



HIGH COURT OF AUSTRALIA

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Details of Filing

File Number: S23/2021
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Registry: Sydney
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Filing party: Respondent
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Important Information

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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: **CNS PHARMA PTY LTD** (ACN 121 515 400)
Appellant
and
SANDOZ PTY LTD (ACN 075 449 553)
Respondent

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RESPONDENT'S SUBMISSIONS

Part I: Certification

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

Part II: Issues

2. The issue arising on CNS Pharma's claim is whether Sandoz's sales of escitalopram products in the period when the Patent was not on foot constitute misleading or deceptive conduct. This forms ground 2 of the notice of contention.

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

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

10 **Part IV: Facts**

4. It is sufficient to proceed on the basis of the facts stated in the Applicants' submissions in the Lundbeck Proceeding dated 15 April 2021 (LS), the Applicant's submission in the CNS Pharma proceeding dated 15 April 2021 (CS), and the Respondent's submissions in the Lundbeck Proceeding dated 6 May 2021 (SS). Capitalised terms used in this submission have the same meanings as in SS.

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

5. CNS Pharma's claim cannot succeed if the patent claims made by Lundbeck fail. In that respect, Part V of SS is equally applicable to these submissions.
6. Further, even if the patent claim were to succeed, CNS Pharma's claim should fail,
20 for the reasons set out in Part VI below.

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

Misleading or deceptive conduct (notice of contention, ground 1) (Lundbeck Proceeding notice of contention, ground 2)

7. CNS Pharma's claim (and Lundbeck's claim) for misleading or deceptive conduct in contravention of s 18 of the *Australian Consumer Law (ACL)* and s 52 of the *Trade Practices Act 1974 (Cth) (TPA)* was premised on the patent claim, in that it relied upon an alleged misrepresentation by a seller that the goods do not infringe the Patent. Accordingly, it could not succeed if the Patent claim failed. Its forensic

significance was in particular that it would provide a cause of action akin to patent infringement to parties who do not have standing under the Patents Act.

8. Whether a representation is misleading or deceptive is a question of fact, to be determined at the time the alleged representation is made. Because of the unusual chronology of this case, temporal considerations are critical to the analysis of the ACL/TPA claim.
9. The primary judge found that Sandoz achieved its sales to pharmacists “*on the basis of an implied misrepresentation that its products did not infringe any patent*”: PJ [545]¹ (emphasis added). The terms of that representation are important. It is a representation as to *present* fact at the time of sale of the products. The primary judge erred in finding that such a representation was misleading because, at that time, the Patent had expired, no extension had been granted, it was unknown whether any extension would be granted, Lundbeck had no right to commence proceedings, and accordingly, the products did not in fact infringe any patent. A representation of present fact in those terms could not found an ACL/TPA claim.
10. Rather, at the time of sale of the products commencing in June 2009, there existed a possibility that Lundbeck may apply for an extension of time within which to seek an extension of term and, if successful on that application, a possibility that it might successfully seek an extension of term. As submitted in SS, the primary judge positively found that risk, objectively considered as at February 2007, to be “*remote*”. It was plainly also remote as at June 2009, when neither an extension of time nor an extension of term had been granted, and Lundbeck required an even greater indulgence from the Commissioner because the extension of time Lundbeck needed was more than two years longer, making a total of 10 years. (Indeed, the question whether the Commissioner had the power under the Act to grant the extension of time sought was ultimately determined by a divided, 3:2 judgment of this Court.) Further, if Lundbeck were successful in obtaining both, it was by no means certain that Lundbeck would at that time start proceedings against pharmacists (the purchasers), and indeed, it has never done so. It follows that, considered as at June 2009, the risk that a pharmacist would later be sued by Lundbeck in relation to its dealings with those products involved remoteness upon remoteness (and never in the real world actually occurred). The question is whether

¹ CAB tab 1, 182.

Sandoz, by not warning pharmacists of that possibility, engaged in misleading or deceptive conduct causing damage to Lundbeck.

