



HIGH COURT OF AUSTRALIA

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

S 22 of 2021

S22/2021

BETWEEN:

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

APPELLANTS' SUBMISSIONS

Part I: These submissions are in a form suitable for publication on the internet.

Part II: The Appellants contend that the following issues are presented by this appeal:

(a) Whether a licence for the last two weeks of a patent which was triggered by its anticipated expiry on 13 June 2009, and which did expire on that date, could retrospectively constitute a licence for a period when the patent did not in fact exist, namely the extended term of the patent to 9 December 2012 which was later acquired on 25 June 2014.

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(b) What is the correct approach to construction of a commercial contract in circumstances where the commercial object of the parties was not directed to the circumstances which eventuated, in this case, the grant of an extension of the patent after expiry of the original term on 13 June 2009?

(c) Whether the effect of s 79 of the *Patents Act 1990* (Cth) (**Act**) is that a cause of action for infringement during the extended term arises only on the grant of the extended term and is not available to an exclusive licensee.

Part III: The Appellants have considered whether any notice should be given in compliance with section 78B of the *Judiciary Act 1903*.

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Part IV: The judgments below are *H. Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408; *H. Lundbeck A/S v Sandoz Pty Ltd (No 2)* [2019] FCA 46; *Sandoz Pty Ltd v H. Lundbeck A/S* (2020) 384 ALR 35 and *Sandoz Pty Ltd v H. Lundbeck A/S (No 2)* [2021] FCAFC 47.

Part V: Narrative statement of the relevant facts

A The proceedings below

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1. H. Lundbeck A/S (**H Lundbeck**) is the patentee of patent no 623144 (**Patent**) and Lundbeck Australia Pty Ltd (**Lundbeck AU**, a subsidiary of H Lundbeck) was the exclusive licensee of the Patent.¹ The subject matter of the Patent is escitalopram, a treatment for (among other things) depression. Lundbeck sued Sandoz Pty Ltd (**Sandoz**) (among others) for infringing the Patent by selling generic escitalopram

¹ Where it is not necessary to distinguish between them below, H Lundbeck and Lundbeck AU are referred to together as **Lundbeck**.

pharmaceutical products between 15 June 2009 and 9 December 2012, during the extended term of the Patent. Lundbeck also alleged that Sandoz's conduct amounted to misleading or deceptive conduct. CNS Pharma Pty Ltd (**CNS Pharma**, a subsidiary of Lundbeck AU) also sued Sandoz for misleading or deceptive conduct.

2. The primary judge found that Sandoz had infringed the Patent between 15 June 2009 to 9 December 2012 and that Sandoz's conduct amounted to misleading and deceptive conduct.² The primary judge awarded: (a) damages to H Lundbeck of **\$16,219,000**; (b) damages to Lundbeck AU and CNS Pharma (jointly) of **\$1,369,000**; (c) pre-judgment interest, totalling **\$8,754,000** as at 19 February 2019.³
- 10 3. The primary judge: (a) rejected Sandoz's assertion that it had a defence based on a licence granted by Lundbeck under clause 3 of a settlement agreement entered into in February 2007 (**Settlement Agreement**);⁴ (b) found that, on a proper construction of s 79 of the Act, both H Lundbeck (as patentee) and Lundbeck AU (as exclusive licensee) had the right to start infringement proceedings in respect of conduct which took place during the extended term of the Patent;⁵ (c) reduced the damages to be paid by 5% to reflect vagaries, and an additional 25% to reflect the likelihood that some of Sandoz's sales were not lost sales to Lundbeck or CNS Pharma, but rather to other suppliers of generic escitalopram pharmaceutical products.⁶
- 20 4. The Full Court allowed Sandoz's appeal and set aside the declaration of infringement and the award of damages and interest.⁷ The Full Court found that: (a) under clause 3(1)(a) of the Settlement Agreement, Sandoz had a licence to sell its generic escitalopram products commencing from 31 May 2009 and which did not have an end date, so that Sandoz had a complete defence to infringement during the extended term

² *H. Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 (**Primary Judgment #1**), [1], [113] – [115], [534] – [538], CAB tab 1, 179 – 180, Order 1 of the orders made 19 February 2019, CAB tab 3, 198.

³ Order 2 of the orders made 19 February 2019, CAB tab 3, 199. In relation to the calculation of damages, see Primary Judgment #1, [374] – [523], CAB tab 1, 130 – 175, and *H. Lundbeck A/S v Sandoz Pty Ltd (No 2)* [2019] FCA 46 (**Primary Judgment #2**), [1] – [15], CAB tab 2, 190 – 195. In relation to interest, see Primary Judgment #1, [524] – [533], CAB tab 1, 175 – 178.

⁴ Primary Judgment #1, [247] – [303], CAB tab 1, 92 – 109.

⁵ Primary Judgment #1, [164] – [195], CAB tab 1, 64 – 74.

⁶ Primary Judgment #1, [407] – [425], CAB tab 1, 138 – 143, and Primary Judgment #2, [1] – [15], CAB tab 2, 190 – 195.

⁷ Orders made 4 August 2020, CAB tabs 11 and 12. The Full Court also set aside the costs orders made in favour of the Appellants – see the judgment and orders of the Full Court dated 30 March 2021.

of the Patent;⁸ (b) under s 79 of the Act, Lundbeck AU (as exclusive licensee) did not have any right to commence proceedings for infringement of the Patent in respect of conduct which occurred during its extended term;⁹ (c) Lundbeck and CNS Pharma would not have been entitled to pre-judgment interest prior to 25 June 2014 (when the extension of the term of the Patent was granted) because their cause of action did not arise until then;¹⁰ (d) had the primary judge's findings of infringement stood, the additional 25% discount on damages should not have been imposed and an additional discount of 2-3% (over and above the 5% for vagaries) should have been imposed.¹¹

10 5. Lundbeck respectfully submits that the Full Court's findings in relation to issues (a), (b) and (c) above were erroneous and that the primary judge's approach to those issues ought to be upheld. However, the Full Court was correct that the discount of 25% imposed by the primary judge on damages should be set aside and substituted by an additional discount of 2-3%. As a result, the order should be that the matter be remitted to the primary judge for entry of judgments in amounts which reflect an overall discount on damages of 7-8%.

