HIGH COURT OF AUSTRALIA

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### Details of Filing

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**Form 27D—Respondent's submissions**
Note: See rule 44.03.3.

IN THE HIGH COURT OF AUSTRALIA No S20/2026
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**
Fourth Appellant

and

**SUN PHARMA ANZ PTY LTD**
Respondent

## RESPONDENT'S AND CROSS-APPELLANT'S SUBMISSIONS

## PART I: FORM OF SUBMISSIONS

1. These submissions are in a form suitable for publication on the internet.

## PART II: CONCISE STATEMENT OF ISSUES

2. ***The appeal.*** The principal issue is whether the term "pharmaceutical substance" in s 70 of the *Patents **Act** 1990* (Cth)[1] (as defined in Schedule 1 to the Act) includes within its scope formulations containing an active substance (e.g., an active pharmaceutical ingredient (**API**))[2] and inactive excipients: AS [2]?[3] The answer is "no".

3. However, even if the Appellants (**O/L**) succeed on the first question, the following issues arise. **(1)** Whether any of the **Freeze-dried Formulations**,[4] satisfies s 70(2)(a) of the Act, given their application does not involve a chemical interaction, or physico-chemical interaction, with a human physiological system as required by the definition of "pharmaceutical substance"?[5] **(2)** Whether, if the relevant "pharmaceutical

[1] The relevant version of the Act is the version in force as at 13 August 2014 (ID C2014C00301) (**2014 Reprint**), being the date of the Extension Request: see also FCJ [131].
[2] Noting that "API" is a "somewhat inapt label" because of the broad range of active substances: FCJ [175]-[176]. *See* also [37] below.
[3] Unless otherwise defined in these submissions, these submissions adopt the defined terms from O/L's submissions dated 24 April 2026 (**AS**).
[4] A formulation that in substance falls within the scope of any of the **Freeze-dried Formulation Claims**, being 16, 19, 21 and 25 of the Patent (i.e. "Substance X") (AFM, Tab 1).
[5] Sun Pharma's Amended Notice of Contention before the FFC, Ground 1.

substance" for the purpose of s 70(2)(a) is one of the **Injectable Formulations**,[6] the ARTG Goods[7] contain or consist of the Injectable Formulations for the purpose of satisfying s 70(3)(a) of the Act?[8] **(3)** Whether the "pharmaceutical substance *per se*" requirement of s 70(2)(a) of the Act is satisfied in circumstances where each of the PTE Claims includes "process integers" that are additional to the pharmaceutical substance?[9] The answer to each of these questions is "no".

4. ***The cross-appeal***. The principal issue is whether the FFC erred in finding that the primary judge adopted a test for lack of definition within s 40(2)(b) in respect of a claim limited by result that "*places the bar too high*"? The answer is "yes".

10 **PART III: SECTION 78B OF THE *JUDICIARY ACT 1903* (CTH)**

5. No notice is required under s 78B of the *Judiciary Act 1903* (Cth).

**PART IV: FACTS**

6. AS [8] refers to the absence of an aripiprazole compound patent in Australia, however, there was a compound patent in the US: FCJ [14] (CAB, Tab 8). In any event, O/L's commercial decision-making has little relevance to the question of statutory construction before this Court, except insofar as it demonstrates—should O/L's construction be accepted—the potential for consecutive extended statutory monopolies over the same active substance.

7. In each of the Formulations, the only active substance is aripiprazole. The therapeutic
20 effect of aripiprazole is that it binds to receptors in the brain, which is useful in treating schizophrenia and bipolar I disorder: FCJ [2]; AS [8]. Only aripiprazole can exert the desired therapeutic effect and the excipients in the Formulations are "therapeutically inert": FCJ [16]. The primary judge held (and O/L did not contest on appeal), based upon the expert evidence, that none of the excipients in the Formulations are for a "therapeutic use" (as defined) "whose application involves a chemical or physico-chemical interaction with a human physiological system" (as required by the definition of "pharmaceutical substance"): PJ [164]-[170] (CAB, Tab 1).

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[6] A formulation that in substance falls within the scope of any of the **Injectable Formulation Claims**, being 1, 3, 6 and 14 of the Patent (i.e., "Substance V").
[7] As defined in FCJ [3] and PJ [4]. *See* also [9] below.
[8] Sun Pharma's Amended Notice of Contention before the FFC, Ground 2.
[9] Sun Pharma's Amended Notice of Contention before the FFC, Ground 5; see also FCJ [292].

8. Further to AS [6], the PTE Claims are comprised of two different types of claims requiring different features. The Injectable Formulation Claims require controlled release liquid (i.e. ready to use) formulations having a release profile of "at least one week". The Freeze-dried Formulation Claims require freeze-dried (i.e. lyophilised) controlled release formulations having a release profile of "at least about two weeks".

9. The ARTG Goods, ABILIFY MAINTENA, are kits comprising a vial of freeze-dried powder (aripiprazole and vehicle) and another vial containing a solvent for injection: FCJ [3], [277]. This is how they are included in the ARTG.[10] Those goods do not contain Injectable Formulations. In contrast, O/L has since obtained regulatory approval for injectable (ready to use) liquid formulations, namely ABILIFY ASIMTUFII.[11]

10. Contrary to AS [7], [50], [51] and [78], the PTE Claims are not "product claims" *simpliciter*, but rather "include process integers in addition to the pharmaceutical substance (aripiprazole) itself": FCJ [292]. This finding was based on the experts' agreement that each of the PTE Claims includes: (a) a process of injection of the Formulations; (b) a parameter for the release of aripiprazole (which is the dissolution of aripiprazole molecules from an aripiprazole particle depot at the injection site); and (c) a defined discrete boundary for release expressed in weeks: FCJ [5], [288]; PJ [9].

11. O/L contends in AS [12] that Sun Pharma did not "dispute the newness/inventiveness of any of the PTE Claims". This position was taken (along with not contesting infringement) only to enable the proceeding to be heard on an expedited basis.: FCJ [6], Parties' Agreed Chronology (Exhibit 4, Tab 1) (RFM, Tab 1). It does not bear on the issues before the Court.

12. As identified in AS [15], Sun Pharma did not contend before the primary judge that ***Cipla*** *Australia Pty Ltd v Novo Nordisk A/S* (2024) 185 IPR 299 was "plainly wrong", however, reserved its position to do so before the FFC (which it did).

13. Finally, O/L incorrectly contends that the FFC's reasoning on the Further Contention Grounds was "largely based" on its earlier conclusion that the Formulations were not "pharmaceutical substances": AS [18]. The FFC determined the Further Contention Grounds on independent bases (FCJ [261], [267], [281], [284], [292]). Alternatively,

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[10] AFM, Tabs 2 and 3.

[11] See Exhibit 7 "Extract PBS Website Dated 06/12/2024" which records that Lundbeck Australia sought PBS listing of ABILIFY ASIMTUFII: Respondent's Book of Further Materials (**RFM**), Tab 2.

insofar as it did not do so, it nonetheless reached the correct conclusions: Leave is sought to file the annexed amended Notice of Contention (**NoC**) at [5]-[6].

## PART V: ARGUMENT

### A. "Pharmaceutical substance" in the *Act* does not include formulations

14. ***(i) Overview:*** The relevant version of the legislation is as it appears in the 2014 Reprint.[12] The patent term extension (**PTE**) regime (**PTE Regime**) was introduced into the Act pursuant to the *Intellectual Property Laws Amendment Act 1998* (Cth) (**1998 Act**), and then amended by the *Intellectual Property Laws Amendment Act 2006* (Cth) (**2006 Act**).[13] Accordingly, the 2006 Act and the 1998 Act are to be read together with the Act "*as a combined statement of the will of the legislature*": *Commissioner of **Stamps** (SA) v Telegraph Investment Co Pty Ltd* (1995) 184 CLR 453, 463; *Plaintiff S297/2013 v Minister for Immigration and Border Protection* (2014) 255 CLR 179 at [25]; *see also* s 11B of the AIA. O/L fails to do this. AS does not even refer to the 2006 Act. Insofar as the FFC held that the 2006 Act was not relevant to the proper construction of the term "pharmaceutical substance", it erred: *cf* FCJ [206].

15. The task of statutory construction must begin, and end, with a consideration of the statutory text and this must be done by interpreting the text in its context and in light of its purpose: *SAS Trustee Corporation v Miles* (2018) 265 CLR 137 at [64] citing *Federal Commissioner of Taxation v Consolidated Media Holdings Ltd* (2012) 250 CLR 503 at [39]. That context includes extrinsic materials and legislative history. Explanatory memoranda can be an important and weighty extrinsic source in understanding the policy intentions underlying legislation, and in disclosing the parliamentary intention in respect of the statutory text and context in an Act: see e.g., ***Harvey** v Minister for Primary Industry and Resources* (2024) 278 CLR 116 at [75], [78], [91]-[92].

16. While "pharmaceutical substance" is defined in the Schedule, a definition in a statute does not enact substantive law. Rather, to construe the definition before its text is inserted into the fabric of the substantive enactment invites error as to the meaning of the substantive enactment: see e.g., *Kelly v R* (2004) 218 CLR 216 at [103]; *Qantas Airways Ltd v Transport Workers' Union of Australia* (2023) 278 CLR 571 at [32], [80].

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[12] This is because the Extension Request was made on 13 August 2014. O/L appears to agree: AS, Annexure, 2.
[13] The *Statute Law Revision Act 2011* (Cth) amended s 70(6) to state "Secretary **of**" instead of "Secretary **to**".

17. When regard is had to the use of the term "pharmaceutical substance" in s 70 (and related sections) and the context of the definition of "pharmaceutical substance", then it is clear that a "pharmaceutical substance" is confined to active substances (e.g., APIs) and does not extend to formulations.

