HIGH COURT OF AUSTRALIA

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Details of Filing

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Important Information

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Form 27C—Intervener's submissions

Note: See rule 44.04.4.

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN: **OTSUKA PHARMACEUTICAL CO., LTD**
First Appellant

H. LUNDBECK A/S
Second Appellant

LUNDBECK AUSTRALIA PTY LTD
Third Appellant

OTSUKA AUSTRALIA PHARMACEUTICAL PTY LTD
Fourth Appellant

and

SUN PHARMA ANZ PTY LTD
Respondent

SUBMISSIONS OF THE GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION FOR LEAVE TO BE HEARD AS *AMICUS CURIAE*

I CERTIFICATION

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

II BASIS OF APPLICATION FOR LEAVE TO BE HEARD

2. The Generic and Biosimilar Medicines Association (**GBMA**) seeks leave to be heard as *amicus curiae* in this case.

3. GBMA is the national association representing companies that manufacture, supply and export generic and biosimilar medicines in Australia: affidavit of Nicole Davis dated 27 May 2026 (**Davis Affidavit**) at [9]. The generic and biosimilar medicines sector plays a significant role in providing cost savings to the Commonwealth Government: Davis Affidavit at [10]. A particular aspect of the work of GBMA relates

Date of document: 27 May 2026 **Filed on behalf of:** the Generic and Biosimilar Medicines Association

to contributing to public debate and awareness on issues concerning pharmaceutical patents and advocating for an appropriate balance between the competing interests of patentees of pharmaceutical patents and the public interest in the unrestricted use of pharmaceuticals after the expiration of the term of such patents: Davis Affidavit at [13]-[14].

4. GBMA seeks leave to be heard on the basis that the interests of its members, and the broader public interest, will be affected by the decision of this Court: Davis Affidavit at [16], [19].

III WHY LEAVE SHOULD BE GIVEN

5. GBMA supports (and does not seek to repeat) the Respondent (**Sun Pharma**)'s primary submission that the expression "*pharmaceutical substance*" in s 70 of the *Patents Act 1990* (Cth) (the **Act**) does not include a formulation: Respondent's and Cross-appellant's submissions dated 20 May 2026 (**RS**) [2], [14]-[72].

6. Leave is sought on the basis that:

   (a) GBMA wishes to make a submission that the meaning of "*pharmaceutical substance*" advanced by Sun Pharma is consistent with the policy, purpose and object of the patent term extension (**PTE**) regime and, in particular, s 77 of the Act.[1]

   (b) GBMA also seeks to present an additional and alternative argument that if the expression "*pharmaceutical substance*" in the Dictionary to Sch 1 of the Act "*includes a formulation*" (AS [33]), the expression "*pharmaceutical substance per se*" in s 70(2)(a) of the Act does not. This question was expressly left open in ***Cipla** Australia Pty Ltd v Novo Nordisk A/S* (2024) 185 IPR 299 at [177].

7. The proposed argument in paragraph 6(b) above is complementary to, but distinct from, Sun Pharma's submission that each of the Formulations is not a pharmaceutical

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[1] Such considerations can inform the Court's task of statutory construction, but not insofar as they deflect from a consideration of the policy and purpose of the regime by reference to the language of the Act itself: ***Alphapharm** Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247 at [42] (Crennan, Bell and Gageler JJ); *Alcan (NT) Alumina Pty Ltd v Commissioner of Territory Revenue* (2009) 239 CLR 27 at [47] (Hayne, Heydon, Crennan and Kiefel JJ); ***Merck Sharp & Dohme** Corp v Sandoz Pty Ltd* (2022) 291 FCR 26 at [65]; s 15AA of the *Acts Interpretation Act 1901* (Cth).

substance *per se* within the scope of the PTE Claims because each of the PTE Claims include process integers: RS [88]-[90]. GBMA's proposed argument is that further, and in any event, a claim to a combination of components by way of a formulation (i.e., an active pharmaceutical ingredient (**API**) and excipients), is not a claim to a pharmaceutical substance *per se*.