B The history of the Patent and its extended term

6. The Patent is dated **13 June 1989**. The (unextended) term of the Patent therefore expired on **13 June 2009**.¹²
- 20 7. On **27 April 2004**, the Commissioner of Patents (**Commissioner**) granted to H Lundbeck an extension of the term of the Patent to **13 June 2014**, based on the Australian Register of Therapeutic Goods (**ARTG**) registration for H Lundbeck's LEXAPRO product.¹³
8. On **19 May 2006**, at the invitation of Alphapharm Pty Ltd (**Alphapharm**, a generic pharmaceutical supplier), the Commissioner decided to correct that extension, so that the extended term would end on **9 December 2012**.¹⁴ In reaching that conclusion, the Commissioner accepted that the extension of the term should have been based on the

⁸ *Sandoz Pty Ltd v H. Lundbeck A/S* (2020) 384 ALR 35 (**Full Court Judgment**), [21] – [69], CAB tab 10, 251 – 264.

⁹ Full Court Judgment, [83] – [110], CAB tab 10, 270 – 279.

¹⁰ Full Court Judgment, [135] – [147], CAB tab 10, 287 – 291.

¹¹ Full Court Judgment, [120] – [134], CAB tab 10, 281 – 287. The effect of removing this discount would be to increase the damages payable to H Lundbeck and Lundbeck AU by approximately \$6M. Primary Judgment #1, [4], CAB tab 1, 14, Full Court Judgment, [6], CAB tab 10, 247.

¹³ Primary Judgment #1, [5], CAB tab 1, 14, Full Court Judgment, [7] and [8], CAB tab, 10 248.

¹⁴ Primary Judgment #1, [5], [8], CAB tab 1, 14 – 15, Full Court Judgment, [8], CAB tab, 10 248.

ARTG registration for H Lundbeck's CIPRAMIL product.

9. The dispute about the Patent then came before the Federal Court. H Lundbeck appealed the decision of the Commissioner to reduce the duration of the extension of term. Alphapharm, Sandoz and Arrow Pharmaceuticals Pty Ltd (**Arrow**, another generic supplier) challenged the validity of the Patent and of the extension of the term.¹⁵
10. In **February 2007**, Lundbeck and Sandoz entered into the Settlement Agreement to resolve Sandoz's challenge to the validity of the Patent.¹⁶
11. On **24 April 2008**, Lindgren J upheld the validity of the Patent (except claim 5) and held that the extension of term was invalid and should be removed altogether. On **19 June 2008**, Lindgren J ordered that the Register of Patents be rectified to remove the extension of term, but that order was stayed pending appeal.¹⁷
12. On **11 June 2009**, the Full Court upheld Lindgren J's judgment. On **12 June 2009**, the Full Court continued the stay of the rectification order, pending the determination of an application for special leave to appeal to this Court.¹⁸
13. On **12 June 2009**, H Lundbeck also applied to the Commissioner for an extension of time to seek an extension of term based on CIPRAMIL (**Extension of Time Application**).¹⁹
14. On **15 June 2009**, Sandoz (among other generic suppliers) commenced supplying generic escitalopram pharmaceutical products in Australia.²⁰
15. On **11 December 2009**, the High Court refused the applications for special leave to appeal from the Full Court's June 2009 judgment. Consequently, on **9 February 2010**, the extension of the term of the Patent was removed from the Register.²¹
16. Sandoz (among others) opposed the Extension of Time Application. However, on **1 June 2011**, the Commissioner granted that application. That decision was upheld by

¹⁵ Primary Judgment #1, [6], [9], CAB tab 1, 14 – 15, Full Court Judgment, [9], [10], CAB tab 10, 248.

¹⁶ Primary Judgment #1, [247] – [303], [329] CAB tab 1, 92 – 109, 115, Full Court Judgment, [21] – [69], CAB tab 10, 251 – 264.

¹⁷ Primary Judgment #1, [10], [11], CAB tab 1, 16, Full Court Judgment, [11], CAB tab 10, 248.

¹⁸ Primary Judgment #1, [12], [13], CAB tab 1, 16, Full Court Judgment, [12], CAB tab 10, 248 – 249.

¹⁹ Primary Judgment #1, [15], CAB tab 1, 17, Full Court Judgment, [13], CAB tab 10, 249.

²⁰ Primary Judgment #1, [17], CAB tab 1, 17, Full Court Judgment, [14] CAB tab 10, 249.

²¹ Primary Judgment #1, [18], [19], CAB tab 1, 17, Full Court Judgment, [12], CAB tab 10, 248 – 249.

the Administrative Appeals Tribunal, the Full Court and the High Court.²²

17. Sandoz (among others) then opposed H Lundbeck's application for an extension of term based on CIPRAMIL. However, on **25 June 2014**, the Commissioner granted that application. That decision was upheld by the Federal Court and the Full Court and special leave to appeal to this Court was refused.²³
18. Accordingly, the term of the Patent was (conclusively) extended to **9 December 2012**, but that extension was not granted until **25 June 2014**.

