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**To the IP Australia Commissioner,**

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

**Reference: IP Australia website:**

*<http://www.ipaustralia.gov.au/about-us/public-consultations/Consultation-on-our-proposed-examination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/>*

I am a research scientist at The University of Queensland but I am writing in my capacity as a private citizen, not as a representative of the University. I have worked extensively in medical research and biotechnology, am a patent holder myself and appreciate the importance of patent protection over the products of medical research. Nonetheless I support the High Court's interpretation in this case, believing that it is important to find a balance between incentives to develop diagnostic testing on the one hand, and on the other, the social implications for the health needs of individuals when it comes to maintaining a fair and competitive regime for diagnostic testing.

It is also important that IP Australia develop an internally consistent policy which will lead to stability and certainty for future patent applications.

As stated in your proposal, the upshot of the decision was that *"a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible."*

Your proposal, however, goes on to imply that *a claim to an isolated nucleic acid that represents information coding for a regulatory region affecting the expression of a polypeptide is patent eligible.*

This is a serious inconsistency which carries the potential for great harm. Biology has long ago left behind the idea that disease-causing genetic mutations are due only to defects in polypeptides (the "one gene one enzyme" theory of Beadle and Tatum). As you will be aware, disease-related genes such as BRCA1 can be subject to nucleic acid mutations which act not only within the polypeptide coding sequence, but also within many non-coding parts of the gene. These include

splicing defects, non coding RNA defects, promoter and enhancer defects and various other problems with the production of a mature polypeptide.

This proposal creates the situation where disease-causing nucleic acid mutations in BRCA1 (or any other disease-causing gene) though equally amenable to sequence analysis by PCR, for example, are arbitrarily separated into two classes; (1) defects in the polypeptide coding sequence that are not patent protected and (2) defects involving other sequences in the gene which remain subject to patent protection, even though they also consist merely of variant DNA sequences (e.g. a defect in a promoter) and as such fall into the same category of "information" that was highlighted for polypeptides in the Myriad case.

Consider for example, the case of a point mutation at the edge of a splice site. Here, the codon is in black, the splice site in red.

NNN**AGT**\_\_(intron)\_\_\_**AG**TTNNN

Normally this is spliced so that the following polypeptide sequence results:

NNN**ATT**NNN

A point mutation in the last position of the codon just prior to the splice site (e.g. "A" to "T") will produce an amino acid substitution or (if lost) a frameshift (which will also change the polypeptide sequence). This, according to your proposal, would not be patentable. A point mutation in the very next nucleotide in the genome (e.g. "G" to "C") will disrupt splicing, which would also change the polypeptide sequence, but under your proposal, WOULD be patentable, because it is not part of the "protein coding sequence". It would (at least in the wild type case) be classed as being "intergenic DNA". Worse, the loss of a base pair in the last codon (i.e. loss of "A") would now bring the first intergenic base pair ("G") into position as the last base pair of the last codon before the intron.

NNN**GT**\_\_(intron)\_\_\_**AG**TTNNN

How is this nucleotide ("G") to be viewed? Is it still "intergenic"? or is it now "protein coding"? The definition is purely a matter of arbitrary classification. The central functional issue, however, is *exactly that identified by the High Court in the Myriad case*, namely that the information in the nucleotide sequence is what is of interest, and this was found to be not patentable.

The case of noncoding RNAs is also a concern. A noncoding RNA can be equivalent to a protein in every functional respect except that it is chemically composed of RNA and not amino acids. Many noncoding RNAs are molecular machine, produced by transcription from the genome in the same way as a

protein, including the occurrence of splicing. The RNA elements of the ribosome and telomerase are cases in point. Such a noncoding RNA is considered to be a "gene" just as much as any protein-coding sequence.


To establish an arbitrary difference between the "information" in a protein-coding region and the "information" in some other region of the gene that similarly results in a defect, begs for a further inevitable challenge to extend the High Court decision to these situations, with all the uncertainty and disruption that will ensue. Not only expensive and time-consuming litigation will result, but delays, confusion and loss of certainty within medical research and the biotechnology industry. Most importantly, vested interests will already have been established under this proposal which will create losers and winners in the event of a challenge. It would be far better to begin with a proposal which incorporates the sense of the High Court's approach and extends it in a logical fashion rather than employing a legalistic restriction to its scope which will be unlikely to prevail in the future.

Clearly genetic elements – including DNA coding for polypeptides - can still be patented within the scope of a particular use, or when suitably modified (for example, when a promoter is used as an artificial control element for transgenic applications) so the loss of patentability of the sequence itself in the context of the Myriad decision should not prevent useful inventions employing these elements.

Therefore I urge you to exclude from patentability at least the following classes:

- Naturally occurring isolated regulatory DNA (e.g. promoters, enhancers, inhibitors, intergenic DNA)
- Isolated non-coding (e.g. "Junk") DNA
- Isolated non-coding RNA (e.g. miRNA)

Sincerely,

A handwritten signature in black ink, appearing to be 'I. Ross', written over two horizontal lines.

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