HIGH COURT OF AUSTRALIA

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| | |
|---|---|
| File Number: | S20/2026 |
| File Title: | Otsuka Pharmaceutical Co., Ltd & Ors v. Sun Pharma ANZ Pt |
| Registry: | Sydney |
| Document filed: | Form 27E - Reply |
| Filing party: | Appellants |
| Date filed: | 02 Jun 2026 |

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**Form 27E – Appellant's reply**

Note: see rule 44.05.5.

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

**APPELLANTS' REPLY**

**Part I: Form of submissions**

1. These submissions are in a form suitable for publication on the internet. These submissions use defined terms from the Appellants' submissions in chief (**AS**).

**Part II: Argument**

**Reply and answer to Amended Notice of Contention**

**A. "Pharmaceutical substance" includes formulations**

2. ***(i) Overview.*** The parties appear to agree that the FFC's approach to construing "pharmaceutical substance" was methodologically flawed, in that it did not begin with the statutory text and involved construing the definition before its text was "inserted into" s 70 of the Act: AS [38], [41]-[42], [47]; Respondent's submissions in answer (**RS**) [16], [19], [20]; cf RS [61]-[63].

3. RS focuses heavily on the 1998 REM/2006 EM (e.g., RS [14]-[15], [18]-[19]), seeking to elevate statements therein above the clear words of the Act. RS does not properly engage with the purpose of the EoT Scheme discernible from the statutory text against the background of the previous scheme or explain how this would be facilitated by excluding formulations from it: AS [23]-[30]; cf RS [70]-[72].

4. To a significant extent, RS relies on assertions as to scientific facts concerning technical terms in ss 70 and 119A: e.g., RS [24], [32] (insofar as it concerns "compound of

substances"), [42] (last sentence), [81] (first sentence). In the absence of evidence[1] or findings about these matters, the Court should not proceed based on those assertions.

5. ***(ii) Section 70.*** Contrary to RS [22]-[28], ss 70(2)(b), (3)(a), (3)(b), (5) and (6) of the Act do not support limiting "pharmaceutical substance" to active substances.

6. As to s 70(2)(b) (cf RS [22]-[24]), this subsection concerns pharmaceutical substances made by a particular *process*. It may be contrasted with s 70(2)(a), which does not concern the process by which the pharmaceutical substance is made: e.g., *Cmr of Patents v AbbVie Biotechnology Ltd* (2017) 253 FCR 436 at [54]-[57]. The phrase "*one or more substances produced by a process that involves the use of recombinant DNA technology*" does not prevent the "pharmaceutical substance" in s 70(2)(b) from being a formulation. A formulation which contains (for example) recombinant protein(s) and one or more *excipients* has been "*produced by a process that involves the use of recombinant DNA technology*". See also *Cipla* at [131] (original emphasis): "*Section 70(2)(b) only requires the process to involve the use of recombinant DNA technology.*"

7. As to s 70(3)(a) (cf RS [25]-[26]), an ARTG good: "contains" a "pharmaceutical substance" when the goods are (for example) a container which holds the "pharmaceutical substance", such as an injectable, inhaler or a bottle with an applicator: see also *Cipla* at [134]-[135]; and "consists of" a "pharmaceutical substance" when the good is an API or formulation alone: see *Cipla* at [133] (second sentence).

8. As to ss 70(3)(b), 70(5) and 70(6) (cf RS [28]), the "*first regulatory approval date for the substance*" is the date on which a product containing the substance first receives regulatory approval: see also *Cipla* at [137].

9. The TG Act's recognition that different formulations are separate "therapeutic goods" is more likely to inform the Court's construction than the matters in RS [27].

10. ***(iii) Definition of "pharmaceutical substance".*** O/L agrees with RS [32] (first two sentences) and the statement in RS [35] that "*a formulation is a mixture of substances comprising an API(s) and excipients*".[2]

11. As to RS [30] (see also RS [34]-[35]), Sun Pharma's assertion that *each* "substance" in a mixture or compound of substances must be for "*therapeutic use whose application*

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[1] Expert evidence may assist the Court to understand technical terms and concepts in legislation: *Woodside Energy Ltd v Cmr of Taxation* (2006) 155 FCR 357 at [53]-[56] per French J (as his Honour then was).
[2] As to the phrase "compound of substances" (cf RS [32], last sentence), this carries a different meaning compared with the word "compound" solus. It refers to a substance made by compounding other substances, for example compounding in a pharmacy. This includes a formulation.

*(or one whose applications) involves [the requisite interaction]*" ignores the wording and structure of the definition: see AS [32]-[35], [49].[3] So too does Sun Pharma's emphasis on the asserted "focus" of the definition (RS [31]), which it impermissibly seeks to substitute for the text Parliament enacted: see also AS [48].