Part VI: Outline of argument

10 A The Settlement Agreement (Ground 2)

The key terms of the Settlement Agreement

19. The relevant terms of the Settlement Agreement are set out in Primary Judgment #1 at [251].²⁴ For present purposes, the key terms are as follows (emphasis added):

3 Licence to exploit the Patent

- (1) Lundbeck Denmark and Lundbeck Australia jointly and severally grant Sandoz an **irrevocable non-exclusive licence to the Patent effective from:**

- (a) **31 May 2009 if the Patent expires on 13 June 2009;**
- (b) 26 November 2012 if the Patent expires on 9 December 2012;
- (c) 31 May 2014 if the Patent expires on 13 June 2014; or
- (d) 2 weeks prior to the expiry of the Patent if the Patent expires on a date other than a date described in clause 3(a) to (c).

- (2) In addition to the licence granted under clause 3(1), Lundbeck Denmark and Lundbeck Australia jointly and severally grant Sandoz an **irrevocable non-exclusive licence to the Patent, effective from the beginning of the calendar month in which the licence granted under clause 3(1) becomes**

²² Primary Judgment #1, [20] – [23], [27], CAB tab 1, 17 – 18, Full Court Judgment, [15], CAB tab 10, 249.

²³ Primary Judgment #1, [24], [25], [28] – [30], CAB tab 10, 18, Full Court Judgment, [16], [17], [19], CAB tab 10, 249– 250.

²⁴ CAB tab 1, 93 – 95, A complete copy of the Settlement Agreement is located at An SM-2 to the affidavit of Stefanus Maritz sworn 23 June 2017 (**Maritz Affidavit**), AFM tabs 1 – 2.

effective, for the sole purpose of manufacturing, importing, marketing and offering to sell (but not selling or supplying) pharmaceutical products containing escitalopram.

20. “Patent” is defined in the Settlement Agreement as meaning the Patent.

The competing constructions of clause 3 of the Settlement Agreement

10 21. The primary judge and the Full Court reached radically different constructions of the licence granted under clause 3 of the Settlement Agreement. The primary judge found that Sandoz had a licence under clause 3(1) (from 31 May 2009) and under clause 3(2) (from 1 May 2009), both of which ran until 13 June 2009. Consequently, that licence provided no defence to the infringement case which concerned conduct between 15 June 2009 and 9 December 2012.²⁵ In contrast, the Full Court found that Sandoz had a licence under clause 3 which commenced in May 2009 and did not have any end date, with the effect that the licence runs for the entire extended term of the Patent.²⁶ In practical terms, the primary judge construed the licence granted as having a duration of two weeks (31 May 2009 to 13 June 2009), whereas the Full Court construed it as having a duration of 3½ years (31 May 2009 to 9 December 2012).

The construction of the primary judge

22. The key elements of the primary judge’s reasoning were as follows.

20 23. **First**, in its terms, the licence was a licence to the Patent, not a licence to the invention the subject of the Patent (the latter option was rejected in the course of negotiating the Settlement Agreement).²⁷ Such a licence pre-supposes that there is a Patent on foot which has not expired and which can provide subject matter for the licence.²⁸

24. **Secondly**, the alternatives set out in clause 3(1) all contemplate a licence for two weeks before a possible expiry date.²⁹ As the primary judge found (at [296], CAB tab 1, 107 – 108):

²⁵ Primary Judgment #1, [303], [329], CAB tab 1, 109, 115.

²⁶ Full Court Judgment, [67] – [69], CAB tab 10, 264.

²⁷ Compare the amendment to cl 3(1) in An SM-7 to the Maritz Affidavit to the Settlement Agreement, AFM tab 6, 45.

²⁸ Primary Judgment #1, [280], [296], CAB tab 1, 103, 107 – 108.

²⁹ Primary Judgment #1, [280], [298] CAB tab 1, 103, 108. Support for this aspect of the primary judge’s construction is also found in contemporaneous correspondence about the Settlement Agreement – see Primary Judgment, [271] – [273], CAB tab 1, 100 – 101. See also An SM-3, An SM-4 and An SM-6 to the Maritz Affidavit, AFM tabs 3 – 6.

... As I have said, one thing is clear from cl 3(1). It is that the parties agreed that the period of the licence was two weeks before its expiry ... It is not to the point that cl 3(1) does not say that the licence expires on expiry of the patent ... What the parties bargained for was for Sandoz to receive a licence “to the Patent” for the period of two weeks before the patent expired. If, as I consider, the patent expired on 13 June 2009, the licence also must have ended on 13 June 2009 ...

25. **Thirdly**, when the Settlement Agreement was executed, the parties anticipated knowing the outcome of the proceeding before Lindgren J (and any appeal therefrom) before 13 June 2009. It was only a remote possibility that the parties would not have this knowledge before 13 June 2009. The parties must be taken to have accepted this risk, which would have appeared to be insignificant.³⁰
26. **Fourthly**, the parties were aware of the relevant provisions of the Act, including the possibility that H Lundbeck might rely on the extension of time provisions to seek an extension of term. That was a mere possibility, attended by considerable doubt³¹ and does not drive the construction of clause 3. If H Lundbeck had not obtained an extension of term before 13 June 2009, the Patent would expire for the purposes of the Settlement Agreement. The mere fact of an application for an extension of time being on foot could not obviate that event of expiry.³²
27. **Fifthly**, as a matter of fact, the term of the Patent ended on 13 June 2009 and the Patent then expired. Between 13 June 2009 and 25 June 2014, it remained the case that the Patent had expired.³³ The contingency contemplated by clause 3(1)(a) was satisfied. Accordingly, Sandoz had an irrevocable licence under clause 3(2) from 1 May 2009 and under clause 3(1) from 31 May 2009.³⁴
28. **Sixthly**, as the Patent expired on 13 June 2009, the licence also ended then because the licence was a licence to the Patent (rather than the invention itself) and can only be operative while the Patent is on foot.³⁵ Thus, the primary judge did not construe it as a grant of a freedom to do an act consisting of the invention. Sandoz had no need for

