



## HIGH COURT OF AUSTRALIA

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#### Details of Filing

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IN THE HIGH COURT OF AUSTRALIA  
 SYDNEY REGISTRY

S23/2021

BETWEEN:

**CNS PHARMA PTY LTD** (ACN 121 515 400)

Appellant

and

**SANDOZ PTY LTD** (ACN 075 449 553)

Respondent

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**RESPONDENT'S OUTLINE OF ORAL SUBMISSIONS**

**PART I:** **CERTIFICATION:** this outline is in a form suitable for publication on the internet.

**PART II:** **PROPOSITIONS TO BE ADVANCED IN ORAL ARGUMENT:**

**A. THE SETTLEMENT AGREEMENT ISSUE**

1. **The express terms:** objectively considered, the express terms of cl 3(1) are clear. The clause specifies a start date and no end date for the licence, and the licence is irrevocable. It is common ground that the Patent expired on 13 June 2009, so that sub-para (a) applied, and the licence commenced on 31 May 2009. It follows that Sandoz had a licence for the period covered by Lundbeck's claim, being 14 June 2009 to 9 December 2012.

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- (a) Full Court judgment (**FCJ**) [67], [69] (CAB 10/264)
- (b) Primary judgment (**PJ**) [295] (CAB 1/107)
- (c) Settlement Agreement (Appellant's Book of Further Materials 2/13)
- (d) Sandoz's submissions in S22/2021 (**SS**) [18]-[23], [25]-[26]

2. **Object of the agreement:** objectively considered, the object of the agreement was a comprehensive disposal of all current and future disputes between Sandoz and Lundbeck relating to the proceedings, including releases of any claims Lundbeck may have. In return, Sandoz granted releases and gave up its right to seek revocation of the Patent, a central defence to any future infringement claim. In that context, cl 3 established circumstances in which Sandoz would be free to sell its products without fear of infringement.

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- (a) FCJ [21]-[23], [64], [69] (CAB 10/251, 262-264)
- (b) SS [19], [33]

3. **The surrounding circumstances:** as the primary judge held, the provisions of the *Patents Act* formed part of the background knowledge available to the parties at the time of the Settlement Agreement. On that basis it was objectively possible that Lundbeck might seek an extension of term based on Cipramil, in circumstances where the Patent could first expire before such extension was granted. The express terms of cl 3(1)(a) accommodated that possibility, which as at February 2007 was "*objectively remote*".

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- (a) FCJ [69] (CAB 10/264)
- (b) PJ [260], [291]-[293] (CAB 1/97, 106-107)
- (c) SS [13]-[14], [39], [41], [43]-[45], [87]

4. **Nature of the licence:** a licence is a permission or freedom to do something that might otherwise be unlawful. Here, the licence in cl 3(1) was to “*the Patent*”, which carried with it contingent rights in respect of the period covered by s 79. Those rights arose on the grant of the Patent and were capable as at February 2007 of being the subject of a permission or freedom to engage in acts which might otherwise infringe. The Patent, and thus the licence, did not cease to exist, or become spent, on expiry of the 20 year term.
- (a) *Banks v Transport Regulation Board* (1968) 119 CLR 222 at 230 (JBA Pt C 10/307)  
 (b) *Grain Pool v Cth* (2000) 202 CLR 479 at [83]-[85] (JBA Pt C 13/444)  
 (c) FCJ [50]-[54] (CAB 10/259-260)  
 10 (d) See also PJ [183(2)], [187], [191], [193] (CAB 1/70-73)  
 (e) SS [29], [49]-[55]
5. **No basis for implied term:** the result contended for by Lundbeck requires that there be a term implied into cl 3(1)(a) to the effect that the licence terminated two weeks after it commenced. There is no basis for implying such a term. It would not be reasonable and equitable; necessary to give business efficacy; or so obvious that ‘it goes without saying’. It would be unacceptably uncertain in its operation in that, if the Patent were to expire before an extension was granted, it would likely not be known for an indefinite period of time thereafter whether the extension would be granted, and thus whether Sandoz could continue to sell. And it would contradict the express terms of cl 3(1), which provides that  
 20 the licence is “*from*” a particular date, is irrevocable, and has no end date.
- (a) *BP Refinery v Hastings* (1977) 180 CLR 266 at 283 (see SS [27])  
 (b) FCJ [65] (CAB 10/263)  
 (c) SS [27]-[28], [30]-[48]
6. **Allocation of risk:** there is no reason why the parties should be taken to have agreed, as at February 2007, that Sandoz should bear the risk of a post-expiry extension of term arising. The agreed language required that Lundbeck bear that risk. The uncertainty of such a licence (see para 5 above) would have been unacceptable. The timing of and basis for any application for a post-expiry extension of term was within the knowledge and control of  
 30 Lundbeck, not Sandoz, and would require a lengthy extension of time with an exercise of discretion in Lundbeck’s favour and proof of an “*error or omission*” on its part.
- (a) FCJ [65] (CAB 10/263)  
 (b) SS [41]-[46]; see also [15]
7. **The extrinsic evidence:** the pre-contractual correspondence does not assist Lundbeck. The parties’ subjective intentions are irrelevant. There is nothing in the notion of a “*two weeks early entry*” licence that Sandoz may have to exit the market two weeks after entering it; the purpose of entering a market is to stay in it. The change from “*the invention the subject of the Patent*” to “*the Patent*” does not affect the analysis; the source of the licensed rights remained the same. The internal Sandoz documents from 2009 are irrelevant.
- (a) FCJ [50]-[54] (CAB 10/259)  
 40 (b) SS [34]-[35], [47], [54]-[55]
8. **The decisions below:** the primary judge erred in reading down cl 3(1) to refer only to the Patent “*before it has expired*”. The Full Court correctly held her Honour erred and gave effect to the express terms of cl 3(1)(a) in the context of the agreement as a whole.
- (a) FCJ [55]-[58], [64], [67]-[69] (CAB 10/260-264)  
 (b) PJ [296], [298] (CAB 1/107-108)  
 (c) SS [57]-[70]

