

**SUBMISSION BY THE DEPARTMENT OF HEALTH AND AGEING
TO THE SENATE LEGAL AND CONSTITUTIONAL AFFAIRS COMMITTEE
INQUIRY INTO THE PATENT AMENDMENT BILL 2010**

The Department of Health and Ageing welcomes the opportunity to make a submission to the Senate Legal and Constitutional Affairs Committee Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Private Senators' Bill).

The key policy objective for the Health and Ageing portfolio is to ensure affordable access to appropriate and high quality healthcare while supporting and maintaining the biomedical research and innovation activities that are necessary to continue to improve health outcomes. These issues were canvassed in detail in the Department's earlier submission to the Senate Community Affairs References Committee Inquiry into gene patents (the Senate Inquiry) – see [Attachment A](#).

Advances in medical research and commercialisation of inventions are time consuming, expensive and risky ventures. Patent protection provides for a time-limited monopoly to exploit an invention and is a key government mechanism to allow investors and industry to recoup the costs of innovation and translate basic biomedical research into products and/or treatments for the community's benefit. To maintain investment in scientific research, and to support the equitable provision of effective healthcare, a balance is required between encouraging the publication and use of information on natural phenomena to promote continued scientific discovery, and allowing the patenting of scientific inventions to reward technological innovation.

The Department is of the view that genes (or portions of genes) and biological materials that have a natural homologue (i.e. are identical to those that are 'naturally-occurring') are not inventions and hence should not be considered patentable subject matter. The intrinsic nature and function of a gene is not altered when it is isolated, purified or cleaved to remove the regions that do not code for the formation of proteins. While the full sequence of the normal human genome has been published, future investigations will increasingly uncover mutations and expressions of the genome that are associated with disease. Free access to genetic material, including the normal genome and its mutations (as well as information relating to the association of genes with disease), is essential to promote continued innovation in the prevention, diagnosis, prognosis and treatment of disease.

The focus of the recent Senate Inquiry, and other related reviews, has been on affordable and timely access to diagnostic tests for single-gene mutations. Increasingly however, scientific research points to a complex interaction involving multiple genes in causing disease such that, in the near future, restraint on access to any one gene will impede progress in developing diagnostics and targeted treatments, thus reducing the scope for open competition to produce affordable medicines and therapies for a range of conditions.

Comments on the Bill

The Private Senators' Bill follows the Senate Inquiry which considered, among other things, whether an isolated gene should be classified as a discovery or an invention. If enacted, this Bill would amend the definition of 'patentable inventions' under section 18 of the *Patents Act 1990* to include a specific prohibition on the granting of patents over genes and some biological materials.

The Department supports the intention of this Bill which is to clarify the distinction between discovery and invention as it applies to biological materials, including isolated and purified genetic material. As drafted, this Bill would not preclude patents over novel methods and processes. Nonetheless, the Department has reservations about certain elements of the Bill that may have unintended consequences on key Health and Ageing portfolio objectives.

As currently proposed, this Bill appears to seek a broader exclusion than genes and biological materials with naturally-occurring homologues. Such a possibility arises from the open definition of 'biological materials' (i.e. use of the term '*includes*' rather than '*means*'), and the exclusion of '*biological materials, their components and derivatives*' that are '*substantially identical to such materials as they exist in nature*'. The Department is of the view that certainty regarding any exclusion from patentability is required, preferably by more specific definition of terms.

Finally, the Bill does not provide clarity over the application of this Bill to patent applications currently being considered by IP Australia. This could be remedied by the inclusion of transition provisions to provide greater certainty to researchers, health professionals and industry alike, and to ensure that existing, settled property rights are not disturbed.

Comments on the potential consequences of the Bill

The Department acknowledges the Bill arose from community concern and parliamentary debate over whether the current practice of allowing patents over isolated genes should continue. While agreeing that isolated genes are discoveries and not inventions, the Department is concerned that any amendment to the *Patents Act 1990* must be carefully constructed and tested to ensure that the restriction on patentable inventions targets only the intended subject matter.

Technological developments relating to prognosis, diagnosis and therapy are increasingly stemming from advances in human genetics and biotechnology. It is therefore essential to carefully consider whether current ways of managing intellectual property, including claims over novel diagnostic and therapeutic technologies, are congruent with community needs. However, attempts to codify a narrowly targeted prohibition, for technologies where relatively minor changes can have significant functional implications, may prove difficult.

Similarly, the Department is mindful of the tension between clarifying the distinction between discovery and invention and ensuring that Australia's patent law remains compliant with obligations under international treaties and trade agreements to afford patent protection to all inventions, without discrimination.

Summary

The Department supports the intention of this Bill to the extent that it seeks to clarify the distinction between discovery and invention as it applies to genes and biological materials, including isolated and purified materials (whether normal or mutant) that are identical to those that occur in nature. However, as presently worded, the Department believes this Bill may apply more broadly than genes and biological materials with naturally-occurring homologues, with potentially significant consequences on Australia's biotechnology research and development sector.

The Department encourages further and broader debate on the scope, potential application and consequences, both intended and collateral, of this Bill in relation to access to scientific knowledge gained through discovery, as well as to innovative diagnostic tests, vaccines, targeted medicines and other therapies within the healthcare system.

The Department again thanks the Senate Legal and Constitutional Affairs Committee for the opportunity to contribute to the debate over this important issue, which has potentially wide-reaching ramifications for Australia's healthcare system.