HIGH COURT OF AUSTRALIA

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Details of Filing

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Important Information

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Form 27F – Outline of oral submissions

Note: see rule 44.08.2.

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

APPELLANT'S OUTLINE OF ORAL SUBMISSIONS

Part I: These submissions are in a form suitable for publication on the internet.

Part II: Propositions to be advanced during oral argument:

Appeal and contention

The invention – regulatory approval

1. The invention the subject of the Patent is a controlled release injectable formulation of aripiprazole for the treatment of schizophrenia and bipolar I disorder: FCJ [1], [2], [13]; AS [8]. The therapeutic mechanism of action is the binding of aripiprazole molecules to receptors in the brain: PJ [3], FCJ [2], [13], AS [8].

2. The Patent Example 1 formulation used in Example 4 (ABFM 25, 29; PJ [57], [59]; FCJ [24]) is an intramuscular (IM) depot formulation consisting of an aqueous suspension of microparticulate aripiprazole in water with the excipients carmellose (carboxymethyl cellulose, a suspending agent), mannitol (a bulking agent), sodium phosphate (a buffer) and sodium hydroxide (a pH adjusting agent) (ABFM 23 first table).

3. The ARTG registered freeze-dried formulation includes the same excipients (ABFM 47).

4. The injection of the formulation creates an intramuscular depot trapping the aripiprazole particles until they are slowly released and ultimately absorbed into the bloodstream where they are transported to the relevant receptors in the brain (PJ [37]).

5. Claims 1, 3, 6 and 14 are for the ready to use formulation and claims 16, 19, 21 and 25 for the kit form (ABFM 31-34). The relevant claims are product claims (FCJ [292], PJ [176]) limited by result with the implication that the conditions of manufacture can be adjusted by the reader of the specification to secure the specified result (PJ [200], [236]; FCJ [44], [45]). Conditions of manufacture comprehend the physical integers of the product. The invention is a combination of physical integers. As a valid patent, it is taken to be novel and involve an inventive step (*ABS v Ramset* 194 CLR 171 at [10]).

6. The ABILIFY MAINTENA ARTG registration is for once monthly injection (PJ [185]), a substantial advantage for patient compliance in treating serious mental illness: AS [9]. The pre-existing immediate release ABILIFY tablets require daily dosing (FCJ [21]).

7. ABILIFY MAINTENA is an embodiment of the relevant claims pre and post constitution (PJ [185], [189]). It is a distinct therapeutic good because of its formulation, dosage form, model and directions for use (TGA as in force at 13 August 2014, s 16(1)(a), (c), (f); JBA Tab 13 p185). It could not be supplied without ARTG registration and

thus satisfying the TGA as to its safety and efficacy for one monthly dosing to treat schizophrenia and bipolar I disorder (TGA s 19B(4)(a)(iv), (b)(i), s 25(1)(d); JBA Tab 13 p 188, 191; AS [25]).

8. The first regulatory approval for ABILIFY MAINTENA was the date of its inclusion on the ARTG register on 25 July 2014, more than 9 years after the date of the Patent of 18 October 2004 (filing date per s 65), a period of at least 5 years (see s 70(3)(b)).

9. The "pharmaceutical substance" per se within the above Patent claims is the formulation (the **Patent Formulation**) contained in the goods the subject of the ARTG registration (s 70(3)(a)). It supports the extension granted by the Commissioner pursuant to the application filed 13 August 2014 and (subject to s 40) upheld by the primary judge.

"Pharmaceutical substance" includes formulations

10. The relevant version of the Act is that in force at the time of the application for extension namely 13 August 2014: JBA Tab 5 24/6/2014-25/02/2015.

11. The EoT Scheme was relevantly introduced in 1998: ***Alphapharm*** *v Lundbeck* 254 CLR 247 (JBA Tab 19) at [57]. The history appears in *Alphapharm* generally at [49], [51], [52], [56], [57] and *Cipla v Novo* 185 IPR 299 (JBA Tab 32) as to "pharmaceutical substance" at [45]-[48], [51]-[54], [71]-[73], [78], [82], [89].

12. The earlier extension regime applied to all patents and required a consideration of merit and causes of delay including delay due to commercial decisions: *Alphapharm* at [47]. E.g., *Re Appn Sandoz* 14 IPR 541 at 562 line 45 - 563 line 30; *Re Appln Pfizer* 4 NSWLR 566 at 575C.