12. As to RS [33], O/L does not suggest that the words in brackets "*constrict the definition*". The ordinary meaning of a substance is "*a species of matter of definite chemical composition*": cf RS [29].[4] The 'work' performed by the words in brackets is to clarify that a substance may be made up of multiple substances: see also *Cipla* at [126]. This clarification is "useful and pertinent" (*Project Blue Sky Inc v Australian Broadcasting Authority* (1998) 194 CLR 355 at [71]) because it puts the matter beyond doubt.[5] In any event, for a multitude of reasons, Parliament is "*sometimes guilty of 'surplusage'*": *Western Australian Planning Commission v Southregal Pty Ltd* (2017) 259 CLR 106 at [55]; *Palmanova Pty Ltd v Cth of Australia* (2025) 99 ALJR 1362 at [73]-[74].

13. As to RS [37], if the legislature had intended to limit the definition to "active substances", it could have used that terminology.

14. ***(iv) Sections 78/119A.*** Sections 78 and 119A of the Act, which concern 'springboarding' were enacted into the Act by the *Intellectual Property Laws Amendment Act 2006* (Cth) (**2006 Amendment Act**).

15. Section 70 and the "pharmaceutical substance" definition were part of the Act before the 2006 Amendment Act. Neither was amended by the 2006 Amendment Act: AS [21]; RS [38]; *Cipla* at [89]. Accordingly, while it may be accepted that the Act and the 2006 Act are to be read "*as a combined statement of the will of the legislature*" (RS [14]), the Court would be slow to hold that later springboarding provisions changed the meaning of an earlier (unamended) definition, such that the same definition had different

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[3] Insofar as RS suggests everything within a "pharmaceutical substance" must have the requisite interaction, this could not be satisfied by most if not all APIs, as APIs generally contain impurities which do not have the requisite interaction: e.g., The Therapeutic Goods Administration's Guidance 18: Impurities in drug substances and drug products (v 1.0, August 2013). The purpose of the statutory text would include any substance which has impurities (an example of which is a racemic mixture, where one enantiomer may be inactive), but Sun Pharma's construction would exclude it: see also the submissions of The Institute of Patent and Trade Mark Attorneys of Australia dated 27 May 2026 at [28] ff.

[4] See e.g., Macquarie Dictionary Online (2026), 2.; Oxford English Dictionary Online (2026), II.8.a; Macquarie Dictionary, 1st ed, 2nd revision (1987), 2; Oxford English Dictionary, 2nd ed (1989), 8b.

[5] As stated in P Herzfeld and T Prince, Interpretation (3rd ed, Law Book Co, 2024) at p 755, "belts-and-braces" expressions "may be used deliberately for… avoidance or doubt".

meanings at different times: see also *Cipla* at [102], [103], [106].[6]

16. As to s 78 (cf RS [39]), this mirrors the wording of s 70(2)(a)-(b). Contrary to RS [42], for the following reasons, s 119A(3) does not support Sun Pharma's construction. *First*, s 119A(1) is an infringement exemption in respect of exploiting a "pharmaceutical patent" (as defined in s 119A(3)) for purposes connected with obtaining regulatory approval. It does not form part of the EoT Scheme.

17. *Secondly*, the first limb of the "pharmaceutical patent" definition concerns a patent claiming a "pharmaceutical substance": s 119A(3)(a). This includes a patent claiming a formulation. Read this way, a formulation is not a "*product relating to a pharmaceutical substance*" under s 119A(3)(b)) – it *is* a pharmaceutical substance.[7]

18. *Thirdly*, further or in the alternative, the presence of the 'or' between the options in s 119A(3(a)) and (b) does not mean that they are to be construed as mutually exclusive: see *Williams v Toyota Motor Corp Australia Ltd* (2024) 419 ALR 373 at [156] (and authorities cited therein) and, in the context of s 119A(3), *Cipla* at [99]-[106].

19. ***(v) The 1998 REM and 2006 EM.*** RS [43]-[58] relies on the 1998 REM and 2006 EM in an effort to displace the clear meaning of the statutory text. This is contrary to orthodox principles of statutory construction: cf AS [39]-[40].

20. Further and in any event, the 1998 EM does not disclose an intention for the EoT Scheme to exclude formulations and be "*limited to active substances*"; indeed, the 1998 REM supports O/L's construction: see AS [51]-[56].

