IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No S 97 of 2014

BETWEEN:

ALPHAPHARM PTY LTD
ACN 002 359 739
Appellant

and

H LUNDBECK A/S
First Respondent

COMMISSIONER OF PATENTS
Second Respondent

ASPEN PHARMA PTY LTD
ACN 004 118 594
Third Respondent

SANDOZ PTY LTD
ACN 075 449 553
Fourth Respondent

APOTEX PTY LTD
ACN 096 916 148
Fifth Respondent

APPELLANT'S SUBMISSIONS

Part I: Suitable for publication

1. This submission is in a form suitable for publication on the internet.

Part II: Issue presented by the appeal

2. The issue presented by this appeal is whether s 223(2) of the *Patents Act* 1990 (Cth) (the **Act**) conferred power on the Commissioner of Patents (the

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Commissioner) to extend the time within which the First Respondent could apply under s 70(1) of the Act for an extension of the term of its Australian Patent No 623144 (the **Patent**), 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**).

Part III: *Judiciary Act* 1903

3. The Appellant (**Alphapharm**) has considered whether any notice should be given in this case in compliance with s 78B of the *Judiciary Act* 1903 (Cth).

Part IV: Citations

10 4. The reasons for judgment of the Full Court of the Federal Court of Australia, from which this appeal is brought, are published as *Aspen Pharma Pty Ltd v H Lundbeck A/S* (2013) 216 FCR 508; [2013] FCAFC 129.

5. The reasons for decision of the Administrative Appeals Tribunal, from which the appeal to the Full Court was brought, are published as *Re Aspen Pharma Pty Ltd and Commissioner of Patents* (2012) 132 ALD 648; [2012] AATA 851.

6. The reasons for decision of the Delegate of the Commissioner, from which the application to the Tribunal was brought, are published as *Alphapharm Pty Ltd v H Lundbeck A/S* (2011) 92 IPR 628; [2011] APO 36.

20 **Part V: Relevant facts**

7. The First Respondent (**Lundbeck**) was the patentee of the Patent, the 20 year term of which expired on 13 June 2009. Claim 1 of the Patent claimed a compound (an enantiomer) known as "(+)-citalopram", which is useful as a pharmaceutical substance in the treatment of depression.[1]

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[1] (2013) 216 FCR 508; [2013] FCAFC 129 at [4], [6], [8], [9].

8. On 9 December 1997, Lundbeck's local subsidiary obtained the inclusion in the Australian Register of Therapeutic Goods (**ARTG**) of a pharmaceutical product called CIPRAMIL, which contained (+)-citalopram (as well as the other enantiomer (-)-citalopram). Subsequently, on 16 September 2003, Lundbeck's local subsidiary obtained the inclusion in the ARTG of a second pharmaceutical product called LEXAPRO, which also contained (+)-citalopram. Both CIPRAMIL and LEXAPRO were marketed in Australia by Lundbeck's local subsidiary.[2]

9. On 22 December 2003, Lundbeck applied to the Commissioner to extend the term of the Patent under s 70(1) of the Act. Section 70 is contained in Part 3 of Chapter 6 of the Act, which makes provision for the extension of term of pharmaceutical patents in certain circumstances. The section sets out certain requirements to be satisfied by such an application, which include:

   (a) that one or more "pharmaceutical substances *per se*" in substance be disclosed in the complete specification and in substance fall within the scope of the claims of the Patent (s 70(2)(a)); and

   (b) that goods containing or consisting of at least one of those substances be included in the ARTG (s 70(3)(a)).

   Section 71(2) sets out the time within which such an application must be made.[3]

10. Lundbeck's application to extend the term of the Patent was based on the inclusion of LEXAPRO in the ARTG three months earlier on 16 September 2003. By contrast, any application to extend the term of the Patent based on the earlier inclusion of CIPRAMIL in the ARTG was required to be made by 26 July 1999, by operation of s 71(2)(c).[4]

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[2] (2013) 216 FCR 508; [2013] FCAFC 129 at [5]-[7], [10].
[3] (2013) 216 FCR 508; [2013] FCAFC 129 at [11]-[15], [28].
[4] (2013) 216 FCR 508; [2013] FCAFC 129 at [28]-[29], [60].

