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LIFE SCIENCES UPDATE

HIGH COURT CONCLUDES METHODS OF MEDICAL TREATMENT ARE PATENTABLE

ON 4 DECEMBER 2013, THE HIGH COURT JUDGMENT IN *APOTEX PTY LTD V SANOFI-AVENTIS AUSTRALIA PTY LTD & ORS* [2013] HCA 50 WAS DELIVERED. THIS IS THE FIRST OCCASION THAT THE HIGH COURT HAS CONSIDERED WHETHER METHODS OF MEDICAL TREATMENT OF THE HUMAN BODY ARE PATENTABLE INVENTIONS WITHIN THE MEANING OF SECTION 18(1) OF THE *PATENTS ACT 1990* (CTH). THE MAJORITY OF THE HIGH COURT CONCLUDED THEY WERE, WHILST PROVIDING IMPORTANT GUIDANCE ON CONTRIBUTORY (OR INDIRECT) INFRINGEMENT IN THE CONTEXT OF PATENTS WHICH CLAIM METHODS OF MEDICAL TREATMENT.

SUMMARY OF THE MATTER

Parties and the patent

By way of background, the patent in issue was Australian Patent No 670491, entitled *Pharmaceutical for the treatment of skin disorders*. Relevantly, the patent claims:

[a] method of preventing or treating a skin disorder wherein the skin disorder is psoriasis, which comprises administering to a recipient an effective amount of [leflunomide].

Sanofi-Aventis Australia Pty Ltd (Sanofi) markets leflunomide in Australia under the brand name ARAVA®.

In 2008, Apotex Pty Ltd (Apotex) obtained registrations for a generic leflunomide product. Shortly thereafter, Sanofi commenced infringement proceedings largely relying on section 117 of the *Patents Act 1990* (Cth) which relates to contributory (or indirect) infringement.

Apotex responded by filing a cross-claim for revocation. Importantly, one of the grounds relied upon in making the argument for revocation was that the patent did not disclose a patentable invention, effectively challenging the patentability of methods of medical treatments.

Pursuant to the *Patents Act*, amongst other things, a patentable invention must be a *manner of manufacture* within the meaning of section 6 of the *Statute of Monopolies*. Apotex argued that methods of medical treatment do not fall within this definition as they are "essentially non-economic" and "not capable of being industrially applied." They further argued that a method of medical treatment involving the administration of a pharmaceutical substance differs to a medicine in that it "improved the condition of a human being, which is not an article of commerce."¹

This is the first occasion that the High Court has been required to consider whether a method of medical treatment "is a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*."²

PATENTABLE SUBJECT MATTER Issues

The majority of the High Court (French CJ, Crennan, Kiefel and Gageler JJ, Hayne J dissenting) concluded that "methods of medical treatment of human beings, including surgery and the administration of therapeutic drugs, can be the subject of patents."³ This is consistent with the approach that has been taken by the Full Federal Court in a number of recent cases.⁴

Their reasoning included detailed consideration of the body of case law in both Australia and the United Kingdom that relates to manner of manufacture. Consideration was also given to the positions held in the European Union, the United States, Canada and New Zealand.

Manner of manufacture is a broad and evolving concept. As identified in the Explanatory Memorandum to the *Patents Bill 1990*:

[i]t means little more than that an invention must belong to the useful arts rather than the fine arts.

The judgments from the majority placed emphasis on the following paragraph derived from the judgment of Lockhart J in *Anaesthetic Supplies Pty Ltd v Rescare Ltd* which neatly encompassed the principles from the leading *National Research Development Corp v Commissioner of Patents*⁵ case:

*"If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture' within s 6 of the Statute of Monopolies."*⁶

The Chief Justice concisely drew the views of the majority together when his Honour stated:

*"The exclusion from patentability of methods of medical treatment represents an anomaly for which no clear and consistent foundation has been enunciated. Whatever views may have held in the past, methods of medical treatment, particularly the use of pharmaceutical drugs, cannot today be conceived as 'essentially non-economic'."*⁷

Implications

The Patent Office has been granting patents for methods of medical treatment, particularly in relation to pharmaceutical products, for many years. This decision now provides the Australian Life Sciences sector with certainty that patents are available for inventions that are methods of medical treatment provided that the invention is otherwise patentable (that is, it meets the requirements of novelty, utility, inventive step and no prior use).

¹ *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50, [217].

² *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252 at 269.

³ *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50, [1] (French CJ).

⁴ *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 and *Bristol-Myers Squibb v FH Faulding & Co Ltd* (2000) 97 FCR 524.

⁵ (1959) 102 CLR 252.

⁶ *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 at 19.

⁷ *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50, [50].

INFRINGEMENT

Issues

Sanofi's case in infringement was dependent on section 117 of the *Patents Act*.

At first instance and on appeal, Apotex was found to infringe the patent. However, the High Court overturned these decisions and found that Apotex had **not** infringed the patent.

Pursuant to section 117 of the *Patents Act*, a person may, in certain circumstances, be liable for contributory (or indirect) infringement if that person supplies a product to another, where the use of that product would infringe a third party's patent rights.

Section 117(1) of the *Patents Act* provides that where "the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement."

Further, section 117(2) describes what constitutes *use of a product*. Relevantly, Sanofi relied on:

- s 117(2)(b), which provides "if the product is not a staple commercial product - any use of the product, if the supplier had reason to believe that the person would put it to that use"; and
- s 117(2)(c), which provides "in any case - the use of the product in accordance with any instructions for the use of the product, or any inducement to use."

The High Court found that because the product information for Apo-Leflunomide strictly stated that:

Apo-Leflunomide is indicated for the treatment of:

- *Active Rheumatoid Arthritis.*
- *Active Psoriatic Arthritis. Apo-Leflunomide is not indicated for the treatment of psoriasis that is not associated with manifestations of arthritic disease.*

It could not be said that there was an instruction within the product information to use the Apo-Leflunomide in a way that would infringe the patent. Therefore the indirect infringement claim pursuant to s 117(2)(c) of the *Patents Act* failed.

In relation to s 117(2)(b) of the *Patents Act*, the majority concluded that Sanofi had not shown (nor could it be inferred) that Apotex had reason to believe that its product would be used contrary to the indications in the Apo-Leflunomide product information. As such, the claim for indirect infringement under this section also failed.

Implications

It is clear that going forward, innovator companies seeking to make a claim of indirect infringement in respect of a method of medical treatment in circumstances where the product information or instructions for use do not provide directions to infringe the patent, will need to ensure that they have sufficient evidence to establish that the product would be used contrary to the directions and in a manner which would infringe the patent.

A QUESTION FOR THE LEGISLATURE?

While this decision provides certainty that methods of medical treatment are patentable subject matter, the High Court highlighted that there are broad public policy considerations to be made in relation to patents in this field. The Chief Justice noted that consideration of "*competing philosophies of proprietarianism and instrumentalism and the relative values to be accorded to different public goods: alleged incentives to innovation on the one hand, and the widest possible availability of new methods of medical treatment to relieve suffering on the other*"⁸ are best left to the legislature.

⁸ *Apotex Pty Ltd v Sanofi-Aventis Australia* [2013] HCA 50, [50].

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