



***BIO Comments on the Draft Report of the
Secretary’s Advisory Committee on Genetics, Health and Society
on Gene Patenting and Licensing Practices
and Their Impact on Patient Access to Genetic Tests***

Good morning. My name is Tom Dilenge and I am the General Counsel and Vice President for Legal & Intellectual Property for the Biotechnology Industry Organization, known as BIO. I want to thank the Committee for giving me the opportunity to make this brief statement on this issue of critical importance to BIO’s membership, as well as patients suffering from terrible diseases around the globe.

BIO’s membership includes more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations – most of which are small, emerging companies heavily reliant on private equity to fund their investment in biotech innovation. BIO’s member companies turn cutting-edge science into healthcare, agricultural, and environmental products that benefit the public and help sustain our planet.

The U.S. leads the world today in biotechnology research and development in large part because of the robust system for protecting intellectual property rights and technology transfer that exists in this country. Many BIO member companies have either spun out of universities or are developing products from university research. Often – but not always – this initial research was funded by NIH and transferred to companies for further research and development. It is through this collaboration fostered by the Bayh-Dole Act – and fueled by massive amounts of private investment – that research is translated into tangible medicines, diagnostic tests, and other healthcare-related products that are saving lives and alleviating suffering for millions of people worldwide. The critical link in this chain is the availability of patents to protect these investments.

This innovative collaboration is the envy of the world. It creates good, high-paying “green” jobs throughout the United States of America – more than 7 million U.S. jobs are directly or indirectly the result of the flourishing life sciences industry, and Governors across the country are busy trying to expand their university-industry partnerships to create biotech hubs in their States. President Obama has recognized this link as well – including \$10 billion in economic stimulus funds for the NIH to further promote research and technology transfer in the life sciences, much of it focused on genomic research.

The United States' success in this area has prodded other countries to take a page from the U.S. Patent Laws and Bayh-Dole Act, with new biotech hubs sprouting up in various corners of the globe. The competition is on, and the U.S. must preserve incentives for investment and innovation, particularly now during a time of deep recession. Now is not the time to undertake or recommend policy changes that would undermine the foundations of American biotechnology innovation – particularly on the scant evidence this Committee has before it.

Therefore, it was with great disappointment that we read some of the findings and policy options set forth in the original draft report issued by this Committee. A detailed discussion of our concerns was included in BIO's May 15, 2009 letter to the Committee, but I will highlight a few here.

This Committee initially sought to evaluate whether patent and licensing practices involving gene-based inventions were causing problems with respect to patient and clinical access to genetic tests – an appropriate but admittedly limited inquiry. Indeed, as the draft report itself concedes in several places, the idea that the Committee should be focusing on the patent system as a potential cause of such problems – rather than issues related to regulation, reimbursement and health insurance reform on which the Committee has previously found solid evidence of problems – is somewhat odd to begin with. But, unfortunately, this is not the first time that well-intentioned individuals have looked to patents as the source of healthcare access problems, despite the overwhelming and consistent evidence to the contrary.

And like those who have studied this issue before it, this Committee's own exhaustive review – including its case studies of examples most likely to uncover problems in this area – found little evidence of broad or consistent pricing, quality or access problems relating to genetic tests, and *no* evidence that could tie any of these isolated problems directly to patents or licensing practices. The only link the Committee could make is that patents and exclusive licensing can “enable” the creation of sole source providers of genetic tests, which admittedly they can and which the Committee seems to believe is a real source of access problems.

Yet the Committee's own report acknowledges that many of these alleged pricing, quality, or access problems can and do occur regardless of whether a patent is involved, and regardless of whether there is a sole source provider or multiple providers. The Committee also ignores the fact that abolishing patents or exclusive licensing would not eliminate the existence of sole source providers, particularly where there are small markets or the technology is especially complex. And it certainly won't do anything about the real patient access problem identified in the Committee's case studies and at the heart of the most high-profile controversies in this area – the fact that certain large insurers are unwilling to cover certain genetic tests, particularly for indigent populations.

So, unable to demonstrate any evidence of actual harm resulting from current patent and licensing practices in this area, this Committee has apparently decided to shift the burden of proof to defenders of the patent system – suggesting that patents and exclusive

licensing are largely unnecessary to spur the development of genetic tests anyway, and thus policymakers should consider restricting them by federal mandate in order to avoid any theoretical problems they might cause in the future. The Committee's draft report then sets forth a range of policy options, from principles to regulations to legislation, all driven by an apparent desire to limit patenting and/or licensing practices in this field. This is intellectually indefensible for several reasons.

First, some of the Committee's own findings and case studies show how patenting and exclusive licensing practices can, indeed, be necessary to foster the development of these valuable tests for patients, particularly those with rare disorders, and that they have other positive impacts – such as incentives to promote physician and patient education, broader insurance coverage, and improved compliance. These are real benefits that the Committee mentions in passing but largely ignores in proposing its over-reaching and restrictive policy options.

The draft report also completely ignores contrary evidence contained in its own Appendix 2 – a study commissioned by the Committee that remains underway. This preliminary study shows that exclusive licenses do often create incentives to bring genetic discoveries to market where they can benefit patients (and in many cases faster than non-exclusive licenses), and that simply labeling an invention as “genetic” or “diagnostic” is a poor predictor of its ultimate application, or the risks and expenses required for development of the invention into a useful commercial product. Thus, policy changes that seek to limit the patenting or licensing of certain types or aspects of genetic inventions are likely to miss their mark and risk serious unintended consequences.

