



HIGH COURT OF AUSTRALIA

NOTICE OF FILING

This document was filed electronically in the High Court of Australia on 15 Apr 2021 and has been accepted for filing under the *High Court Rules 2004*. Details of filing and important additional information are provided below.

Details of Filing

File Number: S22/2021
File Title: H. Lundbeck A/S & Anor v. Sandoz Pty Ltd
Registry: Sydney
Document filed: Form 27B - Appellant's chronology
Filing party: Appellants
Date filed: 15 Apr 2021

Important Information

This Notice has been inserted as the cover page of the document which has been accepted for filing electronically. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties and whenever the document is reproduced for use by the Court.



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File Number: S23/2021
File Title: CNS Pharma Pty Ltd v. Sandoz Pty Ltd
Registry: Sydney
Document filed: Form 27B - Appellant's chronology
Filing party: Appellant
Date filed: 15 Apr 2021

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

S 22 of 2021
S 23 of 2021

ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT OF AUSTRALIA

BETWEEN:

S 22 of 2021

H. Lundbeck A/S
First Appellant

Lundbeck Australia Pty Ltd ACN 070 094 290
Second Appellant

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and

Sandoz Pty Ltd ACN 075 449 553
Respondent

AND BETWEEN:

S 23 of 2021

CNS Pharma Pty Ltd ACN 121 515 400
Appellant

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and

Sandoz Pty Ltd ACN 075 449 553
Respondent

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APPELLANTS' CHRONOLOGY

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Part I: Certification This chronology is in a form suitable for publication on the internet.

Part II: Chronology

	Date	Event	Reference
1.	13 June 1989	H. Lundbeck A/S (Lundbeck A/S) files Australian Patent No. 623144 (Patent).	<i>H. Lundbeck A/S v Sandoz Pty Ltd</i> [2018] FCA 1797 (PJ #1) [4], CAB 14; <i>Sandoz Pty Ltd v H. Lundbeck A/S</i> [2020] FCAFC 133 (FCJ) [6], CAB 247
2.	9 December 1997	Inclusion of CIPRAMIL on the Australian Register of Therapeutic Goods (ARTG).	PJ #1 [7], CAB 15; FCJ [7], CAB 248
3.	27 January 1999	Commencement of the extension of term provisions in the <i>Patents Act 1990</i> (Cth) (Act).	
4.	26 July 1999	Last date to extend the term of the Patent based on CIPRAMIL.	
5.	16 September 2003	Inclusion of LEXAPRO on the ARTG.	PJ #1 [7], CAB 15; FCJ [7], CAB 248
6.	22 December 2003	Lundbeck A/S applies to extend the term of the Patent based on the date of inclusion of LEXAPRO on the ARTG.	PJ #1 [5], CAB 14; FCJ [7], CAB 248
7.	27 April 2004	The term of the Patent is extended to 13 June 2014 (LEXAPRO Extension of Term).	PJ #1 [5], CAB 14; FCJ [8], CAB 248
8.	6 July 2005	Alphapharm Pty Ltd (Alphapharm) commences proceeding NSD 1120 of 2005 to revoke the Patent and remove the LEXAPRO Extension of Term from the Register.	PJ #1 [6], CAB 14; FCJ [9], CAB 248
9.	7 July 2005	Alphapharm writes to the Commissioner of	PJ #1 [5], CAB 14

	Date	Event	Reference
		Patents (Commissioner), notifying the Commissioner that Alphapharm considers that the LEXAPRO Extension of Term was wrongly granted.	
10.	13 July 2005	The Commissioner proposes to reduce the term of the Patent to 9 December 2012 based on the inclusion of CIPRAMIL on the ARTG, pursuant to reg 10.7(7) of the <i>Patents Regulations 1991</i> (Cth).	PJ #1 [263], CAB 98
11.	26 September 2005	Lundbeck A/S licenses Lundbeck Australia Pty Ltd (Lundbeck AU) as the exclusive licensee of the Patent.	PJ #1 [202], CAB 76 FCJ [111], CAB 279
12.	13 April 2006	Sandoz Pty Ltd (Sandoz) commences a proceeding seeking to revoke the Patent and remove the LEXAPRO Extension of Term from the Register (Sandoz Revocation Proceeding).	PJ #1 [9], CAB 15 FCJ [10], CAB 248
13.	19 May 2006	A delegate of the Commissioner, Dr Steven Barker, directs that the term of the Patent be amended to reflect expiry on 9 December 2012 based on the CIPRAMIL registration (Barker Decision).	PJ #1 [8], CAB 15 FCJ [8], CAB 248
14.	16 February 2007	Lundbeck A/S and Lundbeck AU (collectively, Lundbeck) and Sandoz settle the Sandoz Revocation Proceeding (Settlement Agreement).	PJ #1 [9], CAB 15, [259], CAB 97
15.	24 April 2008	Lindgren J finds that the LEXAPRO Extension of Term was invalid and should be removed from the Register (Lindgren Decision).	PJ #1 [10], CAB 16 FCJ [11], CAB 248
16.	26 May 2009	Lundbeck A/S writes to Sandoz (26 May Letter), stating that:	PJ#1 [305], CAB109

