

BETWEEN:

**Alphapharm Pty Ltd** ACN 002 359 739  
Applicant

and

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**H. Lundbeck A/S**  
First Respondent

**Commissioner of Patents**  
Second Respondent

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**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

### INTERVENER'S SUBMISSIONS

#### Part I: Suitable for publication

30 1. I certify that this submission is in a form suitable for publication on the Internet.

#### Part II: Basis for intervention

2. The Institute of Patent and Trade Mark Attorneys of Australia (**IPATA**) seeks to intervene as an *amicus curiae*.

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### Part III: Why leave to intervene should be granted

3. For the reasons set out in the affidavit of Trevor John Davies affirmed on 12 June 2014, any decision of this Court in relation to the availability of extensions of time for extensions of term of a patent is of significant importance to individual patent attorneys, to IPTA and their clients. It will affect patent attorneys' obligations to advise their clients and patent attorneys will potentially be liable to their clients if extensions of time are not available in relation to extensions of term of a patent. In addition, patent attorneys are likely to be affected if the decision retrospectively affects the validity of extensions of term granted subsequent to the grant of an extension of time.

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4. IPTA also wishes to make submissions dealing with matters not dealt with by either party, including:

(a) authorities concerning the purposes of the *Patents Act 1952* (Cth) (the **1952 Act**) and the predecessor to s 223 of the *Patents Act 1990* (Cth) (the **Patents Act**), which suggest that the extension of time provisions should be given a construction beneficial to the patentee given their remedial nature (particularly given that s 223 affords protections to third parties who would otherwise be affected by the grant of an extension of time under the section);

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(b) the extent to which the construction contended for by the Appellant (the **Alphapharm construction**) would:

(i) affect third parties who are protected by s 223, and

(ii) preclude patentees from obtaining an extension of time even where the failure to file an extension of term occurs through no fault of the patentee;

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(c) whether the term "action" in s 223(11) means "act" or whether it means an act done in a certain time, and in that context;

(d) the context provided by the text of Regulation 22.11(4)(a) and (c) of the *Patents Regulations 1991* (Cth) (the **Regulations**).

#### **Part IV: Applicable provisions, statutes and regulations**

5. All of the applicable provisions, statutes and regulations are set out either in Annexure A of the Appellant's (**Alphapharm's**) submissions or in Annexure A of the First Respondent's (**Lundbeck's**) submissions.

#### 10 **Part V: Argument**

6. Regulation 22.11(4)(b) of the Regulations is not susceptible of a simple interpretation. However, the construction preferred by the Full Federal Court (and Patent Office practice) and contended for by the First Respondent (the **Lundbeck construction**) should be preferred to the Alphapharm construction for the following reasons:

20 (a) the Lundbeck construction of Regulation 22.11(4)(b) is that which would best achieve the purpose or object of the legislative scheme constituted by the Patents Act and the Regulations

(b) Decisions of this Court and the Full Federal Court in relation to the equivalent section in the 1952 Act suggest that the extension of time provisions under the Patents Act are remedial provisions and should be applied where they appear to be applicable unless there is some clear indication to the contrary.<sup>1</sup>

(c) The evidence of Dr Davies suggests that s 223 operates to protect patent attorneys as well as patentees.<sup>2</sup> Protection to third parties (such as Alphapharm) who might be affected by the grant of an extension of time is also

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<sup>1</sup> *Scaniainventor v Commissioner of Patents* (1981) 36 ALR 101 (**Scaniainventor**) per Fox ACJ, Franki and Northrop JJ at 105 lines 34 to 36. This decision was referred to with apparent approval in *Australian Paper Manufacturers Ltd. v C.I.L. Inc.* (1981) 148 CLR 551 (**Australian Paper**) (at 555). See also *Lehtovaara v Acting Deputy Commissioner of Patents* (1981) 39 ALR 103 (**Lehtovaara**) per Northrop and Ellicott JJ at 111, lines 40 to 45.

<sup>2</sup> Affidavit of Trevor John Davies affirmed 12 June 2014 (**Davies**) at [15] p 5 lines 1 to 5.

provided by s 223, so that third parties will not be disadvantaged if the Lundbeck construction is adopted.