18. The context includes the *Revised Explanatory Memorandum, Intellectual Property Laws Amendment Bill 1998* (Cth) (**1998 REM**) and the *Explanatory Memorandum, Intellectual Property Laws Amendment Bill 2006* (Cth) (**2006 EM**). The 1998 REM and the 2006 EM contain clear and specific disclosures of Parliament's intention that only patents which claim active substance(s) are eligible for a PTE and not patents which claim formulations. Insofar as the FFC held that the 2006 EM was not relevant to the proper construction of the term "pharmaceutical substance", it erred: *cf* FCJ [205]-[206]. This is because the 2006 EM provides context for the 2006 Act which is to be read together with the Act before it was amended by the 2006 Act "as a combined statement of the will of legislature": *Stamps*, 463.

19. Although the FFC was correct in finding that the term "pharmaceutical substance" is confined to active substances and does not extend to formulations, its sequence of reasoning in reaching that conclusion might have been improved upon. It could have begun by considering the statutory text (which included the 2006 Act), followed by consideration of the context underpinning that statutory text (in particular, the 1998 REM and the 2006 EM). Then the FFC could have turned to the legislative history of the definition of "pharmaceutical substance" pre-dating the Act, which the FFC correctly held supported its construction.

20. The preferable approach is the subject of Sun Pharma's NoC [3] and [4] and is set out in sections (ii) to (vi) below.[14] If, contrary to this position, NoC [3] and [4] are dismissed, then O/L's appeal ought nonetheless be dismissed for the reasons set out in section (vii) below. Section (viii) addresses other matters raised in AS.

21. ***(ii) Immediate statutory context s 70:*** To qualify for a PTE, four requirements in s 70 must be satisfied. These are identified in AS [22]. The use of the term "pharmaceutical substance" in s 70 supports an understanding that it is confined to active substances and does not extend to formulations for the following reasons.

[14] This is also how Sun Pharma presented its case before the FFC.

22. First, s 70(2) requires that "[e]ither or both of the following conditions must be satisfied": (a) "one or more pharmaceutical substances *per se* must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of that specification"; (b) "one or more pharmaceutical substances when produced by a process that involves the use of recombinant DNA technology, must in substance be disclosed in the complete specification of the patent and in substance fall within the scope of the claim or claims of the specification." As explained in paragraphs [76]-[77] below, the words "in substance fall within the scope of the claim" means having all the essential integers of the claim.

10 23. As FCJ [175] explained, recombinant DNA technology produces recombinant proteins being active substances. The words "recombinant DNA" are not defined in the Act and are to be given their ordinary English meaning.[15] The words "recombinant DNA" are defined in the Macquarie Dictionary as meaning "an artificially produced form of DNA achieved by joining fragments of DNA molecules obtained from different organisms."[16]

24. In the circumstances, it is plain that "pharmaceutical substances" when produced by a process that involves the use of "recombinant DNA" technology is referring to the production of active substances and not formulations. As the term "pharmaceutical substance" is to be understood as having the same meaning throughout s 70(a) and (b) (and indeed throughout the Act),[17] that is consistent with the term "pharmaceutical
20 substance" being confined to active substances and not extending to formulations.

25. Second, s 70(3) requires that "[b]oth of the following conditions must be satisfied in relation to at least one of those pharmaceutical substances: (a) goods containing, or consisting of the substance must be included in the [ARTG]; (b) the period beginning on the date of the patent and ending on the first regulatory approval date for the substance must be at least 5 years".

26. Section 70(3)(a) makes clear that the ARTG goods may *contain* (i.e. include) a "pharmaceutical substance". As most ARTG goods are formulated, this is consistent

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[15] It is permissible to have regard to "well-known and authoritative" dictionaries to determine the ordinary meaning: see e.g., *Marquis Camden v Inland Revenue Commissioners (UK)* [1914] 1 KB 641 (CA), 647-648; *Bendixen v Coleman* (1943) 68 CLR 401, 415; *Norrie v NSW Registrar of Births, Deaths and Marriages* (2013) 84 NSWLR 697, [84]; P Herzfeld and T Prince, Interpretation (3rd ed, Law Book Co, 2024) (**Herzfeld**) at [2.130]. Macquarie Dictionary definitions of "recombinant DNA" and "DNA" were provided to the FFC.

[16] Macquarie, Sixth Edition, October 2013 (being the most recent before the date of the Extension Request).

[17] *Project Blue Sky Inc v Australian Broadcasting Authority* (1998) 194 CLR 355 at [69].

with "pharmaceutical substance" meaning active substance, such that the ARTG goods (i.e. formulations) contain the active substance (i.e., the "pharmaceutical substance") together with excipients. Such goods would include, for example, tablets, capsules, injectables. Section 70(3)(a) also allows for ARTG goods that *consist* of the "pharmaceutical substance", meaning active substance(s) alone. Such goods would include, for example, a gas (which does not typically contain an excipient).[18]

27. The ARTG is defined in the dictionary in the Act as meaning "the register maintained under section 9A of the *Therapeutic Goods Act 1989*" (the **TG Act)**. The ARTG includes a wide variety of "therapeutic goods" including but not limited to pharmaceuticals, as well as, for example, medical devices. Accordingly, it is of negligible use in understanding the meaning of "pharmaceutical substance" within s 70 of the Act. O/L refers at AS [25] to s 16(1) of the TG Act as providing that "therapeutic goods" are "taken to be separate and distinct from other therapeutic goods" if they have a different formulation; however, s 16(1) also provides that the same formulations having different names are "separate and distinct" therapeutic goods. Section 16(1A) of the TG Act also provides that medicines with "different active ingredients" are "separate and distinct" therapeutic goods. Further, the definition of "therapeutic use" in the Act is narrower that than the definition for "therapeutic use" in the TG Act.[19]

28. The text in s 70(3)(b) is consistent with the above understanding because it refers to the "first regulatory approval date for the substance" (i.e. active substance) and not the good included in the ARTG (i.e. typically, the formulation). Sections 70(5) and (6) are also consistent with this understanding.

29. ***(iii) Definition of "pharmaceutical substance".*** O/L reproduces the definition of "pharmaceutical substance" in AS [32] (excluding the prefatory words "pharmaceutical substance means…"). The plain ordinary meaning of the words used in the definition supports an understanding that "pharmaceutical substance" be confined to active substances and does not extend to formulations.

30. Cognisant that the definition is a "composite legislative expression" and should be construed as whole,[20] it means a substance for "therapeutic use" (as defined) and whose

[18] See Exhibit 4, Tabs 14 and 15 before the PJ (RFM, Tabs 6 and 7).
[19] 2006 EM, p 42 [149].
[20] *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247 (***Alphapharm HC***) at [61].

application[21] (or one of whose applications[22]) involves the activity described in (a) or (b) but not solely for use in *in vitro* diagnosis or *in vitro* testing. It also allows for "(a mixture or compound of substances)" but plainly, however, "a substance" (preceding the bracketed words) has the same meaning as "substances" (within the bracketed words) such that each "substance", including in a mixture or compound of substances, must satisfy the requirements of the definition including that it be for "therapeutic use whose application (or one of whose applications involves)" and (a) or (b) in the definition.

31. As the FFC explained, "[t]he requirement that the application of a "pharmaceutical substance" must involve an "interaction" or "action" of the specified kinds immediately and naturally puts the focus on the substance which itself produces the therapeutic effect, as distinct from any excipients present in a given formulation with such a substance. Excipients, by definition, are not therapeutically active. They are the non-therapeutic ingredients of dosage forms. It is only the active ingredient that can have a chemical or physico-chemical interaction with a human physiological system, or that can act of an infectious agent, or on a toxin, or other poison, in a human body"; "the natural and ordinary meaning of the words of sub-paragraphs (a) and (b) of the definition of "pharmaceutical substance" operates to limit substances falling within the definition to those which are "active" (i.e., capable of "interacting with" a human physiological system in specified ways, or "acting on" certain harmful presences)": FCJ [170]-[171].

32. The bracketed words "(including a mixture or compound of substances)" clarify that the "substance" may be a combination of "substances", regardless of whether in a "mixture" or "compound". These words are not defined in the Act and are to be given their ordinary meaning. The Macquarie dictionary[23] defines in chemistry: (a) a "mixture" as "an aggregate of two or more substances which are not chemically united, and which exist in no fixed proportions to each other"; and (b) a "compound" as "a substance, consisting of two or more elements joined chemically in fixed proportions, which has properties different to those of the original elements." A "mixture of substances" are multiple

[21] As explained in [73] below, the word "application" either means "physical application" to the subjects referred to in (a) or (b) or "use or purpose". However, determination of this issue is not relevant to whether the definition of "pharmaceutical substance" is confined to active substances or extends to formulations.
[22] The words "or one of whose applications involves" recognises that limbs (a) or (b) must be satisfied even if the substance is also for use *in vitro* diagnosis/testing or for another use such as, for example, veterinary use.
[23] Sixth Edition, October 2013.

active substances (e.g., APIs) that are not chemically joined and a "compound of substances" are multiple active substances (e.g., APIs) that are chemically joined.[24]

33. Contrary to AS [33] (fn 11), the words in the brackets expand rather than constrict the definition which would otherwise only encompass single active substances, by extending it to multiple active substances. Relatedly, despite asserting in AS [33] that the word "substance" must bear its ordinary meaning, O/L does not identify what that ordinary meaning is, beyond such meaning "includ[ing]" a formulation. Significantly, O/L's contention that the ordinary meaning of the word substance "captures" a substance "consisting of multiple components or substances" is not an ordinary meaning and reads out the words in the brackets, namely, "including a mixture or compound of substances". A construction that gives work for those words to do should be preferred to a competing construction that renders them otiose.[25]

34. AS [49] incorrectly contends that FCJ [170]-[171] (as reproduced in [31] above) has the "effect of rewriting the introductory words" to state "a substance (including a mixture or compound of such substances)…". The natural and ordinary meaning of the phrase is as set out above, namely that "a substance" (preceding the bracketed words) has the same meaning as "substances" (within the bracketed words) except one is singular and the other is plural, and each substance must meet the requirements of the definition.

