HIGH COURT OF AUSTRALIA

CRENNAN, KIEFEL, BELL, GAGELER AND KEANE JJ

ALPHAPHARM PTY LTD APPELLANT

AND

H LUNDBECK A/S & ORS RESPONDENTS

Alphapharm Pty Ltd v H Lundbeck A/S
[2014] HCA 42
5 November 2014
S97/2014

ORDER

Appeal dismissed with costs.

On appeal from the Federal Court of Australia

Representation

S C G Burley SC with C Dimitriadis for the appellant (instructed by King & Wood Mallesons)

R M Niall QC with K J Howard SC for the first respondent (instructed by Corrs Chambers Westgarth Lawyers)

Submitting appearance for the second to fifth respondents

CATCHWORDS

Alphapharm Pty Ltd v H Lundbeck A/S

Intellectual property – Patents – Extension of term – Application to extend time for applying for extension of term of patent – Section 71(2) of *Patents Act* 1990 (Cth) required application for extension of term of patent to be made during term of patent and within six months after latest of three specified dates – First respondent made application for extension of term of patent during term of patent but more than six months after latest of three specified dates – Whether Commissioner of Patents had power to grant extension of time.

Words and phrases − "filing, during the term of a standard patent", "prescribed action", "relevant act".

Patents Act 1990 (Cth), ss 70(1), 71(2) and 223.
Patents Regulations 1991 (Cth), reg 22.11(4)(b).

1 CRENNAN, BELL AND GAGELER JJ. The issue in this appeal is whether s 223(2) of the *Patents Act* 1990 (Cth) ("the Act")[1] conferred power upon the second respondent, the Commissioner of Patents ("the Commissioner"), to extend the time within which the first respondent, H Lundbeck A/S ("Lundbeck"), may apply under s 70 of the Act for an extension of the term of its Australian Patent No 623144 ("the Escitalopram Patent")[2].

2 The appellant ("Alphapharm") appeals from a decision of the Full Court of the Federal Court of Australia dismissing an appeal from a decision of the Administrative Appeals Tribunal ("the Tribunal"). There were two questions before the Tribunal concerning s 223(2). The first was whether s 223(2)(a) conferred power on the Commissioner to grant an extension of time in respect of an application for an extension of term filed during the term of the patent. The second, which depended on the first question being answered "yes", was whether the Commissioner's delegate erred in exercising the discretion to grant Lundbeck an extension of time within which to make an application for an extension of the term of the Escitalopram Patent[3]. By its decision, the Tribunal affirmed the delegate's decision to grant Lundbeck an extension of time within which to apply for an extension of the term of the Escitalopram Patent, notwithstanding opposition to that extension of time from Alphapharm and the third to fifth respondents in this appeal[4].

3 On the grant of special leave[5], the appeal was limited to the question of whether 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) for an extension of the term of the Escitalopram Patent,

---

1 As in force at the time of the hearing before the Administrative Appeals Tribunal (13-17 August 2012).

2 That description distinguishes the Escitalopram Patent from Lundbeck's earlier Australian Patent No 509445 ("the Citalopram Patent") (described below) and conforms with the descriptions given to both in complex, related patent litigation. See *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618; *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151.

3 See Act, ss 207, 209 and 210.

4 *Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628.

5 *Alphapharm Pty Ltd v H Lundbeck A/S* [2014] HCATrans 079 (11 April 2014).

having regard to the provisions of s 223(11) of the Act and reg 22.11(4)(b) of the Patents Regulations 1991 (Cth) ("the Regulations")[6].

4 The Commissioner filed an appearance submitting to the jurisdiction of the Court.

Relevant provisions

5 Before setting out the detail of the relevant provisions it is convenient to make two general observations.

6 First, the statutory context is provided not only by s 223 of the Act and reg 22.11, both of which concern extensions of time, but also by Pt 3 of Ch 6 (ss 70-79A) of the Act, entitled "Extension of term of standard patents relating to pharmaceutical substances"[7] ("the extension of term scheme"), which came into operation on 27 January 1999.

7 Secondly, like all Australian patent legislation since 1903, the Act and the Regulations prescribe many time limits within which an act permitted to be done is required to be done. A measure of the complexity of some of the time limits can be gauged by the types of cases in which an extension of time has been found to be justified[8]. It is (and has been) commonplace for the legislature to cast many

---

6 As in force at the time of the hearing before the Tribunal. Both the Act and the Regulations have subsequently been amended, but not in a manner material to this appeal. Relevantly, the Regulations have been amended by the Intellectual Property Legislation Amendment (Raising the Bar) Regulation 2013 (No 1) (Cth).

7 The expression "pharmaceutical substance" is defined in the Act, Sched 1 – Dictionary.

8 See for example *Australian Paper Manufacturers Ltd v CIL Inc* (1981) 148 CLR 551; [1981] HCA 64 (extension of time for making an Australian application based on a Convention application); *Lehtovaara v Acting Deputy Commissioner of Patents* (1981) 39 ALR 103 (extension of time for acceptance of a standard patent); *Danby Pty Ltd v Commissioner of Patents* (1988) 82 ALR 491 (extension of time for lodging a notice of opposition to the grant of a patent); *Kimberly-Clark Ltd v Commissioner of Patents* (1988) 84 ALR 685 (affirming the width of s 160(2) of the *Patents Act* 1952 (Cth) but refusing an extension of time for lodging a notice of opposition to the grant of a patent). See also *Kimberly-Clark Corporation v Procter & Gamble Co* (1992) 24 IPR 345 (extension of time to file evidence in support of a notice of opposition); *Thomas v Jiejing Pty Ltd* (1994) 29 IPR 441 (extension of time for acceptance of a patent application); *Re Solar-Mesh Pty Ltd and Commissioner of Patents* (1995) 38 ALD 136 (extension of time for lodging a

(Footnote continues on next page)

such time limits in mandatory terms using the word "must"[9], including those prescribed in respect of an application (once a petition) for an extension of term[10]. However, the potential for inflexibility to occasion serious injustice is (and has been) addressed both by the general power to extend time, as in s 223 of the Act (and, before it, s 160 of the *Patents Act* 1952 (Cth) ("the 1952 Act")), and by specific discretionary provisions to extend times – especially those cast in permissive terms[11]. Regulation 22.11(4)(a) provides a handy example of the different ways of extending times: the time requirements cast in mandatory terms in regs 5.3, 5.3AA, 5.4(a), 5.8(1)(a)(i) and 5.9A can be extended under the general power to extend times in s 223(2); whereas the time requirements cast permissively for the "prescribed actions" in reg 22.11(4)(a) can be extended by the specific discretionary power in reg 5.10[12].

---

notice of opposition to the grant of a patent); *Re Sanyo Electric Co Ltd and Commissioner of Patents* (1996) 36 IPR 470 (extension of time for payment of renewal fee); *Re Application by Foldi* (1997) 38 IPR 131 (extension of time for payment of renewal fee for a patent); *Bausch & Lomb Inc v Allergan Inc* (1997) 39 IPR 541 (extension of time to file notice of opposition to the grant of a patent); *Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften EV v Amgen Inc* (1997) 40 IPR 325 (extension of time to oppose application for an extension of time to pay renewal fees). See further *Oz Technology Inc v Boral Energy Ltd* (1999) AIPC ¶91-480 (extension of time for filing a notice of opposition to the grant of a patent). A similar point has been made in respect of applications for extensions of time made to the European Patent Office and the United Kingdom Intellectual Property Office in Cornish, Llewelyn and Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 8th ed (2013) at 168 [4-23].

9 For an example from the Regulations, see regs 5.3, 5.3AA, 5.4(a), 5.8(1)(a)(i) and 5.9A.

10 For an early example, see s 84(1) of the *Patents Act* 1903 (Cth) ("the 1903 Act"), considered in *In re Robinson's Patent* (1918) 25 CLR 116 at 137-138; [1918] HCA 35.

11 Earlier examples include s 84(7) of the 1903 Act (as amended by the *Patents Act* 1921 (Cth)) and ss 59(1) and 90(1) of the 1952 Act; reg 5.10 is a more recent example.

12 Regulation 5.10 provides a power to extend a "period prescribed ... by such further period as the Commissioner reasonably allows".

Extension of time

8 Section 223, headed "Extensions of time", is a provision of general application. It is found in Ch 22 (ss 212-230), and relevantly provides:

> "(2) Where, because of:
>
> (a) an error or omission by the person concerned or by his or her agent or attorney; or
>
> (b) ...;
>
> a relevant act that is required to be done within a certain time is not, or cannot be, done within that time, the Commissioner may, on application made by the person concerned in accordance with the regulations, extend the time for doing the act.
>
> ...
>
> (3) The time allowed for doing a relevant act may be extended, whether before or after that time has expired.
>
> ...
>
> (6) ... a person may, as prescribed, oppose the granting under subsection (2) ... of the application.
>
> ...
>
> (11) In this section:
>
> ***relevant act*** means an action (other than a prescribed action) in relation to a patent, a patent application, or any proceedings under this Act (other than court proceedings), and includes the making of a Convention application within the time allowed for making such applications."

9 Section 223 resembles, without duplicating, s 160 of the 1952 Act (as amended by s 28 of the *Patents Act* 1960 (Cth) and s 7 of the *Patents Amendment Act* 1989 (Cth) ("the 1989 Act")). In particular, s 223(2) follows closely the text and structure of s 160(2), but in plain English.

10 Regulation 22.11 is directed to the Commissioner's power to grant an extension of time under s 223. The expression "relevant act" is employed in sub-ss (1), (2), (2A), (3), (3A), (7), (9) and (11) of s 223, invariably to identify a

time by which a relevant act is required to be done. Regulation 22.11(4)[13] isolates "prescribed actions" so as to exclude certain time requirements from the remedial power under s 223 to extend times:

> "For the definition of ***relevant act*** in subsection 223(11) of the Act, each of the following actions is prescribed:
>
> (a) an action or step prescribed in Chapter 5, other than an action or step taken under regulation 5.3 or 5.3AA, paragraph 5.4(a), subparagraph 5.8(1)(a)(i) or regulation 5.9A;
>
> (b) filing, during the term of a standard patent as required by subsection 71(2) of the Act, an application under subsection 70(1) of the Act for an extension of the term of the patent;
>
> (c) ..."