21. As to RS [44]-[45], there is an inherent contradiction in Sun Pharma's position. It contends "pharmaceutical substance" does not mean "API", relying on the description of the term as "*somewhat inapt*" at FCJ [176]: RS [37]. Yet it also relies on the statement in the 1998 EM that "pharmaceutical substance" *may* comprise "*combinations of active*

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[6] See also: **(1)** *AQO v Minister for Finance and Services* (2016) 93 NSWLR 46 at [163]-[165], [175]-[177] per Basten and Ward JJA that "*while the Act as amended should be read as a single expression of legislative intendment, the fact that one provision may assume that another has a particular meaning does not convey an implied amendment of the latter provision*"; and **(2)** *Interlego AG v Croner Trading Pty Ltd* (1992) 39 FCR 348 at 382, where Gummow J (Black CJ and Lockhart J agreeing) said that considering a later amendment was "*a curious way of revealing parliamentary intention at the time of passing the earlier provision*".

[7] Even if the Court considers that a formulation is a "*product relating to a pharmaceutical substance*" for the purposes of s 119A, all that would follow is that both a formulation and an "active substance" could fall within s 119A(3)(a) and (b). A formulation could fall within s 119A(3)(b) because "a method, use or product relating to a pharmaceutical substance" is inclusive. An "active substance" could fall within s 119A(3)(b) because a "pro-drug", "metabolite" or "derivative" of the "pharmaceutical substance" may itself be an "active substance": see e.g., *Merck & Co Inc v Arrow Pharmaceuticals Ltd* (2003) 59 IPR 226 at [4], [14], [25], [26], [29]-[32], where Wilcox J concluded that LHA, the metabolite of a pro-drug, was a "pharmaceutical substance".

*ingredients or single active ingredients*", and seeks to extrapolate that the phrase has the effect of limiting the "pharmaceutical substance" definition to a single *active substance* or combination of *active substances*.

22. As to RS [46], Sun Pharma again seeks to construe a passage in a lengthy explanatory memorandum as though it were the text of a statute. As to RS [47], see AS [52] and [60]. The passage at REM p 3-4 supports O/L's construction.

23. As to RS [49], the statement in the 1998 REM at p 4 that the rationale of the EoT Scheme was "*to provide a patent system which is competitive with other developed nations*" involved justifying the competitive need for extensions of term for standard pharmaceutical patents; p 3 notes that such extensions were available for pharmaceutical patents in the US, the EU and Japan. The statement did not concern whether those jurisdictions' extension schemes encompassed formulation patents. In any event, extensions of term for formulation patents were available in 1998 (at least) in the US.[8]

24. Contrary to RS [50], for the reasons set out above, there was nothing in the 1998 REM for the 2006 EM to "reverse": cf ***Harvey*** *v Minister for Primary Industry and Resources* (2024) 278 CLR 116 at [75].

25. As to the 2006 EM, for the following reasons, in addition to that at [19] above, it does not bear on the proper construction of "pharmaceutical substance". As a result, the FFC was correct to observe that the fact that the drafter of the EM 2006 adopted a particular construction of the EoT Scheme "*is not relevant*": FCJ [205] (CAB 144).

26. *First*, the 2006 EM concerned the 2006 Amendment Act, which enacted provisions concerning springboarding. It did not amend s 70 of the Act or the "pharmaceutical substance" definition: see [14]-[15] above.

27. *Secondly*, O/L repeats AS [39], [40], [42(1)-(2)]. The statements in the 2006 EM are based on an erroneous assumption as to the scope of the "pharmaceutical substance" definition: see also *Cipla* at [104]. They rise no higher than "*what an officer of the executive may have conjectured to be its meaning*": see AS [42(1)].

28. *Thirdly*, the 2006 EM is internally inconsistent. For example, in commenting on the "pharmaceutical patent" definition to be enacted as s 119A(3) of the Act, it states at [159(g)] (emphasis added):

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[8] See e.g., 35 U.S.C. § 156 and the USPTO Manual of Patent Examining Procedure at Section 2751. Extensions of term for formulation patents are available in Japan: Supreme Court Decision Heisei-21-(Gyo-Hi)-326. The PPR 2013 states at p 93 that extensions are available for formulations in the US, Europe, UK and Japan.

> *The term 'pharmaceutical substance' is defined in Schedule 1 to the Patents Act. ... It is intended that patents claiming the following methods, products and uses relating to a pharmaceutical substance would be covered by the definition of 'pharmaceutical patent':...* ***other features of the pharmaceutical substance such as the colour or shape of a pill or packaging****".*

29. "Packaging" is not a *feature* of an API (or indeed a formulation).

30. The reference to a "pill" is also inconsistent with a pharmaceutical substance being an "active substance". A "pill" cannot be a "feature" of an active substance.

31. These inconsistencies cannot be avoided by an attempt to redraft the relevant passage, as Sun Pharma seeks to do: see RS footnote 32. Rather, they betray confusion on the part of the draftsperson, which further limits the weight that can be given to the 2006 EM as an interpretative tool.

32. ***(vi) Pre-existing law before the Act.*** RS [60] (first two sentences) seeks to construe the 1989 EM Limitation as though it were a statute, and in doing so repeats the error in the FCJ: see AS [42]-[44]. Explanatory memoranda lack both the force of law and the precision of parliamentary drafting: AS [42(2)].

