HIGH COURT OF AUSTRALIA

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IN THE HIGH COURT OF AUSTRALIA No S20 of 2026

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

10 Fourth Appellant

and

SUN PHARMA ANZ PTY LTD

Respondent

INTERVENER'S SUBMISSIONS

Unless otherwise defined, this submission adopts defined terms from the Appellants' Submissions dated 24 April 2026 (**AS**) and FCJ.

Part I: Suitable for publication

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

Part II: Basis for application for leave to be heard or intervene

20 2. The Institute of Patent and Trade Mark Attorneys of Australia (**IPTA**) seeks leave to make the following submissions, and to be heard, as *amicus curiae*[1] on the Appellants' (**O/L**'s) appeal from FCJ, in respect of the first appeal question only,[2] and only to the extent that the submissions do not duplicate the submissions of a party.

3. Leave is sought on the basis that:

   (a) IPTA wishes to present arguments in addition to those made in AS and by the Respondent (**SP**) in its submissions dated 20 May 2026 (**RS**).

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[1] *Levy v Victoria* (1997) 189 CLR 579 at 604-605.

[2] Referred to as the "*principal issue*" at AS [2].

(b) IPTA wishes to make submissions as to the relevant matters of principle and the implications of the FCJ approach, which provide a larger view of the matter before the Court than that put, or likely to be put on appeal, by the parties (see in particular paragraphs 9 to 12 below).[3]

(c) The legal interests of clients for whom IPTA's members act are likely to be substantially affected, and the professional practice of IPTA's members is directly affected, by FCJ and any decision of the High Court in this case.[4] However, IPTA does not submit that any legal interest of IPTA will be directly affected by the outcome of this case.[5]

10 4. IPTA's application is sought to be made in support of an affirmative answer to the first appeal question (that is, that the Full Court did err in construing "*pharmaceutical substance*" to exclude anything "*comprised of anything other than active ingredients*"). IPTA does not seek to, and does not, express any view on the answer to the second appeal question in this case.

5. IPTA relies on the affidavit of Claire **Gregg** affirmed 27 May 2026 in support of the application for leave to be heard.

Part III: Why leave should be granted

6. IPTA represents the interests of patent attorneys in Australia, including for the purpose of "*promoting improvements in the laws and regulations relating to*
20 *patents*…".[6] The role and privileges of registered patent attorneys in the preparation of documents, transacting business and conducting proceedings for the purposes of the Act are enshrined in the Act.[7] The patent attorney members of IPTA represent manufacturers and developers of inventions including pharmaceutical inventions, and are involved in the preparation and prosecution of patents that relate to pharmaceutical inventions, as well as PTE applications.[8] Approximately 90% of registered patent attorneys in Australia are IPTA members.[9]

7. Leave should be granted to IPTA by reason of the following matters.

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[3] *Wurridjal v The Commonwealth* (2009) 237 CLR 309 at 312.
[4] ***Roadshow*** *Films Pty Ltd v iiNet Limited* (2011) 248 CLR 37.
[5] Cf *Roadshow* at [2].
[6] Gregg, [9].
[7] Act, s 200.
[8] Gregg, [7] and [12].
[9] Gregg, [7].

8. *First*, the submissions which IPTA seeks to make, set out in Part IV below, present arguments additional to those of the parties, and IPTA only seeks leave to the extent that its submissions do not duplicate the submissions of a party.[10]

9. *Secondly,* the submissions in Part IV are made at the level of principle, including important issues concerning the proper construction of the Act, from a perspective that is not constrained by the particular interest O/L (or SP) has in succeeding on the facts of this case.

10. Specifically, in circumstances where O/L must succeed in respect of the subsidiary issues identified in AS [3] (the **reconstitution and characteristics issues**) in order to succeed on appeal,[11] IPTA wishes to make submissions in respect of the matters above from a perspective that is unconstrained by those considerations (i.e. considerations specific to pharmaceutical products that need to be reconstituted before administration or claims which describe characteristics of the product).

11. IPTA's submissions in Part IV focus in particular on the implications of the FCJ's "blanket" judge-made exclusion of "formulations" from the PTE scheme for a significantly broader range of pharmaceutical inventions and new medicines. Those submissions seek to demonstrate difficulties in trying to reconcile the FCJ approach with cases the subject of established Full Court authority which did not involve the reconstitution or characteristics issues, and is not apt to achieve the Full Court's stated policy outcome in any event.