11. On 27 May 2004, the Commissioner granted the extension of term of the Patent based on the inclusion of LEXAPRO in the ARTG. The term was extended by 5 years to 13 June 2014 and an entry was made in the Register of Patents (the **Register**) to that effect. The length of the extension was based on the formula set out in s 77 of the Act. Any extension of term based on the earlier inclusion of CIPRAMIL in the ARTG would have been considerably shorter, approximately 3.5 years, to 9 December 2012.[5]

12. On 6 July 2005, Alphapharm commenced a proceeding in the Federal Court seeking revocation of the Patent and removal from the Register of the extension of term, on the basis that Lundbeck's application for the extension had been incorrectly based on the inclusion of LEXAPRO in the ARTG. On 7 July 2005, Alphapharm notified the Commissioner of the earlier inclusion of CIPRAMIL in the ARTG.[6]

13. On 13 July 2005, the Commissioner determined that Lundbeck's application to extend the term of the Patent should have been based on the inclusion of CIPRAMIL, and not LEXAPRO, in the ARTG. The Commissioner proposed to correct the Register pursuant to reg 10.7(7) of the Regulations by adjusting the term of the extension to expire on 9 December 2012 (ie, the shorter extension of approximately 3.5 years instead of 5 years). On 19 May 2006, the Commissioner issued a decision confirming that determination. Both Lundbeck and Alphapharm appealed that decision to the Federal Court.[7]

14. On 24 April 2008, Lindgren J delivered reasons for judgment in the Federal Court proceedings referred to in paragraphs 12 and 13 above, finding that Lundbeck's application to extend the term of the Patent should have been based on the inclusion of CIPRAMIL in the ARTG and was filed out of time. The consequence was not merely that the term of the extension should be

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[5] (2013) 216 FCR 508; [2013] FCAFC 129 at [28], [31].

[6] (2013) 216 FCR 508; [2013] FCAFC 129 at [29].

[7] (2013) 216 FCR 508; [2013] FCAFC 129 at [30]-[31].

shorter, as the Commissioner had found. Since the time limit in s 71(2) was not met, his Honour ordered that the Register be rectified by removing the recordal of any extension of term of the Patent. This was the position for which Alphapharm had contended.[8]

15. Lundbeck appealed to the Full Court. On 11 June 2009, the Full Court delivered reasons for judgment, upholding Lindgren J's findings on the extension of term issue. The Full Court made final orders on 12 June 2009. On 11 December 2009, the High Court refused Lundbeck special leave to appeal from the Full Court's decision. The extension of term was subsequently removed from the Register on 9 February 2010.[9]

16. On 12 June 2009, after final orders had been made by the Full Court on that day, being the day before the 20 year term of the Patent was due to expire, Lundbeck applied to the Commissioner under s 223(2) of the Act for an extension of time within which to file a second application to extend the term of the Patent, this time based on the inclusion of CIPRAMIL in the ARTG. The extension of time sought was nearly 10 years, from 26 July 1999 (being the date by which any such application was required to have been filed) to 12 June 2009 (being the actual date of the application).[10]

17. In mid-June 2009, after the 20 year term of the Patent had expired, Alphapharm and the Third to Fifth Respondents launched generic pharmaceutical products containing (+)-citalopram (as a hydrobromide salt).[11]

18. Alphapharm and the Third to Fifth Respondents opposed Lundbeck's application for an extension of time pursuant to s 223(6) of the Act. These oppositions were heard by a Delegate of the Commissioner and, in a decision dated 1 June 2011, the Delegate granted the extension of time. On

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[8] (2013) 216 FCR 508; [2013] FCAFC 129 at [32].
[9] (2013) 216 FCR 508; [2013] FCAFC 129 at [32]-[36], [91].
[10] (2013) 216 FCR 508; [2013] FCAFC 129 at [33], [60].
[11] (2013) 216 FCR 508; [2013] FCAFC 129 at [34], [126]-[127].

4 December 2012, the Tribunal affirmed the Commissioner's decision on a merits review under s 224(1)(a) of the Act and s 43 of the *Administrative Appeals Tribunal Act* 1975 (Cth) (the **AAT Act**). On 18 November 2013, the Full Court dismissed an appeal from the Tribunal under s 44 of the AAT Act.

19. In the proceedings before the Delegate, the Tribunal and the Full Court, Alphapharm and the Third to Fifth Respondents opposed the extension of time on several bases, including that there was no power to grant the extension under s 223(2) of the Act and discretionary grounds. Alphapharm appeals by special leave from the Full Court's decision on the question of the power to grant the extension under s 223(2).

Part VI: Argument

Overview of Alphapharm's position

20. Each of the Delegate, the Tribunal and the Full Court held that s 223(2) of the Act conferred power on the Commissioner to grant the extension of time sought by Lundbeck, though their reasons for doing so differed. In Alphapharm's submission, the power was not available in this case because it was specifically excluded by regulations made pursuant to the Act.

21. The Act imposes time limits for the doing of acts permitted or required to be done under the Act. Section 223 makes general provision for the extension of such time limits in certain circumstances. Relevantly for the purposes of this appeal, s 223(2) and (11) provide as follows:

> *(2) 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;*
>
> *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.*

(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.*

The full text of s 223 appears in **Annexure A** to these submissions.