33. As to RS [60] (last sentence), the fact that the phrase "mixture or compound of substances" appears in the Customs Regulations (but not the 1989 EM Limitation) does not assist Sun Pharma, because the FFC construed the 1989 EM Limitation without having regard to the phrase: see AS [46]. To the extent that the pre-existing law before the Act bears on the construction issue – including when regard is had to the phrase "mixture or compound of substances" in the *Customs Regulations* – it favours O/L's construction: see [10]-[12] above and AS [33]-[35], [43] and [45].

34. ***(vii) Approach of the FFC.*** At RS [61]-[63], notwithstanding its concession concerning the FCJ's methodological flaws (see [2] above), Sun Pharma seeks to defend the FFC's approach, relying on this Court's reasoning in *Alphapharm* and *Harvey*.

35. Neither decision provides support for the FFC's approach. In *Alphapharm (HC)* and *Harvey*, the Court considered the legislative history and pre-existing law before construing the statutory text in the form of the legislation in issue. In contrast, in the FCJ, the FFC construed "pharmaceutical substance" as it appeared in an explanatory memorandum in respect of earlier legislation and erroneously carried that construction forward to the statutory text in the (later) legislation in issue: see AS [41]-[47].

36. ***(viii) Other matters.*** As to RS [66], if (contrary to AS [64]) footnote 40 in *Alphapharm (HC)* is to be afforded any weight, it does not indicate that "pharmaceutical substance"

excludes formulations: see e.g., *Cipla* at [176], [178].

37. As to RS [67] (first sentence), the earlier appellate authorities did not contain reasoning which supported Sun Pharma's proposed construction: see AS [50]. None of those authorities had a *ratio* which covered the present issue: see also FCJ [216], [232] (last sentence) (CAB 147, 149). As to the balance of RS [67], Sun Pharma's attempt to marginalise the first instance authorities, which had held that formulations can be "pharmaceutical substances", does not meet the point; the long-entrenched uniformity of that position underscored the need for legislative intervention, if that position was contrary to the legislature's intention.

38. As to RS [68], while *Pharmacia* and *Spirit* were first instance decisions, it can be expected that their conclusion that "pharmaceutical substance" includes formulations was known to the legislature given the importance of the issue and its ramifications both for the development and availability of new pharmaceutical products and the cost of the Pharmaceutical Benefits Scheme, both being considerations discussed in the 1998 REM. Further, *Spirit* was cited in the Productivity Commission report referred at AS [62(4)], considered by the Government in 2017, in support of the state of the law being that a formulation is a "pharmaceutical substance *per se*" within s 70(2)(a) of the Act.

39. As to RS [70] (first sentence), the assertion that there is a difference in regulatory delay in registering a drug containing a new active substance compared with a formulation containing an existing API is unsupported; indeed, the delays are roughly the same: see AS [60] (third and fourth sentences).

40. RS [70] (second sentence) takes the 2006 EM out of context. As quoted at RS [52], the 2006 EM stated (emphasis added): "*The lead time for R&D and regulatory approval to bring* ***a generic medicine*** *to market is between two and six years, and sometimes longer*." That is, the stipulated time period is for a generic medicine, not for a *new formulation* of an existing API.[9]

41. As to RS [71], there is no evidence or material which suggests that patentees have delayed or would "*delay in seeking regulatory approval for the second product containing or consisting of the formulation*". In any event, there is no incentive for a patentee to do this because delay will reduce the length of any extension it obtains for

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[9] As to RS [70] (last sentence), a formulation patent will not be a "blocking patent" unless the patented formulation is the only way in which the API can be formulated. In the present case, the Patent would not have "blocked" an immediate release product: see AS [8]-[9].

the relevant patent: s 77 of the Act.

42. As to RS [72], the public interest also includes pharmaceutical companies being incentivised to develop and make available new pharmaceutical products, which may be "*compromised*" if companies "*are unable to achieve an appropriate return on products*": see the 1998 REM at p 5, 6; see also AS [28] and footnote 9.

**B. The Freeze-dried Formulations satisfy s 70(2) of the Act**

43. RS [3(1)] begs the question. The issue is whether, on the proper construction of "pharmaceutical substance", the "application" of the Freeze-dried Formulations "*involves a chemical interaction, or physico-chemical interaction, with a human physiological system*": see also AS [3] (second sentence).

44. RS [73]-[74] addresses the meaning of "application" in the definition. In context, "application" means the use to which the pharmaceutical substance is put. This is also how it was construed at FCJ [267] (CAB 155), PJ [131] (CAB 36) and in *Cipla* at [124].

