

2 November 2015

The Commissioner
Secretariat for the PCG
mdb-patents-consultation-group@ipaaustralia.gov.au

Re: Consultation on IPA's proposed examination practice following the High Court decision in D'Arcy v Myriad Genetics Inc (<http://www.ipaustralia.gov.au/about-us/public-consultations/Consultation-on-our-proposed-examination-practice-following-the-High-Court-decision-D'ArcyvMyriad-Genetics-Inc/>);

The Royal College of Pathologists of Australasia notes the revised examination process proposed by IP Australia following the High Court's recent decision regarding patentability of the BRCA1 gene. We understand that IP Australia is seeking responses to the proposed examination process, and we submit the following observations for your consideration.

The High Court allowed the appeal against the patentability of the BRCA1 gene on the basis of its general consideration of the patentability of genetic material. The court concluded that

- A claim cannot apply to
 - a fact such as naturally occurring information¹
 - the association between facts².
- A claim may apply to
 - the use of facts (in a process)
 - the vehicle for accessing or using facts (as a product)but only to the extent that such claims do not encompass the facts or associations³.
- A claim cannot cover a process or product for which breach can only be evident after the event⁴.

We recognise that the High Court was addressing an appeal regarding specific claims of a specific patent, but the basis on which the appeal was allowed was general and was not restricted to the specifics of the individual case. The Court clearly recognised that this was an instance in which case law was defining a general aspect of patent law (see paragraph 7 of the High Court ruling).

On this basis, we are concerned to note that the principles articulated by the High Court and used as the basis for their decision do not appear to be reflected in the revised examination process proposed by IP Australia. We note some specific concerns below:

- IPA proposes that naturally-occurring regulatory DNA, non-coding DNA, and non-coding RNA be patent eligible. This is contrary to the rationale articulated by the High Court. The High Court did not limit its considerations to naturally-occurring

¹ see paragraphs 6, 89, 91, 121, 134, 137, 146, 162, 165, 168, and 229 of the High Court's ruling.

² see paragraph 165.

³ see paragraphs 148, 150.

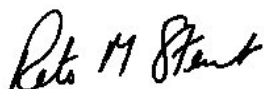
⁴ see paragraphs 93, 138, 259.

variation in coding sequences, but addressed the more general issue of the patentability of naturally occurring facts. On this basis, non-coding DNA would be no more patent eligible than coding DNA.

- Similarly, IPA proposes that natural and synthesised polypeptides be patent eligible. This is contrary to the general considerations articulated by the High Court. The principles by which the High Court concluded that a copy of naturally-occurring DNA sequence is not patent eligible apply equally to a natural or synthesised polypeptide.
- IPA proposes that polyclonal antibodies be patent eligible. The normal biological activity and polypeptide sequences of polyclonal antibodies represent naturally-occurring facts. If this fact is used in a novel process or a novel purpose, then the process or purpose may indeed be patent eligible. But, on the basis of the fundamental principles articulated by the High Court, the polyclonal antibodies themselves would not be.
- Similarly, the IPA proposal that fusion proteins be patent eligible is not necessarily in keeping with the rationale articulated by the High Court. Fusion proteins do occur in nature (they are a common phenomenon in cancer, and a universal phenomenon in the development of antibodies). Such fusion proteins would not be patent eligible as per the rationale articulated by the High Court. However, novel fusion proteins that do not occur in nature could potentially be patent eligible. This distinction is not provided in the IPA proposal.
- We note that naturally occurring bacteria, viruses, cells, and stem cells all contain information which would comply with the High Court's definition of a natural fact. A product claim may well founder because of the information implicit in the definition of bacteria, viruses etc. A process claim based on the properties of these organisms may indeed be patent-eligible. This distinction is not provided in the IPA proposal.
- IPA proposes that anti-sense RNA molecules be patent eligible. However, such molecules do occur in nature and, as such, would be deemed patent ineligible on the basis of the High Court's ruling. Of course, an anti-sense RNA molecule that differs from that found in nature, or that is used for a novel process or product could be patent eligible. This distinction is not provided in the IPA proposal.

The College is concerned that the rationale provided by the High Court in this recent important case does not appear to be reflected in the proposals to guide the examination process by IPA.

Yours sincerely



A/Prof Peter Stewart
President