22. As is apparent, these provisions contemplate that the power to extend time will not be available in relation to every act that has a time limit under the Act. In particular, the power to extend time under s 223(2) is available only for a "relevant act". That term is defined in s 223(11) as being, relevantly, "an action (other than a prescribed action) in relation to a patent". The reference to a "prescribed action" engages the general power in s 228(1)(a) of the Act to "make regulations, not inconsistent with this Act ... prescribing matters required or permitted by this Act to be prescribed".

23. Accordingly, in applying s 223(2), it is necessary, first, to identify an action in relation to a patent, and secondly, to consider whether that action is a prescribed action. If it is a prescribed action, it follows that it is not a relevant act and thus falls outside the ambit of the power to extend time.

24. As to the **first** step, in this case, the "action ... in relation to a patent" was the filing of an application to extend the term of the Patent. Section 70(1) of the Act made provision for the filing of such an application, and s 71(2) of the Act made provision for the time within which it was required to be filed.

25. As to the **second** step, reg 22.11(4) prescribed certain kinds of actions for the purposes of s 223(11). At the time of the hearing before the Tribunal, the regulation relevantly provided:

> *(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.*

26. That is a description of the act for which an extension of time was sought in this case. The act for which the extension was sought was precisely that described in reg 22.11(4)(b): it was the filing, during the term of the patent as required by s 71(2) of the Act, of an application under s 70(1) of the Act for an extension of the term of the Patent. It follows that the action in question was a prescribed action, and was outside the definition of "relevant act" in s 223(11). It was therefore not a relevant act in respect of which time could be extended under s 223(2).

The Full Court's reasons

10 27. The Full Court avoided this result by treating the filing of an application to extend the term of a patent under s 70(1) as involving not one action, but rather two separate actions. In this regard, Yates J, with whom Jessup and Jagot JJ agreed, said:[12]

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

28. On this basis, the Full Court held that the power to extend time was available in this case, because Lundbeck sought an extension of time for "filing the application within six months of the applicable date", by which the Court meant 6 months after the latest of the dates referred to in s 71(2)(a) to (c) (ie, the second "action" identified by the Court), but not "filing the application ... during the term of the patent" (ie, the first "action" identified).

29. Alphapharm respectfully submits that the Full Court's approach was in error for the reasons set out below. In summary, the Full Court construed reg 22.11(4)(b) in a manner that is inconsistent with the Act, which plainly
30 makes provision for only a single action in relation to a patent under s 70(1).

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[12] (2013) 216 FCR 508; [2013] FCAFC 129 at [51].

It is necessary in this context to approach the matter by starting with the wording of the Act, before considering the wording of the regulations made pursuant to the Act.

30. **First**, the Full Court's approach artificially treats s 70(1) as dealing with two separate actions in relation to a patent, when on its proper construction, that section deals with only one such action: the filing of an application to extend the term of a patent. This is apparent from the wording of s 70(1), which provides simply that "[t]he 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". The additional sub-sections set out the requirements to be met by such an application.

31. An "action" is, relevantly, "something done; an act; a deed".[13] There is only one action (thing, act or deed) to be done under s 70(1), and it is only done once. To illustrate the point, on the facts of this case, the action taken by Lundbeck on 12 June 2009 was the filing of a single application to extend the term of the Patent. Lundbeck did not file two applications, or require an extension of time for filing one application but not the other.[14]

32. **Secondly**, s 71(2) does not affect this analysis. It provides that the single application referred to in s 70(1) must be filed within a particular time or deadline. It does not convert what is in fact a single action into two separate actions:

> *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);*

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[13] *Macquarie Dictionary*, Fifth Edition (2009), definition of "action" (as a noun, item 2).

[14] Letter dated 12 June 2009 from Corrs Chambers Westgarth, solicitors for Lundbeck, to the Commissioner (with enclosures).

(c) the date of commencement of this section.

33. As is apparent, the timing requirement in s 71(2) is the product of several conditions, but those conditions are cumulative. The sub-section provides for one deadline by which the action must be done. There are not alternative means of compliance for the action. Nor are there time limits to be complied with separately by taking more than one action.

34. To similar effect, the balance of the provisions in Part 3 of Chapter 6 of the Act, which contains the extension of term regime, consistently refer to the patentee making "an application" or "the application" for an extension of the term of a patent: see ss 71(1), 72, 73, 75 and 76A.

35. **Thirdly**, in Alphapharm's respectful submission, the Full Court incorrectly used the wording of the regulation as the basis for arriving at a construction of the Act. The Full Court first identified the two separate actions by reference to the wording of reg 22.11(4)(b), and then reasoned that they were two separate actions under s 70(1) for the purposes of s 223(2) and (11) of the Act. This is apparent from the extract from the reasons quoted in paragraph 27 above.

