



## HIGH COURT OF AUSTRALIA

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File Number: S22/2021  
File Title: H. Lundbeck A/S & Anor v. Sandoz Pty Ltd  
Registry: Sydney  
Document filed: Form 27D - Respondent's submissions  
Filing party: Respondent  
Date filed: 13 May 2021

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IN THE HIGH COURT OF AUSTRALIA  
SYDNEY REGISTRY

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

10 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

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**RESPONDENT'S SUBMISSIONS**

## Part I: Certification

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1. The respondent (**Sandoz**) certifies that this submission is in a form suitable for publication on the internet.

## Part II: Issues

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2. These submissions respond to the submissions of the Appellants (**Lundbeck**, unless it is necessary to distinguish between them) dated 15 April 2021 (**LS**). Capitalised terms used in LS have the same meaning in these submissions.
3. The primary issue is as follows:
  - (a) Is there an implied term in clause 3(1)(a) of the Settlement Agreement to the effect that the licence granted thereunder terminated two weeks after it commenced, notwithstanding that that clause contains a start date for the licence and no end date?
4. If that question is answered in the negative, the consequence is that Sandoz had the benefit of the licence at all relevant times, and the appeal should be dismissed.
5. The following issues arise only if that question is answered in the affirmative:
  - (b) Does an exclusive licensee have standing to commence proceedings under s 79 of the Act?
  - (c) When does a cause of action under s 79 of the Act arise for the purposes of determining the date from which pre-judgment interest runs?
  - (d) Do Sandoz's sales of escitalopram products in the period when the Patent was not on foot constitute misleading or deceptive conduct?
6. Issues (b) and (c) arise on the appeal, and (d) on Sandoz's notice of contention.
7. By contrast, LS Part II presents the issues tendentiously, and without precision.
8. LS issue (a) is not framed as a question of construction of the relevant clause. Instead, it starts with the question begging premise that there was a licence for the last two weeks of the patent, and then states the issue in terms of what that licence could retrospectively "*constitute*". As set out below, the consequence of this is that LS takes a circular approach to construction, and frequently addresses the wrong time frame in doing so.
9. LS issue (b) is similarly not framed soundly, because it rests upon the erroneous premise that the "*commercial object of the parties*" was that the licence should terminate after two weeks and was not directed to the extension that eventuated.
10. LS issue (c) conflates the two issues set out at [5](b) and (c) above. They are separate, and were addressed separately by the primary judge and the Full Court.

### Part III: Notice under s 78B of the Judiciary Act 1903

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11. No notice is required to be given under s 78B of the *Judiciary Act 1903* (Cth).

### Part IV: Facts

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12. The factual matters put forward in LS Part V are not in contention, as distinct from matters of construction or inference, though they are in some respects incomplete.

13. Relevantly, the circumstances at the time of the agreement in February 2007 were:

(a) the original 20 year term of the Patent would have expired on 13 June 2009;

(b) there was a question whether an extension of the term of the Patent based on the registration of Lexapro would be revoked, which was to be determined in

10 accordance with the “*Alphapharm proceedings*” then on foot (FCJ [7]-[12])<sup>1</sup> (ultimately, the Lexapro extension was revoked, in a decision of April 2008 that survived appeals);

(c) it was objectively possible, based on the provisions of the Act, that Lundbeck might seek an extension of term based instead on the registration of Cipramil, in circumstances where the Patent could first expire before such extension was granted (PJ [260]; FCJ [69]);<sup>2</sup> and

20 (d) if Lundbeck were to seek such an extension of term, it would first need to seek a very substantial extension of time within which to do so. In order to succeed in obtaining such an extension of time, it would need to identify that, in failing to pursue that course earlier, it had made an “*error*” or “*omission*” under s 223(2)(a). In that sense, if the objective possibility materialised, it would be the fault of Lundbeck.

14. The primary judge and the Full Court acknowledged the possibility referred to in (c) above, albeit as one that was “*objectively remote*” (PJ [291]-[293]; FCJ [69]).<sup>3</sup>

15. That possibility ultimately materialised. In June 2009, ten years out of time, on the day before the Patent expired, Lundbeck made an application to extend the term of the Patent based on the registration of Cipramil, and at the same time an application to extend time within which to apply for the extension of term (FCJ [13]).<sup>4</sup> The basis of that application was that Lundbeck had made an error in thinking that it could not extend the term based on the registration of Cipramil. The extension of  
30 time was granted by the Commissioner on 1 June 2011, and that decision survived

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<sup>1</sup> CAB tab 10, 248 - 249.

<sup>2</sup> CAB tab 1, 97; CAB tab 10, 264.

<sup>3</sup> CAB tab 1, 106 - 107; CAB tab 10, 264.

<sup>4</sup> CAB tab 10, 249.

successive appeals. The extension of the term of the Patent was ultimately granted in June 2014. By reason of s 79 of the Act, it operated retrospectively, the extended term being 13 June 2009 to 9 December 2012.

16. Some additional procedural history is relevant to the relief sought by Lundbeck, namely 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%*”: LS [5]. Any orders made by this Court should take account of the fact that Lundbeck is not in any event entitled to relief because Sandoz separately has a complete answer to the claim, namely a licence granted by the Commissioner of Patents under s 223(9) of the Act: *H Lundbeck A/S v Sandoz Pty Ltd* [2019] APO 18.

