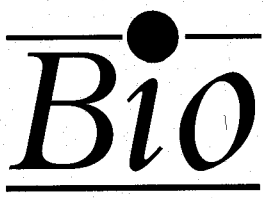

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

BIOTECHNOLOGY INDUSTRY ORGANIZATION
ON
BAYH-DOLE AND TECHNOLOGY TRANSFER
BEFORE THE
PRESIDENT'S COUNCIL ON SCIENCE AND TECHNOLOGY
OFFICE OF SCIENCE AND TECHNOLOGY POLICY

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SUMMARY

The biotechnology industry is the most research and development intensive and capital-focused industry in the world. The United States currently leads the world in the area of biotechnology because U.S. patent laws and legislation such as the Bayh-Dole Act have provided favorable incentives to mitigate the high risks. The biotechnology industry relies on the protections afforded by the patent laws and on the opportunity to exclusively license discoveries from academic partners through the mechanisms established in the Bayh-Dole Act. Without these protections and incentives, many life-saving discoveries would not have been realized. Prior to the Bayh-Dole legislation, federally funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public. There was little incentive for businesses to undertake the financial risk to develop a product. The result was that only 5% of NIH-funded discoveries ever led to new or improved products. The change in policy affected by Bayh-Dole dramatically stimulated the commercialization of federal government-supported research, resulting in important new therapeutics and the wide array of diagnostic testing options available to the medical community today.

The United States leads the world in the area of biotechnology and patents. It is the bedrock for the entire world of biomedical research. Over 50% of total G-7 medical R&D investment is now made in the U.S. No other industry spends more on research and development per employee than biotechnology. Furthermore, no industry faces a lengthier or more complex regulatory process before bringing its products to market than the biotechnology industry. Continued strong intellectual property protection and favorable licensing opportunities are critical incentives if the United States is to maintain its lead.

BIO and the Biotechnology Industry

The Biotechnology Industry Organization (BIO) is a trade association of more than 1,000 companies, universities, research institutions, and affiliated organizations worldwide. BIO members are engaged in biotechnology research on medicines, diagnostics, agriculture, and environmental and industrial applications. BIO represents an industry that has already provided more than 250 million people with benefits from more than 130 commercially approved drugs, biologics and vaccines. [i/] More than 75 percent of these medicines have been approved in the past six years. There are more than 350 biotech drug products and vaccines in late-stage clinical trials to treat more than 200 diseases, including various cancers, AIDS, Alzheimer's disease, heart disease, diabetes, multiple sclerosis and arthritis. In addition, biotechnology companies and researchers are responsible for the development of hundreds of medical diagnostic tests, many biotechnology-derived foods, environmental products and other industrial products. [ii/]

There are over 1,300 biotechnology companies in the United States, of which about 25 percent are publicly traded. [iii/] The revenue of these companies was about $25 billion in 2000 and the market capitalization of the industry topped $350 billion in mid-2000, although it is somewhat lower today. This research-intensive industry spent $13.8 billion on R&D in 2000, with the top five companies spending an average of $89,400 per employee on R&D. This intensity in R&D spending is more than double the average of the pharmaceutical industry (both on a per-employee basis and as a percentage of sales), and the pharmaceutical industry is several times more R&D intensive than any other industry.

The biotechnology industry is also a dynamic one. According to an economic impact report by BIO and Ernst & Young, the industry doubled in size between 1993 and 1999. In 1999, biotechnology supported 437,000 U. S. jobs, including 150,800 direct jobs. The industry recorded revenues that year of about $20 billion, and additional revenues for companies supplying inputs or selling goods to the industry totaled $27 billion. The industry as a whole is not yet profitable, yet biotechnology companies make tax payments of about $10 billion per year, including income, corporate and other federal, state and local taxes. [iv/]

Before generating its first dollar of product revenue, a biotechnology company typically spends more than $500 million over the course of 10 to 14 years. And such companies are the rare few that actually get products approved by the FDA. This research and development profile is unsustainable without patent protection and the opportunity to exclusively license discoveries from academic partners through the mechanisms provided for in the Bayh-Dole Act.

