Consultation on the proposed examination practice following the High Court decision in Darcy v Myriad Genetics Inc

This submission is in direct response to IP Australia's consultative process to solicit response to proposed changes to IP Australia's practice on patent eligible subject matter following the High Court decision in D'Arcy v Myriad Genetics Inc.

Summary

The changes proposed by IP Australia have been reviewed and either directly accepted, or should be subject to qualification and clarification.

WEHI experience in IP matters

As one of Australia's major contributors to medical research and its translation, we believe that our experience in discovery, invention, intellectual property and commercialisation, provides relevant insight into patent prosecution at the global level. WEHI currently invests more than $100 million per year in medical research. Most of these funds are provided by public funding agencies such as the National Health and Medical Research Council and the National Institutes of Health (US). We have extensive research collaborations with the public sector, and with private sector partners such as Genentech, Abbvie and Merck in the US, Cancer Research Technologies in the UK, Laboratoires Servier in France and CSL and Bionomics in Australia. As a not-for-profit, tax exempt research institute, our core business is the conduct and dissemination of world-class medical research, with the goal of improving human health. While WEHI benefits from commercialisation of its IP, this comes as a consequence of our primary focus on uncompromising world-class medical research and accountability to tax payers who provide most of our funds. Translation of our research to benefit the community requires a strong intellectual property position that is currently based on more than fifty patent families and a new provisional patent application approximately every month.

Proposed practice of IP Australia

The Commissioner considered the High Court's decision and concluded that a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible. On this basis, the Commissioners have proposed that claims defining the following are not patent eligible:

- 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

The Commissioner has proposed 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
• Isolated non-coding RNA (e.g. miRNA)
• Naturally occurring isolated bacteria
• Naturally occurring isolated virus
• Isolated polypeptides
• Synthesised/modified polypeptides
• Isolated polyclonal antibodies
• Chemical molecules purified from natural sources (e.g. new chemical entities, antibiotics, small molecules)
• Isolated cells
• Isolated stem cells
• Probes
• Primers
• Isolated interfering/inhibitory nucleic acids (e.g. antisense, ribozymes)
• Monoclonal antibodies
• Fusion/chimeric nucleic acids
• Transgene comprising naturally occurring gene sequences
• Vectors/microorganisms/animals/plants comprising a transgene

WEHI welcomes the approach of IP Australia which is in contrast to the interpretation of the USPTO of the corresponding case in the United States and saw the USPTO extend patent ineligibility to claims defining all isolated biological material. However, WEHI does question the exclusion from patentability of cDNA by IP Australia, which is in contrast to the approach in the US that was based on the "law of nature" exception. Noting that cDNA can also be claimed in Europe Australia becomes an "exceptional jurisdiction".

The majority decision of the High Court identified that the essential element of the invention claimed by Myriad was the information in the genetic sequences because the nucleic acid sequence is used in the diagnostic testing and the information stored in the isolated sequence of nucleotides coding for the mutated BRCA1 polypeptide is the same information as contained in the naturally-occurring DNA.

IP Australia has interpreted the High Court’s ruling to preclude cDNA from patentability supposedly based on paragraph 89 of the decision:

"... 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."

In the High Court decision the majority held that the exons would also include the BRAC1 mutations and polymorphisms. Arguably, where there is a distinction, these cDNA should not be excluded. cDNA lacks introns and is "artificially created".

1 D’Arcy v Myriad Genetics Inc [2015] HCA 35, 41 [89].
The validity of the first three claims that related to isolated nucleic acid was at issue and the method of diagnosis was not an issue. In fact, the court commented that a process or method of detecting the increased likelihood of malignancy may be patentable subject matter, as a process.

IP Australia has adopted a pragmatic approach but when the boundaries of patentable subject matter are changed, there is concern that the doors are open to misuse of the law in the courts. How will the test results (presence or absence of a biomarker) be interpreted? Is this information?

IP Australia must also provide clarity on the implications of this decision on granted and pending applications, and applications awaiting examination. Immediate questions follow:

- If nucleic acid sequences are not considered patentable subject matter, then what will be the future of those patents that have been granted to date?
- If their validity is to be challenged, who will challenge them and undertake the associated costs?
- Who will be responsible for the cost of compensation if legislation is passed to disallow the patenting of sequences?
- How will it be possible to allow granted patents but disallow future claims to similar subject matter?
- Will the total cost of such an action result in any benefits beyond those already being achieved?
- What will be the cost to Australia of a seriously anomalous patent system? Will it have a direct negative impact on uptake of inventions that are patented in other jurisdictions?

Questions also arise about new technologies and what factors may arise for consideration in the future. We maintain that despite the initial high level of potential concern that often occurs with the introduction of a new technology, the issues associated with such a technology are managed through mechanisms already in place. This was evident in the history of gene patenting. WEHI submits that the broad benefits of gene patents and the strengths of Australia's patent system were threatened on the basis of a rare but high-profile example (BRCA1/2). No new moral or ethical issues have arisen in the last nearly 30 years since the first gene patents were allowed. There were few cases, if any, beyond the Myriad/GTG case, presented as examples of threat to healthcare costs and access in Australia. It is essential that Australia's patent system is harmonised with global agreements, retains its technology neutrality and that Australia is viewed as harmonised and relevant in its practices.

Issues of equity of access should be addressed through other means. The cruel irony is that the decision has done nothing to solve issues of access and that the remaining claims of the Myriad patent are in force for the lifetime of the patent. The few historical problems that have arisen with gene patents are mainly related to commercialisation strategies and not patent law. Governments already have rights under law to intervene when patent rights are inappropriately exercised. These include crown use and compulsory licensing provisions. Issues should be resolved through several potential legal avenues of change to ensure access for patients to medical therapies, diagnosis and prevention rather than changing the patent system, and ignoring the critical issue of fair access.

We emphasise the importance of human gene patents in realising such valuable biotherapeutics as insulin, growth hormones, erythropoietin, interferons and cytokines, as well as their contribution to diagnosis and targeted therapies. The integrity of the patent system must be maintained and the evolution of new technologies must be encouraged through our patent system.

In closing, we request that IP Australia provides clarity on the proposed examination practice. We trust that the above will be of assistance to IP Australia and offer our services should further information be required.
Yours sincerely

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