



HIGH COURT OF AUSTRALIA

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Details of Filing

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Important Information

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY
No. S22 of 2021

BETWEEN:

H. LUNDBECK A/S & Anor

Appellant

and

SANDOZ PTY LIMITED

Respondent

No. S23 of 2021

BETWEEN:

CNS PHARMA PTY LIMITED

Appellant

and

SANDOZ PTY LIMITED

Respondent

APPELLANTS' OUTLINE OF ORAL ARGUMENT

Part I: Internet publication

1. This outline is in a form suitable for publication on the Internet.

Part II: Propositions to be advanced in oral argument

Settlement Agreement Issue

2. The application for extension of the Patent until 9/12/12 was determined on 25/6/14, after expiry of the original 20 year term on 13/6/09. Section 79 *Patents Act, 1990 (Act)* presumes expiry of the patent. AS[17], [18], [27]; PJ[15],[20]-[25], [286]; ss 65, 67, 70, 71, 72, 74-79, 223 Act; *Alphapharm v Lundbeck* (2014) 254 CLR 247.
3. The Settlement Agreement dated February 2007 makes no specific provision for that circumstance: AS[19]; PJ[251]; cl 3 ABFM 15 at 18-19.

Settlement Agreement: Commercial purpose, objects, genesis, background, context and market of the transaction (see eg Electricity Generation v Woodside 251 CLR 640 at [35])

4. The following were objectively mutually known or understood as at February 2007.
5. The Patent expiring 13 June 2009 (absent extension) gave Lundbeck the exclusive right to exploit escitalopram, the S enantiomer of the racemic compound cipramil: AS[1]; PJ[47].
6. Lundbeck's ARTG registration of escitalopram on 16 September 2003 as a treatment for depression enabled it to be supplied commercially in Australia as "Lexapro": PJ[7].
7. From 2003 Lundbeck supplied Lexapro with no external licences, creating a valuable market for escitalopram: AS[46]; PJ[2], [7], [240], [264], [407], [452]; ASBFM pp17, 41.
8. On 22/12/03 Lundbeck sought an extension of term based on the Lexapro registration which the Commissioner granted on 27/4/2004 until 13/6/14 but amended on 19/5/2006 until 9/12/12: AS[7], [8]; PJ[5], [8].
9. Sandoz, Alphapharm and Arrow were keen to launch their own escitalopram products and commenced proceedings to revoke the Patent or to remove the 13/6/14 extension as wrongly based on Lexapro, rather than Cipramil (citalopram: registered 9 December 1997 last filing date 26/7/99). Lundbeck defended the 13/6/14 extension: PJ[6], [7], [9], [264].
10. There was no infringement cross-claim in the Sandoz proceedings. PJ[6], [9], [269].
11. Lundbeck defended the Patent and pursued the extension to maintain its market exclusivity. Any generic entry would erode that market: AS[46]; ASR [9]; PJ[269], [421].
12. There was limited benefit to Lundbeck of discontinuance by Sandoz as the Alphapharm proceedings continued: AS[29], [44]; PJ[269].
13. The validity of the Patent and the length of any extension would be known by May 2009: AS[39], [45]; PJ[265], [294]; FCJ[59], [60], [62], [64].

14. The objective possibility of an extension of time and an extension of term based on the Cipramil registration was remote: AS[26]; PJ[292], [260]-[263]; FCJ[69].
15. The commercial object of the proposed Settlement Agreement was the grant to Sandoz of a two week early entry licence of the Patent in exchange for discontinuance of the Sandoz proceedings. AS[39], [42]; PJ[271], [272], [296]; FCJ[50]-[54]; ABFM p30, 29, 33.
16. The object did not include addressing a post expiry extension: AS[47]; PJ[293]; FCJ[59].
17. Sandoz had rights to oppose any Lundbeck extension of time application to lodge an extension of term application based on Cipramil or any consequent extension of term or to seek, if relevant, a s 223(9) licence: PJ[20]-[30], [550]; RS[17]; ASR[15].
18. A royalty free licence for any post expiry extension makes no commercial sense and would render the extension substantially inutile: AS[46]; PJ[269], [300], [421]-[425]; Order 2 p199; FCJ[63]-[65], [69], [125]-[134].
19. A two week licence prior to expiry on 13/6/09 with the parties left to their contractually unimpeded rights under the Act to deal with the low risk of a post expiry extension is commercially sensible: AS[44]; PJ[291].