³⁰ Primary Judgment #1, [265], [294], CAB tab 1, 99, 107.
³¹ Primary Judgment #1, [260] – [263], CAB tab 1, 97 – 99.
³² Primary Judgment #1, [292], CAB tab 1, 106 – 107.
³³ Primary Judgment #1, [286], CAB tab 1, 104 – 105.
³⁴ Primary Judgment #1, [295], CAB tab 1, 107.
³⁵ Primary Judgment #1, [296], CAB tab 1, 107 – 108.

such a grant as absent the existence of a patent, Sandoz was free so to act.³⁶

29. **Seventhly**, there was sound commercial sense in such a bargain for all of the parties. In this regard, the primary judge found (at [269], CAB tab 1, 100):

... given that three generic entities were trying to revoke the 144 patent ... it would have been apparent to the parties to the Sandoz settlement agreement that Sandoz had little to gain from continuing in the proceedings and little to lose by trying to do a deal to exit the proceedings. The parties also would have appreciated that, for generic entities, every day counted for entry into a market to maximise the opportunity to take market share and so any early entry Sandoz could negotiate in exchange for discontinuing its proceedings would have value to Sandoz. And for Lundbeck A/S, one less party to deal with was not without value, but they still had to contend with Alphapharm ... and Arrow who were both seeking revocation of the relevant claims of the 144 patent.

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30. **Eighthly**, the primary judge considered that her construction avoided "... violence to the manifest common intention of the parties for Sandoz to have a royalty free licence for the period of two weeks before expiry of the patent ...".³⁷ As the primary judge observed (at [301], CAB tab 1, 108 – 109):

[Sandoz's case] ... has the effect of transforming Sandoz's two week early entry licence ... into a royalty free licence for three years for the extended term ..., which is inconsistent with the deal the parties bargained. It also gives "Patent" a meaning it cannot bear in the context of the settlement agreement, such as "the patent before it expires on 13 June 2009 and, if Lundbeck happens to obtain an extension of term after that date, the patent as subject to that extension of term".

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31. **Finally**, the primary judge also considered that her construction was supported by the fact that the licence was royalty free. A royalty free licence made commercial sense for a two week early entry licence, but not in the context of a broader licence to exploit the Patent (or, for that matter, the invention while the Patent was expired).³⁸

³⁶ See *The Grain Pool of Western Australia v Commonwealth of Australia* (2000) 202 CLR 479, [83] – [85].

³⁷ Primary Judgment #1, [299], CAB tab 1, 108.

³⁸ Primary Judgment #1, [299], CAB tab 1, 108.

The construction of the Full Court

32. The key elements of the Full Court’s reasoning were as follows.

33. **First**, like the primary judge, the Full Court found that the contemporaneous correspondence relating to the Settlement Agreement indicated that it was the common intention of the parties that Sandoz would be granted a 14 day early entry licence.³⁹ However, the Full Court appeared to disapprove of the primary judge’s reliance on her finding to that effect.⁴⁰ The Full Court’s rationale appears to have been that contemporaneous correspondence did not reveal any consideration by the parties of what would happen if no extension of term had been validly acquired before the expiry of the original term of the Patent, but was acquired later.⁴¹

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34. **Secondly**, the Full Court endorsed the primary judge’s finding that the “... parties must be taken to have understood that they would know by 1 May 2009 when the Patent would expire.”. As the Full Court observed (at [59]):⁴²

We agree with that finding which reflects the fact that the settlement agreement was entered into in February 2007, more than two years prior to the earliest date on which the Patent could expire. We think it unlikely that the parties turned their mind to the possibility that they would not know by 1 May 2009 when the Patent would expire. Had they done so, we would expect to find some express provision dealing with such an eventuality in the settlement agreement.

20 35. The Full Court went on to find that the Settlement Agreement should not be construed by reference to the possibility that the expiry date of the Patent would not be known by 1 May 2009. The Full Court stated (at [62], CAB tab 10, 262):

... We are not persuaded that both parties entered into the settlement agreement knowing that the expiry date might not be finally determined before 1 May 2009. Nor are we persuaded that it is appropriate to construe cl 3 so that it accommodates such a possibility. The fact that it may be possible to point to a number of reasons why, as at February 2007, the expiry date might not be

³⁹ Full Court Judgment, [50] – [54], CAB tab 10, 259 – 260 (see also the evidence referred to in footnote 29).

⁴⁰ Full Court Judgment, [57], CAB tab 10, 260 – 261.

⁴¹ See Full Court Judgment, [54], CAB tab 10, 260.

⁴² CAB tab 10, 261. See also Full Court Judgment, [60], CAB tab 10, 261.

determined finally by 1 May 2009, should not drive the construction of cl 3 in circumstances where the parties are likely to have proceeded on the basis of a common assumption that the expiry date would be determined by that date. In our opinion the terms of cl 3 show that the parties were proceeding on that basis and that the licence granted under cl 3 to Sandoz would run from a date determined by reference to the expiry date of the Patent which, if the Patent expired on 13 June 2009, would be 31 May 2009.

36. **Thirdly**, the Full Court rejected the distinction made by the primary judge between the Patent prior to and after the extension of term. The Full Court considered that the Patent was one and the same and that Sandoz either had a licence to it or it did not.⁴³
37. **Finally**, having made those findings, the Full Court found (emphasis added, CAB tab 10, 264):

[67] In our opinion the language of cl 3 is relatively clear. It grants to Sandoz an irrevocable non-exclusive licence from 31 May 2009 if the Patent expires on 13 June 2009. Subject to that condition being fulfilled, the licence under cl 3(1) is effective from 31 May 2009 and is irrevocable. The licence was not contingent on there being no extension of term granted after the Patent expired. **The parties' intention, objectively ascertained, was to stipulate a start date for the licence, but without any end date.**

- [68] We do not accept the suggestion that this construction of cl 3 is irrational or lacking in commercial sense. In our view it is the natural result of a negotiation that took place in February 2007 at which time both parties assumed that by 1 May 2009 it would be apparent whether or not the Patent would expire on 13 June 2009 or at some later date.

