APOTEX PTY LTD v SANOFI-AVENTIS AUSTRALIA PTY LTD & ORS (S219/2012)
APOTEX PTY LTD v SANOFI-AVENTIS AUSTRALIA PTY LTD & ORS (S1/2013)

Court appealed from:	Full Court of the Federal Court of Australia [2012] FCAFC 102
Date of judgment:	18 July 2012
Date special leave referred in/granted:	14 December 2012

The Respondents are related companies which supply the drugs "Arava" and "Arabloc". Both of those products contain the compound leflunomide. The Second Respondent holds Australian Patent Number 670491 ("the Patent") which claims a method of treating psoriasis by the administration of leflunomide. It also states that psoriasis was one of numerous medical uses which were the basis of an earlier patent ("the earlier patent") for leflunomide obtained by a predecessor of the Second Respondent. The earlier patent referred to the treatment of "rheumatic complaints". The main rheumatic complaint treated by rheumatologists is inflammatory arthritis, the most common forms of which are rheumatoid arthritis ("RA") and psoriatic arthritis ("PsA"). Psoriasis exists independently of PsA, but most people who have PsA also develop psoriasis.

Entries in the Australian Register of Therapeutic Goods ("the Register") were obtained for both Arava and Arabloc. Those entries state that those products are used to treat both RA and PsA. They also state however that the products' registration does not extend to the treatment of psoriasis that is not associated with arthritic disease. In July 2008 Apotex Pty Ltd ("Apotex") obtained a very similar entry in the Register for a generic product called "Apo-Leflunomide". In doing so Apotex provided descriptions which it had copied from the product information on Arava. The Respondents then sued Apotex for threatened infringement of the Patent. They also alleged breach of copyright and (threatened) misleading or deceptive conduct by Apotex.

On 18 November 2012 Justice Jagot restrained Apotex from marketing or supplying any products that contain leflunomide, as such acts would infringe the Patent pursuant to s 117(1) of the *Patents Act* 1990 (Cth) ("the Act"). Her Honour found that the Patent was valid, as the invention claimed in it was both novel and a "manner of manufacture". Justice Jagot also found that the method described in the Patent contemplated leflunomide as having an effect of treating psoriasis. That effect occurred whether or not the drug was prescribed only for the treatment of PsA. Her Honour held that previous instances of the copying of a competitor's information for the registration of a generic pharmaceutical product did not give rise to a licence implied by custom compelling the Respondents to accept Apotex's copying of Arava's product information. Apotex had therefore breached the Respondents' copyright.

On 18 July 2012 the Full Court of the Federal Court (Keane CJ, Bennett J & Yates J) unanimously dismissed Apotex's appeal. Their Honours found that the Patent was not invalid for lack of novelty, nor was it invalid for want of a "manner of manufacture". The Full Court held however that Apotex's planned supply of Apo-Leflunomide would infringe the Patent because the product information for Apo-Leflunomide would effectively cause leflunomide to be used for the treatment of psoriasis. This is despite that information (and rheumatologists' prescriptions) not referring to that skin condition. Their Honours held that Justice Jagot had correctly found that a licence to copy product information could not be implied on the basis of the industry practice alleged by Apotex.

In matter number S219/2012 the questions of law said to justify the grant of special leave to appeal include:

- When a patent claims the use of a compound for the treatment of a specific disease, can a person who supplies the compound and indicates its use for the treatment of a different disease infringe the patent under s 117(1) of the Act?

In matter number S1/2013 the ground of appeal is:

- The Full Court erred in finding that the claim of the Patent claimed a manner of manufacture within the meaning of s 18(1) of the Act.