17. At PJ [550],<sup>5</sup> the primary judge observed that Sandoz had pleaded by way of defence a licence which it had sought from the Commissioner pursuant to s 223(9) of the Act. Given that that licence would be a complete answer to the claim, and that the application for that licence was shortly to be heard, the primary judge anticipated Sandoz making a stay application. Sandoz did so, and a stay was granted. Subsequently on 11 April 2019, the Commissioner granted Sandoz a licence under s 223(9). Lundbeck applied for a review of that decision in the AAT, and accordingly the stay of the orders of Jagot J was extended on 7 May 2019 to the date 28 days after that application for review is determined. The AAT proceeding progressed and in the meantime, Sandoz was also successful in its appeal to the Full Court in the proceeding below, which rendered the AAT’s review of the statutory licence moot. Subsequently, on 25 August 2020, the AAT proceeding was effectively stayed by vacation of the procedural orders previously made, pending determination of this appeal.

## **Part V: Argument in Answer to the Argument of the Appellants**

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### **A. Construction of the Settlement Agreement (amended notice of appeal, ground 2)**

#### *The express terms*

18. Clause 3(1) of the Settlement Agreement reads as follows (emphasis added):

*(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;*

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<sup>5</sup> CAB tab 1, 183.

(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).

19. Clause 3(1) is to be construed in the context of the Settlement Agreement as a whole, including clause 1 by which Sandoz granted releases in favour of Lundbeck Denmark (the owner of the Patent) and agreed not to seek revocation of any of the claims of the Patent, and clause 2 by which both Lundbeck Denmark and Lundbeck Australia (noting the latter was not a party to the proceedings) granted wide releases in favour of Sandoz with respect to all claims, present and future, relating to the proceedings. The object and effect of the agreement was to achieve a comprehensive settlement of all current and future disputes between Sandoz and Lundbeck relating to the proceedings, including claims that Lundbeck Australia may have. In that context, Clauses 3 and 4 of the Settlement Agreement established circumstances in which Sandoz would be free to exploit its products without fear of any future claim by Lundbeck Denmark or Lundbeck Australia.
20. As the primary judge (PJ [295])<sup>6</sup> and the Full Court (FCJ [67]-[69])<sup>7</sup> held, Sandoz's licence commenced on 31 May 2009, pursuant to clause 3(1)(a). The reason for that is that the Patent expired on 13 June 2009. LS [27] accepts this. No doubt it does so because its infringement case (being a section 79 case) was premised on the proposition that the Patent did expire on that date.
21. Further, clause 3(1) is expressed to be **irrevocable**, commencing "*from*" the start date. Sub-clause (a) does not contain an express end date.
22. The express terms are therefore unambiguous. The Full Court said at FCJ [67]:<sup>8</sup>
- 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.*
23. Accordingly, the only question arising is whether, notwithstanding those matters, a term is to be implied that the licence terminates two weeks after its commencement.

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<sup>6</sup> CAB tab 1, 107.

<sup>7</sup> CAB tab 10, 264.

<sup>8</sup> CAB tab 10, 264.

*Principles*

24. The following matters of principle are familiar. They are recited for convenience here as they are of particular application in this case.
25. **First**, as to construction, the intention of the parties is objectively determined, that is, by reference to what a reasonable businessperson would have understood the contractual words to mean: *Electricity Generation Corporation v Woodside Energy Ltd* (2014) 251 CLR 640 per French CJ, Hayne, Crennan and Kiefel JJ, at [35]; *Mount Bruce Mining Pty Ltd v Wright Prospecting Pty Ltd* (2015) 256 CLR 104 per French CJ, Nettle and Gordon JJ, at [47].
- 10 26. **Secondly**, and relatedly, the objective circumstances surrounding the making of the contract may be used to construe its terms, but not to replace them, and in particular not to replace them with propositions about the subjective intentions of the parties or a vague notion such as the deal the parties bargained: *Arnold v Britton* [2015] AC 1619, [19]-[20]; *JR Consulting & Drafting Pty Ltd v Cummings* (2016) 329 ALR 625 at [59]; *Equuscorp Pty Ltd v Glengallan Investments Pty Ltd* (2004) 218 CLR 471 at [33]; *Gordon v Macgregor* (1909) 8 CLR 316 at 322-323.
27. **Thirdly**, as regards the implication of terms, the Privy Council stated in *BP Refinery (Westernport) Pty Ltd v Hastings Shire Council* (1977) 180 CLR 266 (PC) at 283: “For a term to be implied, the following conditions (which may overlap)
- 20 *must be satisfied: (1) it must be reasonable and equitable; (2) it must be necessary to give business efficacy to the contract, so that no term will be implied if the contract is effective without it; (3) it must be so obvious that ‘it goes without saying’; (4) it must be capable of clear expression; (5) it must not contradict any express term of the contract.”*
28. Requirements (3) and (4) in this passage require a high level of clarity. If a term is uncertain in its operation, it is unlikely to be implied: *Ansett Transport Industries (Operations) Pty Ltd v Commonwealth* (1977) 139 CLR 54, 62; *Codelfa Construction Pty Ltd v State Rail Authority of NSW* (1982) 149 CLR 337.
29. **Fourthly**, as regards licences (whether contractual or otherwise), the nature of a
- 30 licence (including an intellectual property licence such as of a patent or copyright) is that it is a “*permission*” or a “*consent*”. It is a permission to do something which would be otherwise unlawful. Further, it creates no estate or interest in the property to which it relates: *Interstate Parcel Express Co Pty Ltd v Time-Life International (Netherlands) BV* (1977) 138 CLR 534 at 549-550; *Computermate Products (Aust) Pty Ltd v Ozi-Soft Pty Ltd* (1988) 83 ALR 492 at 494-495 per Sheppard, Spender

