Endnotes

1. French CJ, Hayne, Crennan, Kiefel and Bell JJ wrote a joint judgment, Keane J wrote a separate judgment. Gageler J did not sit after recusing himself. His Honour stated that he had, as a solicitor-general of the Commonwealth provided signed legal advice to the attorney-general of the Commonwealth in response to a request for advice which touched on the validity of provisions of the EFED Act: [2013] HCATrans 263.
2. At [35] per French CJ, Hayne, Crennan, Kiefel and Bell JJ; at [115] per Keane J.
3. At [44] per French CJ, Hayne, Crennan, Kiefel and Bell JJ; at [115] per Keane J.
4. At [19] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
5. At [129] per Keane J.
6. At [133] per Keane J.
7. At [134] per Keane J.
8. At [25] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
9. At [158] per Keane J.
10. At [30] per French CJ, Hayne, Crennan, Kiefel and Bell JJ; at [109] per Keane J.
11. At [27] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
12. At [166] per Keane J.
13. At [38] and [43] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
14. At [46] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
15. At [60] and [64].
16. At [56] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
17. At [64] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
18. At [65] per French CJ, Hayne, Crennan, Kiefel and Bell JJ.
19. At [137] and [168] per Keane J.
20. At [141] per Keane J.
21. At [168] per Keane J.

Patents for methods of medical treatment

Emma Beechey reports on *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50

The High Court recently ruled that a method of medical treatment of the human body involving the application of a product to produce a therapeutic or prophylactic result is a 'manner of manufacture' for the purposes of s 19(1)(a) of the *Patents Act 1990* (Cth) (the Act). The court also held that a new therapeutic use of a known pharmaceutical substance having prior therapeutic uses can be a 'manner of manufacture'. This is the first occasion on which the High Court has ruled on the patentability of methods of medical treatment of the human body.

The facts and the proceedings

The drug leflunomide is used to treat psoriatic and rheumatoid arthritis. It was patented in 1979 by Hoechst AG.[1] That patent expired in 2004. In 1994, Hoechst AG applied for a patent for a method of preventing psoriasis by application of leflunomide. That patent is the subject of the proceedings and will expire in 2014.

In 2008, Apotex Pty Ltd obtained registration on the Australian Register of Therapeutic Goods of a generic version of leflunomide (Apo-Leflunomide). The product information supplied with Apo-Leflunomide stated that the product was indicated for the treatment of rheumatoid arthritis and psoriatic arthritis. It stated that it was not indicated for the treatment of psoriasis not associated with arthritic disease.

The respondents brought proceedings in the Federal Court alleging that Apotex would infringe the patent under s 117 of the Act by supplying Apo-Leflunomide for the treatment of psoriatic arthritis. Apotex denied that it would infringe the patent and cross-claimed seeking revocation of the patent.

Lower courts

The primary judge (Jagot J) held that the patent was valid[2] and that the supply of Apo-Leflunomide for treatment of psoriatic arthritis would infringe the patent because the effect of such treatment would be the indirect treatment or prevention of psoriasis.[3]

The full court of the Federal Court dismissed the appeal, upholding the primary judge's finding as to validity of the patent and finding that the supply of the Apotex product would infringe the patent, but for different reasons to those set out by the primary judge.[4] The full court found that the construction of the claim preferred by the primary judge was incorrect; the patent claim was not for treatment

Hayne J, in dissent, held that a method of prevention or treatment of human disease is not a proper subject for the grant of a patent because the product, being the improvement of the condition of a human being, cannot be turned to commercial benefit by the holder of the patent or by any person other than the individual who has been treated.

having the *effect* of treating psoriasis but rather for the deliberate administration of leflunomide for the specific purpose of preventing or treating psoriasis.[5] However, the full court found that Apotex had reason to believe that people would use the product for the treatment of psoriasis (engaging s 117(2)(b) of the Act) and that the product information document contained an instruction to use Apo-Leflunomide to treat psoriasis (engaging s 117(2)(c)) of the Act).[6]

High Court

Patentable invention

French CJ examined the history of the *Patents Act 1900,* going back to the Statute of Monopolies *1623*, from which the 'manner of manufacture' requirement stems. His Honour noted that there was a logical and normative tension between the patentability of pharmaceutical products and the exclusion from patentability of medical treatment. It was 'an anomaly for which no clear and consistent foundation has been enunciated'.[7] His Honour concluded that methods of medical treatment fall within the scope of a manner of manufacture, as it would not serve a logical or normatively coherent application of the concept to hold otherwise.[8]

In coming to this conclusion, French CJ focused on the application of common law processes and, in particular, the endeavour to achieve coherence in the law. His Honour disavowed any attempt to resolve policy questions.