Since the enactment of Bayh-Dole, technology partnerships have led to the founding of more than 1,100 companies based on NIH and university research. These technology partnerships and the patents on which they are based are particularly important to small biotechnology companies, which focus their research on breakthrough technologies that arise from basic biomedical research. Such companies must have strong patent protection to justify the risk of investing in early-stage, unproven ideas. With no revenue from product sales to fund research, most of these firms depend on venture capital and public market investors.

The biotechnology industry continues to lose $5.8 billion per year. Of the over 1,300 companies, only 15 have profitable biologics on the market. Ours continues to be a high-risk, long-term investment sector that has an extraordinarily high rate of failure. Most research licensed from universities is still "early stage" research with no guarantee of success. Failures vastly outnumber successes in this entrepreneurial industry. Balancing these risks are the exclusive licenses provided through the Bayh-Dole Act and the knowledge that, if the research ultimately leads to a marketable product, patent protections will apply.

Some companies look to license research tools rather than discoveries, such as new compounds, that could lead directly to new medicines. These tools may provide a method or a portion of the process for discovering or producing a therapy, but are not a part of the treatment itself. They, too, are not guaranteed to be successful, but the incentive of patent protections makes the benefits from the few successes worth the risks of the greater number of failures.

Bayh-Dole agreements have succeeded in transferring NIH-supported research to the private sector for applied research. In 1980, there were approximately 25 to 30 universities engaged in technology transfer; by 1992, there were 200[v]. Several universities have done well with the royalties paid by companies that have succeeded. Based on an estimate of a 4% royalty, the billions of dollars in product sales represent hundreds of millions in fees to the universities. Companies paid $390 million in royalties and $725 million in license fees to U.S. universities on nearly 7,500 licenses/options in 1998 (according to AUTM's FY 98 Survey Summary). These revenues have spurred greater technology transfer activity. Not only is the science developed further, which may lead to new products, but a portion of the fees and royalties paid to universities gets turned back into additional research, giving a double bang to the government for the appropriated buck, and greater opportunity for future technology transfer.

Without the Bayh-Dole Act, few licensing agreements would be executed between private companies and federally supported research institutions, and the enormous investment our government makes in medical research would be wasted. Note that President Bush has fulfilled his promise to offer a budget completing the five-year doubling of NIH appropriations by FY 2003. But what good is all this research and government financial support if the technologies that arise sit on the shelf undeveloped into potential cures and treatments for diseases?

During the 1990's, two issues, addressed by the Bayh-Dole Act or the Senators themselves in discussing the Act, arose out of public policy initiatives coming out of the White House. The first issue was price controls and was offered for consideration during the Clinton health care reform discussions. The impact and results of a potential price control plan on the biotechnology industry was immediate and powerful. The capital markets crashed and investment nearly dried up for two full years.

A similar result occurred in 1999 when President Clinton was misquoted in the press as opposing gene patents at the time the human genome was "unraveled." Despite a clear correction by the President the next day, it took six months for the biotechnology capital markets to recover.

In both cases, a threat to free-market protection of intellectual property drove investors away from biotechnology and research. The Bayh-Dole Act was designed allow for the protection of intellectual property and patents in order to provide incentive to develop government funded basic research into more applied applications. Changes in public policy can and will have a direct impact on the success of that goal. Attempts to add reasonable price clauses, linking the government's return on investment only to dollars returned, or barring or limiting exclusive licensing are all public policy changes that will directly drive away biotechnology companies from utilizing government research to better the health of all Americans.

The Purpose of Patents

The primary purpose of patents is to offer a limited period of exclusivity [vi/] and an appropriately circumscribed scope of protection against commercial use of an invention by a third party, thereby protecting against the "free riding" that would sap the incentive to innovate. [vii/] The patent system also assures that inventions will eventually be publicly disseminated. Patents are granted for a limited period of time (20 years from filing), and once the patent expires, the

subject matter of the patent enters the public domain. Once an invention is in the public domain it may be freely used by anyone. In addition, the patent system promotes scientific progress by offering valuable additions to the existing art in the field. This is especially true now that patent applications must be published within 18 months after filing. The existence of patents actually can foster competition [viii/] by pointing potential competitors toward a way to invent around a patent or invent improvements to the patent subject matter. [ix/]

