



BIO RESPONSE TO REPORT ENTITLED “TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION”

The proposition advanced by the study recently released by McGill and Duke universitiesⁱ --that the protection of intellectual property rights serves as an obstacle to innovation in the life sciences and hampers further research and collaborations among scientists-- has repeatedly been debunked and has no empirical basis in fact. According to a report prepared for the National Academies of Scienceⁱⁱ, intellectual property rights do not impede research: only 1% of the random sample of 398 academic respondents reported suffering a project delay of more than a month due to patents on knowledge inputs necessary for their research, and *none* of them had stopped a research project due to the existence of patents. Further, as BIO and other experts in this area previously have found, there is an utter lack of hard evidence, except for the occasional anecdotal example, supporting the study's exaggerated conclusions.^{iii iv v}

To the contrary, a robust system for protecting intellectual property rights is critical to establishing an environment in which biotechnology innovation can flourish. The presence of patents and strong IP rights in no way precludes collaborations and partnerships with companies, governments, non-governmental organizations (NGOs), or others. Rather, it is precisely *because* of patents and strong IP rights that such collaborations and partnerships can, and do, take place at an ever increasing rate.^{vi}

As an example, a researcher, typically in a university laboratory, discovers a novel DNA sequence that is expressed only by a particular type of cancer cell. Translating this initial discovery into a tangible product can take more than a decade and more than a billion dollars^{vii}. The exclusivity and potential return on investment offered by the patenting of this early discovery is what investors rely upon to provide the further funding necessary for applied research and development of actual products. Of course, the road to a final product from this point is long and torturous, has a significant likelihood of failure, and is fraught with other commercial setbacks. However, the faith that the discovery will help improve the lives of people around the world, and the confidence that patent rights will protect products that are ultimately developed, propel the transfer of technology through licensing and collaborations, and the further research and development work that follows. Without patent rights, this efficient process simply would not be possible, and either initial discoveries would sit on laboratory shelves and never be commercialized, or inventors would keep their discoveries as trade secrets for as long as possible – neither of which would serve the public interest or the goal of spurring innovation.

The above example is not an illustration relevant solely to the health sector. BIO members are involved in the research and development of innovative agricultural, industrial and environmental, and renewable energy biotechnology applications as well. Our members have, over time, developed more than 200 biotech drugs and vaccines, including products to treat cancer, diabetes, and HIV/AIDS, to name just a few, with hundreds of new therapies and cures in the development pipeline. Our members also have produced high-yield and insect-resistant crops to help feed a growing world. Industrial biotech applications, among other things, have led to cleaner processes that produce less waste and use less energy and water, and are at the forefront of the next generation of renewable energy sources.

Market-based incentives for transferring technology have made great progress in spurring such R&D and innovation. For example, the U.S. Bayh-Dole Act permits universities and other research entities to retain patent rights for inventions created by U.S. government-funded research programs. Experiences in the United States under the Bayh-Dole Act show that this type of simple mechanism can result in significant transfers of technology and incentives for the dramatic growth of industries such as the biotechnology sector. BIO believes that such mechanisms promote close interactions between universities and the non-profit research community and the biotechnology industry – particularly small businesses.

Strong IP rights are not the reason that so many developing countries lack access to the products and technologies enjoyed by developed economies, particularly in the public health arena. While many factors play primary roles in this access problem, such as lack of infrastructure and capacity, lack of trained personnel, and trade barriers, patents are rarely an obstacle. According to Amir Attaran,^{viii} only 19 of 319 items on the World Health Organization Essential Medicines List have patent protection postdating 1 April 1982. And patents on two of these products were donated by the inventor to the WHO for the public good.^{ix}

That said, BIO and its members recognize the need to continually enhance research on new biotech products and global access to them. Our members are highly supportive partners in facing the challenges of building a sustainable R&D framework to contribute to global needs. BIO is fully supportive of improving international coordination between industry, governments, and non-governmental organizations to achieve practical results to improve the lives of people all around the world. To that end, BIO has participated in the World Health Organization as a “concerned entity” and has provided constructive proposals on how industry can play a role in achieving this goal. BIO also has been actively engaged in the Convention on Biological Diversity regarding the sustainable use and benefit sharing of genetic materials.

BIO’s members are committed to efforts that will enhance partnerships and collaborations with conventional and non-conventional partners as well. In March 2008, BIO teamed up with the Bill and Melinda Gates Foundation and BIO Ventures for Global Health (BVGH) to co-sponsor the “Partnering for Global Health Forum” in Reston, Virginia, to address the pressing need for accelerating the development of medicines for

neglected diseases of the developing world. Over 500 stakeholders from all over the globe attended this conference. The Forum explored the need for innovation and avenues of progress in this area by focusing on lessons learned, market incentives, innovative business models, and new potential partnerships. The Forum also highlighted what a recent BVGF study showed: that biotechnology companies are willing and have the unique expertise needed to close the innovation gap with respect to neglected diseases. The study found that expanded research funding, new product development partnerships and other market-based collaborative efforts to harness resources in the public, private, and academic sectors will help to unlock this expertise and facilitate greater participation by the biotechnology industry in this effort.

BIO and its members also understand the importance of working with others in the developing world to build their innovative capacity. One practical way that this can happen is through the sustainable development of countries' genetic resources. Strong IP protections, efficient technology transfer mechanisms, and robust research funding can entice companies to seek out developing country counterparts. In 2004, BIO adopted its "*Guidelines for BIO Members Engaging in Bioprospecting*," which provides assistance to those BIO member companies who wish to collaborate with other countries. The guidelines, which were later supplemented with a Model Material Transfer Agreement, identify certain "best practices" and options for consideration in such agreements, including upfront benefits, research training and capacity building.

About BIO: BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

ⁱ *Toward a New Era of Intellectual Property: From Confrontation to Negotiation* , September 2008.

ⁱⁱ Walsh et. al. Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions Patents, Material Transfers and Access to Research Inputs in Biomedical Research, September 20, 2005.

ⁱⁱⁱ Ted Buckley, *The Myth of the Anticommons*, May 31, 2007.

<http://bio.org/ip/domestic/TheMythoftheAnticommons.pdf>.

^{iv} Claude Barfield and John Calfee, *Biotechnology and the Patent System, Balancing Innovation and Property Rights*, 2007.

^v Hansen et. al. *Intellectual Property Experiences in the United States Scientific Community*, AAAS, 2007.

^{vi} AUTM FY 2006 Licensing Survey, www.autm.net.

^{vii} Tufts Center for Drug Development, *Impact Report Cost to develop new biotech products is estimated to average \$1.2 billion*, Vol. 8, No. 6, November/December 2006.

^{viii} Amir Attaran *How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* *Health Affairs*, 23 No. 3 pp. 155-166, 2004.

^{ix} *Supra*.