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BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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James C. Greenwood
President & CEO

Mr. Darren Greninger
National Institutes of Health
Office of Biotechnology Activities
6705 Rockledge Drive, Suite 700
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*RE*: *Comments on draft report of Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetics Tests*

Dear Mr. Greninger:

On behalf of BIO's member companies, we appreciate the opportunity to comment on the recently issued public consultation draft report on *"Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests"* (hereinafter, the "draft report"). BIO's membership includes more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. States. BIO members – the vast majority of whom are small, emerging companies with little revenue and no marketed products – are involved in cutting-edge research and development of health care, agricultural, industrial, and environmental biotechnology products that are revolutionizing patient treatment, greatly expanding our ability to feed a growing world population, and offering the promise of reducing our dependence on oil and other fossil fuels and leaving a cleaner environment for future generations.

While the exact number of companies that work in the area of genetic diagnostics, both *in vitro* and *in vivo*, is not known, it is estimated that the United States has approximately 650 such companies in 46 States.[1] Moreover, there are hundreds of other companies that work in the area of therapeutic development. A great many of these companies are members of BIO. As such, the potentially harmful impact of recommendations relating to patents and licensing on the development of novel genetic tests and other important future products such as nucleic acid-based medicines is of great interest to BIO.

Unfortunately, the outcome of this committee's work, based on case studies, literature and case law and consultations, is a series of policy recommendations that do not correlate with the draft report's own findings. While the recommendations in large part appear to focus on restricting or eliminating patent protections and licensing flexibility

[1] www.manta.com Vital Info on Small Businesses. In Vitro and In Vivo Diagnostic Substances Companies in the United States.





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for genetic tests, some of the policy options (e.g., Policy Option F3) go far beyond the focus of the draft report. Likewise, suggestions for broadening the research use exemption (e.g. Policy Option 8E) risk unintended consequences for the development and availability of important new biomedical research tools, despite a notable lack of evidence that these proposals will address any real problem in the genetic testing domain. Considerable attention has been paid to research use practices since the *Duke v. Madey* decision[2] and still there is no compelling data suggesting a statutory change is needed. Moreover, the draft report's research findings show that patents and licensing are not creating actual problems with respect to the price of or access to genetic tests. BIO strongly urges the committee to avoid making any final policy recommendations that are not supported by the research findings.

**About the Biotechnology Industry**

The biotechnology industry, fueled by the strength of the U.S. patent system, has spurred the creation of jobs for more than 7.5 million people in the U.S., and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and environmental products. 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.

Biotechnology innovation has the potential to provide cures and treatments for some of the world's most intractable diseases, such as cancer, Alzheimer's disease, Parkinson's disease, diabetes, and HIV/AIDS, and to address some of the most pressing agricultural and environmental challenges facing our society today and those on our doorstep. Yet biotech innovation is not inevitable, and we do not have to look too far backwards to recall a time when such innovation was not occurring.

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 U.S. 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 biological materials and living organisms. As a result of these two events, the U.S. has experienced an incredible wave of biotech innovation, including, among other things, the commercialization of hundreds

[2] *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002)

of innovative therapeutics, diagnostics and research tools, industrial processes, renewable fuels, and agricultural products of benefit to society, as well as the millions of new, high-paying American jobs resulting therefrom.

All of these accomplishments have occurred despite the decades-long development time, massive investment needs, and complex regulatory processes the industry must overcome to bring its products and applications to market. The Milken Institute, in a 2006 report entitled "*Mind-to-Market: A Global Analysis of University Biotechnology Technology Transfer and Commercialization*,"[3] 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 (IP) 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.

**The Role of Patents in Biotechnology**

Biotechnology is a long-term, capital-intensive, and high-risk endeavor. Let's take as an example a typical healthcare-related biotech discovery. A researcher discovers a gene whose presence is only found in a particular type of cancer. The researcher also determines that the presence of this gene signals the presence of a quantifiable amount of a particular protein. Translating this initial discovery into a therapeutic application can take decades and hundreds of millions of dollars. However, it is at this early stage when the promise of a therapy is on the horizon that the researcher can seek patent protection on the various aspects of the discovery. By way of a patent, the researcher can generate interest in the further development of this potential new product by, for example, licensing the invention, or leveraging his patent to attract venture capital investment. In both cases, the patent is the asset that creates a forward trajectory for the project. In the former case, an interested company partner would, among other things, review the strength and scope of the IP protecting the early-stage discovery to determine the worth of the investment. In the latter case, the IP generates the interest of institutional investors, venture capitalists, or other partners encouraging the creation of an early-stage company. In any event, the early-stage discovery is now on its way to development. Of course, the road to development from this point is long and torturous, and often fraught with setbacks, but the wheels are set in motion.

