Health Law Alert

How Does The Recent High Court Patent Case Affect The Research And Innovation Pathway For Biologicals?

***D'Arcy v Myriad Genetics Inc.* [2015] HCA 35 7 October 2015**

By Alison Choy Flannigan, Partner

The recent High Court Case of *D'Arcy* v *Myriad Genetics Inc. & Anor* [2015] HCA 35 highlights the debate over balancing:

(a) the rights of inventors and creators to commercialise and profit from their inventions; and

(b) the interests and needs of the wider society to be able to access biological developments for research and the improvement of public health and welfare.

Those seeking the protection of intellectual property rights argue that the protection of exclusive rights to the intellectual property enables investment which is necessary for the expensive process of taking research to clinical trials, commercialisation and the market.

Those seeking the protection of human rights argue that the granting of monopoly rights restricts further research and also grants access only to those who can afford to pay, to the detriment, for example of poorer nations.

Myriad Genetics Inc. owns Australian Patent Number 686004 (the **Patent**). The Patent is over the invention of certain methods of detecting the gene BRCA1 and of using components and mutations of that gene in the diagnosis of predisposition to breast cancer and ovarian cancer.

The Patent has 30 different claims, the validity of three was challenged by Ms D'Arcy.

The *Patents Act 1990 (Cth)* (**Act**) enables the registration of patents. A patent gives the patentee exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention.

Section 18(1)(a) of the Patent's Act states in relation to a standard patent:

"18 Patentable inventions

Patentable inventions for the purposes of a standard patent

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention."

Section 18(2) states that human beings, and the biological processes for their generation, are not patentable inventions.

The High Court held that an isolated nucleic acid, coding for a BRCA1 protein, with specific variations from the norm that are indicative of susceptibility to breast cancer and ovarian cancer, was not a "patentable invention" within the meaning of section 18(1)(a) of the Act.

The term "nucleic acid" includes two kinds of molecules, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), which are found inside a human cell. A gene is a functional unit of DNA which encodes a particular protein produced by the cell. The protein produced depends on the sequence of nucleotides. The BRCA1 gene codes for the production of a protein called BRCA1.

High Court Decision

The High Court unanimously held that, having regard to the relevant factors, an isolated nucleic acid, coding for the BRCA1 protein, with specified variations, did not fall within the concept of a manner of manufacture.

French CJ, Kiefel, Bell and Keanne JJ held (at para 94) that 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 human action was required to *isolate* the nucleic acids), that is not sufficient to support its characterisation of a manner of manufacture. The substance of the invention as claimed and the considerations flowing from a "manner of manufacture" involves an extension of that concept, which is not appropriate for judicial determination. Further, to include this class of claim within that concept would not contribute to coherence in the law as was the case in *Apotex Pty Ltd* v *Sanofi-Aventis Australia Pty Ltd (2013) 253 CLR 284*. Nor do Australian international obligations and the differently framed patent laws of other jurisdictions….support the conclusion that this class of claim should fall within the concept.

So what is patentable?

In Australia, the Parliament has left it to the courts to carry out a case-by-case development of a broad statutory concept according to the common law method in a representative democracy (para 25).

From para 28 the Court referred to a number of factors which may be relevant in determining whether exclusive patent rights should be granted as manner of manufacture. These include:

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action;

2. Whether the invention as claimed has economic utility;

3. Whether patentability would be consistent with the purposes of the Act and in particular:

    (A) Whether the invention as claimed, if patentable under section 18(1)(a), could give rise to a large new field of monopoly protection with potentially negative effects on innovation;

    (B) Whether the invention as claimed, if patentable under section 18(1)(a), could, because of the content of the claims, having a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee;

    (C) Whether to accord patentability to the invention as claimed would involve the court in assessing important and conflicting public and private interests and purposes.

4. Whether to accord patentability to the invention as claimed would enhance or detract from the coherence of the law relating to inherent patentability.

5. Relevantly to Australia's place in the international community of nations:

    (A) Australia's obligations under international law;

    (B) The patent law of other countries.

6. Whether to accord patentability to the class of invention as claimed would involve law-making of a kind which should be done by the legislature.

Factors 3, 4 and 6 are of primary importance. Those primary factors are not mutually exclusive.

Factors 1 and 2 were discussed by the High Court in light of *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (**NRDC**).

The *inventive step,* which emerged as an independent requirement, reflected the balance of policy considerations in patent law of encouraging and rewarding inventors without impeding advances and improvements by skilled, non-inventive persons.

It follows that the purpose of the Act would not be served by according patentability to a class of claims which by their very nature lack well-defined boundaries or have negative or chilling effects on innovation. There may also be flow-on consequences for the balance that the Act seeks to strike and the coherence of the law as developed by judicial decision in giving effect to the purposes of the law. If there is a significant risk of such a consequence, the existence of that risk will weigh against inherent patentability (para 29).

Conclusion

The High Court decision was not particularly surprising as it is consistent with the previous US Supreme Court decision of the *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.* 186 L Ed 2d 124; 569 US (2013).

What the case does mean for researchers is that *mere isolation* of a gene or biological is insufficient, you need an additional inventive step to claim exclusive rights by way of the grant of a patent. It is important to note that only a fraction of the claims made by Myriad were contested.

New Home Care Packages Operational Manual

By Alison Choy Flannigan, Partner

The Commonwealth Department of Social Services published on 29 September 2015 a new Home Care Packages Operational Manual, replacing the Home Care Packages Programme Guidelines 2014. The Operational Manual is a useful guide for providers to support the delivery and management of the Home Care Packages Programme on a consumer directed care basis. The Operational Manual is available at: https://www.dss.gov.au/ageing-and-aged-care-programs-services/home-care-packages-operational-manual

Key changes from the Guidelines include:

- Updated information on fees and charges;
- Expanded information for providers on the care planning process; and
- Detailed information for providers when establishing individualised budgets and monthly statements with their consumers.

Sydney

Level 17 Angel Place
123 Pitt Street
Sydney NSW 2000
T:+61 2 9390 8000
F: +61 2 9390 8390

Melbourne

Level 17
200 Queen Street
Melbourne VIC 3000
T:+61 3 9691 1200
F: +61 3 9462 3183

Brisbane

Level 13
175 Eagle Street
Brisbane QLD 4000
T:+61 7 3235 0100
F: +61 7 3235 0111