

BETWEEN:

**APOTEX PTY LTD ACN 096 916 148**  
Applicant/Appellant

and

**SANOFI-AVENTIS AUSTRALIA PTY LTD**  
First Respondent  
**SANOFI-AVENTIS DEUTSCHLAND GMBH**  
Second Respondent

**AVENTISUB II INCORPORATED**  
Third Respondent

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**APPLICANT'S/APPELLANT'S CHRONOLOGY**

**Part I: Certification as to form**

This chronology is in a form suitable for publication on the internet.

**Part II: List of principal events leading to the litigation**

Date	Event
14 December 1979	Hoechst AG <sup>1</sup> filed Australian Patent No. 529,341 entitled "5-methylisoxazole-4-carboxylic acid-4-trifluoromethyl-anilide with antirheumatic, antiphlogistic and antipyretic effect" (the <b>341 Patent</b> ).
19 June 1980	The 341 Patent became publicly available.

<sup>1</sup> Hoechst AG merged with Rhone-Poulenc to form Aventis in 1999 and became part of the Second Respondent in 2004.

Filed on behalf of the Applicant/Appellant, Apotex Pty Ltd  
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Date	Event
26 September 1986	The Second Respondent filed Australian Patent No. 588,629 entitled " <i>Medicaments to combat chronic graft-versus-host diseases and to combat autoimmune diseases, in particular systemic lupus erythematosus</i> ".
2 April 1987	Australian Patent No. 588,629 became publicly available.
24 October 1990	The Second Respondent filed Australian Patent No. 649,421 entitled " <i>Isoxazole-4-carboxamides and hydroxyalkylidene-cyanoacetamides, drugs containing these compounds and use of such drugs</i> ".
10 December 1991	Australian Patent No. 649,421 became publicly available.
31 March 1993	Priority date for Australian Patent No. 670,491, entitled " <i>Pharmaceutical for the treatment of skin disorders</i> " filed by Hoechst AG (the Patent).
23 March 1994	A divisional application no. 662,465 to Australian Patent No. 649,421 was filed.
29 March 1994	The Patent was filed.
3 November 1999	Sanofi obtained a 5 year extension of term for the 341 Patent.
11 October 1999	Leflunomide was listed on the Australian Register of Therapeutic Goods indicated for the treatment of Rheumatoid Arthritis (RA).
1 February 2000	Leflunomide was listed on the Schedule of Pharmaceutical Benefits for the treatment of severe active RA in patients for whom other disease modifying anti-rheumatic drugs (including methotrexate) are inappropriate and/or ineffective.
November 2004	The Second Respondent applied to the Therapeutic Goods Administration (TGA) to extend the indications for which Leflunomide was registered on the ARTG to include active PsA.
14 December 2004	The 341 Patent expired.
26 September 2006	Australian Patent No. 588,629 expired.
23 October 2008	The Respondents commenced proceedings against the Applicant/Appellant in the Federal Court of Australia.

Date	Event
30 October 2008	Orders of Justice Lindgren: <ul style="list-style-type: none"> <li>• restraining the Applicant/Appellant from infringing the Patent;</li> <li>• restraining the Applicant/Appellant from copying the product information for the Respondents' product; and</li> <li>• requiring all issues as to liability to be heard prior to, and separately from, any issues as to quantum.</li> </ul>
24 October 2010	Australian Patent No. 649,421 expired.  Divisional patent application no. 662,465 expired.
10 March 2011	Final hearing at first instance commences.
24 March 2011	Final hearing at first instance ends.
29 July 2011	Judgment of Jagot J in <i>Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)</i> (2011) 196 FCR 1; [2011] FCA 846.
18 November 2011	Judgment of Jagot J on the form of the final orders - <i>Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 4)</i> (2011) 202 FCR 56; [2011] FCA 1307.
21 December 2011	The Applicant/Appellant filed and served its Notice of Appeal to the Full Federal Court of Australia.
24 February 2012	Judgment of Jagot J on costs at first instance – <i>Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 5)</i> [2012] FCA 112.
16 March 2012	The Applicant/Appellant filed and served its Further Supplementary Notice of Appeal.
30 April 2012	Appeal to the Full Federal Court commences.
1 May 2012	Appeal to the Full Federal Court ends.
18 July 2012	Judgment of Keane CJ, Bennett and Yates JJ in <i>Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)</i> (2012) 204 FCR 494; [2012] FCAFC 102.

Date	Event
14 August 2012	The Applicant/Appellant filed and served its Application for Special Leave to Appeal to the High Court of Australia.
14 December 2012	<p>Application for special leave to appeal to the High Court is heard.</p> <p>Orders of French CJ and Kiefel J:</p> <ul style="list-style-type: none"> <li>• granting special leave to appeal on Ground 2 in the Draft Notice of Appeal filed on 10 September 2012 (<b>Draft Notice of Appeal</b>); and</li> <li>• referring Ground 3 of the Draft Notice of Appeal to an enlarged bench for further consideration.</li> </ul>
2 January 2013	The Applicant/Appellant filed and served its Notice of Appeal to the High Court of Australia.
29 March 2014	Subject to any order for revocation, the Patent will expire.

Dated: 25 January 2013



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