and Gummow JJ; *Banks v Transport Regulation Board (Vic)* (1968) 119 CLR 222 at 230; *National Phonograph Co of Australia Ltd v Menck* (1908) 7 CLR 481 at 538–9; *Calidad Pty Ltd v Seiko Epson Corp* [2020] HCA 41 at [177].

*The licence has no implied end date*

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30. As submitted, there is no express term and no other language providing for a termination date for the licence referred to in clause 3(1)(a). LS repeatedly suggests that the text of the clause provides for a “two week licence” (see, e.g., LS [41]), but that is not correct. To the contrary, the clause provides a commencement date and no end date, and provides that once the licence has commenced, it is irrevocable.
31. LS [39] further wrongly suggests that the Full Court found that the “*commercial object of the transaction was a two week licence*” referring to FCJ [62].<sup>9</sup> No such finding is made there, or anywhere else. To the contrary, as set out below, the Full Court repeatedly observed that the licence was intended not to have an end date. For the same reason, LS [40] is quite wrong to suggest that the Full Court “[took] an end date from clause 3(1)(b)”. The Full Court took no end date.
32. Accordingly, Lundbeck’s submission that the Settlement Agreement provides for a “two week” licence asserts the desired conclusion as a reason for reaching it.
33. Similarly, Lundbeck’s suggestion that the “*commercial object*” of the Settlement Agreement was to provide a “two week licence” is also flawed. The commercial object of the transaction was to settle the proceedings by which Sandoz challenged the validity of the patent by obtaining wide releases from Lundbeck, in return for the grant of releases and the grant of a licence in accordance with clause 3.
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34. Lundbeck’s submissions confuse the commercial object of the transaction, which is an objective concept founded on the text of the agreement and the objective circumstances surrounding its making, with observations that were made by the Full Court after it had considered Lundbeck’s reliance upon some email correspondence between the parties. The Full Court concluded at FCJ [53]<sup>10</sup> that the pre-contractual correspondence had nothing to say as to what would happen in the event that the Patent expired before any extension of term was granted, and did not suggest that Sandoz might be required to withdraw its product from the market at some time thereafter in the event that the Patent was extended after it expired.
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<sup>9</sup> CAB tab 10, 262.

<sup>10</sup> CAB tab 10, 259.



35. Further, as the Full Court said, the reference to “two weeks early entry” in the email referred to at FCJ [50] and [53]<sup>11</sup> was directed to providing Sandoz with a two week head start (“early entry”) in the escitalopram market; it was not directed to providing Sandoz with only a two week participation in the escitalopram market (cf LS [42]). That would be commercial nonsense, because withdrawing from a market for a pharmaceutical product in Australia two weeks after launch would self-evidently be a damaging endeavour. Thus, there is no suggestion in the notion of a “two week early entry” licence that Sandoz may have to exit the market two weeks after entering it. To the contrary, the purpose of entering the market two weeks early is to stay in it. Further, if the objective possibility that Lundbeck might not be granted an extension of term until after expiry were to materialise, in all likelihood Sandoz would not know, at the end of that two week period, whether that extension of term would ultimately be granted. That uncertainty tells against any intention that Sandoz would have to exit the market. As the Full Court stated at FCJ [65]:<sup>12</sup>

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*On the other hand, if Lundbeck’s construction of the settlement agreement is accepted, Sandoz was left in a position of much greater uncertainty. Even if the Patent had expired or was certain to expire on 13 June 2009, there still remained the possibility that the Patent might thereafter be extended with the consequence that Sandoz might never know whether it could rely on the licence it was granted until after any outstanding or future application to extend the term of the Patent was heard and finally determined. The measure of uncertainty that this would create for Sandoz seems to us to be inconsistent with a clause that specifies a start date for the relevant licence by reference to an event that either would or would not occur by 13 June 2009.*

36. Further and in any event, the Full Court proceeded to put aside all questions as to the subjective states of mind of the parties and based its decision upon the plain and natural meaning of the language chosen by the parties (FCJ [67]-[69]).<sup>13</sup>

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37. Consistently with this, LS apparently does not suggest that the parties actually intended the licence to terminate after two weeks. Rather, Lundbeck makes a different submission, namely that a termination date should be implied because the parties did not contemplate that a licence would be required after two weeks, the

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<sup>11</sup> CAB tab 10, 259.

<sup>12</sup> CAB tab 10, 263.

<sup>13</sup> CAB tab 10, 264.

Patent having expired. Thus, LS [41] submits that “*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 flawed basis for this proposition is advanced at LS [28].