36. Alphapharm respectfully submits that such a process of construction is not permissible. It is not legitimate to construe a statute by reference to the wording of the regulations made under it: see *Webster v McIntosh* (1980) 32 ALR 603 at 606 per Brennan J; *Hunter Resources Ltd v Melville* (1988) 164 CLR 234 at 244 per Mason CJ and Gaudron J; *Master Education Services Pty Ltd v Ketchell* (2008) 236 CLR 101 at [19] per Gummow A-CJ, Kirby, Hayne, Crennan and Kiefel JJ.

37. **Fourthly**, the wording of reg 22.11(4)(b) does not lead to the conclusion reached by the Full Court in any event. The regulation prescribes the action of "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". This naturally comprehends the single

action of filing an application to extend the term of a patent under s 70(1) within the time limit provided for by s 71(2).

38. In particular, the words "as required by subsection 71(2) of the Act", as they appear in reg 22.11(4)(b), comprehend the whole of the timing requirement of s 71(2), which is the product of all of its constituent conditions including those in sub-paragraphs (a), (b) and (c). Indeed, had there been an intention to identify and prescribe only the requirement to file the application under s 70(1) within the term of the patent – even assuming that this would have been permissible – the words "as required by subsection 71(2) of the Act" would not have been necessary.

39. Contrary to the Full Court's reasons, this does not ignore the presence in reg 22.11(4)(b) of the words "during the term of a standard patent".[15] Those words appear as part of the composite phrase quoted in paragraph 37 above that identifies the action by reference to its applicable time limit. A similar approach can be seen in the reference in s 223(11) to "the making of a Convention application within the time allowed for making such applications".

40. In any event, the presence of those words in the regulation could not alter the scope of the power delegated by the Act to prescribe an "action ... in relation to a patent". The regulation is required to be consistent with the Act,[16] and a construction of the regulation that avoids debate as to its validity is to be preferred.[17] The wording of s 223(11), read in light of the general regulation making power in s 228 (and s 228(1)(a) in particular), does not accommodate the result reached by the Full Court which disaggregates the composite requirements of ss 70 and 71(2).

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[15] Cf (2013) 216 FCR 508; [2013] FCAFC 129 at [49].

[16] *Master Education Services Pty Ltd v Ketchell* (2008) 236 CLR 101 at [19] per Gummow A-CJ, Kirby, Hayne, Crennan and Kiefel JJ.

[17] *Widgee Shire Council v Bonney* (1907) 4 CLR 977 at 983 per Griffiths CJ; *Eremin v Minister for Immigration, Local Government and Ethnic Affairs* (1990) 21 ALD 69 at 75-76 per Lockhart, Gummow and Foster JJ; *Airservices Australia v Canadian International Airlines Ltd* (1999) 202 CLR 133 at [229] per McHugh J.

The Tribunal's reasons

41. The Tribunal reached the same conclusion as the Full Court, but the reasons it gave for doing so were somewhat different. Accepting submissions put by Lundbeck, the Tribunal construed reg 22.11(4)(b) as though it operated on "time requirements" as opposed to an "action ... in relation to a patent".[18] The Tribunal accepted Lundbeck's submission to the following effect:[19]

> *Lundbeck submits that the second time requirement that an application be filed within 6 months of the latest of the dates in section 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.*

42. This led the Tribunal to conclude that reg 22.11(4)(b) "operates on only one of the two time limits referred to in s 71(2)".[20] Notwithstanding its difference in reasoning from that of the Tribunal, the Full Court held that the Tribunal was correct to accept Lundbeck's contention to that effect.[21]

43. The approach of the Tribunal disregards the fact that the power delegated pursuant to s 223(2) and (11) is to prescribe an action in relation to a patent, not to modify or dissect the timing requirement for such an action as provided for by the Act. Once an action is prescribed under s 223(11), it is outside the definition of "relevant act" and not within the ambit of s 223(2). Similarly, reg 22.11(4)(b) identifies an action: it does not draw a distinction between types of breach of the time limits of s 71(2). If that is what was intended, something far more precise would have been required.

44. The points made above in relation to the approach adopted by the Full Court otherwise apply to that of the Tribunal.

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[18] (2012) 132 ALD 648; [2012] AATA 851 at [41]-[43].
[19] (2012) 132 ALD 648; [2012] AATA 851 at [42].
[20] (2012) 132 ALD 648; [2012] AATA 851 at [43].
[21] (2013) 216 FCR 508; [2013] FCAFC 129 at [53].

The Delegate's reasons

45. The Commissioner's Delegate accepted that there was no power to extend time in this case based on a literal reading of reg 22.11(4)(b).[22] This was in contrast to the reasons of the Tribunal and the Full Court.

