

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No S 97 of 2014

BETWEEN:

ALPHAPHARM PTY LTD
Appellant

and

H LUNDBECK A/S
First Respondent

COMMISSIONER OF PATENTS
Second Respondent

ASPEN PHARMA PTY LTD
Third Respondent

SANDOZ PTY LTD
Fourth Respondent

APOTEX PTY LTD
Fifth Respondent



APPELLANT'S REPLY

Part I: Suitable for publication

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

Part II: Reply to the arguments of Lundbeck and IPTA

2. The contention that Alphapharm "starts at the wrong end by asking whether an application to extend a term of a patent is a single act" (Lundbeck's submissions (LS) 28) is misplaced. Unlike Lundbeck, Alphapharm applies the words of s 223(11), which require, as a first step, identification of an "action ... in relation to a patent". The scheme of s 223 is to allow the executive to identify certain actions for which extensions of time are not permitted. The power delegated is to prescribe an act, not to modify or dissect the timing requirement for such an act.
3. Lundbeck focuses on "time limits" and "time requirements" and treats s 223(11) and reg 22.11(4)(b) as though they operate on such requirements and not on "an action" (other than a prescribed action) (LS 9, 14-20, 33). This reflects the reasoning of the Tribunal, which was incorrect for the reasons previously given (Alphapharm's submissions in chief (AS) 41-44). The imprecision in Lundbeck's approach is illustrated by its submission that the Tribunal accepted "the requirement that Lundbeck's application be filed within

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six months of the applicable date in s 71(2) was a ‘relevant act’ in respect of which time could be extended” (LS 8; emphasis added).

4. The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) seeks leave to intervene as *amicus curiae*. It has filed submissions (IS) which support, but add no substantively different arguments to, those of Lundbeck. The supporting affidavit (Davies Affidavit) contains untested factual assertions which are made to advance IPTA’s construction arguments (IS 6(c), 13, 20(a), 22-24). Those assertions were not before the Tribunal and do not fall within s 15AB of the *Acts Interpretation Act 1901* (Cth).

10 **Two acts or time limits**

5. Lundbeck’ arguments (LS 26, 27; IS 32, 35) involve treating an application to extend the term of a patent under s 70(1) as requiring two separate “acts” in relation to a patent when, on its proper construction, the subsection provides for only one. It is artificial, and not supported by the wording the Act, to regard the making of an application under s 70(1) as involving two notional actions, or two applications, that are separate and distinct.¹ Lundbeck’s contention that s 71(2) imposes two separate and distinct time limits (LS 14, 21-33, 45; IS 33) should also not be accepted. As submitted (AS 32-33), s 71(2) imposes a single time limit or deadline for the doing of a single act. That time limit is the product of dual interrelated conditions. The act is either done within the time required or it is not. It is not done twice, once with respect to each of two time limits (c.f. especially LS 22, last sentence).

“Within a certain time”

6. Lundbeck relies on the words “within a certain time” in s 223(2) (LS 17, 26). This argument was not raised below. It does not assist Lundbeck now.
7. First, it disregards the fact that the words “within a certain time” do not appear in the definition of “relevant act”. Section 223(11) defines a “relevant act” as being, relevantly, “an action (other than a prescribed action) in relation to a patent”. The prescription in reg 22.11(4)(b) applies in relation to such an action, not by reference to “a certain time”. Further, Lundbeck misquotes s 223(11), which does not use the phrase “time limit” (c.f., LS 27). The words “within the time allowed for making such applications” provide no support for Lundbeck’s attempt to distinguish between different “time limits” applicable to the same action. Consistently with this, there is only a single time limit for making a Convention application.²
8. Secondly, the words “within a certain time” in s 223(2) simply denote the (single) time allowed for doing the particular act, and distinguish that usage of “time” from the phrase

¹ Lundbeck has not disputed that the words “act” or “action” in this context refer to something that is done – i.e., an act or a deed (AS 31, fn 13). IPTA adds that an “action” is a “process of doing something” (IS 27(a)); however, contrary to IPTA’s submission, that observation does not justify importing a timing limitation into the concept.

² Within 12 months after the filing of the first “basic application”: s 94 of the Act and reg 8.5(2) of the Regulations. The same time limit applied under the *Patents Act 1952* (Cth) in *Australian Paper Manufacturers Ltd v CIL Inc* (1981) 148 CLR 551, referred to by Lundbeck (in LS 28).