38. This argument has multiple difficulties. **First**, it ignores the language chosen by the parties in clause 3(1), including the fact that the absence of an end date in sub-clause (a) must be regarded as a deliberate choice having regard to the fact that it is that sub-clause that embraces the circumstance in which the Patent is extended after its expiry. **Secondly**, the proposition that the licence in clause 3(1)(a) necessarily ended on 13 June 2009 when the Patent expired is wrong, and ignores the true nature of that licence; as explained at [29] above and [53] below. **Thirdly**, Lundbeck’s contention goes well beyond the extrinsic evidence, as demonstrated by the Full Court’s analysis at FCJ [50]-[54].<sup>14</sup> **Fourthly**, Lundbeck’s proposition that an end date was not required if the Patent expired (notwithstanding a pending extension application) tends against the implication of a term specifying such an end date rather than for it. *BP Refinery* factor (2) identifies necessity as a requirement for implication of a term. Lundbeck wishes to emphasise that it was contemplated that Sandoz did not require a licence to remain in the market after the two week period. However, Lundbeck ignores the necessary corollary of this. That is, it was contemplated that Sandoz would remain, and would be entitled to remain, in the market beyond that period. That Sandoz would be entitled to do so is antithetical to the notion that a specified end date for the licence was contemplated. As the Full Court stated at FCJ [69]:<sup>15</sup>

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

39. **Fifthly**, and most fundamentally as the foregoing passage demonstrates, Lundbeck’s argument commences wrongly because it takes a subjective, rather

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<sup>14</sup> CAB tab 10, 259-260.

<sup>15</sup> CAB tab 10, 264.

than an objective, approach to the parties' contemplation, as required by the authorities, and is thereby inaccurate. What was or was not in the subjective contemplation of one or other of the parties is not the relevant question. Rather, the relevant question is what was objectively contemplated. The answer is, as is apparent from the reasoning of both the primary judge (PJ [265], [291]-[292])<sup>16</sup> and the Full Court in the above passage, that it was highly likely that any extension of term of the Patent would be known by May 2009, but there remained an objective, though remote, possibility that it would not be, and that the term may be extended retrospectively some time after the Patent expired. On the likely scenario, Sandoz would not require a licence to remain in the market two weeks after entry, but on the remote one, it would. The language chosen by the parties allowed for that contingency. (It may be noted in this respect that clause 7(c) acknowledged that the parties had obtained legal advice on the content and the effect of the agreement.)

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40. In those circumstances, the question is whether it goes without saying that the parties intended the licence to terminate two weeks after commencement, notwithstanding the following matters:

- (a) it contained no end date;
- (b) the licence is expressed to be irrevocable once commenced;
- (c) the absence of an end date must be regarded as a deliberate choice having regard to the fact that it is sub-clause (a) that embraces the circumstance in which the Patent is extended after its expiry;
- (d) the absence of an end date stands in some tension with the wide releases granted to Sandoz under clause 2 of the Settlement Agreement and the commercial object of the transaction; and
- (e) if any significance is to be attached to the intentions revealed by the pre-contractual email exchange between the parties, then as the Full Court said at FCJ [53]<sup>17</sup> it only discloses an intention to provide Sandoz with a two week head start without any contemplation that Sandoz might be required to withdraw its product from the market at some time thereafter in the event that the Patent was extended after it expired.

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Each of the matters just mentioned is flatly inconsistent with any intention to expose Sandoz to s 79 infringement proceedings in the event that a patent extension were to be granted after 13 June 2009.

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<sup>16</sup> CAB tab 1, 99 and 106.

<sup>17</sup> CAB tab 10, 259.

41. The answer is that the suggested implication does not go without saying. There is no reason why the parties must be taken to have agreed that Sandoz should bear the risk of the remote possibility materialising. Indeed, the expressly chosen language required that Lundbeck should bear that risk. The risks to Sandoz of agreeing to a different form of words (as Lundbeck now seeks to imply) would have been significant, including the substantial financial and reputational costs of entering the market for a pharmaceutical drug in Australia, only to withdraw from that market almost immediately. That arrangement would be entirely uncommercial.
- 10 42. In this respect, it is significant that the implied term would be unacceptably uncertain in operation. As submitted, in all likelihood, if the Patent were to be extended after expiry, it would not be known until a substantial period of time thereafter whether that extension would be granted or not. Accordingly, Sandoz would have launched, but would not have known until some entirely unpredictable later time whether it would have to withdraw from the market two weeks after that launch. That would render the alleged implied term, and the licence, so uncertain as to be of no utility, contrary to *BP* factors (3) and (4) (see FCJ [65]).<sup>18</sup>
- 20 43. Lundbeck has suggested that Sandoz’s approach “*construes*” the Settlement Agreement as constituting a 3 ½ year licence: LS [46], [21]. This is erroneous, because it expresses the effect of the licence retrospectively, rather than construing the meaning of it as at February 2007. As at that date, the risk that the Patent term may be extended after expiry was remote and, if it materialised, it was unknown when that would occur, or what the terms of it would be.
44. A similar error underlies Lundbeck’s submissions directed towards suggesting that the consideration flowing from Sandoz for the licence, namely to give up its challenge to the validity of the Patent, was not “*proportionate*” (LS [44]). Lundbeck appears to suggest that this consideration was not an adequate quid pro quo for a 3 ½ year licence. That also commits the error of treating as certain that which as at February 2007 was only a remote possibility.
- 30 45. For the reasons given above, the true position is that, considered as at February 2007, if the remote possibility of the patent term being extended after expiry materialised, the consequences could be severe for Sandoz if it had to bear them, not just for Lundbeck. Indeed, as the Full Court observed at FCJ [65],<sup>19</sup> Lundbeck’s

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<sup>18</sup> CAB tab 10, 263.

