

Australian Patent Office Proposes Focused Interpretation of Gene Patent Decision

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Welcome news for the Australian Biotechnology sector. The Australian Patent Office [proposes](#) to exclude nucleic acids coding for polypeptides from patentability and retain patent eligibility for most other naturally occurring products, such as antibodies, polypeptides and stem cells.

The proposal from IP Australia has issued in light of the High Court of Australia's ruling that an isolated nucleic acid, coding for a mutant BRCA1 protein, is not a "patentable invention". A summary of the decision can be found [here](#).

While the High Court's decision related to claims encompassing isolated nucleic acids, it remained unclear how broadly the decision would be applied by the Australian Patent Office. Pleasingly, the Patent Office proposes a focused interpretation of High Court's ruling.

The Patent Office accepts the High Court's judgment establishes that "a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible", concluding that the following are not patent eligible:

- naturally occurring human and non-human nucleic acid sequences encoding polypeptides or functional fragments thereof - either isolated or synthesised
- cDNA, nor
- naturally occurring human and non-human coding RNA - either isolated or synthesised.

However, the Patent Office proposes that it will continue to treat claims directed to most other naturally occurring products which were not addressed directly by the High Court's decision as patent-eligible. In particular, the Patent Office proposes that the following remain patent eligible as they do not merely represent information coding for a polypeptide:

- naturally occurring isolated regulatory DNA (e.g. promoters, enhancers, inhibitors, intergenic DNA)
- isolated non-coding (e.g. "Junk") DNA and RNA (e.g. miRNA)
- naturally occurring isolated bacteria and viruses
- isolated polypeptides and synthesised/modified polypeptides
- isolated polyclonal antibodies and monoclonal antibodies
- chemical molecules purified from natural sources (e.g. new chemical entities, antibiotics, small molecules)
- isolated cells including isolated stem cells
- probes and primers
- isolated interfering/inhibitory nucleic acids (e.g. antisense, ribozymes) and fusion/chimeric nucleic acids, and
- transgenes comprising naturally occurring gene sequences and vectors, microorganisms, animals and plants comprising a transgene.

The Patent Office's proposal marks a good start towards restoring confidence amongst the Australian Biotechnology sector. In particular, because the proposed examination practice is markedly different to the US Patent Office's response to the corresponding decision of the US Supreme Court.

At present, claims which recite 'nothing more' than an isolated natural product generally cannot be patented at the US Patent Office, whereas many such claims would be considered patent eligible by the Australian patent Office under the current proposal.