



HIGH COURT OF AUSTRALIA

NOTICE OF FILING

This document was filed electronically in the High Court of Australia on 03 Jun 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 27E - Reply
Filing party: Appellants
Date filed: 03 Jun 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.

IN THE HIGH COURT OF AUSTRALIA
 SYDNEY REGISTRY

BETWEEN:

H. Lundbeck A/S

First Appellant

Lundbeck Australia Pty Ltd (ACN 070 094 290)

Second Appellant

and

Sandoz Pty Ltd (ACN 075 449 553)

Respondent

10

APPELLANTS' REPLY

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

Part II: The Appellants (together, **Lundbeck**) make the following submissions in reply to the Respondent's submissions in answer dated 13 May 2021 (SS).

The Settlement Agreement

1. Sandoz submits that, objectively construed, clause 3(1)(a) was a deliberate choice of words to embrace a post expiry date extension (SS [38] second sentence). That construction is driven by the objective possibility of Lundbeck seeking such an extension (SS 13(c), [14], [41], [43], [45]). However, that submission is inconsistent with concomitant findings that such a remote possibility did not drive construction of the Settlement Agreement (LS [26], [34], [35]).¹
- 20 2. The wording of clause 3(1)(a) is inapt to accommodate a post expiry extension. Clause 3 contemplates that the "Patent" referred to would have only one expiry date as submitted at LS [54], not two expiry dates as would be a necessary feature of a post expiry extension.
3. Moreover, clause 3(1)(a) does not address the circumstance that after 13 June 2009, the Patent had expired and therefore did not exist as a statutory monopoly in respect of which a licence could be given (LS [39]). That position remained until the grant of the extension in 2014. Clause 3(1)(a) does not in terms say that if, after expiry of the
- 30 Patent, there is a grant of an extension, the licence extends to such rights. In truth, it is

¹ Primary Judgment #1 [260]–[263], CAB tab 1, 97–99; Full Court Judgment [59], [62], CAB tab 10, 261, 262.

Sandoz that needs an implied term to support its position (contra SS [3], [23], [30]).

4. In an attempt to address the fundamental difficulty that the clause 3(1)(a) licence was spent by the time the infringing conduct began, Sandoz submits that it should be understood as a licence to contingent rights which ultimately resulted in an extended term (SS [52], [53]). The agreement does not refer to such rights and they were not in the parties' contemplation.² Further, the extended term granted was based on an application which had not been made at the time of the Settlement Agreement.
5. Sandoz's arguments are attempts to grapple with the problem identified by the primary judge³ — the Settlement Agreement was only intended to deal with the circumstance of any extension granted before expiry of the original term. That is reflected in the structure of the clause and explains why the Patent referred to is one which is extended (if at all) before the 13 June 2009 expiry date.
6. Contrary to SS [31], the clause 3(1)(a) licence is not "open ended". It is a licence to the Patent, which relevantly expired on 13 June 2009. A commencement date is specified because the expiry date of the licence is necessarily the expiry date of the Patent that triggers the commencement date. A term of 2 weeks is inherent in the express terms and structure of the clause. The clause simply is not designed to address a Patent which expires on 13 June 2009 and, then after an extension 5 years later, is retrospectively extended to a date in 2012. To make it do so distorts the commercial object. The clause does not contemplate that the Patent could have one expiry date that triggers the commencement of the licence and another that determines its end. Sandoz's construction gives rise to three (or more) different possible durations – 2 weeks, 3½ years, or 5 years. No commercial party grants a licence with an unknown duration. The construction question is whether the expiry date of the Patent for the purposes of the commencement of the licence, is the same expiry date for the purposes of determining the term of the licence? The primary judge correctly found that it was.
7. Sandoz submits that it makes no sense for it to have agreed to a two week early entry licence but then to have to leave the market. That submission is a fiction, created retrospectively to obscure the interpretation of the Settlement Agreement. It fails to grapple with the effect of the expiry of the Patent. Absent the licence, Sandoz would

² Full Court Judgment, [54], [59], CAB tab 10, 260, 261.

³ Primary Judgment #1, [296], CAB tab 1, 107–108.

have entered the market on the expiry of the Patent (13 June 2009), as the other generics did. The risk of a successful post expiry date extension was inherent in that course of action for Sandoz and the other generics. The risk was offset by the unlikelihood of such an extension and the ability of Sandoz and the other generics to oppose it (as they did vigorously). In the Settlement Agreement as signed, Sandoz accepted greater risks of patent infringement.⁴ It is impermissible to construe the Settlement Agreement by reference to the risk that materialised for Sandoz in June 2009, when that was not within the contemplation of the parties when the agreement was formed or the commercial object of the agreement.