35. All the above supports an understanding that the definition of "pharmaceutical substance" is confined to active substance(s) and does not extend to formulations. Whilst it may be accepted that a formulation is a mixture of substances comprising an API(s) and excipients, the excipients are not substances that satisfy the requirements of the definition. This is because they are not for "therapeutic use" (as defined) and whose application (or one of whose applications) involves the activity described in (a) or (b), as the composite legislative expression requires.

36. As AS [36] observes neither "active" nor "formulation" is used in the definition, however, it plainly describes the *type* of activities that are required, namely: (a) a chemical interaction, or physico-chemical interaction, with a human body; or (b) action on an infectious agent, or on a toxin or other poison, in a human body, but does not

[24] Examples of mixtures of active substances include medical gases (see Exhibit 4, Tabs 14 and 15 (RFM, Tabs 6 and 7)) and compounds of active substances include co-drugs (being two active substances chemically joined).
[25] See e.g., *Northern Land Council v Quall* (2020) 271 CLR 394 at [61]; *Minister for Immigration, Citizenship, Migrant Services and Multicultural Affairs v ERY19* (2021) 285 FCR 540 at [100]; Herzfeld at [5.20], [5.170].

include a substance that is solely for use *in vitro* diagnosis or *in vitro* testing. Further, the definition, *excludes* more than just "a substance that is solely for use in *in vitro* diagnosis or *in vitro* testing": *cf* AS [36], fn 14. It excludes all substances for therapeutic use whose application does not involve an activity described in (a) or (b) such as, for example, a formulation, a pacemaker, a surgical ligature or a prosthetic limb.

37. In response to O/L's submission that if the legislature had intended the definition to be limited to only APIs that term could have been used,[26] the FFC explained "API" is "somewhat inapt" and "a broader term which encompasses all such therapeutically active substances is required", which is met by the definition: FCJ [175]-[177]. Whilst "API" is sometimes used colloquially to refer to any active substance in a pharmaceutical product, API is commonly used in the patent context to describe small molecules which undergo a physico-chemical interaction with a human physiological system. There are, however, many other active substances such as monoclonal antibodies, antigens or recombinant proteins (the subject of s 70(2)(b) of the Act). In addition, the statutory definition recognises that the substance may not have the activity described in (a) but rather have the activity described in (b): FCJ [175]-[177].

38. ***(iv) Wider statutory context: ss 78 and 119A*** support Sun Pharma's interpretation. Section 78 was amended and s 119A was introduced by the 2006 Act to allow for more generous "springboarding" by generic pharmaceutical manufacturers. Both allow for exceptions to infringement of patents. Both sections include the same language as in s 70(2)(a) and (b) and therefore are to be understood consistently that those sub-sections including their use of "pharmaceutical substance" (see [24] above).[27]

39. Section 78(a) provides that the patentee's exclusive rights will not be infringed during a PTE by a person exploiting a pharmaceutical substance that satisfies either ss 70(2)(a) or (b) (as s 78(a) uses the same wording), for a purpose other than therapeutic use. That would include e.g. veterinary or agricultural use. Section 78(b) provides that the patentee's exclusive rights will not be infringed during a PTE by a person exploiting

[26] Contrary to AS [36] (fn 13), the insertion of "active ingredient" into the TG Act in 1999 and into the TG Regulations in 1997 does not assist. Section 52F related to "complementary medicines" (e.g., vitamins, minerals) and was repealed in 2009. The *in pari materia* principle has no application: see e.g., *SZTAL v Minister for Immigration and Border Protection* (2017) 262 CLR 362 at [24]; Herzfeld at [8.300]. The TG Regulations also do not assist - it is not permissible to refer to regulations made under an Act in order to construe the Act, and this is a further step removed, being a different term in the Regulations to a different Act: see *Alphapharm HC* at [39].

[27] See e.g., *Regional Express Holdings Ltd v Australian Federation of Air Pilots* (2017) 262 CLR 456 at [21].

any form of the invention other than a pharmaceutical substance that satisfies either ss 70(2)(a) or (b) (as s 78(b) uses the same wording). That would include e.g. a claim for a diagnostic product or test that included the substance or a claim for a method for producing the substance that did not involve the use of recombinant DNA technology.

40. Section 119A(1) provides that the rights of a patentee of a "pharmaceutical patent" are not infringed if the exploitation is solely for: (a) purposes connected with obtaining the inclusion in the ARTG of goods that are intended for therapeutic use that are not medical devices or therapeutic devices as defined in the TG Act; or (b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country. Section 119A(2) provides that s 119A(1)(b) does not apply unless there is a PTE and the goods contain or consist of a pharmaceutical substance that satisfies either ss 70(2)(a) or (b) (as it uses the same wording as those sub-sections).

41. In s 119A(3) "pharmaceutical patent" is defined: "a patent claiming (a) a pharmaceutical substance; or (b) a method, use or product relating to a pharmaceutical substance, including any of the following: (i) a method of producing a raw material needed to produce the substance; (ii) a product that is a raw material needed to produce the substance; (iii) a product that is a pro-drug, metabolite or derivative of the substance."

42. The wording of s 119A(3) supports Sun Pharma's interpretation of "pharmaceutical substance" because the definition of "pharmaceutical patent" includes, a patent claiming *inter alia* (a) a pharmaceutical substance (e.g., active substance or API); or (b) a *product relating to* a pharmaceutical substance i.e. a formulation. Sun Pharma submits that the "or" between (a) and (b) in the definition in s 119A(3) can only sensibly be read disjunctively, reinforcing that a patent claiming a "pharmaceutical substance" in s 119A(3)(a) does not include a formulation, whereas a patent claiming a "product relating to a pharmaceutical substance" s 119A(3)(b) includes a formulation. In addition, an ordinary understanding of "a pro-drug, metabolite or derivative of the substance" can only be referring to "a pro-drug, metabolite or derivative of [an API]" and not of a formulation because there are no such things.

43. ***(v) Context to the PTE Regime: the 1998 REM and 2006 EM*** support Sun Pharma's interpretation of "pharmaceutical substance."

44. The 1998 REM discloses Parliament's intention that the PTE Regime did not include formulations, and was limited to active substances: FCJ [182]-[183]. It states at p 18,

[8] (emphasis added) that a "'pharmaceutical substance' is defined in Schedule 1 of the [Act] and may comprise combinations of active ingredients or single active ingredients". It also states at p 19, [23] (emphasis added) that the spring-boarding provision in s 78(2) "has the effect of enabling a generic manufacturer to produce a generic pharmaceutical formulation containing the patented pharmaceutical substance solely for the purpose of obtaining regulatory approval while the patent is still in force. It therefore prevents a patentee from ending up with a further de facto extension of term which would occur if a generic producer could not commence any work on the patented pharmaceutical substance to meet these requirements until the extended term expired". Section 78(2) provided that the exclusive rights of the patentee were not infringed during a PTE by a person exploiting a pharmaceutical substance that satisfies either ss 70(2)(a) or (b) (as s 78(2) uses the same wording) solely for the purpose in connection with having the goods included in the ARTG (or obtaining approval overseas).

45. In respect of p 18, [8] above, O/L contends that the use of the word "may" has the result that such statement is non-exhaustive: AS [53]. However, as the FFC correctly explained, it is "plain enough" that the possibility contemplated by the word "may" related to the potential for combinations of active substances or single active substances (FCJ [184]), that is, as opposed to encompassing a range of other things that are not even mentioned in the paragraph, including non-active substances.

46. O/L also erroneously seeks to undermine the plain statement at p 19 [23] (above) by submitting that "[a] generic pharmaceutical formulation may contain an API or a patented formulation": AS [54]. That is a strained reading of the extrinsic materials. If the intention was that "pharmaceutical substance" included formulations, then the statement would merely have read: "enabling a generic manufacturer to produce a patented pharmaceutical substance …". Instead, it distinguishes between a "formulation" and a "pharmaceutical substance."

47. In respect of the purpose of the PTE Regime,[28] the 1998 REM pp 3-4 (ss 2 and 3) refers to (emphasis added) "[t]he development of a new drug is a long process, estimated to average around 12 years, which requires a new chemical entity to be patented early in the process in order to secure its intellectual property rights. … As a consequence, patentees of new drugs usually have considerably fewer years under patent in which to

[28] Reproduced by the High Court in *Alphapharm HC* at [58].

maximise their return. It is expensive to bring a drug to market, around US $380 million, and involves considerable risk." As FCJ [194] explains, "chemical entity" "is plainly the active ingredient in a product that is ultimate brought to market" and "drug" refers to APIs: see, e.g., FCJ [197]. As the FFC explained: "ARTG registration of a medicine containing a new chemical or biological entity follows years of research and development and a comprehensive review by the [TGA] of the medicine's quality, safety and efficacy. The number and extent of biopharmaceutic studies required to obtain regulatory approval for a new formulation of an already approved active ingredient is less than those required for regulatory approval of a medicine containing a new chemical or biological entity": FCJ [196].[29]

48. At AS [55], O/L submits that the FFC erred in failing to appreciate that a formulation can be used to patent a new chemical entity and the PTE Regime is not limited to "new chemical entities." Of course, patentees unilaterally define the scope of their claimed monopoly using words of their own choosing.[30] However, a patentee's commercial decision as to whether (and how) to patent a new active substance (if at all, noting the Appellants decided not to patent aripiprazole in Australia) is irrelevant to the proper construction of the Act. In addition, O/L's submission that the PTE Regime is not limited to "*new* chemical entities" distracts from the fact that the reference to "chemical entities" is a reference to active substances (which O/L appears to accept in AS [55]).

