Australian Government

Department of Health and Ageing

SECRETARY

Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
Parliament House
Canberra ACT 2600

Dear Ms Dennett

The Department of Health and Ageing (the Department) appreciates the further opportunity to provide the Committee with the Department's perspective on the issues surrounding the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, and the patenting of genes more broadly, in light of issues that were raised in evidence presented to the Committee's recent public hearings.

As you are aware, representatives of the Department, including myself, appeared before the Committee on 29 April 2011. Having reviewed the proof Hansard transcript, the Department would like to further elaborate and clarify the issues touched upon by Senators that are relevant to the Health and Ageing portfolio.

The Department firmly supports the granting of patents for novel therapeutic goods ('subject-matter' patents) or processes ('method' patents). Patents provide an important tool to reward innovation and encourage the commercialisation of medical research. Ultimately, the translation of biomedical research into inventive and useful treatments, therapies and diagnostics ensures Australians continue to have access to affordable, effective healthcare.

To maintain Australia's standing in the field of biotechnology, the Department supports efforts to improve the quality of Australian patents by raising the thresholds of 'novelty', 'inventiveness' and usefulness to bring Australia's patent system in line with international practice and ensure that patent monopolies only reward true innovation. Likewise, the introduction of a research exemption will provide greater certainty and protection to many research institutes, who currently operate in an atmosphere of legal uncertainty.

However, these reforms do not address the issue which is the focus of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 and which was explored by the recent Senate Community Affairs References Committee inquiry into gene patents: the current practice of granting patents over isolated, naturally-occurring genes.

It is the Department's view that isolated gene sequences that are homologous to those that occur naturally are discoveries, and we have concerns about these being considered patentable subject matter eligible for the grant of a patent monopoly. Despite the energy and ingenuity expended to identify the natural function of a particular gene, its mere isolation from the larger human genome and extraneous cellular material does not give rise to an

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invention where the isolated gene sequence remains identical to the sequence of its native homologue.

The term 'deconstruction', as used during the Committee hearing, is a non-technical term; and, like the similar phrase 'isolation and purification', the Department remains of the view that isolation (or 'deconstruction') without transformation does not result in a genetic sequence structurally or functionally different from its native homologue.

It is the Department's view that an isolated, naturally-occurring gene that is transformed through engineering into a product with a structure and/or function distinct from the naturally-occurring sequence (such as a vaccine) is truly a product of human ingenuity; and the Department is supportive of these being considered patentable subject matter. Similarly, the process for isolating and engineering the gene sequence may be patentable, provided that other thresholds of 'inventiveness', 'novelty' and usefulness are met. However, inclusion of an isolated, naturally-occurring gene sequence in a patent over the engineered product, or the process of its manufacture, restricts access to fundamental genetic information that may be necessary for the prevention, diagnosis or treatment of human disease.

As previously indicated, the Department supports the intention of the Patent Amendment (Human Genes and Biological Materials) Bill 2010, to the extent it seeks to clarify this long-standing distinction between a 'discovery' and an 'invention'. However, we continue to have reservations about the breadth of Bill and its effectiveness as a tool to ensure unfettered access to naturally-occurring genetic information necessary to deliver affordable, high-quality healthcare. The Department agrees with submissions that existing patents over diagnostic processes, for example the BRCA test, are likely to remain unaffected if this Bill is passed.

The Department notes that current practice in comparable countries is to allow patents over naturally-occurring genes. However, the Department is also aware of ongoing international and domestic debate and litigation that is revisiting this practice in light of community concerns and the historical rationale of the patent system as a social compact to reward genuine innovation and encourage the dissemination of research.

I thank the Committee for providing a forum to debate this important issue and for inviting the Department to contribute to its deliberations.

Yours sincerely

Jane Halton PSM
Secretary

24 May 2011