HIGH COURT OF AUSTRALIA

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Form 27F – Respondent's outline of oral submissions

Note: see rule 44.08.2.

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 / CROSS-APPELLANT'S OUTLINE OF ORAL SUBMISSIONS

PART I: FORM OF OUTLINE

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

PART II: OUTLINE OF ORAL ARGUMENTS

A. <u>Construction of "pharmaceutical substance"</u> (O/L appeal (*OLA*) [2(a)]; NoC [3]-[4])

2. ***Methodological issues***: **(1)** The constructional choice should be resolved by giving to the definition of "pharmaceutical substance" a meaning which best fits with the text, context, purpose and legislative history. **(2)** This requires attention not just to s 70 but to the spring-boarding provisions (ss 78, 119A). **(3)** The legislative history, whether read backwards or forwards, supports the FFC's conclusion. **(4)** The whole of the history must be considered, including the text and EM for the most recent amendments, being the 2006 amendments.

3. ***The definition:*** It is a "composite legislative expression" that is to be construed as a whole. It means a substance for "therapeutic use" (as defined) and "whose application (or one of whose applications) involves" the activity identified in (a) or (b), but not solely for use in *in vitro* diagnosis or *in vitro* testing: RS [29]-[30]. The bracketed words clarify that the "substance" may be a combination of "substances", e.g. in a "mixture" or "compound": RS [32]. Each "substance", including in a mixture/ compound, must satisfy the requirements of the definition: RS [30]-[31]. Excipients do not: RS [35]; RR [3].

4. ***Formulations:*** A formulation is a common but not exclusive type of 'mixture', being a combination of active and inactive ingredients which are not chemically united. As such

a mixture is capable of satisfying the first part of the definition provided it is for a therapeutic use. However, the formulation, taken as a whole, is incapable of satisfying the added limitations that follow in (a) and (b). That does not preclude any active ingredients within the formulation satisfying such limitations.

5. ***Section 70*** supports SP's construction: RS [21]-[28]. The term "pharmaceutical substance" must be construed uniformly. Section 70(2)(b) makes clear that that term is confined to active substances because recombinant proteins (being active substances) are produced by "a process that involves the use of recombinant DNA technology", whereas a formulation is produced by a subsequent process: RS [22]-[24]; SP's reply submissions (**RR**) [2]. Section 70(3)(a) requires that the ARTG goods must contain (i.e. include) or comprise the s 70(2) "pharmaceutical substance". As most ARTG goods are formulated (such as tablets, capsules, injectables), they "contain" the active substance(s) together with excipients. Other ARTG goods "consist" of the active substance(s): RS [26].

6. O/L's construction (1) that "a substance" includes multiple substances renders the words in brackets otiose; and (2) gives inconsistent meaning to "substance" because it depends upon at least some "substances" not needing to satisfy the requirements of the definition: RS [32]-[34]; RR [3]. The absence of the terms "active", "API" or "formulations" in the definition is of no moment ("API" colloquially refers to "active substance" although technically it is a subset). Such terms are "inapt" as compared to the wording of the definition chosen by the legislature: RS [36]-[37]; RR [6]; FCJ [175]-[177].

7. ***Sections 78, 119A*** allow springboarding by generic pharmaceutical manufacturers: RS [38]-[39]. Section 78 provides for circumstances where a patentee's exclusive rights will not be infringed during a PTE. Before the 2006 Act, s 78(2) had 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" (1998 REM p. 19, [22]-[23]): RS [44]. This also reinforces that "goods included in the [ARTG]" in s 78(2)(c) referred to formulations, which would equally apply to ss 70(3) and 70(5): RR [4].