<sup>19</sup> CAB tab 10, 263.

contention that an end date should be read or implied into clause 3(1)(a) presented much greater uncertainties and risks for Sandoz than for Lundbeck.

46. Further, it is relevant that, considered as at February 2007, if the Patent term were later to be extended after expiry based on the Cipramil registration, that would require an extension of time consequential on an error or omission by Lundbeck pursuant to s 223(2). That objective circumstance further tends against any suggestion that it was contemplated that Sandoz, rather than Lundbeck, should bear the risk of the consequences of Lundbeck having made that error or omission.

10 47. LS [45] refers in this context to Sandoz subjectively taking the view in 2009 that it was launching “*at risk*”. That, however, is irrelevant. It refers to circumstances of launch in 2009, and the risk contemplated by Sandoz at that later time, that the February 2007 agreement might be construed unfavourably. It is irrelevant to the present question of the construction of the Settlement Agreement, based on the objectively determined contemplation of the parties as at February 2007.

48. Accordingly, there is no basis for implying a term to the effect that the licence terminated two weeks after it commenced.

*Licence not capable of operating post-expiry?*

20 49. In the face of these difficulties, LS [48]-[55] appears also to advance an argument that travels beyond construction, by suggesting that the licence was not capable of operating in the period between expiry and the grant of the extension, regardless of the parties’ intention.

50. Thus LS [50] asserts unconditionally “*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*”. This submission ignores both the nature of a licence on the authorities set out above, and the status of the Patent in that intervening period.

30 51. As indicated in *Time Life, Calidad* and the other authorities referred to above, a licence is a permission to do an act which may otherwise be unlawful. In the context of a patent, a licence simply requires the licensor to have rights with respect to a patent which may permit the licensor to sue the licensee for acts which may infringe the patent. The licence is a permission to do those acts.

52. In the period after expiry of the Patent, a permission of that kind had work to do: though the Patent had expired, it was not a nullity. Lundbeck had on foot an application to extend the term of the Patent. If successful, that application would then allow Lundbeck, under s 79 of the Act, to sue for infringement of the Patent

retrospectively in respect of any acts of exploitation in the meantime. In that sense, Lundbeck had contingent rights to sue for patent infringement in that period.

(Contrary to LS [53], no question of “*feeding title*” arises, because Lundbeck was at all times the holder of all rights in relation to the Patent, including after its expiry as the registered proprietor and applicant for an extension of term.)

53. It is opportunistic for Lundbeck now to suggest that, though it had after expiry the contingent right to sue retrospectively under s 79 for patent infringement in respect of exploitation between expiry and any grant of an extension, it did not have power to grant a licence in respect of those acts. In fact, Lundbeck did have that power, because the permission constituted by the licence in that context had work to do: it made lawful that which was contingently unlawful. That is, it made Sandoz’s acts of exploitation between expiry and any grant of an extension lawful, when they would otherwise be unlawful. Contrary to LS [54] the licence was therefore not “*spent*” and nor did it need to be “*recharged*”. Furthermore, Lundbeck advanced a directly contrary submission at trial (PJ [248])<sup>20</sup> and before the Full Court (FCJ [29])<sup>21</sup> to the effect that, as long as there was an outstanding extension application as at 13 June 2009, Lundbeck had sufficient title to grant a licence for the period from 26 November 2012 to 9 December 2012, as contemplated by clause 3(1)(b).

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20 54. In this respect LS [23], [42] also seeks to derive some assistance from drafts of the Settlement Agreement which referred to a licence of the “*invention*” or a licence to sell a “*product*” rather than a licence to the “*Patent*”. The submission appears to be that a licence to the “*Patent*” is somehow narrower than a licence to the “*invention*” or the “*product*”. That, however, is not correct. The licence was a permission to do that which may otherwise be unlawful. Whether the licence was expressed as a licence to the “*invention*” or to the “*product*” or to the “*Patent*”, the acts (exploitation of Sandoz’s escitalopram products) and the source of the unlawfulness of them (the Patent) remained the same in each case. Accordingly, the work for the permission to do was the same: it made lawful the exploitation of the escitalopram products when those acts were contingently unlawful.

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55. It may be noted in this respect that the definition of a “*licence*” in the Schedule to the Act (existing as at February 2007) is a “*licence to exploit...the patented invention*”. That draws no relevant distinction between the patent and the invention,

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<sup>20</sup> CAB tab 1, 92.

<sup>21</sup> CAB tab 10, 252.

and further supports the proposition that there was no relevant narrowing intended by that change in wording in the course of the negotiation.

56. The errors of the primary judge, and the contrasting approach of the Full Court, may be analysed against that background.

