



IN THE HIGH COURT OF AUSTRALIA

SYDNEY REGISTRY
ON APPEAL FROM THE FEDERAL COURT OF AUSTRALIA

S
No. 97 of 2014
A

BETWEEN:

Alphapharm Pty Ltd ACN 002 359 739
Applicant

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

FIRST RESPONDENT'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 By s 71(2) the respondent (**Lundbeck**) was required to make its application for an extension of the term of its patent by 27 June 1999. For reasons accepted by the AAT, it

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failed to do so and sought, and was granted, an extension of time under s 223(2) of the *Patents Act* 1990 (the **Act**). The issue in this appeal is whether making an application under s 70 to extend the patent term within the time required by s 71(2)(a) to (c) is a “prescribed action” within the meaning of s 223(11) of the Act and reg 22.11(4)(b) of the *Patents Regulations* 1991. Lundbeck contends that the delegate, the AAT and the Full Court were correct in holding that there was power under s 223(2) to extend the time.

Part III: Judiciary Act 1903

3 Lundbeck has considered whether any notice should be given in compliance with s 78B of the Judiciary Act 1903. No notice is required.

10 **Part V: Citations**

4 Lundbeck agrees with the relevant citations provided by Appellant.

Part VI: Argument

Application of s 223 to the Lundbeck Application

5 Lundbeck’s application for an extension of the term of its patent was required to comply with two time limits in s 71(2): first, that it make its application within the term of the patent and, secondly, that it make its application within 6 months after the latest of the three dates described in s 71(2)(a), (b) or (c).

6 Lundbeck did not require any dispensation from the first requirement: it had lodged the application on the day before the term expired.

20 7 The second requirement meant that Lundbeck was required to make its application before 26 June 1999¹. Lundbeck’s application for extension of term was made outside of that time limit.

8 The AAT accepted that the requirement that Lundbeck’s application be filed within six months of the applicable date in s 71(2) was a “relevant act” in respect of which time

¹ Being 6 months from the date of commencement of s 70: see s 70(2)(1)(c) and Sch 1 *Intellectual Property Laws Amendment Act* 1998.

could be extended under s 223(2) of the Act. The Full Court held that it was correct to so hold².

9 The making of an application for an extension of term of a patent within six months of the applicable date in s 71(2)(a), (b) or (c) is not a “prescribed act” and that time limit can be extended. That is because:

(a) *Section 71(2) provides first, that the application be lodged within the term of the patent and second, that the application be lodged within 6 months of the applicable date;*

(b) *Section 223(2) operates independently upon both of those two time limits; and*

10 (c) *the prescription in reg 22.11(4)(b) only applies where the application is lodged outside of the term of the patent and means that no extension can be granted to overcome that time limit.*

10 Lundbeck’s application was made within the term of the patent and, accordingly, reg 22.11(4)(b) had no application; s 223(2) gave the Commissioner and, on review, the AAT, the power to extend the time. The Full Court was correct to so hold.

The interplay between ss 70, 71 and 223

11 As this Court has repeatedly emphasized, the starting point is the words of the Act, read in their context³.

12 Section 223 provides a power, and in certain circumstances a duty, to extend the time for
20 doing an act under the Act. Section 223(2) applies where “a relevant act” is “required to be done within a certain time” but has not been done within that time. Accordingly, the starting point in order to apply s 223(2) is to identify whether there was an act in relation to a patent⁴ that was required to be done by a certain time.

² Reasons of the Full Court at [53] per Yates J, Jessup and Jagot JJ agreeing.

³ *Northern Territory v Collins* (2008) 235 CLR 619 at 642 [99]; *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27 at 47 [47]; *Saeed v Minister for Immigration and Citizenship* (2010) 241 CLR 252 at 265 [33].

⁴ Or in relation to a patent application or any proceedings under the Act other than court proceedings: see definition of relevant act in s 223(11).

13 Section 70 provides for applications for extension of term of pharmaceutical patents. It is an important provision designed to ensure that the fair exploitation of a patent term is not truncated by delays in obtaining regulatory approval for a pharmaceutical substance. Its history, to the extent relevant to construction, is set out below at paragraph 34 and following.