12. *Thirdly*, by reason of those difficulties, FCJ is apt to create significant uncertainty for patent attorneys going forward and will, if not overturned on the "blanket" exclusion of formulations, have profound implications for the practice of IPTA's patent attorney members and the interests of those they act for.

13. Those implications logically extend to advising on the drafting of patent specifications and claims, and advising on validity and infringement, not just the prosecution of PTE applications, for both originator and generic pharmaceutical clients.

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[10] See *Roadshow* at [7].
[11] See e.g., AS [19].

14. IPTA's members are responsible for the day to day conduct of these matters in accordance with the Act and thus IPTA is well-placed to assist the Court in understanding the impact of FCJ on established practice.

15. *Fourthly*, IPTA's intervention will not materially lengthen or interfere with the appeal. If the Court were minded to hear any oral argument on matters arising out of the submissions in Part IV below, such argument would be extremely brief and as directed by the Court.

Part IV: IPTA's submissions

The Full Court's blanket exclusion of "formulations" is an erroneous construction of the Act

16. IPTA supports the submissions at AS [20]-[64] regarding statutory construction and the errors made by the FFC.

17. Prior to FCJ, the contours of the "*per se*" requirement in s 70(2)(a) of the Act as a textual boundary between PTE-eligible and PTE-ineligible types of patents had been developed through over 20 years of case law: see e.g., *Cipla* at [130].

18. Here, the Full Court, as the central step in its reasoning, supplanted the Act's definition of "*pharmaceutical substance*" by a dichotomy between on the one hand "*active pharmaceutical ingredients*" or "*active substances*", and on the other "*formulations*", terms which do not appear anywhere in the text of the Act.

19. In so doing, the Full Court found that certain aspects of the reasoning in three earlier single judge decisions of the Federal Court were incorrect: *Cipla*, *Pharmacia*, and *Spirit*. While FCJ canvassed a wide range of other single judge and Full Court decisions dealing with PTE, FCJ did not suggest that any of those previous single judge or Full Court decisions was incorrect.

20. As indicated in AS [17] and [20], the FFC concluded that as a matter of statutory construction the PTE scheme excludes "formulations" on the basis that "*pharmaceutical substance*" is "*limited to active substances and…formulations do not fall within the scope of the definition*".

21. It is apparent from FCJ [170]-[171] that the effect of the FFC's construction is impermissibly to re-write the relevant part of the definition of "*pharmaceutical substance*" as follows:

> *"**pharmaceutical substance*** means a substance (including a mixture or compound of [***pharmaceutical***][12] substances) for therapeutic use whose application (or one of whose applications) involves:
>
> (a) a chemical interaction, or physico-chemical interaction, with a human physiological system…" (**requisite interaction**)

22. That is, FCJ's construction of the Act requires in such cases not only that there be a "mixture or compound of substances" for therapeutic use whose application (i.e. the application of the mixture or compound) involves the requisite interaction, but additionally that it be a "mixture or compound of substances" for therapeutic use wherein the application of <u>each</u> of those substances involves the requisite interaction.

23. Put another way, the FFC discerned an expression of legislative intent that a "*pharmaceutical substance*" cannot be "*comprised of anything other than active ingredients*": see e.g., FCJ [170]-[171], [176], [178], [184]. The FFC's reasoning is premised on the notion that "*It is only the active ingredient that can have a chemical or physico-chemical interaction with a human physiological system…*" (FCJ [170]).

24. In addition, the FFC failed to define clearly what a "formulation" is, except that they are to be conceptually distinguished from active ingredients. Presumably, on the FCJ approach, any mixture or compound of (i) one or more "active" substances the application of which involves the requisite interaction; and (ii) one or more "inactive" substances the application of which does not involve the requisite interaction constitutes a "formulation" and is thus ineligible to qualify as a pharmaceutical substance.

25. Accordingly, the underlying *premise* of FCJ is thus that only a patent containing a claim to solely "active ingredients", or to a mixture or compound of solely "active ingredients", can be eligible for term extension.