(d) Both the text and the context of s 223 of the Patents Act suggest that the word “action” in the definition of relevant act refers not just to the act to be done but also to the time by which the act is to be done. This construction is also consistent with an earlier decision of this Court in relation to the construction of the predecessor section to s 223.<sup>3</sup>

10 (e) In light of this construction, it is apparent that there are two separate **actions** under ss 70(1) and 71(2) of the Patents Act which must be undertaken in order for the single **act** of making an extension of term application to be completed. First, the extension of term application must be made during the term of a patent (the **first action**). Secondly, the extension of time application must be made within six months after the latest of the dates mentioned in paragraphs 71(2)(a) to (c) (the **second action**). The reasoning of the Full Federal Court in this respect should be upheld.<sup>4</sup>

20 (f) Both the text and the context of Regulation 22.11(4)(b) suggest that the prescription in relation to the extension of term provisions is circumscribed and applies only to the first action contemplated by ss 70(1) and not the second action in paragraph 71(2).

7. Each of these reasons is set out in more detail below.

**Section 15AA of the *Acts Interpretation Act 1901* (Cth) and section 13(1)(a) of the *Legislative Instruments Act 2003* (Cth): The purpose or object of the Patents Act**

30 8. For the reasons set out below in paragraphs 25 to 47, it is respectfully contended that it is clear, from the text and context of s 223(11) and Regulation

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<sup>3</sup> *Australian Paper*

<sup>4</sup> Reasons of the Full Court at [51] per Yates J, Jessup and Jagot JJ agreeing.

22.11(4)(b), that the regulation was intended to prescribe the first action of making an extension of term application during the term of the patent, but not the second action of making an extension of term application within six months after the latest of the specified dates. If there is nevertheless any lack of clarity, the Court should have regard to the purpose or object underlying the Patents Act in construing the section. IPTA generally agrees with the observations made by Lundbeck in this respect and makes the following additional observations.

10 9. The purpose or object of the 1952 Act, and of the extension of term provisions contained in that Act, were considered by the Full Federal Court in *Parke Davis Pty Limited v Sanofi and the Commissioner of Patents*.<sup>5</sup> Under Section 90 of the 1952 Act, the application for an extension of term was required to be made “at least 6 months before the expiration of the term of the patent, or within such further period as a prescribed court allows”. The patentee applied to extend the term of its patent, after expiry of the patent, and the court considered whether “within such further period as a prescribed court allows” meant a period before the expiry of the patent, or whether the section allowed an application to be made after expiry.

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10. A majority of the Court (Bowen CJ and Ellicott J) concluded<sup>6</sup> that the purposes of the 1952 Act would not be achieved if the extension of term provisions under the 1952 Act were applied to allow the patentee to apply for an extension of term *after* expiry.<sup>7</sup>

11. On appeal in *Sanofi v Parke-Davis Pty Ltd [No. 2]*,<sup>8</sup> a majority of this Court rejected this conclusion. The majority, Mason ACJ, Wilson and Dawson JJ, said:<sup>9</sup>

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<sup>5</sup> (1982) 43 ALR 487

<sup>6</sup> (1982) 43 ALR 487 at 492, lines 1 to 3.

<sup>7</sup> It is apparent that the court considered that the purposes of the 1952 Act would not be undermined if an extension of time in which to apply for an extension of term were granted, provided that the extension of term application was made before the expiry of the patent.

<sup>8</sup> (1982) 152 CLR 1

We refer to the broad consideration [of the Full Federal Court] derived from a view of the purpose and object underlying the Act. Their Honours expressed that purpose in terms of the encouragement of inventors by granting a monopoly for an invention which on the expiry of the monopoly was to be fully available to the public unless for reasons of inadequate remuneration a court extended its term. Speaking of the right to petition for an extension of the term of a patent, their Honours considered that if it were left unrestricted it would seriously encroach upon the interests of the public which the Act otherwise sought to secure. They thought it would also mean an undetermined *de facto* extension of the monopoly, since no commercial concern would consider the expenditure of capital moneys in connexion with exploitation of the invention while the patent remained under threat of extension. With all respect to their Honours, we think that such a conclusion is inconsistent with the history of the legislation. It is to be remembered that Australian practice since the introduction of reg. 8 in 1914 would appear to have been uniform and to have allowed a petition praying for the extension of the term of a patent to be presented after the term had expired. [...] In the light of this practice implemented consistently in Australia for nearly eighty years, we can only assume that it is not inimical to the true purpose or object underlying patent legislation. The purpose or object of the extension of time provisions in s.160 of the 1952 Act were also considered by this Court in *Australian Paper Manufacturers Ltd. v C.I.L. Inc.* (1981) 148 CLR 551 (**Australian Paper**). Stephen J, with whom Mason and Wilson JJ agreed, approached the construction of s.160 as a remedial provision to be construed beneficially.<sup>10</sup>