46. However, the Delegate, again accepting Lundbeck's submissions, avoided that result on the basis that it would be "manifestly absurd" to read the regulation in that way.[23] As submitted below, there is no absurdity in the result contended for by Alphapharm, which accords with the scope and purpose of the legislation and the extrinsic material.

10 47. Further, the Delegate's reasons are affected by a misapprehension as to the nature of the action referred to in reg 22.11(4)(b). The Delegate appeared to consider that the regulation referred to the act that was in fact done by the patentee in this case (the late-filing of its application to extend the term of the Patent) rather than the act that was required to be done and for which an extension of time was being sought (the filing of such an application within the time provided for in s 71(2)). The Delegate's view that the result was a "manifestly absurd" one flowed from that misapprehension.

48. As the Delegate noted,[24] the predecessor provision to reg 22.11(4)(b) was considered in *Boehringer Ingelheim International GmbH* (1999) 48 IPR 177,
20 where the Deputy Commissioner of Patents decided that s 223(2) could not be used to extend the time for filing an application to extend the term of a patent which was in fact made after the term of the patent had expired. That result is correct, as far as it goes, though not for the reasons given by the Deputy Commissioner. It is correct because the effect of reg 22.11(4)(b) is to exclude any application to extend the term of a patent from the ambit of s 223(2), as submitted above.

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[22] (2011) 92 IPR 628; [2011] APO 36 at [41].

[23] (2011) 92 IPR 628; [2011] APO 36 at [42]-[54].

[24] (2011) 92 IPR 628; [2011] APO 36 at [35]-[39].

The extrinsic material

49. The construction contended for by Alphapharm accords with an Explanatory Statement that accompanied the introduction of the predecessor provision to reg 22.11(4)(b), being former reg 22.11(3)(c), which was in substantially the same terms.[25] This Explanatory Statement stated that the regulation "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".[26]

50. Both the Tribunal and the Delegate instead placed considerable reliance on an Explanatory Memorandum[27] that accompanied the *Intellectual Property Laws Amendment Bill* 1997 (Cth).[28] That Bill led to the introduction of the extension of term provisions in Part 3 of Chapter 6 of the Act, but predated the introduction of the regulation. The Full Court also referred to the Explanatory Memorandum but considered that recourse to the extrinsic materials was unnecessary.[29]

51. In any event, the Explanatory Memorandum does not lead to the conclusion reached by the Full Court, the Tribunal or the Delegate. It states that "[t]he extension of time provision under section 223 ... will apply to all acts required to be done under the extension of patent term scheme provided that the relevant criteria are satisfied". Plainly, the "extension of time provision under s 223" includes all parts of s 223, including s 223(11) and the provision for regulations to be made prescribing particular actions in relation to a patent as not being "relevant acts". The Explanatory Memorandum also

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[25] Explanatory Statement to the *Patents Amendment Regulations 1998* (No 8) 1998, p 2. See Annexure A for the wording of former reg 22.11(3)(c).

[26] Quoted by the Full Court at (2013) 216 FCR 508; [2013] FCAFC 129 at [57].

[27] Revised Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill* 1997 (Cth), Notes on Clauses, p 18 at [14].

[28] (2012) 132 ALD 648; [2012] AATA 851 at [46]; (2011) 92 IPR 628; [2011] APO 36 at [47]-[48].

[29] (2013) 216 FCR 508; [2013] FCAFC 129 at [57]. The text of the Explanatory Memorandum under consideration appears at (2013) 216 FCR 508; [2013] FCAFC 129 at [55].

refers to the "relevant criteria" being satisfied. It does not state that the power under s 223(2) will be available for every act that is required to be done under Part 3 of Chapter 6 of the Act.

52. Further, the Explanatory Memorandum was followed by the introduction of reg 22.11(4)(b) and its predecessor provision in reg 22.11(3)(c), each of which (as the Full Court held) plainly prescribed an action in relation to a patent for the purposes of s 223(11) of the Act. Even on the Full Court's construction of the provisions, the power to extend time under s 223(2) is not available for "all acts required to be done" under Part 3 of Chapter 6.

10 53. Each of the Explanatory Statement and the Explanatory Memorandum is consistent with the construction for which Alphapharm contends. As the Full Court observed, the Explanatory Statement recites the substance of the words of reg 22.11(4)(b),[30] but its existence confirms that there was an intention to exclude certain actions in relation to a patent under Part 3 of Chapter 6 of the Act from the ambit of s 223(2).

Context, purpose and policy considerations

54. Alphapharm's construction accords with the context and purpose of the Act and the Regulations. Section 223(2) is, on its face, a provision of general application. It applies to any "action ... in relation to a patent" under the Act,
20 provided that the action is not excluded under s 223(11) and the criteria for the exercise of the power in s 223(2) are satisfied. The existence of reg 22.11(4)(b), however construed, makes it plain that the legislature considered it appropriate to limit the application of that general power in the context of extensions of term under Part 3 of Chapter 6 of the Act.