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[12] Or, as it is put in OS [49], "*a substance (including a mixture of compound of <u>such</u> substances)*".

26. FCJ [197] defends that approach on the basis that "*[a] construction of 'pharmaceutical substance' which has the effect of restricting extensions of terms to patents for newly discovered drugs, such as new chemical or biological entities or APIs, that have taken an extended effort and time to achieve regulatory approval is consistent with the object articulated in the extrinsic materials to which we have referred above*".

27. Even if that approach were an otherwise permissible exercise in statutory construction by reason that it would achieve the effect mentioned, the matters and examples outlined below suggest that the FCJ approach may achieve the contrary result and that if FCJ is correct, then previous Full Court authority has been affected by error and/or would entail absurd results (notwithstanding that the Full Court purported to rely on those authorities without adverse comment).

FCJ applied to racemic mixtures / the Lundbeck Cases leads to absurd results

28. The *Lundbeck Cases* addressed certain issues arising from the development of a drug that was initially tested, and approved in humans, as a "*racemic mixture*".

29. The *Lundbeck Cases* are discussed at FCJ [217]-[232].

30. A "racemate" or "racemic mixture" is a *mixture* that contains equal amounts (50:50) of two enantiomers, which are molecules that are non-superimposable mirror images of one another.[13] In the case of racemic citalopram, the (+)-enantiomer was "*one hundred times more active than the (-)-enantiomer*".[14]

31. In the *Lundbeck Cases*, Lundbeck patented the racemate in January 1977 (**Racemate Patent**).[15]

32. The "*project*" to prepare the individual (+)- and (-)-citalopram enantiomers extended from 1980 to 1988, and was described in the evidence as "*one of the most difficult pieces of research that [a named inventor] had ever been involved in*".[16]

33. Lundbeck applied for a patent claiming the (+)-enantiomer (**Enantiomer Patent**) in June 1989.

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[13] *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247 (***Alphapharm HC***) at [24].
[14] *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151 (***Alphapharm FFC***) at [4].
[15] *Alphapharm HC* at [24].
[16] *Alphapharm Pty Ltd v H Lundbeck A/S* [2008] FCA 559; (2008) 76 IPR 618 (***Alphapharm FCA***) at [247] and see also [251]-[274].

34. A first medicine, CIPRAMIL, contained *racemic* citalopram and was registered on the ARTG in December 1997. Nearly six years later, in September 2003, LEXAPRO, a medicine containing (+)-citalopram was registered on the ARTG. Both were registered in the name of Lundbeck's Australian subsidiary.[17]

35. The Enantiomer Patent was ultimately extended on the basis of CIPRAMIL, not LEXAPRO.

36. One implication of FCJ (if correct) is that a PTE would not have been available for the team that developed and patented racemic citalopram (i.e. active (+)- and inactive (-)-citalopram), and obtained regulatory approval of CIPRAMIL ([racemic] citalopram hydrobromide).[18]

37. In *Alphapharm FFC* at [235], Bennett J (Middleton J agreeing) observed that "*The racemate is made up of equal parts of the (+) and (-) enantiomers and (+)-citalopram is the* ***major, if not the only, active ingredient in Cipramil***".

38. Applying the central premise of FCJ, a claim to a racemate (as one would expect to see in the Racemate Patent or any "first generation" patent claiming a biologically active racemate) that contains a largely inactive enantiomer would presumably be considered a "*formulation*" because the presence of that largely inactive enantiomer as a component of the "*mixture"* would render the racemic mixture a mixture of (i) a substance whose application involves the requisite interaction ((+)-citalopram) and (ii) a substance whose application does not ((-)-citalopram) and would therefore be ineligible for term extension.

39. That is despite the racemate being a "*newly discovered drug*" (cf FCJ [197]) and the product of primary research and development, and the Racemate Patent presumably qualifying as a paradigm example of a "*compound patent*".[19]

40. To avoid ineligibility, the patentee of a racemate patent would, on the FCJ approach, presumably have to demonstrate by some evidence that the application of the (-)-enantiomer itself *involves a chemical or physico-chemical interaction with a human physiological system…*" (FCJ [170]). That is because the FCJ necessarily concluded that it is not enough, for the purpose of the "*pharmaceutical substance*" definition, that the application of the "*mixture or*

[17] *Alphapharm HC* at [24].
[18] Putting to one side the fact that more than 20 years passed between the date of the Racemate Patent and the ARTG registration of CIPRAMIL.
[19] This terminology is picked up in, for example, FCJ [14].

compound of substances" *collectively* involves the requisite interaction (thanks to the presence of the active enantiomer).[20] A patentee in that situation would need to demonstrate that each of the substances *alone* involves the requisite interaction.