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12. The purpose or object of the extension of time provisions in s.160 of the 1952 Act were also considered by this Court in *Australian Paper Manufacturers Ltd. v C.I.L. Inc.*(1981) 148 CLR 551 (*Australian Paper*). Stephen J, with whom Mason and Wilson JJ agreed, approached the construction of s.160 as a remedial provision to be construed beneficially. The conclusions of the High Court in relation to the purposes of the 1952 Act apply with equal force to the Patents Act, having regard to the Patents Act as a whole and the extension of time provisions in particular. Provisions allowing an extension of time application to

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<sup>9</sup> (1982) 152 CLR 1 at 14-15

<sup>10</sup> At 555-7- discussed more fully at paras 17 - 18 below.

be made in relation to the filing of an extension of term application are remedial provisions, consistent with and not inimical to the purposes of the Patents Act, particularly given that:

(a) these provisions apply not only where the relevant act cannot be done in time because of patentee error or patent attorney error, but also where the relevant act cannot be done because of the error or omission of the Patent Office (s 223(1));

10 (b) s 223(2) does not confer an automatic right of extension on the patentee, and the Commissioner has the discretion to refuse the application (s 223(2)); and

(c) the rights of third parties are protected by:

(i) the requirement that certain applications for extension be advertised (s 223(4));

(ii) the provision that applications which do not relate to errors by the patent office can be opposed (s 223(6));

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(iii) the provision for the protection or compensation of third parties who have taken steps to exploit an invention because of the failure to do an act in certain circumstances (s 223(9)); and

(iv) the provision that infringement proceedings cannot be brought in respect of an infringement committed when a patent application is lapsed or a patent has ceased (s 223(10)).

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(IPTA notes that the Applicant in these proceedings has availed itself of the protections referred to in subparagraphs 12(c) ii and iii above).

13. The evidence from Dr Davies that:

(a) since 1999, the Australian Patent Office Manual of Practice and Procedure has advertised that the extension of time provisions are generally applicable to the extension of term provisions, except to extend the time for filing a request under section 70 after the expiry of a patent;<sup>11</sup> and

(b) extensions of time for extension of term applications have been granted at least 40 times since 2000, and extension of terms have been granted in 37 of those cases,<sup>12</sup>

10 supports the conclusion that there is a long standing practice of allowing applications for an extension of time in relation to extension of term applications.

14. It is apparent from the matters set out above that the Lundbeck construction supports and is not inimical to the purpose of the Act.

#### **The principles applicable to remedial provisions**

20 15. Judicial authority, including decisions of this Court, indicate that s 223 is a remedial provision, and should be construed beneficially to the patentee.

16. The predecessor section to s 223, s 160(1), was considered by the Full Federal Court in *Scaniainventor*. In that decision, the Full Court was required to determine whether s 160 applied to the making of a convention application under the 1952 Act (since the Commissioner asserted that the patent applicant was not **required** to take the act or step of filing a convention application within a certain time). The Full Court unanimously held that s 160 did apply. In reaching its decision, the Full Court stated:

30 *There is nothing in their history which suggests that s 160(2) should not apply to s 141(1). They were introduced together in 1952 in terms not*

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<sup>11</sup> Davies [19], p 5 lines 19 – 22 and Annexure TJD-3 (pp 16 – 20).

<sup>12</sup> Davies [23] to [25], p 6, lines 13 to 27.