Crennan and Kiefel JJ examined the provisions of the Act, noting where the Act distinguished between product and method claims and where the Act referred to pharmaceutical patents as including both substances and methods. Their Honours examined the relevant English and Australian authorities and then considered the positions in Europe, the UK, the USA and Canada. In introducing the overseas positions, their Honours noted that the Act includes provisions designed to harmonise Australian patent law with the laws of Australia's major trading partners and to ensure compliance with Australia's international obligations. Their Honours drew specific attention to the Agreement on Trade-Related Aspects of Intellectual Property Rights (1995) (TRIPs),[9] to which Australia is a signatory, which gives all contracting states the option to 'exclude from patentability … diagnostic, therapeutic and surgical methods for the treatment of humans'.[10] Australia made amendments to the Act consequent upon its entry into TRIPs but it did take up this option.[11]

Their Honours set out seven reasons why Apotex's submission that the subject matter of the patent was 'essentially non-economic' must be rejected.[12] The critical reason, which Gaegler J also found the most compelling, was that product claims, method claims for new products and method claims for known products could not be distinguished in terms of economics or ethics.[13] Patentability was consistent with the Act and with the practices of the Australian Patent Office since at least 1984.[14] To find otherwise would be to 'introduce a lack of harmony between Australia and its major trading partners, where none exists at present'.[15]

Gaegler J agreed with Crennan and Kiefel JJ but added an additional reason for accepting the patentability of the invention: the position reached by the Federal Court in *Rescare*[16] and *Bristol-Myers*[17] has been accepted as representing orthodoxy in Australian patent law, informing both legislative assumptions when the Act was amended in 2006 and legitimate commercial expectations, and should not now be departed from.[18]

Hayne J, in dissent, held that a method of prevention or treatment of human disease is not a proper subject for the grant of a patent because the product, being the improvement of the condition of a human being, cannot be turned to commercial benefit by the holder of the patent or by any person other than the individual who has been treated. His

Honour analysed the cases and found that a wrong turn had been taken in the English case of *Schering AG's Application*[19] and in the Australian case of *Joos v Commissioner of Patents*[20] (a single judge decision of Barwick CJ). For Hayne J, the fact that a process produces a result for which people are prepared to pay (as found in *Schering*) is not sufficient for the grant of a patent.

Infringement

Crennan and Kiefel JJ (with whom French CJ and Gaegeler J agreed) agreed with the full court that the patent was limited to the *purpose* of treating or curing psoriasis (rather than the effect of psoriasis being cured) and therefore the patent was not directly infringed by the use of leflunomide to treat psoriatic arthritis.[21] However, their Honours found that the full court was incorrect in its other findings as to infringement. The High Court found that Apotex did not have reason to believe that its product would be used to treat psoriasis and that its product information document contained 'an emphatic instruction to recipients' to restrict their use of the product to the non-patented uses.

Remaining question

There remains the question of whether surgical or diagnostic methods are patentable inventions. It appears from the reasons of Crennan and Kiefel JJ that such methods are excluded from the scope of patentable inventions in Europe[22] and the UK.[23] In the USA, surgical methods may be patented but actions for patent infringement against medical practitioners are barred.[24] In Canada, methods of medical treatment are not patentable but novel uses of known compounds are considered patentable, so long as they do not include a medical or surgical step.[25]

Crennan and Kiefel JJ found it unnecessary to decide this point but noted that such procedures are 'essentially non-economic' and not capable of industrial application, so are unlikely to satisfy the test for patentability.[26] Gaegler J stated that the question of '[w]hether *all* processes for treating the human body ought now to be recognised as within the concept of a manner of manufacture … need not be determined'.[27] Although French CJ referred to cases in which ethical concerns were expressed regarding patenting of surgical procedures,[28] his Honour ultimately appeared to accept patentability of all medical treatment for reasons of logic and normative coherence.[29] The question did not arise for Hayne J. The resolution of this question remains for another day.

Endnotes

1. Hoechst AG later became a part of the second respondent. The parties drew no distinction between the respondents, all of which were associated companies.
2. *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* (2011) 196 FCR 1.
3. Ibid at [154]-[155], [264]-[266].
4. *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2012) 204 FCR 494.
5. Ibid., at [37], [40], [45]-[46], [124]-[125], [128]-[129].
6. Ibid., at [54], [57]-[58], [143], [146], [148], [155].
7. *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50 at [50] (*Apotex*).
8. Ibid., at [50].
9. Annex 1C to the Marrakesh Agreement establishing the World Trade Organization [1995] ATS 8.
10. TRIPs, Art 27(3).
11. *Apotex* [2013] HCA 50 at [280].
12. A proposition first rejected in *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 (Gummow J); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (full court) and *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524.
13. Ibid., at [282].
14. Ibid., at [190], [284].
15. Ibid., at [280].
16. *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205 (Gummow J); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 (full court).
17. *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 97 FCR 524.
18. *Apotex* at [315].
19. [1971] 1 WLR 1715.
20. (1972) 126 CLR 611.
21. *Apotex* at [294].
22. Ibid., at [246].
23. Ibid., at [258].
24. Ibid., at [271].
25. Ibid., at [272]-[274].
26. Ibid., at [287].
27. Ibid., at [312], emphasis in original.
28. Ibid., at [39], [42].
29. Ibid., at [50].