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Committee on Science and Technology
U.S. House of Representatives
Bayh-Dole – The Next 25 Years
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Chairman Wu, Ranking Member Gingrey, and members of the Subcommittee, it is my privilege to address you on the topic of Bayh-Dole – The Next 25 Years. My name is Susan Butts, and I am the Senior Director of External Science and Technology Programs at The Dow Chemical Company. My group oversees all of Dow's research collaborations with universities, independent laboratories, government laboratories, and government agencies around the world. Dow is the second largest chemical company in the world, and we spend over one billion dollars every year on research. Most of that funding is spent on internal programs but we also support almost 200 external sponsored research collaborations, research grants, and research consortium memberships. I am also the current Vice President of the University-Industry Demonstration Partnership, an organization operating under the auspices of the Government-University-Industry Research Roundtable which is in the National Academies.

There are three key points that I would like to make. First, although the Bayh-Dole Act has enabled the transfer of technology developed with federal funds from US universities to industry it has also contributed to a contentious climate around the issue of intellectual property (IP) rights which discourages research collaborations between industry and US universities. Second, most foreign universities, which do not have the IP expectations created by Bayh-Dole, allow industry research sponsors to own or control inventions resulting from the research that they fund. This much more favorable treatment of IP is causing companies to do more of their sponsored research abroad. Both of these trends will have an adverse impact on US competitiveness since they will diminish US-based collaborations which can generate new knowledge, technologies, and business opportunities. Third, small changes in the Bayh-Dole Act and tax regulations to clarify the intent of Congress relative to ownership or control of intellectual property resulting from industry-sponsored research could improve the climate for university-industry research partnerships in the United States.

The Bayh-Dole Act is an important and pivotal piece of legislation. It has successfully accomplished one of its primary stated purposes – to promote the commercialization of federally funded university research. There has also been, however, a negative and unintended consequence. Namely, that US universities, in stark contrast with most foreign universities, have become substantially less attractive as research partners for companies. As US universities increasingly focus on controlling intellectual property and maximizing their revenues from licensing inventions they have become more like competitors than partners to companies that sponsor research with their faculty and

students. This is occurring at a time when global scientific challenges, such as climate change, renewable energy, health, and nutrition require collaboration like never before.

In 1980 when the Bayh-Dole Act was passed the federal government was the main source of funding for research and development in the United States so research partnerships with companies were neither common nor necessary for universities. Universities published their research results and companies used the published information to assist their internal research programs. Now, however, industry spends twice as much on research and development as the federal government so industry could be a significant source of research funding for universities (Figure 1).[1] More importantly, such research collaborations would benefit the US economy by speeding the development of new products that draw on both company and university technology and capabilities. This is unlikely to happen, however, as long as companies and universities are at odds on how to treat intellectual property that comes from company-sponsored research. Although the amount of university research funding from companies has grown steadily over the last 25 years it still represents a small percentage of the total received by US universities (Figure 2).[1] In a speech given in the fall of 2006 Dr. John Marburger, Director of the Office of Science and Technology Policy, made the following observation about the necessity of looking beyond the federal government to find sufficient funding to sustain US university research: **"**More likely in the foreseeable future is an increasing intensity of competition for a large and expanding but finite federal research fund by a growing number of research capable universities… More promising is the prospect of increasing the share of research funding contributed by the states and by the private sector, particularly by industries that benefit from technologies that build on the scientific products of the universities. Unlike the Domestic Discretionary budget, the assets of the private sector do grow with GDP, and industrial investment in R&D has consequently increased much more rapidly than the federal contribution."[2]

