

IP Australia's proposed change in patent examination practice

Response from Cancer Council Australia, Clinical Oncology Society of Australia

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Cancer Council Australia is Australia's peak non-government national cancer control organisation. Its member bodies are the eight state and territory Cancer Councils, which it represents on a national level.



The **Clinical Oncology Society of Australia (COSA)** is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.



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Why IP Australia's proposal runs counter to the public interest

In the view of Cancer Council Australia and COSA, IP Australia's proposed change in patent examination practice is inconsistent with the High Court's unanimous judgement in the case of *D'Arcy v Myriad Genetics Inc*. If adopted as standard practice by IP Australia, the proposed changes could:

- compromise equitable access to diagnostic tests and other health services;
- lead to gene and other biological monopolies that could threaten the viability of independent, competitive medical research; and
- lead to more lengthy court cases and undermine the clarity of precedent set by *D'Arcy v Myriad Genetics Inc*.

In our view IP Australia is applying the narrowest possible interpretation of the High Court's unanimous judgement. IP Australia's interpretation would encourage patent claims for materials that should, by our interpretation of the judgement and long-held position, not be patentable subject matter.

IP Australia has sought to narrow its interpretation of the judgement down to: "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".

This, in our view, is inconsistent with the clear, decisive logic and principles applied throughout the judgement. The High Court judgement has in our view confirmed our long-held position that

all “naturally occurring” substances (e.g. DNA sequences), whether in situ, isolated, purified or replicated, are discoveries and not inventions and should not be patentable subject matter.

The High Court’s judgement is applicable to a wide range of biological materials. In our interpretation (as supported by our key stakeholders across multiple sectors), the High Court’s reasoning is centred around an “isolated nucleic acid” only because such an isolated nucleic acid was the subject of the immediate patent at hand. All three judgments, however, make it clear that their reasoning should not be limited to the immediate factual circumstances of the BRCA1 patent.

The complexities and breadth of cancer as a disease group, and the rapid evolution of cancer research, mean that almost every component of the human body, and external materials that invade the body, could be vital in cancer research, prevention, diagnosis or therapy. This is the case whether the naturally occurring substances are in situ, isolated, purified or replicated.

Cancer Council Australia agrees with the concerns raised by the High Court judges that patents over naturally occurring materials, such as those which IP Australia suggests should remain patent-eligible, will have a “chilling effect on research”.¹ In the case of the BRCA1 and BRCA2 patents, we have seen how commercial monopolies over natural substances can impose risks to equitable healthcare and competitive research.²

On the same basis, the patenting of “naturally occurring isolated bacteria” and “naturally occurring isolated viruses” could lock up access to newly discovered biological materials vital to competitive research in immunology – an increasingly important science in cancer control. Polyclonal antibodies are already applied in cancer therapy, but their use requires further research, undertaken competitively in an open environment. The same is true of isolated regulatory DNA, a potential mechanism for carcinogenesis. The list goes on. Also of great concern (see following), some of these substances are not clearly defined.

Cancer Council Australia/COSA’s expert advisory committee network and professional groups comprise some of the world’s most distinguished cancer researchers, including advisers to the International Agency for Cancer Research, the WHO’s most senior cancer research body. Our expert scientific advisers point out (with concern) that, of the 18 substances recommended by IP Australia as patentable, only very few such as synthesised/modified polypeptides and monoclonal antibodies would in most cases meet the criteria for patentability in view of the High Court’s judgement.

Several other substance types recommended for patenting by IP Australia are clearly “naturally occurring” (e.g. DNA sequences, the isolation and characterisation of which involves discovery, not invention). In addition, of particular concern to our scientific advisers, there are a number of listed substances whose specification is so imprecise and/or uncertain, and/or is jargon, that it is impossible to specify their patentability in relation to the High Court judgement. These include isolated polypeptides, isolated polyclonal antibodies, “probes”, “primers” and “transgenes”. For a critical and complex matter to be subject to unscientific definitions so soon after a decisive High Court decision is of great concern to the cancer science community. It suggests a rapid announcement aimed at maximising patent claims, rather than a scientific and evidence-based interpretation of a unanimous decision by the High Court in respect of the public interest.

¹ HCA, *D’Arcy v Myriad Genetics Inc.* Page 5, par. 8

² Commonwealth of Australia, report of a Senate inquiry into gene patents (2009)

Why the public interest must come first

The “public interest” is a key consideration throughout the High Court’s unanimous judgement.

As noted in the judgement, “there is a public interest in using the grant of a monopoly to encourage technical innovation”.³ As Australia’s largest non-government funder (collectively) of cancer research, we fundamentally agree. Cancer Councils funds many of the nation’s leading biomedical researchers. COSA includes among its professional membership a number of leading medical researchers, who are rightly rewarded for innovation by the patent system. We therefore support and value a robust medical research sector that protects and rewards innovation. However, as noted throughout the High Court’s judgement, the method of manufacture in the BRCA1 patent claim was not inventive – nor is the isolation, purification or replication of other naturally occurring substances.

It should also be noted that the High Court’s judgement observes that the public interest is served by “ensuring unconstrained access by medical practitioners and their patients to new medical methods and processes”.⁴ Commercial monopolies over human biological materials, whether in situ, isolated, purified or replicated, compromise the public interest in this respect.

One of the most salient examples of the risks to the public interest posed by commercial monopolisation of genetic and other materials is what could have occurred in 2008, when Myriad Inc.’s Australian licensee for BRCA1 and BRCA2, Genetic Technologies Ltd, demanded that public testing laboratories ceased offering BRCA1 and BRCA2 tests to Australian women. The company later withdrew its demands. However, there was no clarity in law at that time to protect Australian women’s access to publically available genetic tests. There were well-documented concerns about a commercial monopoly imposing increased costs on consumers, inequities for those at higher risk, compromising the coordinated provision of support services (such as genetic counselling) and deterring researchers wishing to access patent-protected materials to develop new healthcare interventions.

Until 7 October 2015, there was no mechanism to prevent similar demands from being made, relating to similarly (now invalid) patent claims, affecting a range of essential medical interventions. (There are other examples of commercial monopolies compromising access to healthcare and independent medical research.⁵)

In our view, and the view of our multisector stakeholders, the High Court’s decisive, unanimous, principles-based judgement of 7 October 2015 provided a clear and much needed precedent in Australian law to ensure healthcare consumers, professionals and researchers are protected from inappropriate application of patent law.

If IP Australia’s proposed patent examination practice is adopted, the public interest would again be at risk of being compromised by unclear application of patent law.

³ HCA, *D’Arcy v Myriad Genetics Inc.* Page 91, par. 262

⁴ HCA, *D’Arcy v Myriad Genetics Inc.* Page 91, par. 262

⁵ See Cancer Council Australia/COSA submissions to Australian Law Reform Commission review of gene patents (2004), response to ACIP review of patentable subject matter (2008), response to Australian Senate inquiry into gene patents (2009) etc.

If the narrowest possible interpretation of *D'Arcy v Myriad Genetics Inc.* is applied, Australia is likely to see similar patent claims again disputed in the courts. Given the clarity provided in the judgement of *D'Arcy v Myriad Genetics Inc.*, this would be a waste of public resources, legal costs and cause unnecessary anxiety for healthcare consumers, professionals and researchers.