14 Section 71 governs the making of applications for an extension of term, including both as to form and by imposing (two) time limits. Section 71(2) provides that an application to extend the term of the patent is subject to two distinct and independent time limits:

- (a) the application must be made before the expiry date of the patent; and
- 10 (b) the application must be made within 6 months after (the latest of) the date of grant, the date on which a good containing the pharmaceutical substance was included in the Australian Register of Therapeutic Goods (**ARTG**) or the date on which the extension of term provisions were enacted as identified in s 71(2)(a), (b) and (c) (the **6 Month Deadline**).

Time limit based on regulatory approval

15 The first relevant aspect of s 71(2), requires, amongst other things, that the making of an application for an extension of term must be made within 6 months after the latest of three dates: patent grant, regulatory approval or the commencement of s 71 (27 January 1999). The time limit for making an application based on the date of obtaining regulatory approval was introduced in 1999⁵.

16 The amendments to the Act in 1999, which tied the substantive criteria for an application for an extension of term to regulatory approval, imposed a time limit by reference to that process. That is reflected in s 71(2)(a), (b) and (c).

17 The latest of those three dates provides a “certain time” within which the application for extension must be made.

⁵ Schedule 1, *Intellectual Property Laws Amendment Act 1998* commencing 27 January 1999.

18 Plainly, for the purposes of s 223, the making of an application for an extension of term is
required to be done within that 6 month period. This is an act that s 71(2) identifies as
"required to be done within a certain time". If it is not done within that time, unless the
subject of prescription, the Commissioner has the power, under s 223, to extend that
time. If the reason for the failure to meet the time limit is the fault of the Patent Office,
s 223(1) requires that the extension must be given.

Time limit based on the term of the patent

19 In addition to that time limit, s 71(2) also provides that an application under s70 must be
made during the term of the patent. By s 67 the term of the patent is 20 years from the
10 date of grant. The requirement in s 71(2) that the application for an extension of term be
made during the term of a patent is also an act that is "required to be done within a
certain time". It follows that, for the purposes of s 223(2), the making of an application for
an extension must be done within the term of the patent, and again subject to
prescription, that time limit may be extended by the Commissioner on application.

20 In tying the time for an application for extension to the term of the patent, s 71(2) follows
a course that has been familiar for over 100 years⁶. The history of the time limit based
on the term of the patent is addressed below.

The two time limits are distinct and s 223(2) applies to each

21 The two time limits in s 71(2) just identified are distinct because they identify different
20 time limits based on different criteria: one is focused on regulatory approval and the other
on the term of the patent. As this case demonstrates, they are independent because
satisfaction of one does not necessarily mean satisfaction of the other.

22 In accordance with s 223(2), each of these time-limits stipulates a "certain time" within
which "an act is required to be done". While both requirements must be complied with,
the obligations are separate and distinct. The mere fact that an application filed on a
particular date may satisfy both requirements does not mean that there is a single time
limit or that the two components together specify "a certain time" for the purposes of

s 223(2). To the contrary, the time limits are different for each act required to be done and they cannot be considered jointly as a single act with a single time limit (that is, a certain time), rather, they are two different “act[s] required to be done within a certain time”⁷.

23 The question posed by the interaction between s 71 and s 223 is not whether, in the abstract, an application under s 70 constitutes one or two acts. That approach, which underpins the Appellant’s argument, ignores the words of s 223 and its context including its purpose. The concept of act (or its cognate “action”) has no meaning outside of s 223 and takes its meaning from the requirement that it be “in relation to a patent”⁸ and the words that follow in subsection (2): “that is required to be done within a certain time”.

10

24 Rather, the critical issue presented by s 223(2) is whether s 71 requires an act in relation to a patent to be done within a certain time⁹. For some sections that might produce a single answer, for s 71 it produces two. Section 71 requires that the application under section 70 be both an application within the term of the patent and an application within the 6 month period, and s 223(2) must be applied separately in respect of each time limit. In a given case, a particular application may require one of the two time limits to be extended, both of them or none. In that context, s 223(2) cannot be applied as if s 71(2) were concerned with a single temporal limitation.

20

25 Neither the text of s 223 nor its context requires that the two time limits in s 71(2), which operate independently from each other, should, for the purpose of considering whether an extension should be granted, be collapsed into a single time limit on the basis that, taken together, they apply to a single act required to be done within a certain time. The Appellant’s submissions to the contrary should be rejected.