45. Contrary to RS [74], there is no difficulty in the definition referring to two kinds of use by different words, i.e. "therapeutic use" (as defined, which includes specified purposes) and "application" (the "*use to which the substance is put*"). They do different work. The former concerns whether the substance is "for" a specified purpose. The latter concerns whether the substance as used has the requisite interaction(s).

46. In contrast, construing "application (or one of whose applications)" as "physically applied", as Sun Pharma proposes, involves reading a word into the definition ("physically") that does not form part of it. The bracketed words "or one of whose applications" also militate against this construction; on Sun Pharma's approach, those words would entail that there can be multiple physical applications, some of which did not result in the requisite interaction(s). This strained reading gives those words no sensible work to do: see also *Cipla* at [114]-[123].

47. As to RS [75] and [80], the facts that: **(1)** upon reconstitution the Freeze-dried Formulations "no longer exist"; and **(2)** the reconstituted form (a liquid) unsurprisingly has different properties compared with the unreconstituted form (a solid), are beside the point. The use to which the Freeze-dried Formulations are put, with water added to them, involves the requisite interaction: see AS [66]-[67].

48. As to RS [76]-[79], it is not in dispute that the Freeze-Dried Formulations "in substance fall within the scope of" claims 16, 19, 21 and 25 of the Patent: AS [13].

49. As to RS [81], the fact that an API *may* (although not necessarily will) continue to exist

after its inclusion in a formulation[10] is a distinction that makes no difference. The key point is that, for both an API and an unreconstituted formulation, other elements are required to facilitate the requisite interaction.

**C. The Injectable Formulations satisfy s 70(3) of the Act**

50. RS [86]-[87] misses the point. The question is not whether s 70(3)(a) refers to "form" or "supply"; it is how to characterise the "goods". This does not involve "re-writing" s 70(3)(a); it involves properly construing it. ABILIFY MAINTENA is a "prolonged release suspension" in an injection vial: FCJ [277] (CAB 156); see also AFM 46, 48. This is what is in fact administered to the patient.

51. Contrary to RS fn 43, *Grove Hill Pty Ltd v Great Western Corporation Pty Ltd* (2002) 55 IPR 257 at [330]-[335] provides an apposite analogy. There, the appellant had sold the Versasweep assembly, being "a *kit containing separately both the forward and rear components*" of row cultivators: [335]. In concluding that this involved a direct infringement, Gyles J (with whom French J, as his Honour then was, and Dowsett J agreed) held that the *product* sold was the *assembled form* of those components.

**D. The Formulations are "pharmaceutical substances *per se*"**

52. RS [3(3)] also begs the question. The features of the PTE Claims are not "*additional to the pharmaceutical substance*"; rather, they characterise the pharmaceutical substance: see AS [3] (last sentence), [78]-[80].

53. As to RS [88] (see also RS [10]), it is inapt to classify the PTE Claims as "product claims [which]… do include process integers": cf FCJ [292] (CAB 158). The Act recognises only two categories of claimed inventions, i.e., products and methods/processes: see the definition of "exploit" in Schedule 1 and e.g., *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* (2020) 279 FCR 354 at [193]. There is no category for a product claim "*with process features*".[11] The PTE Claims are product claims, not method/process claims.

54. Insofar as FCJ [288] (CAB 158) relies on how the experts characterised the "elements" of the claims, it is well-established that the construction (or proper characterisation of the form) of the specification, including the claims, is a matter of law for the Court, not for expert witnesses: e.g., *Minnesota Mining and Manufacturing Co v Beiersdorf (Aust)*

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[10] There is no evidence to support RS [81], which is disputed. Further, in comparison with an API alone, a formulation containing the API has (for example) different physical and pharmacokinetic properties, and different stability characteristics: cf RS [80].

[11] Where a claim which is drafted as a product claim is in truth a "'disguised' process claim", it will be treated as such: *D'Arcy v Myriad Genetics Inc* (2015) 258 CLR 334 at [145].

*Ltd* (1980) 144 CLR 253 (***3M***) at 270. Plainly, the construction of the claim does not depend on the choice of language used by the experts in describing its elements.

55. As to RS [89] (first three sentences), O/L agrees that the fact that claims are product claims does not of itself mean that they are to a "pharmaceutical substance *per se*": AS [77]. However, in answer to RS [89] (last two sentences) and [90] (first two sentences), the PTE Claims do not: **(1)** claim anything *additional to the pharmaceutical substance* (e.g., the container as in *Boehringer*); or **(2)** claim how the pharmaceutical substance is used (e.g., as part of a method of treatment). This is underscored by the fact that PTE Claims would be exploited (and thereby infringed) by the sale of a product which possesses its integers; "use" of the product would not be required.[12]

56. As to RS [90] (last sentence), if (contrary to O/L's position) a tablet is a "form of delivery system" this does not assist Sun Pharma's position. The PTE Claims are to the formulation, not to (e.g.) the vial containing the formulation.