11 It should be noted that the period for which an extension of time is needed may be considerable, particularly if the application is opposed.

The extension of term scheme

12 As mentioned, Pt 3 of Ch 6 contains the statutory scheme for an extension of term. Section 70 governs applications for an extension of term. Relevantly, s 70(1) permits a patentee of a standard patent to apply to the Commissioner for an extension of the term[14] of a standard patent if "requirements" set out in sub-ss (2), (3) and (4) are satisfied ("a s 70(1) application"). In essence, a patentee is not permitted to make a s 70(1) application until a patent for a pharmaceutical substance is granted *and* regulatory approval for marketing relevant goods has been obtained.

13 For present purposes, the most important of the cumulative requirements are that goods "containing, or consisting of" a pharmaceutical substance *per se*[15] must be included in the Australian Register of Therapeutic Goods ("the

---

13 As previously noted, the Regulations, including reg 22.11(4), have been amended since the hearing before the Tribunal.

14 The determination of "the term" is governed by ss 65(a) and 67 considered together.

15 Act, s 70(2)(a) and (3)(a).

ARTG")[16], and the first regulatory approval[17] for the substance must be at least five years after the date of the patent[18]. Further, the term must not have been previously extended under Pt 3 of Ch 6 of the Act[19].

14 Section 71(1) prescribes the *form*, and s 71(2) prescribes the *timing*, in respect of a s 70(1) application. Section 71(2) provides:

> "An application for an extension of the term of a standard patent must be made during the term of the patent and within 6 months after the latest of the following dates:
>
> (a) the date the patent was granted;
>
> (b) the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain, or consist of, any of the pharmaceutical substances referred to in subsection 70(3);
>
> (c) the date of commencement of this section."

15 The requirement that a s 70(1) application be made during the term of the patent will be referred to in these reasons as "the first time requirement". The requirement to make such an application within six months after the latest of the dates specified in s 71(2)(a), (b) and (c) will be referred to as "the second time requirement".

16 Paragraphs (a) and (b) of s 71(2) cover the circumstance of a patentee whose patent is granted on or after 27 January 1999, who may not apply for an extension of term under s 70(1) until a patent has been granted *and* a regulatory approval obtained. The order in which these two conditions are satisfied may vary from patent to patent. Paragraph (c) is directed to patentees whose patent was granted *and* a first regulatory approval was obtained before the commencement date of Ch 6, being 27 January 1999, making the relevant date under s 71(2)(c) 26 July 1999.

---

16 Act, s 70(3)(a).

17 See Act, s 70(5).

18 Act, s 70(3)(b).

19 Act, s 70(4).

17 A notice must be placed in the Official Journal that a s 70(1) application has been made and that the application is open to public inspection[20]. The Commissioner must accept a s 70(1) application if the Commissioner "is satisfied that the requirements of sections 70 and 71 are satisfied in relation to the application"[21] and, if so satisfied, publish a notice of the acceptance in the Official Journal[22]. Interested parties may oppose the grant of an extension of term on the ground that one or more of the requirements of ss 70 and 71 are not satisfied[23]. The Commissioner must grant the extension of term if there is no opposition to the grant or if, in spite of opposition, the Commissioner's decision is that an extension should be granted. In that case a notice of grant must be published in the Official Journal[24].

18 Section 77 provides for the calculation of any extension of term by reference to the period between the date of the patent and the earliest first regulatory approval date, reduced by five years, so long as that does not result in a figure below zero[25]. However long the period of regulatory delay, the maximum extension of term permitted is five years[26]. The Commissioner may not grant an extension of term if "relevant proceedings in relation to the patent are pending"[27].

19 It is important to note that the interests of persons who may be affected by an extension of term are protected. A competitor who exploits a pharmaceutical substance during the term of a patent (including an extended term) for "purposes connected with obtaining the inclusion in the [ARTG] of goods" (colloquially, "springboarding") will not, subject to the satisfaction of various conditions,

---

20 Act, s 72.

21 Act, s 74(1).

22 Act, s 74(2)(b).

23 Act, s 75.

24 Act, s 76.

25 Act, s 77(1).

26 Act, s 77(2).

27 Act, s 79A.

infringe the patentee's exclusive rights[28]. A patentee is protected against the circumstance that an extension of term is granted after a patent term has expired[29].

20 Regulations 6.8 to 6.11 are directed to the Commissioner's power to extend the term of certain patents under Pt 3 of Ch 6 of the Act and prescribe the "information" and documents which must "accompany" a s 70(1) application (that is, which must be "filed" with the s 70(1) application)[30].

The issue

21 The issue mentioned at the outset of these reasons comes down to competing constructions of reg 22.11(4)(b). Does reg 22.11(4)(b) exclude from s 223(2)(a) both of the time requirements in s 71(2) (Alphapharm's construction), or only the first time requirement – that an application for an extension of term must be made "during the term of the patent" (Lundbeck's construction)? There was no dispute that the regulation excludes the first time requirement from s 223(2)(a).

22 These reasons will show that Lundbeck's construction is correct and that the appeal should be dismissed. Notwithstanding an awkwardness in its reasoning, the Full Court was correct to conclude that the Commissioner has power under s 223(2) to extend the time requirement calculated by reference to s 71(2)(a), (b) and (c).

The background facts

23 A little more needs to be said about the Escitalopram Patent. Lundbeck, a Danish pharmaceutical company, applied for the Escitalopram Patent[31] on 13 June 1989 (the expiry date of which became 13 June 2009[32]), for an invention

---

28 Act, s 119A, which came into operation on 25 October 2006 pursuant to the *Intellectual Property Laws Amendment Act* 2006 (Cth). Section 119A's narrower predecessor provision, s 78(2), continues to apply to any exploitation of patents that occurred prior to the commencement of s 119A.

29 Act, s 79.

30 See, for example, regs 6.8 and 6.11(5).

31 As a Convention application; see Act, Ch 8, Pt 2.

32 Pursuant to the operation of s 4 of the *Patents (World Trade Organization Amendments) Act* 1994 (Cth) ("the 1994 Act"), amending s 67 of the Act.

(Footnote continues on next page)

entitled "(+)-Enantiomer of citalopram and process for the preparation thereof". There are six claims – claims 1 to 5 are product claims and claim 6 is a method claim, which, for present purposes, can be put to one side[33]. Claim 1 claims a compound (an enantiomer) known as "(+)-citalopram" and its non-toxic acid addition salts, and claims 3 and 5 claim a pharmaceutical composition comprising, as an active ingredient, that compound. The pharmaceutical substance disclosed in the complete specification, (+)-citalopram, is used to treat depression[34].

24 Citalopram, a racemate, also an invention of Lundbeck's, is the subject of the Citalopram Patent, dated January 1977 (the term of which was originally 16 years from that date[35]). A racemate, or racemic mixture, comprises two enantiomers in equal measure. Enantiomers are non-superimposable mirror images of each other and are designated (+) or (-) based on how they rotate polarised light. On 9 December 1997, Lundbeck's local subsidiary successfully obtained the inclusion of a pharmaceutical product called CIPRAMIL in the ARTG based on the Citalopram Patent. CIPRAMIL comprises two enantiomers: (+)-citalopram; and the mirror image enantiomer (-)-citalopram. On 16 September 2003, Lundbeck's local subsidiary successfully obtained the inclusion in the ARTG of a second pharmaceutical product, LEXAPRO, based on the Escitalopram Patent, which consisted of (+)-citalopram. In the complete specification of the Escitalopram Patent, it was explained that the isolated

---

Section 67 provides: "The term of a standard patent is 20 years from the date of the patent." The "date of the patent", in this case, is the date of filing of the relevant complete specification (s 65(a)).

33 Relevantly, the extension of term scheme under the Act covers standard patents for pharmaceutical substances *per se* pursuant to s 70(2)(a), hence patents for pharmaceutical methods or tablets do not fall within the scheme. It can be noted that pharmaceutical substances produced by a process that involves the use of recombinant DNA technology, the subject matter of s 70(2)(b), are not relevant to this case.

34 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618 at 625-627 [2]-[10].

35 As explained below, until 1995, the term of a patent was 16 years and the increase of the term from 16 to 20 years occurred as a result of Australia's membership of the World Trade Organization and obligations under Art 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which is Annex 1C to the Marrakesh Agreement establishing the World Trade Organization [1995] ATS 8, which entered into force in Australia and generally on 1 January 1995.

enantiomer (+)-citalopram is "therapeutically more active" and "more than 100 times more effective" in treating depression than the racemate[36].

Lundbeck's first application to extend the term

25 On 22 December 2003 (thus, "during the term"), Lundbeck made a s 70(1) application for an extension of the term of the Escitalopram Patent based on the inclusion of LEXAPRO in the ARTG three months earlier, on 16 September 2003 (which appeared to conform with the time limit in s 71(2)(b), set out above). Any application to extend the term of the Escitalopram Patent based on the earlier inclusion of CIPRAMIL in the ARTG was required to be made by 26 July 1999 so as to conform with the time limit in s 71(2)(c), also set out above. On 27 May 2004, the Commissioner granted the extension of term sought, based on the inclusion of LEXAPRO in the ARTG. Pursuant to s 77, the term was extended by five years to 13 June 2014 and an entry was made in the Register of Patents[37] ("the Register") to that effect.

26 On 7 July 2005, Alphapharm notified the Commissioner of the earlier inclusion of CIPRAMIL in the ARTG. On 13 July 2005, the Commissioner determined that Lundbeck's application to extend the term of the Escitalopram Patent should have been based upon the inclusion of CIPRAMIL, not LEXAPRO, in the ARTG. This had the effect (when s 77 was applied) of reducing the extension of the term of the Escitalopram Patent from 13 June 2014 to 9 December 2012.

