HIGH COURT OF AUSTRALIA

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Form 27A—Appellant's submissions

Note: See rule 44.02.2.

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' 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 principal issue which arises on this appeal is whether or not the expression "pharmaceutical substance" in s 70 of the *Patents Act 1990* (Cth) (**Act**) as defined in the Schedule to the Act includes both an active pharmaceutical ingredient (**API**) and a formulation consisting of an API and excipients (inactive substances), such that the extension of patent term scheme in Pt 3 Ch 6 of the Act (**EoT Scheme**) applies to patents for pharmaceutical formulations?

3. If the answer is yes, then the following issues arise. First, as to the "pharmaceutical substance" definition, does the fact that a formulation needs to be reconstituted (i.e. have water added to it) before it can be administered to a patient preclude it from satisfying the definition? Second, as to s 70(3)(a), does the fact that goods need to be reconstituted before they can be administered to a patient preclude the goods from satisfying that subsection? Third, as to s 70(2)(a), does the presence of features in the claim that describe the characteristics of the formulation preclude the formulation from being a "pharmaceutical substance per se"?

Part III: Section 78B Notice

4. No notice pursuant to s 78B of *the Judiciary Act 1903* (Cth) is required.

Part IV: **Reasons for Judgment**

5. The primary judgment is *Sun Pharma ANZ Pty Ltd v Otsuka Pharmaceutical Co Ltd* (2025) 184 IPR 399 (**PJ**: Core Appeal Book (**CAB**) 5). The Full Federal Court's judgment is *Otsuka Pharmaceutical Co Ltd* v *Sun Pharma ANZ Pty Ltd* (2025) 313 FCR 1 (**FCJ**: CAB 96).

Part V: Facts

6. The First Appellant is the patentee of Australian Patent No. 2004285448 (**Patent**: Appellants' Book of Further Material (**AFM**) 5), which was filed on 18 October 2004 and (subject to extension) due to expire on 18 October 2024: FCJ [1] (CAB 100). It includes claims to (e.g., FCJ [26]-[27]: CAB 107; PJ [63]-[66]: CAB 23): controlled release liquid (ready to use) injectable aripiprazole formulations (**Controlled Release Injectable Formulations**), i.e., claims 1, 3, 6 and 14; and freeze-dried (lyophilised) controlled release aripiprazole formulations (**Freeze-dried Controlled Release Formulations**), i.e., claims 16, 19, 21 and 25 (together, **Formulations**). Each such claim (**PTE Claims**, short for "Patent Term Extension Claims") is to a formulation including at least aripiprazole of a particular mean particle size and a vehicle therefor (which contains excipients), "*which upon injection releases aripiprazole over a period of [a specified time ranging from at least one week to at least four weeks]*" (**Relevant Feature**).

7. The PTE Claims are product claims, not method of treatment claims: FCJ [292] (CAB 158); PJ [176] (CAB 44).

8. Aripiprazole is an antipsychotic agent used to treat schizophrenia and bipolar I disorder: FCJ [2], [13] (CAB 100, 102). The mechanism of action is the binding of aripiprazole molecules to receptors in the brain: PJ [3] (CAB 11). There was no aripiprazole compound patent in Australia: FCJ [14] (CAB 102). ABILIFY, a specific formulation of an immediate release tablet form of aripiprazole, was first included on the Australian Register of Therapeutic Goods (**ARTG**) in May 2003: FCJ [15] (CAB 102); PJ [5] (CAB 11); AFM 50-61.

9. Drug release profiles can be immediate or controlled release. For controlled release, the drug's release rate is retarded relative to an immediate release

formulation, such that the drug is released over time. This enables the required frequency of dosing of the drug to be reduced, which can also reduce issues with patient compliance: FCJ [17] (CAB 103); PJ [33], [47], [52] (CAB 16, 18, 20).

10. On 25 July 2014, the First Appellant obtained an ARTG listing for ABILIFY MAINTENA, comprising vials of a freeze-dried powder (aripiprazole and vehicle) and a solvent (water): FCJ [3], [277] (CAB 100, 156); AFM 46-49. ABILIFY MAINTENA needs to be reconstituted before injection: PJ [149]-[152] (CAB 39). It satisfies the Relevant Feature; indeed, regulatory approval was obtained for once-monthly injection: PJ [185]-[189] (CAB 44-45). In contrast, ABILIFY is taken daily: e.g., PJ [52] (CAB 20).

11. There was a delay of ~10 years between the filing date of the Patent (18 October 2004) and ABILIFY MAINTENA's listing on the ARTG (25 July 2014). On 13 August 2014, the First Applicant applied to the Patent Office for an extension of term (**Extension Request**), which in due course was granted, extending the Patent's expiry date to 25 July 2029 (**Extension**): FCJ [3] (CAB 100).

12. The Respondent (**Sun Pharma**) supplies generic versions of ABILIFY MAINTENA (**Sun Pharma Products**): FCJ [6] (CAB 100). Sun Pharma commenced these proceedings challenging the validity of the Extension and contending the PTE Claims lacked clarity/definition. The Appellants (**O/L**) cross-claimed for, *inter alia*, threatened infringement of the Patent and threatened contravention of the *Australian Consumer Law* by reason of a failure to warn: e.g., FCJ [4], [6] (CAB 100); PJ [12(8)], [16] (CAB 13, 14).[1] Sun Pharma did not dispute the newness/inventiveness of any of the PTE Claims or that the Sun Pharma Products fell within the PTE Claims: e.g., FCJ [6], [295] (CAB 100, 159).

13. In answer to the challenge to the Extension's validity, O/L relied on various substances as satisfying s 70,[2] including: **(1)** "Substance V", an injectable formulation including water, which upon injection releases aripiprazole over a period of at least about one week and falls within the scope of claims 1, 3, 6 and

[1] As the Sun Pharma Products have since been sold etc, O/L now seeks relief for *actual* infringement: see proposed orders 3 and 6 set out at [83] below.