55. There is no reason in principle why any power to extend time should be available for the filing of an application to extend the term of a Patent under Part 3 of Chapter 6 of the Act. Nor is there any reason why the provisions

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[30] (2013) 216 FCR 508; [2013] FCAFC 129 at [58].

said to confer such a power should be construed "beneficially", a proposition advanced by Lundbeck below.

56. An application to extend the term of a patent goes to the extension of an existing monopoly in favour of a patentee beyond its 20 year term provided for by the Act. A limitation on the term of such monopolies has been a central feature of this exception to the prohibition of the grant of monopolies since the *Statute of Monopolies* 1623. The filing of such an application should be subject to clear timing requirements, not least because the public is entitled to rely on the face of the Register as reflecting the term of the monopoly rights of the patentee. Third parties should be able to plan their affairs on the basis of the Register.[31] Delay in seeking an extension of term is corrosive of the public interest because it undermines the reliability of the Register as a statement of the term of the monopoly granted. Letters patent are of their nature "open letters", not sealed up but exposed to view and addressed to the public at large.[32]

57. The timing of an application to extend the term of a patent is within the control of the patentee, and depends upon matters that can reasonably be expected to be within the knowledge of the patentee. These include the matters referred to in sub-paragraphs (a), (b) and (c) of s 71(2). The provision generously allows the patentee up to 6 months after the latest of those dates, provided that the application is filed within the term of the patent. The Full Court found that the latter condition is one that is not capable of being relaxed by any extension of time under s 223(2).

58. Plainly, one aim of the scheme in Part 3 of Chapter 6 of the Act is to provide third parties with certainty in relation to the term of pharmaceutical patents.

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[31] As to the purpose of the Register in providing certainty to third parties regarding patents, see the discussion in *Stack v State of Queensland* (1996) 68 FCR 247 at 252 per Kiefel J.

[32] See Lahore, *Patents Trade Marks and Related Rights* (looseleaf) at [5005]; Miller *et al*, *Terrell on the Law of Patents*, 17th Edition at [1.02]. See also the definition of "patent" in Schedule 1 to the Act.

The construction of reg 22.11(4)(b) contended for by Alphapharm promotes that objective.

Overseas jurisdictions

59. The position for which Alphapharm contends is not inconsistent with the position in key overseas jurisdictions. While such regimes involve different statutory wording, it assists to have regard to the approach adopted elsewhere.[33] In general terms, the overseas regimes reflect a continuing strictness in relation to applications to extend the term of patents.

60. In particular, in the United States, no extension of time is available for the filing of an application to extend the term of a patent under 35 USC 156(d)(1), which sets a deadline for the filing of such an application but is accompanied by no extension of time provision.[34] The *Manual of Patent Examining Procedure* of the United States Patent and Trademark Office states:[35]

> *An application for patent term extension under 35 USC 156(d)(1) may only be filed within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The statutory time period is not extendable and cannot be waived or excused.*

61. Patent term extensions are not presently available at all in Canada or New Zealand, so the issue does not arise in those jurisdictions.

62. The position in Europe is more complicated. It appears that a discretion exists under European regulations, which has been exercised to grant limited extensions of time in some countries, including the United Kingdom, in narrow circumstances. In practice, however, the power to grant an

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[33] See *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 88 ALJR 261; [2013] HCA 50 at [243] ff per Crennan and Kiefel JJ (in the context of the issue of patentability).

[34] This is the case notwithstanding the requirement in the *Australia-United States Free Trade Agreement*, Art 17.9 (Patents) that both countries introduce patent term extension protection for pharmaceutical patents: see Art 17.9, cl 8. Both the United States and Australia must implement a patent term extension regime, yet only Australia would allow extensions of time for filing applications for extensions of term on the Full Court's construction.

[35] USPTO *Manual of Patent Examining Procedure*, para 2754.01.

extension of time has been treated as being narrowly confined, and as permitting extensions of only limited duration.[36]

63. Notably, the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1995) (**TRIPS Agreement**) and other intellectual property treaties impose no obligation on Member States to provide for extensions of time in the context of applications to extend the term of patents. The TRIPS Agreement requires only that pharmaceutical (and other) patents have a term of not less than 20 years from the filing date.[37]

Conclusion

10 64. On the Full Court's approach in this case, an extension of time to file an application under s 70(1) of the Act may be granted regardless of the length of the extension of time sought, provided that the application is made within the term of the patent. Here, the extension of time sought by Lundbeck was nearly 10 years in length, and was applied for on the day before the 20 year term of the Patent expired. The availability of an extension of time of that length for the taking of an action that is of central significance to the patent system is apt to deprive the system of certainty and impact adversely on the interests of third parties, as it in fact did in this case.