Alphapharm's proceedings for revocation

27 One day earlier, on 6 July 2005, Alphapharm commenced proceedings in the Federal Court of Australia seeking revocation of the Escitalopram Patent[38] or, alternatively, rectification[39] of the Register by removal of the entry recording the extension of term (the latter on the basis that Lundbeck's application for the

---

36 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618 at 625 [5], 648 [110].

37 Act, s 186.

38 Pursuant to s 138 of the Act.

39 Pursuant to s 192 of the Act.

extension of term had been incorrectly founded upon the inclusion of LEXAPRO in the ARTG, as opposed to CIPRAMIL)[40].

28 The revocation proceedings initiated by Alphapharm included a sustained attack on the validity of the Escitalopram Patent, including attacks based on want of novelty and obviousness, citing as prior art the Citalopram Patent[41]. Lundbeck established the validity of claims 1, 3 and 5 of the Escitalopram Patent, which is important in the context of infringement[42].

29 Relevantly, on 24 April 2008, as part of those proceedings, the primary judge (Lindgren J) held that Lundbeck's application to extend the term of the Escitalopram Patent should have been based upon the inclusion of CIPRAMIL in the ARTG. The essential reason was that the racemate "contained" the pharmaceutical substance disclosed in the Escitalopram Patent[43]. The consequence was not merely that the term of the extension should be shorter (as the Commissioner's delegate had found), but rather that the Register needed to be rectified by removing the record of extension of term of the Escitalopram Patent as being void *ab initio*[44]. Lundbeck's subsequent appeal to a Full Court of the Federal Court on that point was dismissed[45], with final orders made on 12 June 2009. A subsequent application for special leave to appeal to this Court by Lundbeck was dismissed on 11 December 2009[46].

Lundbeck's second application to extend the term

30 Meanwhile, on 12 June 2009, after final orders had been made by the Full Court, and one day before the 20 year term of the Escitalopram Patent was due to expire[47], Lundbeck made a second s 70(1) application to the Commissioner to

---

40 A full account of these and related proceedings can be found in *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618.

41 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618 at 627 [11].

42 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618 at 739 [660], 746 [697].

43 Act, s 70(3)(a).

44 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618 at 718 [544].

45 *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151.

46 *Alphapharm Pty Ltd v H Lundbeck A/S* [2009] HCATrans 324.

47 In accordance with ss 65 and 67 of the Act.

extend the term of the Escitalopram Patent, this time based upon the inclusion of CIPRAMIL in the ARTG, coupled with an application under s 223(2) for an extension of time as required.

31 Following the expiration of the 20 year term of the Escitalopram Patent (13 June 2009), Alphapharm and the third to fifth respondents launched generic pharmaceutical products containing (+)-citalopram, the pharmaceutical substance disclosed in the complete specification. On 9 February 2010, the Commissioner amended the Register by removing the entry relating to the extension of term until 9 December 2012.

32 Consideration of the background facts shows: (1) Lundbeck experienced a relevant regulatory delay based on CIPRAMIL of nearly eight and a half years[48]; (2) the Federal Court litigation occupied the last four years of the term of the Escitalopram Patent, as extended by the 1994 Act; and (3) the extension of time sought by Lundbeck is from 26 July 1999 to 12 June 2009, being the date ("during the term") on which the second s 70(1) application was made.

33 The upshot is that if the extension of term sought is granted (which depends significantly on the grant of an extension of time), infringers will, subject to any defences, be liable for damages for infringement from 13 June 2009 until 9 December 2012 in respect of any sales of products containing the pharmaceutical substance disclosed in the Escitalopram Patent. Without objection, this Court was informed, on the oral hearing, that Alphapharm is exercising its rights to oppose the grant of an extension of term to Lundbeck[49].

The proceedings

34 Alphapharm and the third to fifth respondents opposed Lundbeck's application for the grant of an extension of time in respect of Lundbeck's second s 70(1) application[50]. These four oppositions were heard by a delegate of the Commissioner, and on 1 June 2011 the delegate granted Lundbeck the extension of time sought[51]. That decision was then appealed to the Tribunal.

---

48 From 13 June 1989 to 9 December 1997.

49 As it was permitted to do under s 75 of the Act.

50 Act, s 223(6).

51 *Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628.

Tribunal decision

35 On 4 December 2012, the Tribunal affirmed the decision of the Commissioner's delegate to grant the extension of time sought. The Tribunal construed reg 22.11(4)(b) as identifying the first of the two time requirements in s 71(2) – that is, "filing" an application for an extension of term "during the term of the patent". The Tribunal described Lundbeck's submission, which it accepted[52]:

> "Lundbeck submits that the second time requirement that an application be filed within 6 months of the latest of the dates in s 71(2)(a)-(c) is *not* excluded by the definition in the regulation and is a relevant act in respect of which time can be extended. This time requirement in which to seek an extension of term is therefore capable of being extended. It is the requirement that an application for the extension of *term* must be made *during* the term of the patent that is not capable of extension." (emphasis in original)

36 This led to the conclusion that since reg 22.11(4)(b), in its terms, operates only on the first time requirement referred to in s 71(2), the regulation does not preclude the grant of an extension of time from the due date (26 July 1999) to the later date sought (12 June 2009)[53]. As will be explained, that reasoning is correct.

Full Court

37 On 18 November 2013, the Full Court (Jessup, Jagot and Yates JJ) dismissed an appeal from the Tribunal brought pursuant to s 44 of the *Administrative Appeals Tribunal Act* 1975 (Cth)[54]. In the Full Court, Yates J (with whom Jessup J and Jagot J agreed) said[55]:

> "Properly understood, reg 22.11(4)(b) distinguishes between separate actions and prescribes one, not the other. The result is that the action of

---

52 *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648 at 653 [42].

53 *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648 at 653-654 [43]-[51].

54 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508.

55 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508 at 520-521 [51].

> filing the application under s 70(1) during the term of the patent is prescribed and cannot, therefore, be a relevant act to which s 223(2) refers. On the other hand, the action of filing the application within six months of the applicable date is not prescribed and is taken to be a relevant act to which s 223(2) can respond."

38 An awkwardness appears in that reasoning in the first sentence, in describing the two time requirements as "separate actions" – especially as the whole of the paragraph in which this passage can be found indicates that the expression "separate actions" operates as a trope for separate time requirements. Once that is recognised, the reasoning is not relevantly different from that of the Tribunal. The awkwardness reflects the drafting of s 223(11) and reg 22.11(4), which exclude time requirements from the general remedial power to extend time under s 223(2)(a) by excluding "prescribed actions" from "relevant acts" covered by s 223(2)(a).

Arguments

39 The parties did not contest the established principle of statutory construction that, while it may be useful to read regulations together with the statute under which they were made in order to understand a legislative scheme, it is not legitimate to construe a statute by reference to the wording of regulations made under it[56]. Further, in conformity with the approach to statutory construction explained most recently by this Court, the parties' primary arguments were directed to the text of the relevant provisions[57]. However, both parties went on to draw support for their arguments on the meaning of the text of reg 22.11(4)(b) from the wider context[58] – the legislative history, extrinsic

---

56 *Master Education Services Pty Ltd v Ketchell* (2008) 236 CLR 101 at 109-110 [19] per Gummow ACJ, Kirby, Hayne, Crennan and Kiefel JJ; [2008] HCA 38. See also *Hunter Resources Ltd v Melville* (1988) 164 CLR 234 at 244 per Mason CJ and Gaudron J; [1988] HCA 5; *Webster v McIntosh* (1980) 32 ALR 603 at 606 per Brennan J. Section 228, in a familiar form, provides for the making of regulations not inconsistent with the Act.

57 *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27 at 46-47 [47] per Hayne, Heydon, Crennan and Kiefel JJ; [2009] HCA 41; *Federal Commissioner of Taxation v Consolidated Media Holdings Ltd* (2012) 250 CLR 503 at 519 [39]; [2012] HCA 55.

58 *CIC Insurance Ltd v Bankstown Football Club Ltd* (1997) 187 CLR 384 at 408 per Brennan CJ, Dawson, Toohey and Gummow JJ; [1997] HCA 2; *Project Blue Sky*

(Footnote continues on next page)

materials and changes in legislative direction – as indicative of the general purpose and policy of the Act.

Alphapharm

40 Alphapharm submitted that the power of the Commissioner to extend time under the general remedial provision, s 223, was "specifically excluded" by reg 22.11(4)(b) in respect of a s 70(1) application. That argument was underpinned by the major premise that the correct construction of s 223(2) and (11) and reg 22.11(4)(b) required: first, an identification of a "relevant act" (or "action"); and, second, a determination of whether that "relevant act" (or "action") is "prescribed" under the regulation. The minor premise was that the "relevant act" (or "action") permitted by s 70(1) in relation to a patent was "filing an application to extend the term" of the patent. It was a short step then to a conclusion that reg 22.11(4)(b) was directed, in terms, to the single action of "filing" and, in particular, to contend that the words "as required by subsection 71(2) of the Act" (as they occurred in reg 22.11(4)(b)) comprehended both the first and second time requirements in s 71(2). Alphapharm relied on the awkwardness in the Full Court's reasons referred to above as demonstrative of error.

Lundbeck

41 Lundbeck submitted that s 71(2) involved two separate and independent time requirements and that reg 22.11(4)(b) should not be applied as if s 71(2) were concerned with a single time requirement. Lundbeck also relied on the different purposes of the first and second time requirements. The first was directed to the expiration of the term of the patent, and the second, it was said, was directed to delay in obtaining regulatory approval. The first time requirement was said to reflect an aspect of the law concerning extensions of time in extension of term applications (once petitions), which had subsisted since 1903[59]. In contrast, the second time requirement was new and reflected the novel aspects of the extension of term scheme, in which delay in obtaining regulatory approval functions as a proxy for inadequate remuneration, which once needed to be proven. Emphasis was laid on the text of the regulation as limited, in terms, to the first time requirement. This was said expressly, alternatively implicitly, to not exclude the second time requirement from s 223(2)(a).

Inc v Australian Broadcasting Authority (1998) 194 CLR 355 at 384 [78] per McHugh, Gummow, Kirby and Hayne JJ; [1998] HCA 28.