**E. O/L's position regarding proposed interveners**

57. O/L does not oppose either of the applications for leave to intervene filed 27 May 2026. As to [20]-[33] of the Generic and Biosimilars Medicines Association's submissions dated 27 May 2026, if "pharmaceutical substance" is construed such that it includes a formulation, so too does "pharmaceutical substance *per se*". The suggestion that the words "call out" the API, to the exclusion of other parts of the formulation, is untenable. The words "per se" cannot have the effect of narrowing what the pharmaceutical substance is. Rather, their function is as set out at [55] above and AS [76]-[77].

**Respondent's Cross-Appeal (NoCA)**

58. Special leave to cross-appeal ought not be granted. The law as to claim definition – a ground of invalidity rarely invoked[13] – has long been settled. In *Interlego AG v Toltoys Pty Ltd* (1973) 130 CLR 461 at 480, this Court held that, as a matter of claim definition, it is permissible for a product claim to be limited by result so long as the limitation is "*sufficient to characterise the construction of the article claimed*".

59. Further, as the UK Court of Appeal held *in* ***General Tire*** *& Rubber Co v Firestone Tyre*

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[12] PJ [15] and see Amended Defence to Cross-Claim dated 28 May 2024 at [23(a)], [25(b)] and [27(b)].

[13] When relied upon, it is frequently coextensive with the lack of clarity ground under s 40(3), which Sun Pharma does not press: RS [93], third sentence. In ***Sanofi*** *v Amgen Inc (No 3)* [2025] FCA 87 at [179], Nicholas J quoted the following passage from Bodkin, *Patent Law in Australia* (4th ed, Thomson Reuters, 2024) at [22.910]: "It is difficult, if not impossible, to conceive of a situation in which a claim could fail to define the described invention but nevertheless be clear…"

*& Rubber Co Ltd* [1972] RPC 457 at 458-459 (emphasis added):

> *"... the issue of definition is to be considered in relation to the facts of each case, that* ***allowance is to be made for any difficulties to which the circumstances give rise****, and that all that is required of the patentee is to give* ***as clear a definition as the subject matter admits of****... the issue of definition is to be* ***considered as a practical matter and little weight is to be given to puzzles set out at the edge of the claim*** *which would not as a practical matter cause difficulty to a manufacturer wishing to satisfy himself that he is not infringing the patent... definition of the scope of a claim is* ***not necessarily insufficient because cases may arise in which it is difficult to decide whether there has been infringement*** *or not provided the question can be formulated which the court has to answer..."*

60. The FFC referred to this settled law at FCJ [78]-[79] (CAB 118-9), observing that the above passage from *General Tire* had been cited "numerous times in Australian cases",[14] and went on to apply it. Sun Pharma accepts that *General Tire* is authority for how the Court is to assess whether a claim lacks definition: RS [105].

61. The principles from *General Tire* also apply to claims limited by result. The relevant integer in *General Tire* was limited by result (FCJ [82]: CAB 119), as Sun Pharma accepts: RS [106] (second sentence).

62. It follows that Sun Pharma's asserted "question of public importance" – that is, the test to be "*applied in determining whether s 40(2)(b) of the Act is satisfied in respect of a claim limited by result*" – does not arise and in any event has long been settled.

63. Moreover, the errors in the PJ were not limited to the application of the wrong legal test; they also concerned the proper construction of the Patent: see further [68(a)-(b)] below. Insofar as it concerned the lack of definition ground, the FFC involved the conventional application of established principle based on the proper construction of the Patent. The NoCA has insufficient prospects of success to warrant special leave being granted.

64. ***Context for the cross-appeal.*** Sun Pharma's case at trial was that the PTE Claims lack clarity and definition based on the integer "*which upon injection releases aripiprazole over a period of [a specified time]*" (**Relevant Feature**): FCJ [26]-[28] (CAB 107).

65. In the Relevant Feature, the phrase "releases aripiprazole" refers to "the dissolution of aripiprazole molecules from the depot at the injection site": FCJ [72] (CAB 118).

66. Sun Pharma accepted that its product possessed the Relevant Feature: PJ [14]-[15] (CAB 13-14). Its case thus involved a "theoretical construct": FCJ [113] (CAB 126).

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[14] E.g., ***BlueScope Steel*** *Ltd v Dongkuk Steel Mill Company Ltd* (2019) 152 IPR 195 at [715] (Beach J); *Sanofi* at [184] (Nicholas J); *H Lundbeck A/S v Sandoz Pty Ltd* (2018) 137 IPR 408 at [83] (Jagot J); *Wake Forest University Health Sciences v Smith & Nephew Pty Ltd* (2011) 92 IPR 496 at [808] (Dodds-Streeton J).

