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27 October 2015 Our Ref: GF109/Consultation

Attention: The Commissioner

Dear Madam,

Re: **Consultation on IP Australia's proposed examination practice following the High Court Decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35**

We refer to the Notice dated 16 October 2015, inviting comment on IP Australia's proposed examination practice following the High Court Decision in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 ("the Myriad Decision").

We note that the Commissioner has interpreted the Myriad Decision as meaning that a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible. On this basis, claims to the following categories of subject matter are to be considered as not patent eligible:

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

The above conclusions are not set out in the Myriad Decision in these terms. We respectfully submit that the above interpretation of the Myriad Decision is incorrect.

The proposed categories fail to clearly define any subject matter. Furthermore, the proposed categories seek to extend the conclusions of the Myriad Decision beyond the subject matter considered by the High Court to lack patent eligibility.

The proposed categories fail to clearly define any subject matter

The first two categories do not include references to naturally occurring, functional polypeptides.

Naturally occurring nucleic acid sequences encoding polypeptides

The High Court made clear its understanding that isolated nucleic acid sequences are incapable of producing a functional BRCA1 protein. There was no statement by the High

Court relating to a generalised exclusion of nucleic acid sequences "*encoding polypeptides*". All "*encoding*" references in the Myriad Decision are made specifically within the context of the BRCA1 protein (or variant thereof), a naturally occurring, functional protein.

We submit that the generalised term "*encoding polypeptides*" lacks clarity. The word "*encoding*" is passive, requiring only that a polypeptide sequence be inherent in the nucleic acid sequence. By definition, all nucleic acid sequences (even primer sequences) encode polypeptides, in each of the six (6) frames present in the nucleic acid sequence.

We refer to the first sentence in paragraph 49 of the Myriad Decision:

> "The so-called "genetic code" consists of groups of three nucleotides, called "codons" or "triplets", each coding for an amino acid. …" (emphasis added)
>
> and to paragraph 52, spanning pages 27 to 28:
>
> "The mRNA molecule moves through the nuclear envelope into the cytoplasm. Its nucleotide sequence is used as a template in a process of "translation" resulting in the manufacture of the polypeptide chains comprising the relevant protein. That manufacture takes place in the ribosomes located in the cytoplasm. The RNA sequence is scanned in groups of codons which each define a specific amino acid. Depending upon which strand of DNA is read and the start site for its transcription and translation, different mRNAs and different proteins can result from the same stretch of DNA. It is also possible that a single stretch of DNA may be transcribed in two different directions, resulting in two different proteins with different amino acid sequences. The notion of one gene per protein is now understood to be simplistic." (emphasis added)

This means that a polypeptide sequence can be theoretically derived from each of the six (6) frames of a nucleic acid sequence, irrespective of whether a functional polypeptide having that sequence can be produced from the nucleic acid sequence. In other words, every nucleic acid sequence arguably encodes polypeptide sequences, most of which will be nonsense non-functional sequences. Such sequences will not be produced due to lack of translation signal sequences.

The above-mentioned categories therefore include nucleic acid sequences falling within the categories that are considered by IP Australia to be patent eligible. That is, primers and probes consisting of nucleic acid sequences, proposed to be defined as patent eligible, will also fall within the excluded categories.

Furthermore, the reference to "*synthesised*" is a direct contradiction to the earlier reference to "*naturally occurring … nucleic acid sequences*". The High Court did not refer to synthesised nucleic acid in these terms but rather as set out in paragraphs 89 and 197 of the Myriad Decision:

> "…Used in that sense, the 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. It is the existence of that information which is an essential element of the invention as claimed. The product is the medium in which that information resides. That

> characteristic also attaches to cDNA, covered by the claims, which is synthesised but replicates a naturally occurring sequence of exons."
>
> …
>
> "It is possible to create synthetic DNA. For example, complementary DNA (cDNA) is an artificial form of DNA which is made using a form of RNA (mRNA) as a template to create DNA that is complementary, but not identical, to naturally occurring DNA. cDNA is used in research."

It is submitted that such subject matter relating to synthetic molecules would be more appropriately classed in category 3, as outlined below.

In summary, to clarify that the information contained within the nucleic acid sequence relates to a functional polypeptide or protein which occurs in nature, we suggest that the following categories should be amended as follows:

1. Naturally occurring (human) nucleic acid sequences encoding naturally occurring polypeptides or functional fragments thereof ~~– either isolated or synthesised~~
2. Naturally occurring (non-human) nucleic acid sequences encoding naturally occurring polypeptides or functional fragments thereof ~~– either isolated or synthesised~~

The proposed categories seek to extend the conclusions of the Myriad Decision too far

The third and fourth categories are broader than the first two categories, and are couched in terms beyond that contemplated by the High Court.

cDNA

It is submitted that the High Court did not conclude that cDNA *per se* lacks patentability. Not even the decision by the U.S. Supreme Court in analogous proceedings went this far, as referred to in paragraph 79 of the Myriad Decision:

> "…The Supreme Court had accepted that the creation of a cDNA sequence from mRNA resulted in an exon-only molecule that was not naturally occurring and was therefore patentable. …."

To derive the wording of the proposed category 3 from the Myriad Decision is to seek to extend the conclusions of the Myriad Decision too far.

All reference to the term "*cDNA*" in the Myriad Decision occurs within the context of the information encoded by the cDNA. We refer again to paragraph 197 of the Myriad Decision, set out above, which refers to cDNA as complementary to the naturally occurring sequence. That is, nucleic acid sequence encoding a naturally occurring polypeptide. In line with the above, we suggest that this category should be amended as follows:

3. cDNA insofar as it corresponds to the naturally occurring sequence of uninterrupted genomic DNA

Naturally occurring human and non-human coding RNA

We submit that the term "*nucleic acid*" in the first two categories encompasses RNA. There is therefore no need to separately define RNA as distinct from nucleic acid.

To derive the wording of the proposed category 4 from the Myriad Decision is, again, to seek to extend the conclusions of the Myriad Decision too far.

It is also not clear what the term "*coding RNA*" means as all RNA includes code. If this term is intended to equate to "*encoding polypeptides*" as discussed above, then it is not clear why the different terminology of "*coding*" has been used. Furthermore, it is not clear why a distinction has been made between "*coding RNA*" and noncoding RNA.

We suggest that category 4 be deleted as already covered by category 1 and 2.

Yours respectfully,

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Encl.