26 *First*, the text is against it. The words of s 223 are directed to an act which is required to be done within “a certain time” and the power exists to extend “that time”. In context, the

⁶ Section 84, *Patents Act 1903*.

⁷ Full Court reasons at [51].

⁸ Or in relation to a patent application or any proceedings under the Act other than court proceedings.

use of the singular should be seen as deliberate. The Full Court was correct to record that s 71(2) sets two time limits¹⁰, so much follows from the text of s 71(2) itself. Having identified that two time limits are in operation, it would be a misuse of language to then ask whether that time limit should be extended.

27 In the context with which s 223 is concerned, it is wrong to divorce the act from the time limit. That is why Yates J observed¹¹, with respect correctly, that the terms of s 223(2) do not preclude an act being identified by reference to a particular time limit. That conclusion is reinforced by the terms of s 223(1) itself which provides the definition of relevant act expressly includes “the making of a Convention application within the time
10 limit allowed for making such applications”. That provides an example that s 223 employs of an act being identified by reference to a time limit.

28 *Second*, the Appellant ignores the purpose of the provision and the purpose for which an act is identified, which is to extend time limits. The focus is on the time limit (i.e. the time within which the act is required to be done) and whether that limit should be extended. The Appellant starts at the wrong end by asking whether an application to extend a term of a patent is a single act¹². This approach reflects that taken by this Court in *Australian Paper Manufacturers Ltd v CIL Inc*¹³.

29 To approach the intersection of s 223(2) and 71 in that way accepted by the Full Court involves no artificiality but gives proper recognition to the purpose of identifying an act in
20 relation to a patent in the first place: namely to decide whether the certain time in which the act was required to be done should be extended. The construction means that the power in s 223 is able to respond to the structure of s 71.

⁹ *Australian Paper Manufacturers Ltd v CIL Inc* (1981) 148 CLR 551 at 555 Stephen J, Mason and Wilson JJ agreeing.

¹⁰ Full Court reasons at [50].

¹¹ Full Court reasons at [52].

¹² Appellants' Submissions at [21], [31] and [34].

¹³ (1981) 148 CLR 551, which was concerned with whether an act or step was required to be done.

30 *Third*, there is no sound reason for treating the two different limbs of s 71(2), which were imposed for quite different policy reasons, as giving rise to a single time limit for the purposes of the extension of time provisions.

31 *Fourth*, it would rob s 223(11) of an important degree of flexibility. If both relevant aspects of s 71 are construed as giving rise to a single “certain time” limit for the purpose of s 223, there could be either: no prescription under s 233(11), with the result that both time limits are extendable (including making an application after the Expiry Date), or any prescription would have to cover both time limits in s 71(2), meaning that in no circumstances could an extension of time be granted.

10 32 *Fifth*, any application for an extension of time has to take into account the reason for the failure to do the relevant act within time. Where there is both a requirement to file the application within the term and within the 6 month period, the circumstances of non compliance and its significance may be different as between each other. Treating the time limits as producing a single certain time would make the provisions of s 223 impossible to apply.

33 The legislative history supports the present dichotomy in s 71 between a requirement that the application be made during the term of the patent and that it be made within the 6 month period. It also explains the form of the regulation in issue.

Legislative history of extension of term provisions

20 34 The Act and its precursors have long allowed for extensions of term of a patent but stipulated that any application for extension be made before the expiration of the term of the patent¹⁴. This time limit has always been extendable¹⁵, and at least until the commencement of the 1990 Act, an extension of time for bringing an application could have been sought even after the term of the patent had expired.

¹⁴ The history is set out in this Court in *Sanofi v Parke Davis* (1982) 152 CLR 1 and in *Parke Davis v Sanofi* (1982) 43 ALR 487. The power to extend a term was removed by Act No 154 of 1994 but was restored by Act No 100 of 1998 (see below at [42]).

¹⁵ See *Sanofi v Parke Davis* (1982) 152 CLR 1.