“extend the time for doing the act” later in the subsection. The subsection does not contemplate more than one “certain time” for a given “relevant act”.³

9. The effect of Lundbeck’s construction is to make the power to extend time conditional upon the nature of the breach: an extension of time is available where a late application to extend the term of the patent is filed before the end of the term, but not after. However, when s 223(2) refers to a “relevant act that is required to be done within a certain time”, it means the act the legislation requires to be done, not the act in fact done by the patentee in default of the timing requirements. This is reinforced by reg 22.11(4)(b), which refers to the filing “as required by subsection 71(2) ... of an application under subsection 70(1)”.

Construction of regulation 22.11(4)(b)

10. Alphapharm’s construction does not render the words “during the term of a standard patent as required by subsection 71(2) of the Act” otiose (LS 51; IS 42, 46). As submitted (AS 39), those words are part of a composite phrase identifying the filing of an application to extend the term of a patent by reference to its applicable time limit.⁴ On Alphapharm’s approach, all of the words in reg 22.11(4)(b) can be given meaning. The words “as required by subsection 71(2)” comprehend the whole of the timing requirement of s 71(2), which is the product of all of its constituent conditions including those in s 71(2)(a)-(c). On Lundbeck’s reasoning, applied to its own construction of the regulation, it can equally be said that the words “as required by subsection 71(2)” are otiose; it would have been sufficient simply to say “during the term of the patent”. The authorities in LS 52 do not assist Lundbeck.

Context, purpose and policy

11. There is no evidence that the so-called “two different limbs” of s 71(2) were introduced for “quite different policy” reasons (LS 30). The conditions in s 71(2) all respond to the same policy: that the public should have certainty in relation to the term of patents. If there were markedly different policy objectives, one might have expected this to be reflected in the Act: for example, by provision being made for the relaxation of one condition but not the other. Instead, the matter was left for prescription under s 223(11).
12. Lundbeck submits that, on Alphapharm’s construction, no extension of time to apply for an extension of term can be granted “even where it is entirely the fault of the Patent Office” (LS 58). This presumably refers to the fact that the definition of “relevant act” in s 223(11) applies not only to s 223(2), but also to s 223(1), which deals with errors by the Commissioner. However, it is difficult to conceive of any case in which the **failure by a patentee to file** an application for extension of term under s 70(1) could be the fault of the Patent Office – much less “entirely” its fault as hypothesised by Lundbeck. Lundbeck’s point also overlooks the fact that, even on its construction, there would be no power under s 223(1) to grant an extension of time in which to apply for an extension

³ C.f. also IS 27. Further, contrary to IS 30, the decision of the Court in *Australian Paper* is of no assistance; s 160 of the *Patents Act 1952* (Cth) contained no definition of “relevant act”.

⁴ A similar approach is seen in s 223(11). Indeed, on Lundbeck’s reasoning, the words “within the time allowed for making such applications” in s 223(11) would also be otiose. The Court would not lightly adopt such a construction, as LS 52 acknowledges.

of term after the relevant patent has expired, regardless of the cause. As submitted (AS 57), it is precisely because the timing of an application to extend the term of a patent is within the control of the patentee, and depends upon matters within the knowledge of the patentee, that Alphapharm's construction is appropriate.

13. The suggestion by IPTA that one policy rationale underlying s 223(2) is to protect patent attorneys who fail to meet timing deadlines (IS 22-24) is not supported by admissible evidence (see paragraph 4 above). The permissible extrinsic materials do not support such a proposition.

10 14. Lundbeck's assertion (LS 32) that s 223 is "impossible to apply" on Alphapharm's construction is without foundation and should be rejected.

The legislative history

20 15. The legislative history preceding the introduction of Part 3 of Chapter 6 of the Act does not aid Lundbeck's position (c.f. LS 34-44). Previous patent term extension schemes were markedly different. They applied to all patents, and depended on criteria relating to the adequacy of remuneration under the patent.⁵ Moreover, under earlier legislation, the extension of term schemes incorporated a general discretion on the part of the Court as to the timing of the application: see *Sanofi v Parke Davis Pty Ltd (No 2)* (1983) 152 CLR 1 at 6, discussing s 90(1) of the *Patents Act 1952* (Cth) (**1952 Act**). The extension of term provisions under the current Act are far narrower than under the 1952 Act, and the policy considerations under the current Act can not be considered to be coterminous with those considered in *Sanofi* (c.f. IS 8-10).