Patents play a significant role in the investment of capital in the biotechnology markets. Investors measure opportunities in the biopharmaceutical sector through potential sales of the drug/product, the strength of market protection from patents, and other forms of exclusivity (such as orphan drug exclusivity). The patent plays a critical role in helping the innovator take his initial discovery to fruition.

With this backdrop in mind, we will focus our comments on the draft report in three areas. First, the policy options are incongruous with the study findings. Second, the

[3] Mind to Market Study.
http://www.milkeninstitute.org/publications/publications.taf?function=detail&ID=576&cat=ResRep

patent and licensing system is constantly evolving and should maintain flexibility in order to deal with complex issues that require case-by-case examination. And third, both the patent system and Bayh-Dole Act have made the U.S. a world leader in turning publicly-funded R&D in our universities and federal laboratories into new, life-saving and life-improving products and technologies, good jobs, and thousands of companies that have served to grow the economy and foster scientific discovery.

## I. Policy Options Are Incongruous with Study Findings

Before we discuss the draft report, we would like to highlight a recent editorial published by *Nature* entitled *"Property Rights: The granting of patents on human genes has so far not been the disaster it was predicted to be."*[4] Excerpts of the editorial are below:

> "In 1980, the Bayh-Dole Act gave U.S. universities the right to patent discoveries made with government funding. Not long after, universities and companies began the much-criticized practice of patenting genes, laying claim to human DNA sequences for research and diagnostic purposes. Europe and Japan followed suit, legalizing gene patenting in the 1990s.
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> "Researchers and health professionals alike attacked the strategy. They worried that patents would make it harder to develop new genetic diagnostic tests; that corporate monopolies would hamper patients' access to the tests; and that thickets of interlinked intellectual property would scare off those interested in researching and improving the tests. To solve these ills, suggestions have included patent pools in which developers would share buy-in rights for a collection of patents – and even total abolition of gene patents. But for all the fuss, few, if any of the initial concerns have been borne out.
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> "In the United States, the longer history with gene patents and the privatized nature of health care have indeed enabled a few companies to secure a monopoly on some tests. But as described in the Commentary on page 405, genetic tests from companies with exclusive licensing rights are no more expensive or harder to access than those offered by various providers under non-exclusive license.
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> Nor is there any empirical evidence to suggest that companies are quashing innovation. A survey last year revealed that for more than 40,000 gene patents, only six instances of litigation came up in relation to diagnostic testing...All six were settled or dismissed within a year and half, suggesting that the scale of litigation is not as high as some suspected. Reports of researchers being blocked from access to patented DNA sequences or being sued for infringement are extremely rare, and workarounds are not difficult from a legal perspective. Moreover, a study by Loet Leydesdorff at the University of Amsterdam and Martin Meyer of the Catholic University of Leuven in Belgium set to be

[4] "Property Rights: The granting of patents on human genes has so far not been the disaster it was predicted to be," *Nature* 458, 385 (26 March 2009)

published in Scientometrics later this year, suggests that the trend of patenting genes is waning among universities as they increasingly recognized that the return on investment is not as high as had been predicted."

The *Nature* editorial concluded the following:

> "*Dire predictions that patents will cripple genetics research should be viewed with skepticism on both sides of the Atlantic"* (emphasis added). This is not an argument for complacency. Nor is it a defense of the patent system as a whole, which needs major reform to address the scope and purpose of patents. If academics are going to continue to patent intellectual property, they need to recognize that it must be respected and licensed properly. Moreover, patent holders need to accept that patent rights come with a responsibility to honor the spirit in which they are awarded. *Patents are meant to encourage and reward innovation* (emphasis added), and, although this shouldn't happen at the cost of further innovative development, *it is a premise that shouldn't be discarded purely because there is a vague hint that harm might one day occur.*" (Emphasis added)