**B. THE EXCLUSIVE LICENSEE ISSUE**

9. The words of s 79 are clear: only “*the patentee*” has the right to start proceedings in respect of acts occurring after the expiry of a patent but before a subsequent extension of term is granted. In contrast to s 120, no such right is conferred on an exclusive licensee. Further, ss 13 and 78 confer no right to start proceedings, and do not refer to an exclusive licensee at all. This result is not anomalous: s 79 confers an exceptional, retrospective right of action which arises only after a post-expiry extension of term is granted.

- (a) FCJ [98]-[105], [107]-[110] (CAB 10/276-279)  
 (b) PJ [187]-[189], [191]-[193] (CAB 1/71-73)  
 (c) SS [79]-[86]

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**C. THE INTEREST ISSUE**

10. The infringement cause of action arises under s 79, which provides that if a patent expires before an extension of term application is granted, “*the patentee has, after the extension is granted, the same rights to start proceedings ...*”. Thus the cause of action does not arise until the extension is granted. Interest runs from that date.

- (a) FCJ [140]-[146] (CAB 10/289-291); cf PJ [532] (CAB 1/178)  
 (b) SS [72]-[78]  
 (c) *Sevcon v Lucas Cav* [1986] 1 WLR 462 at 467D-E (JBA Pt D 18/555)  
 (d) *Patents Act 1949* (UK), s 13(4) (JBA Pt B 9/293)

**D. THE ACL/TPA CLAIM ISSUE**

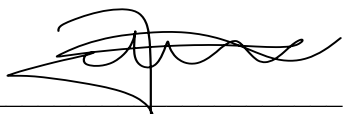
11. The primary judge erred in awarding damages for misleading conduct on the footing that Sandoz made “*an implied misrepresentation that its products did not infringe any patent*”. No such representation was implied by the sale of Sandoz’s products. Such a representation would not have been misleading, as the Patent had expired so the products did not infringe, and the risk that Lundbeck might one day have retrospective rights to sue was remote. And the claimants did not establish loss or damage, as there was no evidence pharmacists would have declined to purchase the products if informed of that remote possibility.

- (a) Australian Consumer Law, ss 18, 236 (JBA Pt B 4/269)  
 (b) *Trade Practices Act 1974* (Cth), ss 52, 82 (JBA Pt B 5/273)  
 (c) Cf the authorities cited at PJ [538]-[545] (CAB 1/180-182)  
 (d) Sandoz’s submissions in S23/2021 [7]-[18]

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**E. OTHER MATTERS**

12. Any orders made by this Court remitting the matter should preserve the ability of Sandoz to seek to rely, if necessary, on the separate licence which has been granted in its favour by the Commissioner of Patents under s 223(9) of the Act: see SS [16]-[17].

**8 October 2021**


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