Australian Full Federal Court takes a different approach to the US Supreme Court regarding patentability of isolated nucleic acid molecules

By: Dr Karin Innes, Senior Associate
*FB Ric*e, *Patent & Trade Mark Attorneys*

Take home message

Claims directed to isolated nucleic acid molecules, whether DNA (genomic or cDNA) or RNA, are patentable subject matter in Australia. This finding represents a departure from current US law.

Summary

On Friday 5 September 2014, the Full Court of the Federal Court of Australia (by unanimous joint judgment of an expanded five judge panel), upheld the finding of Justice Nicholas at first instance in February 2013 (*Cancer Voices Australia v Myriad Inc [2013] FCA 65*) that isolated nucleic acid molecules are patentable. The Court was not swayed by issues of morality or public policy and neither were they influenced by the US Supreme Court findings to the contrary.

The legal action has generated much public interest in Australia and was borne out of concerns that the patenting of the BRCA1 gene would stifle innovation, restrict medical research and make genetic testing costs too prohibitive. In their decision, the judges made a particular point of stating that the case was "not about whether, for policy or moral or social reasons, patents for gene sequences should be excluded from patentability" since this issue was previously the subject of The Australian Law Reform Commission into gene patenting.

Issue

The Court was asked to determine whether a claim to an isolated nucleic acid molecule that covers naturally occurring nucleic acid, either DNA or RNA that has been isolated from a cell is patentable subject matter. The claims were the subject of Australian Patent 686004 granted to Myriad Genetics, Inc and cover isolated mutant and polymeric forms of the BRCA1 gene.

The Court only considered the patentability of claims 1-3, directed to compositions of matter (i.e. the nucleic acid molecules). The challenge to validity was based on

whether the claims were a “manner of manufacture” according to the definition of invention recited in the Australian *Patents Act 1990*. Other grounds of invalidity including lack of novelty, lack of inventive step, lack of utility or lack of fair basis) were not challenged. Claims directed to the diagnosis of breast or ovarian cancer based on sequence alterations of the BRCA1 gene were not challenged.

Rationale for patentability of claims to isolated nucleic acid molecules

In formulating their reasoning, the Court looked to previous jurisprudence, namely the principles established by the High Court in NRDC (National Research Development Corporation v Commissioner of Patents [1959] HCA 67) which is regarded as the “long accepted articulation of the principles to be applied to patentability and to the question of what is the proper subject matter for a patent” (at paragraph 106). NRDC was also affirmed in the recent High Court decision in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50.

The principle established in NRDC is that what constitutes patent eligible subject matter is constantly evolving and should not to be constrained by what previously qualified for patent protection. The term “manner of manufacture” refers to expressions of principles and concepts designed to keep up with advances and the evolution of research and technology. According to NRDC, to qualify for patent eligibility, it is sufficient for a product to result in ‘an artificially created state of affairs’ leading to ‘an economically useful result’.

Applying the NRDC principle to the claims at issue, the Court found that the act of human intervention resulted in a nucleic acid molecule having a different chemical composition from its state in the body, creating an artificial state of affairs with economic utility thus satisfying patentability. The isolated nucleic acid molecules were deemed to have a different chemical composition, attributable to structural and functional differences as a result of the isolation, from that which exits in the human body.

Australia distinguishes itself from the United States

The US Supreme Court in *Association for Molecular Pathology v Myriad Genetics, Inc*, 596 US 12-398 (2013) held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that synthetic cDNA is patent eligible because it is not naturally occurring. The US decision has resulted in many US applications relating to isolated naturally occurring

substances such as proteins, chemicals, antibodies and cells as allegedly also not relating to patentable subject matter.

The Australian judges disagreed with the US Supreme Court's emphasis on the information contained in the genetic sequence and commented that the focus, rather, should be on the specific chemical composition of a particular molecule.

The Court also stressed that a consideration of whether the composition of matter is a so-called "product of nature", as was done in the United States, is irrelevant to the issue of patentable subject matter in Australia.