

ALPHAPHARM PTY LTD v H LUNDBECK A/S & ORS (S97/2014)

Court appealed from: Full Court of the Federal Court of Australia
[2013] FCAFC 129

Date of judgment: 18 November 2013

Date of grant of special leave: 11 April 2014

Australian Patent No. 623144 (“the Patent”) claims the (+)-enantiomer component of citalopram, known as “escitalopram”, certain salts of it and methods for preparing it. The Patent was held by H Lundbeck A/S (“Lundbeck”), which had applied for it on 13 June 1989. Citalopram hydrobromide is marketed by Lundbeck as the anti-depressant drug Cipramil. Cipramil was first included in the Australian Register of Therapeutic Goods (“the ARTG”) on 9 December 1997. Lundbeck also markets escitalopram oxalate, as an anti-depressant drug known as Lexapro, which was first included in the ARTG on 16 September 2003 (“the Lexapro date”).

In December 2003 Lundbeck applied, under s 70 of the *Patents Act* 1990 (Cth) (“the Act”), to extend the term of the Patent. In purported compliance with s 71(2) of the Act, that application was made within six months of the Lexapro date. The Commissioner of Patents (“the Commissioner”), after finding that the relevant date for the application’s timeliness was the Cipramil date, not the Lexapro date, nevertheless extended the term of the Patent to 9 December 2012. The Appellant (“Alphapharm”) challenged that extension, on the basis that Lundbeck’s application had not been made within the time limit imposed by s 71(2) of the Act. That challenge succeeded in June 2008, when the Federal Court ordered that the Patent’s extension of term be removed from the Commissioner’s register. An appeal by Lundbeck to the Full Court of the Federal Court was dismissed, as was a subsequent application for special leave to appeal to this Court. The resulting position was that, by virtue of s 71(2)(c) of the Act, the latest within-time date on which Lundbeck could have applied to the Commissioner to extend the term of the Patent was 26 July 1999.

On 12 June 2009 Lundbeck lodged an application (“the Time Application”) with the Commissioner for an extension of time (from 26 July 1999) in which to apply afresh to extend the term of the Patent. On 13 June 2009 the Patent expired, upon which Alphapharm and the Third, Fourth and Fifth Respondents (together, “the Competitors”) immediately launched their own generic products containing escitalopram. On 1 June 2011 the Time Application was granted by a delegate of the Commissioner. The Competitors each applied to the Administrative Appeals Tribunal (“AAT”) for a review of that decision.

On 4 December 2012 the AAT (Deputy President Tamberlin & Senior Member Nicoletti) affirmed the delegate’s decision. The AAT found that Lundbeck had not acted unreasonably by relying on the Lexapro date in its first extension-of-term application, nor by its delay in making the Time Application (in the belief that the Federal Court’s orders of June 2008 would be set aside on appeal). The AAT also found that the Commissioner’s power under s 223(2) of the Act to

extend time for a “relevant act” had been properly exercised to grant the Time Application.

The Competitors together appealed to the Federal Court.

On 18 November 2013 a Full Court of the Federal Court (Jessup, Jagot & Yates JJ) unanimously dismissed the Competitors' appeal. Their Honours held that the AAT, having duly considered s 223(11) of the Act and reg 22.11(4)(b) of the *Patents Regulations* 1991 (Cth) ("the Regulations") had correctly found that the Commissioner had power under s 223(2) to extend the time limit set by s 71(2) of the Act. The Full Court found that the various conclusions reached by the AAT were open to it on the evidence before it. Their Honours also found that the AAT's exercise of its discretion in granting Lundbeck a ten-year extension of time had not miscarried.

On 13 June 2014 the Institute of Patent and Trade Mark Attorneys filed a summons, seeking leave to intervene in this matter as *amicus curiae*.

The ground of appeal is:

- The Full Court erred in finding that s 223(2)(a) of the Act conferred power on the Commissioner to extend the time within which Lundbeck could apply under s 70(1) of the Act for an extension of the term of the Patent having regard to the provisions of s 223(11) of the Act and reg 22.11(4)(b) of the Regulations.