STATEMENT OF

JOHN C. VAUGHN

EXECUTIVE VICE PRESIDENT

ASSOCIATION OF AMERICAN UNIVERSITIES

ON BEHALF OF

ASSOCIATION OF AMERICAN UNIVERSITIES

AMERICAN COUNCIL ON EDUCATION

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS

COUNCIL ON GOVERNMENTAL AFFAIRS

BEFORE THE HOUSE JUDICIARY SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION AND THE INTERNET

"PRIOR USER RIGHTS: STRENGTHENING U.S. MANUFACTURING AND INNOVATION"

FEBRUARY 1, 2012

10:00 A.M.

2141 RAYBURN HOUSE OFFICE BUILDING

One of the most contentious issues debated over the course of the effort to reform U.S. patent law was whether to expand the existing prior user rights provisions, which were available as a defense against infringement of business method patents only. The higher education community was strongly opposed to the proposed expansion of prior user rights to be available as a defense against infringement of all patents, while private sector groups argued for the need for a broad prior use defense, particularly if the U.S. were to move from a first-to-invent to a first-inventor-to-file system for determining patent priority. The America Invents Act (AIA) includes a carefully crafted set of prior user rights provisions that addresses the concerns raised by the higher education community while responding to the legitimate interests of private sector companies.

University Research

To understand the concerns of the higher education community about a broad expansion of a prior use defense and how the AIA effectively addresses those concerns, it is useful to review the nature and history of the research conducted by U.S. universities.

Universities perform the largest portion of the nation's basic research. In 2008, universities performed 56% of basic research, more than the private sector, federal government, and other nonprofit organizations combined. Universities also performed about 12% of the nation's applied research, slightly less that the federal government.

University research has greatly strengthened the nation's innovative capacity and economic competitiveness. More than half of U.S. economic growth since World War II has resulted directly from technological innovation, much of which stems from scientific, medical, and engineering research at our universities.

The capacity of the nation's research universities to contribute to innovation and economic competitiveness was greatly enhanced by the passage of the Bayh-Dole Act in 1980. Prior to 1980, the federal government retained patent and licensing rights to the results of federally funded research. On the face of it, that made good sense: taxpayers had paid for the research, and the federal government therefore ought to retain title to inventions resulting from that research. But the consequence of that policy was that most inventions remained on the shelf, undeveloped. Senators Bayh and Dole introduced legislation that allowed universities and small businesses to retain the rights to inventions resulting from federally funded research. The result of enactment of that legislation was a dramatic increase in university – industry technology transfer:

- In 1985, shortly after the legislation was passed, 500 patents were issued to the top 200 research institutions,

- In 2009, university research led to the issuance of 3,417 patents, 596 new companies, and 658 new commercial products.[1]

[1] http://www.autm.net/AM/Template.cfm?Section=Documents&Template=/CM/ContentDisplay.cfm&ContentID=5237

- A 2009 study by the Biotechnology Industry Organization estimated that university-based inventions contributed $450 billion to the U.S. gross industrial output and created 280,000 new high-tech jobs between 1999 and 2007.[2]

Federally funded university research has played a critical role in the development of the laser and its myriad applications, microprocessors, magnetic resonance imaging and later MRI applications, the CAT scan and PET/CT scanner, synthetic Taxol, and the Global Positioning System to name just a few.

University research has produced not only ground-breaking inventions that have led to valuable products, processes, medicines, medical treatments, and new technologies in a wide range of fields, but also have led to the creation new companies — as noted above, 596 new companies in 2009. The Science Coalition has produced a list of 100 companies that have grown out of federally funded university research.[3] These include major companies such as Google, Cisco Systems, Genentech, Sun Microsystems, and Xenogen, a leader in "in vivo" optical imaging.

Given the productivity and promise of university research, both the federal government and universities have given increased attention to ways to increase the breadth and pace of commercialization of university research. The Bayh-Dole Act and subsequent development of highly professional university technology transfer offices have greatly expanded university technology transfer, but it is clear that more can and should be done. One of the key obstacles to increasing the breadth and pace of the commercialization of university research is the so-called "valley of death," the gap between early-stage university technologies and the development of commercial products and processes that benefit the nation. Universities and their researchers do not have the resources to support the proof-of-concept work, market analysis, and mentoring often needed to move very early-stage discoveries effectively into the commercial market.

The importance of proof of concept programs has been recognized by the European Research Council (ERC), which has announced a new proof of concept funding initiative to help bridge the gap between ERC-funded research and the earliest stage of marketable innovations.[4] The Wallace H. Coulter Foundation has established a proof of concept grant program in biomedical engineering for both individual researchers and institutions.[5] Coulter program projects have generated a 5-1 overall return on investment (ROI) in new follow-on funding, and a 42-1 ROI for the top 10 percent of portfolio projects. The reauthorization of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs includes authorization of $5 million for the National Institutes of Health to implement a proof of concept program.