*materially different from those operative in 1979. With this in mind, it is relevant to observe that while certain provisions are expressly excluded from the operation of s.160(2) by sub-section (8) (including s.52B, which relates to convention applications), s.141(1) is not one of them. **Section 160 is a remedial section and should be applied where it appears to be applicable unless there is some clear indication to the contrary. This view is supported by the provisions of s.160(8).***<sup>13</sup>(emphasis added)

10 17. The question of whether s 160(2) applied to a convention application was subsequently considered again by the High Court in *Australian Paper*. A majority of the Court (Stephen, Mason and Wilson JJ) held that it did. Stephen J, who delivered the leading judgment, referred with approval to *Scaniainventor*.<sup>14</sup> After analysing the provision in relation to convention applications and concluding that the section did involve an act or step (a) which was in relation to an application for a patent (b) which could be described as to be done or taken within in a certain time and (c) which could be said to be “required to be done or taken” within that time, Stephen J said:<sup>15</sup>

20 *s. 141 (1) does as a matter of language involve the very situation for which s. 160 (2) legislates; it provides for an act or step, the initial making of formal application for an Australian patent, which relates to an application for a patent and which may properly be described as required to be done or taken within a certain time, in this instance within twelve months. **In those circumstances it would require quite compelling contextual or other considerations for s. 160 (2) nevertheless to be held inapplicable to s. 141 (1).** Despite the attractive arguments of counsel for the appellant, no such consideration seems to me to exist.*(emphasis added)

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<sup>13</sup> *Scaniainventor* (1981) 36 ALR 101 at 105, lines 29 to 37.

<sup>14</sup> (1981) 148 CLR 551 at 555.

<sup>15</sup> *Australian Paper*(1981) 148 CLR 551 at 557.

18. The analysis undertaken by Stephen J applies with equal force to the actions contemplated by s 71(2). In the absence of a clear indication that **each** of the actions in relation to an extension of term application is intended to be prescribed by Regulation 22.11(4)(b) (a matter which is dealt with in greater detail below in paragraphs 33 to 47), the second action of filing an extension of term within six months after the latest of the three dates specified in s 71(2)(a) to (c) should be treated as a relevant act, since it is plainly an action relating to a patent which is required to be done or taken within a certain time.

10 19. The Full Federal Court considered the nature and scope of s 160 again in *Lehtovaara*. In that case, a majority of the Court (Northrop and Ellicott JJ) held that s 160 applied to the non-acceptance of a patent by the Commissioner, despite the fact that the 1952 Act contained another provision allowing for the extension of time in relation to non-acceptance. After concluding that the acceptance of a patent application was an act or step in relation to an application for a patent which was required to be done within a certain time, the majority noted that the section had been characterised in *Scaniainventor* as remedial and in *Australian Paper* as applicable in the absence of compelling contextual or other considerations. They considered whether the existence of  
20 separate extension of time provisions in relation to the acceptance of applications constituted a clear indication that s 160 was not to apply. The majority continued:<sup>16</sup>

*Section 160 operates on the provision of its own force and does not depend on any indication in it that it should apply. [...] In our opinion, the real test, in construing such provisions, is whether they contain a clear indication that s.160 should not apply. [...] However, an important matter to bear in mind, in our view, in construing sections such as these is that s.160 is in part mandatory and is intended on its face to deal with  
30 extensions needed in special cases, i.e. where there is an error or omission on the part of the office, the agent or attorney, or the person concerned, or where there are circumstances beyond that person's*

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<sup>16</sup> (1981) 39 ALR 103 at p 112 line 31 to p 113 line 3.

*control. It does not confer a general discretion to extend and is careful to ensure protection to those who might be affected.*

20. The considerations articulated by the Full Court in relation to s 160 of the 1952 Act also apply to s 223 of the Patents Act. That is:

10 (a) despite the submissions made by Alphapharm at [57] of its submission that an extension of term application is a matter within the patentee's control, s 223 also makes provision for extensions of time which are necessary because of errors by the Patent Office, patent attorneys, or matters outside the patentee's control. It is apparent from the affidavit of Dr Davies that of the 22 applications for an extension of time in which to file an extension of term application which relate to Current Patents, two applications have been made on the basis of errors by the patent attorney and ten applications have been on the basis of an error or omission by the licensee.<sup>17</sup> That is to say, more than half related to matters outside the patentee's control. There is no rational policy basis for excluding extensions of term from s 223 in relation to applications of this kind.

20 (b) As set out in paragraph 12(b) above, s 223 does not confer an automatic right of extension.

(c) As set out in paragraph 12(c) above, s 223 ensures protection for those who might be affected by the grant of an extension of time.

21. To adapt the words of Stephen J in *Australian Paper*, where s 223 appears on its face to apply to a given action, it would require quite compelling contextual or other considerations for the section nevertheless to be held inapplicable in a particular case.<sup>18</sup> If there is any doubt as to the meaning of Regulation 22.11(4)(b), the regulation should be given a beneficial construction and s 223 should be held to be applicable to the second action of filing an extension of

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<sup>17</sup> Davies [27] p 7 lines 7-9.