- [69] On its proper construction cl 3 provided Sandoz with the opportunity to prepare to enter the market from 1 May 2009, and to commence supplying product from 31 May 2009, without risk of liability for patent infringement if the Patent expired on 13 June 2009. It conferred on Sandoz the right to enter the market on 31 May 2009 in circumstances where, provided the Patent expired on 13 June 2009, it would not need to concern itself with what was, in February

⁴³ Full Court Judgment, [56], CAB tab 10, 260.

2007, the remote possibility that the term of the Patent might be extended sometime after it had expired.

The Full Court’s construction of clause 3 was erroneous and the primary judge’s construction should be upheld

38. The Full Court’s construction of clause 3 was erroneous and should be rejected, and the primary judge’s construction should be upheld, for the following reasons.

39. **First**, the concomitant factual findings of the primary judge and the Full Court were that the commercial object of the transaction was a two week licence to a patent the ultimate term of which would be known before 13 June 2009.⁴⁴ The subject matter of the licence was the Patent as it stood when the agreement became operative (i.e. unextended). The unextended Patent was the only Patent in existence to which clause 3(1)(a) licence could attach as at May 2009. Both the primary judge and the Full Court correctly found that the clause 3(1)(a) licence commenced on 31 May 2009 because the condition precedent to such a licence, namely “if the Patent expires on 13 June 2009”, was satisfied. The primary judge correctly found that licence ended after two weeks on 13 June 2009 being the expiry date of the Patent which triggered the commencement of the licence. Thereafter, for the duration of Sandoz’s conduct, there was no patent to which any continuation of the licence could attach.

40. In error, the Full Court used the expiry date of clause 3(1)(a) to trigger the commencement of the licence but not its end. It incorrectly elided clauses 3(1)(a) and (b), taking the start date from clause 3(1)(a) and the end date from clause 3(1)(b). Different language would have been required to accommodate such a licence, the effect of which would be the grant of a licence to commence on 31 May 2009 if the Patent expired on 13 June 2009, but to continue thereafter as a licence of any inchoate retrospective rights as a result of any post expiry extension of the Patent (**s 79 Rights**). No such language is found in the clause as no such licence was contemplated.

41. **Secondly**, the Full Court’s construction does not reflect the contractual intention of a two week licence as reflected in the structure and text of clause 3. Clauses 3(1)(a)-(d) anticipated a licence period of two weeks, working back from potential expiry dates

⁴⁴ Primary Judgment #1, [260] – [263], [292], CAB tab 1, 97 – 99, 106 – 107, Full Court Judgment, [62], CAB tab 10, 262.

(which define the term). There was no need to specify end dates because there was no contemplation that the licence could extend beyond the Patent expiry date which triggered it. The alternative commencement dates were necessary because, when the Settlement Agreement was executed, it was not clear whether H Lundbeck would secure an extension of term and, if so, when it would end.⁴⁵ The Full Court's construction failed to recognise that the structure and text of clause 3(1) is predicated on the alternative licences each having a duration of two weeks (i.e. a two week early entry licence). In contrast, the primary judge's approach expressly recognised this and gave proper effect to it.⁴⁶

10 42. **Thirdly**, the Full Court's construction did not properly take account of the circumstances surrounding the Settlement Agreement, including contemporaneous communications about the nature of the licence. The Full Court itself found that the surrounding circumstances indicated that it was the common intention of the parties that Sandoz receive a two week early entry licence.⁴⁷ This is reinforced by amendments made to the Settlement Agreement rejecting a licence to the *invention* (as opposed to a licence to the Patent). Lundbeck also refused a separate clause proposed by Sandoz permitting it to exploit its *product* from the date of commencement of the licence.⁴⁸ However, the Full Court's construction disregarded its finding in relation to the common intention of the parties and transformed the agreement into a licence of
20 some 3½ years. In contrast, and consistently with many decisions of this Court,⁴⁹ the primary judge gave careful attention to the circumstances surrounding the Settlement Agreement and her construction gave effect to them.

43. **Fourthly**, the Full Court's construction of clause 3 results in a commercially nonsensical outcome.

44. Standing in the shoes of the parties at February 2007, the logic of a two week royalty free early entry licence expiring on 13 June 2009 is commercially understandable as a bargain to resolve the litigation then on foot as between Sandoz and Lundbeck. As the

⁴⁵ Full Court Judgment, [25], CAB tab 10, 252.

⁴⁶ Primary Judgment #1, [280], CAB tab 1, 103.

⁴⁷ See Full Court Judgment, [54], CAB tab 10, 260.

⁴⁸ See the amendments to cl 3(1) and cl 4 in An SM-7, AFM tab 6, 49 – 50.

⁴⁹ See, by way of examples, *Maggbury Pty Ltd v Hafele Australia Pty Ltd* (2001) 210 CLR 181, [11], *Pacific Carriers Ltd v BNP Paribas* (2004) 218 CLR 451, [22], *Toll (FGCT) Pty Ltd v Alphapharm Pty Ltd* (2004) 219 CLR 165, [40], *Electricity Generation Corporation v Woodside Energy Ltd* (2014) 251 CLR 640, [35] and *Rinehart v Hancock Prospecting Pty Ltd* (2019) 366 ALR 635, [26].

primary judge found, the parties all obtained a proportionate benefit from such a licence. However, H Lundbeck still faced the independent risks of its continuing litigation with Alphapharm and Arrow.