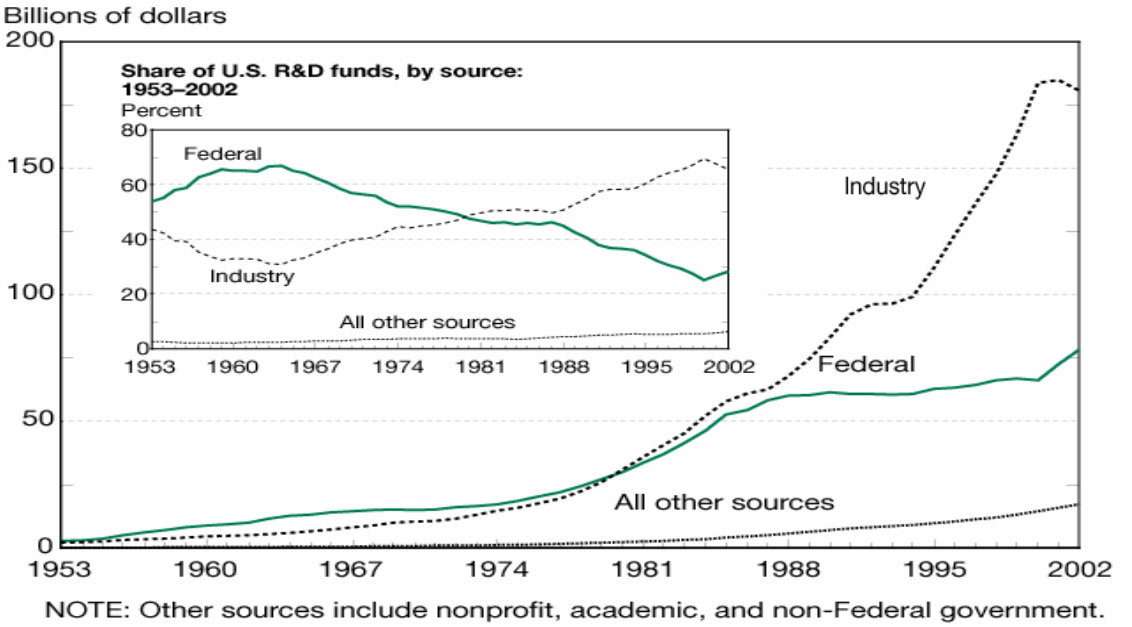


Figure 1

Funding for US University Research by Source (shown as percentage of total)

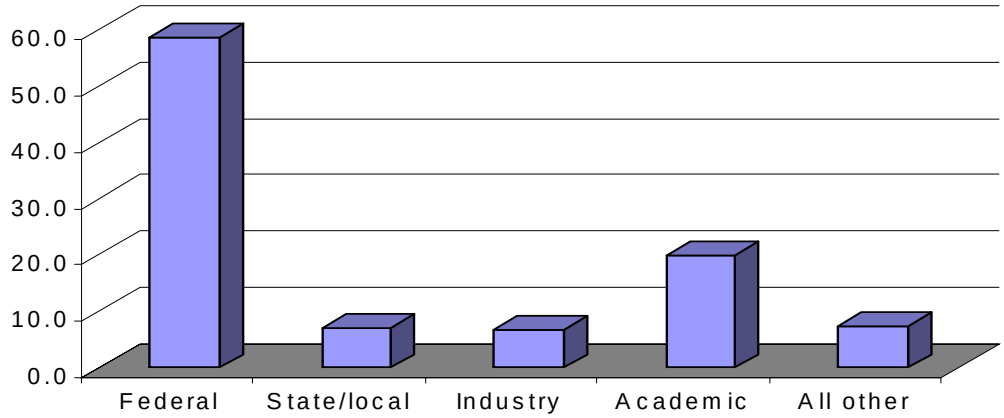
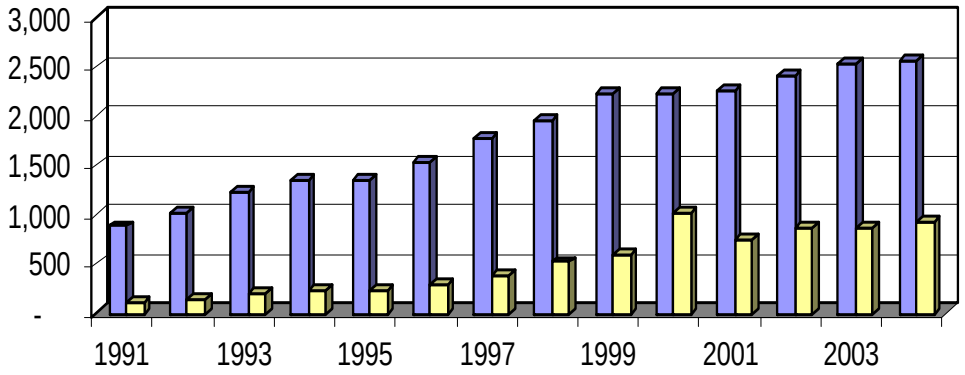