67. Sun Pharma succeeded at trial. The FFC concluded that the primary judge erred in finding that the PTE Claims lacked both clarity and definition: FCJ [115] (CAB 127). Sun Pharma no longer disputes that the PTE Claims are clear: RS [93], third sentence.

68. RS [98] suggests the FFC only found a single error in the reasoning in the PJ. However, the FFC held the primary judge had erred in multiple ways, including by:

    (a) as to construction, failing to find that blood plasma concentration was used in the Patent as a surrogate for the "release of aripiprazole" in the PTE Claims: FCJ [93], [103], [108] (CAB 122, 124-5). The effect of the PJ's construction was to require identification of a release period by a means which was not possible. This is because the findings at e.g., PJ [257], [265] (CAB 55, 57) were that it was common general knowledge (**CGK**) that there was no practical means of measuring release before a drug's entry into the blood: see also FCJ [102] (CAB 124);

    (b) relying on the evidence of Sun Pharma's expert, Prof Winter, that blood plasma concentration could not be "*an accurate measure of release*", in circumstances where the PTE Claims did not require "*specificity as to the precise time at which the release occurs*": FCJ [105]-[106] (CAB 125);

    (c) relatedly, proceeding on the footing that it was necessary for O/L to prove that taking a blood plasma concentration vs time curve could "accurately measure" release of aripiprazole: FCJ [107]-[108] (CAB 125);

    (d) asking whether a skilled person could determine whether *all embodiments* otherwise falling within the PTE Claims would fall within or outside the Relevant Feature, based on the Patent's disclosure and the CGK: FCJ [91] (CAB 121-2); and

    (e) in finding a lack of clarity and definition, relying on "*unstated, hypothetical formulations at the margins of the claims*" that were not in dispute, rather than "*more realistic, practical formulations*": FCJ [112]-[114] (CAB 126-7).

69. ***NoCA 3.*** Contrary to RS [101], there was an error in law in the primary judge's approach as to the test to apply to determine whether claims limited by result satisfy s 40(2)(b). Despite having referred at PJ [197] (CAB 47) to a passage quoting *General Tire*, the primary judge did not apply the principles therein: see [68(d)-(e)] above. The test is the same irrespective of whether the claims are limited by result: see [60] above.

70. As noted at RS [99], at PJ [202] (CAB 48) the primary judge quoted *Bluescope* at [719], which quoted **Blanco White** QC, *Patents for Inventions and the Protection of Industrial Designs* (5th ed, The Law Book Company, 1983) at [4-703]. The primary judge applied

that passage at PJ [266] and [296] (CAB 57, 62). In contrast with the many Australian authorities which have cited *Interlego* or *General Tire* (including *Bluescope* at [715]: see footnote 14 above), no Australian authority before the PJ had cited Blanco White at [4-703] or *Bluescope* at [719]. There was no basis for the primary judge to apply those passages as the law, rather than the well-established principles from *General Tire*.

71. As to RS [100], the primary judge in any event misapplied the passage in *Bluescope* at [719]. In particular, the primary judge's consideration as to:

    (a) "*whether the instructions in the Patent for attaining the Relevant Feature are meaningless to those skilled in the art*" (PJ [266]) was infected by the errors in construing the PTE Claims set out at [68(a)-(c)] above. Blood plasma concentration was far from "meaningless": FCJ [103], [114] (CAB 124, 126, 127);

    (b) whether the experiments required to identify whether a formulation fell within the claim were "simple" (PJ [296]: CAB 62) failed to pay due regard to the principles from *General Tire* that: **(1)** a claim does not lack definition simply because cases may arise in which it is difficult to decide whether there has been infringement: FCJ [79], [113] (CAB 119, 126); **(2)** the fact that "*special care*" and a "*number of tests*" would be required was "*not unreasonable*": FCJ [80]-[81] (CAB 119).

72. As to RS [102], the FFC did not err in characterising the primary judge's approach as including "hypothetical" embodiments and emphasising that the test for lack of definition is to be applied in practical terms: see FCJ [90], [91], [112]. This accords with the part passage of *General Tire* set out at [58] above.

73. Sun Pharma's case, based on a "theoretical construct", did not involve it adducing evidence of any "particular formulation" that would be subject to the difficulties which it asserted. As to non-theoretical formulations: **(1)** the experts had no difficulty in using the Figures in the Patent to conclude that the Example 1 formulation had a release period longer than the minimum claimed duration: FCJ [113]-[114] (CAB 126-7); and **(2)** as noted at [64] above, Sun Pharma admitted its product possessed the Relevant Feature.

