Published on *The National Law Review* https://natlawreview.com

Australia High Court Rules Against Gene Patents

Article By:

Courtenay C. Brinckerhoff

Colleagues in ***Australia*** have been spreading the bad news: The High Court of Australia followed the lead (?) of the ***U.S. Supreme Court*** and determined that Myriad cannot patent the isolated BRCA1 gene in Australia. Thanks to Adam Denley, Ph.D., Senior Associate at Freehills Patent Attorneys, for providing the article below on the October 6, 2015 decision which seems to invalidate Australian gene patents. Tania Obranovich, Ph.D. , Special Counsel at Watermark, considers far-reaching implications of the decision–including the surprising ruling against cDNA claims–in her article.

Dr. Denley On The Australia High Court Decision

The High Court of Australia addressed whether claims to the isolated BRCA1 gene constitute a manner of manufacture (i.e. patentable subject matter) under Australian law in D'Arcy v Myriad Genetics Inc [2015] HCA 35. A unanimous decision from the seven-member bench of the High Court held that an appeal by Yvonne D'Arcy to an earlier decision from the Full Court of the Federal Court of Australia should be allowed, and that claims 1, 2 and 3 of Myriad's patent (AU 686004) should be revoked.

The patent at issue is directed to mutations in the breast cancer gene BRCA1, associated with an increased risk of breast cancer. The patent also relates to diagnostic methods for detecting breast cancer, based on the presence of a mutated BRCA1 gene. The appeal, however, related only to claims 1 to 3 of the patent, each of which was directed to an "isolated nucleic acid."

In responding to the appeal, counsel for Myriad relied heavily on well-accepted principles of patentable subject matter, as established by the High Court in National Research Development Corporation v Commissioner of Patents [1959] HCA 67 ("NRDC"). In particular, it was argued by Myriad that the relevant isolated nucleic acid molecules should be patentable because they are "an artificially created state of affairs" by virtue of the fact that "the isolated nucleic acid claimed by the Patent is 'chemically cleaved' from the surrounding components of the cell, including other genome sequences."

The High Court, however, in arriving at its decision, looked not only at the form of the claims but at their substance and breadth. The substance of the invention was determined to be the sequence of nucleotides which, in a cellular environment, can ultimately be translated into the BRCA1 polypeptide

which the Court concluded "can properly be described as 'information." Used in that sense, "the information stored in the sequence of nucleotides coding for the mutated or polymorphic BRCA1 polypeptide is the same information as contained in the DNA of the person from which the nucleic acid was isolated."

The Court was also concerned with the scope of the claims including "the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly."

Although clearly obiter as the method of diagnosis claims were not at issue, the Court appears cognizant not to stray into the U.S. Supreme Court's Mayo v Prometheus territory, commenting that "[i]t is not disputed that a process or method of detecting the increased likelihood of certain kinds of malignancy…..may be patentable subject matter as a process."

Dr. Obranovich On The Focus On "Information"

As Dr. Obranovich notes in her article, the High Court's focus on the "information" encoded by the BRCA1 gene led it to conclude that cDNA is just as non-patentable as genomic DNA. According to the High Court:

> [T]he 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.
>
> 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". That it does lie at the boundaries is further evidenced by the odd consequence that if the claims are properly the subject of a patent, the patent could be infringed without the infringer being aware of that fact. That consequence coupled with the very large, indeed unquantified size of the relevant class of isolated nucleic acids, all of which bear the requisite information, raises the risk of a chilling effect upon legitimate innovative activity outside the formal boundaries of the monopoly and risks creating a penumbral de facto monopoly impeding the activities of legitimate improvers and inventors .
>
> Although it may be said in a formal sense that the invention as claimed, referring to isolated nucleic acids, embodies a product created by human action, that is not sufficient to support its characterisation as a manner of manufacture. …..

The USPTO has been criticized for extrapolating the U.S. Supreme Court's *Myriad* decision to reach claims directed to other natural products, but at least the USPTO was constrained by the U.S. Supreme Court's approval of cDNA claims. As Dr. Obranovich emphasizes, the Australian patent office (IP Australia) is likely to follow the USPTO's lead and apply this decision "to all other isolated naturally occurring substances," and may decide that the ruling even extends to "new versions of

naturally occurring molecules which omit functionally unnecessary regions.” As in the U.S., “[t]he crucial issue will be determining at what point the structural changes to a molecule are sufficient to render it patentable.” Until those lines are drawn, there will be “a significant element of uncertainty to the issue of the patentability of modified natural products.”

National Law Review, Volume V, Number 281