41. In addition to that outcome being contrary to what the FCJ identified as the effect of its construction ("*restricting extensions of term to newly discovered drugs*"), it also raises a significant question as to how, ethically, any patentee could conduct experiments to demonstrate what, if any, activity the enantiomer known to be "*inactive*" or "*one hundred times less active*" has when administered to humans *without* the therapeutically beneficial "*active*" or "*one hundred times more active*" enantiomer, in order to meet the FCJ's requirement that *each* substance forming part of the mixture have the requisite activity.

42. But if one adopts the correct construction of the definition of "*pharmaceutical substance*", being one which is satisfied by a mixture or compound of substances whose application (i.e. collective application) involves the requisite interaction, that *would* mean that a newly discovered drug in the form of a racemic mixture can qualify as a pharmaceutical substance (notwithstanding the presence of an inactive enantiomer), and would avoid the ethical and practical difficulties attendant in the FCJ approach outlined above.

43. By contrast, a PTE would (as it was ultimately found to be in the *Lundbeck Cases*) be available, based on the [racemic] CIPRAMIL ARTG registration, to a research team that took the known racemate and succeeded in separating the (+)-enantiomer from the inactive (-)-enantiomer after around seven years of work, patented it, and registered a new medicine LEXAPRO containing isolated (+)-citalopram enantiomer.

44. This is notwithstanding that, as stated in the Enantiomer Patent itself, "*Citalopram, which has been disclosed…has proven to be an efficient antidepressant compound in man*" and "*[a]ll work in the development of this compound has been made with the racemate*".[21]

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[20] Further, on the FCJ approach, (+)-citalopram could not be the nominated pharmaceutical substance for the purpose of the Racemate Patent, as (+)-citalopram *per se* does not fall within the claims of the Racemate Patent, which additionally require the presence of (-)-citalopram.

[21] *Alphapharm FFC* at [41].

45. As it happens, in the *Lundbeck Cases*, it was one of the inventors of racemic citalopram whose team also carried out the work to separate the enantiomers: see *Alphapharm FCA* at [246]-[247] and [272]-[273]. But had a third party been the first to separate and patent (+)-citalopram on the same dates that the Lundbeck team did, that third party would have been entitled to a PTE based on the regulatory delay Lundbeck encountered in the approval of its racemic product, notwithstanding that, on the FCJ approach, Lundbeck itself would not have been entitled to a term extension in respect of the citalopram patent.

FCJ is inconsistent with the approach to salt complexes taken by the Full Court in Novartis AG v Pharmacor Pty Limited

46. FCJ also raises potential difficulties in its application to registered medicines containing "*salt complexes*".

47. Salt complexes were considered in *Novartis AG v Pharmacor Pty Limited* [2025] FCAFC 33 (***Novartis FFC***). The active ingredient in "*Entresto*" was found to be "*TSVH*", "*a salt complex of the anionic forms of sacubitril and valsartan, sodium cations, and water molecules…*" in a "*co-ordinated complex arrangement involving ionic bonding, hydrogen bonding and a range of other non-covalent interactions*": *Novartis FFC* [24], citing ***Novartis*** *AG v Pharmacor Pty Limited* [2024] **FCA** 1307; 186 IPR 24 at [96].

48. Valsartan, an angiotensin receptor blocker, "*target[s] and predominantly block[s] AT-1 receptors*": *Novartis FCA* at [56] and [62]. Sacubitril, a NEP inhibitor, inhibits neutral endopeptidase (also known as neprilysin): *Novartis FCA* at [34] and [134]. More precisely, sacubitril is a prodrug of sacubitrilat: [134]. The relevant product information described the mechanism of action as "*simultaneously inhibiting neprilysin via sacubitrilat as the active metabolite of sacubitril, and by blocking the AT-1 receptor via valsartan*".[22]

49. That is, although given the label "*active ingredient*" by the Court, TSVH was itself a complex of active substances and inactive substances (e.g., water).

