Patentability of isolated nucleic acid: US vs. Australia

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By: Lisa A. Haile | Nicholas Tyacke | Eliza Jane Saunders | Louis Italiano

Patents directed to genetic material have been the subject of significant public discourse and legal challenge worldwide, leading to a divergence of governing law between jurisdictions and heightened industry uncertainty in the US, especially in the molecular diagnostics area.

Subject matter eligibility

Subject matter eligibility in the US is based on Section 101: “Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter...may obtain a patent....”

Until recently, as long as the subject matter fell within one of the four statutory classes and involved human intervention, it was patent eligible.¹

Patentable subject matter in Australia must be a “manner of manufacture.” The guiding test was established by the High Court of Australia in National Research Development Corporation v. Commissioner of Patents (1959), which held a product that amounts to an “artificially created state of affairs” (something which, but for human intervention, would not exist) and which also has economic significance constitutes a “manner of manufacture.”

These respective principles were applied to isolated genetic material by the US Supreme Court in Association for Molecular Pathology v. Myriad Genetics, Inc. (2013) and the Full Court of the Australian Federal Court (FFC) in D'Arcy v. Myriad Genetics Inc. (2014).

The Myriad BRCA gene patents in suit

Nine composition claims from three patents were at issue in the US Myriad case, but ultimately, in both the US and Australia, only the threshold subject matter eligibility test for patentability was considered.

The US Myriad decisions

The US Supreme Court in Association for Molecular Pathology v. Myriad Genetics, Inc. ruled last year in a unanimous 9-0 decision that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.” 133 S. Ct. 2107, 2111. “To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.” Id. at 2117.

In the US, Myriad has been extended beyond the patentability of genes, creating a roadblock to the patentability of other naturally occurring biologics. The USPTO has begun to examine and consistently reject patent claims for
proteins, stem cells and other biologics under the *Myriad* test. In many instances, unless a DNA or protein sequence is claimed in combination with a detectable label, or linked to a solid support, the claims are rejected as lacking patentable subject matter under *Myriad*.

**The Australian *Myriad* decisions**

Applying a broader test than in the US, the FFC held that “the isolated nucleic acid, including cDNA, has resulted in an artificially created state of affairs for economic benefit” and therefore the claimed product is patentable subject matter.

The FFC stated that “the analysis should focus on differences in structure and function [of the isolated molecule] effected by the intervention of man and not the similarities” (at [155]).

An application has been made to appeal the FFC decision to the High Court. In the meantime, isolated genetic material remains patentable subject matter in Australia.

**USPTO guidelines**

Earlier this year, the USPTO issued “Guidance for determining subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, and natural products,” setting out guidelines to determine subject matter eligibility.

Particularly constraining, the Guidelines state that a “claimed product must be both non-naturally occurring and markedly different from naturally occurring products.”

A revision of the Guidelines is expected to provide that, in addition to examining structural differences, functional differences must be considered in assessing whether a claim is directed to a product that is different from a naturally occurring product.

In contrast, the Australian Patent Office continues to grant patents over isolated genes with known functions, as long as such patents do not fail for lack of novelty or inventive step.

**Ambry**

Following the US case, a number of Myriad’s competitors, including Ambry Genetics, announced their intent to market their own versions of Myriad’s BRCA diagnostic test. Myriad instigated proceedings against those parties in the District of Utah, alleging such tests would infringe patent claims that had not been struck down, including:

- “Primer claims” directed to single-stranded DNA primers used in the polymerase chain reaction process for replicating BRCA1 and BRCA2 genes and
- “Method claims” directed to techniques for screening BRCA genes for mutations by comparing patient sequences with ordinary “wild-type” sequences.

The district court denied Myriad’s motion for a preliminary injunction, finding the primer claims may not constitute patentable subject matter because they may fall within the ambit of claims to mere isolated DNA, and that the method claims may be rejected in light of the Supreme Court’s decision in *Mayo Collaborative Services v. Prometheus Laboratories*.

Myriad appealed to the Federal Circuit, arguing primers are essentially the same as cDNA, which the Supreme Court found to be patent-eligible. Myriad further argued its methods are applications of the discovery of the BRCA gene sequences, which the Supreme Court has held are patent-eligible. A decision has not yet been delivered.

**Conclusion**

Isolated nucleic acid sequences are patentable in many jurisdictions, among them Australia, Canada, China, Europe, Japan, Russia and South Korea, but not in the US.

The US biotech industry requires certainty rather than the uncertainty introduced by the *Myriad* decisions and the USPTO Guidelines. The current chaotic environment is disincentivizing research and development by US companies of new and useful diagnostic or therapeutic products from subject matter of biological origin.
Meanwhile, the Australian Patent Office and Australian judiciary’s preparedness to leave such subject matter exclusions to the legislature provides a more certain environment, conducive to research, development and investment.

AUTHORS

Lisa A. Haile
Partner
San Diego (Golden Triangle) | T: +1 858 677 1400
lisa.haile@dlapiper.com

Nicholas Tyacke
Partner
Sydney | T: +61 2 9286 8000
nicholas.tyacke@dlapiper.com

Eliza Jane Saunders
Special Counsel
Melbourne | T: +61 3 9274 5000
eliza.saunders@dlapiper.com