*The primary judge*

57. The principal error of the primary judge was to hold that the term “*Patent*” should be read down to refer only to “*the 144 patent before it has expired*” at PJ [298] (emphasis added). The effect of this was to exclude circumstances in which the Patent term is extended after it has expired. It has the same effect as implying a provision terminating the licence after two weeks. Notably, Lundbeck does not appear to suggest in LS that the word “*Patent*” should be read down in this way. There is no proper foundation for such a limitation.
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58. **First**, if Lundbeck had wished to provide for such an exclusion it could have expressly done so. This is supported by the primary judge’s finding that there was an objectively ascertainable possibility, though remote, that such circumstances might arise because of an extension of term application based on the registration of Cipramil (PJ [265], [291]-[292]).<sup>22</sup> No words of limitation were included.
59. **Secondly**, the primary judge’s apparent justification for including such a limitation is flawed. Her Honour considered that failing to include that limitation “... *has the effect of transforming Sandoz’s two week early entry licence under cl 3(1) into a royalty free licence for three years for the extended term of the 144 patent, which is inconsistent with the deal the parties bargained*” (PJ [301]; see also [298]-[300]).<sup>23</sup> As submitted above, this is impermissibly retrospective and circular reasoning as a matter of contractual construction, and seems to advance a contractual theory that is based on her Honour’s view about the parties’ subjective intentions. Even considered as a commercial matter, it is one-sided, contrary to the need to consider the interests of both parties, as expressed by the Full Court in *JR Consulting* at [59]. In particular, it fails to acknowledge that, on her Honour’s view of the licence, Sandoz would be entitled to launch its product, but then have to withdraw it from
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- the market two weeks later, and would not be permitted to sell thereafter to the end of the extended term. That is equally inconsistent with the primary judge’s notion of “*the deal the parties bargained*”, being an “*early entry*” arrangement. Early entry involves ongoing sales; by contrast, on her Honour’s view of the licence,

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<sup>22</sup> CAB tab 1, 99 and 106.

<sup>23</sup> CAB tab 1, 108.

Sandoz would get a single two week period of sales, not only involving the cost and damage of launch and withdrawal within two weeks, but also foregoing sales of its Esitalo products for a substantial period thereafter. To adopt the language of the primary judge at PJ [300],<sup>24</sup> that arrangement would not “*make sense*” for Sandoz.

60. **Thirdly**, limiting the “*Patent*” to “*the Patent before it has expired*” reflects an approach which mandates that the term of the patent be determined before its expiry. That would likely only occur by means of the Alphapharm proceedings. However, her Honour had rejected a construction of expiry by reference to the Alphapharm proceedings at PJ [275]-[280].<sup>25</sup> It is difficult to see, having done so, how the word “*Patent*” could be limited in that way. There is also tension between her Honour’s conclusions that Sandoz’s licence did not continue after the Patent expired, while Lundbeck Australia’s licence, giving it standing to sue, did.
61. **Fourthly**, the primary judge failed to construe or give effect to the clear language chosen by the parties in clause 3(1)(a).
62. **Fifthly**, even if (contrary to the above) there were some lack of clarity or ambiguity about the language used in clause 3(1)(a) then, for the reasons already submitted above, her Honour’s construction would not be preferred because it would lead to a high degree of uncertainty. The extension of term application would likely not be determined for a substantial period after the period in which, on her Honour’s construction, the licence operated (in the events which happened, 5 years afterwards). Accordingly, Sandoz would not be in a position to comply with any theoretical obligation to withdraw on 14 June 2009.

*The Full Court*

63. The Full Court identified this error of construction in the primary judge’s reasoning at FCJ [56],<sup>26</sup> holding that it was not open to construe the word “*Patent*” as applying only to the Patent before expiration.
64. At FCJ [58]<sup>27</sup> the Full Court referred to an underlying difficulty with the primary judge’s reasoning in this respect, namely that “*it is based on an assumption that the parties intended that Sandoz would be entitled to enter the market prior to expiry of the Patent in accordance with clause 3(1) but may at some later point in time be required to withdraw from the market on account of Lundbeck having obtained an extension of the term of the Patent (perhaps years) after the Patent had expired.*”

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<sup>24</sup> CAB tab 1, 108.

<sup>25</sup> CAB tab 1, 102 - 103.

<sup>26</sup> CAB tab 10, 260.

<sup>27</sup> CAB tab 10, 261.



This aspect of the Full Court’s reasoning is important, because the paragraphs which follow are directed to explaining why that assumption could not be made.

65. Thus, at FCJ [65],<sup>28</sup> quoted above, the Full Court identified that the approach required by that assumption would lead to unacceptable uncertainty.

66. The Full Court also considered matters concerning the parties’ understanding as to when the determination of any extension of term would be made. At FCJ [59]<sup>29</sup> the Full Court considered 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. Similarly, the Full Court considered that the parties were likely to have been operating under the common assumption that the expiry date of the Patent would have been established by May 2009 (FCJ [60]).<sup>30</sup>

67. At FCJ [61]<sup>31</sup> the Full Court referred to a submission by Lundbeck to the effect that, notwithstanding those matters, it was objectively possible as at February 2007 that the parties might not know by 1 May 2009 when the Patent would expire. Addressing this, at FCJ [62],<sup>32</sup> the Court rejected the submission that “*both parties entered into the settlement agreement knowing that the expiry date might not be finally determined before 1 May 2009*” and stated “*Nor are we persuaded that it is appropriate to construe cl 3 so that it accommodates such a possibility*”. By these passages, the Full Court was explaining why it was rejecting the assumption, referred to in FCJ [58],<sup>33</sup> that the parties intended Sandoz to withdraw from the market if an extension were granted subsequent to Patent expiry. In that context, the Full Court was addressing the reliance that Lundbeck placed, and the primary judge appeared to place, upon the subjective intentions of the parties. Hence, the Full Court repeatedly referred to the likely/unlikely state of mind of the parties. The Full Court’s conclusion was that the parties did not subjectively intend to create any such special rule dealing with the circumstance in which the Patent is extended after expiry. Furthermore, only that view is consistent with the way in which the Full Court then turns at FCJ [67]-[69]<sup>34</sup> to consider the objective meaning of the clear language used in clause 3(1).