8. Section 119A is part of the PTE Regime; as it requires the "term of the patent has been extended under Part 3 of Chapter 6" and uses the language in ss 70(2), 78: RR [5]. Section 119A(3) supports SP's construction because the definition of "pharmaceutical patent" includes a patent claiming, *inter alia,* (a) a "pharmaceutical substance" (i.e., active substance); **or** (b) a "… product relating to a pharmaceutical substance" (e.g., including

a formulation): RS [40]-[42]. The word "or" used in s 119A(3)(a) can only be read disjunctively: RR [5], fn 4. O/L's construction is circular and illogical: RR [7].

9. ***The 1998 REM and the 2006 EM*** are important extrinsic sources disclosing the "one manifested parliamentary intention" in respect of the statutory text; containing "very clear and specific" statements that confirm that PTEs are confined to active substances: RS [15], [57]-[58]; *Harvey* [91]-[92], [116]-[119].

10. The 1998 REM: **(1)** states that "'pharmaceutical substance' …may comprise combinations of active ingredients or single active ingredients"; "generic pharmaceutical formulation containing the patented pharmaceutical substance"; **(2)** emphasises the regulatory delay/cost in bringing an active substance to market: RS [44]-[49]; RR [7].

11. The 2006 EM identifies that: **(1)** "only patents which claim a pharmaceutical substance (ie API) are currently eligible for patent extension in Australia" in contrast to patents for *inter alia* "formulation of a medication" which are not eligible; **(2)** that for s 119A(3) a "product relating to a pharmaceutical substance" includes a "formulation incorporating a pharmaceutical substance" (i.e., the API): RS [50]-[56]. SP's characterisation of [159(g)] of the 2006 EM ought to be preferred: RR [7]; RS fn 32.

12. ***Pre-existing law before the Act.*** To the extent the pre-existing regime is relevant, the FFC was correct: RS [59]-[60]. The meaning of pharmaceutical substance as found by the FFC was *'locked in'* via the 1989 Act. As the surrounding Act changed around that definition, the FFC was entitled to enquire whether subsequent Parliaments intended to change the work the definition was doing: see *Alphapharm HC, Harvey,* and *Palmanova.* ***Other matters***: **(1)** the legislature's purported "failure to amend" does not assist O/L: RS [67]-[68]; **(2)** footnote 40 in *Alphapharm HC* supports SP's construction: RS [66]; (**3**) *Alphapharm FC* supports SP's construction: RS [69]; **(4)** O/L's contentions as to purpose ought to be rejected: RS [70]-[72]; RR [4] (fn 2).

B. Freeze-Dried Formulations do not satisfy s 70(2) (OLA [2(a)]; NoC [5]-[6(a)])

13. The requirement in s 70(2)(a) that a "pharmaceutical substance *per se*" must "in substance fall within the scope of the claim" means that the substance, having all the essential integers of the claim, must meet the requirements of the definition of "pharmaceutical substance": RS [76]-[77]. A Freeze-Dried Formulation does not meet those requirements because it does not involve a chemical interaction, or physico-chemical interaction, with a human physiological system: RS [78]. This is so regardless of what "application" means: RS [73]-[74]. A Freeze-Dried Formulation must be changed to an Injectable

Formulation for the required interaction; whereupon it no longer exists and, necessarily, does not have all the essential claimed features: RS [75], [80]-[81].

C. Injectable Formulations do not satisfy s 70(3) (OLA [2(b)]; NoC [5]-[6(b)])

14. The s 70(3) inquiry is factual, i.e. do the goods as they are registered in the ARTG contain, or consist of, the s 70(2) pharmaceutical substance(s): RS [84]-[87]. Where the claims for s 70(2)(a) are the Injectable Formulation Claim(s), the Injectable Formulations do not satisfy s 70(3)(a) because the ARTG Goods (being kits comprising a Freeze-Dried Formulation and a separate vial of water (FCJ [277])), do not contain, or consist of, that substance. O/L's attempt to recharacterise the goods should be rejected: AS [72]; RS [86].

