SUBMISSION TO THE AUSTRALIAN SENATE LEGAL AND CONSTITUTIONAL AFFAIRS COMMITTEE

INQUIRY INTO THE PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

GOVERNMENT OF SOUTH AUSTRALIA

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Introduction

The Government of South Australia welcomes the opportunity to make the following submission to the Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill).

On 26 November 2010, the Senate referred the Bill for inquiry and report.

The purpose of this Private Senators' Bill (introduced by Senators Coonan, Heffernan, Siewert and Xenophon) is to amend the *Patents Act 1990* to prevent the patenting of human genes and biological materials existing in nature.

Key Messages

1. The South Australian Government supports the Bill. The proposed amendment explicitly defines the identification of human genes and biological materials as a discovery and, therefore, not patentable subject matter.

2. The South Australian Government is supportive of a patent system where the scope of the patent awarded is commensurate with the invention that has been created. The proposed amendments provide greater clarity in this regard by ensuring that the discovery of naturally existing biological material is not patentable.

3. The enforcement of broad patent claims specifically related to human genes and biological materials, as they exist in nature, have been shown to have an adverse impact on the provision of health care, including medical research, the scope of provision of training and accreditation of health care professionals and the cost of performing certain genetic tests within South Australia. Removing the opportunity to broadly patent human genes and biological materials, as they exist in nature, will reduce these negative impacts.

Background

In March 2009, the South Australian Government made a submission to the Senate Community Affairs References Committee Inquiry into Gene Patents. The Inquiry focussed on the impact of granting patents in Australia over human and other genes. The South Australian Government submission highlighted the significant impacts of these patents on the public health system. The submission is available at the following address:

http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/submissions/sub16.pdf.

The Senate Community Affairs References Committee tabled their Report on the Inquiry into Gene Patents on 26 November 2010. The Committee recommended this current Inquiry into the Bill.

Patents on biological materials are regulated like any other patent under the *Patents Act 1990* (the Act). The aim of the Act is to encourage openness in developing new products and processes to foster further development and commercialisation.

It has long been accepted under Australian patent case law that discoveries are not patentable subject matter, as per section 18 of the Act. The identification of a biological material, as it would exist in nature, would appear to be what is considered a discovery.

The Bill seeks to amend the Act to expressly exclude from patentability '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'.

Discussion

The aim of patenting is to encourage openness in developing new products and processes to foster further development and commercialisation. The South Australian Government is supportive of a patent system that fosters research that will lead to better health outcomes for all South Australians.

The proposed amendment explicitly defines the identification of human genes and biological materials as a discovery and, therefore, not patentable subject matter.

While the initial discovery of the naturally existing biological material may not be patentable, the flow on applications of the naturally existing biological material would still appear to be patentable, including:

- use of the biological material in treatments and diagnostics
- compositions and formulations containing the biological material
- methods of extracting, making, isolating, purifying, or modifying the biological material.

The South Australian Government supports the amendment and is supportive of a patent system where the scope of the patent awarded is commensurate with the invention that has been created. The proposed amendments provide greater clarity in this regard by ensuring that the discovery of naturally existing biological material is not patentable.

The enforcement of overly broad patents, specifically related to human genes and biological materials, as they exist in nature, has shown to have an adverse impact on the provision of health care, including medical research, the training and accreditation of health care professionals and the cost of performing certain genetic tests within South Australia.

Removing the opportunity to broadly patent human genes and biological materials, as they exist in nature, will reduce these negative impacts, which are discussed in further detail below.

Impact on progress in medical research

Broad gene patents put a claim on a wide scope of the technology (covering both current and potential uses) thus making it impossible for health and medical researchers to expand their investigation into a gene. Overly broad patent considerations that cover potential applications prevent researchers from being innovative, which defeats the objectives of research and development. Researchers are often concerned that potential patent challenges could negatively impact their research and budgets.

Impact on the scope of provision of training and accreditation of health care professionals

The broad patenting of human genes, as they exist in nature, adversely affects the scope of provision of training and accreditation of health care professionals. Patent considerations could discourage public laboratories from exploiting certain genes, thus limiting the development of knowledge on those genes and the amount of laboratory time committed to those genes.

High licence fees

Broad gene patents potentially allow non-Government organisations to impose their monopoly upon public health services by charging high licence fees for the use of their gene patents. Increased costs limit the ability of the health system to have access to new patented technologies.