11. Lundbeck bore the onus of establishing that case. Though it called a pharmacist during each of the hearings before the primary judge, it did not adduce any evidence from them as to what they understood or assumed the vendor was representing, when it sold escitalopram products in the absence of such a warning. No evidence was adduced as to whether the pharmacist understood the vendor was warranting that a third party could never obtain rights to sue the pharmacist (or anyone else). No evidence was adduced as to whether, if they *had* been warned as to the particular remote risk in this case, they would have chosen not to purchase the products in the face of that risk.
12. No doubt Lundbeck had its own forensic reasons for not adducing that evidence. However, in the absence of it, those propositions cannot be presumed, and Lundbeck's burden was not discharged.
13. It may be observed in this respect that the primary judge found that Sandoz's decision to launch notwithstanding the risk was reasonable in the circumstances, in particular because of the remoteness of the risk PJ [337], [338].² One might infer that a pharmacist, acting reasonably, would also not have refrained from purchasing the products, particularly as the risk of a pharmacist being sued by Lundbeck was even more remote than Sandoz being sued. In any event, it certainly cannot be inferred, without evidence, that the pharmacist would have assumed that there was no risk or that, in the face of the remote risk, they would have refrained from purchase.
14. More generally, having regard to the principle of *caveat emptor* a vendor would not normally be taken, merely by selling a product, to be warranting that the product does not infringe an intellectual property right, which is yet to be acquired and may never be. One would not ordinarily imply such a term into a commercial contract as required for the purposes of business efficacy: it is the purchaser's risk, and if a warranty of that kind is desired by a purchaser to reduce its risks, it can be sought expressly. In those circumstances, a suggestion that misleading conduct would arise under the ACL/TPA ought to be treated with caution: See *Kimberley NZI Finance Ltd v Torero Pty Ltd* (1989) ATPR (Digest) 46-054 at 53,195 per French J;

² CAB tab 1, 119 - 120.

Demagogue Pty Ltd v Ramensky (1992) 39 FCR 31 at 41; *ASIC v ActiveSuper Pty Ltd (in liq)* (2015) 235 FCR 181 at [388].

15. Indeed, the Full Court authority in this field, as referred to by the primary judge (PJ [538]-[543],³ citing *Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1999) 164 ALR 239 at [66]-[68] and *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd (No 2)* (2012) 204 FCR 494 at [91]) warrants some scrutiny because it does not provide a satisfactory answer to the question why the supplier of a product should be taken to be representing that it does not infringe a patent.

10 16. However that may be, the present case is critically different from *Ramset* and *Sanofi-Aventis* because those were not s 79 cases. The primary judge erred in holding otherwise: PJ [545].⁴ Those cases involved a patent which was in force at the time of sale of the products and accordingly, there was contemporaneous infringement. Her Honour put this distinction to one side by relying upon what may be imprecisely described as the backdating effect of s 79. Relevantly, s 79 permits a patentee to sue, after an extension of term is granted, in respect of certain acts committed before the extension was granted. It does not change the facts which existed at the time those acts were done. It also does not retrospectively affect the operation of the ACL/TPA, which requires determining whether the alleged acts
20 were misleading or deceptive at the time those acts were done.

17. At the time of the alleged misrepresentation, the preconditions for the operation of s 79 had not been satisfied (the grants of an extension of time and an extension of term), and it was not known whether they would be satisfied. Indeed, that was only a remote prospect. The error of the reasoning is that it treats as certain that which was at the time of the alleged representation not certain, and indeed unlikely to occur. That makes this case very different from *Sanofi-Aventis* and *Ramset*. (It may also be observed that neither of those cases involved an entity asserting an ACL/TPA claim which had no standing to sue for patent infringement, as CNS Pharma does here; a matter which would also warrant caution.)

30 18. Before the Full Court, the ACL/TPA case fell away because the patent case failed. Accordingly, the Full Court did not need to consider these matters. This Court should do so if necessary.

³ CAB tab 1, 180 - 181.

⁴ CAB tab 1, 182.

Part VII: Estimate of Time


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

Dated 13 May 2021

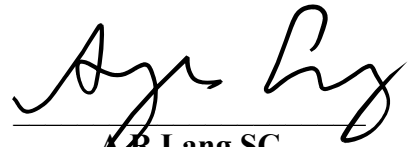
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ANNEXURE

Australian Consumer Law, Sch 2 to Competition and Consumer Act 2010 (Cth) (as at 4 August 2020): s 18

Patents Act 1990 (Cth) (as at 4 August 2020): s 79

Trade Practices Act 1974 (Cth) (as at 15 June 2009): s 52