<sup>18</sup> *Australian Paper* op cit at 557.

term application within six months after the latest of the dates mentioned in Section 71(2)(a) to (c).

### The protection of patent attorneys

22. The considerations in relation to the remedial nature of s 223 apply with particular force since, as Dr Davies sets out in his affidavit, s 223 not only operates to protect patentees, but also to protect patent attorneys.<sup>19</sup> It is Dr Davies' evidence that if s 223 was not available in relation to extension of term applications, patent attorneys would be faced with a significant potential liability in relation to acting on such applications.<sup>20</sup> In relation to the Current Patents, there may be adverse consequences for the patent attorney profession if the extensions of term were retrospectively to be found invalid.<sup>21</sup>
23. In this respect, it should also be noted that there is a particular need for a remedial provision in relation to extension of term applications because identifying the correct product which will trigger the six-month deadline under s71(2)(b) of the Patents Act is not always straightforward (unlike, say, the payment of a renewal fee, where ascertaining the relevant deadline is straightforward). That fact is demonstrated by the current proceedings. It is also demonstrated by earlier proceedings between Merck & Co and Arrow Pharmaceuticals Limited. In those proceedings, the extension of term application was based on the registration of a product which included the relevant pharmaceutical substance (a metabolite) as an impurity, in very small amounts. The Patent Office refused the extension of term application (in *Merck & Co., Inc v Arrow Pharmaceuticals Limited* [2002] APO 13).
24. The Federal Court (in *Merck & Co Inc v Arrow Pharmaceuticals Ltd*; 59 IPR 226) overturned the decision of the Patent Office and held that the extension of term should be allowed. Having regard to the wording of s 71(2)(b), it is even

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<sup>19</sup> Davies [15] p 5 lines 1 -5.

<sup>20</sup> Davies [30] p 7 lines 20 – 25; [32] to [33] p 8 lines 8 to 17.

<sup>21</sup> Davies [29] p 7 lines 14-19.

possible that the deadline might be triggered by a third party's registration of a drug containing the relevant pharmaceutical substance as an impurity (which may not be known to the patentee). Given the complexities involved in identifying the date in s 71(2)(b), it is desirable that some protection be afforded to patentees and patent attorneys who by error or omission fail to do so and therefore fail to apply for an extension of term in time.

### The text and context of Section 223 of the Patents Act

- 10 25. Section 223 of the Patents Act sets out the circumstances in which the Commissioner may provide an extension of time for doing a relevant act. Extensions may be available where a **relevant act** which is required to be done within a certain time is not, or cannot be, done within that time.
26. The definition of "relevant act" is provided by s 223(11) of the Patents Act, which states:

*In this section,*

20 **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.

27. Two observations can be made in relation to the definition of "relevant act":

(a) It refers to an "action", rather than an "act", which is used elsewhere in the section. This choice of words suggests that a "relevant act" means something  
30 different from an "act". The first listed Macquarie Dictionary definition of action, "the process or state of acting or of being active"<sup>22</sup> as well as with the first listed Oxford Dictionary definition: "The fact or process of doing something,

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<sup>22</sup> The Macquarie Dictionary, fifth edition.

typically to achieve an aim”,<sup>23</sup> suggests that an “action” involves an element of the process involved in doing an act. Section 223 only deals with one element of the process related to the doing of acts: the time in which they must be done. The use of the word “action” rather than “act” in the definition of “relevant act” therefore suggests that a “relevant act” and a “prescribed action” are defined not only by the act which is to be done, but the time by which it is to be done.

10 (b) This construction is supported by the only instance of a relevant act set out in s 223(11) –the making of a Convention application within the time allowed for making such applications (s 223(11)). This further suggests that an “action” is defined not only by the act itself (“the making of a Convention application”) but also the time in which the act must be completed (“within the time allowed for making such applications”). The fact that an action is defined by reference to its applicable time limit is accepted by Alphapharm at paragraph [39] of its submissions.

20 28. Thus, as the definition of “relevant act” refers to an action, it is defined both by the act to be done and the time by which it is to be done. If the act can be described as being required to be done or taken within that time, the action (the specified act and the specified time limit) will be a relevant act and s 223 will apply unless the action is a “prescribed action” within the meaning of s 223(11).

