BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

May 25, 2010

James Kohlenberger
Chief of Staff
Office of Science and Technology Policy

Diana Farrell
Deputy Assistant to the President for Economic Policy
National Economic Council

Re: Request for Information: Commercialization of University Research
Email: NECGeneral@who.eop.gov

Dear Mr. Kohlenberger and Ms. Farrell:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to the Request for Information issued by the Office of Science and Technology Policy and the National Economic Council on Commercialization of University Research. BIO is a trade association representing over 1,200 companies, academic centers and research institutions who are involved in the research and development of innovative biotechnology products and services. Our members are primarily small and medium enterprises working to develop and commercialize products in the area of healthcare, agriculture and the environment. Since its inception roughly 30 years ago, the biotechnology industry has spurred the creation of 7.5 million direct and indirect jobs in the United States and hundreds of innovative products that are helping to heal, feed, and fuel the world. In the healthcare sector alone, the industry has developed and commercialized more than 300 biotechnology drugs and hundreds of diagnostics that are helping more than 325 million people worldwide; another 400 or so biotechnology products are in the pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land water and nutrients, and increasing farm income. Biotechnology companies are also leading the way in creating alternative fuels from renewable sources without compromising the environment.

But we have yet to scratch the surface of the tremendous innovative potential that exists within the industry. By its very nature, and because it has sprung from early-stage/hypothesis-driven research laboratories, the biotechnology industry is highly innovative – and thus very risky. Biotechnology researchers work every day to identify the causes and treatments for some of the world's most intractable diseases, such as cancer, Alzheimer's, Parkinson's, diabetes, and HIV/AIDS, and to address some of the most pressing agricultural and environmental challenges facing our society over the short and long term. Developing biotechnology discoveries into

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products for the public is, even under the best of circumstances, a time-, risk-, and capital-intensive endeavor. However, today's economic and investment climate has only served to exacerbate this difficult process. It is precisely for this reason that our members are keenly interested in this Request for Information, which we hope will provide you with the input necessary to help create an environment conducive to risk-taking and one that will unleash the tremendous potential of biotechnology.

What follows provides the general view of the biotechnology industry regarding the two questions set forth by the Request for Information: 1) whether Proof of Concept Centers (POCC) can be a means of stimulating the commercialization of early-stage technologies by bridging the "valley of death"; and 2) how to further enhance commercialization of university research.

We appreciate the opportunity to provide our views on this important topic. Please do not hesitate to contact myself or Lila Feisee, Vice President, Global Intellectual Property Policy, at 202-962-9200, for additional information.

Sincerely,

Jim Greenwood

James C. Greenwood
President and CEO

Comments of
The Biotechnology Industry Organization (BIO)

To the Office of Science and Technology Policy &
The National Economic Council on the
Commercialization of University Research

May 25, 2010

INTRODUCTION

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to the Request for Information issued by the Office of Science and Technology Policy and the National Economic Council seeking comments on, first, whether Proof of Concept Centers (POCC) can be a means for stimulating commercialization or early-stage research and, second, how to further enhance commercialization of university research. To fully appreciate the answers to the questions set forth from a biotechnology perspective, it is necessary to clearly understand the nature of the biotechnology enterprise. Biotechnology research and development is extremely risky and capital intensive. It is generally acknowledged that it takes more than a decade and costs on average $1.2 billion[1] to bring a biotechnology therapy to market. The industry is replete with anecdotes of meticulous, lengthy and expensive experiments that have failed. It is estimated that for every successful medicine, 9,999 experimental compounds never make it to market.[2]

Furthermore, biotechnology R&D largely relies on a series of complex relationships among actors within the life sciences community, including venture capital. It is often in university laboratories that exciting discoveries are initially made. Researchers might, for example, identify the correlation of a particular DNA or protein with a particular disease state. They then work through their university technology transfer offices to patent their discoveries, and to find an appropriate partner or partners to develop and commercialize the numerous potential products or technologies that could be built off these initial discoveries. Most of these discoveries are early stage and require lengthy additional research and development, as noted above, which in turn requires a massive infusion of private capital. These partners often are small start-ups, backed by venture capital.

All of this activity takes place with no guarantees that these initial discoveries will ever lead to safe, effective, and commercially viable products. Accordingly, policies and programs that help reduce the risk companies must endure will help to stimulate investment and commercialization. In particular, policies that encourage full funding of basic research, predictability of patents, and flexible technology transfer, and that provide early-stage funding opportunities and incentives, will serve to stimulate biotechnology innovation.