65. The Act involves a balance between the rights of patentees and the public.
20 A central tenet of the Act and the other regimes referred to above continues to be that third parties and the public in general are entitled to know when a statutory monopoly will end. This allows them to plan and to make decisions as to whether, and if so when, to exploit the invention, as they are entitled to do following the expiry of the patent term. The availability in this context of the general power to extend time under s 223(2) of the Act has the potential to undermine these objectives. On the construction contended for by Alphapharm, the prescription in reg 22.11(4)(b) reflects a recognition that, in

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[36] See the discussion in *In re Abbott Laboratories' SPC Application* [2004] RPC 20 at [32]-[50], esp at [33].

[37] TRIPS Agreement, Art 33 (Term of Protection). See also fn 34 above.

the particular context of extensions of term of pharmaceutical patents under Part 3 of Chapter 6 of the Act, the interests of certainty should prevail.

66. For the above reasons, there was no power to grant the extension of time sought by Lundbeck in this case. The Full Court's orders should be set aside, and orders should be made in accordance with the notice of appeal as set out in Part VIII below.

Part VII: Applicable provisions

67. The applicable provisions of the Act and Regulations, as they existed at the time of the hearing before the Tribunal,[38] are set out in **Annexure A** to these submissions. The text of the Regulations has changed since that time, as also set out in Annexure A. In Alphapharm's submission, the changes do not affect the determination of the appeal.

Part VIII: Orders sought

68. Alphapharm seeks the following orders:

1. *An order that the appeal be allowed.*

2. *An order that order 1 made by the Full Court of the Federal Court of Australia on 18 November 2013 be set aside and in lieu thereof orders that:*

   (a) *the decision of the Administrative Appeals Tribunal given on 4 December 2012 be set aside;*

   (b) *the decision of the Delegate of the Commissioner of Patents given on 1 June 2011 be set aside;*

   (c) *the application by the First Respondent for an extension of time under s 223(2)(a) of the Act be refused.*

3. *An order that the First Respondent pay the Appellant's costs in this Court and the Full Court of the Federal Court of Australia.*

4. *Such further or other orders or relief as the Court thinks fit.*

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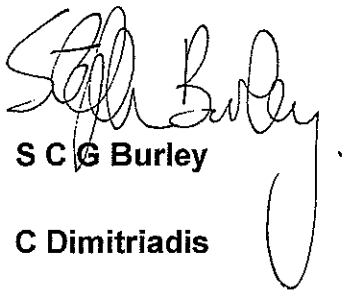
[38] 13-17 August 2012.

Part IX: Oral argument

69. Alphapharm estimates that approximately 1.5 hours (including reply) will be required for the presentation of its oral argument.

DATED: 16 May 2014



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ANNEXURE A

APPLICABLE LEGISLATIVE PROVISIONS

Patents Act 1990 (Cth), ss 70, 71 and 223, as these provisions existed at the time of the hearing before the Tribunal (13-17 August 2012):

70 Applications for extension of patent

(1) 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.

(2) Either or both of the following conditions must be satisfied:

(a) one or more pharmaceutical substances per se must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification;

(b) one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification.

(3) Both of the following conditions must be satisfied in relation to at least one of those pharmaceutical substances:

(a) goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods;

(b) the period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years.

Note: Section 65 sets out the date of a patent.

(4) The term of the patent must not have been previously extended under this Part.

*(5) For the purposes of this section, the **first regulatory approval date**, in relation to a pharmaceutical substance, is:*

(a) if no pre-TGA marketing approval was given in relation to the substance—the date of commencement of the first inclusion in the Australian Register of Therapeutic Goods of goods that contain, or consist of, the substance; or

(b) if pre-TGA marketing approval was given in relation to the substance—the date of the first approval.

*(6) For the purposes of this section, **pre-TGA marketing approval**, in relation to a pharmaceutical substance, is an approval (however described) by a Minister, or a Secretary of a Department, to:*

(a) market the substance, or a product containing the substance, in Australia; or

(b) import into Australia, for general marketing, the substance or a product containing the substance.

71 Form and timing of an application

Form of application

(1) An application for an extension of the term of a standard patent must:

(a) be in the approved form; and

(b) be accompanied by such documents (if any) as are ascertained in accordance with the regulations; and

(c) be accompanied by such information (if any) as is ascertained in accordance with the regulations.

For this purpose, ***document*** includes a copy of a document.

Timing of application

(2) 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.

223 Extensions of time

(1) The Commissioner must extend the time for doing a relevant act that is required to be done within a certain time if the act is not, or cannot be, done within that time because of an error or omission by:

(a) the Commissioner or a Deputy Commissioner; or

(b) an employee; or

(c) a person providing, or proposing to provide, services for the benefit of the Patent Office.