- (a) Section 84 of the *Patents Act 1903* (the **1903 Act**) empowered this Court or a Supreme Court on a petition to grant an extension of term not exceeding 7 years but required that the petition “must be presented at least six months before the time limited for the expiration of the patent”;
- (b) Section 90 of the *Patents Act 1952* (the **1952 Act**), allowed a patentee to apply for an extension of term on the ground that the patentee had been “inadequately remunerated”. Such an application was required to be made “at least 6 months before the expiration of the term”;
- (c) Section 70(1) of the Act, as enacted, provided that a patentee may apply for an extension of term “not later than 12 months before the end of the term of the patent”; and
- (d) In its current form, s 71(2) provides an application for extension of term must be made “during the term of the patent”.

10

35 The various stipulations that an application for extension of term be made “at least 6 months before the expiration of the term”; “not later than 12 months before the end of the term” and “during the term” each imposed a time in which the application was required to be made. As this Court observed in *Sanofi*, which was concerned with the 1952 Act, the time limit was extendable, and the practice (implemented consistently in Australia to that point for over eighty years) allowed an extension of term application to be

20 made after the term had expired.

36 When s 70 was re-enacted in 1999, the application was required to be made within the term and, absent contrary prescription that time limit is extendable under s 223.

Extension of term under the 1990 Act

The 1990 Act as enacted

37 As enacted, s 70 permitted an extension of term of patent relating to a pharmaceutical substance. An application for extension of term had to be brought “not later than 12 months before the end of the term of the patent”.

38 That time limit was extendable under s 223(2). However, by s 223(5), an application could not be made for an extension of time for more than 3 months for an act or step required to be done or taken for the purposes of Div 2 of Pt 3 of Chapter 6, which included s 70.

39 The net of those two provisions was that an application had to be made at least 12 months before expiry but an extension could be granted up to 9 months before expiry of the term. In other words, in a departure from the history explained in *Sanofi*, the 1990 Act did not allow an application for extension of term to be made after the term expired. Nonetheless an extension of time was still available albeit of a more limited kind.

10 ***The 1990 Act is amended in 1994: no extension possible***

40 By s 5 of the *Patents (World Trade Organization Amendments) Act 1994*, Div 2 of Pt 3 of Chapter 6, including s 70, was repealed. No extensions of term were then permitted. However, the term of all standard patents was extended from 16 years to 20 years¹⁶. Immediately before the repeal of s 70, the term of standard patents was 16 years with the ability to extend patents in respect of pharmaceutical substances. The term was extended for all patents to 20 years and the extension of term provision in s 70 was repealed. Section 223(5) was also repealed¹⁷.

The 1990 Act: January 1999 power to extend term restored

41 Section 70 was re-enacted by s 3 of the *Intellectual Property Laws Amendment Act 1998*
20 and commenced on 27 January 1999. It applies to patents for pharmaceutical substances and the extension is explicitly based on the timing of regulatory approval.

42 The reintroduction of patent term extensions, after a short hiatus, occurred after extensive consultation and consideration. The Explanatory Memorandum (EM) to the *Intellectual Property Laws Amendment Bill 1997*¹⁸ recorded that extensions of up to five years on the standard 20 year term are available for pharmaceutical patents in the United States, the European Union and Japan, in recognition of the exceptionally long

¹⁶ Section 4, *Patents (World Trade Organization Amendments) Act 1994*.
¹⁷ Section 6.

development time and regulatory requirements. The purpose of the extension power was to provide “an effective patent life” being a period after marketing approval is obtained to allow a return on investment more in line with other fields of technology¹⁹.

43 It was further recorded that a “strong patent system” is an important contributor to the competitiveness of Australia’s investment climate and that the extension of term scheme was important to the pharmaceutical industry and to consumers²⁰. Those policy factors underpinned the provisions which were said to apply to all patents with a standard 20 year term to “optimize industry activity and employment in Australia and also maximize the returns to research based companies in Australia for investment”²¹.

10 44 In the notes on clauses to the Bill, the EM also expressly stated that the extension of time powers in s 223 would apply to all acts required to be done under the extension of patent term scheme provided that the relevant criteria are satisfied²².

45 Both the text, legislative history and extrinsic material supports the construction of s 71 advanced namely that it provides two independent time limits and that s 223(2) empowers the Commissioner to extend either or both time limits in an appropriate case.

Construction of the Regulation

46 From that starting point the question then becomes is whether the making an application within the 6 month time period is prescribed with the consequence that the time limit is not extendable. The issue is to be resolved by construing the regulation in its context.

