IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No. S97 of 2014

BETWEEN:

Alphapharm Pty Ltd ACN 002 359 739
Appellant

and

H. Lundbeck A/S
First Respondent

Commissioner of Patents
Second Respondent

Aspen Pharma Pty Ltd ACN 004 118 594
Third Respondent

Sandoz Pty Ltd ACN 075 449 553
Fourth Respondent

Apotex Pty Ltd ACN 096 916 148
Fifth Respondent

INTERVENER'S SUBMISSIONS

Part I: Suitable for publication

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

Part II: Basis for intervention

2. The Generic Medicines Industry Association (**GMIA**) seeks to intervene as an *amicus curiae*.

Part III: Why leave to intervene should be granted

3. For the reasons set out in the affidavit of Belinda Wood sworn on 31 July 2014 (**Wood Affidavit**), any decision of this Court in relation to the availability of extensions of time for an extension of term of a pharmaceutical patent is of significant importance to members of the generic pharmaceutical

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industry in Australia. It will affect the manner in which generic pharmaceutical companies decide to pursue the development of new generic versions of existing patented medicines in Australia. In particular, as explained in the Wood Affidavit, the construction of s 223 of the *Patents Act 1990* (Cth) (**Act**) contended for by the First Respondent (**Lundbeck**) would:

(a) undermine the reliability of the Patent Register to the extent that it relates to patent terms,

and consequently,

(b) create uncertainty for members of the generic pharmaceutical industry in Australia; and

(c) interrupt (and potentially delay) public access to more affordable, generic medicines in Australia.

4. The GMIA also seeks to respond briefly to a matter raised in the Institute of Patent and Trade Mark Attorneys of Australia's (**IPTA**)submissions. That matter is the supposed protections afforded by s 223(9) of the Act and Regulation 22.21 of the *Patents Regulations 1991* (Cth) (**Regulations**). The GMIA respectfully submits that those "protections" are insufficient to offset the uncertainty that the construction propounded by Lundbeck would create.

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 submissions or in Annexure A of the Lundbeck's submissions.

Part V: Argument

Reliability of the Patent Register

6. As the Appellants' submissions note, third parties should be able to plan their affairs on the basis of the Patent Register.[1] Lundbeck's construction of s 223

[1] Appellants' submissions at [56]; *Stack v State of Queensland* (1996) 68 FCR 247 at 252 per Kiefel J.

of the Act will, if accepted by this Court, have a prejudicial effect on the ability for generic pharmaceutical companies to do this.

7. The extension of term provisions in the Act are directed to patents which disclose and claim pharmaceutical substances.[2] Generic pharmaceutical companies seeking to compete with a patentee are therefore affected by any extension of the term of that patentee's monopoly.

8. Generic pharmaceutical companies rely heavily on the Patent Register for accurate information. The Wood Affidavit explains that it takes years to develop a new generic medicine. The decision to embark on such activities is typically contingent on the future expiry of a patent which the generic medicine would otherwise infringe. Currently, the only reliable source of information about when a given patent will expire is the Patent Register. Generic pharmaceutical companies therefore rely heavily on the Patent Register well before the expiry date to accurately indicate the date on which a given pharmaceutical patent will expire.

9. Should Lundbeck's construction of s 223 of the Act be accepted, generic pharmaceutical companies will no longer have the ability to confidently anticipate when a particular pharmaceutical patent will expire. This is because Lundbeck's construction would open the way for the terms of pharmaceutical patents to be extended by the filing of an extension of term application, accompanied by an extension of time application, well after the 6 month period following the inclusion of the originator medicine in the ARTG as contemplated by s 71(2)(b) of the Act and up to and including the last day that the patent is in force. If this is the case, the only way certainty would be achieved about patent expiry would be to wait until a period of time after the patent actually expires to see if any last minute application to extend the time to file an extension of term application is advertised by the Patent Office.

10. Any generic pharmaceutical company continuing to rely on the Patent Register, while bearing in mind the date of inclusion of the originator medicine in the ARTG, to plan its product pipelines would be assuming the

[2] Patents Act 1990 (Cth), s 70(2).

considerable risk that, upon or shortly before the expiry date of a patent is reached, a late application to extend the term of the patent will be made. Any steps taken by that generic pharmaceutical company to exploit the product in a timely manner may then have been premature. Many generic manufacturers would not be willing to assume such a risk. The timely introduction of generic medicines onto the Australian market (and the resulting cost savings to the Australian public) would thus be frustrated and the patentee would receive a de facto extension of its monopoly.

11. Therefore, the overall impact of a finding in Lundbeck's favour will be to hinder the ability of generic pharmaceutical companies to fairly compete with patentees. This can only lead to delays in providing the Australian public with access to more affordable generic medicines and flow-on expenditure consequences for the Pharmaceutical Benefits Scheme.

12. In addition, the timing of extension of term applications could well become subject to gaming. Pharmaceutical companies are not averse to pursuing novel patent strategies in the courts, no matter how obscure. At its most extreme, a generic pharmaceutical company may be forced to withdraw a newly launched generic medicine pending the outcome of an (ultimately unmeritorious) extension of time application to extend an otherwise expired patent.

13. Further, even patent attorneys, who rely on the Patent Register to advise clients,[3] will be adversely affected in their ability to provide reliable advice on the terms of pharmaceutical patents.

Protection or compensation under s 223(9) of the Act

14. IPTA's submissions in support of their application for leave to intervene as *amicus curiae* raise a point at paragraph 12(c) not squarely dealt with in the other parties' submissions. The point is that the rights of third parties are said to be protected by the provision in s 223(9) of the Act for the protection or compensation of third parties.

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[3] Affidavit of Trevor John Davies affirmed on 12 June 2014 at [5](b) in support of IPTA's application to intervene as *amicus curiae*.

15. This provision is no answer to the GMIA's concerns stated at paragraphs 6 to 13 above. The mechanism provided by s 223(9) of the Act and regulation 22.21 of the Regulations is for affected third parties to apply to the Commissioner for a licence to exploit the patent. As the Wood Affidavit points out at paragraph 22, this mechanism suffers from three disadvantages that together make the mechanism inadequate:

(a) the onus falls on the generic pharmaceutical company to obtain a licence from the Commissioner, creating a burden where previously none existed;

(b) the grant of a licence can be opposed by the patentee, and is therefore inherently unreliable; and

(c) even if the Commissioner is reasonably satisfied that a licence should be granted, the terms of that licence are on "such terms as the Commissioner thinks reasonable". There is therefore no certainty that any such licence would provide the generic pharmaceutical company with compensation commensurate with what would have been an unrestricted freedom to exploit the invention.

Conclusion

16. For the reasons set out above, the GMIA:

(a) seeks leave to be heard as an *amicus* curiae by having these submissions considered by the Court on the hearing of the appeal; and

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

Part VI:

17. The GMIA does not seek leave to present its arguments orally.

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