

SUBMISSION BY AJ PARK ON PROPOSED EXAMINATION PROCESS IN VIEW OF *MYRIAD*

AJ Park has considered the High Court decision in *D'Arcy v Myriad Genetics Inc* HCA [2015] and the examination practice proposed by IP Australia following the decision. AJ Park accepts that the proposed practice is generally appropriate in the light of this decision.

Limited Scope of Decision

IP Australia notes correctly that the High Court was asked to decide whether claims 1-3 of Australian Patent No. 686004 defined patent eligible subject matter. The decision of the majority is clearly restricted to the specific subject matter in suit:

"This court is not concerned in this appeal with 'gene patenting' generally, but with whether the invention as claimed in claims 1 to 3 falls within established applications of the concept of manner of manufacture." [paragraph 39]

IP Australia notes correctly that claims 4-30 of Australian Patent No. 686004 were not in suit. Claim 4 is directed to a probe, claims 5 and 6 relate to a vector, claim 7 is directed to a host cell transformed with a vector, claims 8 and 9 are concerned with methods for the production of polypeptides, claims 10-14 with polypeptides, claims 15 and 16 with certain uses of the polypeptides, and claims 17 to 30 are directed to methods of diagnosing a predisposition for breast or ovarian cancer. The High Court did not consider these claims so there is no basis to extend the decision to any such subject matter.

The majority indicates that the Court was not concerned with gene patenting generally. Thus the decision does not invite extension to any and all issues surrounding patenting of biotechnological inventions.

Rationale of the Majority

IP Australia indicates that "the decision clearly concludes that a claim to an isolated nucleic acid that merely represents information coding for a polypeptide is not patent eligible."

The majority indicates at paragraph 88 that the identification of the subject matter of the claims as a class of chemical compounds by the Full Federal Court "elevates form over substance to the detriment of the developmental function entrusted to the Court as explained in NRDC". In paragraph 87, characterisation as a product claim "without further inquiry into the breadth of the claims or their substance" could result in them being comfortably characterised as a manner of manufacture.

The substance of the claim is important. At paragraph 6:

"Despite the formulation of the claimed invention as a class of product, its substance is information embodied in arrangements of nucleotides. The information is not 'made' by human action. It is discerned." [emphasis added].

At paragraph 89:

"...the information stored in the sequence of the 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." [emphasis added]

At paragraph 93:

"When proper regard is paid to their emphasis on genetic information, the subject matter of the claims lies at the boundaries of the concept of 'manner of manufacture'."

Genomic DNA contains information within its sequence that constitutes a code. The information in gDNA may be discerned but is not made by human action. When DNA is transcribed to produce polypeptides the amino acid sequence of the polypeptide is determined by the information embodied in the arrangement of nucleotides. mRNA and cDNA (as mentioned in paragraph 89) also embody this code. AJ Park accepts that the decision of the majority is applicable to these forms of nucleic acid where the molecule corresponds to a natural coding sequence. AJ Park also acknowledges that there is no distinction in the reasoning of the majority between natural and synthetic nucleic acid molecules if the sequence of the synthetic molecule is the same as natural sequence, nor as to whether the nucleic acid molecule is of human or non-human origin if it is a natural sequence.

The High Court decision is restricted to nucleic acids that contain sequence information which constitutes a code. There are various classes of nucleic acids where the substance does not lie in the information they carry. Functional nucleic acids including aptamers, microRNAs, siRNA, ribozymes and any DNAs or RNAs have a function beyond coding and should continue to be patent eligible.

Products of Nature

The majority acknowledges the debate on "products of nature" versus "artificially created state of affairs" in paragraph 91 and indicates that this "may be distracting from the central issue", the central issue being a consideration of whether claims characterised by genetic information are patent eligible.

AJ Park submits that there is no basis in the reasoning presented by the majority to extend IP Australia's practice to exclude "products of nature". The majority made it plain that the substance of the claims in suit is sequence information which constitutes a code. There is no "information" of this sort conveyed by any other type of natural product.

Summary

AJ Park generally supports the proposal by IP Australia to retain patent eligibility for naturally occurring isolated regulatory DNA, isolated non-coding DNA, isolated non-coding RNA, naturally occurring microorganisms, isolated polypeptides, synthesised/modified polypeptides, isolated polyclonal antibodies, chemical molecules purified from natural sources, isolated cells, isolated stem cells, probes, primers, isolated interfering/inhibitory nucleic acids, monoclonal antibodies, fusion/chimeric nucleic acids, transgenes comprising naturally occurring gene sequences, and vectors and so forth comprising a transgene.