16. When the extension of term provisions of the current Act were introduced, extensions of term were confined to pharmaceutical patents and strict time limits were introduced. Further, as Lundbeck observes, the Act as initially enacted included an express provision in s 223(5) that an extension of time of more than 3 months was not available for an application to extend the term of a patent (LS 38). Thus there was a hard deadline that had to be complied with. That reflects the position under the current scheme consistent with Alphapharm's construction of the provisions.

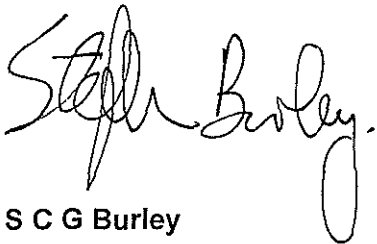
30 17. What the history does reveal is a progressive tightening of the requirements for the filing of applications to extend the term of patents, with an insistence under the Act (as initially enacted) on strict compliance with time limits. In fact, the legislative history and extrinsic material available prior to the coming into force of the Act on 30 April 1991 demonstrate a policy recognition of disadvantage to the public interest arising from a lack of certainty in the term of patents: Industrial Property Advisory Committee report *Patents, Innovation and Competition in Australia*, 29 August 1984 (**IPAC Report**), Recommendation 11 and pp 38-39; Minister for Science and Technology's response to the IPAC Report, *Official Journal of Patents, Trade Marks and Designs* Vol 56, No 47, 18 December 1986, pp 1466-1467; Explanatory Memorandum to *Patents Amendment Bill 1989*, Item 31; Second Reading Speech to Patents Bill 1990, 29 May 1990, pp 1271, 1272.

⁵ See Lawson C, *How are pharmaceutical patent term extensions justified? Australia's evolving scheme*, (2013) 21 JLM 379.

18. At various places, Lundbeck paraphrases the language of the Explanatory Memorandum for the current extension of term scheme (e.g., LS 44, 45, 61). This did not state that the power to extend time would be generally available. It simply said “[t]he extension of time provision under section 223” would apply “provided that the relevant criteria are satisfied”. Those criteria included the existence of a “relevant act”, and s 223(11) included the power to prescribe such acts.

Administrative practice

- 10 19. Lundbeck relies on statements by IP Australia to support its argument (LS 68, 72). The United Kingdom authorities it cites (LS 68, fn 35) have not been applied in Australia, and reservations have been expressed about the principle in question.⁶ The statements on which Lundbeck relies have no legislative status and do not meet the requirements of s 15AB of the *Acts Interpretation Act 1901* (Cth). They cannot displace the statutory text.⁷ The Full Court was correct to hold that statements of this kind were irrelevant.⁸
- 20 20. Lundbeck also submits that the re-enactment of reg 22.11(4)(b) is relevant and shows that its construction is accepted by the executive (LS 70, 71). That approach has been criticised in this Court.⁹ In any event, until this case, there was no judicial decision on point. The decision of the Deputy Commissioner in *Re Boehringer Ingelheim International GmbH* (1999) 48 IPR 177 was concerned with different facts and held that an extension of time was **not** available. The re-enactment of the regulation as part of a more general package of amendments¹⁰ during the course of the proceedings below is equally consistent with the proposition that the executive either gave no attention to the matter or was content to wait until the case had run its course before considering the position.



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⁶ *Re Apthorpe v The Repatriation Commission* (1987) 71 ALR 571 (cited in LS 68, fn 35).

⁷ See *Federal Commissioner of Taxation v Consolidated Media Holdings Ltd* (2012) 87 ALJR 98 at [39]; *Thiess v Collector of Customs* (2014) 88 ALJR 514 at [22].

⁸ (2013) 216 FCR 508; [2013] FCAFC 129 at [56].

⁹ *Salvation Army (Victoria) Property Trust v Shire of Fern Tree Gully* (1952) 85 CLR 159 at 174, 182; *R v Reynhoudt* (1962) 107 CLR 381 at 388; *Flaherty v Girgis* (1987) 162 CLR 574 at 594.

¹⁰ By the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) and the *Intellectual Property Legislation Amendment (Raising the Bar) Regulation 2013* (No 1) (Cth).