Senate Standing Committee on Community Affairs
ANSWERS TO QUESTIONS ON NOTICE
Public Hearing of 19 March 2009
Senate Inquiry into gene patents
Department of Innovation, Industry, Science and Research

Nature of Question	**Senator**	**Hansard Reference**
Use of exclusions under TRIPS Article 27(3)(a) and US FTA Article 17.9(2)(b)	Heffernan	CA22

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Question

Agency: IP Australia

Topic: Senate Inquiry into gene patents

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Senator HEFFERNAN—I just want to say that the US free trade agreement and the TRIPS document state:

Each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application.

It says that in both documents. It continues:

A Party may exclude from patentability—

And it goes through that. This is what they may exclude from patentability in both the free trade agreement and the TRIPS document:

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

It says it in both documents. So if we want to, we can actually exclude the patents. Do you agree?

Answer:

The TRIPs and AUSFTA passages quoted by Senator Heffernan are from Articles 27.1 and 27(3)(a) of the TRIPs Agreement, which are replicated in Articles 17.9.1 and 17.9.2(b) of AUSFTA.

Articles 27.3(a) and 17.9.2(b) (hereafter 'the Articles') give Australia the ability to exclude certain subject matter from patentability should it wish to exercise that right. The exclusion is confined to 'diagnostic, therapeutic and surgical *methods* for the treatment of humans or animals'. Therefore, Australia could, should it wish to do so, exclude such *methods* from patentability, but it could *not* rely on those Articles to exclude products such as isolated human gene sequences from patentability. It is also not clear whether the Articles could be relied on to exclude a diagnostic method to treat humans if the method contains a product as an integral component.

Our understanding of the effect of applying the exclusion from patentability available under the Articles on typical claims of a 'gene patent' is noted in Figure 1.

In choosing to apply the Articles, regard needs to be had to Article 17.9.14 of the AUSFTA which is a 'best endeavors' undertaking to reduce differences in law and practice between respective patent systems.

Also, the Committee's attention is drawn to the many submitters to the Inquiry who argue against patenting of isolated gene sequences per se, but support patenting of new methods or uses of the sequences, e.g. diagnostic tests and therapeutic methods to better treat humans against diseases.

Figure 1: Gene Patent

Typical Product Claims	**Effect of Articles**
• Isolated gene sequence *per se* • Isolated protein encoded by the gene sequence • Vectors harbouring the isolated gene sequence • Cell lines transformed with the vectors or sequence • Recombinant protein expressed from the cell lines • Antibodies produced using the sequence or fragments of the sequence • Probes comprising the sequences or fragments • Vaccines and compositions comprising the sequence or protein • Kits comprising the sequence or specific primers or fragments of the sequence	None of these would be excludable
Typical Method Claims	
• Use of the gene or protein sequence to diagnose or prognose disease or disorders associated with the gene	Ability to exclude **uncertain** because use of the isolated gene/protein (i.e. product) per se is necessary for the diagnosis (ie integral to the method)
• Use of the sequence and/or protein as a therapeutic to treat a disease or disorder associated with the gene	Ability to exclude **uncertain** because the use of the isolated gene/protein per se is necessary in the treatment (ie integral to the method)
• Methods of identifying molecules that modulate or interact with the gene wherein the methods are directly based on the use of the sequence	Not excludable because this is not a diagnostic or therapeutic method to treat human/s as required under the Articles
• Gene therapy using the sequence	Ability to exclude **uncertain** because the isolated gene per se is necessary in the therapy (ie integral to the method).