

**Patent Amendment (Human Genes and Biological
Materials) Bill 2010**

**Submission to the Senate Legal and Constitutional
Affairs Legislation Committee**

by the

Biotechnology Industry Organization

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About BIO/Introduction

The Biotechnology Industry Organization (BIO) welcomes the opportunity to make this submission in response to the proposed *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

BIO is a trade association representing more than 1,100 companies, universities, research institutions, investors, and other entities in the field of biotechnology. BIO's members are located in 32 different countries, including 22 members located in Australia. Numerous other BIO member companies conduct business and research activities in Australia on a regular basis. The vast majority of our members are small- and medium-sized enterprises that have no product on the market, but have as their sole or principal assets the intellectual property on innovative research and discoveries. They are thus heavily dependent on private investment from venture capital funds and other similar sources to launch and continue their expensive research and development activities.

Our member companies focus their innovative efforts in the areas of healthcare, agriculture, energy, and the environment, researching and developing cutting-edge products and technologies that are helping to feed, fuel and heal the world. Our members are working on cures and other therapies for life-threatening diseases such as cancer, diabetes, multiple sclerosis, Alzheimer's, and HIV/AIDS, as well as on agricultural innovations to boost crop yields, farm incomes, and overall agricultural sustainability. Other BIO members are developing the next generation of biofuels and other renewable energy sources in order to reduce climate change and dependence on fossil fuels, while still others are focused on bio-based products and other technologies to help clean and sustain our global environment. Each of these critical areas of biotechnology innovation relies heavily on the patenting of nucleic acid and other biological discoveries from humans, plants, animals, and other living organisms – patenting that would be banned by the Patent Amendment Bill 2010.

A typical biotechnology invention starts in a laboratory where a scientist may discover a gene or other biological component of particular interest. Based on the function and characteristic of this discovery, the scientist can determine its potential for practical application and produce an isolated and purified form useful for such purpose. However, the time period from this very early stage to when a product actually makes it to market can be more than a decade and cost hundreds of millions of U.S. dollars. Further, in the vast majority of cases, the efforts to gain regulatory approval or otherwise successfully commercialize the product fail. Innovators and their investors can take this significant risk because countries like Australia provide strong protection for fundamental biotechnology inventions such as nucleic acids.

“Genes” Are Not Patentable

At the outset, it is important to stress that the term “gene patent” is a misnomer, because genes as they exist in the body cannot be patented. Because a naturally-occurring gene – even a newly-discovered one – cannot be patented, patents do not provide ownership rights over our genes, and nobody can infringe a patent by having a certain gene, or by passing it on to their children.

While natural genes are not eligible for patenting, artificial preparations of DNA molecules are, because they have new qualities that distinguish them from natural genes. Like other chemicals that are derived from nature (such as antibiotics or natural dyes), preparations of DNA molecules are patentable because they have been transformed through human intervention into something that is sufficiently different from the natural state as to qualify as new, useful, and man-made. This transformation begins with the purification and isolation of the natural DNA. Patented DNA preparations contain isolated DNA molecules that are purified and stripped of everything that is necessary for the normal operation of a gene in the human, animal, or plant body. Such purified DNA molecules are also often reconfigured in ways that eliminate large parts of the genetic sequence of the natural gene, giving rise to DNA sequences that do not exist in nature. Natural genes, on the other hand, exist as segments of DNA on chromosomes, where they are integrated, regulated by other genes, chemically modified, and bound to proteins.

Further, isolating and purifying is not enough to make a DNA preparation eligible for patenting. The resulting DNA preparation must have new qualities, advantages, and technical applications that allow it to be used in important new ways that are not possible with the natural gene, making it different not just in degree, but in kind – for example, to conduct gene transfer experiments, to make DNA vaccines, or to produce therapeutic proteins in large scale cell culture. It is impermissible to patent a DNA molecule, even if isolated and purified, unless the scientist establishes the detailed biological function of the gene from which it was derived and identifies a credible, specific and substantial utility for it. Identifying a gene’s biological role and establishing a credible, specific and substantial use for the claimed DNA molecule are often harder than identifying the new gene itself, and certainly meets the standard thresholds for inventiveness. Furthermore, in every case, the inventor has to satisfy the standard requirements under which the claimed DNA must be new and distinct from all preexisting scientific knowledge. Identifying, deriving, characterizing, and describing a DNA sequence in this way requires the same level of human ingenuity as synthesizing a new chemical, composing a new metal alloy, or other human creations that are commonly deemed patentable.

For these reasons, virtually every nation in the developed world recognizes the patentability of DNA-based inventions.

BIO's Position on Proposed Amendment

BIO believes that the proposed amendment to the Australian patent law would, if adopted, have significant unintended and adverse consequences in all sectors of biotechnology and for patients and consumers in Australia. This amendment would exclude from patent protection “any” biological material, whether a human gene or otherwise, that is substantially identical to a naturally-occurring biological material. Specifically, the amendment states that the following materials would be categorically declared unpatentable:

“biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.”

The proposed amendment defines “biological materials” broadly to “include,” but apparently not limited to, such fundamental biotechnology building blocks as “DNA, RNA, proteins, cells and fluids.”

As almost any biological material can be said to be “substantially identical” to some other natural biological material, this change would have the effect of banning large swaths of previously patentable innovative biological discoveries – thus, removing the protection needed to incentivize investment in biotechnology-related innovation in drugs and biological therapies, preventative treatments such as vaccines, animal healthcare products, renewable energy production and other “green” technologies, environmental mitigation and remediation, biodiversity, farming, food, nutrition, household cleaners, and industrial fermentation for food and fuel production.

BIO and its members believe that excluding biological inventions from patent protection is inconsistent with the demonstrated evidence of social benefit from isolating and purifying active compounds from previously ineffective mixtures occurring in nature. For example, the invention of isolated polymerase from certain thermophilic bacteria has provided valuable methods for amplifying DNA that enables forensic DNA analysis to establish guilt or innocence of crimes, the development of life-saving medical diagnostics, and molecular breeding for improved plants. If the amendment had been law, it would have prevented the patenting – and thus development – of significant advances in human health, like purified insulin, adrenaline, and antibiotics; vitamin D and B-12 compositions; human growth hormone; erythropoietin, and numerous vaccines and anti-cancer treatments on the market today.

Accordingly, BIO believes that this amendment, if adopted, would fail to affect its intended purpose of advancing medical and scientific research and the diagnosis and cure of human illness and disease. Indeed, it would slow such progress immeasurably. The public demands continuing the patent incentive for such biologic innovation.

BIO also believes that the amendment would bring Australian law into possible conflict with Australia's obligations under international law. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) Article 27.1 states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application." TRIPS Article 27.1 also requires that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." By carving out a specific field of technology from patent eligibility, the amendment would contravene these principles, raising questions about Australia's long-time commitment to neutral application of patent law.

Conclusion

BIO strongly opposes this amendment and calls on the Senate Committee on Legal and Constitutional Affairs to recommend that the Patent Amendment Bill 2010 be rejected by the Australian Parliament.

BIO appreciates this opportunity to submit comments on this issue and stands ready to assist the Committee in any way during its inquiry into this critical matter. If the Committee desires any additional information, a representative should contact Ms. Lila Feisee, BIO Vice President for Global Intellectual Property, at lfeisee@bio.org.