THE PATENTABILITY OF DIAGNOSTIC METHODS IN AUSTRALIA – THE AUSTRALIAN SEQUEL TO SEQUENOM, MYRIAD AND MAYO

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Since 2012, the highest courts of the US and Australia have delivered five decisions regarding the patentability of particular types of life sciences inventions. On all three occasions, the impact of the US Supreme Court's decision has been to deny patent eligibility; most recently in the Sequenom case in relation to a diagnostic method. In Australia, the High Court has held one class of life sciences invention to be patent eligible, while holding the claimed invention in another case not to be. Sequenom has recently commenced patent infringement proceedings in Australia asserting diagnostic method claims. Will Australian courts reach the same conclusion regarding patentability as the US courts, or will the divergence between US and Australian law regarding patentable subject matter lead to a different outcome?

MAYO AND MYRIAD IN THE US

As discussed in our earlier article in 2012, the US Supreme Court held in *Mayo*[1] that a method of optimising a therapy based on the relationship between concentrations of metabolites in a patient's blood and the likelihood that a particular drug dosage would be either harmful or ineffective was not patentable.

As also discussed in our earlier articles in 2015, the US Supreme Court held in *Myriad*[2] that *"a naturally occurring DNA segment is a product of nature and not patent eligible …"*

SEQUENOM

In 1997, Oxford University researchers discovered that the cell free fractions of pregnant women's blood (serum and plasma), which had previously been discarded as medical waste, contain cell-free foetal DNA (**cffDNA**) that can be used to detect foetal genetic characteristics and conditions as well as pregnancy-associated conditions such as pre-eclampsia. Diagnostic methods relating to these discoveries were the subject of patents in a number of countries, including the US and Australia, which were then licensed to Sequenom, Inc (**Sequenom**).

US SEQUENOM CASE

As also discussed in our earlier articles in June 2015, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*[3] (**US Sequenom Decision**), the US Court of Appeals for the Federal Circuit (**USCAFC**) held that the claims-in-suit to pre-natal diagnostic methods were patent ineligible because the claimed methods began and ended with a mere natural phenomenon – the presence of cffDNA in maternal plasma or serum – without any further inventive concept to transform that phenomenon into patent-eligible subject matter. The USCAFC held the claims to be invalid despite acknowledging that the discovery represented "*a positive and valuable contribution to science*".

In December 2015, an *en banc* panel of the USCAFC denied Sequenom's petition for rehearing and in June 2016, the US Supreme Court denied Sequenom's petition for review, leaving in place the lower courts' finding that the subject matter of the claimed Sequenom invention was patent ineligible. Accordingly, inventions directed to diagnostic or prognostic assays reliant on a method involving a natural principle or relationship are not patent eligible in the US if they lack any further 'inventive concept'.

THE AUSTRALIAN MYRIAD CASE

As discussed in our earlier articles in *D'Arcy v Myriad Genetics Inc.*[4] (**Myriad**), the High Court of Australia unanimously held that the claims-in-suit of Myriad's patent to isolated nucleic acids coding for mutations or polymorphisms of the BRCA1 gene, associated with susceptibilities to certain breast and ovarian cancers, did not meet the requirements of a 'manner of manufacture' within the meaning of the *Patents Act 1990* (Cth) (**Act**) and were therefore not patentable and invalid. The High Court held that, properly characterised in accordance with *substance rather than form*, the essential element of the claimed invention was the 'genetic information' of the nucleotide sequences coding for

[1] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).
[2] *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013).
[3] 788 F.3d 1371 (Fed. Cir. 2015).
[4] [2015] HCA 35.

mutated or polymorphic BRCA1 polypeptides, rather than a class of chemical compounds. Based on this construction, the High Court held that the claims-in-suit were not within the established boundaries of the concept of a 'manner of manufacture'.

The majority of the High Court held that where an invention falls within the existing concept of manner of manufacture, it is normally sufficient to determine patentability based on whether the claimed invention is a product or process that has been made by human intervention and whether it has economic utility (collectively the **NRDC[5] Factors**), but where a class of claim involves a significant new application or extension of the concept of 'manner of manufacture', the following additional factors may be relevant to determining whether the concept of 'manner of manufacture' should be extended by judicial decision to include that class of claim: potential negative effects on innovation; the potential chilling effect on activities beyond the scope of the patent; consistency with the purposes of the Act; the doctrinal coherence of patent law; international factors; and whether such a decision should be left for Parliament (collectively the **Myriad Factors**). The majority held that these considerations militated against characterising the claimed invention as a 'manner of manufacture'.

THE PATENTABILITY OF METHODS OF METHODS OF MEDICAL TREATMENT IN AUSTRALIA

In contrast to the Myriad decision, as also discussed in our earlier articles prior to its decision in Myriad, in 2013, the High Court confirmed that methods of medical treatment are patentable in Australia, doing so on the basis of the NRDC Factors.

THE AUSTRALIAN SEQUENOM PROCEEDINGS

Around the time that it was unsuccessful before the US Supreme Court, Sequenom commenced legal proceedings in the Federal Court of Australia against Ariosa Diagnostics, Sonic Healthcare and Clinical Laboratories (**Australian Sequenom Proceedings**) for infringement of an Australian patent that is related to the US patent that was the subject of the abovementioned US proceeding. The Australian patent broadly claims, among other things, a "*method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample*". In August 2016 the respondents filed cross-claims for invalidity of Sequenom's patent on the basis of, amongst other grounds, lack of patentable subject matter.

In contrast to the position in the US, Australian law does not contain an explicit 'laws of nature' exception to patentability, which played a critical role in the US Sequenom Decision. Instead, the first critical issues for the Federal Court in assessing patentability will likely be to determine the substance of the invention and then to determine whether that invention falls within the existing concept of manner of manufacture. If it holds that it does, then the court's decision as to patentability is likely to turn on whether the claimed invention satisfies the first of the NRDC Factors identified above. If it determines that the invention involves a significant new application or extension of the 'manner of manufacture' concept, then the abovementioned Myriad Factors are likely to play a significant role in the court's decision as to patentability.

CONCLUSION

Over the last four years, the US Supreme Court has delivered decisions in three life sciences cases that have had the effect of denying patentability to the classes of invention involved. During that time, the Australian High Court has found one class of life sciences invention to be patentable while finding the claimed invention in another case to be unpatentable. It is likely that the Australian High Court will be asked to determine the patentability of the diagnostic method claims at issue in the Australian Sequenom Proceedings, just as the US Supreme Court was asked to do in the US Sequenom case.

In view of the potential to significantly impact the patentability in Australia of diagnostic methods, and perhaps other classes of life sciences inventions, the outcome of the Australian Sequenom Proceedings will be of great interest to the life sciences industry.

[5] *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.