Figure 2

Impact of Bayh-Dole

Bayh-Dole recognized a fundamental reality – that companies are the primary engine for technology commercialization and the primary channel for getting new products to market for the benefit of society. Neither the government nor universities can or should fulfill those roles. So, in order to develop nascent inventions from the university and deliver them as new products to the market place companies are an essential partner. By giving universities the right to take title to inventions from federally funded research and the obligation to try to commercialize those inventions through licensing, the Bayh-Dole Act provided the legal framework to facilitate the transfer of technology from universities to industry. This has undoubtedly benefited the United States. Since universities were allowed to set licensing fees and royalties and to keep all the licensing revenue Bayh-Dole also created the expectation that universities should control intellectual property and generate income from their inventions. As financial pressures on universities have increased the prospect of filling the funding gap through licensing revenue is very attractive. However, although licensing income has grown steadily as university technology transfer offices have licensed significant numbers of inventions, the total net licensing revenues reported by universities to the Association of University Technology Managers are not sufficient to fill the research funding gap. In fact, the licensing income is only about one third of the total research funding that the same universities are receiving from industry (Figure 3).[3] Thus, it seems that the best interests of the universities will not be served by trying to increase licensing revenue at the expense of research funding from industry.

US University Licensing Revenue and Industry Research Funding (Millions of Dollars)



Key: Light bars represent net licensing revenue; Dark bars represent research funding from industry

Figure 3

Influence of Bayh-Dole on University-Industry Research Collaborations

Bayh-Dole has undoubtedly fostered some university-industry collaborations but it has had the unintended consequence of impeding many more.

Bayh-Dole has enabled licensing transactions and some new research to support the transfer of the inventions. For instance, when a company licenses a university invention that resulted from federal funding it may choose to engage the faculty inventor in follow-on research to further develop or refine the invention for commercial practice. This is more likely to happen when the licensee is a small company with limited internal research and development capabilities.

Bayh-Dole has not, however, fostered research partnerships – those in which a company is not seeking to license an existing university invention but, rather, to engage a faculty member and his or her students to perform research of interest to the company. In those research partnerships the company provides the funding for the research (including university overhead), frames the research problem, and may provide other resources to the university project such as company-generated research or testing results, proprietary technical, business or market information, non-commercial samples or prototypes, access to company facilities, and consultation with company researchers. In return, the faculty member and student(s) have an interesting real-world research problem to work on and usually the right to publish the research results. These company-sponsored projects thereby support the educational, research, and information dissemination missions of the university.

There is a fundamental difference between federally funded research and company funded research. In the former case the funding comes from tax dollars so it is reasonable to promote a use of resulting inventions in a manner that generally benefits

society. That societal benefit comes in two ways: invention licensing income provides financial support for the university and successful commercialization of inventions brings new products to the public. The university, the licensee, and tax payers all benefit. In the latter case, that of company sponsored research, the research funding comes from the company's owners or shareholders and not U.S. taxpayers in general. Company profits pay for the research investment, and company owners/shareholders expect this investment to produce a return which generally comes from a competitive advantage for its products in the market place.

US universities have taken the position that virtually all privately sponsored research is at least "touched" in some way by federal funds and, therefore, subject to the Bayh-Dole Act. By this reasoning it then follows that the university, not the sponsor, should own and control any inventions resulting from the sponsored research and that the university should be free to license these inventions as it sees fit. This very broad interpretation seems to be in conflict with both the stated intention of the act and the language of the implementing regulations. In fact, the policy and objective section of the Bayh-Dole Act lists, among others, the following two objectives: to promote collaboration between commercial concerns and nonprofit organizations, including universities and to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.[4] The section of the implementing regulation which defines its scope states: "To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology."[5]

Before beginning a company-sponsored research project the university and sponsor generally execute a research agreement that, among other things, determines how any inventions that may occur will be treated. As mentioned above US universities generally claim ownership of inventions made by their faculty and students in the course of performing research sponsored by a company. The research agreement terms typically offered by US universities give the sponsor a time-limited option to negotiate a license for the invention and require the research sponsor to pay patenting costs. The sponsor has to pay for the research and pay for the patenting without any guarantee that it can obtain a license at a reasonable cost. In fact, if the sponsor and university can not reach agreement on the value of the invention and licensing terms then the university is free to license the invention to another company, even a competitor of the research sponsor. This is indeed a "nightmare scenario" for the company sponsoring the research because, although it framed the research problem and paid for the research activity, the resulting invention could give a competitive advantage to its competitor! Because of these risks and uncertainties many companies hope that no inventions result from their sponsored

research at US universities. This is an unfortunate situation since it limits the scope of the research partnerships and the potential benefit from them, for all parties.