	Date	Event	Reference
		<ul style="list-style-type: none"> the Settlement Agreement does not deal with the situation where the date on which the Patent will expire is not known with clarity; if the term of the Patent is determined not to end on 13 June 2009 Sandoz' conduct in seeking PBS listing of its escitalopram products may have breached the Settlement Agreement and infringed the Patent; Lundbeck A/S requires an undertaking from Sandoz that it will not promote, market or distribute, offer to sell or sell escitalopram products until the Full Court has made orders dispensing with the appeal of the Lindgren Decision; and should Lundbeck be unsuccessful in obtaining a judgment upholding the LEXAPRO Extension of Term, it will seek an order that the term of the Patent be amended to conclude on 9 December 2012, and seek special leave to appeal to the High Court. 	
17.	27 May 2009	Sandoz begins importing escitalopram products into Australia.	PJ #1 [304], CAB 109
18.	28 May 2009	<p>Lundbeck A/S writes to Sandoz, setting out the following undertakings foreshadowed in the 26 May Letter:</p> <ol style="list-style-type: none"> from Sandoz to Lundbeck, that 	PJ #1 [304] – [305], CAB 109

	Date	Event	Reference
		<p>unless released from the undertaking or the finding of the Full Court is to the effect that the Patent expires on 13 June 2009, Sandoz will not promote, market, distribute, offer to sell or sell escitalopram products without providing Lundbeck at least five days' written notice;</p> <p>2. from Lundbeck to Sandoz, that if Lundbeck is unsuccessful on the issue of the LEXAPRO Extension of Term, it will pay damages to Sandoz for any disadvantage Sandoz may sustain by reason of the undertaking; and</p> <p>3. from Lundbeck to Sandoz, that Lundbeck will notify Sandoz as soon as possible once it receives notice of the date on which the Full Court will deliver judgment.</p> <p>The letter also confirms that Sandoz may import escitalopram products into Australia pending the outcome of the Full Court appeal, on the condition that such importation is only into its own possession and not for further distribution.</p>	
19.	11 June 2009	The Full Court upholds the finding in the Lindgren Decision that the LEXAPRO Extension of Term is invalid (FFC #1 Decision).	PJ #1 [12], CAB 16 FCJ [12], CAB 248
20.	12 June 2009	Lundbeck applies for an extension of time to	PJ #1 [15], CAB 17

	Date	Event	Reference
		extend the term of the Patent based on the inclusion of CIPRAMIL on the ARTG (Extension of Time Application), as well as a corresponding application to extend the term of the Patent (CIPRAMIL Extension of Term Application).	FCJ [13], CAB 249
21.	13 June 2009	The original term of the Patent comes to an end.	PJ #1 [16], CAB 17 FCJ [14], CAB 249
22.	15 June 2009	Sandoz begins supplying escitalopram products in Australia.	PJ #1 [17], CAB 17 FCJ [14], CAB 249
23.	11 December 2009	The High Court refuses special leave to appeal the FFC #1 Decision.	PJ #1 [18], CAB 17 FCJ [12], CAB 248
24.	1 June 2011	A delegate of the Commissioner, Ms Karen Ayers, grants the Extension of Time Application (Ayers Decision).	PJ #1 [21], CAB 17 FCJ [15], CAB 249
25.	4 December 2012	The Administrative Appeals Tribunal affirms the Ayers Decision (AAT Decision).	PJ #1 [22], CAB 17 FCJ [15], CAB 249
26.	9 December 2012	The term of the Patent as extended by the CIPRAMIL Extension of Term Application comes to an end.	PJ #1 [25], CAB 18 FCJ [17], CAB 250
27.	18 November 2013	The Full Court upholds the AAT Decision (FFC #2 Decision).	PJ #1 [23], CAB 17 FCJ [15], CAB 249
28.	18 December 2013	Sandoz files an application for a licence to exploit an invention the subject of the Patent pursuant to s 223(9) of the Act (Licence Application) before the Commissioner of Patents.	PJ #1 [24], CAB 18 FCJ [16], CAB 249
29.	25 June 2014	A delegate of the Commissioner, Dr Steven Barker, grants the CIPRAMIL Extension of Term Application (Barker #2 Decision).	PJ #1 [25], CAB 18 FCJ [17], CAB 250