59 Apart from the lull in extension of term schemes between 1 July 1995 and 27 January 1999, discussed below.

The pre-existing law

42 The pre-existing law and the legislative history should not deflect the Court from its duty to resolve an issue of statutory construction, which is a text-based activity[60]. However, both parties recognised that the task of statutory construction in this case required some appreciation of the pre-existing law and the legislative history of relevant provisions. Undoubtedly, questions of policy can inform the Court's task of statutory construction[61].

43 Long historical developments in the United Kingdom concerning extensions of term for patents were reflected in the 1903 Act[62] and the 1952 Act[63]. These included developments in the curial jurisdiction to extend the time for presenting a petition to extend the term of a patent *after* the term had expired[64].

---

60 See *Northern Territory v Collins* (2008) 235 CLR 619 at 623 [16] per Gummow ACJ and Kirby J; [2008] HCA 49. See also *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27 at 46-47 [47].

61 See *Thomas v Mowbray* (2007) 233 CLR 307 at 348-351 [80]-[93] per Gummow and Crennan JJ; [2007] HCA 33. See also *Zheng v Cai* (2009) 239 CLR 446 at 453 [18], 455-456 [28]; [2009] HCA 52; *Assistant Commissioner Condon v Pompano Pty Ltd* (2013) 87 ALJR 458 at 467 [23]-[24] per French CJ; 295 ALR 638 at 646; [2013] HCA 7.

62 Division 5 of Pt IV (s 84), entitled "Extensions of Patents".

63 Part IX (ss 90-96), entitled "Extension of Patents".

64 See *Robinson's Patent* (1918) 25 CLR 116 at 135-139; *Sanofi v Parke Davis Pty Ltd [No 2]* (1983) 152 CLR 1 at 14-15 per Mason ACJ, Wilson and Dawson JJ; [1983] HCA 32. See also *Parke Davis Pty Ltd v Sanofi* (1982) 43 ALR 487 at 503-507 per Deane J.

44 The extension of term regimes considered in *In re Robinson's Patent*[65] and *Sanofi v Parke Davis Pty Ltd [No 2]*[66] (under the 1903 Act[67] and the 1952 Act[68] respectively) permitted an extension of term in respect of standard patents, covering any subject matter, on the grounds of inadequate remuneration (or, after 1921[69], on the grounds of war loss). Each regime contained a statutory time requirement, within which a petition to extend the patent term was required to be brought.

45 In *Robinson's Patent*, Isaacs J found that, notwithstanding the mandatory language of the 1903 Act's statutory time requirement, the time could be extended because subsequent wartime legislation and regulations gave the Solicitor-General a general power to extend time for "doing any act under the [1903 Act]"[70].

46 Decades later, a majority in *Sanofi* (Mason ACJ, Wilson and Dawson JJ) rejected an argument that the statutory time requirement under the 1952 Act precluded the grant of an extension of time to bring a petition for an extension of term *after* the expiration of the term. In their joint judgment, their Honours

---

65 (1918) 25 CLR 116 at 137.

66 (1983) 152 CLR 1 at 14-16 per Mason ACJ, Wilson and Dawson JJ.

67 Section 84(1) of the 1903 Act relevantly provided:

> "A patentee may ... present a petition ... praying that his patent may be extended for a further term, but such petition *must* be presented at least six months before the time limited for the expiration of the patent." (emphasis added)

68 Section s 90(1) of the 1952 Act relevantly provided:

> "A patentee ... may ... present to a prescribed court, at least 6 months before the expiration of the term of the patent, or within such further period as a prescribed court allows, a petition praying that his patent be extended for a further term."

69 See s 84(6) of the 1903 Act (as amended by s 4 of the *Patents Act* 1921 (Cth)); s 95 of the 1952 Act.

70 *Robinson's Patent* (1918) 25 CLR 116 at 135.

observed that a consistent Australian practice, for over 80 years[71], to permit a petition for an extension of term to be presented *after* the term of a patent expired was not inimical to the purposes of extension of term legislation. The purposes identified were to balance the interests of an inadequately remunerated inventor against the public interest in unrestricted use of the invention after expiration of the monopoly (that is, the term)[72]. To the extent that permitting an application to be made *after* the term of a patent had expired might prejudice a competitor, the court had jurisdiction under the 1903 Act and the 1952 Act to resolve the problem by imposing conditions on any grant of an extension of term or re-grant[73].

47 Because of the way in which the balance was struck under the extension of term regimes in the 1903 Act and the 1952 Act, patentees bore a heavy onus, as inadequate remuneration alone was not necessarily sufficient to warrant an extension[74]. All the circumstances of the case were relevant, including the nature and merits of an invention in relation to the public. Extensions of term were rare (at least until the 1970s) and proceedings for extensions of term (particularly if the patentee sought an "exceptional" term[75]) were complex and expensive[76]. As a

---

71 Derived from *Robinson's Patent* and Isaacs J's construction of the legislative scheme in the 1903 Act.

72 *Sanofi* (1983) 152 CLR 1 at 15-16.

73 *Sanofi* (1983) 152 CLR 1 at 15-16 per Mason ACJ, Wilson and Dawson JJ. See, generally, *Ex parte Celotex Corporation; In re Shaw's Patents* (1937) 57 CLR 19; [1937] HCA 31; *Gillette Industries Ltd v Commissioner of Patents* (1943) 67 CLR 529; [1943] HCA 25. See also *In re Usines de Melle's Patent* (1954) 91 CLR 42 at 50-51; [1954] HCA 32.

74 See, for example, *In re Dunlop's Patent* (1922) 31 CLR 579 at 580-581; [1922] HCA 43; *Re NV Philips Gloeilampenfabrieken's Patent [No 2]* (1967) 121 CLR 83 at 96-98; [1967] HCA 53.

75 Exemplified by *E I Du Pont De Nemours v Commissioner of Patents (No 3)* (1989) 15 IPR 296 at 311.

76 See, for example, *Re Imperial Chemical Industries Ltd's Patent Extension Petitions* [1983] 1 VR 1 (decided in 1979); *Re Henri Vidal's Patent Extension Petition* [1983] 1 VR 16; *Re Sanofi's Patent Extension Petition* [1983] 1 VR 25; *Re Application of Eli Lilly and Co* [1982] 1 NSWLR 526; *Re Application of Merck & Co Inc* [1983] 2 NSWLR 645. See, generally, Lawson, "How are pharmaceutical patent term extensions justified? Australia's evolving scheme", (2013) 21 *Journal of Law and Medicine* 379 at 385-386.

result, extensions of term (and the need to balance the competing interests of patentees and the public (including competitors)) became the subject of sustained policy debates in Australia (and elsewhere) for some 20 years before the extension of term scheme relevant to this appeal came into operation on 27 January 1999.

48 The extension of term scheme for pharmaceuticals is simplified by comparison with the pre-existing law. As observed succinctly and correctly by senior counsel for Alphapharm, regulatory delay is now the proxy for inadequate remuneration and merit is now assumed for a pharmaceutical substance suitable for human use. Once the Commissioner is satisfied that the conditions in s 70 and the procedural time requirements in s 71 have been met (subject to opposition), the Commissioner can directly proceed to consider the date of the patent and the date of the first regulatory approval and apply s 77 to calculate an extension of term.

The legislative history

49 When first enacted, the Act[77] introduced significant changes to Australian patent legislation, as recommended by the 1984 report of the Industrial Property Advisory Committee ("the IPAC")[78], but not those relevant to extension of term provisions. Relevantly, in the IPAC Report, Recommendation 11 (in two parts) recommended retaining the standard patent term (then 16 years under the 1952 Act) and went on to recommend that procedures for "granting of extensions of the terms of standard patents be eliminated in toto"[79].

50 The federal Minister for Science responded in 1986. He said the Government approved the proposal in principle but was aware of special circumstances with pharmaceutical products where delays in obtaining regulatory approval eroded "the effective patent lives of these products"[80].

---

77 Which came into force on 30 April 1991.

78 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, (1984) ("the IPAC Report"). The IPAC was commissioned in 1979 to review the 1952 Act. See, generally, *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 88 ALJR 261 at 302-303 [186]-[193]; 304 ALR 1 at 51-53; [2013] HCA 50.

79 IPAC Report at 5 [11].

80 "Government Response to the Report of the Industrial Property Advisory Committee, 'Patents, Innovation and Competition in Australia'", *Official Journal of*

(Footnote continues on next page)

51 As foreshadowed, the 1989 Act (substantially re-enacted in the Act (as first enacted)) repealed Pt IX of the 1952 Act and substituted a new Pt IX, entitled "Extension of Certain Patents", limited to patents for pharmaceutical substances. The primary objects of a more limited extension of term scheme were explained in the second reading speech of the Minister for Justice for the relevant Bill[81]:

> "The Bill abolishes the present complex procedures for extending the term of a patent and replaces them with more straightforward procedures applicable only to pharmaceuticals ... This Bill implements the Government's response to recommendation 11 of the [IPAC Report] ... The arrangements acknowledge that the effective patent life for pharmaceuticals for human use is reduced by the stringent and time-consuming evaluation procedures that the Department of Community Services and Health is required to conduct to ensure both the safety of patients and the efficacy of drugs."

52 The extension of term scheme enacted by the 1989 Act permitted a patentee to apply to the Commissioner "not later than 12 months before the end of the term of the patent"[82]. An extension of term of four years from a 16 to a 20 year term was permitted[83]. Competitors were permitted to springboard in the last two years of any extended term[84]. An application to extend the term had to be advertised and could be opposed[85]. Neither the 1989 Act nor the Act (as first enacted) contained any equivalent to s 71(2)(a), (b) and (c), for reasons which will become obvious.

53 The immediate predecessor to s 223, s 160 of the 1952 Act, was also amended by the 1989 Act[86]. Section 160(4A) was added in order to limit any

---

Patents, Trade Marks and Designs, 18 December 1986, vol 56, No 47 at 1466-1467.

81 Australia, Senate, *Parliamentary Debates* (Hansard), 23 May 1989 at 2451-2452.

82 1952 Act (as amended by the 1989 Act), s 90(1).