45. The primary judge also found that the parties accepted an insignificant risk that the expiry date of the Patent would not be known by May 2009 and the Full Court endorsed that finding.⁵⁰ Consistently with a reasonable party in the shoes of Sandoz accepting such a risk, the primary judge found that when Sandoz in fact entered the market on 15 June 2009, it did so with knowledge of H Lundbeck's extension of time application and that it was at risk of infringement.⁵¹
- 10 46. A royalty free licence for 3½ years to a generic competitor to exploit a valuable patent is commercially incomprehensible. This is particularly so for the Patent, which was generating significant profits and was not licensed externally.⁵² Such a licence would render pointless the pursuit of an extension of term post expiry – Sandoz would be in the market and would inevitably soak up much if not all of the generic market that it would otherwise have had to share with other generic competitors.
47. **Fifthly**, despite both the primary judge and the Full Court accepting that the Settlement Agreement was not intended to address the circumstance of an extension post expiry of the Patent on 13 June 2009,⁵³ the Full Court construed it to do just that. The Full Court effectively deployed a retrospective construction based on how
20 H Lundbeck's efforts to obtain an extension of the term of the Patent played out subsequently to the execution of the Settlement Agreement and, critically, after the expiry of the Patent on 13 June 2009.
48. **Sixthly**, the reasoning of the Full Court failed to consider how clause 3(1)(a) could operate as a licence to the Patent after 13 June 2009. This gap in the Full Court's reasoning cannot be filled and discloses error.
49. Between 13 June 2009 and 9 December 2012, the Patent had expired and was not on foot. This was acknowledged by the Full Court, but not in connection with the

⁵⁰ Primary Judgment #1, [313], [339] – [341], [346], [348], [358], [359], [363], [526], CAB tab 1, 111 – 112, 120 – 122, 125 – 126, 175 – 176, Full Court Judgment, [59], CAB tab 10, 261.

⁵¹ Primary Judgment #1, [265], [294] (and see also [339] – [341], [346], [348], [526]) CAB tab 1, 99, 107, 120 – 122, 175 – 176.

⁵² See Primary Judgment #1, [300], CAB tab 1, 108.

⁵³ Primary Judgment #1, [260] – [263], [292], CAB tab 1, 97 – 99, 106 – 107, Full Court Judgment, [59], CAB tab 10, 261.

construction of the Settlement Agreement. At [78] (dealing with a defence raised (unsuccessfully) by Sandoz under s 223(10) of the Act), the Full Court stated:

The primary judge said at [151]:

... Once a patent reaches the end of its term, the exclusive rights of the patentee under s 13 of the Patents Act come to an end. Once an extension of term is granted, the term of the patent is extended and by s 79 the patentee is vested with the same rights as if the extension had been granted at the time when the (infringing) act is done. The patent's term is extended and, as a result, s 79 creates new rights in the patentee for the intervening period ...

10 We respectfully agree with her Honour.

See also Full Court Judgment, [89] and [98] (CAB tab 10, 269, 272 – 273, 276).

50. The acts of Sandoz during the extended term were not at the time they occurred acts of infringement because there was no patent. There was no licence which could be given to the Patent in respect of that period. As at 13 June 2009, Lundbeck had no capacity or title to fulfil an offer or promise of a licence to the Patent which extended beyond 13 June 2009. Equally, clause 3(1)(a) did not offer or promise a licence to the Patent that extended beyond 13 June 2009 or to the s 79 Rights. The licence offered under clause 3(1)(a) pre-supposed that there would be no Patent (and, consequently, no subject matter for a licence) on 13 June 2009 because the Patent expired at the end of its (unextended) term. The primary judge correctly recognised this, but the Full Court did not.⁵⁴

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51. It appears that the Full Court proceeded on the basis that, when the term of the Patent was ultimately extended, H Lundbeck acquired rights which gave substance retrospectively to the licence for the period of 13 June 2009 to 9 December 2012. This appears to rest on s 79 of the Act, which applied to the extension of term granted on 25 June 2014. As the primary judge correctly observed, this section creates a legal fiction which treats the extension as granted at the time the infringing acts were done when in fact the acts occurred within the gap between the expiry of the patent and the grant of the extension of term.⁵⁵ It has a retrospective operation.

⁵⁴ Primary Judgment #1, [296], CAB tab 1, 107 – 108, Full Court Judgment, [55], [56], CAB tab 10, 260.

⁵⁵ Primary Judgment #1, [151], [187], CAB tab 1, 60, 71.

52. The s 79 Rights were acquired by H Lundbeck after the execution of the Settlement Agreement and after the date on which the licence under clause 3(1)(a) was activated and ended. It appears that the Full Court has fed the s 79 Rights into the offer or promise of clause 3(1)(a), albeit without explaining why or how.
53. In some cases, it may be possible to feed a contract with a later acquired title. This might arise, for e.g., where a vendor has agreed to sell a property to which it has no title at the time of the contract. If the vendor subsequently acquires the title which would enable it to fulfil its agreement before it is terminated, the later acquired title feeds the contract. This has been described as a species of estoppel.⁵⁶ The vendor is estopped from denying that it was the owner of the property at the time of the contract.⁵⁷
54. That principle cannot be applied to the Settlement Agreement. The primary judge's conclusion that the clause 3(1)(a) licence was spent on 13 June 2009 was correct.⁵⁸ The Settlement Agreement was no longer operative when H Lundbeck acquired the s 79 Rights. There was no occasion or need to feed any title into the spent agreement. The clause does not contemplate that the licence could be "recharged" by a later extension of the term. Lundbeck could not be estopped from asserting that the extended Patent does not constitute the Patent for the purposes of clause 3(1)(a). Clause 3(1)(b) expressly provided for the Patent being extended to 9 December 2012. Clause 3 does not contemplate that the Patent could "expire" twice or that the Patent could satisfy more than one of the mutually exclusive clauses 3(1)(a) to (d).
55. The primary judge's construction is not vexed by such conceptual difficulties. The primary judge's construction recognised that clause 3(1)(a) was triggered by the expiry of the (unextended) term of the Patent. The primary judge then found that, as a licence to the Patent, the licence triggered under clause 3(1)(a) endured until the (unextended) term of the Patent expired. The primary judge's approach faithfully reflects what the parties sought to achieve (and the risks they accepted) through clause 3(1)(a) – a two week early entry on the premise that the Patent expired on 13 June

⁵⁶ See *Patten v Thomas Motors Pty Ltd* (1964) 66 SR (NSW) 458, 461, *Allco Steel Corporation Pty Ltd v Australian Development Corporation Pty Ltd* [1996] NSWCA 11, p 11 – 12 (per Beazley JA) and *Coshott v Principal Strategic Options Pty Ltd* [2001] NSWCA 110; (2001) 38 ACSR 547, [21] – [26].