	Date	Event	Reference
30.	26 June 2014	Lundbeck commences proceedings for infringement of the Patent against Sandoz (Infringement Proceeding).	PJ #1 [26], CAB 18 FCJ [17], CAB 250
31.	5 November 2014	The High Court dismisses the appeal of the FFC #2 Decision.	PJ #1 [27], CAB 18 FCJ [15], CAB 249
32.	6 November 2014	Rares J dismisses the appeal of the Barker #2 Decision (Rares Decision).	PJ #1 [28], CAB 18 FCJ [19], CAB 250
33.	22 September 2015	The Full Court dismisses the appeal of the Rares Decision (Full Court #3 Decision).	PJ #1 [29], CAB 18 FCJ [19], CAB 250
34.	11 March 2016	The High Court refuses special leave to appeal the FFC #3 Decision.	PJ #1 [30], CAB 18 FCJ [19], CAB 250
35.	30 May 2016	CNS Pharma Pty Ltd commences proceedings against Sandoz for breaches of the <i>Australian Consumer Law and Trade Practices Act 1974</i> (Cth) in supplying escitalopram products.	PJ #1 [26], CAB 18
36.	8 July 2016	A delegate of the Commissioner, Mr Philip Spann, declines to dispose of the Licence Application on the basis that it does not meet the threshold requirements of the Act (Spann Decision).	
37.	3 February 2017	Beach J makes a declaration that the Licence Application is not invalid, dismissing Lundbeck A/S's application for judicial review of the Spann Decision.	PJ #1 [33], CAB 19 FCJ [20], CAB 250
38.	16 April 2018 – 4 May 2018	Hearing on validity and infringement of the Patent in the Infringement Proceeding before Jagot J.	CAB 8
39.	2 October 2018 – 10 October 2018	Hearing on the quantum of relief in the Infringement Proceeding before Jagot J.	CAB 8

	Date	Event	Reference
40.	19 November 2018	First hearing of the Licence Application in the Patent Office.	
41.	21 November 2018	Jagot J hands down judgment in the Infringement Proceeding finding infringement of the Patent between June 2009 and December 2012 (Jagot Decision).	CAB tab 1
42.	29 January 2019	Jagot J publishes reasons confirming finds that Lundbeck's damages should be discounted by 25% to reflect the fact that some of Sandoz' sales would have been made by other sellers of generic escitalopram products (25% Discount Decision).	CAB tab 2
43.	19 February 2019	Final orders are made in the Infringement Proceeding to give effect to the Jagot Decision and the 25% Discount Decision).	CAB tab 3
44.	18 March 2019	Second hearing of the Licence Application in the Patent Office regarding the impact of the Jagot Decision.	
45.	11 April 2019	A delegate of the Commissioner, Dr Steven Barker, grants the Licence Application, granting Sandoz a licence to exploit the Patent from 13 June 2009 to 9 December 2012.	FCJ [20], CAB 250
46.	6 May 2019	Lundbeck appeals the decision to grant the Licence Application to the Administrative Appeals Tribunal.	FCJ [20], CAB 250
47.	8 – 10 May 2019	Hearing of the appeal of the Jagot Decision before Nicholas, Yates and Beach JJ.	CAB 242
48.	4 August 2020	The Full Court allows the appeal of the Jagot Decision (Full Court #4 Decision).	CAB tab 10
49.	11 February 2020	The High Court grants special leave to appeal the FFC #4 Decision.	CAB tab 14

	Date	Event	Reference
			CAB tab 17
50.	30 March 2021	The Full Court makes costs orders in relation to the Full Court #4 Decision and publishes reasons in support of those orders.	

Dated 15 April 2021



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