49. The 1998 REM p 4 states that as part of the rationale "[i]t is also intended to provide a patent system which is competitive with other developed nations." At the time of the 1998 REM, the extension regimes in the US, EU (including the UK) and Japan were limited to extensions of term based on the first regulatory approval of an active substance (or combination of active substances), not formulations.[31]

50. If Parliament had wanted to reverse its explanation of the meaning of "pharmaceutical substance" in the 1998 REM it had the opportunity to do so in the 2006 EM, but elected not to do so: see e.g. *Harvey* at [75]. Rather, as the FFC recognised, the 2006 EM

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[29] See also Exhibit 4, Tab 5 at p 1 and Tab 6 at p 3-6 (RFM, Tabs 3 and 4).

[30] *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] 1 All ER 667; (2004) 64 IPR 444 at [34] (Lord Hoffmann); cited with approval in, for example, *Nichia Corp v Arrow Electronics Australia Pty Ltd* [2019] FCAFC 2; 175 IPR 187 at [50] (Jagot J).

[31] See 35 U.S.C. § 156; EEC Regulation 1768/92, Art 1 and 3. In Japan, prior to Heisei-21-(Gyo-Hi)-326 and relevantly in 1998, extensions of term were not available based on the regulatory approval of new formulations: see, e.g., Intellectual Property High Court, Case No. 2005 (Gyo-Ke) 10345.

discloses Parliament's intention that the PTE Regime is limited to active substances: FCJ [200]-[204]. The FFC, however, erred in finding that the 2006 EM was not relevant to the proper construction of the term "pharmaceutical substance": FCJ [205]-[206].

51. The 2006 EM p 41 [139], [140] explained that the purpose of the 2006 Act was to make the "springboarding" provisions in the Act "more generous". As explained, "[s]pringboarding is a colloquial term that refers to using the subject matter of a patent to collect the data required to obtain regulatory approval of a generic version of the patented product, when the patent is still in force. Prior to these amendments, the Patents Act contained a limited provision that only allowed springboarding on pharmaceutical patents after they had received an extension of patent term." This was contained in s 70(2) (which existed in the Act before the 2006 Act): see [44] above.

52. The 2006 EM, pp 18-19 stated: "[a] generic version of a medicine has the same active ingredient, is manufactured to the same standard, and has the same clinical effect as the original version" and "[t]o obtain approval for a generic version of a drug, generics companies need to demonstrate equivalence to the existing product. They do not need to do the level of clinical trials the originator does as they are relying on the originator's data, so the development of a generic is less expensive. … However, the generic drug cannot be registered until the originators' data exclusivity period has expired and cannot go onto the market until the patent has expired … 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. This means that if the patents surrounding a drug are not eligible for springboarding in Australia it can take two to six years after patent expiry for a generic company to bring the product to market if the development work is done in Australia."

53. In respect of s 70(2), the 2006 EM p 19 explained that it was inserted by the 1998 Act and that "[s]pringboarding can only be undertaken on pharmaceutical substance patents once an extension is granted". It also explained that (emphasis added): "[t]here are broadly four types of pharmaceutical patent: those on the active pharmaceutical ingredient (API); the formulation of the medication; the process for making the API; and methods of use of the medication. **Only patents which claim a pharmaceutical substance (ie API) are currently eligible for patent extension in Australia.** Pharmaceutical products are frequently the subject of multiple patents which cover different aspects of the product. These patents are potentially of different types, some of which may not be eligible for extension. In some cases the most important (or

'blocking') patent may not be extended and thus the most important springboarding work cannot be done until this patent expires in Australia." It can be interpolated that those "blocking" patents which cannot be extended include formulation patents.

54. The 2006 EM p 19 stated that "[p]harmaceutical substance patents are granted an extension of patent term (and consequently become subject to springboarding) in recognition of the lengthy regulatory approval process …". As indicated in [47] above, the 1998 REM estimated the lengthy regulatory approval process to "average around 12 years" and requiring a "new chemical entity [API] to be patented early."

55. As indicated above, the 2006 Act made the springboarding provisions more generous by repealing s 78(2) and inserting a new s 119A. In respect of the latter, the 2006 EM p 43 ([159]) stated that (emphasis added): "[t]he definition of 'pharmaceutical patent' is intended to cover all patents that a generic pharmaceutical company would need to exploit in order to seek inclusion of a good other than a medical device or a therapeutic device on the ARTG. 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'… (f) **a product or formulation incorporating a pharmaceutical substance or a mixture of pharmaceutical substances**, including products such as layered or coated tablets."[32] This supports Sun Pharma's interpretation that a "pharmaceutical substance" is an active substance (e.g., API) and a "product relating to a pharmaceutical substance" includes a formulation: see [42] above.

56. The 2006 EM at p 44 [160] states that: "[t]he reference in subparagraph 119A(3)(b)(iii) to 'pro-drug' is intended to cover pro-drugs that metabolise into pro-drugs, as well as pro-drugs that metabolise into pharmaceutical substances. The reference to 'metabolite' is intended to cover anything into which a metabolite is subsequently metabolised." This supports Sun Pharma's interpretation that a "pharmaceutical substance" is an active substance (e.g., API) and not a formulation, because only a chemical entity may be metabolised to or from an active substance, and not a formulation: see [42] above.

57. As noted by Edelman J, "[a]ll context must be reconciled [and] [t]here can be only one manifested parliamentary intention" and given the "central role of Ministers and their

[32] The 2006 EM [159(g)] refers to "*other features of the pharmaceutical substance such as the colour or shape of a pill or packaging*." In context, it appears that (g) was intended to build upon (f) which specifically refers to "tablets" such that (g) should read "other features of the tablets incorporating a pharmaceutical substance such as the colour or shape of a pill or packaging."

departments in drafting Explanatory Memoranda…these materials are more reflective of 'government intent'" than other extrinsic materials: *Harvey* at [91], [92], [116], [118]-[119] *cf.* AS, [42]. Here, both the 1998 REM and the 2006 EM are "important and weighty extrinsic source[s] of information" and these must be considered and reconciled as part of one manifested parliamentary intention, namely, that "pharmaceutical substance" be limited to active substances: *cf* AS [56].

58. AS [56] seeks to downplay the relevance of the 1998 REM by contending that "little is to be gained by trawling through the extrinsic material with a fine gauge net": ***Pilbara*** *Infrastructure Pty Ltd v Australian Competition Tribunal* (2012) 246 CLR 379 at [74]. But in *Pilbara* the construction issue pertained to Part IIIA of the *Trade Practices Act* and there was a "*very large body of extrinsic material*". In contrast, the 1998 REM (which O/L seeks to sideline) and the 2006 EM (which AS ignores completely) were explanatory memoranda to the Act pertaining to the very construction issue before this Court and are thus highly relevant. Instead, AS [60] and [62] focus on the *Pharmaceutical Patent Review 2013* and the 2016 *Productivity Commission Inquiry Report No 78*, neither of which were published prior to the 1998 Act or 2006 Act, nor constitute "important and weighty" sources of information like explanatory memoranda.

59. ***(vi) Pre-existing law before the Act*** can form part of the relevant context, however, that "should not deflect the Court from its duty to resolve an issue of statutory construction, which is a text-based activity": *Alphapharm HC* at [42]. To the extent that the pre-existing law before the Act bears on the ultimate question of construction, the FFC was correct in finding that the definition of "pharmaceutical substance" in the *Patents Act 1952* (Cth) (the **1952 Act**) as inserted by the *Patents Amendment Act 1989* (Cth) (**1989 Act**) was limited to active substances only: FCJ [178].

60. Contrary to AS [43], [48] it is implausible that the legislature (in the 1989 Act) chose to adopt the language used in the EM 1989 Limitation to merely exclude devices such as surgical ligatures. It could have done so by using words such as "(devices such as surgical ligatures are not included)"; instead, it focused on specific types of activity. Also, contrary to AS [46], nothing turns on the EM 1989 Limitation not including the phrase "a mixture or compound of substances" because the EM 1989 referred to "therapeutic substances" in the terms of the Customs Regulations (which included the phrase "a mixture or compound of substances)" *with added limitations*.

61. ***(vii) Approach of the FFC***. If, contrary to Sun Pharma's primary position, NoC [3] and [4] are dismissed, then O/L's appeal ought nonetheless be dismissed. The FCJ demonstrates that the FFC was cognizant of the proper principles of statutory construction, and applied those principles in construing the term "pharmaceutical substance": see e.g., FCJ [135]-[139]; [169]-[171]; [192], [199].

62. Contrary to AS [41], [42], the FFC's methodology of considering the legislative history and pre-existing law before construing the statutory text is not dissimilar to the approach in *Alphapharm HC*: see [42]-[60], [61]-[74]; [86]-[103], [104]-[121].

63. The FFC's methodology of considering whether there was a change in meaning of "pharmaceutical substance" from its entry in the first version of the Act to the 2014 Reprint is not dissimilar to the approach in *Harvey.* This case is also an example of where the High Court commenced with a consideration of the pre-existing law and the legislative history before construing the statutory text. This case concerned the scope of the terms "right to mine" and "infrastructure facility" under the *Native Title Act 1993* (Cth) (**NT Act**): [5]. In doing so, the plurality first considered the original NT Act, including the definitions under that Act ([17]-[20]), notwithstanding that it was "substantially amended" in 1998. The plurality then reviewed the extrinsic materials for the amending Act, before considering the statutory text: [65]-[66]. The plurality held that the proposed construction was "consistent with the broad and inclusive definition of 'mine'" and also "consistent with the description in the Supplementary EM": [71].