20 It is in the above statutory context that the terms of reg 22.11(4)(1)(b) fall to be construed²³.

¹⁸ enacted as the *Intellectual Property Laws Amendment Act 1998* (Act No 100 of 1998).

¹⁹ EM, p 3.

²⁰ EM, p 9.

²¹ EM, p 9.

²² EM, Notes on Clauses, p18 at [14].

²³ *Master Education Services Pty Ltd v Ketchell* (2008) 236 CLR 101 at 110 [19].

47 The *Patents Amendment Regulations 1998 (No. 8)* amended the regulations to insert what was then paragraph 22.11(3)(c)²⁴. Being part of the extension of term scheme, that regulation commenced on the same day as the Act.

48 On a plain reading, the prescribed act, being a relevant act that is required to be done within a certain time, is the act of filing of an application within the term of the patent as required by s 71(2).

49 The language of the regulation carefully follows the text of s 223(2). It states:

10 "filing, during the term of a standard patent as required by section 71(2) of the Act, an application under subsection 70(1) of the Act for an extension of the term of the patent."

50 The regulation prescribes the action that is required to be done within a certain time as filing an application during the term of the patent. In doing that, the regulation means that the certain time (filing during the term) cannot be extended under s 223(2).

51 On the construction advanced by the Appellant, the words: *during the term of a standard patent as required by section 71(2) of the Act* are otiose.

52 A court construing a statutory provision must strive to give meaning to every word of the provision. The lengths to which the Court must go to in that regard are usefully captured by the passage from Griffith CJ's reasons in *Commonwealth v Baume*²⁵ extracted in *Project Blue Sky* at [71]:

20 ...such a sense is to be made upon the whole as that no clause, sentence, or word shall prove superfluous, void, or insignificant, if by any other construction they may all be made useful and pertinent.²⁶

53 Both the legislative history and extrinsic material support the construction.

²⁴ Schedule 1.

²⁵ (1905) 2 CLR 405 at 414.

²⁶ See also Plaintiff M47/2012 v Director General of Security (2012) 86 ALJR 1372 at 1419, [206].

54 As the analysis of s 71 above demonstrates, the requirement in s 71(2) that an application be filed during the term of the patent has been an important aspect of this area of discourse since 1903. It currently constitutes but one of the two temporal requirements imposed in relation to an application for an extension of term. The absence of any reference in the regulation to the other requirement, namely it be filed within the 6 Month Deadline is important and should be seen to be deliberate.

55 In preventing an extension of time to bring an application after the term of the patent has expired, the regulation reflects the position that has existed under the 1990 Act since its enactment²⁷.

10 56 Given the importance of the extension of term scheme and the express reference in the EM that s 223 would apply, it would be a most improbable construction of the regulation that the extension of term scheme was removed entirely from the protective scope of s 223.

57 By contrast, although an extension of time had been available even after the term had expired for most of the last century, since the 1990 Act no such extension has been available²⁸. In that context, the regulation, on the construction favoured by Full Court, reflects the position that had applied under the 1990 Act: an extension of time was available but not after the term of the patent had expired. The history of the Act since 1990, in marked contrast to its predecessors, was that an extension of term could not be
20 applied for after the term of the patent expired. That legislative choice is reflected in the regulation and explains its introduction. However, both its text and the fact that the Act was also imposing a new time limit divorced from the term of the patent explains the selective nature of the regulation and why the EM referred²⁹ to s 223 as applying to the extension of term scheme.

²⁷ Section 223(5), *Patents Act 1990* (as enacted).

²⁸ *Ibid.*

Context, purpose and policy considerations

58 The construction of the regulation advanced by the Appellant means that 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. That construction should not be adopted unless it is abundantly clear because it renders nugatory the beneficial powers in s 223 in relation to extension of the term of a patent.

59 The Appellant calls in aid what it contends are certain policy reasons underpinning its construction.

60 The submission³⁰ that there is no reason in principle why any power to extend time
10 should be available in relation to an extension of term is unsound.

61 *First*, Parliament has provided for such a power. It did so, in circumstances in which the Explanatory Memorandum specifically adverted to the application of s 223 to the extension of term provisions.

