

OUR REF: General

YOUR REF: *Myriad Consultation*

By email only

6 November 2015

The Commissioner
IP Australia
Woden
ACT 2606
Australia

Consultation on proposed examination practice following the High Court decision in *D'Arcy v Myriad Genetics Inc*

In response to the request for submissions on the proposed examination practice following the decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 (Myriad), we would like to state that we agree with the proposed practice.

The majority of the Judges (French CJ, Kiefel, Bell, Keane and Gordon JJ) in Myriad emphasised that an essential element of the claimed invention was the information encoded by a naturally occurring nucleic acid sequence (see for example paragraphs 91-94 and 244-249). Under this rationale naturally occurring nucleic acid sequences (whether human or otherwise and whether DNA or RNA) and sequences which encode the same information as a naturally occurring sequence (such as cDNA) should not be patentable subject matter.

However, where information is not an essential element of the invention, then there is no basis in the majority judgement in *Myriad* to exclude subject matter. For example, in certain cases a nucleic acid molecule may have a function divorced from the informational nature of the compound (for instance ribozymes).

Non-naturally occurring sequences, such as transgenes do not encode information which exists in nature and therefore likewise do not fall within the principles of Myriad. Information content is not an essential feature of proteins, small molecules, micro-organisms etc and therefore these too should remain patentable.

We consider that the proposed practice appropriately draws the line at only those naturally occurring nucleic acid sequences whereby an essential element of the invention is the information encoded by the sequence.

Note on the decision of Gageler and Nettle JJ

Although in the end result Gageler and Nettle JJ concurred with the majority discussed above, their reasoning differed, referring to a so-called "threshold quality of inventiveness". We submit that this reasoning is a minority opinion and therefore much less persuasive than the majority decision. Accordingly we consider that the test suggested by these judges should not be applied without further judicial consideration.

Yours faithfully
HENRY HUGHES IP
Australia and New Zealand



David Nowak
Registered Patent Attorney – Australia and New Zealand