For industries like my own (the chemical industry) patents are critical to business success. The cost of taking an invention from concept to commercial product is very high and the probability of success is low. It is not unusual for development and commercialization to take 10 to 15 years. Construction of a world-scale chemical plant costs hundreds of millions of dollars. Products and plants have a long lifecycle. Most chemical companies are unwilling to make such a large investment unless they have the protection provided by ownership or exclusive control of the supporting product and process patents. They are also unwilling to make these investments if their licensing fees and royalty obligations make the profit margins too low.

Effects of the Increasing Globalization of Research

Global competition is an inevitable consequence of capitalism and free trade, two of the foundations of the US economy. US companies must produce products that are better or less expensive than those produced by competitors in order to stay in business. US companies also want to access to foreign markets in order to grow. These and other factors, (fast, reliable, and inexpensive global telecommunications and air travel to name a few) have led US-based companies to expand their research, manufacturing, and marketing assets abroad. This expansion leads naturally to the establishment of research partnerships with universities located in the same regions as the company's research or manufacturing facilities.

At the same time companies are finding that research partnerships with foreign universities offer a distinct advantage with regard to intellectual property use. Most foreign universities, in both the developed and developing world, readily provide the research sponsor with exclusive or controlling access to inventions resulting from the research. Such exclusivity comes through a variety of treatments of inventions ranging from outright assignment of ownership to the sponsor to joint ownership to granting of an exclusive license. In most cases, the exclusive access is provided in return for payment of the cost of the research and the cost of obtaining the patent. In some cases, the company sponsor pays an additional, modest, predetermined fee.

Figures 4 and 5 provide data to support the observation that foreign universities provide more favorable intellectual property terms to research sponsors. In 2003 Dow compared the intellectual property terms from more than one hundred sponsored research agreements between Dow and universities around the world. Figure 4 shows that in 69% of agreements with US universities the university took title to sole inventions (those made by faculty or students in the course of performing the research sponsored by Dow). In contrast, Figure 5 shows that in 85% of agreements with foreign universities sole university inventions were assigned to Dow or Dow was made a joint owner.