13. The EoT Scheme assumes merit and uses regulatory delay as a proxy for inadequate remuneration. The "effective patent life for pharmaceuticals for human use is reduced" by "stringent and time-consuming evaluation procedures": *Alphapharm* at [48], [51].

14. Almost universally, therapeutic pharmaceutical goods are approved and supplied as a formulation, which includes inactive excipients. There is no discernible statutory purpose in distinguishing between patents for inventive pharmaceutical formulations and 'active substance' patents: AS [26]-[31], [40]; RS [70]-[72].

15. The "pharmaceutical substance" definition (JBA Tab 5 p 66) includes as part of its context the word "pharmaceutical": ***SkyCity*** *v Treasurer (SA)* 282 CLR 479 at [32]. "Pharmaceutical" means relating to "drugs". A formulation is a drug product.

16. The ordinary meaning of "substance" includes both a single substance and a mixture of

substances as confirmed by the words in parentheses: AS [33]; ASR [10], [12]; *Cipla* at [126]. Patent legislation has long used "substance" in that sense: s 155(1)(b) of the *Patents Act 1952* (Cth); ss 50(1)(b), 101B(2)(e)-(f), 101E(1)(a)(v)-(vi) of the Act (as in force at date of extension application). A formulation is a mixture. In fact, many active ingredients will inevitably be mixtures with impurities: ASR fn 3; *Lundbeck v Alphapharm* 177 FCR 151 (JBA Tab 36) at [235], [244]; *Lundbeck v Sandoz* 137 IPR 408 at [85], [86].

17. The Patent Formulation is for "therapeutic use": AS [34]; PJ [125], [127]; FCJ [161]. "[T]herapeutic use" includes purposes such as "the purpose of … preventing, curing or alleviating disease" (JBA Tab 5 p 69). That reflects the purposes to which pharmaceutical formulations requiring ARTG registration are put.

18. The words "whose application" refer to the use to which the pharmaceutical substance is put: ASR [44]; PJ [131]; FCJ [267]; *Cipla* [124]. They are not limited to a "physical application". Such a limitation cannot be reconciled with "chemical interaction" in para (a) of the "pharmaceutical substance" definition. The application of the Patent Formulation is the treatment of schizophrenia (PJ [133], FCJ [268]). Such a use reflects the treatment of disease by administering registered therapeutic goods which inevitably include formulations.

19. The Patent Formulation "involves a "physico-chemical interaction" when the aripiprazole molecules in the Formulation bind with receptors in the brain (PJ [133]). Whether there is the requisite interaction is assessed by reference to *the substance* (i.e. as a whole), not a particular part of it: contra FCJ [170]-[171]. The Respondent's proposed construction that each part of the substance must have the requisite interaction involves reading in a limitation or qualification which is not part of the definition: cf *SkyCity* at [32]. See AS [35], [37], [48], [49]; ASR [11]; contra RS [30], [34], RSR [3].

20. The requirement in s 70(2)(a) that the "pharmaceutical substance *per se*" must be disclosed and fall within a claim is simply that the pharmaceutical substance by or in itself be the subject matter of the claim and not part of a claim to a method or process, or product with features other than the pharmaceutical substance (e.g., a container). It does not exclude formulations: AS [76]. The relevant Patent claims are to the substance itself and satisfy s 70(2)(a) (PJ [178]); contra FCJ [286]-[295], [129].

21. Section 70(2)(b) includes a pharmaceutical substance produced by a specific process *involving* the use of recombinant DNA technology, but does not exclude the addition of

excipients to produce the ultimate pharmaceutical substance: *Cipla* [131]; ASR [6]; contra RS [22]-[24] and RSR [2]. Even if it that be wrong, s 70(2)(b) does not logically limit the meaning of pharmaceutical substance to active ingredients.