64. Insofar as O/L suggests in AS [39]-[42], that in circumstances where the statutory text is so clear as to make material extrinsic to the Act unnecessary to consider, then that is wrong as a matter of principle. As the plurality in ***Palmanova*** *Pty Ltd* v *Commonwealth* [2025] HCA 35 stated at [6]: "Focus on the statutory text is not to the exclusion of extrinsic material that has the potential to assist in fixing its meaning." *Palmanova* is another example of where the Court considered extrinsic material including the relevant explanatory memorandum before considering the statutory text.

65. ***(viii) Other matters.*** In addition to the above, AS is also wrong in the following respects.

66. *Alphapharm HC*, fn 40: Contrary to AS [64], the footnote is to the effect that *both* methods *and* tablets are not pharmaceutical substances *per se*. It can be interpolated that the latter is because a tablet is a type of formulation. O/L disputes such interpretation because claims 3-5 of the patent in issue were to formulations, and the majority did not

explicitly state such claims were outside the definition of "pharmaceutical substance": AS [64]. However, the only relevant claim for the PTE was claim 1, being for the active substance, and not claims 2-5. Nevertheless, if O/L is correct, then that supports Sun Pharma's position in respect of the Formulations not being to a pharmaceutical substance *per se*; see further [D] below.

67. The legislature's alleged failure to amend: AS [62] ignores earlier appellate authorities[33] which contained reasoning on the meaning of "pharmaceutical substance" consistent with the construction adopted by the FFC: FCJ [216], [229], [260]. AS [15] also incorrectly suggests there was a uniform ratio in the earlier single instance cases. The only case that considered the issue in any detail was *Cipla*, which was in error: FCJ [258]-[260]. In *Spirit*, the issue "was not actually argued", and it erroneously misstated the definition of "pharmaceutical substance": FCJ [249], *Cipla* [169], [181]. *Pharmacia* impermissibly treated the Patent Office Manual as extrinsic material that could be used as an aid to statutory construction (*Cipla* at [153], [181]) and, in any event, was incorrect: FCJ [241]. Similarly, O/L's attempt to rely on the Patent Office Manual as supporting its construction should be rejected: AS [62] (fn 17).

68. Contrary to AS [63], FCJ [207] was not contrary to *Probuild Constructions (Aust) Pty Ltd v Shade Systems Pty Ltd* (2018) 264 CLR 1 at [52]. As noted by Edelman J in *Greylag Goose Leasing 1410 Designated Activity Co v PT Garuda Indonesia Ltd* (2024) 282 CLR 341 at [148], the principle "depends wholly upon context", including "… how well-known or established the decision is or might be expected to be; and the extent to which extrinsic materials to the re-enactment or amendment make express or implied reference to the decision." Neither *Pharmacia* nor *Spirit* (both being first instance decisions) rise to that standard and were not referred to in the Explanatory Memorandum to the *Intellectual Property Laws Amendment Bill 2014*: cf AS [62].[34]

69. *Alphapharm FC* [242]: Contrary to AS [50], "improvement in the delivery of a known pharmaceutical substance already listed on the ARTG" was not a reference to method claims but rather product claims of the type here being claims for an improved delivery of aripiprazole, which are not eligible for a PTE: see FCJ [123], [129].

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[33] *Alphapharm HC*, *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151 (***Alphapharm FC***), ***Boehringer** Ingelheim International GmbH v Commissioner of Patents* [2001] FCA 647; 112 FCR 595 and ***Prejay** Holdings Ltd v Commissioner of Patents* [2003] FCAFC 77; 57 IPR 424.

[34] The 2015 Amendments inserted s 70(5A) in response to Australia's international TRIPS obligations.

70. O/L's further contentions on "purpose": AS [31] ignores the differences in expense, risk and regulatory delays in registering a drug containing a new active substance compared with a formulation containing an existing API. As the 1998 REM and the 2006 EM explain, the lead time for research and development and regulatory approval for drugs containing new APIs is "estimated to average around 12 years" compared with formulations containing already approved active ingredients is "between two and six years". Contrary to AS [60], the FFC had this material before it. Also, an originator will typically have already had the benefit of a PTE for the active substance (i.e. 20 years extended up to a maximum of 5 years) as well the standard 20 years in respect of the patent claiming the formulation. As the 2006 EM explained, although formulation and other types of patents are not eligible for an extension, they nonetheless are "blocking" patents which restrict the activities of generic pharmaceutical companies.

71. For new active substances, the patentee has no incentive to delay regulatory approval because that approval will be the first product containing or consisting of that active substance (s 70(3)(a)), and therefore the pre-condition to any economic exploitation of that active substance. By contrast, if formulations are treated as separate pharmaceutical substances, there is an incentive and opportunity for patentees to delay in seeking regulatory approval for the second product containing or consisting of the formulation because the patentee is already being protected by the extended term of the patent for the API. The effect of O/L's construction of "pharmaceutical substance" would "dramatically increase the potential scope of the regime": see FCJ [198]; *cf* AS [63].

72. As the majority in *Alphapharm HC* at [60] explained by reference to the 1998 REM, "[t]he purposes of the extension of term scheme are 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 the pharmaceutical invention (including by a competitor) after the expiration of the monopoly (that is, the term)." The public interest includes access to lower priced generic drugs on the Pharmaceutical Benefits Scheme.[35] The balance of the competing interests is achieved by "pharmaceutical substance" being construed as being confined to APIs.

## B. The Freeze-dried Formulations do not satisfy s 70(2) of the *Act*[36]

[35] 1998 REM, p 6.

[36] See Sun Pharma's Amended Notice of Contention before the FFC, Ground 1.

73. Even if O/L succeeds on the first question, the Freeze-dried Formulations do not satisfy s 70(2)(a) because their application does not involve a chemical interaction, or physico-chemical interaction, with a human physiological system as required by the definition of "pharmaceutical substance". This is so regardless of whether, "application(s)" is construed as referring to **(i)** the physical application of the pharmaceutical substance on the "subjects" identified in limbs (a) or (b) in respect of which the actions identified in limbs (a) or (b) occur;[37] or **(ii)** as the FFC held, it is to be construed as referring to the "use" or "purpose" of the pharmaceutical substance: FCJ [267].[38]

74. Sun Pharma submits that construction **(i)** should be preferred over **(ii)** because: (a) to construe "application(s)" as meaning "use" would mean that the definition uses two different words to refer to "use"; and (b) construction **(ii)** involves a tautology because the term "therapeutic use" is already defined as "means use for the purpose of…". In respect of the Freeze-dried Formulations: if construction **(i)** is preferred, they are not physically applied to a human physiological system. If construction **(ii)** is preferred, as the FFC held, their use or purpose does not involve a "chemical interaction, or physico-chemical interaction, with a human physiological system". Rather, the use or purpose of the Freeze-dried Formulations is to maintain the stability of the aripiprazole during storage and prior to use: FCJ [270].[39]

75. Regardless of which construction of "applications(s)" is preferred, as the FFC held, the Freeze-dried Formulations require reconstitution prior to administration as which point they no longer exist: FCJ [269], [270], [273]. As they no longer exist, they cannot be physically applied to a human physiological system, nor can they involve a "chemical interaction, or physico-chemical interaction, with a human physiological system."

76. Contrary to AS [67], the text of s 70(2)(a) and the definition of "pharmaceutical substance" (when read together) require that the "pharmaceutical substance *per se*" must in substance be disclosed in the complete specification and in substance fall within the scope of the claim(s) and meet the requirements of the definition of "pharmaceutical substance." The expression "in substance fall within the scope of the claim[s]" in s 70(2)

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[37] For limb (a), the "subject" to which the substance is applied is a "*human physiological system*" in respect of which the substance involves "a chemical interaction, of physio-chemical interaction." For limb (b), the subject is an "*infectious agent, toxin or other poison, in a human body*" in respect of which the substance involves an "action." This construction does not require the insertion of "target" as found in *Cipla* at [118]; see FCJ [265].

[38] NoC, [6(a)].

[39] Patent, p 5 line 9-10.

is also used in s 102(a) of the Act (which concerns allowability of amendments).[40] The EM 1989 (p 17, [94]) stated that the "criterion corresponds closely to criteria in clause 102 in relation to the allowability of new or amended claims in a specification."

77. As made clear by the High Court in *AMP v Commissioner of Patents* (1974) 3 ALR 283 at 289-290, when construing s 78(2) of the 1952 Act (which concerned allowability of amendments), the words "in substance fall within the scope of the claims" requires all of the essential features of the claim(s) to be taken i.e. akin to an infringing embodiment. The Full Court has also held that the words "in substance fall within the scope of the claim[s]" in s 70(2)(a) means that the pharmaceutical substance *per se* must take all of the essential features of the claim(s): *Boehringer* at [31], [35]-[38], [42]; *Prejay* at [10], [23], [24], *Commissioner of Patents v* ***AbbVie*** *Biotechnology Ltd* (2017) 253 FCR 436 at [52]-[54]. See PJ [100]-[109].

78. A formulation that "in substance falls within the scope of any of the Freeze-dried Formulation Claims"[41] does not meet the requirements of the definition because its application (or one of whose applications) does not involve a chemical interaction, or physico-chemical interaction, with a human physiological system. Rather, it must be changed into a different formulation which no longer "in substance falls within the scope of" any of the Freeze-dried Formulation Claims before physical application or use (i.e. regardless of which construction of "application" is preferred).

79. Contrary to AS [67], the substance that is "applied to the human body" is not a Freeze-dried Formulation with "additional elements such as water." Rather, it no longer has all the essential features of any of the Freeze-dried Formulation Claims which require "a freeze-dried controlled release aripiprazole formulation." Instead, it is an injectable Formulation, which takes all the essential features of the Injectable Formulation Claim(s); which are different claims for the purpose of s 70(2)(a).