8. Defined terms used in this application are the same as those in RS unless otherwise indicated.

IV SUBMISSIONS

The meaning of "pharmaceutical substance" derived from the purpose and object of the PTE regime

9. The purpose of the PTE regime is:

   (a) to *balance* the competing interests of a patentee of a pharmaceutical substance whose exploitation of monopoly has been delayed (because of regulatory delay) and the public interest in the unrestricted use of that pharmaceutical substance (including by a competitor) after the expiration of the term of the patent;[2] and

   (b) to provide other interested persons with a level of *certainty* as to the term of a monopoly in relation to a pharmaceutical substance.[3]

10. These objects are consistent with the objects clause in s 2A of the Act.[4] The PTE regime should not be construed so as to achieve a "*commercial outcome for a patentee*".[5] There is nothing in the Act to suggest that a patentee is to be rewarded more than once.[6]

11. The cost to the public of patent term extensions is the restriction of competition from

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2 *Alphapharm* at [60] (Crennan, Bell and Gageler JJ); *Merck Sharpe & Dohme* at [70].

3 *Alphapharm* at [120] (Kiefel and Keane JJ, albeit in dissent in the result). See also *Commissioner of Patents v* ***Ono*** *Pharmaceutical Co Ltd* (2022) 291 FCR 1 at [51].

4 *Merck Sharpe & Dohme* at [71].

5 *Ono* at [115], [116].

6 *Calidad Pty Ltd v Seiko Epson Corporation* (2020) 272 CLR 351 at [92].

off-patent generic supply.[7]

12. Section 77 of the Act balances the range of competing interests by calculating the term of extension of a patent by reference to the *earliest* first regulatory approval date of *any* of the pharmaceutical substances referred to in s 70(2) of the Act; *not* by reference to the first regulatory approval date of the pharmaceutical substance chosen, nominated or selected by the patentee.[8] This balance is clear from the language used in s 77(1)(a) of the Act.[9]

13. The first appellant is the registered proprietor of, and has brought patent infringement proceedings in relation to, at least: Australian patent no 2002226752 for the use of *aripiprazole* for the production of a medicament, filed no later than 29 January 2002;[10] Australian patent no 2005201772, also for the use of *aripiprazole* for the production of a medicament;[11] and Australian patent no 2002334413, for an improved form of *aripiprazole* having reduced hygroscopicity, filed on 25 September 2002.[12]

14. O/L now seek to further extend the first appellant's monopoly not by reference to a new pharmaceutical substance, but by reference to a reformulation of *aripiprazole*; i.e., a known pharmaceutical substance first included in the ARTG in May 2003: FCJ [15]. This sits uneasily with the balance sought to be struck by the PTE regime.

15. A patentee may choose to file successive patents for alternative formulations of the same API (whether by filing divisional patents deriving from the same 'parent' application under s 79B of the Act or filing new patent applications). Such successive formulations may be commercially important and may be inventive. Indeed, new

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7 Industry Commission's Report No. 51, *The Pharmaceutical Industry*, dated 3 May 1996 at 16.3, which is part of the policy background identified in the 1998 REM.

8 *Ono* at [128], [129], [137]; *Merck Sharpe & Dohme* at [85].

9 *Ono* at [138]-[139]; *Merck Sharpe & Dohme* at [77]-[79].

10 *Otsuka Pharmaceutical Co Ltd and Anor v Generic Health Pty Ltd* (No 4) (2015) 113 IPR 191 (***Otsuka No. 4 FC***) at [57] (identifying the priority date of 29 January 2001) and [96] (identifying the claims); and on appeal *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd (No 2)* (2016) 120 IPR 431. The filing date of the application must be within 12 months of the date of the priority document.

11 *Otsuka No. 4 FC* at [2].

12 *Bristol-Myers Squibb Co and Anor v Apotex Pty Ltd* (No 5) (2013) 104 IPR 23 at [40] and [42]; and on appeal: *Bristol-Myers Squibb Co and Anor v Apotex Pty Ltd* (No 5) (2015) 228 FCR 1.

invention is required for the purposes of the PTE regime.[13] But that is not sufficient. The invention disclosed and claimed must also answer the description of a "*pharmaceutical substance*": s 70(2).