Settlement Agreement Construction

20. The commercial object of a two week licence is reflected in the terms and structure of the Settlement Agreement: AS[24]; PJ[298].
21. A reasonable person in the position of the parties would not have understood it had any application to a post expiry extension or that any clause 3(a) licence extended beyond 13 June 2009: AS[39]; PJ[248(1)], [296], [298], [303], [324]; contra FCJ[67].
22. The licence was to the Patent, not to the invention, so that the expiry date which triggered the clause 3(a) licence, necessarily identified its end point. The Patent having more than one expiry date was not contemplated. The “Patent” is the Patent as it stood before its expiry, in this case, unextended: AS[39]; ASR[5]; PJ[296], [298], [299], [302], [303].
23. The agreement was not directed to assuring Sandoz of freedom from the Patent and the releases were limited: PJ[317]-[328]; FCJ[68], [69]. FCJ[69] contradicts FCJ[59].
24. The Full Court does not address how the licence operated during the infringing period when no Patent existed. No doctrine of feeding title could apply: AS[48]-[55].
25. It is a construction issue, and no implication is required, but the words “two week” could equally readily be implied before “licence” in the clause 3(1) chapeau: ASR [14].

Exclusive Licence Issue: s 79

26. Because Lundbeck AU (exclusive licensee) and CNS Pharma (its wholly owned subsidiary) operated as a single economic entity, a single sum of damages was awarded to

both of them. Thus, if Lundbeck AU is entitled to claim damages as exclusive licensee, the misleading conduct CNS Pharma claim is financially moot: Order 2(a) AB199.

27. A patentee's rights are defined in s 13, without reference to an exclusive licensee, and constitute the rights to sue for infringement. Section 120 prescribes the Court in which proceedings may be commenced by the patentee or an exclusive licensee and limitation provisions, but not the content of rights to sue or start proceedings: AS[67], [68].
 28. Contrary to FCJ[99], the source of the patentee's right to start proceedings is not s 120. None of the 1903, the 1952 Australian Acts and the UK 1949 Act included a provision "entitling" the patentee to commence proceedings. Section 113 (1952 Act) assumed such right. Section 114 (1952 Act) introduced an exclusive licensee's right to commence proceedings following its introduction in s 63 *Patents Act 1949* (UK).
 29. The words in s 79 "*the patentee has ... the same rights to start proceedings*" refers to the patentee's rights under s 13. Those are rights which the patentee can confer on an exclusive licensee, who can, by dint of s 120, pursue those rights in proceedings: AS[71].
 30. Similarly, s 78 which refers only to the patentee and applies both to extensions pre and post expiry of the patent, limits the rights of an exclusive licensee indirectly by dint of the combination of s 78 and s 13. See also s 57: AS[67], [68], [70].
 31. There is no logic in a legislative scheme which permits post-expiry extensions but limits the patentee's capacity to exploit the rights via an exclusive licensee, and for example, require it to manufacture and sell itself if it wishes to claim lost sales damages.
 32. The primary judge's analysis of the statutory scheme is apposite. The Full Court's approach does not support a sensible legislative purpose: PJ[173]-[195]; FCJ[104]-[110].
- Interest Up to Judgment Issue – Date on which Cause of Action Arises*
33. Infringement proceedings must be started within 6 years of the day the infringing act is done (section 120(4)(b)). The infringing acts were done between 15/6/09 and 9/12/12.
 34. Section 79 operated to deem the acts as infringing acts for the limitation provision in s 120(4)(b), and a *fortiori* for fixing the date when the cause of action arose for interest up to judgment : AS[58]-[59]; PJ[532]; 51A FCA, 1976; contra FCJ[140].
 35. Patent rights are *sui generis*: *General Tire v. Firestone* [1975] 1 W.L.R. 819 at 836. Preference cases are not relevant: AS[60]-[65]; contra FCJ[144]-[146].

Dated: 8 October 2021



A J L Bannon



L Merrick



C Cunliffe