⁵⁷ Yates J has applied the principle in a copyright licence case – see *Chhabra v McPherson as Trustee for McPherson Practice Trust* [2018] FCA 1755, [108].

⁵⁸ Primary Judgment #1, [296], CAB tab 1, 107 – 108.

2009. It also avoids the intractable difficulty inherent in the Full Court’s approach of trying to find subject matter for the licence after 13 June 2009 where none existed.

B Accrual of cause of action and pre-judgment interest (Ground 3)

56. The Full Court should have found that, by the operation of s 79 of the Act, Lundbeck’s cause of action accrued at the time of Sandoz’s infringing conduct. The primary judge’s findings in relation to this issue were correct.⁵⁹

57. Section 79 of the Act provides:

If:

(a) a patentee applies for an extension of the term of a standard patent; and

10 (b) the term of the patent expires before the application is determined; and

(c) the extension is granted;

the patentee has, after the extension is granted, the same rights to start proceedings in respect of the doing of an act during the period:

(d) commencing on the expiration of the term of the patent; and

(e) ending on the day on which the extension was granted;

as if the extension had been granted at the time when the act was done.

58. Section 79 creates rights during the period between expiration and extension.

20 Although the right to commence proceedings does not crystallise until the extension is granted, the extension has retrospective effect, so the cause of action is deemed to have arisen upon the expiry of the original term. When Sandoz’s infringing conduct took place, Lundbeck was not able to bring an action. However, when the Commissioner granted the extension of the term on 25 June 2014, Lundbeck’s cause of action was made complete and s 79 was engaged (with retrospective effect).

59. Lundbeck’s cause of action is accordingly deemed to be complete throughout the period of extension. The words “after the extension is granted” in s 79 do not lead to any other conclusion, because the express purpose and effect of s 79 is to create rights with retrospective effect, which are stated to be “the same” as the rights a patentee

⁵⁹ See Primary Judgment #1, [531] – [532], CAB tab 1, 177 – 178, Full Court Judgment, [138] – [139], CAB tab 10, 288 – 289.

would normally have. These rights include the right to claim interest. Section 79 does not expressly or impliedly impose any limitation on those rights.

60. That analysis is consistent with the approach taken by the House of Lords in two cases dealing with analogous provisions. In *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd.* [1975] 1 W.L.R. 819 (***General Tire***), the question was whether there was a right to interest in relation to infringements which occurred after the patent application was filed (in 1951) but before the patent was granted (in 1963).⁶⁰ It was necessary to decide when the cause of action arose having regard to s 13(4) of the *Patents Act 1949* (UK), which provided as follows:⁶¹

10 After the date of the publication of a complete specification and until the sealing of a patent in respect thereof, the applicant shall have the like privileges and rights as if a patent for the invention had been sealed on the date of the publication of the complete specification:

 Provided that an applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.

61. Analogously to s 79, s 13(4) retrospectively granted the right to bring proceedings.
62. Lord Wilberforce gave the leading judgment and held:⁶²

 A patent right is sui generis; the relation of relevant dates [...] is not analogous to other dates in other situations, the whole depending purely on statutory provision.

20 In my opinion section 13(4) of the *Patents Act 1949* can only be construed [...] so that the cause of action arose in 1951.

63. *General Tire* was applied in *Sevcon Limited v Lucas Cav Limited* [1986] 1 WLR 462 (***Sevcon***), a case which considered whether the *Limitation Act 1980* precluded a patentee from bringing an action in relation to infringements which had occurred between 1974 and 1977, when the application was filed in 1968, and the patent was sealed in 1984. The House of Lords held that the patentee was barred by the *Limitation Act*, given the terms of s 13(4). See especially 464-465 and 467 of *Sevcon*.

⁶⁰ *General Tire*, 823.

⁶¹ *General Tire*, 836.

⁶² *General Tire*, 836. Viscount Dilhorne, Lord Diplock and Lord Kilbrandon agreed (at 837) as did Lord Salmon on this issue (at 840-841).

64. The Full Court sought to distinguish *Sevcon* on the basis that it involved a different statutory provision and held that the cause of action under s 79 did not arise as a matter of form or substance until the grant of the extension of term.⁶³ The Full Court relied upon cases⁶⁴ which relate to claims to recover a preference, before the date of appointment of a liquidator. Those cases are not analogous because the cause of action is vested in the person who is the liquidator, and only the liquidator can bring the proceedings. There is no cause of action until a liquidator is appointed and makes a demand, and no suggestion of it being backdated. By comparison, in this case, the cause of action accrues (albeit retrospectively) from the date of the extension.⁶⁵ As the House of Lords observed, a patent right is *sui generis* in this respect.

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65. The reasoning in *General Tire* and *Sevcon* is apposite, and the Full Court erred in rejecting it. Further, the analysis that interest is available is consistent with the Full Court's acceptance that Lundbeck had a right to declarations and damages as from the date of infringement.⁶⁶ Such remedies are only logically available if the patentee's cause of action is treated as having accrued as at the date of the infringing acts.

C Exclusive licensee's rights under s 79 of the Act (Ground 4)

66. The Full Court should have found that, on a proper construction of s 79, Lundbeck AU as exclusive licensee had the right to pursue infringement proceedings in relation to Sandoz's conduct during the extended term of the Patent.⁶⁷ The Primary Judge's reasoning was correct and reflected a wider statutory scheme.