[2] Section 70 of the Act recognises that its terms can be satisfied by "more than one pharmaceutical substance": see also *Cmr of Patents v* ***Ono*** *Pharmaceutical Co Ltd* (2022) 291 FCR 1 at [119]. Further, the EoT Scheme does not operate by reference to the nomination of pharmaceutical substances in any extension request, but rather by objective determination of whether the terms of s 70 are satisfied: *Ono* at [104], [119], [126], [137]; *Merck Sharp & Dohme Corp v Sandoz Pty Ltd* (2022) 291 FCR 26 at [34].

14 of the Patent; and **(2)** "Substance X", a freeze-dried formulation, which upon constitution with water forms an injectable formulation, which releases aripiprazole over a period of at least about two weeks and falls within the scope of claims 16, 19, 21 and 25 of the Patent. See FCJ [5], [9(e)] (CAB 100, 101).

14. The primary judge held the PTE Claims were invalid for lack of clarity and definition, such that the Extension was wrongly granted: e.g., FCJ [7] (CAB 101); PJ [19] (CAB 14). Subject to validity, the primary judge would have upheld the Extension's validity based on Substances V and X, including as the Formulations are "pharmaceutical substances" which satisfied the elements of the definition: e.g., PJ [114], [119], [125], [127], [131]-[133], [153], [175]-[178] (CAB 33-36, 39, 44).

15. As Sun Pharma did not contend that the ratio of ***Cipla*** *Australia Pty Ltd v Novo Nordisk A/S* (2024) 185 IPR 299 that "pharmaceutical substance" includes formulations was "plainly wrong", the primary judge followed *Cipla*: PJ [110]-[114] (CAB 32-33). (*Cipla* was consistent with two earlier decisions holding that "pharmaceutical substance" include formulations: ***Pharmacia*** *Italia SpA v Mayne Pharma Pty Ltd* (2006) 69 IPR 1 at [103]-[107]; ***Spirit*** *Pharmaceuticals Pty Ltd v Mundipharma Pty Ltd* (2013) 216 FCR 344 at [47]-[54].)

16. Sun Pharma also argued that if "pharmaceutical substance" includes formulations, the Formulations did not satisfy s 70, including for reasons which were the subject of Notice of Contention Grounds 1, 2 and 5 before the FFC (**Further Contention Grounds**: CAB 97). The primary judge rejected the Further Contention Grounds, holding that: the Freeze-dried Controlled Release Formulations met the "pharmaceutical substance" definition; the Controlled Release Injectable Formulations satisfied s 70(3)(a); and the fact the PTE Claims, being product claims, had "process or in-use" features did not prevent them from being to a "pharmaceutical substance per se": PJ [133], [153], [175]-[178] (CAB 36, 39, 44).

17. The FFC held the PTE Claims did not lack clarity or definition: FCJ [115] (CAB 127). However, based on its conclusion that as a matter of statutory construction the EoT Scheme excludes formulations (FCJ [261]: CAB 154), the FFC held that the Extension was wrongly granted, such that the Patent had expired and the Sun Pharma Products did not infringe it: FCJ [6], [8], [11] (CAB 100-102).

18. The FFC said it was "not necessary" to consider the Further Contention Grounds, "*which proceed on the basis that… the Formulations are pharmaceutical*

substances": FCJ [261] (CAB 154). Nevertheless, it allowed them: FCJ [11(1)], [262]-[295] (CAB 102, 154-159). In doing so, its reasoning was largely based on the earlier conclusion that the Formulations were not pharmaceutical substances: see [69], [74] and [81] below.

19. To succeed in this Court, O/L needs to overturn the FFC's conclusions as to Notice of Contention Grounds 3 and 5, and either of Grounds 1 and 2 (CAB 180).[3]

Part VI: **Argument**

"Pharmaceutical substance" includes formulations[4]

20. The Full Court erred in holding that "pharmaceutical substance" is "*limited to active substances and… formulations do not fall within the scope of the definition*": FCJ [261] (CAB 154).

21. As explained in *H Lundbeck A/S v* ***Sandoz*** *Pty Ltd* (2022) 276 CLR 170 at [15], s 70 was first inserted into the Act by the *Intellectual Property Laws Amendment Act 1998* (Cth) (**1998 Act**).[5] It is modelled in part on provisions inserted into the *Patents Act 1952* (Cth) (**1952 Act**) by the *Patents Amendment Act 1989* (Cth) (**1989 Amendment Act**), which were carried over into the 1990 Act but repealed in 1994.

22. To qualify for an extension, four relevant requirements must be satisfied, summarised in ***Alphapharm*** *Pty Ltd v H Lundbeck A/S* (2014) 254 CLR 247 at [12]-[20], [77], [78]; *Sandoz* at [15]-[21]; and *Ono* at [118]-[127]. First, "*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*": s 70(2). Second, "*in relation to at least one of those pharmaceutical substances … goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods*" (**Relevant Goods**): s 70(3)(a).[6] Third, "*in relation to at least one of those pharmaceutical substances … 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*

[3] Notice of Contention Grounds 1 and 2 (CAB 84-87) concern different substances, i.e. the Freeze-dried Controlled Release and Controlled Release Injectable Formulations, respectively. Only one substance needs to satisfy the terms of s 70 of the Act. Further, if the Freeze-dried Controlled Release Formulations are to "pharmaceutical substances per se" (cf Notice of Contention Grounds 1 and 5 (CAB 84-85, 90-91)), it is not necessary for Notice of Appeal ground 1(b) to be allowed for O/L to succeed.
[4] Cf Notice of Contention Ground 3 in the FFC (CAB 87-88).
[5] The "pharmaceutical substance" definition (set out at [32] below) was already part of the Act at the time: see e.g., FCJ [179]; CAB 139.
[6] The pharmaceutical substance(s) which satisfy s 70(3) must also have satisfied s 70(2): *Ono* at [124].

years" (**Relevant Period**): s 70(3)(b). The date of the patent is, relevantly, the date of filing of the complete specification: s 65. The "first regulatory approval date" is relevantly the date of commencement of the first inclusion in the ARTG of Relevant Goods: s 70(5)(a). Fourth, "*the term of the patent must not have been previously extended*": s 70(4).[7] If these requirements are satisfied, the period of extension is the period by which the Relevant Period exceeds 5 years up to a limit of a period of extension of 5 years: s 77; *Sandoz* at [17].