62 *Second*, as the legislative history revealed in *Sanofi* demonstrates, the power to grant relief from a time limit in the context of an extension of term has been part of the legislative fabric since 1914. In *Sanofi*, the respondent submitted that an application to extend the term of patent made after the expiry of a patent (and an extension of time to permit that course) would be inconsistent with the purpose and object underlying the Act and the limited grant of monopoly. That submission is echoed in the Appellants'
20 submissions in the present matter at AS [56].

63 The Court rejected the submission. The plurality observed that, in the light of a practice of more than 80 years, "we can only assume that [an extension of time] is not inimical to the true purpose or object underlying patent legislation"³¹. The extension of time provisions form part of, and are not antagonistic to, the scheme erected by the Act.

²⁹ EM at 18.

³⁰ AS [55].

³¹ (1983) 152 CLR 1 at 14-15 (Mason ACJ, Wilson and Dawson JJ); Brennan J agreeing at 18-19.

64 That is not to say that the time limits may be lightly put aside³². Rather, the Act allows,
and in certain cases commands, that time limits be relaxed. The Appellant's submission
that an application for extension can be granted "regardless of the length of the
extension" provided it is within the term of the patent, does not assist in the interpretation
exercise before the Court, both as to the Act and the Regulation. The existence of a
power is not contradicted simply because the circumstances in which it might be asked to
be exercised may be extreme.

65 *Third*, in light of the timing of the 6 Month Deadline, which may be triggered by regulatory
approval and be years before the expiry date, and the safeguards in s223 to protect third
10 parties (including the Commissioner's discretion)³³, there is no reason to consider that
there had been an intention to wholly exclude the operation of s223.

66 *Fourth*, the construction accepted by the Full Court gives proper recognition to the
beneficial nature of the extension power in s 223³⁴.

Administrative practice

67 Regulation 22.11(4)(b) has, from its introduction, been applied consistently by the
Commissioner as permitting an extension of time in relation to the 6 Month Deadline but
as prescribing the act of making the application during the term of the patent. The
regulation has never been applied in accordance with the Appellant's construction.

68 Further, a contemporaneous official statement of the meaning of regulations from the
20 government department that administers them may be taken into account.³⁵ Prior to the

³² A point emphasized by the plurality in *Sanofi* 152 CLR at 15.

³³ EM, Notes on Clauses at p6, "...in the normal course of events, gearing-up for production or marketing would not occur in Australia until the last two years of the patent term..."

³⁴ *G S Technology v Commissioner of Patents* (2004) 63 IPR 9; *Husky Injection Molding v Commissioner of Patents* (1990) 26 FCR 45.

³⁵ Bennion, *Statutory Interpretation*, Fifth edition, 703. *Ellis v Bristol City Council* [2007] EWCA Civ 685, [2007] All ER (D) 76 at [33]; *Wicks v Firth* (1983) 2 AC 214 at 230; *Re Robert Harry Apthorpe v the Repatriation Commission* [1987] FCA 91 at [15]. See also *SOK v Minister for Immigration and Multicultural and Indigenous Affairs* (2005) 144 FCR 170 per Branson J, "...reference may be made to the various definitions of "domestic violence" contained in the *Domestic Violence Interagency Guidelines...In my view, material that illustrates the meaning attributed to the expression "domestic violence" by the executive branch of Australian government has particular relevance in the circumstance of reg 1.23. Regulation 1.23 is found in an instrument of delegated legislation made by the Governor-General acting with the advice of the executive council: see 504 of the Act and s 16A of the Interpretation Act 1901 (Cth).*"

commencement of the extension of term regime, IP Australia published an Official Notice explaining the way in which the new regime would operate³⁶. Section 25.12 of the Official Notice provides:

The provisions of s.223 are generally available to the various stages of an application for an extension of term of a patent – except to extend the time for filing a request under s.70 for a date after the end of the 20 year term of the patent.

Specifically, the limitation under s.223 is provided by regulation 22.11(3)(c)...This excludes the application of s.223 to file an application after the end of the 20 year term. NOTE that it does not exclude s.223 from extending the due date to a date before the end of the term of the patent (which, if it were to be excluded, by reg. 22.11(3)(c), would specify the due date for making the application as set by the Act).³⁷

69 This position has been reflected in each version of the Australian Patent Office Manual of Practice and Procedure (**Manual**) since February 1999³⁸.

