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A handwritten signature in blue ink that reads "Sia Lagos".

Registrar

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Abbey Laboratories Pty Ltd & anor v Virbac (Australia) Pty Ltd

NSD1847/2025

APPELLANTS' OUTLINE OF SUBMISSIONS IN REPLY

A. INTRODUCTION

1. The primary judge's finding to the effect there was no disclosure of the specific combinations in the Virbac Patent, is another way of expressing the primary judge's finding about the need for a skilled addressee to make "*choices*". The effect of the primary judge's reasoning at J [194]-[195] was that, because a skilled person would need to make "*choices*", there was therefore no disclosure of the specific combination – one would have to make the "*choices*" to get there. Contrary to Virbac's submissions in answer (VS) at [1] and [9], there is no real difference between those findings, so Abbey cannot be criticised for challenging one but failing to challenge the other – Abbey's central appeal point addresses them both.
2. Contrary to VS [2], Abbey is not searching the interstices of the document to mosaic them together, and it is not seeking to 'plug gaps' with CGK (a criticism, so far as Abbey can tell, that applies only to disclosures as to stability and the form of levamisole). As a matter of substance, the specific combinations of the Virbac Patent are anticipated, because 984 gives clear recommendations (or directions, if there be a relevant difference) corresponding to each integer of the claimed formulation.
3. Abbey addresses Ground 1 of the appeal in these reply submissions because of its significance for the Appeal.

B. GROUND 1

4. ***Theoretical breadth does not reflect a pragmatic reading of 984.*** At VS [6] and [8] Virbac points to the theoretical breadth of 984 as a way of undermining the sufficiency of the disclosure. While the mathematical flourishes are interesting, they don't reflect the pragmatic way a skilled reader would approach 984. The skilled addressee would not set out to contrive every possible permutation before identifying a fully formulated candidate. The better view is that the skilled reader would turn to the paragraphs beginning 984 p 69, understand them as the culmination of the specification, and read each as providing a series of progressively narrowing instructions for preparing a veterinary parasite treatment.
5. The natural reading of those paragraphs is that they teach that a series of choices may be made in the formulation of such a product. For instance, when it comes to solvent selection, 984 para 13 directs the skilled reader to four solvents – amongst them, DMI is specifically directed (thus claim 1) as is DMI with diethylene glycol monoethyl ether (a glycol ether, thus claim 3). Although Virbac seeks to diminish this by pointing to the fact that the number of possible combinations is larger – amounting to "15 possible combinations" at VS [8]– even that is hardly a disclosure so obscured that it is "*buried*" in the prior art *cf* VS [11] citing *Dr Reddy's*. To the contrary, 984 para 13 contains individualised recommendations for the claimed solvents. Put another way, if one were to

follow the teaching in para 13 of 984, the skilled addressee would find a direction to use an infringing solvent. This is sufficient to anticipate the relevant integers of claims 1 and 3.

6. Further, and in the language of *Hill v Evans* (1862) 4 DeG., F & J. 288 (see VS [11]), the disclosures in 984 para 13 are obviously qualitatively “*equal to*” the claim 1 integers concerning solvents:

(a) 984 para 13 states the carrier “*is*” one of four solvents, or mixtures thereof;¹

that disclosure is equal to:

(b) Virbac Patent claim 1, where the formulation is to be dissolved in “*one or more solvents selected from*” four solvent options², and

(c) Virbac Patent claim 3, where the solvents must “*includ[e] a blend*” of DMI and one of four other solvents (generously counting “glycol ethers” as one).³

7. ***Narrower disclosures do not ‘withdraw’ wider recommendations.*** At VS [7] and [20], Virbac emphasises that there are narrower disclosures of 984 (e.g. as to praziquantel, 984 para 15) which do not anticipate the claims, in an attempt to diminish the fact there are earlier disclosures that *do* anticipate integers concerning ingredients of the formulation. However, the fact there are further, narrowing recommendations at 984 para 15 for the use of praziquantel as an anthelmintic does not mean the clear recommendations in 984 for anthelmintics other than praziquantel (i.e. levamisole) at paras 1 and 10, are somehow ‘withdrawn’ such that they are not sufficiently clear to anticipate. Nor does it ‘teach away’ in the manner Virbac suggests at VS [20].