83 1952 Act (as amended by the 1989 Act), s 95.

84 1952 Act (as amended by the 1989 Act), s 96.

85 1952 Act (as amended by the 1989 Act), ss 93, 94.

86 1989 Act, s 7.

relevant extension of time within which to apply for an extension of term[87]. The practical effect of that amendment was that, even if granted an extension of time under s 160(2), a patentee had to make the application expeditiously, no later than nine months before the expiration of the term.

54 By comparison with the time requirements considered in *Robinson's Patent* and *Sanofi*, these provisions obviated any gap in the records of the Register. Such a gap could previously arise where a patent lapsed on expiration of the term but a patentee subsequently obtained an extension of time within which to petition for an extension of term[88]. This was a matter commonly dealt with under the pre-existing law by imposing conditions, as explained.

55 Policy debates which continued in relation to the desirable term of a standard patent in Australia (and elsewhere) raised the suggestion that the term of all standard patents should become 20 years (rather than 16 years) with the possibility that patents for pharmaceutical substances be extended beyond a 20 year term because in the pharmaceutical industry research and development costs were high, imitation costs low, and regulatory delays significant[89].

56 As events transpired, the 1994 Act provided for the extension of term of all standard patents to 20 years and repealed Div 2 of Pt 3 of Ch 6 of the Act, as it had operated since the 1989 Act (as substantially re-enacted in the Act). Transitional provisions in the 1994 Act permitted a patentee who had been granted an extension of term beyond 16 years under the repealed provisions to take advantage of that extension to 20 years[90]. Because the term was extended to 20 years, the extension of term scheme limited to standard pharmaceutical patents, first instituted in 1989, was repealed[91].

---

87 An application for an extension of time for more than three months could not be made in respect of "an act or step required to be done or taken for the purposes of Part IX" (which included the 12 month time limit within which an application for an extension of term could be made).

88 See *In re Dunlop's Patent* (1922) 31 CLR 579 at 580-581.

89 See, for example, Bureau of Industry Economics, *The Economics of Patents*, Occasional Paper 18, (1994) at ix, 24, 43-45.

90 1994 Act, ss 3, 4, 7, 8, 12, 13.

91 See Australia, House of Representatives, Patents (World Trade Organization Amendments) Bill 1994, Explanatory Memorandum at 1. See also Australia, House of Representatives, *Parliamentary Debates* (Hansard), 18 October 1994 at

(Footnote continues on next page)

57 The extension of term scheme relevant to reg 22.11(4)(b) was instituted by the *Intellectual Property Laws Amendment Act* 1998 (Cth) ("the 1998 Act")[92]. The principal objects of the 1998 Act were summarised in the Revised Explanatory Memorandum for the relevant Bill[93]:

> "The Bill amends the *Patents Act 1990* to give effect to the government's decision to provide for an extension of term scheme for pharmaceutical patents. An extension of up to five years will be available for a standard patent relating to a pharmaceutical substance that is the subject of first inclusion on the [ARTG]. The scheme will apply to all existing 20 year patents, as well as those patents granted after the commencement date.
>
> The new arrangements make provision for 'spring-boarding' activities. This allows manufacturers of generic drugs to undertake certain activities at any time after the extension is granted solely for the purposes of meeting pre-marketing regulatory approval requirements."

58 The rationale for reintroducing extension of term legislation was explained in detail[94]:

> "The development of a new drug is a long process, estimated to average around 12 years, which requires a new chemical entity to be patented early in the process in order to secure its intellectual property rights. However, considerable research and testing is still required before the product can enter the market. As a consequence, patentees of new drugs usually have considerably fewer years under patent in which to maximise their return.

2189; Australia, Senate, *Parliamentary Debates* (Hansard), 7 November 1994 at 2472.

92 The subsequent Australia-United States Free Trade Agreement required Australia to make extensions of term available for pharmaceuticals: [2005] ATS 1, Art 17.9(8).

93 Australia, Senate, Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum at 2.

94 Australia, Senate, Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum at 3-4. See also at 8-9.

It is expensive to bring a drug to market, around US$380 million, and involves considerable risk. As such, research based pharmaceutical companies rely heavily on patents to generate the substantial cash flows needed to finance the development of new drugs from the discovery stage, through the pre-clinical and clinical development phases, to eventual marketing.

A country's patent system is also an important factor in contributing to a company's decision on whether to invest or not. If Australia has a weak patent system, relative to it's [sic] competitors, there is a risk that investment in research and development will be lost to those offering stronger patent protection.

The objective of this proposal is to provide an 'effective patent life' – or period after marketing approval is obtained, during which companies are earning a return on their investment – more in line with that available to inventions in other fields of technology. It is also intended to provide a patent system which is competitive with other developed nations."

59 Section 223 was noted in the following terms[95]:

"Section 71 sets out the requirements of the form and timing of the application. The extension of time provision under section 223 of the *Patents Act 1990* will apply to all acts required to be done under the extension of patent term scheme provided that the relevant criteria are satisfied."

60 The purposes of the extension of term scheme are to balance the competing interests of a patentee of a pharmaceutical substance whose exploitation of monopoly has been delayed (because of regulatory delay) and the public interest in the unrestricted use of the pharmaceutical invention (including by a competitor) after the expiration of the monopoly (that is, the term).

Construction of reg 22.11(4)(b)

61 It is not always appropriate to dissect a composite legislative expression into separate parts, giving each part a meaning which the part has when used in isolation, then combine the meanings to give that composite expression a

---

95 Australia, Senate, Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum at 18.

meaning at odds with the meaning it has when construed as a whole[96]. Alphapharm makes errors of this kind.

62 First, Alphapharm relies on words forming part only of the parenthesis in reg 22.11(4)(b) – "as required by subsection 71(2) of the Act" – to "read up" the regulation to encompass both the first and second time requirements in s 71(2). Time is critical to ss 223(2)(a) and 71(2) and reg 22.11(4)(b). The critical expression in the regulation is "during the term of a standard patent", which must be construed in its immediate context in accordance with the principles expressed by this Court in *Project Blue Sky Inc v Australian Broadcasting Authority*[97]. The part only of the parenthesis upon which Alphapharm relies so heavily merely identifies the statutory source of the critical time requirement. The text, syntax and immediate context of reg 22.11(4)(b) show that the natural and ordinary meaning of the "prescribed action" identified is the "filing (or making) of a s 70(1) application during the term of the standard patent" (that is, before the term of the patent has expired).

63 Secondly, Alphapharm bases its preferred construction of reg 22.11(4)(b) on the proposition that it is only necessary to ask whether there is a "relevant act" (or "action") for the purposes of s 223(2)(a), then to ask whether it is "prescribed" under the regulation. That proposition detaches reg 22.11(4)(b) from its immediate context, and falls well short of establishing that reg 22.11(4)(b) encompasses both the first and second time requirements in s 71(2).

64 The immediate context of reg 22.11(4)(b) is to be found in ss 223 and 71(2) of the Act. It can be observed generally that, subject to reg 22.11, there is no reason to suppose that s 223 of the Act lacks the broadly protective and remedial operation accorded to its immediate predecessor by numerous courts, including this Court[98].

---

96 *XYZ v The Commonwealth* (2006) 227 CLR 532 at 543-544 [19] per Gleeson CJ, 592-593 [176] per Callinan and Heydon JJ; [2006] HCA 25.

97 (1998) 194 CLR 355 at 381-382 [69]-[71] per McHugh, Gummow, Kirby and Hayne JJ.

98 See *Australian Paper Manufacturers Ltd v CIL Inc* (1981) 148 CLR 551 at 557 per Stephen J (Mason and Wilson JJ agreeing). See also *Scaniainventor v Commissioner of Patents* (1981) 36 ALR 101; *Lehtovaara v Acting Deputy Commissioner of Patents* (1981) 39 ALR 103 at 111-113; *Kimberly-Clark Ltd v Commissioner of Patents* (1988) 84 ALR 685 at 694-695.

65 As a general remedial provision, s 223 is concerned only with extensions of time. Section 223(2)(a) empowers the Commissioner to extend the time for doing a relevant act which has been required to be done within a certain time and has not been so done because of an error or omission by the person concerned or his or her agent or attorney. Section 223(11) limits the power to extend time under s 223(2)(a) by excluding a "prescribed action" from a "relevant act". Regulation 22.11 is likewise concerned only with extensions of time. All "prescribed actions" in reg 22.11(4) are subject to time requirements, which are to be excluded from the general remedial power to extend time. To focus on a single "relevant act" (or "one action") to the exclusion of time requirements, and to ask only whether that "relevant act" (or "one action") is "prescribed", as Alphapharm does, is to misapprehend the real purpose of s 223(2)(a) – to confer a general remedial power to extend time – and the derivative purpose of reg 22.11(4) – to exclude a limited number of times from that general power to extend time.

66 Alphapharm's arguments, which depend only on asking whether a "relevant act" (or "action") is "prescribed", provide an incomplete and inadequate foundation for construing reg 22.11(4)(b). The correct description of the prescribed "relevant act" (or "action") under s 223(2)(a), for present purposes, is "making (or filing) a s 70(1) application in the time within which that is required to be done under s 71(2)".

67 Section 71(2), which is critical to the task of correctly construing reg 22.11(4)(b), is concerned only with the timing of a s 70(1) application. It imposes two cumulative time requirements, both of which need to be satisfied to establish the "certain time" (in Alphapharm's words, "the deadline") by which a s 70(1) application must be made.

68 The first time requirement, namely that a s 70(1) application must be made "during the term" of the patent (that is, before the expiration of the term of the patent), imposes a time requirement having a recognisable origin in earlier cognate provisions and associated practices explained in *Sanofi*[99], which date back to 1903. As recognised in *Sanofi*, under the pre-existing law, courts were wary of granting an extension of term which might prejudice or inhibit the public interest (including the interests of commercial competitors) in exploiting a disclosed invention on the expiration of the term[100]. This reluctance was compounded by uncertainty in the Register which could occur if there was a gap

---

99 (1983) 152 CLR 1 at 14-15.