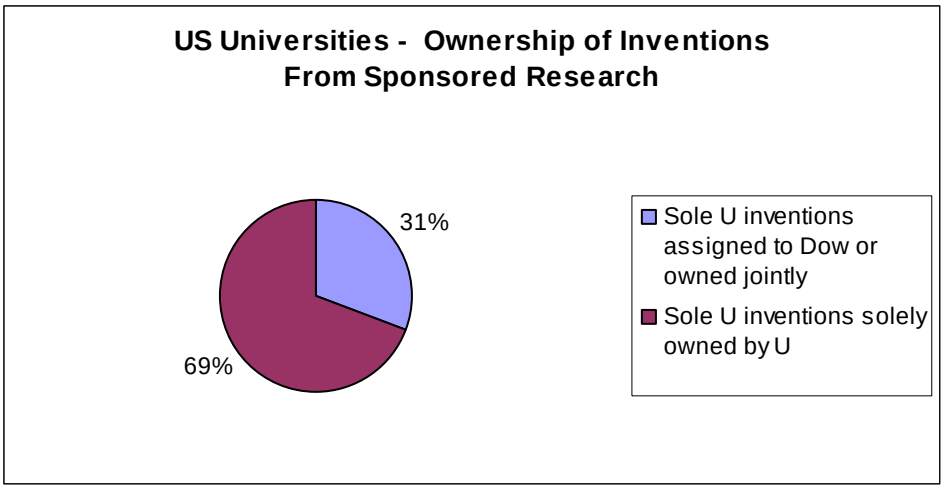


Figure 4

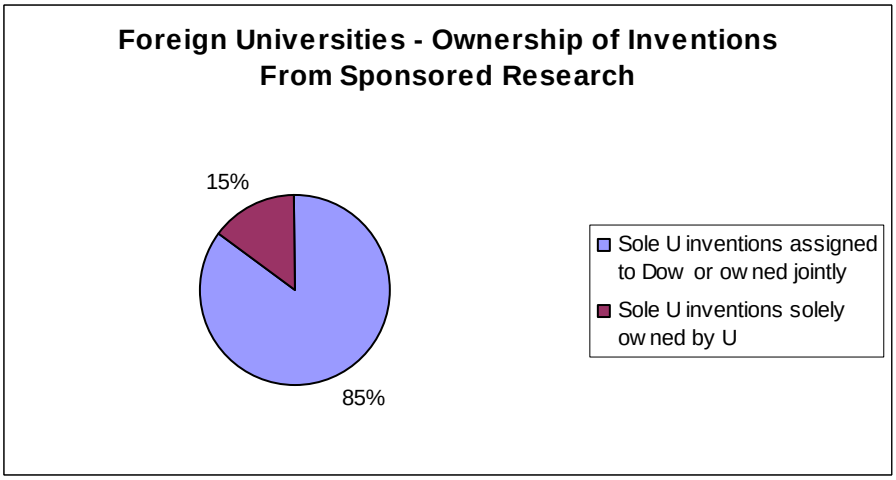


Figure 5

It has also been Dow's experience that it is much faster and easier to negotiate a research agreement with foreign universities. Not only does this allow research projects to get started in a timely manner but it also reduces the transactional costs associated with the negotiation. In 2002 Dow measured the average cycle time for executing a research agreement with US universities. We found that, on average, it took over five months from the time that the Dow researcher and faculty member finalized the research plan until both parties signed the research agreement. The most time-consuming step was negotiating the intellectual property terms. In some cases we were not able to reach an agreement, and we just walked away from the project. In contrast, when we set up agreements with universities outside the US most negotiations were quite fast and easy, being completed in a few weeks rather than many months.

The high quality of research being performed at many universities outside the US, the favorable intellectual property terms that these same institutions offer to research sponsors, and the relative speed and ease of negotiating the supporting research agreements makes it increasingly attractive for companies in the US to set up more of their research partnerships with universities abroad. At a recent meeting of the External Technology Directors Network, a working group within the Industrial Research Institute, members of the network conducted a straw poll to find out whether member companies were, indeed, increasing the amount of their sponsored research being done abroad.[6] Of the 23 companies represented at the meeting 17 responded that they are doing more of their sponsored research with foreign universities than they did in the past. Of the 17 who responded in the affirmative, 9 agreed that either better intellectual property terms and/or ease of negotiating the agreements were major reasons for their decision to do more work with foreign universities.

Influence of Bayh-Dole on Academic Collaborations and the Broad Dissemination of Knowledge

Bayh-Dole has had both positive and negative influences on academic collaborations and dissemination of information. Academic collaborations are fostered by the fact that all universities have clear and equal standing with regard to their faculty's inventions that come from collaborations in which each party receives funding directly from the federal government. The situation is more complicated when there are joint inventions or when funding flows from one university to another since each party strives to maximize its rights to intellectual property.

Perhaps the most serious impediment to academic collaboration occurs when a university fails to make research results or materials available to the rest of the research community. Material transfer agreements between institutions have become very difficult to negotiate. Some universities have elected to patent and license research tools that result from federally funded research. It is hard to make a compelling argument that society is better served by limiting access of the research community to research tools developed with federal funding. Such tools have a limited number of potential users in the research community and don't have to be commercialized in order to be useful. Patent protection is not needed because little or no investment is required to make the tools available for others to use. Putting research tools into the public domain satisfies the intent of the Bayh-Dole Act with regard to public benefit. Generating income and limiting access appear to be the main reasons for universities to patent and license research tools.[7]

Changes in Bayh-Dole Legislation Needed to Promote US Economic Development

US competitiveness and, hence, US economic development will be adversely impacted if no improvements are made in the climate for university-industry research and development partnerships. The US economic engine can not be fully engaged and functional if the three main components of the technology enterprise (Industry, Universities, and Government Laboratories) do not work together effectively to investigate science and translate technology into new products. US companies with

technology-based products will do more and more of their research collaborations with foreign universities. The potential impact on US competitiveness of such a shift is well described in the report from The National Academies, *Rising Above the Gathering Storm*.[8] Many individuals and organizations, such as the University-Industry Demonstration Partnership, are working to lower the barriers to research collaborations between universities and companies in the US but there are still some practices and expectations regarding intellectual property as well as some statutory and regulatory issues that are problematic.

