Gene patents and the limits of 'invention'

Natasha Case reports on *D'Arcy v Myriad Genetics Inc.* [2015] HCA 35.

In *Myriad*, the appellant sought the revocation of three claims made in the respondent's patent pursuant to s 138 of the *Patents Act 1990* (Cth) (Patents Act). The appellant argued that these claims were for naturally occurring genetic information and were not patentable inventions. The Federal Court,[1] and a unanimous Full Federal Court,[2] disagreed with this proposition.

The High Court unanimously upheld the appeal. In three judgments, the majority (French CJ, Kiefel, Bell and Keane JJ), Gageler and Nettle JJ in a joint judgment and Gordon J each took different approaches to the question of patentability.

The patent

The patent related to a human gene which produces a protein called BRCA1 ('the patent').[3] Certain mutations in the BRCA1 protein, when detected in a woman, indicate likely susceptibility to breast and ovarian cancer.

Claims 1 – 3 of the patent ('the claims'), which were challenged in the proceedings, extended to all mutations of the BRCA1 protein identified in tables attached to the patent. Each of the claims was to the 'isolated nucleic acids' which were capable of producing those mutant BRCA1 proteins.

The 'isolated nucleic acids', the subject of the claims, were collected from many patients over many years using well-known and long-standing techniques of extraction, isolation and amplification. Those processes were not the subject of the claims. Nor were the 'isolated nucleic acids' produced using these processes altered in substance from their natural state. In form, however, they were clearly different from their natural state. For this reason, they were said by the respondent (and by the courts below) to be a 'product'.[4]

The majority judgment

Patentable subject matter

A patentable invention is defined in s 18(1)(a) of the Patents Act as 'a manner of manufacture within the meaning of section 6 of the Statute of Monopolies'. The majority recognised the explicit role that this definition accorded to the courts in the development of patent law in Australia, and endorsed the 'widening' approach to patentability endorsed in *National Research Development Corporation v Commissioner of Patents* (NRDC).[5] However, the majority cautioned that the courts should approach their role with 'modesty and constraint'.[6]

In *NRDC*, the formula adopted for determining whether a claim could be classified as a 'method of manufacture' was the identification in the claim of:

(a) an artificially created state of affairs and

(b) the economic significance of the product.[7]

However, while satisfaction of those criteria would in many cases demonstrate patentability, it did not 'mandate a finding of inherent patentability'.[8] The question arising was:

> …whether the claimed invention lay within the established concept of a manner of manufacture and, if not, whether it should nevertheless be included in the class of patentable inventions as defined in s 18(1)(a) of the Act.[9]

Where the subject matter of a patent is not clearly or analogously within the 'established boundaries' of patentability, the courts should be mindful of the 'limits of judicial lawmaking'. At these outer reaches, the 'purposive and consequentialist'[10] implications of extending patentability to new classes of claim may be relevant to determining whether a class of claim was patentable.

Considerations at the boundaries of patentability

The majority identified four considerations, further and in addition to the *NRDC* criteria of artificiality and economic significance, as potentially relevant to determining whether to extend the concept of 'manner of manufacture' to include the claim:

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

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

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

   3.3 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:

   5.1 Australia's obligations under international law;

   5.2 The patent laws 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.'[11]

The respondent sought to characterise the claims as claims for a chemical compound, falling squarely within the established boundaries of 'method of manufacture'.[12] The court found that the claimed product was 'genetic information'[13] not differing in substance from naturally occurring genes and therefore not falling within the established boundaries of the concept of method of manufacture'.[14]

Consequently, consideration of whether that concept should be applied or extended to incorporate 'genetic information' as a new class of claim was required.[15]

Application of the considerations

The court considered that factors 3, 4, and 6 were significant in this case.[16]

Under consideration 3, the court observed that the claimed product was as a class, large, wide, diverse, without limit and unquantified. Breach of the patent could not be predicted and therefore risked a 'chilling effect' on innovative activity falling outside the purpose of the patent.[17]

Under consideration 4, the court found that both the Federal Court and Full Federal Court had incorrectly assumed that the claimed product was 'within existing conceptions of 'manner of manufacture"[18] an 'assumption which elevates form over substance and to the detriment of the developmental function entrusted to the court'.[19]

Under consideration 6, the court found that the extension of the concept of 'method of manufacture' to isolated nucleic acids was 'not appropriate for judicial determination'[20] and was a matter appropriate for the parliament to determine.

