that federal agencies prove "exceptional circumstances" before they can declare that patenting is the wrong approach towards commercialization in a particular area of federally funded research. It's worth looking into whether such a high bar is necessary, particularly because it appears agencies sometimes ignore this requirement in any event. (Rai & Eisenberg 2003). Second, the so-called march-in provisions of Bayh-Dole, which allow compulsory licensing when a university patentee is not commercializing appropriately, might be worth examining. As matters currently stand, they have never been used. This may be in part because of the high procedural hurdles to their use. March-in rights can not take effect until after elaborate administrative proceedings, and subsequent court appeals, have been exhausted. (Rai & Eisenberg 2003).

At a minimum, march-in rights should not be weakened. Even though they have not been used, in some cases they appear to have served a valuable role as a threat that the government could use against a recalcitrant university patentee. (Eisenberg & Rai 2004).

Royalty Recoupment

The issue of royalty recoupment is an important and interesting one. The argument for royalty recoupment is straightforward - without recoupment, the public has to pay twice, once for the research itself and once again through the monopoly pricing that the patent affords. (Eisenberg 1996). Relatedly, one might argue that the federal government should get a return on its investment. In fact, California's recent $3 billion stem cell research initiative (Proposition 71) was promoted in part on the promise that the state would receive a large royalty stream from the licensing of technologies that emerged from the state-funded research. (Gilbert 2006)

There is little evidence, however, that the federal government would be likely to recoup significant sums from its investment in federally funded research. In fiscal years 2003 and 2004, U.S. universities had net licensing income that represented only 2.5% of their sponsored research expenditure. In FY 2004, for example, sponsored research expenditures were $37 billion while net licensing revenue was $925 million. (AUTM 2003; AUTM 2004).

In fact, there are good reasons to expect relatively low direct financial returns on the type of basic research the federal government typically funds. Economists have long noted that even though basic research generates significant economic dividends, these dividends are too long term and diffuse for any single party to capture. Indeed, the argument for government support of basic research emerges from the insight that it is valuable economically but will not be generated by ordinary private sector financial incentives. (Arrow 1962).

Moreover, aggressive attempts to use patents to capture gains from basic research, whether by universities or by the government, may create obstacles to development and commercialization. I have already mentioned situations where universities appear to have used software patents to "hold up" commercializing firms. Additionally, particularly in the information technology industries, aggressive patenting may cause licenses to multiple university inventions to become necessary, with the result being significant transaction cost hurdles to development. (Shapiro 2000).

In the best case scenario, universities (and the government) might make some money through licensing royalties that operate as a modest tax on commercialization. The famous Cohen-Boyer patent on recombinant DNA, which made

hundreds of millions for the universities involved, arguably operated in this fashion. (Eisenberg 1996). But even in that case, it is worth asking whether broad-based taxation of the income generated by the many firms that have been formed or have flourished based on public research might be a better way of recouping the public's investment.

Conclusion

In sum, there is little reason to believe we need a major overhaul of the current system of technology transfer. However, universities should be educated about the reality that one size does not fit all when it comes to technology transfer. Further, some tweaks in the "exceptional circumstances" and march-in provisions of Bayh-Dole are worth studying. Finally, given the early-stage nature of the research that the federal government funds, we should be cautious about viewing technology transfer as a mechanism for raising revenue.

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