23. The crux of O/L's argument is that the plain words of the "pharmaceutical substance" definition include both an API and a formulation of API and inactive excipients: see further [32]-[37] below. Moreover, so construed, the above four requirements conform with and evince the statutory purpose of the EoT Scheme as found by this Court in *Alphapharm*. Furthermore, a construction that limits the definition to an API reflects no discernible statutory purpose.

24. The EoT Scheme is inherently only referable to valid patents. Thus, as to the first requirement, the claim within which the "pharmaceutical substance" must fall is a valid claim to an invention, and necessarily involves an inventive step, is novel, is useful and is to a manner of manufacture. It is a putatively valuable addition to the substances available for treating human disease.

25. As to the second requirement, pursuant to s 20 of the *Therapeutic Goods Act 1989* (Cth) (**TGA**) as in force when the EoT Scheme was enacted,[8] the supply of "therapeutic goods" in Australia is prohibited unless the goods are included on the ARTG. Therapeutic goods are defined to include goods for therapeutic use: s 3(1). "Therapeutic use" is defined to include *inter alia* use in preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons: s 3(1). Therapeutic goods are taken to be separate and distinct from other therapeutic goods if they have a different formulation: s 16(1)(a). To achieve inclusion in the ARTG, an applicant must satisfy the regulator that the particular therapeutic good, being almost universally a particular formulation including both an API and inactive excipients, is safe for use in human treatment: e.g., TGA ss 23, 25, 26.

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[7] Notably, s 70 does not prevent the same Relevant Goods having previously been relied upon for the purposes of extending the term of a different patent. This is what occurred in *Cipla*.

[8] Since 2006, the equivalent prohibition has been s 19B of the TGA: see *Therapeutic Goods Amendment Act (No. 1) 2006* (Cth). The other provisions of the TGA referred to in [25] were in relevantly the same form at the time when the EoT Scheme was enacted and at the date of the Request.

26. As to the third requirement, having regard to the above, a delay of more than 5 years from the date of the patent to the date when the pharmaceutical substance can be commercially supplied in Australia represents a substantial reduction in the effective useful life of the patent.

27. Before the ultimate introduction of s 70, an extension of term of any patent could be sought on the ground of inadequate remuneration and regard was had to all the circumstances of the case, including the nature and merits of the invention in relation to the public. Consequently, proceedings for an extension of term were complex and extensive: *Alphapharm* at [47]. The EoT Scheme is simplified by comparison with the pre-existing law, with regulatory delay being the proxy for inadequate remuneration and merit is assumed: *Alphapharm* at [48].

28. Thus, in *Alphapharm* at [51] the majority found that a primary object of the EoT Scheme is to "*acknowledge that the effective patent life for pharmaceuticals for human use is reduced by the stringent and time-consuming evaluation procedures ... to ensure both the safety of patients and the efficacy of drugs*". Further, the identified objective is "*to provide an 'effective patent life' more in line with that available to inventions in other fields of technology*": *Sandoz* at [16].

29. The statutory purposes of the EoT Scheme "*are to balance the competing interests of*": first, "*a patentee of a pharmaceutical substance whose exploitation of monopoly has been delayed (because of regulatory delay)*"; and secondly, "*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)*": *Alphapharm* at [60];[9] *Sandoz* at [16].

30. The above findings as to statutory object and purpose are based on and discernible from the language of the requirements in s 70, including the repeal of previous extension schemes permitting extension applications for any standard patent and the notorious fact of the time taken to achieve an ARTG listing. While background materials may reinforce the findings, they are not dependent on such materials.

31. There is no discernible statutory purpose in drawing a dichotomy as to eligibility for the EoT Scheme between patents for formulations and patents for one or more

[9] The dissent stated at [120]: "*There is no doubting that the purpose behind s 70(1) is to benefit and encourage research and development*."

APIs/"active substances".[10] Both are susceptible to regulatory delays. Insofar as they achieve ARTG listing, the merit of both is assumed: see [27] above.

32. "Pharmaceutical substance" is defined in the Dictionary in Sch 1. It provides as follows (divided into components for ease of reference):

> "*A substance (including a mixture or compound of substances)*
> - *for therapeutic use*
> - *whose application (or one of whose applications involves):*
> *(a) a chemical interaction, or physico-chemical interaction, with a human physiological system; or*
> *(b) action on an infectious agent, or on a toxin or other poison, in a human body;*
>
> *but does not include a substance that is solely for use in in vitro diagnosis or in vitro testing.*"

33. The word "substance" is not defined and bears its ordinary meaning. That ordinary meaning captures a "substance" consisting of multiple components or "substances". So much is confirmed by the parenthetical words "including a mixture or compound of substances".[11] In short, the plain ordinary meaning of "substance" includes a formulation.