Proof of Concept Centers (POCC)

While BIO is open to creative means of stimulating commercialization, it is important to recognize at the outset that there is no single approach that will work across the board in all of the complex and differing biotech R&D scenarios. Proof of Concept Centers (POCCs), whatever their benefits may be, will not be a panacea for the life sciences sector. Indeed, those that exist today seem to be focused on information technology projects. Although they appear to have

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[1] Grabowski, Henry. "Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition" *Nature* 7 June 2008 Pg 482
http://www.nature.com/nrd/journal/v7/n6/full/nrd2532.html

[2] Ernst & Young report, Beyond Borders 2002

worked fairly well in the high-tech sector where the upfront expense and time for demonstrating proof of concept is significantly less than what is required in the life sciences sector, their success is not necessarily replicable under different conditions. The biotechnology enterprise, across all of its sectors, is more amenable to the availability of a well-capitalized fund similar to the recently-enacted Cures Acceleration Network, or a model based on the successful In-Q-Tel program that has proven successful in the development of strategic technologies in other fields, both of which will be discussed later in this document. Accordingly, BIO urges OSTP to avoid focusing too intently on any one commercialization model, and instead explore how best to support a proliferation of different models that might prove more successful across a broader range of technologies and R&D situations.

In this regard, OSTP should look to the States, where there are many examples of ways that job creation is being stimulated through commercialization of life sciences research. A 2008 report conducted by Battelle[3] has many examples of successful models that can be further supported through sound policies and funding. This report will be updated in May 2010. A preview of some examples include the Ben Franklin Partnership at http://benfranklin.org/ , San Diego CONNECT at www.connect.org, Colorado Advancement of New Bioscience Discoveries Initiative, and the Kansas Bioscience Initiative, http://www.kansasbio.org/news/events/07presskit/kansasbioscienceiniativesheet.pdf. Each of these initiatives touches on areas where the life sciences sector needs support in order to further commercialization activities, such as assisting small biotech companies in finding investment and partnership opportunities.

BIO's Views on Ways to Enhance Commercialization of University Research

Preserve the strength and predictability of the patent system that fuels the innovative process.

The United States currently leads the world in biotechnology in large part because of the strength and breadth of its patent system. The biotechnology industry pinpoints its modern origin to two seminal events that occurred in 1980: The passage of the Bayh-Dole Act and the landmark Supreme Court decision of *Diamond v. Chakrabarty*. By allowing universities and research institutions to patent and retain title to their inventions, and allowing flexibility in licensing without excessive government intervention, the Bayh-Dole Act provided the necessary foundation for technology transfer, and provided the incentives for the private sector to further develop and ultimately commercialize the fruits of publicly-sponsored research. And the Supreme Court decision in *Chakrabarty* opened the door for the patenting of key biotechnology inventions, including those arising from biological materials and living organisms.
As a result of these two events, the United States has experienced an incredible wave of biotech innovation for the benefit of society, including, among other things, the commercialization of hundreds of innovative therapeutics, diagnostics and research tools, industrial processes,

[3] Battelle/BIO State Bioscience Initiatives, June 2010.
http://www.bio.org/local/battelle2010/Battelle_Report_2010.pdf

renewable fuels, and agricultural products, as well as the millions of new, high-paying American jobs resulting therefrom. Today, there are efforts to roll back and perhaps eliminate the very patents that helped to spur an entire new sector of the U.S. economy. Decisions such as that recently issued in a New York federal district court[4] invalidating so-called "gene patents" may call into question the very foundation of biotech patents, and in so doing may jeopardize the United States' leadership position and global competitive advantage. In an industry where it can take decades and hundreds of millions of dollars to move from invention to market, the very instrument for enticing risk-taking – a strong patent portfolio – may now become undermined, at the very time when other nations around the globe are striving to become the next biotech hub. BIO cautions against any effort that would weaken U.S. patent protections for biotech inventions. BIO urges Congress and the Administration to defend the broad eligibility parameters of current patent law, and to permit the Patent & Trademark Office (PTO) to raise – and keep – the fees necessary for the timely issuance of patents upon which our innovative society is built.

Maintain the flexibilities that exist under Bayh-Dole and provide greater support for university technology transfer offices.