Interestingly, Appendix 2 also shows that universities have been more successful in managing their genetic patent portfolios to support robust technology transfer than the Federal government has been with its more restrictive rules. Such findings make it even more puzzling that the draft report would suggest that the Federal government should seek to restrict university practices in this area or impose its Federal rules on government grantees as a default. Rather, if the goal is to enhance patient access to not only the genetic tests of today but also those of tomorrow, it would appear that Federal agencies would do well to copy the more flexible university licensing practices.

Second, the Committee's study was never designed to look at the much-different question of whether and under what conditions patents and exclusive licensing may be necessary to promote innovation, and its approach of using a handful of self-selected case studies simply cannot, from an intellectual or scientific method standpoint, support such a sweeping determination on the role of patents in this incredibly diverse area of innovation. With all due respect, the composition of this Committee also would probably need to be different in terms of the necessary expertise to evaluate such evidence and the serious innovation-related implications of the Committee's tentative recommendations in this regard. At the very least, the Committee should await the completion of the study in Appendix 2 before making any conclusions or recommendations on this issue.

Third, suggestions in the report that exempting certain activities relating to genetic tests from patent infringement liability could find precedent in other statutory provisions are seriously off the mark. The limited exemption for medical practitioners from infringement liability with respect to patented surgical methods expressly excludes patented compositions of matter or machines, or the use of such patented articles. It only protects doctors from infringing patents on abstract methods of conducting medical procedures, which are largely inapposite in this context. And the Hatch-Waxman Act research exemption only covers the research and development of drugs and biologics, not the actual marketing or sale of such products in violation of another's patents. Thus, the draft policy options suggested by the Committee are potentially much more far-reaching than anything previously considered or adopted in patent law.

We also question why this Committee, given its limited mandate to review patient access issues and its lack of findings related to genetic research, would suggest a recommendation to broaden the current research use exemption under patent law as applied to genetic tests. This vague and ill-informed suggestion risks unintended consequences for the development and availability of important new biomedical research tools, and finds no basis of support in either the Committee's own fact-finding, or that of previous efforts by the National Academies and other expert bodies that have specifically and thoroughly reviewed the question of whether gene patents inhibit research.

Fourth, the Committee's suggestion that policymakers consider restricting or prohibiting "association" patent claims would likely sweep in many valuable and appropriate claims and have a chilling effect on research and technology transfer in this important area of genetics. While the draft report's contention that patenting does not serve as a powerful incentive in this particular area may have some basis with respect to basic research performed by purely academic researchers, such an analysis ignores the fact that great research in this area is also done by for-profit entities, and that the applied research and development process is the more difficult and costly part and is largely carried out by the private sector. Association patents are a complex area best left to the experts at the Patent & Trademark Office and the courts.

Finally, the notion that this Committee would suggest fairly radical changes to the legal and policy landscape surrounding gene patents based only on, as the draft report puts in, "several issues of concern that, if not addressed, might result in future barriers to patient access," is simply stunning. The Committee would be well advised to consider the conclusions of *Nature* in its March 26, 2009 editorial entitled "*Property Rights: The granting of patents on human genes has so far not been the disaster it was predicted to be.*" After reviewing the dire predictions made 25 years ago by researchers and public health advocates about the impact of permitting patents on genetic inventions, here's what *Nature*'s well-respected editors said:

But for all of the fuss, few, if any of the initial concerns have been borne out... Patents are meant to encourage and reward innovation, 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.

Unfortunately, it appears that this “vague hint that harm might one day occur” was indeed the driving force of the draft report.

The patent, licensing, and tech transfer system in this country is, by any objective measure, working quite well overall. There will always be some examples where things go wrong, but we must maintain the system's current flexibility to deal with complex issues as they arise. The evidence shows that decisions about what patents to seek and how best to license them are decisions that are best made by the researchers and their commercial partners, who have the greatest incentives to achieve widespread patient access to their discoveries. They understand the risks and strategies needed to take an early-stage discovery from the laboratory to the marketplace better than anyone. We respectfully submit that the Federal bureaucracy, as evidenced by 40 years of limited success with technology transfer before passage of the Bayh-Dole Act, should not insert itself into this process, except in exceptional circumstances.

Proposed changes in long established Federal laws and policies are not trivial matters and should not be recommended lightly. This is especially true in the context of biotechnology, which has become fundamental to the economy of the United States and its global competitiveness, and which promises solutions to so many of the world's gravest human and environmental challenges. Recommendations that would weaken or threaten this foundation must meet a very high standard of proof. The Committee's draft report and potential policy recommendations do not even remotely approximate this mark.

In conclusion, let me be clear that BIO strongly supports the mission of this Committee and its goal of improving patient access to genetic tests. More broadly, BIO strongly supports President Obama's goal of achieving universal healthcare access. Our members work hard each and every day to develop products to help patients, and policies that restrict access to our products are not in our interest. We pledge to work with the members of this Committee in breaking down remaining barriers. But the Committee's draft report shoots at the wrong target, and its recommendations, if implemented, would do more harm to patients than good, particularly the patients of tomorrow who are relying on biotech innovation to bring the promises of personalized medicine to reality.

We ask that this Committee carefully consider the views and experiences of those who actually bring medical innovation to suffering patients. We are hopeful that the Committee will revise the draft report and policy options to eliminate any suggestion that patenting, licensing, and commercial development are at odds with patient access. They are not. To the contrary, patient access depends on a robust and flexible technology transfer process, like the one under the hugely successful Bayh-Dole Act.

We welcome the opportunity to work with you. On behalf of BIO's broad and diverse membership, I want to thank you for your time and consideration of these views.