34. The "substance" must be "for therapeutic use". Those qualifying words do not qualify any individual component of a "substance". Rather, they qualify anything that is within the ordinary meaning of substance. As a formulation is within that ordinary meaning, it is the formulation which must be for therapeutic use, not any individual component of it.[12] Subparagraphs (a)-(c) of the "therapeutic use" definition in Sch 1 to the Act are identical to those subparagraphs of the "therapeutic use" definition in the TGA. They include, for example, a use for the purpose of "*curing or alleviating a disease, ailment, defect … in persons*" or "*influencing, inhibiting or modifying a physiological process in persons*". The primary judge found that the Formulations are for therapeutic use: PJ [125], [127] (CAB 35). The FFC did not find otherwise; see also FCJ [161] (CAB 136).

35. Similarly, the requirement that the substance's *"application … involves … a chemical interaction, or physico-chemical interaction, with a human physiological system"* is in respect of the substance as a whole. For a formulation, the

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[10] In the case of multiple APIs, neither API needs to a 'new API': see also [55(2)] below.
[11] See also *Cipla* at [126]: "*[I]t is scarcely plausible"* that the parenthetical words *"were inserted to narrow the range of substances that could qualify as pharmaceutical substances… [if so] there were plenty of other, much clearer ways of indicating that such a limitation was intended*."
[12] Sun Pharma's Amended Notice of Contention abandoned Ground 4, which concerned this (CAB 89).

requirement is tested by reference to the formulation as a whole, not any individual component of it. The "application" of a formulation containing both an "active" component and excipients is its administration to a human and "involves" the requisite interaction. The primary judge found that the Formulations satisfied this requirement, as they plainly did: see [14] above.

36. Moreover, neither the word "active" nor "formulation" is used in the statutory definition. Had Parliament intended to limit the definition to substances comprised only of "active" components[13] or to exclude formulations,[14] this could easily have been effected by using those words.

37. Statutory construction begins and ends with a consideration of the statutory text: e.g., *FCT v Consolidated Media Holdings Ltd* (2012) 250 CLR 503 at [39]. A statutory definition is ordinarily framed in language chosen for the grammatical meaning it conveys: *ICAC v Cunneen* (2015) 256 CLR 1 at [77]. It is of "*fundamental importance*" that statutory definitions are construed according to their natural and ordinary meaning, and "*limitations and qualifications are not read into*" them, unless some other course is "*clearly required*": *SkyCity Adelaide Pty Ltd v Treasurer of South Australia* (2024) 419 ALR 361 at [32].

38. When construing a definition, "*the only proper… course is to read the words of the definition into the substantive enactment and then construe the substantive enactment… in its context…*": *Farschi v The King* [2025] HCA 46 at [59]. Reading the "pharmaceutical substance" definition into the provisions which use it – ss 70(2)(a), 70(2)(b), 70(3), 70(5)-(6), 77 and 78 – is consistent with the definition, and thus those provisions, encompassing formulations. None of the above provisions tends against this construction: see also *Cipla* at [128]-[141].

39. Given the clear terms of the definition, regard to extrinsic material and such matters cannot "displace" the clear meaning of the text: e.g., ***Taylor*** *v Attorney-General (Cth)* (2019) 268 CLR 224 at [87]; ***Alcan*** *(NT) Alumina Pty Ltd v Commissioner of Territory Revenue (Northern Territory)* (2009) 239 CLR 27 at [47]; *Alphapharm* at [42]; *Sandoz* at [63].

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[13] In contrast, on 18 December 1997, by reg 3.2 of the *Therapeutic Goods Regulations (Amendment) 1997* (Cth), Parliament inserted the following definition of "active ingredient" in the *Therapeutic Goods Regulations 1989* (Cth): "the therapeutically active component in a drug's final formulation that is responsible for its physiological or pharmacological action". A similar definition was inserted as s 52F of the TGA by the *Therapeutic Goods Legislation Amendment Act 1999* (Cth), Sch 1 item 13.

[14] The only exclusion is "*a substance that is solely for use in in vitro diagnosis or in vitro testing*".

40. The language used in the statutory text is the surest guide to legislative intention: *Alcan* at [47]; *R v **A2*** (2019) 269 CLR 507 at [35]. Indeed, as stated in *Ono* at [115], "*It can be taken that the legislature saw the correct balance as being achieved by the very words it chose to implement [the EoT Scheme]*". As submitted above, the language used in both the definition and the EoT Scheme does not evince any purpose to exclude formulations or to differentiate between patents for APIs and patents for formulations. The four requirements in s 70 apply as a matter of language and logic to both such patents.

41. ***Errors in the FCJ.*** Despite recognising statutory construction must begin with a consideration of *the statutory text* (FCJ [135]: CAB 130-131), the FFC did not follow this fundamental principle. Rather, its construction proceeded by the irregular and methodologically flawed route of first considering the *Explanatory Memorandum, Patents Amendment Bill 1989* (Cth) (**EM 1989**) for the earlier scheme enacted into the 1952 Act by the 1989 Amendment Act: FCJ [167] (CAB 137).

42. This focus on the pre-existing law and the legislative history "deflected" the FFC from the statutory text: cf *Alphapharm* at [42]. Further, the FFC erred in failing to heed the warnings in e.g.: **(1)** *Taylor* at [87], "*The function of the Court is to give effect to the will of the Parliament as expressed in the law, not to bend it to accord to what an officer of the executive may have conjectured to be its meaning*"; and **(2)** *Mondelez Australia Pty Ltd v Automotive, Food, Metals, Engineering, Printing and Kindred Industries Union* (2020) 271 CLR 495 at [72], "*Lacking both the force of law and the precision of parliamentary drafting*", explanatory memoranda "*cannot be taken to be an infallible and exhaustive guide to the legal operation of a provision. Notoriously, explanatory memoranda sometimes get the law wrong*".