The Milken Institute, in a 2006 report entitled "Mind-to-Market: A Global Analysis of University Biotechnology Technology Transfer and Commercialization,"[5] identified five key factors that contribute to the successful commercialization of university biotechnology research: a consistent and transparent national innovation policy that recognizes intellectual property protection and promotes entrepreneurial capitalism; the availability of funding and venture capital; biotechnology clusters not restricted by geographic borders; robust university technology transfer mechanisms; and the availability of patents and flexible licensing arrangements.
A more recent study[6] showed that university research in conjunction with industry partnerships as facilitated by the Bayh-Dole Act has led to the development and approval of 153 new drugs, vaccines or in-vivo diagnostics, 36 of which were Orphan Drugs for rare diseases, and most of which were developed by small or start-up companies. Estimated U.S. sales of the resulting products are $39.6 billion and $100 billion worldwide. These facts stand in stark contrast to the situation prior to enactment of Bayh-Dole, when Congress could not uncover a single instance of federally-funded research leading to the development of a new therapy or cure.[7]

Another recent report[8] about the economic impact of university licensing under Bayh-Dole, commissioned by BIO and evaluating only the period from 1996 to 2007, shows that these university/industry partnerships contributed as much as $186 billion to the Gross Domestic

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[4] *Association for Molecular Pathology v. United States Patent and Trademark Office*, Southern District of New York, March 29, 2010.
[5] Mind to Market Study. http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=576&cat=ResRep
[6] Jonathan Jensen et al. "The Contribution of public Sector Research to the Discovery of New Drugs", presented at BIO Technology Transfer Symposium Oct 28, 2009.
[7] "The University and Small Business Patent Procedures Act" Report of the Committee on the Judiciary, U.S. Senate on S. 414 Dec. 12, 1979 Rep No. 96-480, p. 21.
[8] David Roessner et al. " The Economic Impact of Licensed Commercialized inventions Originating in University Research, 1996-2007, Sept. 3, 2009.

Product, added $457 billion to U.S. Industrial Output, and created more than 279,000 new jobs throughout the United States. BIO also recently surveyed its membership about the importance of university technology transfer[9]. The findings are interesting:

- 50% of BIO companies were founded on in-licensed technologies
- 76% of BIO members in-license university inventions
- 58% of BIO companies *had fewer than 10 employees* before obtaining their first technology license. Two to five years later, 80% had more than 10 employees.
- Approximately 77% say it is "extremely important" or "very important" that they can obtain exclusive licenses for their commercial product development plans.

The U.S. system of commercializing scientific discoveries has made it the world leader in the area of biotechnology in large measure because it takes into account the factors identified by the Milken Report. However, this was not always the case. Indeed, rapid commercialization of scientific discovery did not fully come about until the enactment of the Bayh-Dole Act in 1980. Prior to enactment of this legislation, publicly-funded research was owned by the government and offered for licensing on a non-exclusive basis or simply dedicated to the public. As a result, there was little incentive for business to undertake the financial risk to take these inventions and develop them into commercial products. Prior to Bayh-Dole, only 4% of the patents that resulted from federally-funded research were commercialized (cite). Since Bayh-Dole, not only has the volume of invention resulting from federally-funded research increased enormously, but also the percentage of those inventions being commercialized has increased 10-fold to around 50%. For instance, in 2005, 17,382 inventions were disclosed, 10,270 new patent applications were filed (59%) and 4,932 licenses and options were granted (48% of new patent applications filed). The total pipeline of active licenses from all the years up to and including 2005 is more than 28,000.[10]

The U.S. system of transferring federally-funded research to private companies for research and development as set forth in the Bayh-Dole Act has been so successful that it has become a template for innovation and economic development for other enterprising countries such as South Africa, India and China. The Milken Report shows that, while universities in the United States have clearly set the standard in commercializing research, other countries, particularly in Europe and Asia, have recognized the role of universities in spurring the biotechnology industry. The study suggests that, in order for the U.S. to maintain its leadership in innovation, it must continue to fund research and university technology transfer offices, encourage the transfer of innovative research to the private sector, and ensure strong intellectual property protection. BIO agrees with this assessment, and would urge OSTP to focus on ways to strengthen technology transfer offices through increased funding, training, and information sharing.

Restore the eligibility of small, venture-backed biotech companies for the Federal SBIR program.

