HIGH COURT OF AUSTRALIA

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Details of Filing

File Number:	S23/2021
File Title:	CNS Pharma Pty Ltd v. Sandoz Pty Ltd
Registry:	Sydney
Document filed:	Form 27E - Reply
Filing party:	Appellant
Date filed:	03 Jun 2021

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IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN: **CNS Pharma Pty Ltd (ACN 121 515 400)**
Appellant

and

Sandoz Pty Ltd (ACN 075 449 553)
Respondent

APPELLANT'S REPLY

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

Part II: The Appellant (**CNS**) makes the following submissions in reply to the Respondent's submissions in answer dated 13 May 2021 (**CNS SS**).

The Settlement Agreement

1. Sandoz's main assertion in support of the proposition that CNS' appeal should fail appears to be that, when Sandoz made the relevant sales, the term of the Patent had not yet been extended (CNS SS [8], [9], [10], [16]). Sandoz seeks to use this temporal issue to distinguish this case from well-established line of authority in which similar claims have been upheld by the Federal Court (CNS SS [16] and [17]).[1] Neither the primary judge nor the Full Court made any statement doubting the applicability or correctness of that line of authority.

[1] See *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* [1995] FCA 1199, [77] – [90]; *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 44 IPR 481; *Sanofi-Aventis Australia Pty Ltd v Apotex Pty Ltd (No 3)* (2011) 196 FCR 1, [275] – [282]; *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)* (2012) 204 FCR 494, [91] and *Sandvik Intellectual Property AB v Quarry Mining & Construction Equipment Pty Ltd* (2016) 118 IPR 421, [272] – [277].

2. The answer to Sandoz's point is that when Sandoz launched its generic escitalopram product, it knowingly adopted the risk of infringement and was on notice that Lundbeck had applied to extend the term of the Patent.[2] Internally, Sandoz recognised the risks involved. In such circumstances, it was a misrepresentation for Sandoz to supply its generic escitalopram product without alerting its customers to the risk of infringement that Sandoz itself recognized and adopted.

3. Sandoz's acceptance of risk is reflected in the findings of the primary judge, based on the evidence before her,[3] that:

   (a) Sandoz made a calculated commercial decision to launch its products at risk, knowing that Lundbeck had applied for the extension of time and term, and knowing that the only purpose of Lundbeck in doing so was to be able to bring infringement proceedings;[4]

   (b) a person in Sandoz's position was not entitled to assume that Lundbeck would be unable to satisfy the contingencies to give it rights to enforce the Patent under s 79 of the *Patents Act 1990* (Cth);[5]

   (c) Lundbeck always made it plain to Sandoz that it would seek to secure its patent rights by applying for the extensions of time and term and would hold Sandoz liable for infringement;[6] and

   (d) Sandoz knew that if Lundbeck succeeded in obtaining the extension, it would sue for damages or an account of profits.[7]

4. The primary judge found that given the terms of s 79 and the facts before her, Sandoz achieved its sales to pharmacists on the basis of an implied misrepresentation that its

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[2] Contrary to the suggestion at CNS SS [10] that Sandoz only apprehended a risk of such applications.
[3] Ex 14 – slide deck titled "Escitalopram FCT AU Launch-at-risk" dated 17 June 2009, Appellants' Supplementary Book of Further Material (**ASFM**) tab 2; Ex 15 – email from James Sharkey to Dr Neels and Nicole Meissner dated 28 May 2009, ASFM tab 3; Ex 16 – email from James Sharkey to Dr Neels and Nicole Meissner dated 27 May 2009, ASFM tab 4; Ex 17– Sandoz Briefing Paper dated 5 June 2009, ASFM tab 5; Ex 18 – Sandoz email chain dated 15 June 2009, ASFM tab 6; Ex 19 – 3 June 2009 advice from Wayne Condon of Griffith Hack to Hajo Duken of Sandoz, ASFM tab 7; Ex 20 – Sandoz email chain dated 15 June 2009, ASFM tab 8; Ex 22 – advice from Wayne Condon of Griffith Hack to Hajo Duken of Sandoz dated 15 June 2011, ASFM tab 9; Ex 23 – Sandoz email chain dated 11 May 2012, ASFM tab 10; Ex 24 – email from Hajo Duken to Julia Pyke dated 10 May 2012, ASFM tab 11.
[4] Primary Judgment #1 [346], [348], CAB tab 1, 121–122.
[5] Primary Judgment #1 [358], CAB tab 1, 125.
[6] Primary Judgment #1 [359], CAB tab 1, 125.
[7] Primary Judgment #1 [526], CAB tab 1, 175–176.

products did not infringe any patent, but the products would infringe when and if the extension were granted.[8]

5. It may also be noted Sandoz's submissions in relation to the question of the *Australian Consumer Law* / *Trade Practices Act* claim (especially CNS SS [9], [10], [11] and [17]) stand in stark contrast to its submissions on the question of the construction of the Settlement Agreement (**Lundbeck SS**), where Sandoz accepts that its actions in selling escitalopram between June 2009 and December 2012 were contingently unlawful (Lundbeck SS [53], [54]). It is also contradicted by its own internal documents and legal advice from April to June 2009, where Sandoz:

10 (a) described its strategy as taking "a calculated risk" in circumstances where there was "uncertainty over Sandoz' rights";[9]

(b) obtained external legal advice that launch by Sandoz was at risk (*inter alia* because Lundbeck could apply for an extension of time and an extension of term) and that Sandoz' exposure was to a damages claim by Lundbeck;[10]

(c) undertook an internal analysis of the merits of "Launch-at-risk", which identified the risk that Lundbeck would apply for an extension of time to seek an extension of term;[11] and

(d) prepared a briefing note which identified that Lundbeck had announced its intention to seek an extension of term based on citalopram.[12]

20 6. Sandoz's position is also inconsistent with its internal documents and legal advice received in the period between June 2009 and December 2012, where Sandoz's:

(a) external lawyers told it that Lundbeck stood a very good chance of obtaining an extension of term, in which case it would be entitled to commence proceedings for infringement against Sandoz, from the date of launch until 9 December 2012 and the court was likely to find that the products infringed;[13]

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[8] Primary Judgment #1 [545], CAB tab 1, 182.
[9] Ex 15 – email from James Sharkey to Dr Neels and Nicole Meissner dated 28 May 2009, ASFM tab 3.
[10] Ex 19 – advice from Wayne Condon of Griffith Hack to Hajo Duken of Sandoz dated 3 June 2009, ASFM tab 7.
[11] Ex 14 – slide deck titled "Escitalopram FCT AU Launch-at-risk" dated 17 June 2009, ASFM tab 2.
[12] Ex 17 – Sandoz Briefing Paper dated 5 June 2009, ASFM tab 5.
[13] Ex 22 – advice from Wayne Condon of Griffith Hack to Hajo Duken of Sandoz dated 15 June 2011, ASFM tab 9.

(b) Head of Global IP Litigation identified that Sandoz should have considered its launch at risk;[14]

(c) Head of Global IP litigation identified that Sandoz knew at launch about the possibility of an extension of term and the fact that Lundbeck had applied to have its extension of term "amended", and had assessed its potential damages;[15] and

(d) Head Legal Counsel identified that the Settlement Agreement was not considered by the Australian legal team as "a weapon that will guarantee us victory" in a damages proceeding.[16]

7. In response to CNS SS [11]–[15], in all the circumstances (including most pertinently the fact that Sandoz was far more knowledgeable about about the risks of its sale of the product than pharmacists could objectively be expected to be), pharmacists had a reasonable expectation that if Sandoz knew that there was a risk that the product infringed a patent, it would inform them.[17] Sandoz's failure to inform customers is particularly problematic in circumstances where, as Sandoz was aware, Lundbeck was unable to commence proceedings seeking interlocutory or final injunctive relief or threaten to do so.

8. Sandoz's submission at CNS SS [11]–[12] that Lundbeck did not discharge its onus in relation to this case is misconceived. Lundbeck relied on settled authority that:[18]

> [w]here a representation is relevant to the decision in question, and in its nature persuasive to induce the making of that decision, it accords with legal notions of causation to hold that it has a causative effect. And where a respondent, who may be taken to know his own business, has thought it was in his interests to misrepresent the situation in a particular respect, the Court may infer that the misrepresentation was persuasive.

9. Having been notified of Lundbeck's reliance on this inference in opening submissions at trial,[19] Sandoz elected not to adduce evidence to the contrary or cross-examine

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[14] Ex 23 – Sandoz email chain dated 11 May 2012, ASFM tab 10.
[15] Ex 23 – Sandoz email chain dated 11 May 2012, ASFM tab 10.
[16] Ex 24 – email from Hajo Duken to Julia Pyke dated 10 May 2012, ASFM tab 11.
[17] See *Demagogue Pty Ltd v Ramensky* (1992) 39 FCR 31 at 40; *Miller & Associates Insurance Broking Pty Ltd v BMW Australia Finance Ltd* (2010) 241 CLR 357 at [17] to [20], [91].
[18] Primary Judgment #1, [541], CAB tab 1, 180–181, quoting *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 44 IPR 281; [1999] FCA 898, [68].
[19] See Lundbeck's Outline of Opening Submissions dated 3 April 2018, [49] n 90.

Lundebck's witness on this point, nor even to confront the line of authorities put against it.[20] Any forensic shortcoming is Sandoz's, and Sandoz's alone.

10. Sandoz's contention at CNS SS [16]–[17] that these authorities should be distinguished on the basis that they did not concern s 79 cases can be readily rejected. Sandoz itself (together with other generics) opposed Lundbeck's applications for the extensions of time and term and delayed the ultimate grant of the extension of term for several years – as it was entitled to do. Having done so, however, it cannot enlist the delay caused by its actions as an answer to the primary judge's findings of liability.

10 Dated: 3 June 2021

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[20] Primary Judgment #1, [538]–[545] (in particular [545]), CAB tab 1, 180–182.