The views expressed in the *Nature* editorial are very similar to the actual research findings contained in the draft report. However, subjective comments in the draft report about possible future problems associated with genetic patenting and licensing, and the inclusion of policy options such as prohibiting or limiting patents associated with diagnostic tests or other nucleic acid-based inventions, appear to discard the importance of current patent and licensing practices that are critical to ensuring continued investment in research *and* development of scientific discoveries into products that are available to and benefit the public. Moreover, some of the policy options threaten the very basic protections afforded to fundamental biotech inventions such as "nucleic acid-based" patents. Indeed, nucleic acid patents are the primary instruments that protect investment in a variety of biotech research endeavors, including for therapeutic products. University technology transfer offices and the National Institutes of Health's Office of Technology Transfer understand this phenomenon, and seek to balance competing interests in this area by granting specific field of use licenses on certain types of composition of matter patents.[5]

***Research Is Not Restricted***

The draft report found, at most, minimal evidence that genetic/diagnostic research has been inhibited due to the presence of patents:

> "There is consensus that patents by and large have not prevented new research and that patent protection has indeed encouraged the huge investments that can be required to develop new therapies." (pg. 6)[6]

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[5] See Appendix 2, Preliminary Findings from a Population Level Study of DNA Patents, prepared by Lori Pressman, Mark Rohrbaugh and Stephen Finley.

[6] This critical finding is not a surprise. A similar study, conducted by the National Research Council in 2006, came to the same conclusion. "[F]or the time being, it appears that access to patented inventions or

BRCA Case Study: "Myriad's monopoly and enforcement activities *may* have inhibited research (emphasis added) – more clearly, clinical research on the use of genetic testing rather than basic research. Nonetheless, a considerable amount of research has proceeded, and any chilling effect has been at the margins." (pg. 75)

Hearing Loss Case Study: "There is no evidence that patents have had any impact, positive or negative, on research on the genetics of hearing loss"; and "[p]atents appear to have had little to no impact on the dissemination of information about these tests or on how they are marketed." (pg. 82)

The draft report used the fact that there are 4,270 patents owned by 1,156 different owners to support the assertion that there *may* be a problem for future discoveries, especially in the genetic diagnostic field. However, these numbers could also be indicative of multiple tracks of research and development resulting in new diagnostic tests. Indeed, by all accounts, research and development in this area is more robust than ever before, as evidenced by the increasing number of diagnostic and device companies and the more than 1,300 genetic tests clinically available.[7]

The draft report also discussed how scientific research would continue with or without patents, suggesting that restrictions on patenting would be unlikely to impact such research. Indeed, the policy recommendations relating to statutory and regulatory changes in this area would certainly weaken intellectual property rights. Yet the committee does not seem to have taken into consideration the effect that weakening or limiting intellectual property rights would have on the continued research and development by industry that is necessary to turn those basic discoveries into products that benefit the public. For if the development of new cures and therapies is the true goal of public funding of life science research, the committee must take into consideration the availability of the developed product to the public. It is well documented and acknowledged by this committee (pg. 43) that, prior to the Bayh-Dole Act when the government held title to inventions arising out of government-funded research, less than 5% of such research was commercialized, that is, available to the public in the form of products. Weakening or eliminating IP protections in the manner suggested by the policy recommendations of this committee would be tantamount to a return to the pre-Bayh-Dole era system.

Moreover, it is important to note that it is common practice for universities and federal government labs to maintain rights to continue research for non-commercial purposes, even after commercial licensing. In addition, patent protections allow for publication of scientific discoveries without hindering the ability of companies to raise capital to further develop those scientific discoveries. Thus, while the draft report concludes that there might not be any negative impact on basic research or publication of scientific

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information inputs into biomedical research rarely imposes a significant burden for biomedical researchers." (*NRC 2006 report; pg. 6*)

[7] Genetic Alliance, http://www.geneticalliance.org

discoveries by restricting patenting in this area, the impact of such restrictions would certainly create barriers to technology transfer, which in turn would negatively impact the U.S. biotechnology industry's ability to develop basic discoveries into products that benefit Americans and other people all around the world.

***Cost Barriers and Inhibited Patient Access Are Not Correlated to Patents or Licensing Patents***

The case studies examined a wide range of diseases and explored different patent and licensing practices, in great detail. Yet the end result is that there was no evidence that licensing practices or the existence of patents created access or cost barriers to patients – despite the fact that the case studies chosen were those most likely to provide such evidence.