100 (1983) 152 CLR 1 at 14-16 per Mason ACJ, Wilson and Dawson JJ.

between the lapse of a patent (due to the expiration of the term) and the presentation of a petition *after* the term had expired, as was permitted under the pre-existing law. This could require the imposition of conditions on any extension of term or re-grant (as explained above). As correctly submitted by Lundbeck, were it not for reg 22.11(4)(b), the approach in *Robinson's Patent*, approved in *Sanofi*, may have authorised reliance on the general remedial power in s 223(2)(a) to extend the first time requirement in s 71(2) to a time *after* the term had expired. Regulation 22.11(4)(b), correctly construed, obviates the known problem of uncertainty in the Register which would follow if that were permitted.

69 The second time requirement, which can be expressed using the formula "within six months of the latest of three specified dates" in s 71(2), has an entirely different and unrelated purpose, which is to require a patentee to make a s 70(1) application within six months of the satisfaction of *all* of the necessary conditions for the making of such an application, bearing in mind that the sequence of satisfaction may vary from patent to patent.

70 The second time requirement has a rationale which is not dissimilar to the rationale for another discrete and distinct legislative requirement in relation to annual renewal fees (which must be paid to prevent a patent from lapsing). Those fees escalate sharply as the expiration date of the term of a patent approaches[101]. The escalation is directed to encouraging a patentee to consider the utility of continuing its monopoly and discouraging the maintenance, on the Register, of patents which are not being exploited. The second time requirement is directed to requiring a patentee to decide about extending its monopoly as soon as the requisite conditions are aligned.

71 There is nothing in any of the extrinsic materials, or in the long policy debates on simplifying extensions of term, which would suggest any rationale for excluding the second time requirement from the remedial power to extend time under s 223(2)(a). Alphapharm's senior counsel conceded, correctly, that if Alphapharm's construction of reg 22.11(4)(b) were correct, the remedial power in s 223(2)(a) could never apply to extend time in relation to the second time requirement, no matter what the quality or provenance of any "error or omission" made in respect of that time. Alphapharm's construction would introduce an inexplicable asymmetry between a patentee and a competitor opposing a s 70(1) application. An opponent can access the general remedial power to extend times cast upon it in mandatory terms[102]. Had it been the legislature's intention to

---

101 Regulations, Sched 7, Pt 2, item 211.

102 See Act, ss 75 and 223(6); Regulations, reg 22.11(4)(a).

exclude the second time requirement in s 71(2) from the general remedial power in s 223(2)(a), that would have been simple to accomplish.

72 Alphapharm's construction of reg 22.11(4)(b) gives the regulation an operation which is inconsistent with one of the principal objects of the extension of term scheme. Taking Lundbeck as an example of a patentee who has made a s 70(1) application during the term of the patent, a regulatory delay of nearly eight and a half years should give rise to a straightforward entitlement to an extension of term of nearly three and a half years[103].

Conclusions

73 For the reasons set out above, reg 22.11(4)(b) has the meaning which its text taken as a whole, its syntax and the immediate context support – the only time requirement which is excluded by reg 22.11(4)(b), from the general remedial power to extend time in s 223(2)(a), is the first time requirement in s 71(2).

74 The Tribunal did not err in concluding that s 223(2)(a) conferred power on the Commissioner to extend the second time requirement in s 71(2) from 26 July 1999 to 12 June 2009 and the Full Court did not err in dismissing the appeal from the Tribunal.

Orders

75 The appeal should be dismissed with costs.

---

103 From 13 June 2009 to 9 December 2012.

76 KIEFEL AND KEANE JJ. Citalopram belongs to a class of drugs called selective serotonin re-uptake inhibitors, which are used in the treatment of depression. It is a racemate, comprising two different, mirror-image forms of the same chemical compound, called enantiomers. Enantiomers are designated (+) or (-) depending on how they rotate plane-polarised light. The first respondent, H Lundbeck A/S, was the holder of a patent which claimed, inter alia, a (+)-enantiomer of citalopram called escitalopram ("the patent"). The term of the patent expired on 13 June 2009, but not before the first respondent applied for its extension under s 70(1) of the *Patents Act* 1990 (Cth) ("the 1990 Act").

77 Section 70(1) provides:

> "The patentee of a standard patent may apply to the Commissioner for an extension of the term of the patent if the requirements set out in subsections (2), (3) and (4) are satisfied."

Sub-section (2)(a) limits the patents which may be the subject of an application to those whose complete specification, in substance, discloses one or more pharmaceutical substances, and those substances fall within the scope of the claims of that specification. Sub-section (3)(a) requires that goods containing the pharmaceutical substance or substances be included in the Australian Register of Therapeutic Goods ("the ARTG"). Sub-section (4) provides that the term of the patent must not have been previously extended.

78 Section 71(1) provides for the form of an application for extension of the term of a patent. Section 71(2) governs the time for making such an application. It provides:

> "An application for an extension of the term of a standard patent must be made during the term of the patent and within 6 months after the latest of the following dates:
>
> (a) the date the patent was granted;
>
> (b) the date of commencement of the first inclusion in the [ARTG] of goods that contain, or consist of, any of the pharmaceutical substances referred to in subsection 70(3);
>
> (c) the date of commencement of this section."

The period of any extension of term is to be calculated according to s 77(1), but must not exceed five years (s 77(2)).

79 The first respondent markets two products which contain escitalopram: CIPRAMIL and LEXAPRO. CIPRAMIL was first included in the ARTG on 9 December 1997, and LEXAPRO on 16 September 2003. The first respondent

applied on 22 December 2003 to extend the term of the patent. That application identified the date that LEXAPRO was first included in the ARTG as the relevant date for the purposes of s 71(2)(b). The application was granted by the Commissioner of Patents ("the Commissioner"), without opposition, and the term of the patent was extended to 13 June 2014.

80 A Delegate of the Commissioner subsequently determined that the term of the patent should have been extended only to 9 December 2012[104]. It was considered that the assessment of the period of extension under s 77(1) should have been based upon the date that CIPRAMIL, not LEXAPRO, was included in the ARTG. The Delegate ordered that the Register of Patents be amended accordingly.

81 In an appeal from that determination to the Federal Court of Australia, Lindgren J held[105] that, as the first respondent's application under s 70(1) for the extension of its patent was based upon the inclusion of LEXAPRO in the ARTG, the application did not comply with the time requirement in s 71(2). As a consequence, the extension granted was invalid. His Honour ordered that the Register be rectified[106]. On 11 June 2009, a Full Court of the Federal Court upheld[107] that decision, and final orders were pronounced the following day.

82 On 12 June 2009, which was the day prior to the expiration of the term of the patent, the first respondent filed an application under s 223(2)(a) of the 1990 Act for an extension of time within which to bring an application under s 70(1) for an extension of the term of the patent. It also filed another application under s 70(1), but the validity of that application depended on whether an extension of time could be granted under s 223(2)(a). Section 223(2) provides:

> "Where, because of:
>
> (a) an error or omission by the person concerned or by his or her agent or attorney; or
>
> (b) circumstances beyond the control of the person concerned;

---

104 *Alphapharm Pty Ltd v H Lundbeck A/S* (2006) 69 IPR 629.

105 *Alphapharm Pty Ltd v H Lundbeck A/S* (2008) 76 IPR 618.

106 *Alphapharm Pty Ltd v H Lundbeck A/S (No 2)* (2008) 78 IPR 338 at 344.

107 *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151; an application for special leave to appeal was refused on 11 December 2009: *Alphapharm Pty Ltd v H Lundbeck A/S* [2009] HCATrans 324.

> a relevant act that is required to be done within a certain time is not, or cannot be, done within that time, the Commissioner may, on application made by the person concerned in accordance with the regulations, extend the time for doing the act."

Section 223(11) provides that a "relevant act" means:

> "an action (other than a prescribed action) in relation to a patent ..."

The Patents Regulations 1991 (Cth) designate certain actions as prescribed actions. At the time of the first respondent's application under s 223(2)(a), reg 22.11(4)(b) provided[108]:

> "(4) For the definition of ***relevant act*** in subsection 223(11) of the Act, each of the following actions is prescribed:
>
> ...
>
> (b) filing, during the term of a standard patent as required by subsection 71(2) of the Act, an application under subsection 70(1) of the Act for an extension of the term of the patent".

83 A Delegate of the Commissioner found the requirements of s 223(2)(a) to have been satisfied[109] and granted the first respondent an extension of time for filing an application for extension of the term of the patent, over the opposition[110] of the appellant and others.

84 The Delegate's decision was upheld by the Administrative Appeals Tribunal[111] ("the AAT") and a Full Court of the Federal Court[112]. Special leave to appeal from the decision of the Full Court was granted by Kiefel and Keane JJ,

---

108 The regulation has since been amended, in 2013, by replacing the words "as required by subsection 71(2)" in par (b) with "under subsection 71(2)". At the same time, the words "each of the following actions is", in the chapeau, were replaced with "the following are": see Intellectual Property Legislation Amendment (Raising the Bar) Regulation 2013 (No 1) (Cth), Sched 3, item 7.

109 *Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628 at 641 [64].

110 *Patents Act* 1990 (Cth), s 223(6).

111 *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648.

112 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508.

limited to the question whether s 223(2) confers power to extend the time within which the first respondent could apply under s 70(1) for an extension of the term of the patent.

85 The task of statutory construction starts and ends with a consideration of the text of the statute in question[113]. Nonetheless, the submissions of the parties on the appeal necessitate some reference to the legislative history of ss 70 and 71, and of s 223 and the relevant regulation made under it.

Patent term extensions

86 The two statutes that preceded the 1990 Act – the *Patents Act* 1903 (Cth) ("the 1903 Act") and the *Patents Act* 1952 (Cth) ("the 1952 Act") – both permitted extension of the term of a patent where the court was of the opinion that the patentee's remuneration from the patent during its term had been inadequate[114]. Both the 1903 Act[115] and the 1952 Act[116] in their original forms required an application for an extension of the term of a patent to be brought at least six months before the patent expired. Section 90(1) of the 1952 Act also allowed an application to be brought "within such further period" as the court allowed. In *Sanofi v Parke Davis Pty Ltd [No 2]*[117], s 90(1) was held to permit an extension of the term of a patent to be made after the term had expired.