74. ***NoCA 3(b).*** RS [104]-[105] treat Blanco White – a secondary text – as if it were a statute. In any event, as to Blanco White at: **(1)** [4-413], the FFC considered this at FCJ [88] (CAB 121), italicising "*this like other questions of construction affecting validity is likely in present-day conditions to be decided in favour of an otherwise meritorious patentee*"; **(2)** [4-703], this does not cite *General Tire*. Contrast [4-704] (quoted at FCJ [83] and referred to again at FCJ [89]: CAB 119-121), which did.

75. Contrary to RS [105], the FFC did not focus on only part of the *General Tire* passage set out at [58] above. Rather, as to whether a manufacturer can satisfy itself as to whether there is an infringement, consistent with the passage as a whole, it emphasised the practical nature of the inquiry: FCJ [79], [81], [83], [91], [113] (CAB 119-122, 126).

76. As to RS [106], whether the facts in *General Tire* were "materially different" from the present case is beside the point, as *General Tire* set out general principles. In any event, there was a "problem" in the present case – the person skilled in the art could not measure release at the injection site: FCJ [78], [102] (CAB 118-119, 124). Hence, the Patent taught blood plasma concentration as a surrogate: see [68(a)] above.

77. ***NoCA 4(a) and 4(c).*** RS [107]-[108] submits that the FFC erred by rejecting the primary judge's construction of the Patent, "*informed by the expert evidence*". However, construction is a matter for the Court, not the experts: see [54] above.

78. The FFC discussed Examples 1 to 4 in the Patent, which reported results in Figures 1 to 4 using "*plasma concentrations vs time profiles*" and "*showed a fast onset of release and sustained release for at least 30 days*": FCJ [94]-[100] (CAB 122-124). As the FFC concluded at FCJ [103] (CAB 124, emphasis added), the Patent:

> *"... makes plain by its reporting of the results of the examples that it measured the onset of release and sustained release of aripiprazole by reference to blood plasma levels. All of the reported examples do so, in stating that the corresponding figures show "mean plasma concentrations vs. time profiles of aripiprazole". There can be little doubt that the patentee was there using such blood plasma levels (measured as blood plasma concentration of aripiprazole) as a means for approximating release rates...* ***There was no dispute between the experts that this is what the patentee intended. As the primary judge found at PJ [248], the only manner by which release might be determined that is disclosed in the Patent is the blood plasma concentration data and descriptions contained in Examples 1-4 and Figures 1-3.***"

79. As the emphasised sentences indicate, the FFC's conclusion also accounted for a salient agreement in the expert evidence and a corresponding finding made in the PJ.

80. As to RS [108], given the above matters, the fact there may have been other ways to estimate release – which were not adopted in the Patent – is irrelevant.

81. As to RS [109], the "*patentee (of its own choosing)*" used blood plasma concentration as a surrogate for release. This is consistent with *3M* at 272-274. In *3M*, there was a dispute as to the construction of "inextensible" in the claims. The specification stated that whether tape was "inextensible" was tested by hand-pulling. An expert gave evidence that he had measured inextensibility by stress testing. However, as Aickin J

said at 274, "*the ascertainment of the amount of stretching or extension at breaking point is not a measure of extensibility* ***in the context of this patent***" (emphasis added).

82. ***NoCA 4(b).*** RS [110]-[112] repeat the findings in the PJ and ignore the various errors summarised at [68] above. RS [111] mischaracterises FCJ [114] (CAB 126-127), in which the FFC found (including based on both parties' expert evidence) that a blood plasma concentration vs time profile could be used to ascertain that Example 4 – "*a practical, real-world example of the application of the test set out in the Patent*" – showed that the exemplified product had a release period above the claimed minimum.

83. Contrary to RS [112], the FFC did not disregard that the PTE Claims contain a "limitation by result". Rather, it applied the principles from *General Tire*, itself a case regarding a claimed limitation by result, in respect of them: see [58]-[61] above. It was not necessary for the FFC to consider how a manufacturer could vary factors such as particle size and excipients so as "*to avoid infringement of the PTE Claims*", or remain within their ambit. At most, such matters may have been relevant to sufficiency under s 40(2)(a), but Sun Pharma did not assert this ground: see FCJ [86]-[87] (CAB 120-121), applying *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2011) 119 IPR 194 at [259], which cautions against conflating sufficiency and other invalidity grounds. Invalidity grounds "*are, and must be kept, conceptually distinct*": *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274 at [46].

84. ***NoCA 4(d).*** Contrary to RS [113] there was no need for the FCJ to consider the "confidential Otsuka documents". The primary judge used those documents only to "fortify" her (incorrect) conclusion that the PTE Claims lacked definition (PJ [267]: CAB 57), which was based on the errors outlined above. In any event, the "confidential Otsuka documents" were irrelevant. Patent claims are to be construed in the context of the specification as a whole, in light of the CGK: *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588 at 610. The documents are not referenced in – and on their face were created for regulatory purposes unrelated to – the Patent. Nor were they CGK.

Dated: 2 June 2026

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