68. In any event, contrary to LS [47], the Full Court was not suggesting that clause 3(1)(a) simply did not apply to circumstances in which the Patent was

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<sup>28</sup> CAB tab 10, 263.

<sup>29</sup> CAB tab 10, 261.

<sup>30</sup> CAB tab 10, 261.

<sup>31</sup> CAB tab 10, 261.

<sup>32</sup> CAB tab 10, 262.

<sup>33</sup> CAB tab 10, 261.

<sup>34</sup> CAB tab 10, 264.

extended after expiry. It expressly concluded otherwise. At FCJ [67]<sup>35</sup> the Full Court stated (emphasis added):

*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.*

10 69. Similarly at FCJ [69]<sup>36</sup> the Full Court stated (emphasis added):

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

20 70. Those passages expressly, and rightly, accepted that there was a remote possibility that the Patent might be extended sometime after it had expired, and that the licence would apply on its terms without an end date in such a circumstance. Thus, Sandoz would not need to concern itself with any post-expiry extension, and could remain in the market just as it was intended Sandoz would do in all other scenarios (as to which see FCJ [64]:<sup>37</sup> “Sandoz could move forward knowing that it had the benefit of an irrevocable licence to engage in the activities specified in cl 3(2) and, from 31 May 2009, all other relevant activities that would otherwise amount to an infringement”). That was consistent with the view at FCJ [56]<sup>38</sup> that it was not open to construe the word “Patent” as applying only to the Patent before expiration.

### Conclusion

30 71. Accordingly, the Full Court correctly concluded that the licence on its proper construction commenced on 31 May 2009 and continued throughout the extended term. That is a complete answer to Lundbeck's claim.

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<sup>35</sup> CAB tab 10, 264.

<sup>36</sup> CAB tab 10, 264.

<sup>37</sup> CAB tab 10, 262.

<sup>38</sup> CAB tab 10, 260.

**B. Interest: when does the cause of action arise? (amended notice of appeal, ground 3)**

72. The allegedly infringing acts all occurred prior to the grant of an extension of term. In those circumstances, the question arises as to the date from which interest runs, assuming (contrary to the above) those acts to constitute infringements.

Section 51A of the *Federal Court of Australia Act 1976* (Cth) sets the commencement as the date on which the cause of action arises. The cause of action arises under s 79 of the Act. It provides that if a patent expires *before* an extension of term application is determined, and the extension is subsequently granted, then:

*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.*

73. As the Full Court held at FCJ [140], [145],<sup>39</sup> the underlined words make it clear that the cause of action does not arise until the extension is granted.

74. The primary judge, concluding otherwise, stated at PJ [532]:<sup>40</sup> “*Sandoz’s submissions fail to recognise the operation of s 79 of the Patents Act which provides that once the extension is granted there is the ‘same rights to start proceedings in respect of the doing of an act during the period’ commencing on the expiration of the term of the patent and ending on the day on which the extension was granted.*” However, her Honour ought there to have addressed the effect of the words “*after the extension is granted*” in s 79, because they specify when the rights arise.

75. Instead, the primary judge proceeded: “*This statutory fiction has effect for all purposes. It means that Lundbeck is taken to have had its rights as at the date Sandoz commenced its infringement of the 144 patent on 15 June 2009.*” This imprecise formulation (see LS [58]) obscures the fact that s 79 does not give the patentee the right to start proceedings at any time prior to the grant of the extension.

76. LS [59] makes a similar error, in that it confuses the date on which the cause of action arises with the dates of the acts to which that cause of action applies. That confusion is particularly evident in the submission at LS [65], that the Full Court “*accept[ed] that Lundbeck had a right to declarations and damages as from the date of infringement. Such remedies are only logically available if the patentee’s*

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<sup>39</sup> CAB tab 10, 289 and 291.

<sup>40</sup> CAB tab 1, 178.

*cause of action is treated as having accrued as at the date of the infringing acts.”*

That formulation is incorrect. The true position is that until an extension of term is granted, no cause of action has arisen and there is no right to any remedy. Only once the extension of term is granted are remedies available, and they are available in respect of acts occurring prior to that date.