80. Professors Winter and Evans also agreed that as a matter of science there were differences between a Freeze-dried Formulation and Injectable Formulation including: (1) one is a liquid and one is a solid; (2) the freeze-dried formulation does not have a pH or viscosity; (3) the freeze-dried formulation has several melting points, one for each

[40] Section 102(2)(a) of the Act has included those words since the Act was enacted.
[41] Claims 16, 19, 21 and 25 of the Patent (i.e. "Substance X").

ingredient within the freeze-dried formulation, whereas the injectable (ready to use) formulation does not have a melting point: FCJ [281]; PJ [148].

81. Contrary to AS [68], PJ [134] was not correct because an API still exists when it is administered (together with excipients). In contrast, the Freeze-dried Formulations do not exist upon administration. Relatedly, contrary to AS [68] (fn 21), *Alphapharm FC* [242] does not assist O/L. As the FFC identified, contrary to the present case, "when the (+)-enantiomer of *Alphapharm FC* is formulated for administration, it is still the (+)-enantiomer that continues to exist which, when put to its therapeutic use, has a physicochemical interaction with a human physiological system": FCJ [273].

10 82. As to AS [70], each case must be considered on its facts to determine whether the statutory conditions in s 70 are satisfied. As the Full Court explained in *Commissioner of Patents v Ono Pharmaceutical Co Ltd* (2022) 291 FCR 1 at [115]: "…the extension of term regime seeks to balance a range of competing interests, not just the interests of the patentee. It can be taken that the legislature saw the correct balance as being achieved by the very words it chose to implement that regime."

## C. The Injectable Formulations do not satisfy s 70(3) of the *Act*[42]

83. Even if O/L succeeds on the first question, in circumstances where the relevant PTE Claim(s) for the purpose of s 70(2)(a) are the Injectable Formulation Claim(s), the Injectable Formulations do not satisfy s 70(3)(a) of the Act, because the ARTG Goods,
20 ABILIFY MAINTENA do not contain, or consist of, that substance.

84. The FFC correctly held that the requirement in s 70(3) "takes one or more of the pharmaceutical substances identified in the s 70(2) inquiry and asks whether at least one of those substances satisfies each condition of sub-ss 70(3)(a) and (b)": FCJ [278]. In other words, s 70(3)(a) focuses attention first, to whether goods contain or consist of the identified s 70(2) pharmaceutical substance(s). If the answer is "**yes**", the next question is whether those goods are included in the ARTG. The answer to this question is a simple "**yes**" or "**no**". The s 70(3) inquiry is a factual one: FCJ [279].

85. As the FFC correctly held, where the pharmaceutical substance for the purpose of the s 70(3) inquiry is the Injectable Formulation, the answer to the question is "no". This is
30 because the ARTG Goods are kits comprising a vial of freeze-dried powder

[42] *See* Notice of Contention ground 2 before the FFC.

(aripiprazole and vehicle) (i.e. a Freeze-Dried Formulation) and a separate vial of water for injection. The ARTG Goods do not contain an Injectable Formulation i.e. a liquid injectable formulation that comprises aripiprazole of a certain particle size, a vehicle and water for injection: FCJ [281], [284]. That is, the ARTG Goods do not contain, or consist of, a pharmaceutical substance that "in substance falls within the scope" of any of the Injectable Formulation Claim(s) i.e. taking all the essential features.

86. AS [73] contends that s 70(3)(a) does not confine the "goods" to their form at "supply". Section 70(3)(a) does not refer to either "form" nor "supply". Rather, it is concerned whether, as a matter of fact, there are ARTG goods that contain of or consist of the s 70(2) pharmaceutical substance. The statutory text imposes the relevant point of inquiry as being a comparison of the goods as they are registered in the ARTG as against the identified s 70(2) pharmaceutical substance(s). Relatedly, AS [72] is wrong insofar as it seeks to compare ingredients of the s 70(2)(a) substance with the ingredients of the nominated s 70(3) good. That is not the statutory test.

87. Contrary to AS [73], it is not logical, nor common-sense, to construe statutory text in a manner that is inconsistent with its plain wording.[43] O/L's attempt to re-write the statutory requirements should be rejected; the statutory language must be strictly applied.[44] Instead, O/L seeks to ignore the characteristics of the ARTG Goods "included in the ARTG" which do not contain the identified s 70(2)(a) Injectable Formulations. Contrastingly, a different O/L good is included in the ARTG, namely ABILIFY ASIMTUFII, contains a controlled release injectable aripiprazole formulation.[45] As a matter of science, these goods are different to each other: see [80] above.

## D. The Formulations are not "pharmaceutical substances *per se*"[46]

88. The FFC correctly found that the PTE Claims are not to "pharmaceutical substances *per se*" pursuant to s 70(2)(a) of the Act: FCJ [292], [295]; *cf* AS [75]. In referring to the matters agreed by the experts at [10] above, the FFC correctly found that each of the PTE Claims, although expressed as product claims, included process integers:

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[43] Contrary to AS [73], *Collector of Customs v Agfa-Gevaert Ltd* (1996) 186 CLR 389 at 400-402 is inapposite. It concerned the usage of a trade meaning in construing legislation. Contrary to fn 23, *Grove Hill Pty Ltd v Great Western Corporation Pty Ltd* (2002) 55 IPR 257 is inapposite. It concerned infringement by the sale of parts.
[44] *Northern Territory v Collins* [2008] HCA 49; 235 CLR 619 at [16]; *Alcan (NT)*; *Alumina Pty Ltd v Commissioner of Territory Revenue* [2009] HCA 41; 239 CLR 27 at [47]; *Alphapharm* at [60], [120].
[45] See Exhibit 4, Tab 9 titled "Highlights of Prescribing Information for ABILIFY ASIMTUFII (aripiprazole)".
[46] See Sun Pharma's Amended Notice of Contention before the FFC, Ground 5.

FCJ [288] *cf* AS [78]. The FFC was also correct to find that these process features were additional to a "pharmaceutical substance" *simpliciter* and concerned the use of such substance (i.e. method of delivery, dissolution and release time): FCJ [292]-[294].[47]

89. Contrary to AS [78], [80], [82], the fact that the PTE Claims may be a form of product claim does not determine whether they are for a pharmaceutical substance "*per se*". Section 70(2)(a) does not draw a binary distinction between product and process claims. As *Boehringer* recognises, not all product claims satisfy the *per se* requirement. The question is whether the claim(s) relied upon for s 70(2)(a) claim matter additional to, or involve the use of, the pharmaceutical substance: *AbbVie* at [56]. The PTE Claims do.

10 90. AS [79] ignores the fact that the Relevant Feature ("which upon injection releases aripiprazole over a period of [specified time]") in each of the PTE Claims includes process features. Also there are process features that are additional to the Relevant Feature: for the Injectable Formulation Claims "a controlled release injectable"; and for the Freeze-dried Formulation Claims "a sterile freeze-dried controlled release" and "which formulation upon constitution with water forms a sterile injectable formulation." Finally, if, as indicated in [66]-[66] above, footnote 40 in *Alphapharm HC* is to be understood as characterizing a tablet as a form of delivery system and thus not a "pharmaceutical substance *per se*" then this further supports Sun Pharma's position.

## PART VI: RESPONDENT'S NOTICE OF CONTENTION

20 91. NoC [3], [4] reflect the approach propounded by Sun Pharma in Part V, A (i) to (vii) above. Further, insofar as the FFC determined the issues in Part V, B, C or D above on the basis that the term "pharmaceutical substance" is limited to active substances (which is not accepted), then the FFC ought to have determined those issues favorably to Sun Pharma by reason of the matters in in Part V, B, C and D: NoC [5], [6].

## PART VII: RESPONDENT'S CROSS-APPEAL (NoCA)

92. ***Special leave:*** ought to be granted because the proposed cross-appeal raises an issue of significant general importance, namely, what test is to be applied in determining whether s 40(2)(b) of the Act is satisfied in respect of a claim limited by result. Leave is sought to file the annexed amended Notice of Cross-appeal (**NoCA**).

30 93. ***Context for the proposed cross-appeal***: The primary judge held that s 70(2)(a) of the Act was not satisfied because the PTE Claims were invalid as they did not satisfy

[47] Referring to the Full Court in *Boehringer* at [38].

ss 40(2)(b) and 40(3): PJ [299(2)]. The FFC reversed that finding: FCJ [115]. Sun Pharma seeks leave to cross-appeal in respect of s 40(2)(b) only,[48] which requires that the complete specification must "end with a claim or claims defining the invention". The primary judge also held that the PTE Claims are claims limited by result expressed in terms of a minimum period of release, namely, "which upon injection releases aripiprazole over at least [1 week or about 2 weeks]" (i.e. the **Relevant Features**): PJ [204]-[236]. The FFC upheld that finding: FCJ [38]-[46].

94. The primary judge found, based upon the expert evidence, that as a matter of common general knowledge (**CGK**) of the person skilled in the art (**PSA**), "release" (being the dissolution of aripiprazole molecules from the depot at the injection site) is *not* the same as blood plasma concentration (being the concentration of the drug in the blood at a particular point of time) (**BPC**): PJ [70], [71], [242]-[247], [258], [259].

95. The primary judge also made findings of fact based on the proper construction of the Patent as informed by the expert evidence that the PSA was unable to determine from the "sparse information" provided in the Patent *how* to determine whether a given formulation that otherwise satisfies any of the PTE Claims falls inside or outside the release boundary in those claims: PJ [262]. Having accepted that release could not be measured *in vivo*, the primary judge identified that the "only manner by which release might be determined which is disclosed in the Patent" is the BPC data contained in Figure 3: PJ [248]. However, this BPC data only showed release for at least 30 days (*cf.* the Relevant Features) (PJ [258]) and showed significant inter-patient variability (which was fortified by the confidential Otsuka documents): PJ [255], [267]. The primary judge found that there must have been some undisclosed "intermediate analysis" or "additional thinking" in extrapolating from BPC data to release: PJ [258], [260].