70 Further, the re-enactment of regulation 22.11(4)(b) on three occasions without substantive amendment, following decisions by IP Australia and the AAT, indicates the approval of the interpretation by the executive branch of government. In *Electrolux Home Products Pty Ltd v Australian Worker's Union*³⁹, McHugh J held:

It is no fiction to attribute to the minister and his or her department and, through them, the parliament knowledge of court decisions – or at all events decisions of this court – dealing with that portfolio. Indeed, it would be astonishing if the

³⁶ Appeal Book at 42, Annexure SI-2 to the Witness Statement of Shahnaz Irani. The Commissioner has a broad power, under s 222(3) of the Act, to publish documents such as the Official Notice.

³⁷ Appeal Book at 66, Annexure SI-1 to the Witness Statement of Shahnaz Irani, at 25.12 *Application of S.233 to Applications for an Extension of Term*. See also Appeal Book at 55, 25.3.2 *Time for applying*.

³⁸ Section 25.3.2 "Time for Applying", Manual (February 1999)

³⁹ (2004) 209 ALR 116. See *Alcan* (1994) 181 CLR 96 at 106-7. As to the application of this principle to subordinate legislation see *Dillon v Grange* (1941) 64 CLR 253 at 266 per Williams J, "Since these two decisions, therefore, a new by-law to the same effect as the old by-law has been enacted, and I think it must be assumed that the council was aware of the interpretation placed upon the old by-law by the court and intended it to be followed in the new one."

department its officers and those advising on the drafting of the Act would have been unaware of *Re Alcan*.

71 In 1999, the regulation was first considered by IP Australia in *Boehringer*⁴⁰ and the Commissioner rejected an argument that the regulation should be construed as applying to both deadlines in s 71(2)⁴¹. The *Patents Amendments Regulations 2001 (No. 1)* inserted a new regulation 22.11(3) and modified regulation 22.11(4), but there was no amendment to prevent the continued operation of the interpretation of the regulation that was applied in the *Boehringer* and *Prejay* decisions. A subsequent version of the Manual continued to reflect the construction applied in *Boehringer*⁴².

10 72 The regulation was further amended by the *Patents and Trade Marks Legislation Amendment Regulations 2008 (No. 1)*, again without amending the wording of the regulation. In 2012, the AAT delivered its decision affirming the Commissioner's decision in relation to Lundbeck's extension of time application. Following the AAT's decision, the *Intellectual Property Legislation Amendment (Raising the Bar) Regulation 2013 (No. 1)* made a minor change to the wording of the regulation⁴³ but did not alter its meaning in any material respect. Further, the Manual was amended on 15 April 2013 expressly referring to the decision of the AAT with approval⁴⁴. The re-enactment of the regulation in the same form following its consideration in a number of decisions (of which the administering agency was clearly aware), provides a strong indication that reg 22.11(4)(b)
20 has been interpreted in accordance with its original intention.

Overseas jurisdictions

73 The Appellant relies on the position in foreign jurisdictions⁴⁵. To the extent that there is a relevant analogue, it is the position in the United Kingdom because (1) the 6 Month

⁴⁰ *Re Application by Boehringer Ingelheim International GmbH* (1999) 48 IPR 177.

⁴¹ An extension of time was also granted to file an extension of term application in *Prejay Holdings Limited and Woco Investments Ltd* [2001] APO 18.

⁴² Section 25.3.2 "Time for Applying", Manual (August 2003).

⁴³ The words "as required by s71(2)" were replaced by the word "under s71(2)".

⁴⁴ Manual (current version) at 3.11.1.7.

⁴⁵ AS at [59].

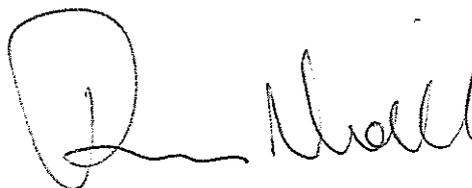
Deadline mirrors the time-limit that applies in the UK⁴⁶ (cf: the 60-day-limit that applies in the US⁴⁷) (2) the application must also be made before the expiry date⁴⁸ and (3) there is a corresponding extension of time provision⁴⁹. In the UK, an extension of time may be sought where the 6 Month Deadline has been missed⁵⁰. While a survey of other jurisdictions is of limited assistance, the authority relied upon by the Appellant suggests that an extension of time application or equivalent reinstatement request may be made where the 6 Month Deadline is missed in other European jurisdictions⁵¹.