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67. Section 13 permits the patentee to authorise an exclusive licensee to exercise its exclusive rights. Section 120 permits an exclusive licensee to commence proceedings for infringement of a patent. Section 78 places limitations on when the exclusive rights of the patentee will be infringed during the extended term of a patent. The limitations imposed by s 78 are, in their terms, limitations applicable to the rights of the patentee. Section 78 does not mention exclusive licensees. Like s 78, s 79 refers

⁶³ See Full Court Judgment [144] – [145], CAB tab 10, 291. At [144], the Full Court described s 57 of the Act as the analogue to s 13(4). Lundbeck contends that s 57 and s 79 have the same substantive effect of granting retrospective rights.

⁶⁴ *Spedley Securities Ltd (In liq) v Western United Ltd (In liq) (No 2)* (1992) ACSR 721, and *Ferrier and Knight (as Liquidators of Compass Airlines Pty Ltd) v Civil Aviation Authority* (1994) 55 FCR 28 at 92.

⁶⁵ Just as the cause of action for patent infringement accrues from the date of publication of a patent application under s 57, but a patentee cannot bring proceedings until a patent is granted.

⁶⁶ See Full Court Judgment, [115] – [134], CAB tab 10, 280 – 287.

⁶⁷ See Full Court Judgment, [89] – [92], CAB tab 10, 272 – 274.

only to the patentee and makes no mention of exclusive licensees.

68. There are three important features of the statutory scheme created by ss 13, 78, 79 and 120. The rights of an exclusive licensee are derived from the rights of a patentee pursuant to s 13. A patentee may appoint an exclusive licensee during the extended term of a patent – that is one of its rights under s 13, and the limitations imposed on s 13 by s 78 do not impact on a patentee’s right to appoint an exclusive licensee. Sections 13 and 120 contemplate that an exclusive licensee may pursue infringement proceedings in respect of conduct which occurs during the extended term of the patent. Where the term of a patent is extended before the expiry of its original term, s 79 has no operation and an exclusive licensee would be entitled to pursue infringement proceedings under s 120. Further, s 57, which relates to the right of applicants to bring proceedings in relation to acts committed before a patent is granted, and which does not refer to exclusive licensees, should be construed in the same way.⁶⁸
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69. The Full Court expressly refrained from considering the legislative object or purpose of the Act in construing s 79.⁶⁹ In doing so, the Full Court failed to apply s 15AA of the *Acts Interpretation Act 1901* (Cth) (AIA) and the principle that the discernment of statutory purpose is integral to contextual construction.⁷⁰ The object of the Act (stated in s 2A) is “to provide a patent system in Australia that promotes economic wellbeing through technological innovation and the transfer and dissemination of technology. In doing so, the patent system balances over time the interests of producers, owners and users of technology and the public”. Section 79 should be construed in a way which is consistent with the treatment of exclusive licensees elsewhere in the Act, and which recognises that the patent system should make provision for the transfer and dissemination of technology.
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70. In construing s 79 without regard to either the object of the Act or the statutory scheme, the Full Court construction gave rise to three anomalies. **First**, where s 79 is engaged, the statutory scheme contemplates an exclusive licence, but would deprive the exclusive licensee the right to pursue infringement proceedings. **Secondly**, the Full Court’s construction creates an arbitrary distinction between extensions of term

⁶⁸ Lundbeck’s submission was recorded at [97] of the Full Court Judgment. The submission was rejected at [104]. See CAB tab 10, 276, 277.

⁶⁹ At [110] of the Full Court Judgment, CAB tab 10, 279.

⁷⁰ *Thiess v Collector of Customs* (2014) 250 CLR 664 at 672 [23].

granted before and after expiry of the original term of a patent. An exclusive licensee would have the right to sue for infringement in respect of the former, but not the latter. **Thirdly**, if “patentee” is understood conformably in ss 78 and 79 as excluding an exclusive licensee as s 18A of the AIA requires, the limitations imposed on the patentee’s rights by s 78 do not apply to the rights of an exclusive licensee. Where a patent is extended before the expiry of its original term (where s 79 is not operative), an exclusive licensee may be able to sue for infringement where a patentee cannot.

71. In construing s 79, it is necessary to remember that an exclusive licensee’s rights to exclude others from the field of the monopoly are derived from the patentee under s 13, and that the rights of a patentee under s 79 may therefore be devolved to an exclusive licensee. These rights involve the right to bring proceedings, subject to the standing requirement imposed by s 120 (which is not limited in its application to the term of the patent). Reading s 79 as part of a statutory scheme with ss 13, 57, 78 and 120 would best achieve the object of the Act because it recognises the importance of the transfer of technology. It also avoids the anomalies identified.

Part VII: The Appellants seek the following orders:

1. The appeal be allowed with costs.
2. Orders 1 to 3 made by the Full Federal Court on 4 August 2020 and orders 1 and 2 made by the Full Federal Court on 30 March 2021 be set aside.
3. The appeal to the Full Federal Court be dismissed with costs.
4. The cross-appeal to the Full Federal Court be allowed with costs.
5. The matter be remitted to the primary judge for recalculation of damages and interest thereon in the light of the Full Federal Court’s adjustment of the primary judge’s 25% discount of the damages amount to a discount of 2 to 3%.

Part VIII: The Appellants estimate that about 2 hours will be required to present their oral argument (in chief and reply).

Dated: 15 April 2021



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ANNEXURE A

Acts Interpretation Act 1901 (Cth) (as at 4 August 2020): ss 15AA, 18A

Patents Act 1990 (Cth) (as at 4 August 2020): ss 2A, 13, 57, 78, 79, 120

Patents Act 1949 (UK) (as enacted): s 13(4)