Patent Eligibility Consultation

Thank you for providing the opportunity for us to comment on your proposals for patent eligibility of various categories of biological materials in light of the recent High Court of Australia decision in *D'Arcy and Cancer Voices v Myriad Genetics*.

Our detailed comments to your proposal are provided below.

The authors of this submission are Assistant Professors in the School of Law and Justice, Faculty of Business Government and Law at the University of Canberra. Their research encompasses issues of property – including intellectual property – rights in the body, isolated parts of the body, and derivative information. That research has been reflected in Australian and overseas law, science and public policy journals.

Wendy Bonython is cross-disciplinary, with a PhD in Molecular Medicine and professional experience in medical research and health administration, in addition to her qualifications and experience in law. Bruce Baer Arnold teaches and researches in the areas of intellectual property, confidentiality and privacy law.

We would be happy to discuss our comments on your proposal further.

Yours sincerely

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Comments on the IP Australia 2015 proposal regarding patentability of biological materials

Introduction

1. This submission is structured as follows:

   It commences by briefly summarising the requirements for Patentability under the Patents Act 1990 (Cth). It then considers the basis of the challenge to Myriad’s patent over the BRCA1 genetic sequence, and the High Court’s response to that challenge, ie D'Arcy v Myriad Genetics Inc [2015] HCA 35.

   It discusses the approach adopted by the High Court in Myriad to what it identified as the ‘threshold issue’ of novelty underpinning the enquiry of whether a particular product representing manner of manufacture could be considered patentable.

   Respectfully, we consider that the Commissioner’s proposal relies on too narrow a construction of the High Court’s test based on the informational properties of the genetic sequence. The submission concludes by identifying specific reasons for rejecting patentability of each of the items proposed.

Patents

2. In order to be patentable under Australian law, an invention is required to be novel, inventive and innovative, and useful, according to Sections 7 and 7A of the Patents Act 1990 (Cth).

3. The test for novelty requires that the invention differ from others already in the prior art. Invention requires that it not ‘have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed’. Innovation requires that the invention varies from the prior art in ways that substantially contribute to the workings of the invention. In order to be ‘useful’ a ‘specific, substantial and credible’ use appreciable by ‘a person skilled in the relevant art’ must be disclosed in the patent application.

The Myriad decision

4. In Myriad, the plaintiffs sought to challenge Myriad’s patent over the BRCA1 genetic sequence (claims 1-3). The basis of the plaintiff’s claim was that the subject matter of the patent— a sequence of the BRCA1 gene containing a mutation associated with increased incidence of breast cancer – was naturally occurring, and therefore was not patentable subject matter.

5. Section 18 of the Patents Act identifies inventions which are patentable under the Act:

   (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

      (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

      (b) when compared with the prior art base as it existed before the priority date of that claim:
(i) is novel; and
(ii) involves an inventive step; and
(c) is useful; and
(d) was not secretly used in the patent area before the priority date of that
claim by, or on behalf of, or with the authority of, the patentee or nominated
person or the patentee’s or nominated person’s predecessor in title to the
invention.

Inventiveness as a threshold for patentability

6. Myriad sought patent protection for the BRCA1 sequences as a method of
manufacture, under s18(1)(a).

7. Counsel for Myriad argued, and the High Court agreed, that “other possible grounds
of invalidity such as lack of inventive step, lack of novelty and lack of utility are
irrelevant” (at [132]).

8. The High Court did, however, find that an invention must satisfy the threshold enquiry
of inventiveness as a preliminary step in determining whether the subject matter of
an invention is patentable (at [133]).

9. ‘Mere discoveries’ and ideas are not patentable under Australian law. ‘Inventiveness’
requires some form of human intervention generating difference between the
invention over which the patent is sought, and a naturally occurring state of affairs.

10. The earlier decision of NRDC established that inventiveness required generation of
‘an artificially created state of affairs of economic significance’. It did so in the context
of considering the meaning of an ‘invention’, rather than in deciding whether an
invention was “a manner of manufacture” for the purposes of s 18(1)(a) of the Act, as
was claimed in Myriad.

11. In Myriad the High Court cited justices Brennan, Deane and Toohey JJ in N V Philips
CLR 655, who said

an alleged invention will remain unsatisfied if it is apparent on the face of the
relevant specification that the subject matter of the claim is, by reason of
absence of the necessary quality of inventiveness, not a manner of new
manufacture for the purposes of the Statute of Monopolies. That does not
mean that the threshold requirement of ‘an alleged invention’ corresponds
with or renders otiose the more specific requirements of novelty and
inventive step (when compared with the prior art base) contained in
s18(1)(b). It simply means that, if it is apparent on the face of the
specification that the quality of inventiveness necessary for there to be a
proper subject of letters patent under the Statute of Monopolies is absent,
one need go no further.

12. In finding that Myriad’s patent over the BRCA mutated sequence was invalid, the
Court stated

Consequently, so far from being a claim for a manner of manufacture of
isolated nucleic acid constituted of the mutated BRCA1 gene, (the) claim …
is in truth a claim for a monopoly over the right to apply long-established
methods for the isolation and amplification of specific nucleotide fragments to
the isolation and amplification of a patient's naturally occurring BRCA1 gene, where and if it is found upon subsequent examination that the patient's BRCA1 gene happened to be afflicted by any of the specified mutations and polymorphisms. That is not a valid claim of a manner of manufacture of a product. By definition, a manner of manufacture is an artificial thing or state of affairs which involves an element of inventiveness. Although the isolation of nucleic acid comprising the BRCA1 gene is a man-made process, it does not involve any element of inventiveness. It is no more than the application of a recognised diagnostic technique to a known purpose of examining fragments of human DNA.