43. Moreover, the FFC misconstrued the EM 1989: cf *Cipla* at [39]-[73]. The EM 1989 stated that the intention of the 1989 Amendment Act was to make the extension scheme in the 1952 Act "*available for 'therapeutic substances' in the terms of the Customs (Prohibited Imports) Regulations*" (**Customs Regulations**): FCJ [155] (CAB 134-135).[15] This plainly included a formulation, being a *"substance … that has a therapeutic use and includes a surgical ligature, suture*

[15] The definition of "therapeutic substance" in the *Customs Regulations 1956* (Cth) came from the definitions of "therapeutic substance" and "substance" in *Therapeutic Substances Act 1953* (Cth).

or dressing": FCJ [156], [163] (CAB 135, 136). The 1989 EM then added a limitation that "*only substances whose use involves a chemical or physico-chemical interaction with a human physiological system … (devices such as surgical ligatures are not included)…"* (**EM 1989 Limitation**): FCJ [155] (CAB 134-135). That is, the intention reflected in the 1989 EM was to exclude devices such as surgical ligatures from the 1952 Act's extension of term scheme.

44. In error, having stated it was "beyond argument" that "therapeutic substances" in the Customs Regulations included formulations, the FFC construed the EM 1989 Limitation (FCJ [161]-[163], [169]-[173]: CAB 136, 137-138) as having the effect that the "pharmaceutical substance" definition in the 1952 Act "*was limited to active substances only*": FCJ [178] (CAB 139). This starting point drove the FFC's erroneous construction of the "pharmaceutical substance" definition in the Act. For example, at FCJ [193] (CAB 142), the FFC asked whether the EoT Scheme effected any change to the meaning of the "pharmaceutical substance" definition.

45. The EM 1989 Limitation does not exclude or even refer to formulations. Indeed, if the intent was to exclude them, this would have been stated. It was not.

46. Underscoring the FFC's error, the FCJ did not advert to the differences between the "pharmaceutical substance" definition in the Act and the 1989 EM Limitation. For instance, the "pharmaceutical substance" definition expressly encompasses "mixtures or compounds of substances": see [32] above. In contrast, while the "therapeutic substance" definition in the Customs Regulations as at July 1988 expressly includes "a mixture or compound of substances" (see FCJ [160]: CAB 135), the 1989 EM Limitation does not include this phrase. This is important because the FFC's reasoning did not grapple with the existence or effect of the phrase: see [32]-35] above and [47]-[48] below.

47. The FFC's key reasoning, at FCJ [170]-[171] (CAB 137), was:

> *"The 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… That is to say, 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)."*

48. This reasoning is flawed. Rather than recognising that what needs to have the requisite interaction/action is the "pharmaceutical substance", the FFC diverted its attention to what it regarded as the "focus" of the definition, not the words of the definition (which include a formulation). Properly understood, the effect of the EM 1989 Limitation is that the pharmaceutical substance (e.g., a formulation) must involve the requisite interaction/action: see by parity of reasoning [32]-[35] above. The EM Limitation's interaction/action requirement excludes substances which have a "therapeutic use" without an interaction/action, e.g., devices such as surgical ligatures (referenced in the EM 1989: see [43] above). It does not transform the definition into something akin to "active substance".

49. The FFC's approach necessitates reading a limitation into the definition which does not arise on its natural and ordinary meaning: cf the principles at [37] above. Where the substance is a "mixture or compound of substances" for therapeutic use whose application (i.e. the application of the mixture or compound) involves the requisite interaction, it requires that each of the substances involves the requisite interaction: cf [35] above. This has the effect of rewriting the introductory words as follows (underlining reflecting words not forming part of the definition): "*a substance (including a mixture or compound of <u>such</u> substances)…*"

50. Before considering the EM 1989 Limitation, at FCJ [123] (CAB 128) the FFC referred to and incorrectly interpreted a statement of Bennett J in *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151 at [243] (***Alphapharm FFC***) as finding that the EoT Scheme does not apply to a patent which claims an improvement in the delivery of a known pharmaceutical substance already listed on the ARTG. But that statement was directed to method claims, not product claims. At FCJ [129] (CAB 129), in supporting its conclusion that formulations were not within the EoT Scheme, the FFC incorrectly described the Formulations as improved delivery claims (echoing the language of Bennett J), rather than as product claims. As the FFC elsewhere accepted, the PTE Claims are product claims: see [7] above.

51. Similarly, at FCJ [182] (CAB 139), the FFC prayed in aid a note at [10] of the *Revised Explanatory Memorandum, Intellectual Property Laws Amendment Act 1998* (Cth) (**1998 REM**) that extensions of term are not available for claims to new processes of making pharmaceutical substances or new methods of using them. In

error, the FFC said "*the claims to the Formulations… are examples of the type of claim*" referred to in the note (CAB139). They are not. They are product claims.

52. The 1998 REM also referred to the costs and risk of developing "new drugs" and the delay in bringing them to market, such that "*patentees of new drugs usually have considerably fewer years under patent in which to maximise their return*": FCJ [194] (CAB 142). As the ordinary meaning of "drug" includes the pharmaceutical product (i.e. the formulation: see e.g., *Spirit* at [54]), if it was relevant to have regard to the 1998 REM, this supports O/L's construction.

53. The FFC gave weight to the statement in the 1998 REM that the "pharmaceutical substance" definition "***may*** *comprise combinations of active ingredients or single active ingredients*" (emphasis added): FCJ [182] (CAB 139). However, the word "may" plainly indicates that the statement is non-exhaustive: see also *Cipla* at [84]. In any event, construction of the statutory text is not assisted by "*resort to paraphrases of the statutory language in extrinsic materials*": *A2* at [35].

54. The FFC erred in giving weight to the phrase used in the 1998 REM at [23], in discussing s 78(2), as to a "*generic pharmaceutical formulation containing the patented pharmaceutical substance*": FCJ [183], [184] (CAB 139-140). A generic pharmaceutical formulation may contain an API or a patented formulation. In any event, this is a "textually weak" basis for grounding any conclusion as to legislative intention: see the principles at [42] above; and *Cipla* at [84].