50. There was no challenge on appeal to the finding in *Novartis FCA* at [98] that:

> "*[f]ollowing oral administration of the tablet, Entresto disintegrates. The salt complex, TSVH, is released and then dissolved in the*

[22] *Novartis FCA* at [275].

gastrointestinal tract fluids. The pharmaceutical composition no longer exists. The salt complex dissociates into solvated anionic sacubitril and anionic valsartan. The anions are then protonated (i.e., they gain a hydrogen atom) into their free acid forms."

51. Importantly, the trial judge in *Novartis FCA* found that "*the pharmaceutical substance, for the purposes of the s 70(3) inquiry, is TSVH*": [295].

52. It is not apparent how that finding (not disturbed on appeal[23]) could stand in the light of FCJ, if FCJ is correct. That is because one of the *"substances*" forming a constituent element of the *"complex*" (which complex might be posited as a "*mixture or compound of substances*"[24]) is water, which does not itself have the requisite effect or contribute to the mechanism of action as described in the product information.

53. That is, "*the pharmaceutical substance*" as found by the trial judge in *Novartis FCA*, TSVH, is itself a *mixture or compound of substances* that includes inactive or inert substances that do not (and could not) contribute to the mechanism of action.[25] The FCJ approach necessarily disqualifies that mixture or compound of substances from the scope of "*pharmaceutical substance*".

54. FCJ cited *Novartis FCA* but did not suggest that it was wrongly decided or proceeded on an erroneous approach to the PTE provisions.

Broader difficulties

55. The two examples dealt with above (racemic mixtures and salt complexes) are intended to demonstrate difficulties and (presumably unintended) consequences that follow from the FCJ "blanket" exclusion of formulations on the basis of a dichotomy between, on the one hand, active substances or mixtures or

[23] The Full Court considered that the resolution of Novartis' appeal on the PTE issues was dependent on acceptance of Novartis' contention on the question of construction, which the Full Court upheld: *Novartis FFC* at [54]. It also appears to be implicit from the use of the word "*the*" in [295] of *Novartis FCJ* that particular goods on the ARTG can only be characterised as containing or consisting of one pharmaceutical substance.

[24] SP's written outline of submissions on the special leave application in the present case identified salt complexes as an example of a "*compound of substances*": fn 8. In its submissions on the appeal, SP submits that "*compounds of active substances include co-drugs (being two active substances chemically joined)*": RS, fn 24.

[25] FCJ also leaves it unclear whether valsartan in salt form, or sacubitril in salt form, would qualify as active substances that contribute to the mechanism of action in circumstances where sacubitril is a prodrug, and the ionic forms of both valsartan and sacubitril are protonated and form free acids in the body.

compounds comprised solely of active substances and, on the other, mixtures or compounds comprised of active and inactive substances. Other examples of medicines that can readily be posited as potentially raising similar issues include, but are not limited to:

a. Pro-drugs that are converted in the body from an "inactive" form which does not itself have the requisite interaction to an "active" form which does have the requisite interaction.

b. Antibody-drug conjugates where the "active" drug component is attached to an antibody by a chemical linker, neither of which has the requisite interaction.

c. A simple scenario where Molecule X is produced as an intermediate in the production of an industrial solvent. It has never been administered to a human and is not known to have any therapeutic properties. A research team that carries out discovery, pre-clinical and clinical work to establish that Molecule X, administered to humans orally with standard excipients, is highly effective for treating all forms of cancer, cannot validly claim Molecule X alone (because it would not be new) but could claim "*a pharmaceutical composition comprising Molecule X and a pharmaceutically acceptable excipient*" as new. On the FCJ approach, it is not clear how the latter claim could support a PTE (irrespective of the regulatory delay the team encounters) and notwithstanding that it appears to fall within the notion of a "*newly discovered drug*".

Part V: Oral argument

56. If the Court wishes to hear oral submissions from IPTA on the issues arising from these submissions, IPTA estimates 15 to 20 minutes for oral argument.

Dated: 27 May 2026

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