As the President's Council of Economic Advisors put it in the recently issued Economic Report of the President:[x/]

> "[I]n many cases, firms or individuals might not embark on developing an innovation because, although the social benefit from it may be large enough to justify its development costs, the firm or individual could not expect to reap enough of that benefit to justify those costs. The consequences of this problem were recognized in the U.S. Constitution, which empowered Congress to develop a body of intellectual property laws, including those establishing patents. A patent for an invention confers on an individual or firm (the patent holder) limited rights to exclude others from making, selling, or using the invention without the patent holder's consent. Patents generally are granted for 20 years, and as the rights they provide imply, the patent holder can license to other individuals or firms the right to use its innovation. Patents give a firm the legal power to keep others from using its innovation to create competing products without bearing the cost of the innovation. Licensing provides a means whereby the innovator can receive compensation, in the form of licensing fees, from others that find a beneficial use for the innovation. Thus policy has long recognized that, to encourage innovation, firms must expect that successful innovations will yield a market position that allows them to earn profits adequate to compensate for the risk and cost of their efforts."

Patents provide the shield for commercialization ventures. Innovation leading to patent protection often occurs early in biotechnology R&D process, but there is substantial lag time to the actual marketing of the patented product. Often times the inventor in a biotech patent is a university researcher on whose behalf the university licenses the invention for commercialization to private sector. The patent that is procured serves the purpose of shielding both the university and private sector partner throughout commercialization process. Patent protection is critical throughout the entire commercialization time line of biotechnology products. Commercialization requires applied research, business strategy, marketing, product support and other variables that are not in mandate of university or federal government and therefore best carried out by the private sector. Failure to commercialize can result from any or several of the above-mentioned variables.

Patents also play a significant role in investment of capital in the biotechnology markets. Investors measure opportunities in the biopharmaceutical and pharmaceutical sector through potential sales of drug/product, the market exclusivity prospect through patent, marketing exclusivity, orphan drug exclusivity or other means and strength and predictability of patent protection.

The major policy objective of the Bayh-Dole act is to use the patent system to promote the utilization of inventions arising from federally supported research or development. One of the key provisions of Bayh-Dole is the right of the patent owner to exclusively or selectively license patent rights. For the biotechnology industry the lure of market exclusivity serves as the incentive to work in cooperation with public institutions. Companies understand that the primary obligation they have under Bayh-Dole is to *commercialize* the licensed technology. The statute provides that failure to commercialize a licensed federally funded invention, or a license requirement for public non-commercial use or failure to meet a health need can be the basis for government March-in rights.

CONCLUSION

The Office of Science and Technology Policy is to be congratulated for undertaking this examination of the benefits of Bayh-Dole. BIO appreciates the opportunity to have appeared before you to describe the nature of the industry and its contributions to the improvement of the human condition. BIO's members are strong supporters of the Bayh-Dole Act, which has opened the door to the creation of many biotechnology companies that have developed important advances in treatment and diagnosis of disease and are in the process of developing the medicines and diagnostics of the future. We caution that policies that suggest that private sector participant in B-D commercialization project may lose market exclusivity through government directed revocation of patent rights destroys capacity to guarantee market exclusivity that is precondition to investment community participation. We can point to lessons learned in the 1990's in studying the Bayh-Dole Act. First, the threat of "reasonable pricing" or other conditions on federal funding will inevitably lead industry away from the source of funding. Second, strings attached to federal dollars add an intolerable new risk factor in an already risky environment, as is the case for biotechnology endeavors. BIO enthusiastically applauds Congress and the Administration for their farsighted approach to healthcare by enactment and effective implementation of the Bayh-Dole Act.