> "Evidence from the case studies did not reveal widespread overpricing for genetic diagnostic tests that were patented and exclusively licensed." (pg. 108)
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> "Thus far, patents covering genetic tests and related licensing practices do not appear to be causing wide or lasting barriers to patient or clinical access. The case studies document several instances in which patient access to genetic tests *may* have been impeded. For the most part, those cases were resolved and access to those testing services is no longer an issue." (pg. 109; emphasis added)
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> BRCA Case Study: "There is little consistent evidence of a price effect directly related to patents to which Myriad holds exclusive versus nonexclusive rights." (pg. 72)
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> Alzheimer's Disease Case Study: "It is difficult to determine whether patents have affected the cost of genetic testing for Alzheimer's disease or limited access in other ways." (pg. 77)
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> Cystic Fibrosis (CF) Case Study: This study discussed the success of non-exclusive licensing in this area, but also appropriately recognized that such a strategy "could not be broadly applied to genetic tests for more rare conditions." (pg. 79) Further, while the draft report did not find hindered access to genetic tests or cost barriers associated with broadly licensed technologies in the CF case study, it similarly did not find lack of access or cost barriers for exclusively-licensed technologies in other case studies, undermining any suggestion that non-exclusive licensing is necessary to avoid such barriers.
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> Hearing Loss Case Study: "...the case study found no specific evidence of patents impeding the clinical adoption or utilization of genetic tests for hearing loss or that patents affected the availability of such tests"; and "[t]here are multiple providers of genetic testing ...and an equally wide range of price points...." (pg. 81)

While we understand the difficulty in assessing the validity of correlations in areas – such as these – in which so many variables come into play, we firmly believe that it would be irresponsible for the committee to recommend final policy options in the absence of much stronger evidence. This is particularly true where such policy options could create countervailing harms to those patients who currently lack any effective therapies or diagnostic tools.

***Quality Is Not Impacted***

The draft report explored the potential for diminished quality of diagnostic tests where there are alleged monopolies or limited providers of such tests. It implied that the inability of clinicians to perform tests outside of the patent or licensing agreements inhibits quality and the ability to validate test results. However, there was no evidence provided to support these notions. Further, the draft report fails to mention the quality controls (post-market surveillance) and validation of tests required for any diagnostics approved by the FDA. BIO also notes that the Alzheimer's disease case study (see pg. 78) actually showed that patent rights helped ensure compliance with professional guidelines for genetic testing.

There are also suggestions in the draft report that exclusive license agreements for a test could create situations where subpar tests were all that were available and would prevent other, more improved tests from being developed. Specifically, the BRCA Case Study seemed to call into question Myriad's original test that missed 12% of large genomic deletions as a potential example on how exclusive licenses might prevent improved diagnostic tests from being developed.

However, as the study itself pointed out, Myriad did in fact improve its test in accordance with the general trend to develop improved and more comprehensive diagnostic tests. Moreover, the evidence in the draft report itself does not support these poor quality suggestions:

> "[T]he general trend for all diagnostic genetic testing has been to move toward more comprehensive analyses that detect deletions and rearrangements...." (pg. 73)

In short, the evidence does not support a finding that patenting and exclusive licensing are creating long-term quality problems; rather, it shows that market mechanisms are working to continually incentivize improvements to diagnostic tests.

**II. Flexibility in Patent and Licensing Practices Should be Maintained**

***Licensing and Patenting Practices Are Constantly Evolving***

Both industry and universities are constantly evolving in how they patent and license genetic information. The draft report illustrates this point by the actions taken by Merck and the Wellcome Trust, which have initiated efforts to publish, without patenting, DNA

molecules. This example shows that the research and industry communities adapt their patent and license practices to the current research and development environment, and to the specific type of discoveries at issue. This does not argue for arbitrary restrictions or weakening of intellectual property across the board, but rather for maintaining a level of flexibility that will allow the system to continue to evolve with the scientific discovery and development environment, with different investment incentives, and with the needs of different patient populations. Ongoing dialogue between the research, patient and industry communities is the best solution to ensure that patent and licensing practices are constantly evolving in a way that progresses research, spurs innovation, and protects the public interest. Prohibiting or limiting patents and/or exclusive licenses on genetic scientific discoveries would severely damage the ability to commercially develop scientific discoveries in the U.S.

The draft report also appears to assume that a "gene patent" always operates to exclude anyone who may want to work with that gene from developing or providing an alternative genetic test. Depending on the particular patent claims involved, however, design-around is often an option. The case studies cite a number of examples where multiple providers offer genetic testing services despite the existence of patents. In some cases the patentee may have chosen not to enforce its patents, in other cases the patents may not be infringed.