22. Section 78 reflects s 70(2).

23. Section 119A was enacted in 2006, after the introduction of the EoT Scheme. It did not amend the "pharmaceutical substance" definition expressly or implicitly. It was introduced with the repeal of s 78(2) to extend springboard protection, which was limited to extended patents, to all "pharmaceutical patents". So understood, the operation of s 119A is agnostic as to whether a pharmaceutical substance includes a formulation (*Cipla* [102]). The "or" between s 119A(3)(a) and (b) is apt to be construed as conjunctive rather than disjunctive (*Cipla* [100(a)], [105]). In any event, "a product relating to a pharmaceutical product" inaptly describes a formulation, of which the active ingredient forms part: ASR [16]-[18]; contra RS [38], [40]-[42].

24. The extrinsic materials cannot "displace" the clear meaning of the text: AS [39], [42].

25. 1998 REM: JBA Tab 58 p1501.8-.9; 1502.8, 1516 [8]-[10], 1517 [23]: AS [52]-[56]; ASR [21]-[24].

26. 2006 EM: JBA Tab 45 p1234.5, 1241 [159(f), (g)]: ASR [25]-[31].

27. 1989 EM: JBA Tab 46 p1245 [8], 1246 [11]: FCJ [155], [160]-[163]; AS [43]-[49].

28. As to RS [70]-[72], there is no evidence as to any meaningful relative difference in delay for a formulation patent. Further, there is no extension if the delay is less than 5 years: AS [58]-[61]; ASR [39]-[42]. Allegations of commercial delay are directed to all pharmaceutical patents: JBA Tab 57 at 1467.8-1468.2.

29. Parliament's failure to amend the "pharmaceutical substance" definition is consistent with the Appellants' construction: AS [62], [63]; ASR [37]-[38].

30. Footnote 40 of *Alphapharm* does not bear on the issue: AS [64]; ASR [36].

Freeze-dried Controlled Release Formulations are "pharmaceutical substances"

31. The Freeze-dried Controlled Release Formulations are reconstituted (i.e. have water added to them) before injection. This fact does not result in those formulations falling outside the "pharmaceutical substance" definition: AS [65]-[70]; ASR [43]-[49].

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

32. The ingredients in ABILIFY MAINTENA are supplied in kit form and must be

reconstituted as an injectable formulation for administration to occur. The PI includes instructions for assembly. The "goods" under s 70(3)(a) are the injectable formulation, not the unreconstituted ingredients. This categorisation of the "goods" reflects a common-sense approach based on how ABILIFY MAINTENA is used. It is consistent with how a product sold in kit form is characterised under patent law, i.e. the product is the assembled form of the kit's components: *Grove Hill v Great Western* 55 IPR 257 (JBA Tab 35) at [330], [333]-[335]. See AS [71]-[74]; ASR [50]-[51].

The PTE Claims are to "pharmaceutical substances per se"

33. The PTE Claims are product claims. Their features characterise the pharmaceutical substance itself: ***Interlego*** *v Toltoys* 130 CLR 461 (JBA Tab 24) at 480 and *Atlantis v Schindler* 39 IPR 29 (JBA Tab 30) at 48-49. They are not additional to the pharmaceutical substance: cf the claims to a container and pharmaceutical substance in *Boehringer v Cmr* 112 FCR 595 (JBA Tab 31). See AS [75]-[82] and ASR [52]-[56].

Cross-Appeal

Notice of Cross-Appeal Grounds 3 and 4(b)

34. The law as to claim definition in the context of claims limited by result is settled: *Interlego* at 480; *General Tire v Firestone* [1972] RPC 457 (JBA Tab 34) at 515-516.

35. The FFC applied the correct legal test: ASR [58]-[62], [69], [70]. The FFC also correctly held that the test was to be applied in a practical manner based on "realistic, practical formulations": ASR [68(d)-(e)], [71]-[75], [82].

36. The test for claim definition should not be conflated with the test for sufficiency under s 40(2)(a) of the Act: ASR [83] and FCJ [86]-[87]; contra RR [8]-[11].

Notice of Cross-Appeal Grounds 4(a), (c)

37. The FFC was correct to hold that, on its proper construction, the Patent uses blood plasma concentration as a surrogate for the release of aripiprazole in the claims: ASR [68(a)-(c)], [77]-[81]. In contrast, the effect of the PJ's construction was to require identification of a release period by a means which was not possible.

Notice of Cross-Appeal Ground 4(d)

38. There was no need for the FFC to address the "confidential Otsuka documents". They are not part of the patent and were not CGK: ASR [84].

Dated: 16 June 2026 A J L Bannon