87 In 1984, a report by the Industrial Property Advisory Committee ("the IPAC") entitled *Patents, Innovation and Competition in Australia* was submitted to the Commonwealth Minister for Science and Technology[118]. Two of its recommendations are presently relevant. The then existing term of a standard patent was 16 years. A majority of the IPAC recommended[119] that there be no increase to that term. As explained below, although this recommendation was

---

113 *Federal Commissioner of Taxation v Consolidated Media Holdings Ltd* (2012) 250 CLR 503 at 519 [39]; [2012] HCA 55.

114 *Patents Act* 1903 (Cth), s 84(5); *Patents Act* 1952 (Cth), s 94(1).

115 *Patents Act* 1903, s 84(1).

116 *Patents Act* 1952, s 90(1).

117 (1983) 152 CLR 1; [1983] HCA 32.

118 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, (1984).

119 Recommendation 11(i); Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, (1984) at 37, 39.

initially approved by the Government in principle[120], the term of standard patents was later extended to 20 years[121].

88 Of more direct relevance is the recommendation of the IPAC that existing procedures for seeking extensions of the term of a patent on the ground of inadequate remuneration should be abolished[122]. The Government approved this recommendation, subject to a qualification that it would "announce a decision at an appropriate time on pharmaceuticals and agricultural and veterinary chemicals for which effective patent life is eroded by regulatory delays"[123].

89 The *Patents Amendment Act* 1989 (Cth) ("the 1989 Amendment Act") amended the 1952 Act by replacing the provisions respecting extensions of the terms of all standard patents with provisions that applied only to certain patents relating to pharmaceutical substances. The new regime permitted the term of such patents to be extended by four years[124]. An application for such an extension was required to be made no later than 12 months before the end of the term of the patent[125]. Provision was no longer made for an application to be brought "within such further period" as the court allowed. When the 1990 Act came into force on 30 April 1991, it contained provisions to the same effect as those introduced by the 1989 Amendment Act[126].

90 Provisions permitting patent term extensions for pharmaceutical patents were temporarily removed from the 1990 Act by the *Patents (World Trade Organization Amendments) Act* 1994 (Cth) ("the WTO Amendment Act"), with

---

120 "Government Response to the Report of the Industrial Property Advisory Committee, 'Patents, Innovation and Competition in Australia'", *Official Journal of Patents, Trade Marks and Designs*, 18 December 1986, vol 56, No 47 at 1466, 1470.

121 *Patents (World Trade Organization Amendments) Act* 1994 (Cth).

122 Recommendation 11(ii); Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, (1984) at 38-39.

123 "Government Response to the Report of the Industrial Property Advisory Committee, 'Patents, Innovation and Competition in Australia'", *Official Journal of Patents, Trade Marks and Designs*, 18 December 1986, vol 56, No 47 at 1470.

124 *Patents Act* 1952, s 95(2).

125 *Patents Act* 1952, s 90(1).

126 *Patents Act* 1990, Ch 6, Pt 3, Div 2.

effect from 1 July 1995. The purpose of the WTO Amendment Act was to bring Australian patents legislation into line with the standards and principles prescribed for patents in the Agreement Establishing the World Trade Organization (1994)[127]. The principal amendment was to increase the term of standard patents from 16 to 20 years[128], and it was said that the repeal of the patent term extension provisions was consequent on this amendment[129]. It was considered that, in light of the general 20 year patent term, a four year extension for pharmaceutical patents would "no longer be necessary"[130]. However, less than four years later, a patent term extension regime was reintroduced into the 1990 Act.

91 The provisions presently under consideration, ss 70 and 71, were introduced by the *Intellectual Property Laws Amendment Act* 1998 (Cth) ("the 1998 Amendment Act"), with effect from 27 January 1999. The provisions introduced by the 1998 Amendment Act permitted a patent term extension of up to five years[131] for a standard patent relating to a pharmaceutical substance that is contained in goods included in the ARTG.

92 The Revised Explanatory Memorandum for the 1998 Amendment Act[132] explained that providing for extension of the term of patents relating to pharmaceutical substances had the purpose of ensuring that research and development in Australia with respect to such substances would not be lost to jurisdictions offering stronger patent protection. The Revised Explanatory Memorandum noted that five year extensions of pharmaceutical patents were already available in the United States of America, the European Community and Japan, in recognition of the exceptionally long development time necessary in pharmaceutical research and to allow for compliance by patentees with regulatory requirements in the field. The aim of the amendments was said to be

---

127 Australia, House of Representatives, Patents (World Trade Organization Amendments) Bill 1994, Explanatory Memorandum at 1.

128 *Patents (World Trade Organization Amendments) Act* 1994, s 4.

129 Australia, House of Representatives, Patents (World Trade Organization Amendments) Bill 1994, Explanatory Memorandum at 2.

130 Australia, House of Representatives, Patents (World Trade Organization Amendments) Bill 1994, Explanatory Memorandum at 1.

131 *Patents Act* 1990, s 77.

132 Australia, Senate, Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum at 3.

to provide an "effective patent life", during which companies could earn a return on their investment, more in line with that available to inventions in other fields of technology.

93 The current text of ss 70 and 71 is, in material respects, the same as that introduced by the 1998 Amendment Act.

Extensions of time

94 Under s 160 of the 1952 Act, the Commissioner of Patents had the power, in certain circumstances, to extend the time for doing an act or taking a step required to be done or taken within a certain time. As expanded by the *Patents Act* 1960 (Cth), s 160 provided that an extension of time would be granted to permit the act to be done or the step to be taken where the failure occurred by reason of an error or omission on the part of the Patent Office (s 160(1)), and could be granted where the failure occurred by reason of an error or omission on the part of the person concerned or the person's agent, or by reason of circumstances beyond the person's control (s 160(2)).

95 The 1989 Amendment Act inserted sub-s (4A) into s 160 of the 1952 Act. That sub-section provided that an application could not be made under s 160(2) for an extension of time of more than three months with respect to an act or step required to be done or taken for the purposes of Pt IX. Part IX, as amended by the 1989 Amendment Act, contained the provisions governing extension of the term of a patent respecting a pharmaceutical substance. It will be recalled that, under the 1952 Act, an application for such an extension was required to be filed no later than 12 months before the end of the term of the patent[133]. The combined effect of this requirement and s 160(4A) was that an application for extension of the term of a pharmaceutical patent could not be filed less than nine months before the end of the patent term.

96 In the Explanatory Memorandum for the 1989 Amendment Act, it was said[134] that s 160(4A) "recognises the need to ensure that the new procedures for extensions of term operate expeditiously, leaving those involved and third parties with the minimum period of uncertainty consistent with the need to resolve matters fairly."

97 Section 223 of the 1990 Act was introduced in substantially similar terms to s 160 of the 1952 Act. When the 1990 Act came into operation, s 160(4A) of the 1952 Act was reproduced in material respects as s 223(5). In 1995, s 223(5)

---

133 *Patents Act* 1952, s 90(1).

134 Australia, Senate, Patents Amendment Bill 1989, Explanatory Memorandum at 7.

was repealed by the WTO Amendment Act. Section 223(5) had become otiose because of the repeal of the patent term extension provisions. However, when the current patent term extension regime was introduced by the 1998 Amendment Act, neither s 223(5) nor an equivalent provision was re-enacted.

98 As noted above, the 1998 Amendment Act introduced the patent term extension provisions that are presently under consideration (ss 70 and 71). The Revised Explanatory Memorandum for the 1998 Amendment Act said[135]:

> "Section 71 sets out the requirements of the form and timing of the application. The extension of time provision under section 223 of the *Patents Act 1990* will apply to all acts required to be done under the extension of patent term scheme provided that the relevant criteria are satisfied."

99 At the same time as the 1998 Amendment Act commenced, the Patents Regulations 1991 were amended by the Patents Amendment Regulations 1998 (No 8) (Cth) ("the 1998 Amendment Regulations"). Regulation 22.11(3)(c), as thereby amended, was materially identical to reg 22.11(4)(b) (the regulation presently under consideration). The Explanatory Statement for the 1998 Amendment Regulations said:

> "Item 7 of Schedule 1 to the Statutory Rules substitutes a new paragraph 22.11(3)(c) of the Regulations. This paragraph prescribes the action of filing an application for extension of term under section 70 of the Act during the term of the patent as being an action for which an extension of time under section 223 of the Act is not available."

The decisions below

100 The AAT referred to the Revised Explanatory Memorandum for the 1998 Amendment Act, set out above, as supporting its opinion that it would be contrary to the remedial intention of s 223 for that section not to be available in relation to an application under s 70(1)[136].

101 The Full Court did not derive the same support from the extrinsic materials. In particular, the Explanatory Statement accompanying the predecessor to reg 22.11(4)(b) was considered to provide no real guidance to the

---

135 Australia, Senate, Intellectual Property Laws Amendment Bill 1998, Revised Explanatory Memorandum at 18.

136 *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648 at 654 [45]-[46].

construction of reg 22.11(4)(b), for it merely recited the substance of the words of the regulation[137]. In any event, the Full Court did not consider that recourse to the extrinsic materials was necessary[138].

102 The Full Court held that the AAT was correct to conclude that the Commissioner had the power under s 223(2) to extend the six month time limit in relation to the date applicable under s 71(2)[139]. In reaching that conclusion, it construed the words appearing in reg 22.11(4)(b) – "during the term of a standard patent under subsection 71(2) of the Act"[140] – as specifically identifying the action that is prescribed. Those words did not, in the view of the Full Court, incorporate a second action referred to in s 71(2), namely filing the application within six months of the date applicable under s 71(2)(a)-(c)[141]. The Full Court concluded that s 223(2) could operate with respect to that second time limit.