55. Also, when focusing on the reference to "new chemical entity" at FCJ [194] (CAB 142), the FFC erred in failing to appreciate that: **(1)** a formulation claim *can* be used to patent a new "chemical entity"; and **(2)** the EoT Scheme is not limited to "new chemical entities". For example, a "pharmaceutical substance" can be a mixture which combines existing APIs, i.e. which are not "new chemical entities".

56. The above matters underscore that the 1998 REM does not evince a clear intention as to the construction issue, and "*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]. The effect of the FCJ was "*to impute erroneously a statutory intention which destroys the effect of a clearly expressed definition*": *Alcan* at [52]. Other errors include the following.

57. Having acknowledged the proper course is to "*read the words of the definition into the substantive enactment and then construe the substantive enactment*" (FCJ [138]; CAB 131), the FFC did not properly engage with the content of, let alone read the definition into, the relevant provisions: cf [38] above.

58. The FFC erred in reasoning that allowing extensions of term "*for improved or modified dosage forms of known drugs already registered on the ARTG"* was inconsistent with the purpose of the EoT Scheme: FCJ [197] (CAB 142-143). Proper analysis of the EoT Scheme's purpose does not reveal any such inconsistency: see [23]-[31] and [40] above. FCJ [197] (CAB 142-143) also failed to recognise that where the API is 'new', the relevant patent may claim a formulation containing the API, rather than solely the API (see [55(1)] above); or, as here (see FCJ [14]: CAB 102), the patentee may not have obtained an Australian patent covering the API at all.

59. The FFC erred in concluding that its construction was "consistent" with the EoT Scheme's purpose based on "policy objectives": FCJ [195]-[199] (CAB 142-143). In doing so, it violated the principle that "*it is not for a court to construct its own idea of a desirable policy, impute it to the legislature, and then characterise it as a statutory purpose*": *Australian Education Union v Dept of Education and Children's Services* (2012) 248 CLR 1 at [28].

60. Insofar as the FFC considered the "policy objectives" were "*evinced in the extrinsic materials*", [51]-[56] above apply *mutatis mutandis*. Otherwise, the FFC's reasoning was based on the premise that the "*number and extent of biopharmaceutic studies required to obtain regulatory approval for a new formulation of an already approved [API] is less than those required for regulatory approval of a medicine containing a new chemical or biological entity*": FCJ [196] (CAB 142). However, there was no material or evidence supporting a meaningful difference in regulatory delay between the two, whether before the enactment of the EoT Scheme or otherwise. Developing formulations can involve substantial and lengthy research; indeed, the Australian Government's *Pharmaceutical Patents Review 2013* (**PPR 2013**) found the time for regulatory approval is around the same for both categories: p 93-4, Fig 5.1. Further, the FFC's construction does not permit extensions of patents to formulations of *new* APIs.

61. Moreover, if in a particular case a new formulation for an already approved API has not been the subject of a delay more than 5 years, the relevant patent will not be eligible for an extension: see s 70(3)(b) and cf FCJ [198] (CAB 143). And if the delay is between 5 and 10 years, the length of the extension is commensurately reduced from the maximum 5-year extension: see s 77.

62. The FFC erroneously concluded that the legislature's failure to amend the "pharmaceutical substance" definition since 1998 was of "no significance". However: **(1)** since 2006, four judges had held at first instance that the EoT Scheme applies to formulation patents. Notably, each decision was underpinned by reasoning that the text of the "pharmaceutical substance" definition was clear in encompassing formulations;[16] **(2)** since shortly after the EoT Scheme's enactment in 1998 (eight years before *Pharmacia*), the Patent Office has proceeded on the footing that the EoT Scheme applies to formulation patents;[17] **(3)** Parliament has not legislated to displace the above long-standing position. Indeed, in enacting amendments to the EoT Scheme in 2015,[18] it did not make any amendments to the "pharmaceutical substance" definition or otherwise to alter the effect of the then existing precedents, *Spirit* and *Pharmacia*, or Patent Office practice; **(4)** in September 2016, *Productivity Commission Inquiry Report No. 78* recommended that the EoT Scheme be amended to limit its availability to patents for APIs: recommendation 10.1 on p 309 (albeit based on the erroneous foundation at p 307). The Australian Government's Response in August 2017 was that "*it has no plans to proceed with this recommendation*", reasoning:

> *"for many pharmaceutical products, the effective patent life – the period between marketing approval and patent expiry – is reduced by the time taken for companies to obtain evidence to support applications under the subsequent regulatory review process. In common with other countries, this can affect incentives to discover and develop new pharmaceutical products".*

63. The FFC reasoned that Parliament's failure to amend the "pharmaceutical substance" was of "no significance" as the definition "already… achieved" limiting

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[16] PJ [123]-[126] (CAB 34-35); *Cipla* [111]-[127]; *Spirit* [47]-[49]; *Pharmacia* [103], [105]-[107].
[17] IP Australia's "Official Notice: Extension of Term for Pharmaceutical Patents" dated 11 January 1999 at [25.2.3]; *Patent Manual of Practice and Procedure* at [7.12.1.1] (published 9 October 2023). Moreover, Article 17.9.8 and footnote 17-17 of the Australia United States Free Trade Agreement, which entered into force on 1 January 2005, proceeds on this basis.
[18] *Intellectual Property Laws Amendment Act 2015* (Cth) at Schedule 1, items 11-13.

the EoT Scheme to active substances: FCJ [207] (CAB 144-145). This was contrary to the principle in *Probuild Constructions (Aust) Pty Ltd v Shade Systems Pty Ltd* (2018) 264 CLR 1 at [52]. It was also circular; based on the matters in [62(1)-(2)] above, the definition has operated for ~20 years to achieve the oppositive objective, i.e. the granting of extensions of term for formulation patents. Indeed, ~8% of granted extensions of term have been for formulation patents: PPR 2013 p 94-5; Fig 2. It also follows that the statement at FCJ [198] (CAB 143) that formulations being eligible for the EoT Scheme would "*dramatically increase the potential scope of the regime*" was in error; it would maintain its current scope.