Gageler and Nettle JJ

Justices Gageler and Nettle cast the issue upon which the appeal turned as that of 'inventiveness', notwithstanding that inventiveness was conceded by the appellant.

Their Honours relied upon and extended the decisions in *Commissioner of Patents v Microcell Ltd*[21] and *NV Phillips Gloeilampenfabriken v Mirabella International Pty Ltd*[22] (*Mirabella*) to find that inventiveness was (or to restore it as) a threshold requirement necessary to establish the subject matter of a patent and therefore for assessing patentability.[23] Their Honours reasoned that as a matter of substance, the monopoly granted by a patent is bounded by the inventive step embodied in the claim, stating '[m]onopolies are granted for inventions, not for the inventiveness of the drafting with which applicants choose to describe them'.[24]

On their Honours' analysis of the claims and the science behind them, no invention could be identified in the claims.[25] In truth, their Honours found, the claims were for the products of a process. The process was not Myriad's invention and the product itself was not new but merely a discovery. [26] Consequently, the patent must be revoked.[27]

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Gordon J

Justice Gordon found that the *NRDC* test was inapposite because that case involved a process claim and the present appeal involved a product claim.[28] The erroneous application of that test by the courts below had produced an incorrect approach to the construction of the claims 'as claimed'.

On a strict approach to the construction of the claims, her Honour determined that their subject matter could not be comprehensively defined by reference to a chemical structure or particular product, was not invented by Myriad in any relevant sense and were too broad. For these reasons, the claims were not 'patentable subject matter'.[29]

Conclusion

The majority observed that this case was not about 'gene patenting generally'. However, the reasoning of the majority accepted that the claims were *prima facie* patentable when assessed against the *NRDC* test and found it necessary to take an additional step in order to resolve the question of whether isolated nucleic acids were patentable.

Neither Gageler and Nettle JJ nor Gordon J applied the *NRDC* test to the claims. Both considered the question of patentability to be determined by the application of different considerations.

Gageler and Nettle JJ applied a threshold test of 'inventiveness' to the concept of 'manner of manufacture', a consideration arising before the application of the *NRDC* test. Gordon J did not consider the test for 'inventiveness' in *Mirabella* to be a separate threshold test but a test of general application. She confined the *NRDC* test to particular types of claim (process claims). The decisions of the majority, Gageler and Nettle JJ arguably commend a cumulative, three-stage test for patentability.

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Endnotes

1. *Cancer Voices Australia v Myriad Genetics Inc* (2013) 99 IPR 567.
2. *D'Arcy v Myriad Genetics Inc* (2014) 224 FCR 479.
3. Each judgment describes the biology the subject of the claims in detail. Any error in the representation of the claims is the author's own.
4. *Myriad* at [73].
5. (1959) 102 CLR 252 at 269.
6. *Myriad* at [24] – [26].
7. Ibid at [19] citing NRDC at 277.
8. Ibid. See also Gageler & Nettle JJ at [167] and Gordon J at [219].
9. Ibid at [24].
10. Ibid.
11. Ibid at [30].
12. Ibid at [27] and [86].
13. Ibid at [89].
14. Ibid at [93].
15. Ibid at [28].
16. Ibid at [31] – [36].
17. Ibid at [93] See also Gordon J at [259] – [264].
18. Ibid at [22] and [74], [88].
19. Ibid at [88].
20. Ibid at [94].
21. (1959) 102 CLR 232.
22. (1995) 183 CLR 655.
23. *Myriad* at [133].
24. Ibid at [145].
25. Ibid at [162].
26. Ibid at [155] and [164].
27. Ibid at [123] and [152].
28. Ibid at [278].
29. Ibid at [229] and [261].

Verbatim

Gladio Pty Ltd v Buckworth **[2015] NSWSC 922 (McDougall J – 14 July 2015)**

[49] .. Not surprisingly, Mr Lane's reply led to considerable discussion between the directors of Ashdown. Those directors included (I think this is a recognised collective noun) a quarrel of lawyers: highly experienced and well-regarded legal practitioners. One matter which arose out of those discussions was 'an additional rule to cover shareholders who are not real persons' ..