16. On O/L's construction, each successive patent would in substance disclose and claim a "*pharmaceutical substance*" and, thus, each such formulation would satisfy the requirements of s 70(2) and (provided the other criteria are met) each such patent would be entitled to an extension of term. On that approach, a patentee could readily avoid the operation of s 77 by filing successive patents for alternative formulations of the same API.

17. In those circumstances, the application of the PTE regime would be dictated by the patentee's choice to bring successive formulations of an API to market and to file successive patents for such formulations. The practical effect would be to permit the patentee to progressively extend its monopoly in relation to that API, albeit by presenting the API in reformulated form.

18. The construction of "*pharmaceutical substance*" advanced by Sun Pharma avoids such distortion of the PTE regime. It ensures that the operation of s 77(1) of the Act cannot be dictated by the choice of a patentee to re-monopolise an API by way of a re-formulation because a formulation would not meet the description of a "*pharmaceutical substance*" in s 70(2). Further, it provides other interested persons with a level of certainty by ensuring that patent term extensions are confined to the first regulatory approval date for the API, irrespective of any subsequent patents claiming reformulations of that API.

19. Accordingly, the construction advanced by Sun Pharma balances the competing interests of a patentee and the public interest in a manner consistent with the balance intended to be struck by s 77 of the Act.

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[13] So much is apparent from the fact the pharmaceutical substance *per se* must fall within the scope of the claim or claims of a standard patent: s 70(2). Section 18 of the Act requires an invention claimed in any claim of a patent to be, amongst other things, new and inventive.

The meaning of "pharmaceutical substance per se"

20. In the present case, the API in each of the Formulations is aripiprazole. The PTE Claims claim, *inter alia*, a formulation which comprises aripiprazole and a vehicle, wherein said vehicle comprises one or more excipients: PJ [63]-[66]. None of the excipients are for "*a therapeutic use whose application involves*" the chemical or physico-chemical interaction required by the definition of "*pharmaceutical substance*" in the Dictionary in Sch 1: RS [7]; FCJ [1]-[3]; [16]; PJ [162]-[170].

21. Against this background, O/L contend that "*substance*" in the definition of "*pharmaceutical substance*" in the Dictionary in Sch 1 of the Act "*captures a 'substance' consisting of multiple components or 'substances'*" and where the substance is a formulation, the requirements of the definition are tested by reference to the formulation as a whole: AS [34]-[35]. On O/L's construction, the word "*substance*" "*includes a formulation*": AS [33]. It would also include the API by itself. In this regard, GBMA strongly supports (and does not repeat) the arguments advanced by Sun Pharma, in particular, RS [32]-[34].

22. If, however, O/L's construction of the word "*substance*" is accepted, a question remains as to whether a formulation is a "*pharmaceutical substance* ***per se***" (emphasis added) within the meaning of s 70(2)(a) of the Act.

23. O/L assume that if a formulation is a "*substance*" that "*as a whole*" answers the requirements of the definition of a "*pharmaceutical substance*", that formulation necessarily answers the description of a "*pharmaceutical substance per se*". That approach is at odds with the appellate authorities discussed below.

24. GBMA contends, instead, that if a "*substance*" includes a formulation (i.e. a mixture of an API and excipients), the words "*per se*" in s 70(2)(a) call out the "*substance*" within the definition of "*pharmaceutical substance*" whose application "*by or in itself*"[14] involves the interaction specified by the definition, that is, the API.

[14] ***Boehringer*** *Ingelheim International GmbH v Cmr of Patents* (No 2) (2001) 112 FCR 595 at [34].

25. Footnote 40 in *Alphapharm* at [23] (referenced at FCJ [124]-[126], [259] and [260]) stated, insofar as is relevant (emphasis added):

> *Relevantly, the extension of term scheme under the Act covers standard patents for **pharmaceutical substances per se** pursuant to s 70(2)(a), hence patents for pharmaceutical methods **or tablets** do not fall within the scheme...*

26. The FFC observed that footnote 40 in *Alphapharm* is an "*example of what is not a pharmaceutical substance per se, i.e. claims to the active ingredient plus other integers concerning excipients in a dose form such as a tablet or modified release tablet...*": FCJ [260]. GBMA embraces that observation.