103 Like the Full Court, the AAT had also focused on the additional words appearing in reg 22.11(4)(b) after the word "filing". The AAT considered that the regulation thereby only excluded from the operation of s 223(2) applications filed after the expiry of the term of a patent[142]. The approach of the Full Court, mentioned above, was to similar effect. The effect of the approaches taken below is that the action identified in reg 22.11(4)(b) is not the filing of the application for extension of the patent, but the action of filing *during the term of the patent*[143].

---

137 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508 at 522 [58].

138 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508 at 521-522 [57].

139 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508 at 522 [59].

140 The Full Court referred to the words as they appeared in reg 22.11(4)(b) following amendment in 2013. As explained above at [82], at the time of the first respondent's application under s 223 (in June 2009), the relevant words of the regulation were "during the term of a standard patent *as required by* subsection 71(2) of the Act" (emphasis added). However, it is not suggested anything turns on this difference.

141 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508 at 520-521 [51].

142 *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648 at 653 [39]-[43], 654 [47].

143 *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508 at 521 [51].

The provisions construed

104 It has repeatedly been said by this Court[144] that the process of construction of statutory provisions starts with the words of the statute, read in their context. Here, the process commences with a consideration of the text of ss 70, 71 and 223.

105 Section 71(2) is expressed to require that an application for extension of the term of a patent under s 70(1) be brought within the times specified. An application "must be made" during the term of the patent and within six months after the latest of the three dates listed in pars (a)-(c) of s 71(2). So expressed, the Commissioner's power to extend the term of a patent depends upon an applicant's compliance with s 71(2).

106 At the same time, s 223(2) empowers the Commissioner to extend the time for doing a "relevant act" that has not been done because of an error or omission on the part of the person concerned or circumstances beyond the person's control.

107 In the construction of ss 71(2) and 223(2), it may be observed that s 223(2) is an earlier, general provision which confers a broad authority to extend the period for doing an act, whereas s 71(2) is a later, specific provision containing a limitation as to the time within which a particular application may be brought. However, the construction of these provisions does not fall to be resolved by asking whether s 71(2) effects a limitation on s 223(2)[145]. Such an enquiry is not necessary because the text of reg 22.11(4)(b), made for the purposes of s 223(11), produces the result that s 223(2) has no operation with respect to an application under s 70(1) for extension of the term of a patent. The effect of reg 22.11(4)(b) is to confirm that the scheme for extension of the term of pharmaceutical patents mandates compliance with the time limits in s 71(2).

108 The power given to the Commissioner by s 223(2) is to extend the time for a person to do a *relevant act*. The definition of "relevant act" in s 223(11) is "an *action* ... in relation to a patent" (emphasis added). The action in question with respect to the patent in this case was the making of an application to extend its term.

---

144 See, for example, *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27 at 46-47 [47]; [2009] HCA 41.

145 See, for example, *David Grant & Co Pty Ltd v Westpac Banking Corporation* (1995) 184 CLR 265 at 275-276; [1995] HCA 43.

109 Consistently with s 223(11), reg 22.11(4) identifies actions. It cannot do otherwise, for s 223(11) only permits an *action* in relation to a patent to be a prescribed action. The action identified in reg 22.11(4)(b) is the filing of an application under s 70(1). The operative part of reg 22.11(4)(b) refers to the action of "filing ... an application under subsection 70(1) of the Act for an extension of the term of the patent". Those words could hardly be clearer. The text of reg 22.11(4)(b) and s 223(11) limits the Commissioner's power to grant an extension of time, such that the power does not apply to filing an application under s 70(1).

110 The first respondent submits that s 223(2) applied to each of the two time limits in s 71(2), separately and distinctly. It contends that reg 22.11(4)(b) would then be read as prescribing only the first time limit, namely that the application be filed within the term of the patent, and allowing s 223(2) to operate with respect to the second. This is how the Full Court construed the provisions.

111 The difficulty with these approaches is that what is prescribed under s 223(11) and by reg 22.11(4)(b) is a "relevant act", and s 71(2) cannot reasonably be read as referring to two actions. There is but one action referred to in s 71(2) – making an application for extension of the term of a patent. That one action is to be done on a date that satisfies the two requirements as to time set out in s 71(2). It is that action to which s 223(2) would apply, were it not for reg 22.11(4)(b).

112 The approaches of the AAT, the Full Court and the first respondent treat s 223(2) as permitting the enlargement of a time specified for the doing of an act, such as the time requirements found in s 71(2). However, s 223(2) does not contain such a power and does not operate in this way. It provides a power to permit the doing of an act which would otherwise be done outside the requirements as to time.

113 Too much weight is given by the first respondent to the additional words appearing in reg 22.11(4)(b). Their obvious purpose is to identify the requirements of s 71(2) as relevant to the action of filing an application under s 70(1). These additional words cannot alter the effect of the operative part of the regulation, which must identify the "relevant act" which is excepted from the operation of s 223(2). Even if it did no more, the Explanatory Statement for the 1998 Amendment Regulations at least identified the action which the predecessor to reg 22.11(4)(b) prescribed – and, to that extent, confirmed its meaning[146].

---

146 *Acts Interpretation Act* 1901 (Cth), s 15AB(1)(a).

114 Resort to the Revised Explanatory Memorandum for the 1998 Amendment Act regarding the operation of s 223(2) is not necessitated by any ambiguity in s 223(11) and reg 22.11(4)(b), read with ss 70 and 71[147]. The terms of these provisions are clear. Thus, the Revised Explanatory Memorandum should be understood to acknowledge simply that the scheme of the 1990 Act is that requirements for the timing of an application for extension of the term of a patent are contained in s 71(2). Section 223(2) will therefore apply to all acts to be done in connection with an extension of a patent term, other than the making of the application for extension itself.

115 It may be accepted that s 223(2) is remedial in nature and should therefore be given a wide operation[148]. It may also be accepted that the effect of it not extending to applications under s 70(1) means that the time for making such an application cannot be extended, even in the case of an error or omission for which the patentee is not responsible. This effect must be taken as intended, given the clarity of the provisions.

116 The legislative history of the scheme for extensions of the terms of pharmaceutical patents does not provide support for the first respondent's argument. It may be accepted that it has for some time been considered necessary to encourage research and development in the area of pharmaceutical substances, and that permitting extensions of patent terms, to allow patentees to recoup costs and to benefit from the patent, is a means of doing so. It does not follow that it was intended that the limits placed upon the time within which an application could be brought were not to be strictly complied with.

117 The scheme specifically providing for extensions of the terms of pharmaceutical patents was first introduced in 1989 against a background where, as a matter of policy, extensions of the terms of patents more generally were disfavoured. It is true that pharmaceutical patents were treated as a special category, warranting a possible extension of the patent term for a finite period; but the provisions as to the time for bringing an application for extension were progressively tightened. The changes to those provisions did more than respond to the decision in *Sanofi*, which permitted an application to be brought even after the patent term expired. The 1989 Amendment Act required an application for extension of the term of a pharmaceutical patent to be brought no later than 12 months before the end of the patent term. The 1998 Amendment Act recalibrated the time limit to be a point during the patent term and within

---

147 *Acts Interpretation Act* 1901, s 15AB(1)(b)(i); and see *Saeed v Minister for Immigration and Citizenship* (2010) 241 CLR 252 at 265 [33]; [2010] HCA 23.

148 *IW v City of Perth* (1997) 191 CLR 1 at 12, 27, 39, 58; [1997] HCA 30.

six months of the last of three dates, being the date of the patent, the inclusion of the relevant pharmaceutical goods in the ARTG or the commencement of s 71.

118 It must be accepted that the predecessor of s 223 of the 1990 Act, s 160 of the 1952 Act, was taken to apply to applications for extension of the term of a pharmaceutical patent. This is evident from s 160(4A), which was introduced by the 1989 Amendment Act and later reproduced as s 223(5) of the 1990 Act. Section 160(4A) was directed to such applications. It will be recalled that it had the effect of limiting to three months the period for which an extension of time could be given for the bringing of such applications. Section 223(5) was removed during the short period between 1995 and 1999, when no patent term extensions were provided for by the legislation.

119 It is noteworthy that no similar provision was reintroduced into the 1990 Act when the current patent term extension regime was enacted, as might have been expected if it were intended that s 223(2) would apply to applications for extension of the term of a patent under s 70(1), as it had previously. The stated policy respecting the predecessor to s 223(5) was that it was necessary to minimise the period of uncertainty as to whether an application for extension of term would be made. There is nothing to suggest that there had been a reversal of that policy when the current regime was introduced. The non-inclusion of s 223(5) (or an equivalent provision) is more likely explained by the fact that the scheme implemented by the 1998 Amendment Act, along with the predecessor to reg 22.11(4)(b), no longer contemplated s 223(2) as applying to applications under s 70(1). A provision such as s 223(5) was simply no longer necessary.

120 There is no doubting that the purpose behind s 70(1) is to benefit and encourage research and development. Other provisions of the 1990 Act, including those for advertisement of and opposition to applications for extension of the term of a pharmaceutical patent[149], recognise that there are interests, other than those of a patentee, which are affected by an extension. The Explanatory Memorandum for the 1989 Amendment Act said as much, in its statement as to the policy behind s 160(4A), when extension provisions for pharmaceutical patents were introduced. Against this background, the requirements of s 71(2), the strictness of which is reinforced by the effect of reg 22.11(4)(b), may be taken as intended to provide those other interested persons with a level of certainty as to whether an application for extension of the term of a patent is to be made by a patentee.

---

149 *Patents Act* 1990, ss 72, 75.

121 In any event, as was said in *Federal Commissioner of Taxation v Consolidated Media Holdings Ltd*[150], legislative history and extrinsic materials cannot displace the meaning of statutory text; nor is their examination an end in itself.

Orders

122 The appeal should be allowed and the order of the Full Court of the Federal Court made on 18 November 2013 set aside. In lieu it should be ordered that the decisions of the AAT given on 4 December 2012 and the Delegate of the Commissioner of 1 June 2011 be set aside and the first respondent's application for an extension of time under s 223(2)(a) of the 1990 Act be refused. The first respondent should pay the appellant's costs of this appeal and the appeal below.

---

150 (2012) 250 CLR 503 at 519 [39].