8. A similar circumstance arose in *Hanwha*,⁴ where the claims of the patent in suit included, amongst other things, a first dielectric layer comprising *aluminium* oxide. The prior art, Isaka, made directions for the layer to be made out of aluminium oxide, but also silicon oxide, or a combination of two. The authors of Isaka then went further, identifying *silicon* oxide as a “*particularly preferable*” material. However as Burley J found, those narrower preferences “***do not withdraw the recommendation that, as the document states, it is***

¹ 984 para 13 reads: *The topical veterinary composition of paragraph 1, wherein [sic] the pharmaceutically acceptable carrier is triacetin, glycerol formal, diethylene glycol monoethyl ether, dimethyl isosorbide, or mixtures thereof.*

² The Claim 1 solvent integer is “...with both of said actives being dissolved in a non-aqueous system including one or more solvents selected from dimethyl acetamide, dimethyl isosorbide, diethyl phthalate and dimethyl phthalate”.

³ Claim 3 is: “A formulation as claimed in any one of the above claims in which the levamisole active ingredient and the at least one macrocyclic lactone active ingredient are dissolved in a system including a blend of dimethyl isosorbide and a second solvent selected from dimethyl acetamide, diethyl phthalate, dimethyl phthalate and glycol ethers”.

⁴ *Hanwha Solutions Corporation v REC Solar Pte Ltd* [2023] FCA 1017.

*preferable that the second passivation film be **one of the three** options mentioned”*: at [489] (emphasis added). Isaka did not fail to anticipate the integer for this reason.⁵

9. ***General Tire is consistent with the way Abbey puts its case.*** As for VS [10], Abbey agrees that the primary judge correctly summarised the relevant principles from *AZ FC* and *General Tire*. Abbey observes that the passage from *General Tire* at 486, extracted at VS [10], is not an obstacle to the way in which it puts its novelty case. The passage contemplates the need for a single, clear direction. The application of *General Tire* principles to the integers of a given claim can be usefully understood against *AZ FC* and the Full Court’s findings about the claim integers impugned in that case:
 - (a) the prior art disclosed the following about diseases: “*The compounds of the present invention inhibit the HMG-CoA reductase, which plays a major role in the synthesis of cholesterol, and thus they suppress the biosynthesis of cholesterol. Therefore, they are useful in the treatment of **hypercholesterolemia, hyperlipoproteinemia and atherosclerosis***”: see *AZ FC* [256]. This amounted to an anticipation of the integer of the patent in suit regarding treatment of hypercholesterolemia: the skilled reader was unmistakably directed to treat the disease the subject of the patentee’s claims;
 - (b) the disclosure as to dosage was different, as Virbac appears to agree at VS [14]. It depended on indeterminates and left variables open to the skilled addressee. In effect it set a puzzle for the reader: “*The dosages **may vary with the administration route, age, weight** condition, and the kind of **disease** of the patients, but are **usually 0.5–200 mg/day, preferably 1–100 mg/day for oral administration and 0.1–100 mg/day, preferably 0.5–50 mg/day for parenteral administration. They may be used in **single or divided** doses***”. Applying *General Tire*, the Full Court found at *AZ FC* [298], the skilled addressee “*might seek to use one or any number of different dosages and dosage regimes*” and while it was possible the skilled addressee might use the dosage regime of claim 1 or 2, “*it was equally possible that such a dosage and dosage regimen might not be used*”. Thus, the *General Tire* test was not satisfied for *this* integer.
10. Turning to the application of those principles in this case, *cf* VS [14], the recommendations identified by Abbey in Ground 1 of the Appeal are not ‘more akin’ to the *AZ FC* ‘dosage’ integer at (b) above. The directions regarding levamisole, macrocyclic lactones, the use of DMI with other non-aqueous solvents, as a pour on for cattle, and as a stable formulation, are each specifically disclosed. 984 thus discloses each integer of claim 1.

⁵ Isaka failed to anticipate the integer for reasons other than the need to make choices - namely, because the way in which Isaka recommended using aluminium oxide *would not work*: see [494].