(2) 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;

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.

(2A) If:

(a) a relevant act that is required to be done within a certain time is not done within that time; and

(b) the Commissioner is satisfied that the person concerned took due care, as required in the circumstances, to ensure the doing of the act within that time;

the Commissioner must, on application made by the person concerned in accordance with the regulations and within the prescribed period, extend the time for doing the act.

(2B) An extension of time under subsection (2A) cannot exceed the period prescribed for the purposes of this subsection.

(3) The time allowed for doing a relevant act may be extended, whether before or after that time has expired.

(3A) Despite subsection (3), the time allowed for doing a relevant act may be extended under subsection (2A) only after that time has expired.

(4) The Commissioner must advertise in the Official Journal:

(a) an application made for an extension of time for more than 3 months; or

(b) an application made for an extension of time for doing a prescribed relevant act in prescribed circumstances.

(6) Subject to subsection (6A), a person may, as prescribed, oppose the granting under subsection (2) or (2A) of the application.

(6A) If the Commissioner is satisfied that an application under subsection (2) or (2A) would not be granted even in the absence of opposition under subsection (6):

(a) the Commissioner need not advertise the application in accordance with subsection (4); and

(b) the application cannot be opposed, despite subsection (6); and

(c) the Commissioner must refuse to grant the application.

(7) Where:

(a) a patent application lapses, or a patent ceases, because of a failure to do one or more relevant acts within the time allowed; and

(b) the time for doing that act or those acts is extended;

the application or patent must be treated as having been restored.

(8) Where:

(a) a provisional patent application lapses under subsection 142(1) at the end of the period prescribed for the purposes of section 38; and

(b) that period is extended;

the application must be treated as if it had not lapsed.

(9) Where the Commissioner grants:

(a) an extension of more than 3 months for doing a relevant act; or

(b) an extension of time for doing a prescribed relevant act in prescribed circumstances;

the prescribed provisions have effect for the protection or compensation of persons who, before the day on which the application for extension of time is advertised under subsection (4), exploited (or took definite steps by way of contract or otherwise to exploit) the invention concerned because of the failure to do the relevant act within the time allowed, the lapsing of the patent application or the ceasing of the patent, as the case may be.

(10) Infringement proceedings cannot be brought in respect of an infringement committed:

(a) between the day on which the patent application lapses and the day on which it is restored; or

(b) between the day on which the patent ceases and the day on which it is restored.

(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.*

Patents Act 1990 (Cth), ss 70, 71 and 223, as currently in force:

There has been no change to the wording of ss 70 or 71 from that set out above. Sub-ss (1), (2A) and (6A) of s 223 have been amended by the insertion of the underlined words set out below, but otherwise, there has also been no change to the wording of s 223.

223 Extensions of time

(1) The Commissioner must extend the time for doing a relevant act that is required to be done within a certain time if the act is not, or cannot be, done within that time because of an error or omission by:

(a) the Commissioner or a Deputy Commissioner; or

(b) an employee; or

(c) a person providing, or proposing to provide, services for the benefit of the Patent Office; or

(d) the receiving Office; or

(e) the International Bureau of the World Intellectual Property Organization.

(2A) If:

(a) a relevant act that is required to be done within a certain time is not done within that time; and

(b) the Commissioner is satisfied, on the balance of probabilities, that the person concerned took due care, as required in the circumstances, to ensure the doing of the act within that time;

the Commissioner must, on application made by the person concerned in accordance with the regulations and within the prescribed period, extend the time for doing the act.

(6A) If the Commissioner is satisfied, on the balance of probabilities, that an application under subsection (2) or (2A) would not be granted even in the absence of opposition under subsection (6):

(a) the Commissioner need not advertise the application in accordance with subsection (4); and

(b) the application cannot be opposed, despite subsection (6); and

(c) the Commissioner must refuse to grant the application.

Patents Regulations 1991 (Cth), reg 22.11(4), as this provision existed at the time of the hearing before the Tribunal (13-17 August 2012):

22.11 Extension of time

*(4) 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) an action or step prescribed in Chapter 20.

Patents Regulations 1991 (Cth), reg 22.11(4), as currently in force:

22.11 Extension of time

*(4) For the definition of **relevant act** in subsection 223(11) of the Act, the following are prescribed:*

(a) an action mentioned in Chapter 5, other than an action or step taken under regulation 5.4, 5.5, 5.10 or 5.11;

(b) filing, during the term of a standard patent under 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) an action mentioned in Chapter 20.

Patents Regulations 1991 (Cth), reg 22.11(3)(c), as in force prior to 24 May 2001:

22.11 Extension of time

(3) For the purposes of the definition of "relevant act" in subsection 223(11) of the Act, each of the following actions is prescribed:

...

(c) 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.