ENDNOTES

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i/ Facts about the biotechnology industry are derived from data compiled by (BIO) *at* <www.bio.org/er/statistics.asp>.

ii/ Kenneth I. Shine, President, Institute of Medicine, "Welcome," *in* National Research Council, *Serving Science and Society in the New Millennium*. Washington, D.C.: Nat'l Academy Press, 1998. (proclaiming that, whereas "the 20th century will be known as the century of physics and astronomy … [b]ut the 21st century will be the century of the life sciences in all their ramifications.").

iii/ In 1994, approximately 70% of U.S. biotech companies were less than 15 years old. *See* National Science Board, "Science and Engineering Indicators – 1996" at 6-28.

iv/ For additional details about the industry and its economic contributions to the United States, *see* Ernst and Young Economics Consulting & Quantitative Analysis, *The Economic Contributions of the Biotechnology Industry to the U.S. Economy*, (May 2000), *available at* <www.bio.org/news/ernstyoung.pdf>. Most biotechnology companies are small; more than two thirds of them employ fewer than 135 workers. BIO, "The United States Is The World's Leader in Biotechnology," available at <www.bio.org.laws.legis2.html>.

v (Association of University Technology Managers (AUTM) informal survey)

vi/ Economic Report of the President, February 2002, p. 133, *available at* <http://w3.access.gpo.gov/usbudget/fy2003/pdf/2002_erp.pdf>.

As one commentator put it, "[i]nvention is an uncertain business," and "[t]o spur investment in it, inventors must be reasonably assured that they will be able to recoup their costs and earn a profit." Rochelle Cooper Dreyfuss, "Dethroning Lear: Licensee Estoppel and the Incentive to Innovate," 72 *Va. L. Rev.* 677, 679 (May 1986).

vii/ Among other things: (1) intellectual property is easier to misappropriate than other forms of property; (2) a patent grants the owner a power of exclusion that, in some respects, exceeds the powers that attach to tangible property; (3) the fixed costs are typically higher and the marginal costs lower than other forms of property; (4) to commercialize a product and earn a return, a larger number of complementary inputs with some degree of market power often must be brought together; and (5) the boundaries of intellectual property defy accurate survey to a much greater extent than do those of tangible property. Richard J. Gilbert and William K. Tom, "Is Innovation King at the Antitrust Agencies?: The Intellectual Property Guidelines Five Years Later, "69 *Antitrust L. J.* 43 n.8 (2001).

Without the reward of a patent and the right of exclusive use that it confers, "firms have weak incentives to absorb the costly expenditures needed to develop intellectual property." Abbott, Alden F. "Developing a Framework for Intellectual Property Protection to Advance Innovation." *Intellectual Property Rights in Science, Technology and Economic Performance: International* Comparisons Eds., Francis W. Rushing & Carole G. Brown. Boulder: Westview Press, 1990. 317. Firms "run the risk that . . . their innovations w[ill] earn insufficient profits to offset the losses stemming from failed research efforts," and that "capital markets w[ill] be far less willing to provide funds for independent research efforts." *Id.* at 321.

One scholar offers an interesting rationale for the Intellectual Property Clause by asserting that it offered a "perfect solution to encouraging the progress of science and useful arts with the least expense." Edward Walterscheid, "To Promote the Progress of Science and the Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution," 2 *J. Intell. Prop. L.* 1, 34 (1994). The alternative of direct government support for promoting science was not possible for a small and "impecunious national government." *Id. at 34-35. Bauer & Cie v. O'Donnell*, 229 U.S. 1, 10 (1913)(the patent system is based on rewarding and protecting invention). *See generally*, Robert P. Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation," *76 Cal. L. Rev.* 803 (July 1988).

viii/ The patent system fosters innovation and investment in research and development through what the U.S. Supreme Court has described as "a carefully crafted bargain." *Bonito Boats, Inc. v.*

Thunder Craft Boats, Inc., 489 U.S. 141, 150-151 (1989). In exchange for "disclosure and the consequent benefit to the community," the law gives inventors exclusive rights to practice their inventions for a limited period of time. *Id*.

ix/ *See, e.g., Yarway Corp. v. Ever-Control USA, Inc.,* 775 F.2d 268 (Fed. Cir. 1985) (discussing the laudable goal of designing around patents and that such is evidence of good faith in instances where an infringer is charged with bad faith copying). *See also State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("One of the benefits of a patent system is its so-called "negative incentive" to "design around" a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace."); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999), *and cases cited therein*.

x/ Economic Report of the President, February 2002, *available at* <http://w3.access.gpo.gov/usbudget/fy2003/pdf/2002_erp.pdf>.