

## **APOTEX PTY LTD V SANOFI-AVENTIS AUSTRALIA PTY LTD - CLAIMING INTENT**

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The Federal Court of Appeal in Australia recently interpreted method of treatment claims as having an element of intention.<sup>1</sup>

In this article we will be focussing on the construction and novelty of the relevant claim. The infringement aspect of the decision will be dealt with in a separate article.

The subject of these proceedings was Australian patent number 670491 to Sanofi-Aventis Deutschland GmbH. It contains a single claim to:

*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 a pharmaceutical composition containing as an active ingredient a compound of formula I or II...*

The compound of formula I is the active known as leflunomide, which is sold in Australia under the trade names "Arava" and "Arabloc" by the Australian subsidiary of the patentee for treatment of rheumatoid arthritis (RA) and psoriatic arthritis (PsA).

Apotex Pty Ltd ("Apotex") registered its generic leflunomide product for treatment of PsA and RA in July 2008 and was subsequently sued for infringement of the method claim of AU 670491 (above) by Sanofi.

At trial,<sup>2,3</sup> the judge found as facts that:

- (i) a person suffering from RA may have or develop psoriasis;
- (ii) a person suffering from PsA will almost always have psoriasis; and
- (iii) by administering leflunomide to a person with RA and/or PsA (as taught in the prior art), any psoriasis that the patient may have or may develop would inevitably be prevented or treated.

The issue was therefore whether the sale of Apotex's generic leflunomide product for the treatment of RA and PsA would infringe the claim.

The trial judge, in accordance with the arguments advanced by Sanofi, construed the claim as being independent of the physician's purpose i.e. the claim included within its scope administration of leflunomide for any purpose (e.g. treatment of PsA), provided that it was in an amount effective to prevent or treat psoriasis, and that such prevention or treatment would therefore occur. The trial judge therefore found that the use of leflunomide to treat RA or PsA would infringe the patent because that use would *inevitably* treat or prevent psoriasis in that patient.

The appeal judges did not agree with the construction given to the claim by the trial judge. Keane CJ stated:<sup>4</sup>

*... the claim is not for the discovery of whatever happens in the human body after the drug is administered... the method necessarily presupposes a deliberate exercise of diagnosis and prescription by a medical practitioner.*

Judges Bennett and Yates agreed with Keane CJ's conclusion and, having reviewed the specification to determine what it considers the invention to be, they concluded that:<sup>5</sup>

*...the primary judge's construction gives the claim a field of operation, and Sanofi-Aventis a resulting exclusive right under s 13 of the Patents Act, that exceeds the description of the invention in the body of the specification.*

Accordingly, the claim was to be construed as being limited to the administration of leflunomide for the objective of preventing or treating psoriasis, regardless of whether other conditions may also be treated, or were sought to be treated, by its administration. This is despite well-established case law that:

- infringement should not rest on the alleged infringer's state of mind;<sup>6</sup> and
- words or meanings must not be imported into a claim that are not expressly present in that claim.<sup>7</sup>

The construction adopted by the Federal Court also meant that the claim was found to be novel over an earlier Sanofi patent (AU 529341), which related to the leflunomide compound and discussed the use of leflunomide for treating (at least) RA and PsA in humans. The Federal Court of Appeal found that AU 529341 did not make public the use of leflunomide *for the treatment of psoriasis*. This reinforces the reluctance of the Australian courts to find a lack of novelty on the basis of an inherent disclosure.

In light of this claim construction, Apotex itself did not infringe the claim, contrary to the finding of the trial judge. However, Apotex was still held to infringe the claim by way of contributory infringement, despite having directed that its generic leflunomide product be used in the treatment of, *inter alia*, arthritic disease, and not psoriasis when it is not associated with arthritic disease. The long-running controversy over the requirement for contributory infringement under the statute was considered but not fully resolved. This will be discussed in our next article.

- Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2) [2012] FCAFC 102
- Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3) [2011] FCA 846
- Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 4) [2011] FCA 1307
- Above n 1 at [37]
- Above n 1 at [124]
- Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd [1996] RPC 76 at 92
- For example, H Lundbeck A/S v Alphapharm Pty Ltd [2009] FCAFC 70 at 58

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