Conclusion

74 The Commissioner had power to extend the time for the bringing of the application for an
10 extension of term. The Full Court was correct to uphold the decision of the AAT. The
appeal should be dismissed with costs.

Part VIII: Oral argument

75 Lundbeck estimates that approximately 1 hour will be required for the presentation of its
oral argument.



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⁴⁶ Medicinal Products Regulation, Regulation (EC) No 469/2009, Article 7(1).

⁴⁷ 35 U.S.C. 156(d)(1).

⁴⁸ Medicinal Products Regulation, Regulation (EC) No 469/2009, Article 3(1).

⁴⁹ *In re Abbott Laboratories' SPC Application* [2004] RPC 20 (**Abbott**) at [47] – [48]. Corresponds to Rule 108 in the *Patents Rules 2007* (UK).

⁵⁰ *Abbott* at [47].

⁵¹ *Abbott* at [33].

ANNEXURE A
APPLICABLE LEGISLATIVE PROVISIONS

Patents Act 1990: s70, s71, s 223 (as considered by the Tribunal) (start date: 16 April 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:*

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.*

- (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.*

- (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.*

Division 2—Standard patents**Application for extension of term of patent relating to a pharmaceutical substance**

70. (1) Where:

- (a) a pharmaceutical substance is in substance disclosed in the complete specification of a standard patent and in substance falls within the scope of the claim or claims of that complete specification; and
- (b) the patentee has requested the issue of a marketing approval certificate in respect of that substance;

the patentee may, by notice in writing in the approved form given to the Commissioner not later than 12 months before the end of the term of the patent, apply for an extension of the term of the patent in respect of that substance and any other pharmaceutical substance which is in substance disclosed in the specification and in substance falls within the scope of the claim or claims of the specification.

(2) Where a patentee applies for an extension of the term of a patent, the patentee must send a copy of the application to the Secretary to the Department of Community Services and Health.

(3) Where a patentee applies for an extension of the term of a patent, the Commissioner must publish in the *Official Journal* a notice stating that the application has been made and is open to public inspection.

(4) A patentee who has applied for an extension of the term of a patent may, by notice in writing to the Commissioner, withdraw the application.

(5) Where an application for an extension of the term of a patent is withdrawn, the Commissioner must publish in the *Official Journal* a notice stating that the application has been withdrawn.

Application for extension to lapse in certain circumstances

71. An application for an extension of the term of a patent lapses if the applicant does not, within the prescribed period, give the Commissioner:

- (a) a marketing approval certificate in respect of the pharmaceutical substance to which the application relates; and
- (b) a proposed claim or claims.

Issue of marketing approval certificate

72. Where:

- (a) a patentee asks the Secretary to the Department of Community Services and Health, in writing, for the issue of a marketing approval certificate in respect of a pharmaceutical substance; and
- (b) the Secretary to the Department of Community Services and Health has approved the marketing of that substance, or a product containing that substance, in Australia;

the Secretary must immediately give a marketing approval certificate in the approved form to the patentee in respect of that substance.

Advertisement of application for extension

73. Where:

- (a) a patentee applies for an extension of the term of a patent; and
- (b) the patentee gives the Commissioner the documents referred to in section 71;

the Commissioner must publish in the *Official Journal* a notice to the effect that the Commissioner proposes to consider the application.

Extensions of time

223. (1) Where, because of an error or omission by the Commissioner, a Deputy Commissioner or an employee, a relevant act that is required to be done within a certain time is not, or cannot be, done within that time, the Commissioner must extend the time for doing the act.

(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.

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

(4) Where an application is made for an extension of time for more than 3 months, the Commissioner must advertise the application in the *Official Journal*.

(5) An application cannot be made under subsection (2) for an extension of time for more than 3 months in respect of an act or step

required to be done or taken for the purposes of Division 2 of Part 3 of Chapter 6.

(6) A person may, as prescribed, oppose the granting of 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 an extension of time for more than 3 months is granted for doing a relevant act, 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 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.