29. Such a construction of “relevant act” is consistent not only with the primary dictionary meaning of the word “action”, but also with the context and purpose of s 223, which is concerned with acts which must be completed by a particular time.

30 30. This analysis is consistent with the decision of this Court concerning section 160(2) of the 1952 Act,<sup>24</sup>(the equivalent section to s 223 of the Patents Act) in

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<sup>23</sup> The Oxford Dictionary of English, third edition.

<sup>24</sup> Section 160(2) provided: “Where, by reason of -(a) an error or omission on the part of the person concerned or of his agent or attorney; or (b) circumstances beyond the control of the person concerned, an act or step in relation to an application for a patent or in proceedings under this Act (not

*Australian Paper* at 555-6. Adapting Stephen J's explanation of that section in *Australian Paper* to the wording of the Patents Act, in determining whether there is a "relevant act", it is necessary to ask whether the section under consideration involves an action:

(a) which is in relation to a patent, a patent application, or proceedings under the Patents Act;

(b) which can be described as to be done "within a certain time", and

(c) which can be said to be "required to be done or taken" within that time.<sup>25</sup>

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31. Under the Patents Act, it is also necessary to consider whether the action is a prescribed action under s 223(11) (in which case it will not be a relevant act).

32. Thus, where multiple time limits apply to a single act to be completed and each of those time limits must be complied with, the completion of the act will involve multiple actions, each of which may either be relevant acts or prescribed actions within the meaning of s 223.

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### **Application of s 223(11) to the extension of term requirements established by S 70(1) and S 71(2)**

33. For the reasons set out by Lundbeck in paragraphs [14] to [22] of its submissions and paragraph 6(e) above, it is apparent that there are two **actions** required by s 70(1) and s 71(2) in relation to the single **act** of making an extension of term application.

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*being proceedings in a court) required to be done or taken within a certain time has not been so done or taken, the Commissioner may, upon application by the person concerned, but subject to this section, extend the time for doing the act or taking the step."*

<sup>25</sup>*Australian Paper Manufacturers Ltd. v CIL Inc* (1981) 148 CLR 551 at 555- 556 (Stephen J, Mason and Wilson JJ agreeing). Stephen J said "The critical question is whether s. 141(1) involves what s. 160 (2) describes as "an act or step in relation to an application for a patent . . . required to be done or taken within a certain time". This question may be analysed as asking whether s. 141(1) involves an act or step (a) which is "in relation to an application for a patent", (b) which can be described as to be done or taken "within a certain time", and (c) which can be said to be "required to be done or taken" within that time."

(a) The first action - making an extension of time application, which can be described as to be done “during the term of a standard patent”, and which can be said to be required to be done or taken during the term of the standard patent; and

(b) The second action - making an extension of time application, which can be described as to be done within six months after the latest of the three dates listed in s 71(2)(a) to (c), and which can be said to be required to be done or taken within six months after the latest of the three named dates.

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34. Both of these actions will constitute relevant acts within the meaning of s 223(11) unless they are prescribed.

#### **The text and context of Regulation 22.11(4)(b)**

35. As the same act may form the basis for two separate actions, it is possible to prescribe only one of those actions, with the effect that in some circumstances, the act may form the basis of a relevant act and in other circumstances, it may form the basis of a prescribed action.

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36. The wording of regulation 22.11(4)(b) has this effect in relation to s 70(1) and s 71(2), in that only the first action involved in making an extension of term application is prescribed, with the consequence that the second action is a “relevant action” for the purposes of s 223(2).

37. In its current form, Regulation 22.11(4)(b) provides that the following action is prescribed:

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*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<sup>26</sup> (emphasis added)*

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<sup>26</sup> The previous form of the provision, as it existed at the time of the hearing before the Administrative Appeals Tribunal, provided that the following is a prescribed action “filing, during the term of a