Because biotechnology is considered more unpredictable than small molecule chemistry or the classical engineering disciplines, courts impose higher standards for meeting the so-called "written description" and "enablement" requirements on biotechnology applicants who seek broad patent claims. In practice, these requirements often operate to limit the scope of claims that are allowed, and sometimes only very narrow claims are issued. In addition, the "utility" requirement prevents patent applicants from prematurely securing patent protection before they have identified the biological function of the claimed genetic sequence and its specific, real-world usefulness. Taken together, the patent law thus has developed several doctrines to ensure that patents related to the same gene meet very stringent standards.

Moreover, patent law continues to evolve in ways that would seem to address underlying concerns in the draft report. For example, recent precedent suggests that gene sequences obtained through routine techniques may no longer be patentable if the gene product is disclosed in the prior art (see *In Re Kubin*[8]); and that broad claims to genetic testing methods that rely predominantly on a newly-discovered correlation between a gene and disease susceptibility may be unpatentable if the method is not either transformative or tied to an apparatus or machine (see *In Re Bilski*[9]; c.f. *LabCorp v Metabolite*[10]).

The committee should avoid recommendations that would disrupt the orderly development of the law in this area. Biotechnology patents are today examined and

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[8] *In re Kubin,* 561 F.3d 1351 (Fed. Cir. 2009)
[9] *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385, (Fed. Cir. 2008)
[10] *LabCorp v. Metabolite*, 548 U.S. 124 (2006)

litigated within a relatively stable doctrinal framework that, by all measures, has been a success story of U.S. patent law.

***Flexible Licensing Practices Ensure Continued Development of Scientific Discoveries***

The draft report discusses the alleged "underutilization" of government march-in rights as a potential problem, yet again lacks any evidence to support such a conclusion. It is equally (if not more) plausible to find that a lack of government utilization of march-in rights demonstrates the exact opposite – that the flexible licensing system is working as intended, to spur commercialization without the need for government intervention. Indeed, the base report does not discuss the fact that it is common practice to have licensing agreements between universities and industry that contain milestone clauses, whereby a licensee that is not actively developing the technology may have its license rights revoked or restricted – even though this exact practice was described in Appendix 2 of the draft report with respect to exclusive license agreements entered into by the National Institutes of Health (NIH). The appendix notes that exclusive license agreements with the NIH generally include "diligence requirements" that require the licensee to invest in developing and commercializing the invention, which helps to ensure that licensed technology is in fact being actively developed and made available to the public. Additionally, as previously discussed, most universities and federal government labs maintain the rights to pursue research for non-commercial purposes, thus ensuring that scientific discovery is constantly progressing even where exclusive licensing arrangements are in place.

Policy options that would create mandates, or the perception of mandates, pertaining to licensing practices (e.g., Policy Options 4 and 5) would remove the flexibility necessary in such a dynamic environment, and could create unnecessary barriers to attracting companies to take licenses in a particular field or technology.

On a more general note, BIO cautions against policies that would weaken market incentives through excessive government intervention. We can point to lessons learned in the 1990s, when concerns that healthcare reform proposals could lead to price controls caused serious perturbations in the market for biotechnology investment. The reaction was immediate and powerful. The capital markets crashed and investment in biotech research nearly dried up. A similar result occurred in 1999, when President Clinton and Prime Minister Blair were cited in the press as supporting the notion that certain classes of patented genetic information should be freely available to all 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 and undermining intellectual property rights drove investors away from biotechnology research. While this draft report is limited to patents and licensing in genetic tests, any decisions in this area could be precedent setting, and it is unlikely that any new restrictions could be so narrowly tailored that they would not have any broader impact.

BIO also notes that President Obama's healthcare initiatives call for continued innovation in healthcare, including a call to "cure cancer" in this generation and to enhance personalized medicine where diagnostic and genetic tools will tailor healthcare to the individual. The Congress just granted the NIH an additional $10 billion as part of the economic stimulus package, in order to spur such initiatives. Yet the wrong message in the committee's final report regarding patents and licensing in these same areas could undermine these laudable efforts.

Proposing targeted bans on exclusive licenses or patents based on potential future problems caused by a variety of factors, including factors outside of the patent or technology transfer system (i.e., healthcare coverage and reimbursement policies), is not sound policy. In fact, the findings contained in Appendix 2 of the draft report "suggest that automatic and default nonexclusivity could have a cost, especially given the apparent impossibility of a priori identifying groups of patents "needing" to be licensed nonexclusively because they are certain or likely to be associated with clinical diagnostic tests of genetic origin." The appendix further states that "[g]iven the apparent impossibility of identifying patents 'needing' to be licensed nonexclusively, and the potential unintended removal of incentives where they could be beneficial, nuanced exclusivity with prudent diligence is an attractive policy option." Not only do these findings *not* support targeted bans on patents or exclusive licenses, they actually conflict with any such policy options.