96. The primary judge also held based upon the expert evidence that to attempt to extrapolate from BPC data to release it would be necessary to experiment for each formulation[49] to identify whether it fell inside or outside the Relevant Feature. This experimentation is not "simple, routine or straightforward", but rather "onerous, time-consuming and would provide variable and unreliable results": PJ [296].

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[48] This is a distinct ground of revocation under s 138(3)(f) of the Act: *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274 at [49].

[49] Using a combination of methods involving formulating an intravenous comparator, and modelling (applying appropriate PK analysis techniques e.g. deconvolution studies): PJ [286], [294], [295].

97. The primary judge held that based on the Patent and CGK, even allowing for routine experimentation, the PSA could not determine whether all formulations otherwise falling with the PTE Claims satisfy the Relevant Feature: PJ [297].

98. The FFC found error in the primary judge's approach, namely that it "place[d] the bar too high" (FCJ [91]) or was a "misstate[ment] of the test" (FCJ [112]). As developed below, the FFC erred in making such a finding, and in doing so adopted the wrong test: e.g., FCJ [89]-[92], [105]-[107], [111]-[112].

99. ***NoCA 3(a) – the primary judge did not "place the bar too high".*** In identifying the test to apply to determine whether claims limited by result satisfy s 40(2)(b), the primary judge referred to the relevant principles including the following passages from *Patents for Inventions and the Protection of Industrial Designs* (5th ed, The Law Book Company, 1983), Mr **Blanco White** QC (emphasis added):

> [4-413]: "To amount to a limitation by result, what is in the claim must at least be a limitation: something that draws a line between two classes of things that would otherwise fall within the claim: with the implication that conditions of the manufacture can be adjusted, by the reader of the specification, to secure the specified result" (reproduced in *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119 at 125–126, per Gummow J): PJ [200]
>
> [4-703] "…a claim limited by result has been held bad for ambiguity where the instructions for attaining the result were meaningless to those in the art. In addition, it must not be forgotten that there is no authority for putting upon the reader of the specification the burden of making any but "simple" experiments…" (reproduced in *BlueScope Steel Ltd v Dongkuk Steel Mill Co, Ltd (No 2*) (2019) 152 IPR 195 at [719] per Beach J): PJ [202].

100. The primary judge applied these principles in determining that **(i)** the PTE Claims lack definition because "the instructions in the Patent are meaningless to those skilled in the art" and "these matters would cause difficulty to a manufacturer wishing to satisfy himself that he is not infringing the PTE Claims" (PJ [266]) and **(ii)** if a PSA was to attempt to extrapolate from BPC data to release, non-routine experimentation would be required (PJ [296]); see [96] above.

101. There is no error of law in the primary judge's approach. It is also consistent with the observations of the Court in *D'Arcy v* ***Myriad*** *Genetics Inc* (2015) 258 CLR 334

including that the "function of the claim mandated by s 40(2)(b)" is "to define clearly with precision the monopoly claimed, so that others may know the exact boundaries of the areas within which they will be trespassers" (at [14]); and on the facts of that case "[n]or is there any conceivable way in which the processes could be adjusted by reference to any disclosed chemical formula to avoid the presence of the specified mutations and polymorphisms and thereby infringement of the patent" (at [154]), comparing Blanco White at 4-413 (at fn 185).

102. The FFC was wrong to characterise the primary judge's reference to "all embodiments" as including "hypothetical" or "impractical" embodiments: FCJ [91], [112]. The FFC did not and cannot point to any examples in PJ where the primary judge considered "all embodiments" to include "hypothetical" or "impractical" embodiments. Rather, the primary judge understood "all embodiments" to include those formulations that "lie closer to the boundaries of the PTE claims" (see e,g. PJ [264]). As the primary judge held, these "discrete boundaries" constituted limitations by result that must be able to be used by a manufacturer to adjust its formulation to determine whether it is outside the boundary, i.e. avoid infringement: PJ [236], [238].

103. ***NoCA 3(b) – the FFC adopted the wrong test.*** Having made the error identified above, the FFC considered it "appropriate on appeal for the Court to consider the position": FFC [92]. However, in doing so, it further erred by adopting the wrong test.

104. The FFC held at FCJ [89] that the "appropriate course" was not to have regard to passage at 4-413 of Blanco White concerning "Effect of limitation by result", but rather to have regard to the passage from Blanco White at 4-704 titled "Borderline cases" (which referred to ***General Tire*** *& Rubber Company v Firestone Tyre & Rubber Company Limited* [1972] RPC 457). Nor did the FFC have regard to the passage at 4-703 titled "Claim limited by result" (notwithstanding it immediately preceded the "Borderline cases" passage). The FFC's approach was in error.

105. *General Tire* is authority for the proposition that the alleged issue of "want of definition" is always to be considered in relation to the particular facts of the case and (**i**) "as a practical matter and little weight is to be given to puzzles set out at the edge of the claim"; but (**ii**) the manufacturer must still be able to satisfy himself that he is not infringing the patent (at p. 511, 515). The FFC focused on the former but not the latter and erroneously treated *General Tire* as displacing that requirement and those set out in the passages of Blanco White referred to in [99] above.

106. The facts in *General Tire* are materially different to the present case. As the FFC correctly recognised at FCJ [82], the claim in *General Tire* was a claim limited by result, however, (unlike the present case) the patent *in suit* in *General Tire* disclosed a test to calculate the prescribed result, being a "computed Mooney" plasticity of at least 90. The "computed Mooney test" was selected by the patentee as the "best available in the circumstances" to overcome an "obvious problem" that "prevented reliance on normal measurement" (pp 511, 516). By contrast, in the present case: **(i)** the subject matter of the Patent permitted a clearer definition of the claimed formulations, using BPC (if BPC was intended to be the relevant measurement); and **(ii)** the Patent did not provide *any* test to determine whether a formulation was within the boundaries of the PTE Claims.

107. ***NoCA4(a) and 4(c): FFC erred in departing from the primary judge's construction of the Patent informed by the expert evidence***. The FFC held that the primary judge erred in failing to find that, as a matter of construction of the Patent, BPC was a surrogate for the release of aripiprazole as set in the PTE Claims: FCJ [93], [103]-[108]. The primary judge did not err. The primary judge found, based upon the expert evidence, that the Patent is not using BPC to refer to extended release and as a matter of CGK, the PSA would not "conflate these concepts": PJ [247]. The primary judge also held, informed by the expert evidence, that **(i)** Figure 3 does not "show" release, rather it only shows BPC and, **(ii)** to extrapolate from BPC data to release requires some intermediate analysis, not disclosed in the Patent, to account for the delay between release and absorption of the drug into the blood plasma and because the drug can remain in the plasma after release has ceased: PJ [258].

108. The FFC's finding that, as a matter of construction of the Patent, BPC should be understood as a proxy for release (FCJ [104]-[108]), is inconsistent with the expert evidence: PJ [241]-[247], [256]-[265].[50] The FFC also misunderstood the evidence of Prof. Winter (which the primary judge accepted) that "release from an intramuscular depot ***in vivo*** in humans is practicably not measurable with precision…" (PJ [257]). The FFC misunderstood that evidence as meaning that nothing could be done to approximate release at all (including outside the body) and therefore BPC must be the proxy for release. However, as the primary judge found, based upon the expert evidence, the PSA

[50] Including where there was a disagreement based upon Prof Winter's evidence (e.g PJ [263]) in circumstances where cogent reasons were given for preferring the evidence of Prof Winter to Prof Evans: [24]-[31]. cf. *Aldi Foods Pty Ltd v Moroccanoil Israel Ltd* (2018) 261 FCR 301 at [53].

would use a "combination of [non-routine] methods" to attempt to approximate release from BPC data: PJ [286], [294], [295]. This was the "additional thinking" and "intermediate analysis" not disclosed in the Patent: PJ [258]-[262] *cf* FCJ [110].

109. The FFC's construction also ignores the fact that the patentee (of its own choosing) claimed release as the limitation by result, and not BPC.[51] There is no warrant for adopting a method of construction that gives a patentee what it might now have wished to claim, rather than what the words of the relevant claim actually say.[52]

110. ***NoCA 4(b) – BPC in Figure 3 does not provide a workable standard.*** The primary judge found that notwithstanding that Example 4 stated that Figure 3 showed "release for at least 30 days", Prof Winter's evidence demonstrated that "the basis for asserting that Figure 3 'shows' release (whether fast or sustained) is neither apparent nor explained, and there must have been some intermediate analysis": PJ [258]. The primary judge also held that "even if it could be said that the evidence established that some formulations, such as that in Example 1 [used in Figure 3], would achieve minimum periods of release, this is not the end of the matter. This is because the issue is whether the [PSA] is able to determine whether other formulations which lie closer to the boundaries of the PTE Claims, such as with a mean particle size that may or may not achieve a specified minimum release period depending upon the formulation, will fall within the PTE Claims. For example, a "formulation with a mean particle size of about 1 micron…would require the day on which the formulation stops releasing (rather than being measurable in blood plasma) to be measured with precision in order to determine whether it released for less or more than two weeks":[53] PJ [264].

