

March 19, 2009

Ms. Lisa Fenn  
Acting Committee Secretary  
Australian Senate  
Community Affairs  
PO Box 6100  
Parliament House  
Canberra Act 2600

Dear Ms. Fenn:

I am writing this letter on behalf of the Biotechnology Industry Organization (BIO) in response to your Committee's Inquiry into Gene Patents. BIO's membership includes more than 1,200 biotechnology companies, academic institutions, and related organizations throughout the world. In Australia, BIO has twenty-nine member companies and works closely with AusBiotech whose membership includes hundreds of biotechnology companies. 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 healthcare, 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.

The biotechnology industry is fueled by intellectual property, primarily patents, and has spurred the creation of jobs and innovative healthcare products (e.g., 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 diagnostics that are currently helping more than 325 million people worldwide; and has another 400 or so biotechnology products in the healthcare pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide use, 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. All of this innovation is possible because biotechnology innovators are able to protect their inventions. This protection also spurs even more innovation by other entrepreneurs looking to improve upon others' inventions.



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We understand that your Committee is undertaking an inquiry which is, in part, designed to determine whether the Australian Patents Act 1990 should be amended to prohibit patents on human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form. In particular, the Committee's inquiry will look at the impact of these patents on the cost of healthcare and advancement of research. As your Committee undertakes this inquiry, we ask that you consider the important role that patents on genetic materials play in the growth and development of the biotechnology industry, and more importantly, in the development of novel biotechnology products, many of which are aimed at improving the health and wellbeing of the world's citizens.

By their very definition, biotechnology inventions are made up of genetic and biological materials. Indeed, a typical biotechnology invention can be a nucleic acid sequence (DNA and RNA), a cell-line, transgenic plants and animals, or various methods of making and using these items. Patents covering nucleic acids are fundamental to biotechnology innovation and the growth of the biotechnology industry.

Development and commercialization of an invention in the biotech sector is a lengthy process requiring significant amounts of capital, often in the hundreds of millions of dollars. Biotech R&D requires public-private collaborations and substantial financing from private capital markets to actually take the product from the idea stage to one that can be used by the public.

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 on that gene, the researcher can generate interest in the further development of this potential new product by, for example, out-licensing the invention, or forming a spin-off company focusing on the R&D of this early-stage discovery. In both cases, the patent—which is limited in its term-- 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 challenging, and often fraught with setbacks, but the wheels of innovation are set in motion.

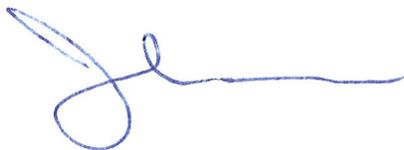
From this point on, patents play a significant role in the investment of capital in the biotechnology markets. Investors measure opportunities in the biotechnology sector through potential sales of the product, the market exclusivity prospect through patent protection, other forms of marketing exclusivity, or other means to gauge the strength and predictability of patent protection. Investors also take into account the anticipated expiration dates of such patents.

The absence or diminution of patent protection on fundamental biotechnology inventions will make it much less likely that biotech companies and venture capital companies would invest in risky, cutting-edge research in this sector which will most assuredly arrest the growth of the biotech sector in Australia. Moreover, such action would likely jeopardize future R&D projects based on genetic inventions, and possibly slow the progress in medical research, as investors and entrepreneurs put their money into projects or products that will better ensure an opportunity for a return on investment.

Instead, our members believe that through strong, predictable, enforceable patent protections, Australia can impel the growth of its nascent biotechnology sector to create high-paying jobs, and to develop innovative, cutting-edge products to help bring down the cost of healthcare and improve the health and wellbeing of the Australian people.

We appreciate the opportunity to provide you with comments for consideration as you undertake your inquiry.

Sincerely,



John Taylor  
Executive Vice President, Health