Weakening or restricting intellectual property rights would only serve to destabilize the patent and licensing system and devalue the main asset of innovative biotechnology companies – their intellectual property. Devaluing intellectual property would make it much more difficult to attract the massive capital investment required to develop scientific discoveries into products that will benefit patients.

**III. The U.S. Patent System and the Bayh-Dole Act Have Made the U.S. A World Leader in Scientific Discovery and Development**

The draft report states that there is not strong evidence that "patents and exclusive licensing practices provide powerful incentives for the development of genetic tests." (pg.111) To the extent this statement invites a conclusion that patent protection and exclusive licensing in this field is therefore not needed, BIO cautions against value judgments that would extend patent rights only to technologies where patent incentives are deemed sufficiently "powerful" and not others. Moreover, as noted above, the draft report limited its scope of examination on this issue to whether researchers would continue to do research – not if that research would be developed into a commercial product – based on eight self-selected and non-representative case studies. Yet there are hundreds if not thousands of diagnostic tests on the market today, many of which are based on proprietary information.

More generally, there is overwhelming evidence that the U.S. patent system and the Bayh-Dole Act have created powerful incentives for scientific development and are the foundations on which the U.S. became and has maintained its position as the world leader

in scientific discovery and development. This is clearly evidenced by the incredible number of products and technologies that have reached the market to date as a result of the flexible and collaborative interaction between the public and private sectors since the passage of Bayh-Dole, and the fact that countries around the world are seeking to emulate this model.

Before the committee recommends that the U.S. make policy changes that could harm our economic competitiveness and reduce incentives for the development of future biomedical breakthroughs to treat or cure currently unmet patient needs, the committee should provide clear evidence that the flexible patenting and licensing practices in this field are not necessary to maintain such incentives, particularly in the absence of any demonstrable harm from such practices. Yet the draft report would seemingly shift the burden of proof to proponents of the current practices to prove that they are in fact needed. As in other areas of the draft report, the committee appears to be looking to solve a theoretical problem that might someday exist, with changes that may well create unintended, harmful consequences. It would be irresponsible to alter current practices in such a knowledge vacuum.

## IV. Conclusion

The actual research and case study findings in the committee's draft report clearly support the findings of prior studies that have found an utter lack of demonstrable barriers resulting from current patenting and licensing practices in the life sciences. Yet the draft report then goes on to set forth a range of policy options – ranging from principles to regulations and legislation – which, rather than being grounded in documented patent-related problems of access, affordability, or quality, appear to be largely based on abstract concerns and preconceived notions about the propriety of gene patents generally.

In BIO's view, the concerns identified in the draft report require significantly more substantiation before they become actionable under such a vast array of regulatory and legislative options. This is not to say that there are not any valid policy justifications for enhanced stakeholder discourse about licensing best practices and other mechanisms to encourage greater access and utilization of genetic diagnostic testing. As emphasized in the draft report, "access to genetic tests may be hindered by high prices, fear of discrimination, difficulty in obtaining the tests, regulatory or certification requirements, lack of coverage by payers or demands by insurance payers for evidence of clinical utility, all of which could be seen at work to a greater or lesser extent in one or more of the case studies." (pg. 70) Accordingly, further dialogue should carefully take into account access and quality problems that have been identified as significant without proceeding under the premise that patent-related concerns need to be the focus of such efforts, especially without further substantiation. Furthermore, any policy discussion should include input from various stakeholders, including from industry.

BIO commends the committee for the time and commitment that it has put into this topic, and for providing an opportunity for public comments to be considered before the report is finalized and submitted to the new Secretary of Health and Human Services for her

consideration. BIO strongly urges the committee to abandon the ill-conceived and factually unsupported policy options contained in the draft report. The unintended yet likely quite harmful consequences of such recommendations on future biotech innovation and the U.S.'s global leadership in scientific discovery and development must be carefully considered by the committee in much greater detail, before it finalizes any such policy options for further public discourse.

BIO appreciates the opportunity to provide these views.

Sincerely,

James C. Greenwood
President & CEO