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[9] BIO Member Licensing Survey--http://bio.org/ip/techtransfer/documents/Session2-Esham.pdf, Oct. 2009
[10] AUTM U.S. Licensing Survey, FY 2005; www.autm.net

Biotech firms typically have less than 50 employees, no product on the market, and rely heavily on a combination of angel investors and venture capital firms in order to raise the considerable funds necessary to make a new therapy or cure commercially available to patients. One of the greatest obstacles in the innovative process, especially in today's economic environment, is the ready availability of capital. Because biotechnology R&D is risky, investors are reluctant to invest significant funds into companies or research projects that are very early in the development phase. It is here that the Federal government can be of assistance in the biotechnology innovation process. The role of the Small Business Innovation Research (SBIR) program in bringing breakthrough therapies to the American people is a matter of record. In 2008, there were 252 FDA-approved biologics that were developed by 163 companies. Thirty-two percent of those companies have received at least one SBIR/STTR award. Despite its noble past, the ability of the SBIR program to provide critical funding for medical research projects will remain hampered unless the SBIR program is reauthorized in a way that restores eligibility for the vast majority of small U.S. biotechnology companies.

Congress created the SBIR program in the early 1980s because it recognized that promising, early-stage scientific research all too often failed to be funded through the markets because it was viewed as too high risk. This failure of the markets is often referred to as the "valley of death."

Advancing science through the valley of death has never been more important than it is right now, as numerous small biotechnology companies are being forced to shelve promising therapies as a result of the current economic crisis and restrictive capital market. The impact of the current economic crises on small biotechnology companies has been and continues to be severe. In fact, since 2008, at least 47 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV/AIDS, cervical cancer, multiple sclerosis, and diabetes. According to the latest available data, 24 percent of small, publicly-traded biotechnology companies are now operating with less than six months of cash on hand, and 38 percent of these companies have less than one year of cash remaining. The total capital raised by the industry saw a 25 percent decline between 2007 and 2009, with venture capital funding dropping 30 percent.

The "valley of death" issues facing small biotech companies have always been challenging, and will continue to be so. However, in one particular area, this was not always the case. For 20 years, small domestic biotechnology companies competed for and often won SBIR grants. In addition to providing funding, these grants were a powerful signal to the private sector that a company's research was compelling and possessed scientific and technical merit, fueling matching private resources. However, in 2003 the Small Business Administration's Office of Hearings and Appeals (OHA) ruled that a biotechnology company, Cognetix, did not meet SBIR eligibility requirements because multiple venture capital investors, in the aggregate, owned more than 50% of the company's stock. The ruling, which is not based on the SBIR statutory language but rather a narrow interpretation of agency regulations, has made the SBIR program off-limits to a wide swath of the biotech industry, and ignores the realities of the marketplace in which small biotechnology firms often must rely on multiple sources of venture capital funding to begin start-up operations. This change also hurts the SBIR program itself, which has experienced

significant declines in applications since the ruling (SBIR applications declined by 11.9% in 2005, 14.6% in 2006, and 21% in 2007).

BIO urges restoring SBIR eligibility for venture-backed firms as one straightforward way the Administration can help speed research commercialization efforts. We believe that restoring eligibility to hundreds of small biotechnology companies would have an immediate impact on stimulating biotechnology innovation.

Fully fund the Cures Acceleration Network that was authorized as a result of the recently-enacted healthcare reform legislation.

The Cures Acceleration Network (CAN) is a new statutorily-authorized program at the National Institutes of Health (NIH) designed to help bridge the "valley of death" in the drug development process. Timely and adequately resourced implementation of CAN, whose passage BIO strongly supported, will help researchers in academia, foundations, and biotech companies bridge the precarious gap between basic research and the eventual development of new cures and treatments for suffering patients. The legislation authorizes grants for public and private entities to further research on discoveries that have shown promise at the laboratory level, but have not been able to advance enough to attract sufficient private investment. If fully funded, CAN has great potential to significantly increase the ability of biotech companies and their partners in academia and disease research foundations to move promising research down the development path to innovative products. In addition to accelerating the development of therapies and cures, funding for CAN will also provide the economy with a much-needed boost – creating more high-wage jobs in the growing life sciences sector. BIO urges that $500 million be provided by Congress to fund CAN in the upcoming budget year.

Support, expand, or create tax credits/grants/investor incentives for development of early-stage research.

Experience has shown that a commercially relevant university technology takes a minimum of five to seven years of further research and development by industry before it is ready for the market. As mentioned above, developing a new drug can take twice that long and hundreds of millions of dollars, with many years of financial losses and no guarantee of commercial success. Federal policies can and do have a profound impact on the research and development ecosystem. The recently enacted, first-of-its-kind, Therapeutic Discovery Project Tax Credit is an excellent example of a federal policy that will help small biotechnology companies survive the recent economic downturn and foster the progression of their innovative pipeline projects.