64. Finally, to the extent the FFC gave weight to footnote 40 in *Alphapharm* at [23] (referenced at FCJ [124]-[126], [259] and [260]: CAB 128, 153 and 154), this was in error. In that footnote, in a section entitled "background facts", the majority said that "*patents for pharmaceutical methods or tablets do not fall within the [EoT Scheme]*" as they are not pharmaceutical substances *per se*. The majority did not suggest that claims 3-5 of the patent there in issue (set out at FCJ [221]: CAB 147-148), which were to formulations, were not to a pharmaceutical substance per se. Thus, the subject matter of the note is not formulations, but rather methods and delivery systems. In any event, footnote 40 is not "*seriously considered dicta*". There was no argument in *Alphapharm* concerning, nor does the footnote contain any reasoning with respect to, the present issue.[19]

Freeze-dried Controlled Release Formulations *are* "pharmaceutical substances[20]

65. The FFC erred in concluding that the Freeze-dried Controlled Release Formulations are not "pharmaceutical substances", as they need to be reconstituted (have water added) before injection: FCJ [270], [273] (CAB 155, 156).

66. As held at PJ [133] (CAB 36), while the "*interaction only takes place after reconstitution and injection*", this is "*an application of that freeze-dried substance, given that ultimately it is the substance which enables the treatment to occur, albeit with the involvement of additional elements*".

67. Neither the text of the definition nor s 70(2)(a) requires the "pharmaceutical

[19] See e.g., P Herzfeld and T Prince, Interpretation (3rd ed, Law Book Co, 2024) at p 755. Note that there is also a debate as to whether a footnote can have any precedential effect: *New South Wales Land and Housing Corporation v Quinn* [2016] NSWCA 338 at [60].
[20] Cf Notice of Contention Ground 1 in the FFC (CAB 84-85).

substance" alone "*to be the thing that is applied to the human body*", that is, absent additional elements such as water: PJ [130], [133] (CAB 36). Put another way, neither serves to exclude from the EoT Scheme substances which require the involvement of additional elements in order for the requisite interaction to occur.

68. To the extent anything turns on it, the primary judge was correct to draw an analogy with APIs, which are a type of "pharmaceutical substance": PJ [134] (CAB 36); cf FCJ [270]-[273] (CAB 155-156). Like freeze-dried formulations, they generally require an additional step before they can be administered and cause the requisite interaction, being their inclusion in a formulation with excipients.[21] In both cases, other elements are required to facilitate the requisite interaction.

69. The crux of the reasoning reflected that for the primary issue, i.e., the aripiprazole molecules (as opposed to the formulation) undergo "*the physico-chemical interaction with a human physiological system*": FCJ [267] (first sentence), [268] (second sentence), [270], [272] (CAB 155-156). This resulted in further error.

70. If "pharmaceutical substance" can encompass formulations, the upshot of the FFC's conclusion is that those requiring reconstitution (or indeed any additional pre-administration step) are nevertheless excluded from the EoT Scheme. However, the purpose of the EoT Scheme discussed above would not be facilitated by such formulations being excluded from it: see also *Acts Interpretation Act 1901* (Cth) (**AIA**) s 15AA. There was no material before the FFC suggesting any difference in the testing required, or regulatory delay, between formulations which require reconstitution and those that do not.

Controlled Release Injectable Formulations satisfy s 70(3)(a) of the Act[22]

71. The FFC erred in holding that the Controlled Release Injectable Formulations do not satisfy s 70(3)(a) as ABILIFY MAINTENA (the "goods") does not contain or consist of the Controlled Release Injectable Formulations: FCJ [284] (CAB 157).

72. ABILIFY MAINTENA is an injectable formulation. It is comprised of the ingredients in the kit: a "*vial of freeze-dried powder (aripiprazole and vehicle) and a separate vial of diluent*". Their only use is to reconstitute the vial of freeze-dried

[21] See e.g., *Alphapharm FFC* at [242]; see also *Cipla* at [16].
[22] Cf Notice of Contention Ground 2 before the FFC (CAB 85-87).

powder as an injectable formulation: PJ [137], [152] (CAB 36, 39). As held at PJ [150]-[153] (CAB 39), it follows that ABILIFY MAINTENA contains or consists of the Controlled Release Formulations.

73. Section 70(3)(a) does not confine the "goods" on the ARTG to their form at supply, including where that form cannot be administered to the patient (here, because reconstitution is required). Indeed, construing s 70(3)(a) as confining the "goods" to ingredients in their unreconstituted state would deny the "*import of logic and common-sense in matters of statutory construction*" (*Collector of Customs v Agfa-Gevaert* Ltd (1996) 186 CLR 389 at 400-402, and authorities cited at footnote 30) and elevate form over substance.[23] Moreover, the purpose of the EoT Scheme would not be served by such a construction; [70] above applies *mutatis mutandis*.

74. The FFC relied on "differences" between ABILIFY MAINTENA and the Controlled Release Formulations: FCJ [281], [284] (CAB 58, 59). This was in error for the reasons at [72]-[73] above. Further, an aspect of the FFC's reasoning was that the "*focus of the [s 70(3)(a)] inquiry, the pharmaceutical substance, is the active ingredient*": FCJ [283] (CAB 59). This was based on the FFC's erroneous conclusion in respect of the primary issue and led the FFC into further error.

The PTE Claims *are* to "pharmaceutical substances per se"[24]

75. The FFC erred in concluding that the PTE Claims are not to "pharmaceutical substances *per se*" under s 70(2)(a) of the Act: FCJ [292], [295] (CAB 61, 62).

