

The Secretariat for the PCG

6 November 2015

Via email: mdb-patents-consultation-group@ipaustralia.gov.au

Dear Commissioner

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

We make the following submissions on the proposed practice of the Commissioner in response to the call for comment. We wish to propose some clarifications of the subject matter considered patent ineligible.

We agree with the observation of the Commissioner that the decision concludes that “a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible.” The Myriad decision and the Commissioner's practice direction are therefore focussed on claims that, in substance, include a nucleic acid sequence that merely represents information. This was a key aspect of the reasoning of at least the majority and, to some extent, all judges. It is also reflected in the categories of claims that the Commissioner proposes will remain patent eligible, such as probes and primers.

The Commissioner outlined 4 categories of claims which are proposed to be patent ineligible:

- Naturally occurring (human) nucleic acid sequences encoding polypeptides or functional fragments thereof - either isolated or synthesised;
- Naturally occurring (non-human) nucleic acid sequences encoding polypeptides or functional fragments thereof - either isolated or synthesised;
- cDNA; and
- Naturally occurring human and non-human coding RNA - either isolated or synthesised.

Each of these categories relates to polynucleotide sequences so the differences between the categories are potentially unclear. For example, RNA has its own category when it also seems to be within the first two categories.

Moreover, we believe that there is no basis in the High Court reasoning for cDNA to be rejected for patentability in its entirety. This majority judgement comment on the patentability of cDNA in paragraph 89 that the same standard should be applied to cDNA as other polynucleotides and therefore cDNA should only be patent ineligible where a claim to cDNA encompasses the information residing in that cDNA. This is the rationale on which the High Court determined that a claim would not meet the requirement of a manner of manufacture. cDNA sequence information is therefore not patentable, according to the majority at least, only to the same extent as any other polynucleotide.

Accordingly, in our submission, the Commissioner's summary of patent claim categories that are patent ineligible in light of the High Court's decision in Myriad could be refined by referring to the “information” element of the reasoning and phrasing as follows:

- Naturally occurring (human) nucleic acid sequence information encoding functional polypeptides or functional fragments thereof - either isolated or synthesised;
- Naturally occurring (non-human) nucleic acid sequence information encoding functional polypeptides or functional fragments thereof - either isolated or synthesised;
- cDNA nucleic acid sequence information of human or non-human origin encoding functional polypeptides; and
- Naturally occurring human and non-human coding RNA sequence information encoding functional polypeptides or functional fragments thereof - either isolated or synthesised.

We have not commented on the list of categories of claims that remain patent eligible as it appears to be presented as a non-exhaustive list and therefore less specificity is necessary. If the Commissioner proposes to alter that list in response to comments on the proposed practice note, we would welcome the opportunity to comment on any proposed changes.

Yours faithfully

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