



Law Council
OF AUSTRALIA

Business Law Section

The Commissioner of Patents
IP Australia
PO Box 200
Woden ACT 2606

Via email: mdb-patents-consultation-group@ipaaustralia.gov.au 16 November 2015

Dear Commissioner,

Proposed examination practice following *D’Arcy v. Myriad Genetics Inc.*

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (IPC) takes this opportunity to make a brief submission in response to the public consultation on the Commissioner’s proposed examination practice following the High Court of Australia’s decision in *D’Arcy v. Myriad Genetics Inc* [2015] HCA 35.

A key determination of the High Court in that decision is at [89] in the judgment, which reads:

The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated in to the BRCA₁ polypeptide. That sequence can properly be described as “information”...

[T]he information stored in the sequence of nucleotides coding for the mutated or polymorphic BRCA₁ polypeptide is the same information as that contained in the DNA of the person from which the nucleic acid was isolated.

On that basis, the relevant claims of the patent were held not to disclose a manner of manufacture.

The IPC does not consider the decision to be to the effect that no isolated naturally occurring material is patentable. The decision is directed to claims in which an isolated nucleic acid *merely represents information*, namely a sequence, coding for a polypeptide. The Court was not asked to, and did not, consider anything other than the particular naturally occurring material the subject of the claims in issue.

In particular, the decision does not appear to impact on the patentability of new biological drugs and products, isolated naturally occurring proteins, molecular probes and primers for diagnostic tests, and genetic and diagnostic tests. Indeed claims of a number of these

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specific kinds were contained in the patent in suit. Their validity was not contested and they survive the decision.

Accordingly, the IPC considers the Commissioner's proposed examination practice to be a measured and appropriate response to the High Court's decision.

If you have any questions regarding this submission, please contact the chair of the IPC, Sue Gilchrist, by phone on 02 9225 5221 or by email at sue.gilchrist@hsf.com.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'John Keeves', with a long horizontal flourish extending to the right.

John Keeves, Chairman
Business Law Section