13. The claim essentially failed the test of inventiveness because the mutated sequence was a naturally occurring state of affairs, and hence could not be a method of manufacture.

Informational properties of DNA

14. Myriad also claimed that its patent related to a chemical compound, a view rejected by the High Court which instead characterised the claim as relating to genetic information, finding:

Identification of the subject matter of the claims as a class of chemical compounds is the premise upon which the Full Court's conclusion is based. It is a premise which, with respect, elevates form over substance to the detriment of the developmental function entrusted to the Court as explained in NRDC and reflected in the continuing use of the "manner of manufacture" formula in s 18(1)(a) of the Act.

The code in the invention as claimed refers to the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide. That sequence can properly be described as "information", the ordinary meaning of which includes:

"Without necessary relation to a recipient: that which inheres in or is represented by a particular arrangement, sequence, or set, that may be stored in, transferred by, and responded to by inanimate things".

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." (at [88-89]).

15. The emphasis on the informational component of the patent was, therefore, that the DNA sequence over which the patent was claimed was essentially an informational storage medium. It was not concerned with the nature of the information stored in that medium.

In that sense, it is over-interpreting the Court's views to restrict the approach to dealing only with DNA which encoded polypeptides, at the expense of DNA which contains information necessary for other functions, such as production of mRNA, or location of binding sites for other polypeptides.
16. Overall, it is clear from the High Court’s opinion in Myriad that there are a number of issues that require consideration in determining whether or not a biological product is patentable. The first of these is whether there is a significant difference between that over which the patent is sought, and the naturally occurring state of affairs it may be derived from. The relevant attributes of the BRCA1 sequence is the mutation associated with cancer predisposition was not created by them, but rather was isolated, or discovered.

As such, the claim lacked the inventiveness to be patentable.

17. The other factor the Court emphasised was the informational properties of DNA, indicating that the value of the sequence over which the patent was stored was attributable to its informational properties (ie predictive indicator of increased cancer risk) rather than its chemical or physical properties. Those informational properties need not be restricted to the information required for coding a polypeptide, and there is nothing to indicate that the court intended that its decision be interpreted on that narrow basis.

The fact that the Court did not specifically consider whether the informational value of a particular DNA sequence could encompass information required for other functions and activities within the cell, such as positioning information for transcription initiation factor binding, or coding for non-translated mRNAs, is a reflection of the circumstances specific to the Myriad claim. It should not be interpreted as an arbitrary determination by the Court that the only sequences that cannot attract patent protection are those that code for polypeptides.

18. Such an interpretation is inconsistent with what the Court said, and logically inconsistent with the principles under consideration in the case. It would potentially create a double standard, whereby a biotechnology company that developed a similar diagnostic test for a disease caused as a consequence of a mutation in a part of a gene which did not code for a polypeptide would be able to obtain patent protection, but a company such as Myriad, whose claim related to a polymorphism within a coding region, would not.

**Specific IP Australia proposals and responses**

19. Not patentable subject matter

- 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
- Naturally occurring human and non-human coding RNA - either isolated or synthesised

**Response:** We agree that these, with the exception of cDNA, should not be patent eligible, as they clearly fail the inventive test for patentability, as they are naturally occurring.

We note that the cDNA entry needs clarification, as cDNA made synthetically from a synthetic DNA sequence will not necessarily fail the inventive test, as it may in fact reflect an artificially created state of affairs, rather than a naturally occurring one.
20. Potentially patentable subject matter

**Response:** We note that the criteria for inclusion on this list - that the items listed 'do not merely represent information coding for a polypeptide' - does not reflect our interpretation of the High Court's decision in *Myriad*, but rather is a narrower interpretation of 'information', abrogated to encompass only polypeptide coding information at the exclusion of information relevant to other functions and processes. For the reasons outlined above, we think this is the wrong criteria to apply.

- 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)

**Response:** We think each of these misinterprets the informational value of the subject matter, restricting it insupportably to polypeptide coding information only.

- Naturally occurring isolated bacteria
- Naturally occurring isolated virus
- Isolated polypeptides
- Isolated polyclonal antibodies
- Monoclonal antibodies
- Isolated cells
- Isolated stem cells
- Isolated interfering/inhibitory nucleic acids (e.g. antisense, ribozymes)

**Response:** We think these items will fail the inventive threshold test, for reasons outlined above (ie they are naturally occurring, rather than an artificially created state of affairs).

- Synthesised/modified polypeptides
- Chemical molecules purified from natural sources (e.g. new chemical entities, antibiotics, small molecules)
- Probes
- Primers
- Fusion/chimeric nucleic acids
- Transgene comprising naturally occurring gene sequences
- Vectors/microorganisms/animals/plants comprising a transgene

**Response:** These items may satisfy the inventiveness step, as they are likely to reflect an artificial, rather than naturally occurring, state of affairs. They are also to be values purely for their information qualities as they relate specifically to polypeptide coding.
Conclusion

21. We believe that the Commissioner's proposal for recognition of patentable subject matter needs to be narrowed, as it is based on an unduly restrictive interpretation of the informational value of DNA.

We also think some proposed categories will fall foul of the inventiveness step required as a threshold criteria for patentable subject matter under Myriad.

We further predict that many specific examples of the items on the list would ultimately fail to satisfy the other tests for patentability, particularly novelty, as the molecular biology techniques used in the generation are becoming routine.

A better approach may be to look at expansion of protections for innovative methods, rather than protections for products of their application.