This credit – which can be cashed in for an actual grant for those companies that do not have tax liability – is available to defray up to 50% of pre-clinical and clinical development expenses incurred in 2009 and 2010 by small biopharmaceutical companies working to develop novel products for patients. The R&D tax credit is another current program that fosters innovation in America's research and development companies. This tax credit program should be

strengthened and made permanent – by doing so, the United States will be more competitive with incentives provided by other countries vying for research investment dollars.

There are other policies in varying stages of development on Capitol Hill that would also serve to bolster America's innovation industry. In 2009, the House passed H.R. 3854, which contained the Small Business Early-Stage Investment Program. This new Small Business Administration program would provide matching funds for venture capital investors who specialize in investing in small high-technology companies (including but not limited to biotechnology companies). Such a program, if enacted, would help encourage venture capital investment in small high-tech companies that are working on the products of tomorrow, while providing a much needed stimuli to regional venture capital funds that were especially impacted by the economic downturn. Lastly, tax incentives for angel investors and other private sector investors would serve to bolster the much-needed infusion of dollars required to develop early-stage research into products that can benefit the American public.

Explore a "Life Science In-Q-Tel"

The United States expends a significant portion of its budget in funding basic research. This investment spans multiple agencies, supporting our unparalleled university and federal laboratory research system. Yet experience shows that university and laboratory discoveries are on average five to seven years away from becoming actual products. Life science discoveries require twice this incubation period and are vastly more expensive to develop. As such, many of these discoveries often never make it through the "valley of death" because they are too early-stage to attract industry or venture funding.

When facing a similar problem finding the technologies needed to meet its mission, the U.S. intelligence community developed a program known as "In-Q-Tel." The program comprehensively nurtures the development of early-stage technologies with important potential applications. In-Q-Tel provides a variety of services ranging from technology acceleration, capabilities building, forums for discussing next stage innovation, and most important, a strategic investment fund managed by commercialization experts.

These are the missing ingredients in the development of many nascent life science discoveries arising from our university and federal laboratory research base. BIO believes that a holistic approach for nurturing potentially important discoveries in the life sciences would go a long way towards incentivizing commercialization, and by extension, innovation, economic growth, and job creation.

The creation of a program based on the successful In-Q-Tel model could be an imaginative response to the life science "valley of death" problem – one that could reap significant benefits for the nation and the world.

Reduce Regulatory Burden on Commercialization of New Agricultural Biotechnology Products

To commercialize agricultural biotechnology products, researchers potentially have three federal regulatory agencies that need to authorize the products. Indeed, even during research and

development, the recordkeeping on plants grown out of doors is extensive and can create a disincentive to researchers who may not be familiar with the protocols, regulations, paperwork, and necessary data collection needs of the agencies. Some of these regulatory requirements exceed the level of risk. BIO encourages OSTP, through the government's Coordinated Framework, to work towards reducing the regulatory burden to be commensurate with the risk of genetically-engineered products. In addition, services or programs could be developed within the U.S. government to help guide potential researchers and developers through the regulatory maze.

CONCLUSION

We applaud OSTP for looking into ways to further stimulate commercialization of federally-funded research. The innovation infrastructure of the United States has worked well in the life sciences over the past 30 years. Substantial federal funding of basic research, combined with patent incentives and flexible technology transfer policies and practices have propelled this nation to new heights in therapeutic development, agricultural efficiency, and environmental products. BIO believes that Congress and the Administration should continue to support this world-class innovation infrastructure by providing additional funding and support for NIH, university technology transfer offices, and the PTO. BIO further urges full funding and timely implementation of new programs such as the Cures Acceleration Network and the Therapeutic Discovery Project Tax Credit, while reforming existing programs such as SBIR. These programs can help to bridge the valley of death that many promising technologies face on the long and risky path to commercialization, and are particularly critical in the current economic environment. Fostering innovation in biotechnology benefits not only the healthcare sector stakeholders, but also stakeholders in the agricultural and environmental space. For all of these segments of biotechnology streamlined and science-based regulation can stimulate commercialization and thereby innovation. Accordingly, we caution against adopting policies that would, weaken market incentives by undermining protections for innovations, or through excessive government regulation of technology transfer or overburden innovators unnecessarily. We urge OSTP to continue its far-sighted approach to innovation as it continues oversight of this very important issue.