38. It should be noted that the structure of Regulation 22.11(4) as a whole suggests that there is a difference between the prescription effected by Regulation 22.11(4)(a) and Regulation 22.11(4)(c) on the one hand and the prescription effected by Regulation 22.11(4)(b) on the other hand.
39. The wording of Regulation 22.11(4)(b) is in stark contrast to the wording of Regulations 22.11(4)(a) and (c), both of which prescribe "an action mentioned in" certain chapters, rather than specifying the prescribed actions and the time limits that apply. It is therefore plain that each of Regulations 22.11(4)(a) and (c) have the effect of catching **all** actions mentioned in the relevant chapters (except those which are excepted from Regulation 22.11(4)(a)).
40. By contrast, Regulation 22.11(4)(b) uses very specific language, which only refers to **one** of the two time limits imposed by s 71(2) (and therefore, one of the actions required by that section). If Regulation 22.11(4)(b) was intended to prescribe each of the actions in s 71(2), one would expect it to take the same form as Regulation 22.11(4)(a) and (c). The fact that it does not take the same form suggests that it was not intended to have the same effect as those regulations.
41. Read in the context of Regulation 22.11(4) as a whole, it appears therefore that the very specific wording of Regulation 22.11(4)(b) was intended to have a particular effect.
42. The wording of regulation 22.11(4)(b) prescribes and reflects the first action required by s 71(2) of the Act. It does not prescribe or reflect the second action. Filing an application for extension of term "within 6 months after"... the latest of three named dates, cannot aptly be described as "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".

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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."

43. If the act itself of filing an extension of term application was intended to be prescribed, so that neither of the two applicable time limits could be extended, Regulation 22.11(4)(b) could clearly and unambiguously have achieved that outcome in one of three ways by:

(a) stating that an action mentioned in s 71(2) was prescribed. As set out above, this approach would be consistent with the form of wording adopted in Regulation 22.11(4)(a) and Regulation 22.11(4)(c);

10 (b) keeping the existing wording but omitting the words “during the term of a standard patent”, so that the regulation read “filing, as required by subsection 71(2) of the Act, an application under subsection 70(1) of the Act”; or

(c) restating the whole of subsection 71(2), rather than some only of the wording in the *chapeau*.

44. Instead, Regulation 22.11(4)(b) defines the prescribed action by reference to the act to be completed (the filing of an extension of term) and one only of the two time limits by which it is to be completed (during the term of the patent).

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45. In order for Regulation 22.11(4)(b) to be construed as Alphapharm contends, as prescribing both of the actions required to be completed in relation to extension of term applications, it is necessary in effect to rewrite the regulation, either by ignoring some of the words (“during the term of a standard patent”) or by reading in the words in (the remainder of s 71(2) from “and within 6 months after” to “commencement of this section”).

46. There are a number of difficulties with the Alphapharm construction.

30 (a) First, it is inconsistent with the language of s. 223(11), which provides that a “relevant act” is an “action”.

(b) Second, the Alphapharm construction does not take any account of the differences in the wording between Regulation 22.11(4)(b) and Regulation 22.11(4)(a) and (c).

(c) Third, as set out at paragraph [51] of Lundbeck's submissions, it means that some of the words of regulation 22.11(4)(b) are superfluous.

(d) Fourth, it is well established that words should only be implied where it is necessary to do so to give effect to the purpose of the statutory scheme.<sup>27</sup> In the present case, for the reasons set out above, it is not necessary to exclude extensions of time for the second action in order to achieve the purposes of the statutory scheme (indeed, the purposes of the Patents Act are served by adopting the Lundbeck construction).

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47. For these reasons, having regard to the text and context of the section, Lundbeck's construction is to be preferred to Alphapharm's construction.

### Conclusion

20 48. For the reasons set out above, IPTA:

(a) seeks leave to be heard as an *amicus curiae*; and

(b) considers that the Full Court's decision was correct and the appeal should be dismissed.

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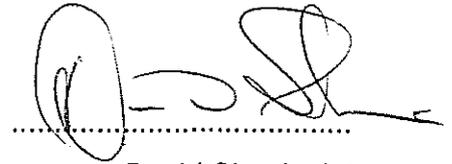
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<sup>27</sup> Pearce and Geddes, *Statutory Interpretation in Australia*, 7th edition (2011), [2.32] and [2.33], pages 54 – 56, and the cases referred to therein.

**Part VI: Time required for oral argument**

49. IPTA estimates that half an hour will be required for the presentation of its oral argument.

Dated : 13 June 2013

A handwritten signature in black ink, appearing to read 'David Shavin', written over a horizontal dotted line.

David Shavin QC

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A handwritten signature in black ink, appearing to read 'Clare Cunliffe', written over a horizontal dotted line.

Clare Cunliffe

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