77. Nor, contrary to LS [60]-[64], is any different result required by the decisions of the House of Lords in *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1975] 1 WLR 819 and *Sevcon Ltd v Lucas Cav Ltd* [1986] 1 WLR 462. Those cases concerned s 13(4) of the *Patents Act 1949 (UK)* (which was not directed to extensions of term, but rather infringements which may arise between the dates of filing and grant). That provision (see LS [60]) is materially different because it provided for “*privileges and rights*” to arise “*after the date of publication and until the sealing of a patent*”. Those rights thus arose immediately, but were subject to a proviso, namely “*Provided that an applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.*”

78. The House of Lords held the proviso was merely procedural in nature. The rights, and thus the cause of action, were expressed to arise on filing *General Tire* at 836G and 841C; *Sevcon* at 467D-E. But, as the Full Court held, s 79 is different. It does not grant rights subject to a procedural proviso prohibiting the commencement of proceedings. It grants nothing other than the right to commence proceedings, and those rights do not arise until after the extension is granted. Accordingly, the cause of action does not and cannot arise until the extension is granted. The Full Court correctly addressed these matters at FCJ [141]-[146].<sup>41</sup>

### **C. Standing of exclusive licensee (amended notice of appeal, ground 4)**

79. As the Full Court held at FCJ [89], [98],<sup>42</sup> it is s 79 of the Act (reproduced above) which provides for the standing of a party to sue for acts occurring after the expiry of a patent and before a subsequent extension of term is granted.

80. Relevantly, it reads “*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...*”

81. As the Full Court held, the unambiguous language of that section confers standing on the patentee only, not the exclusive licensee.

82. By contrast, s 120, otherwise addressing the right to commence an infringement proceeding, confers standing on the patentee and the exclusive licensee.

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<sup>41</sup> CAB tab 10, 289 - 291.

<sup>42</sup> CAB tab 10, 272 and 276.

Section 120 would operate after an extension of term of a patent in respect of acts committed after the grant of that extension. In the present case, however, the relevant acts occurred after expiry and before the grant of the extension of term. If s 120 operated to give a patentee rights to start proceedings in respect of acts occurring in that period, s 79 would have no work to do.

83. LS [70] wrongly suggests that outcome is “*anomalous*”. The first alleged anomaly ignores the fact that the language of s 79 is unambiguous; to suggest that it gives an exclusive licensee a right to commence proceedings would be to redraft it. The second alleged anomaly fails to take into account the special and exceptional nature of the rights conferred by s 79. And the third alleged anomaly is based on a false comparison between ss 78 and 79. Section 78 provides that the exclusive rights of the patentee during the term of the extension are not infringed in certain circumstances. By limiting the exclusive rights of the patentee during the extended term, that removes any possibility of an exclusive licensee (whose rights are derivative) being able to sue for infringement in circumstances where the patentee itself cannot sue by force of s 78. More generally, for the reasons given by the Full Court at FCJ [109]-[110],<sup>43</sup> it is not safe to draw the conclusion there is any anomaly.
84. In this respect, LS [71] calls in aid s 13. It submits that “*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*”.
85. Even putting aside that it is quite unclear what is meant by “*devolved*” in this submission, that reasoning is quite unsound. If it were correct that s 13 permitted an exclusive licensee to exercise the rights of “*the patentee*” in s 79 then it would equally permit a non-exclusive licensee to do so, because s 13 does not distinguish between them. Section 13 provides that a patent “*gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to exploit the invention*” (emphasis added).
86. There is no mention of an exclusive licensee in s 13. It would be extraordinary if a non-exclusive licensee were to have standing to commence proceedings under s 79 when it does not even have standing to commence proceedings under s 120, but that is what the logic of LS [71] based on s 13 would require. The error is to suggest that s 13 confers a right to commence proceedings, whether on the

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<sup>43</sup> CAB tab 10, 278 - 279.

patentee, exclusive licensee or any other person. As the Full Court held (FCJ [99]),<sup>44</sup> it does not. Section 79 does that work, and confers the right only on the patentee.

## Part VI: Argument on the Respondent's Notice of Contention

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### Construction of the Settlement Agreement (notice of contention, ground 1)

87. As submitted in Part V, the better view of FCJ [62]<sup>45</sup> is that the Full Court was explaining why it was rejecting the assumption, referred to in FCJ [58],<sup>46</sup> that the parties intended Sandoz to withdraw from the market if an extension were granted subsequent to expiry. If, however, the Court was expressing the view that a reasonable commercial business person would not have been aware that there was a risk that the parties would not know, before 13 June 2009, whether the term of the Patent would be extended, then that is incorrect, for the reasons given in Part V.

### Misleading or deceptive conduct (notice of contention, ground 2)

88. While the Lundbeck parties asserted claims for both patent infringement and misleading or deceptive conduct, CNS Pharma only asserted the latter. In light of the particular relevance of that cause of action to the CNS Pharma proceeding, this ground is dealt with in the Respondent's submissions in the CNS Pharma proceeding. The same reasoning applies to the Lundbeck proceeding.

## Part VII: Estimate of Time

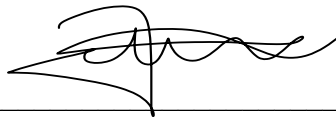
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89. The respondent estimates that it will require approximately 2 hours for the presentation of its oral argument (in both proceedings).

Dated 13 May 2021



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<sup>44</sup> CAB tab 10, 276.

<sup>45</sup> CAB tab 10, 262.

<sup>46</sup> CAB tab 10, 261.

**ANNEXURE**

*Federal Court of Australia Act 1976* (Cth) (as at 4 August 2020): s 51A

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

*Patents Act 1990* (Cth) (as at 16 February 2007): Sch 1 (definition of 'licence')

10 *Patents Act 1990* (Cth) (as at 4 August 2020): ss 13, 78, 79, 120, 223