D. Formulations are not pharmaceutical substances *per se* (OLA [2(a)]; NoC [5]-[6(c)])

15. Both s 70(2)(a) and (b) include the words "in substance fall within the scope of the claim(s)." The difference is that for s 70(2)(a), the pharmaceutical substance *per se* must take all the essential integers of the claim, whereas for s 70(2)(b), the pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology must take all the essential integers of the claim.

16. The PTE Claims do not satisfy s 70(2)(a) because they are not claims for a formulation comprising aripiprazole and excipients *simpliciter*. Each claims matter additional to, or that involves the use of, a pharmaceutical substance: FCJ [292]-[294]; RS [88]-[90]. They include integers that require the delivery to be "injectable" and having "water for injection" (e.g. Claim 1) and "upon constitution with water to form a sterile injectable formulation" (e.g. Claim 16). They also require the freeze-dried formulations to be produced by a lyophilization process (e.g. Claim 16). The PTE Claims also require certain release characteristics in the body when the formulation is injected, namely, "controlled release" and "upon injection releases aripiprazole over [a specified period of time]".

E. Cross-Appeal (NoCA [3]-[4])

17. The FFC applied the incorrect test to determine whether claims limited by result satisfy s 40(2)(b). The FFC ignored the principle that a claimed limitation must be able to be used by the PSA to be able to adjust the article to avoid infringement. If the FCJ stands, then the reason why the law has permitted claims by result is undermined.

18. ***NoCA 3(a), (b).*** The FFC misunderstood *General Tire* 515 and erroneously disregarded Blanco White [4-413] and ignored [4-703] *cf, Myriad* [13], [14], [154]; FCJ [79], [89]-[90], [112], [113]; RS [99]-[106]; RR [11], [13], [14]. The FFC erred in finding that the primary judge applied the incorrect test and, therefore, it was appropriate for it to consider the position: FCJ [91], [92]. The primary judge applied the correct principles including

as informed by the expert evidence, finding that the Patent does not show the PSA how to determine whether or not all formulations (including those which lie closer to the boundaries of the PTE claims) satisfy the claims; "the instructions in the Patent are meaningless to" the PSA; and "these matters would cause difficulty to a manufacturer wishing to satisfy himself that he is not infringing the PTE Claims": PJ [264], [265], [266].

19. ***NoCA 4(a), (c).*** In construing a patent, the court is to place itself in the position of the PSA informed by the expert evidence. The primary judge did so, including by finding that "release" is different to BPC (PJ [70], [71], [244], [245], [247]) and that Example 4 and Figure 3 does not assist the PSA in determining how BPC data can be used to determine release (PJ [253]-[260]): RS [94]-[97]. The primary judge also determined that the PSA could not rely upon the CGK to perform routine experimentation to extrapolate from BPC to release: PJ [283]-[297]. The FFC erred in construing the Patent inconsistently with the expert evidence including by finding that BPC was a "surrogate" for release (FCJ [102]-[108]; RS [107]-[108]; RR [15]), and also erred by ignoring that the patentee of its own choosing claimed "release" as the limitation by result: RS [109].

20. ***NoCA 4(b).*** The FFC erred in finding that Example 1 and Figure 3 provided a "workable standard": FCJ [109]-[115]; RS [110]-[112]; RR [9]-[10]. The invention claimed in the PTE Claims is not defined by a disclosure of a *single* formulation far exceeding the claimed limitation. That information is not sufficient for the PSA to adjust its formulation to avoid infringement. The FFC erred in rejecting the finding at PJ [264] and in doing so ignored that the Relevant Features needed to function as limitations by result.

21. ***NoCA 4(d).*** The FFC erred by ignoring the primary judge's findings that the Otsuka documents: (1) fortified the conclusion that the PTE Claims lacked definition because of the significant inter-patient variability in BPC; and (2) demonstrated that if the PSA was to attempt to extrapolate from BPC to release, such experiments would be non-routine and provide greatly variable results: PJ [267], [294]; RS [113]; RR [16].

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