111. The FFC erroneously held based on Figure 3 that the PSA could use BPC to determine whether a formulation fell inside or outside the scope of the PTE Claims: FCJ [114]. This ignores the fact that the only controlled release formulation used in Figure 3 was the specific formulation in Example 1 (containing 200mg of aripiprazole, having a mean particle size of 2.5 microns and specific excipients in specific amounts) and that it only showed "release for at least 30 days": PJ [253], [258], [264]. In contrast, the PTE Claims included formulations with many variables and release boundaries of at least "1 week"

[51] As contrasted with the claims defined by reference to BPC in *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* (2011) IPR 194, relied on by O/L at first instance to argue that human BPC studies were routine.
[52] *Australian Mud Company Pty Ltd v Coretell Pty Ltd* [2011] FCAFC 121; 93 IPR 188 at [72]-[73]; *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* (2004) 64 IPR 444 at [34].
[53] Insofar as a "practical real-world example" is required, this is one: *cf* FCJ [114].

and "about 2 weeks.[54] That is, the Example 1 formulation and its BPC data in Figure 3 could not be used by the PSA to adjust its manufacture to achieve a non-infringing formulation i.e. having a release of less than 1 week" and "about 2 weeks.

112. The effect of the FFC's reasoning was to disregard the boundaries in the PTE Claims, i.e. not treat them as limitations by result. This is notwithstanding that the FFC upheld the primary judge's finding that the limitations were not "inherent" but were required to be satisfied: FCJ [38]. The FFC also upheld the primary judge's finding that "in order to determine whether a given formulation fell within the Relevant Feature, experimentation would be required", due to the myriad of factors that affected release, including: particle size, excipients, dosage amounts, frequency etc: FCJ [44]; PJ [206]-[218], [285], [289], [290]-[293]. These are real world practical considerations that a manufacturer would need to vary to avoid infringement of the PTE Claims.

113. ***NoCA 4(d) – The FFC ignored the confidential Otsuka documents*:** The primary judge's finding that the PTE Claims were "bad for ambiguity" was "fortified by the content of the confidential Otsuka documents", which (like Figure 3), showed significant inter-patient variability, such that a PSA would not consider that BPC data alone would be sufficient to determine whether the Relevant Feature(s) were met: PJ [267], [285]-[295]. The FFC did not address, nor identify any error in this regard.

114. ***Orders***. NoCA [3], [4] ought to be allowed and the orders in NoCA ought to be made.

## PART VIII: ESTIMATE

115. The Respondent estimates it will need 3.25 hours to present its argument on the appeal, the notice of contention and the cross-appeal including its reply on the cross-appeal.

Dated: 20 May 2026

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[54] Sun Pharma advanced a case that formulations falling within the PTE Claims could not be considered by reference to the concentration vs time analyses in Figure 3 *cf* FCJ [113]: see T81.38-47 before the primary judge.

## ANNEXURE TO THE RESPONDENT'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; Chapter 11, Part 1; and Schedule 1 (Dictionary). | Version in force at date in right hand column. | 13 August 2014, being the date of Extension Request: FCJ [3]. |
| 2. | *Patents Act 1990* (Cth) | C2004C00401 (16 August 2004 – 27 September 2006) | Chapter 3, Part 1; and Chapter 12. | Version in force at date in right hand column. | 18 October 2004, being the date on which the Patent was filed: PJ [1]. |

**Form 27 – Notice of contention**
Note: see rule 42.08.5.

**ANNEXURE TO THE RESPONDENT'S SUBMISSIONS**

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No S20/2026

ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT OF AUSTRALIA

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

## AMENDED NOTICE OF CONTENTION

1. The Respondent wishes to contend that the decision of the Court below should be affirmed, but on the ground that the Court below erroneously decided or failed to decide some matter of fact or law.
2. Unless otherwise defined below, this Notice of Contention (**NOC**) adopts the defined terms from the Appellants' Notice of Appeal dated 26 March 2026 and/or the FCJ.

### Grounds

***Ground 3 of the Respondent's Notice of Contention in the FFC***

3. Having correctly found that the relevant version of the Act which governed the First Appellant's claimed right to extend the Patent was the Act in force at the date of the Request to extend the term of the Patent (13 August 2014) or, alternatively, was such later version of the Act relevant to the matters in dispute that was materially the same (FCJ [131]), the Full Court ought to have begun by considering the statutory text of that Act.

Date of document: 20 May 2026 Filed on behalf of the Respondent

4. Consistently with the above, the FFC ought to have found that:

   (a) the amendments made to the Act by the **2006 Amendment Act** (as defined in FCJ [200]), which included the repeal of s 78(2) and the insertion of s 119A, formed part of the Act and provide contextual support for the conclusion which the FFC otherwise correctly reached on the meaning of "*pharmaceutical substance*" (cf FCJ [206]); and

   (b) the **EM 2006** (as defined in FCJ [201]) was relevant under s 15AB of the *Acts Interpretation Act 1901* (Cth) as part of the exercise of the construction of the Act as in force at the time of the right in suit (cf FCJ [205]) and supported the conclusion which the FFC otherwise correctly reached on the meaning of "*pharmaceutical substance*".

***Grounds 1, 2 and 5 of the Respondent's Notice of Contention in the FFC***

5. Having correctly identified that the Respondent's Notice of Contention Grounds 1, 2 and 5 were advanced whether or not the term "*pharmaceutical substance*" includes formulations (FCJ [10]), the FFC erred insofar as it determined Grounds 1, 2 and/or 5 on the basis that the term "*pharmaceutical substance*" is limited to active substances and does not include formulations (cf FCJ [267], [270], [283], [291]). Otherwise, the FFC correctly upheld Grounds 1, 2 and 5.

6. In particular, insofar as the FFC determined Grounds 1, 2 and/or 5 on the basis described at paragraph 5 above, the FFC ought to have found that, even if the term "*pharmaceutical substance*" does include formulations, then:

   (a) in respect of Ground 1, the Freeze-dried Controlled Release Formulations are not a pharmaceutical substance for the purpose of s 70(2)(a) of the Act, including regardless of which construction of the word "*application*" in the definition of "*pharmaceutical substance*" is adopted (which the Respondent contended below, cf FCJ [262]); and

   (b) in respect of Ground 2, where the relevant PTE Claim(s) for the purpose of s 70(2)(a) of the Act are the Injectable Formulation Claim(s), the ARTG Goods do not contain, or consist of, the Injectable Formulation(s) as required by s 70(3)(a) of the Act (cf FCJ [283]); and

   (c) in respect of Ground 5, the Formulations are not "*pharmaceutical substances per se*" within the meaning of s 70(2)(a) of the Act because they include process

features and/or features which limit the use of the formulations and/or include limitations by result (cf FCJ [291]).

Dated ~~2 April~~ 20 May 2026

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Nina Fitzgerald
Ashurst Australia
Solicitor for the Respondent

AND TO: The Appellants
Corrs Chambers Westgarth

The respondent is represented by Ashurst Australia.

**Form 26 – Notice of cross appeal**
Note: see rule 42.08.2.

**ANNEXURE TO THE RESPONDENT'S SUBMISSIONS**

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No S20/2026

ON APPEAL FROM THE FULL COURT OF THE FEDERAL COURT OF AUSTRALIA

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

## AMENDED NOTICE OF CROSS-APPEAL

1. Subject to the grant of special leave, the Respondent cross-appeals from orders 1, 3 and 11 of the orders made by the Full Court of the Federal Court of Australia (**FFC**) on 3 December 2025, consequent upon the reasons published as *Sun Pharma ANZ Pty Ltd v Otsuka Pharmaceutical Co Ltd* [2025] FCA 44 (**FCJ**).
2. Unless otherwise defined below, this Notice of Cross-Appeal (**NOCA**) adopts the defined terms from the Appellants' Notice of Appeal dated 26 March 2026 and/or the FCJ.

### Grounds

3. The FFC erred in (a) holding that the primary judge erred in adopting a test, for lack of definition within s 40(2)(b) ~~and/or lack of clarity within s 40(3)~~ of the Act in relation to a claim incorporating a limitation by result that "places the bar too high"; (b) adopting the wrong test: FCJ [89], [90], [91]-[92] (see also FCJ [105]-[107], [111]-[112]).
4. The FFC erred:
   a) in holding that the primary judge erred in failing to find as a matter of construction of the Patent that blood plasma concentration was a surrogate for the "release of aripiprazole" as set out in the PTE Claims: FCJ [93] (see also FCJ [103]-[108]);

b) in holding that the primary judge erred in finding that the Patent fails to provide a "workable standard" for measuring release by blood plasma concentration or that the Respondent did not advance a case that formulations falling within the PTE Claims "could not be considered by reference to a concentration vs time analyses as conducted in Example [Figure] 3" of the Patent and the FCC erred in doing so including by disregarding the claimed boundaries: FCJ [109]-[115];

c) generally, in departing from the primary judge's assessment of matters properly informed by expert evidence including Professor Winter's evidence particularly when the primary judge gave cogent reasons for preferring the evidence of Professor Winter to Professor Evans (PJ [24]-[31]) which reasons were untouched by the FFC's analysis: FCJ [105]-[107] and [110]-[114]; and

d) in finding error in the primary judge's reasoning (FCJ [115]) without addressing, or finding error, in the primary judge's analysis of the confidential Otsuka documents which confirmed that a person skilled in the art would not consider that blood plasma concentration data alone would be sufficient to determine if the limitation by result defined in terms of release in the claims has been met in relation to any given formulation: cf. PJ [267]-[297].

**Orders sought**

5. The cross-appeal be allowed.
6. Orders 1, 3 and 11 of the FFC's orders made on 3 December 2025 be set aside.
7. Order 8 of the primary judge's orders made on 13 February 2025 be varied such that the Appellants pay the Respondent's costs of that proceeding No. NSD 172/2024.
8. The Appellants pay the Respondent's costs of the cross-appeal to this Court.

Dated ~~2 April~~ 20 May 2026

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Nina Fitzgerald
Ashurst Australia
Solicitor for the Respondent

AND TO: The Appellants
Corrs Chambers Westgarth

The respondent is represented by Ashurst Australia.

Date of document: 20 May 2026 Filed on behalf of the Respondent