76. The words "per se" have been considered in several Full Federal Court decisions.[25] Their effect is that s 70(2)(a) must be satisfied by the pharmaceutical substance "by or in itself", "intrinsically" or "essentially": *Boehringer* at [34], [37], [42]. In other words, "*the pharmaceutical substance… must be the subject matter of the claim[s]… **not methods or processes**… concerning or involving the pharmaceutical substance*": *Abbvie* at [60] (emphasis added, see also [57]).[26]

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[23] Cf AIA s 15AA. See by analogy the principle that where a product is normally sold in an unassembled kit comprising a "*complete set of parts*", the vendor is considered to have sold the assembled product as a whole: *Grove Hill Pty Ltd v Great Western Corporation Pty Ltd* (2002) 55 IPR 257 at [330], [333]-[335] and authorities cited therein.

[24] Cf Notice of Contention Ground 5 before the Full Court (CAB 90-91).

[25] E.g., ***Boehringer*** *Ingelheim International GmbH v Cmr of Patents (No 2)* (2001) 112 FCR 595; *Cmr of Patents v* ***AbbVie*** *Biotechnology Ltd* (2017) 253 FCR 436; ***Prejay*** *Holdings Ltd v Cmr of Patents* (2003) 57 IPR 424.

[26] See also: *Prejay* at [24]; PJ [99]; and *Cipla* at [5], [130], [135] and [148]).

77. Further, product claims which merely include a "pharmaceutical substance" as an integer are not to a "pharmaceutical substance *per se*". *Boehringer* is an example of this. The claim was to a container with specific features and comprising a particular composition; there was no claim to the composition alone: see [4], [5]. The claim was not to a "pharmaceutical substance *per se*" – it was to the pharmaceutical substance in combination with other features: [37]-[42].

78. The PTE Claims are set out at PJ [63]-[66] (CAB 23). The FFC found, as was not in dispute, that the Claims are product claims: see [7] above.

79. The PTE Claims include both the constituents of the claimed formulations and the Relevant Feature, being a "limitation by result": FCJ [38]-[46] (CAB 110-111). A limitation by result characterises or describes the "physical characteristics" of the claimed product: *Atlantis Corp Pty Ltd v Schindler* (1998) 39 IPR 29 at 48-49 (and authorities cited therein). It "*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*": FCJ [32], [88] (CAB 108, 121).

80. As the primary judge held at PJ [175]-[178] (CAB 44),[27] the PTE Claims, including the Relevant Feature, "*describe the new and inventive substance*", i.e., the product. Further, the PTE Claims are not to a process or method of delivery.

81. Having earlier concluded in the context of the primary issue that the only "pharmaceutical substance" in the Formulations was the API aripiprazole (see FCJ [129]: CAB 129), the FFC's reasoning concerning the present issue proceeded on this erroneous premise: FCJ [292] (first sentence), [294], [295] (fourth sentence) (CAB 158-159). This led the FFC into further error.

82. Moreover, insofar as it was suggested the PTE Claims are to "methods of administration" or "delivery" (FCJ [294] last sentence, [295] fourth sentence: CAB 158, 159), this was in error. They are product claims. In contrast, claims 37-41, 44-48 and 68 of the Patent (not relied on for the PTE) are to methods of administration.

Part VII: Orders Sought

[27] This was consistent with the reasoning in earlier cases: *Pharmacia* at [101]; *Spirit* at [72]-[75].

83. In accordance with its notice of appeal (CAB 174), O/L seek the following orders (defined terms as per FCJ [1], [5] and [6] (CAB 100)):

(1) The appeal be allowed.

(2) Set aside orders 2, 4-7 and 9 of the FFC's orders made 3 December 2025 (CAB 160).

(3) A declaration that the Respondent has infringed each of the PTE Claims by exploiting the Sun Pharma Products.

(4) An order restraining the Respondent, whether by itself, its directors, officers, servants, agents or otherwise, from infringing or threatening to infringe any of the PTE Claims, including by engaging or threatening to engage in any of the following acts within Australia without the licence or authority of any of the Appellants during the term of the Patent:

(a) making, importing, selling, supplying or otherwise disposing of; offering to sell, supply or otherwise dispose of; using or otherwise exploiting; or keeping for the purpose of doing any of the aforementioned acts, the Sun Pharma Products; and

(b) authorising, or procuring or inducing or joining in a common decision with, any other person to do any of the acts referred to in (a) above.

(5) An order for delivery up for destruction of all Sun Pharma Products and other products whose exploitation falls within the scope of the injunction in (4) above.

(6) The matter be remitted to the trial judge for orders in respect of: the Appellants' claim for contravention of the *Australian Consumer Law*; any aripiprazole products exploited by Sun Pharma other than the Sun Pharma Products; and the inquiry as to pecuniary relief.

(7) Sun Pharma pay O/L's costs of the appeal to this Court, the proceedings in the Full Court and the proceedings before the primary judge.

Part VIII: **Estimate for presentation of Appellants' oral argument**

84. Approximately two hours for the appeal.

Dated: 24 April 2026

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ANNEXURE TO APPELLANTS' 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)	C2004C05913 (05 December 1999 - 23 May 2001)	Chapter 6, Part 3; and Schedule 1	Version in force at point of time closest to 27 January 1999, as no compilation available for 27 January 1999. The relevant provisions remained unchanged from 27 January 1999 to 5 December 1999.	27 Jan 1999, being the date of the enactment of the EoT Scheme.
2	*Patents Act 1990* (Cth)	C2014C00301 (24 June 2014 – 25 February 2015)	Chapter 6, Part 3; and Schedule 1	Version in force at date in right hand column.	13 August 2014, being the date of Extension Request: FCJ [3].