- 10 8. Contrary to SS [35], the “two week early entry” was a valuable right because it permitted Sandoz to enter the market before its competitors, who could not enter until the Patent expired. However, the assumption underlying the “two week early entry” was that there would be no Patent in existence after its expiry and the field would be open to the generics generally.
9. Sandoz’s submissions do not address LS [46]. Sandoz invites a construction of clause 3(1)(a) which contemplates Lundbeck pursuing a post expiry date extension but also authorising lawful generic competition for the whole of any extended term. It is commercial nonsense.
- 20 10. Contrary to SS [21], [22] and [40], the licence being “irrevocable” does not inform the duration of the licence. Similarly, Sandoz’s reliance on the terms of the release does not support its construction. The primary judge correctly construed the releases as limited to matters connected with Sandoz’s earlier revocation proceedings.⁵ Any challenge to that finding did not warrant mention by the Full Court and it was not overturned.
11. Lundbeck’s construction of clause 3(1)(a) is consistent with the language of clause 3(1)(a), the structure of clause 3 more generally in which the alternative licences were all of a two week duration, and the meaning which the document would convey to a reasonable person having the background knowledge reasonably available to the parties at the time of the contract. It also reflects the surrounding circumstances

⁴ See LS [42] n 48; and clause 3(3) in An SM-2, AFM tab 2, p 19.

⁵ Primary Judgment #1, [317]–[328], CAB tab 1, 113–115.

known to the parties, and the purpose and object of the transaction.

12. If there were any ambiguity about the scope of rights licensed and the end date of the licence, the context clearly identifies the objectively intended reach of the clause. That context included: (i) patents expire at the end of their term; (ii) the agreement was entered into in the context of court proceedings in February 2007 when the expiry was expected to be known by May 2009;⁶ (iii) the court proceedings involved other generic companies, the agreement would not resolve the litigation for Lundbeck, and Sandoz would not benefit from any licence if the Patent was revoked; (iv) the licence was royalty-free and the product generated significant revenue; (v) pre-contractual communications in which H. Lundbeck A/S offered a two week licence and Sandoz agreed that “this is a good outcome for both our companies”;⁷ (vi) Sandoz prepared a draft (with clause 3(1)(a) in its present form) which “assumed” a two week licence;⁸ (vii) Lundbeck rejected a broader licence sought by Sandoz to allow it to exploit its *product* as well as a licence to the *invention* and Sandoz inherently accepted infringement risk;⁹ and (viii) the pre-contractual communications demonstrate no contemplation of a post-expiry extension or s 79 Rights. It was not the broader object suggested by Sandoz at SS [19].
13. Lundbeck’s construction is to be preferred over Sandoz’s construction because it is consistent with business common sense.¹⁰
14. If, against Lundbeck, the Court considers that Lundbeck’s construction is not made good on the express language alone, a term as to the end of the licence would be implied because it does no more than reflect the patent expiry dates contemplated by each of sub-clauses 3(1)(a) to (c).¹¹ This is clear in the terms as they stand and consistent with primary judge’s construction that the Patent refers to “the 144 Patent *before it has expired*” and the Full Court’s finding that the common assumption was that the expiry date would be established by 1 May 2009.¹²

⁶ Full Court Judgment, [60]–[62], CAB tab 10, 261–262.

⁷ AFM tab 3, 26; tab 4, 29.

⁸ AFM tab 5, 33, clause 3 of the draft is on p 38.

⁹ See LS [42].

¹⁰ *Rainy Sky SA v Kookmin Bank* [2012] 1 All ER 1137 at [21], cited with approval in *Arnold v Britton* [2015] AC 1619 at [76]; *Wood v Capita Insurance Services Ltd* [2017] 2 WLR 1095 at [12].

¹¹ See especially *Devani v Wells* [2020] AC 129 at [33]–[35].

¹² Full Court Judgment, [60]–[62], CAB tab 10, 261–262.

15. Finally, and contrary to SS [16]–[17], Lundbeck says that Sandoz’s licence under s 223(9) is not relevant to the present proceeding, as Sandoz’s counsel acknowledged at the hearing of the appeal before the Full Court.¹³ If this appeal succeeds and if that statutory licence decision is then relevant, the existing appeal against it by way of rehearing will resume. However, if successful in this appeal, Lundbeck will argue before the primary judge that because the trial proceeded without awaiting the Patent Office decision, it cannot be introduced in this proceeding now.

Interest

10 16. In response to SS [72]–[74] and [78] the words “after the extension is granted” in s 79 of the *Patents Act 1990* (Cth) condition when litigation can be commenced, not when the cause of action arises. As soon as the extension is granted, the cause of action is deemed to have existed since the infringement took place.

17. In response to SS [78], Lundbeck agrees that s 79 “grants nothing other than the right to commence proceedings”. The substantive grant of rights occurs when the extension is granted, but with retrospective effect.

Standing of exclusive licensee

20 18. As SS [82] appears to acknowledge, s 120 continues to apply in the case of extensions of term. Section 120 must logically still continue to apply in the case of infringement of s 79 Rights, as it identifies that infringement proceedings must be commenced in a prescribed court, and the limitation period for such actions. There is no reason to give the initial words of that section effect while ignoring the conferral of standing on exclusive licensees.

19. SS [79], [81], [83] [85] and [86] similarly ignore the fact that s 13 is part of a broader statutory scheme, which also comprises ss 13, s 78 and s 120.

Dated: 3 June 2021



AJL Bannon
(02) 9233 4201
bannon@tenthfloor.org



L Merrick
(03) 9225 8837
luke.merrick@vicbar.com.au



C Cunliffe
(03) 9225 6234
cunliffe@vicbar.com.au

30

¹³ Transcript of NSD 22 of 2019 (8 May 2019), p 2.9–3.19, Appellants’ Supplementary Book of Further Materials tab 1.