27. In *Cipla* at [176], Perram J understood this footnote "*as exhibiting the conclusion that a patent for a tablet is a patent for a pharmaceutical method of delivery*". The further observations of Perram J at [177] are apposite:[15]

> *"That may raise an interesting question in this case as to why Cipla did not submit that the 862 Patent was not a patent for a pharmaceutical substance per se. It is not necessary for me to speculate about this, however, and instead it suffices to observe again that Cipla's submission is confined to the contention that the formulation disclosed by the 862 Patent is not a pharmaceutical substance. As I have noted above, it accepts that if it is a pharmaceutical substance, it is also a pharmaceutical substance per se for the purposes of s 70(2)."*

28. The question raised here by GBMA was, thus, expressly left open in *Cipla*.

29. In *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151 (***Alphapharm FC***) at [244], Bennett J, with whom Middleton J agreed, observed that in a racemic mixture containing (+)-enantiomers and (-)-enantiomers in equal proportions, the:[16]

> *"... (+)-enantiomer molecule per se fulfils the requirements of s 70(2). It is the molecule that "works" as a pharmaceutical substance alone, or together with other substances, in goods listed on the ARTG. These other substances may be components of a formulation or may otherwise be described as impurities,*

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[15] See also *Cipla* at [88].

[16] As to the further observations of Bennett J at [242]: see PJ [100]-[109]; FCJ [228]-[229].

such as the (–)-enantiomer."

30. Consistent with this, in *Boehringer* the claim was to a container comprising an aerosol or spray composition for nasal administration; there was no claim to the composition alone.[17] The claim was not to a "*pharmaceutical substance per se*" – it was to a pharmaceutical substance in combination with another product.[18] In essence, a substance that is included in a claim only in combination with other components, as in *Boehringer*, is not a pharmaceutical substance *per se*.[19]

31. For the same reason, GBMA contends that even if a "*pharmaceutical substance*" includes a formulation, a formulation is not a "*pharmaceutical substance per se*" because it is a combination of components which together constitute the packaging and/or a delivery system of a known API, rather than a pharmaceutical substance "*by or in itself*": RS [69], FCJ [123], [129], cf AS [60].

32. There is no conceptual difference between the product claims in *Boehringer* and claims to a formulation. Both relate to the way an API is presented, released, delivered or administered by reference to another component or components (whether that be a container or excipients). The fact that in *Boehringer* the other component was a physical device and in the case of the Formulations it is a "*vehicle*" comprising excipients, is a distinction without a difference. Neither constitute a pharmaceutical substance *per se*.

33. GBMA's construction is consistent with the legislative intent expressed in the 1998 REM that the "*extension of term provisions will be available for patents that include claims to pharmaceutical substances per se (provided that the other criteria are met) ... Claims which limit the use of a known substance to a particular environment... are not considered to be claims to pharmaceutical substances per se.*"[20]

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[17] *Boehringer* at [4], [5].

[18] *Boehringer* at [37]-[42].

[19] *Prejay Holdings Ltd v Commissioner of Patents* (2003) 57 IPR 424 at [22].

[20] 1998 REM, item 3 [9] and [10].

V ESTIMATE

34. If granted leave to make oral submissions, the *amicus* estimates that it requires 15 minutes to present its oral argument.

Dated: 27 May 2026

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ANNEXURE TO INTERVENER'S SUBMISSIONS

No	Description	Version	Provision(s)	Reason for providing this version	Applicable date or dates (to what event(s), if any, does this version apply)
1	*Patents Act 1990* (Cth)	C2014C00301 (24 June 2014 – 25 February 2015)	Chapter 6, Part 3; and Schedule 1	Version in force at date in right hand column.	13 August 2014, being the date of the Extension Request: FCJ [3]