11. As for VS [20], Virbac misunderstands the way in which *AZ FC* [298] applied *General Tire* extracted at VS [10]; and misapplies *AZ FC* [298] to the facts in this case. When *General Tire* referred to the way in which a skilled reader was ‘likely’ to follow a direction, it took each particular direction on its face. In *AZ FC* [298], the Court applied that principle to directions in the prior art that each related to integers of the given claim. The ‘likelihood’ of carrying out those directions was a way of assessing the specificity of the disclosure for a given integer, as set out in [9] above. *Cf* VS [20], in this case, 984 para 10 specifically teaches that levamisole is suitable as the anthelmintic of the formulation, amongst others. A skilled person following *that* direction to use levamisole, would inevitably use levamisole. It is irrelevant that 984 recommends other anthelmintics from which levamisole may be chosen.
12. ***An integer by integer analysis is conventional.*** At VS [12] last sentence, and VS [13], Abbey is criticised for proceeding on an “*integer by integer*” analysis. But there is nothing unorthodox or impermissible in that approach. When analysing whether the essential features of a claim are anticipated, one has to identify those features, and it is a natural part of that analysis that one goes on to consider those features or integers in turn. See for instance *Hanwha* where the analysis proceeded by identifying “the contested integers” [475]ff, then addressing “Integer 9(c) (first dielectric layer comprising aluminium oxide)” ([486]ff) and “Integer 9(d) (thickness of the first dielectric layer)” ([496]ff) in turn; before turning to what dependent claims 12, 13, and 21 ‘added’ to dependent claim 9: [508]ff. Virbac’s insistence that the whole of the claim must be considered as one analytical unit is impracticable, unrealistic, and at odds with the approaches conventionally taken by other litigants in this court that do proceed integer by integer.
13. ***UK cases.*** As for VS [15], the Australian law of novelty is well-established, and there is no need to reach for recent UK authority to clarify it. In any event, the UK cases proceed upon the same principle as the Full Court did in *Bristol Myers* (discussed below) namely, that a ‘mere’ disclosure of the integers of a claim may not always be sufficient for anticipation. The example used in the UK cases cited by Virbac is the Markush formula: such a disclosure may well encompass a claimed compound, but that alone is not necessarily sufficient for anticipation. In the language of the UK courts adopted from the European Boards of Appeal, what is required is an “*individualised description*” of the compound along with a “*specific teaching with regard to technical action*”, the latter of which equates to a teaching or direction, recommendation, or suggestion: see *ModernaTX, Inc v Pfizer Inc* [2025] EWCA Civ 1032 at [44].⁶
14. Abbey observes that the present case is quite different from a ‘mere’ disclosure in the nature of a Markush structure, and there are self-evidently individualised descriptions of

⁶ See also *AstraZeneca AB v Pharmacor Pty Ltd* [2026] FCA 88 at [47].

the relevant integers of the claims (DMI, levamisole etc) in 984, and express teachings to use them in veterinary compositions for the treatment of parasites in cattle.

15. **Abbey conducts a novelty analysis.** As for VS [17], Abbey does not confuse the novelty analysis with an obviousness enquiry. Virbac misunderstands the submission. By identifying 984 para 1 as the ‘starting point’, Abbey was addressing the way in which the document ought to be understood. That is, 984 para 1 identifies the key features of the formulation of 984, with the successive paragraphs providing successively narrower disclosures in respect of them.
16. **Bristol Myers.** As to VS [19], it is not correct to say that Abbey misapplies the decision in *Bristol Myers*.⁷ In support of that submission, Virbac appears to rely on the comments of the primary judge at J [192], which are as follows:

Abbey relies on the statement in Bristol-Myers...to the effect that a prior publication, if it is to destroy novelty, “must give a direction or make a recommendation or suggestion” which will result, if the skilled reader follows it, in the claimed invention. Abbey’s preference for the notion of a “recommendation” as an alternative to a “direction” is reflected at numerous points in the Appendix and in its oral submissions. However, as the Full Court observed in Mylan,⁸... Black CJ and Lehane J were not stating a statutory test, but were seeking to capture and explain the notion conveyed by the cases of the sufficiency of the disclosure that a prior art document must make before it can deprive an invention of novelty, and that notion is not elucidated by exploring the linguistic limits of words such as “recommend” and “suggest” as ordinary English words. Their Honours treated the reasoning of Black CJ and Lehane J as turning on an evaluation of the facts of the case, and not on any new or modified principle of anticipatory disclosure: at [102].

17. It is not altogether clear what the primary judge meant to convey here. The Full Court in *Mylan* was not suggesting that a recommendation would fall short of a direction, or vice versa. Abbey reads the Full Court as accepting that the language of *Bristol Myers* was apt to explain why in that case a merely incidental disclosure, in reports of dosage tolerance trials, of the integers of the claimed methods for a treatment of cancer did not constitute anticipation. Rather, the disclosure needed to be accompanied by some teaching or encouragement to actually use those integers in a method for the treatment of cancer. If the primary judge took the view that such teaching or encouragement needed to be a direction rather than a recommendation then that would be an error: see *Merck & Co Inc v Arrow Pharmaceuticals Ltd* (2006) 68 IPR 511 at [110]. If VS [19] is expressing such a view, that is likewise an error.

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For the Appellants

5 August 2026

⁷ *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* [2000] FCA 316.

⁸ *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd* [2020] FCAFC 116; (2020) 279 FCR 354 at [89] (Middleton, Jagot, Yates, Beach and Moshinsky JJ).