[2] http://www.oregonbio.org/Portals/0/docs/Education/BIO_EDU_partnership_final_report.pdf
[3] http://www.sciencecoalition.org/successstories/
[4] http://news.sciencemag.org/scienceinsider/2011/03/europe-nudges-top-scientists-to.html
[5] www.whcf.org/partnership-award/overview

The commercial potential of university research is evident from the translation of fundamental discoveries into products, processes, and companies that enhance the nation's innovative capacity and strengthen its economic competitiveness. However, the early-stage, high-risk characteristics of discoveries resulting from university basic research create special challenges for translating those discoveries into successful commercial development. The growing recognition of importance of proof of concept programs is one adaptive response to these challenges.

The same early-stage, high-risk characteristics of university discoveries that call for proof of concept programs also call for protection against the increased difficulty of licensing those discoveries that could be brought about by a broad expansion of a prior use defense.

University Research and Prior User Rights

Historically, universities have opposed the inclusion of a broad prior use defense in U.S. patent law on the basis of both principle and impact. As a matter of principle, a broad exclusion from the assertion of patent rights could vitiate the fundamental purpose of patent policy to encourage innovation by granting exclusivity for the commercial use of a patented invention in return for providing the public a full and enabling disclosure of that invention. In terms of impact, an expansive prior use defense could seriously impair the ability of universities to license their patents into the private sector for development. The early-stage, high-risk characteristics of university patents creates challenges in licensing. The prospect of an expansive and expanding pool of trade-secret products immune from the assertion of patent rights could weaken university patents and discourage private sector companies from licensing those patents.

However, over the course of the more than six-year effort to reform U.S. patent law, the university community came to recognize the importance to some private sector companies of the availability of a prior use defense to patent infringement extending beyond the limitation to business method patents. In complex products and manufacturing processes, many containing hundreds or even thousands of patented components, it may not make sense to patent every component or process. But such unpatented products or processes, often developed under trade-secret procedures, could become vulnerable to a charge of infringement from a later-granted patent on the same subject matter, threatening an entire product or process based on an unpatented component. An appropriately structured prior user rights scheme could provide legitimate protection against such a prospect.

The America Invents Act (AIA) effectively balances the concerns and interests of universities and private sector companies with respect to the availability of a prior use defense to patent infringement. The Act addresses these concerns and interests while constraining the development of a massive pool of trade secret products immune from the assertion of patent rights, as well as the prospect that such products could be derived from early disclosures of discoveries for which patent protection will later be sought.

From a university perspective, the most critical provisions of the AIA prior user rights scheme are the following:

- All university patents are exempt from the assertion of a prior use defense, save those resulting from research that could not have been conducted with federal funds.

- Because the exemption inheres in the patent, the protection against the assertion of a prior use defense extends to university licensees, thus mitigating the potential disincentive to license university patents.

- The product or process to which prior user rights may be applied must have been in commercial use at least one year before the effective filing date of a patent against which a prior use defense could be asserted; this one-year separation of commercial use from patent filing offers protection against the prospect of trade secret products being derived from disclosures and then utilized as a prior use defense.

- A product or process eligible for prior user rights must also have been in commercial use at least one year in advance of a disclosure qualifying for the one-year grace period; this provision protects early disclosure and supports the university mission to disseminate the results of research quickly and broadly.

- The one-year separation of commercial use from a patent filing or disclosure qualifying for the grace period is important for university licenses, most of which are start-up companies or small businesses. These companies need to create new technology improvements to the basic university discovery in developing useful commercial products. The one-year separation of commercial use from later patent filings and disclosures reduces the risk that a start-up or small business will be patenting new technologies for a market that includes substantial trade secret products or processes immune from the patent rights of that company. Reducing that risk encourages investment in such new technology at a sensitive early stage.

Conclusion

All countries now operate under a first-to-file system for determining patent priority, and most of these countries have some form of a prior use defense. For many in the university community, prior user rights remains a concept uncomfortably arrayed against the Constitutional and public purposes of U.S. patent law, yet there is evidence that it can promote fairness in protecting a prior commercial user against unintended infringement of a later-granted patent, reduce the pressure for defensive patenting, and provide U.S. businesses with prior use protections available to their foreign competitors in other countries.

The thorough, thoughtful "Report on the Prior User Rights Defense" produced by the USPTO concludes in part: "The recently enacted AIA incorporates a carefully crafted prior use defense consistent with the prior use defense found in many industrialized countries, with certain unique features so that [only the] parties who can prove commercial use at least one year prior to the filing date of the patent application can obtain the defense. The scope of the defense is limited in the type of activities that may be continued in relation to the original prior use activities so that the patentee's rights are not unjustly impinged."

The report recommends that the AIA prior user rights defense should maintained with no changes at the present time, but that USPTO should reevaluate the economic impacts of prior user rights as part of its 2015 report to Congress on the implementation of the AIA. We agree with these recommendations.