



HIGH COURT OF AUSTRALIA

9 March 2021

H. LUNDBECK A/S & ANOR v SANDOZ PTY LTD
CNS PHARMA PTY LTD v SANDOZ PTY LTD
[2022] HCA 4

Today, the High Court delivered judgment in two related appeals from a decision of the Full Court of the Federal Court of Australia ("the Full Court") each on appeal from a single justice of that Court concerning the extension under the *Patents Act 1990* (Cth) ("the Act") of the term of a patent relating to the pharmaceutical substance escitalopram ("the Patent"). The Court unanimously allowed one appeal ("the Lundbeck appeal") primarily on the basis that the Full Court misconstrued the effect of a settlement clause between the parties. The Court unanimously dismissed the other appeal ("the Pharma appeal") holding that the Full Court was correct to find that the respondent had not engaged in misleading or deceptive conduct.

The appellants in the Lundbeck appeal were H. Lundbeck A/S ("Lundbeck Denmark") a Danish pharmaceutical company and its Australian subsidiary ("Lundbeck Australia"). Lundbeck Denmark was the owner of the Patent. Lundbeck Australia held an exclusive licence of the Patent. The appellant in the Pharma appeal, CNS Pharma Pty Ltd ("Pharma"), was a subsidiary of Lundbeck Australia, which sold a generic product containing escitalopram in Australia. The respondent in both appeals, Sandoz Pty Ltd ("Sandoz") was a supplier of generic pharmaceuticals products. When the Patent was due to expire in June 2009 Lundbeck Denmark applied under the Act to extend the term until December 2012; this extension was subsequently granted in 2014. During the extended term Sandoz sold generic escitalopram products. In 2014 Lundbeck Denmark and Lundbeck Australia commenced proceedings against Sandoz claiming that Sandoz had infringed the Patent by selling escitalopram during the extended term. Pharma also commenced proceedings against Sandoz claiming that Sandoz had engaged in misleading or deceptive conduct during the extended term by failing to warn its customers that their supply of generic escitalopram might infringe the Patent. The primary judge found against Sandoz in both proceedings. The Full Court allowed the appeals holding that none of Sandoz's sales amounted to acts of infringement as Sandoz held a non-exclusive licence to exploit the Patent through the operation of a settlement clause in an agreement that Sandoz had entered into with Lundbeck Denmark and Lundbeck Australia in 2007.

In the Lundbeck appeal, the High Court held that the Full Court had erred in its construction of the settlement clause. Properly construed, the settlement clause gave permission to Sandoz to sell the escitalopram products for the two week period before the expiry of the Patent's original term. Section 79 of the Act operated to confer substantive and exhaustive rights only on Lundbeck Denmark as the patentee to start proceedings against persons who had infringed an exclusive right to exploit the Patent during the extended term. Further, Lundbeck Denmark's cause of action under s 79 of the Act only accrued on the grant of the extension of the Patent in 2014. In the Pharma appeal, the Court held Sandoz's conduct did not amount to misleading or deceptive conduct as the evidence did not establish that its customers had the requisite reasonable expectation that they might be exposed to patent infringement proceedings for supplying Sandoz's escitalopram products.

- *This statement is not intended to be a substitute for the reasons of the High Court or to be used in any later consideration of the Court's reasons.*