The Bayh-Dole Act, largely through misinterpretation or misapplication, is offered as one of the main reason why universities must own inventions resulting from company-sponsored research and should have the freedom to license these inventions as they choose. This problem could be mitigated by the addition of language which further clarifies the intent of Congress relative to university research supported with private, rather than government, funding. In particular, clarification of circumstances under which private and federal funding of related research can exist simultaneously without Bayh-Dole rights and obligations being triggered would be very helpful. It would also be very helpful to change some of the tax code provisions, mainly Revenue Procedure 97-14 (recently superseded by Revenue Procedure 2007-47) which creates a safe harbor for universities relative to their tax-exempt bonds only as long as they do not give preference in licensing foreground inventions to an industry sponsor of research. Finally, some of the economic pressures on universities which cause them to try to maximize their licensing revenue could be relieved by raising or eliminating the federal cap on overhead rates.

Although the focus of today's hearing is on how Bayh-Dole has affected university-industry relations it is worthwhile to remember that Bayh-Dole also applies to companies that receive research funding directly from government agencies. A white paper prepared by the Integrated Dual-use Commercial Companies (IDCC) organization makes the following observations and recommendations:[9] "Several aspects of the Bayh-Dole Act represent major barriers preventing most technology rich commercial companies from even considering performing R&D with the Government when there could be laboratory developments with Government funding with significant commercial application. Some of the concerns raised regarding the Bayh-Dole Act include the inability to keep a patentable invention a trade secret, the breadth of the Government-purpose license, march-in rights, and the broad definition of "subject invention," which includes inventions conceived (and possibly even patented) prior to entering into the funding agreement, but first actually reduced to practice under the funding agreement. Other concerns are the mandatory disclosure, election and filing requirements for subject inventions, which can potentially result in forfeiture of title to the inventions if the requirements are not timely followed. An additional concern is the Preference for US Industry requirement, which prohibits the contractor from granting an exclusive license to use or sell a subject invention in the US unless the licensee agrees that any product embodying the subject invention will be substantially manufactured in the US. These concerns have resulted in recommendations from both Government and industry that they be addressed."[10]

"Most of these industry concerns could be simply addressed by amending Section 35 U.S.C. § 210(c) to provide that if a funding agreement is made with a contractor that is subject to the Bayh-Dole Act (35 U.S.C. §§ 200-212), any rights of the Government or obligations of the contractor relating to patents described in 35 U.S.C. §§ 202-204, may be negotiated between the Government and the contractor to reduce such Government rights or contractor obligations, if the head of the contracting activity determines that the interest of the Government and the general public will be served thereby. This same right to negotiate reduced Government rights or reduced contractor obligations relating to patents would apply to those contractors that are large businesses and that are subject to the Statement of Government Patent Policy issued on February 18, 1983."[11]

In summary, the Bayh-Dole Act is an important piece of legislation that has produced many benefits. The unintended negative impact on research collaborations involving industry, universities and government can be mitigated through relatively minor changes in the law and related regulations.

References and Notes

1. National Science Board, *Science and Engineering Indicators 2004*, published by the National Science Foundation.
2. J. Marburger in a speech to the Council on Governmental Relations, Washington, D.C., October 26, 2006 on the topic of *Emerging Issues in Science and Technology Policy*.
3. From data in the *AUTM Licensing Survey – Fiscal Year 2004*, published by the Association of University Technology Managers.
4. See 35 U.S.C. § 200.
5. See 37 C.F.R 401.
6. From a meeting of the Industrial Research Institute (IRI)-External Technology Directors Network (ETDN), Fort Lauderdale, FL, April 19-20, 2007.
7. See, for example, R. Eisenberg, *Science*, **299**, 1018-1019 (2003).
8. N. Augustine et al, *Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future*, The National Academies (2005).
9. IDCC, Integrated Dual-use Commercial Companies, was formed in 1991 by major commercial firms dedicated to improving the efficiency and effectiveness of Federal government procurement and R&D interaction with commercial firms. For additional information on IDCC see www.idcc.org.
10. See Diane M. Sidebottom, *Updating the Bayh-Dole Act: Keeping the Federal Government on the Cutting Edge*, 30 Pub. Cont. L. J. 225 (Winter 2001); Richard N. Kuyath, *Barriers to Federal Procurement: Patent Rights*, 36 the Procurement Lawyer I (Fall 2000). Diane M. Sidebottom, *Intellectual Property in Federal Government Contracts: The Past, The Present, and One Possible Future*, 33 Pub. Cont. L. J. 63 (Fall 2003).
11. Corresponding changes for large business concerns would need to be made to the organic patent statutes applicable to DOE and NASA, 42 U.S.C. 2011, et seq. (DOE), 42 U.S.C. 5901-5915 (DOE), 42 U.S.C. 2451-2459 (NASA).and 42 U.S.C. 2471-2476 (NASA).