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NSD 1847/2025

Federal Court of Australia

District Registry: New South Wales

Division: General

On appeal from the Federal Court

Abbey Laboratories Pty Ltd (ACN 156 000 430)
First Appellant

Abbey Animal Health Pty Ltd (ACN 164 159 764)
Second Appellant

Virbac (Australia) Pty Ltd (ACN 003 268 871)
Respondent

RESPONDENT'S OUTLINE OF SUBMISSIONS IN ANSWER

(29 July 2026)

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A. Introduction

1. Contrary to the central plank of the Appellants' (together, **Abbey**'s) appeal (e.g. AS [1], [14]), the primary judge did not reject Abbey's novelty attack merely because the skilled addressee may need to make "*choices*" to arrive at the claimed invention, or because of the "*existence of alternatives*" in the 984 Patent.[1] Rather, the primary judge applied the settled principles, in particular ***General Tire*** *& Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 as explained in *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324 (***AZ FC***), to find that there was no **disclosure** of the **specific combinations** claimed in the Patent.

2. What Abbey sought to do at first instance, and continues to do on this Appeal, is impermissibly mosaic together disparate parts of the 984 Patent and, where necessary, plug the gaps with common general knowledge (**CGK**): see e.g. *Abbey Laboratories Pty Ltd v Virbac (Australia) Pty Ltd (No 3)* [2025] FCA 1179; 187 IPR 348 (**J**)[2] [195]. The primary judge correctly found that Abbey's approach was "*limited to separating the constituent parts of each claim of the Patent and then seeking to identify any reference to each of those constituents in different parts of the 984 Patent specification*": J [187].[3] The Appeal is fatally afflicted by the same defect and should be dismissed with costs.

3. The Court found claims 1 to 10, 13, 15, 16 and 18 valid and infringed. Abbey conceded infringement below, subject to validity. Abbey must establish that **each** of these claims is invalid to overcome the injunctive relief ordered below and the consequences of infringement.

B. The Patent

4. The Patent[4] states that there is a "*need for a stable topical formulation containing a macrocyclic lactone anthelmintic and levamisole, and that promotes improved transdermal absorption of the two anthelmintic active ingredients as well as reduced tendency for run off*": J [14]. It describes the claimed invention as "*providing an improved ready to use combination of anthelmintics selected from two different anthelmintic classes*", so as to reduce resistance.[5]

5. Importantly, the claimed invention is a very specific combination of levamisole and a macrocyclic lactone, dissolved in precisely identified solvents, in specified proportions, in a stable topical non-aqueous formulation for cattle. The Patent describes a solvent-selection process trialling thirteen solvents, from which it was found, surprisingly, that dimethyl

[1] Appeal Book (**AB**) Part C Tab 214.
[2] AB Part A Tab 11.
[3] The primary judge also found that Dr Alawi failed to approach the novelty analysis appropriately, having treated the 984 Patent as a document that he could deploy in respect of his inventive step "*task*", e.g. that he "*use[d] [his] ability as a skilled formulator to make choices about…how [he] would proceed if [he] read this document*": J [195].
[4] AB Part C Tab 213.
[5] Patent 6:7-9.

isosorbide (**DMI**) performed best: J [17]. Because of the cost of DMI, the Patent also identifies the desirability of a co-solvent, including dimethylacetamide (**DMA**) and diethyl phthalate (**DEP**): J [19]. The Patent contains 22 claims, set out in full at J [25]. Importantly for following the argument, a **non-aqueous solution** including **levamisole** and **one or more of DMI, DMA, DEP or dimethyl phthalate** in a **topical formulation for administration to cattle** are all essential integers of claim 1.

C. The 984 Patent

6. The primary judge reviewed the 984 Patent at J [148]-[188]. At least until closing submissions (J [187]), Abbey's novelty case below was advanced through Dr Alawi, to whose evidence Professor Bunt responded. The primary judge preferred the evidence of Professor Bunt.[6] There is no challenge to that finding. As the primary judge accepted, the 984 Patent is a "*shopping list patent*", providing "*several 'shopping lists' of potential active ingredients, potential target parasites, potential modes or forms of administration, potential target animals, and potential excipients (including solvents)*".[7] The scale (and number) of those lists and their consequential permutations is instructive. For example, the 984 Patent refers to dozens of active ingredients and "*very long list[s] of solvents*", "*taking up about fifteen lines of text*" on page 6 and "*fourteen lines*" on page 39: e.g. J [152], [158]. Its embodiments include several different forms of administration, including emulsions, pastes, gels or creams, which Dr Alawi accepted would contain water, and would "*plainly enough*" not be a solution.[8]

7. Each of the Examples in the 984 Patent is limited to cats, using a "*spot-on*" formulation, which have very different formulation considerations: J [151], [167]. None of the five examples uses levamisole and instead identifies praziquantel as the anthelmintic agent. Critically, where the 984 Patent claims a specific anthelmintic within a specific formulation (e.g. "paragraph 15" or claim 15), it, again, is not levamisole but rather praziquantel: J [186(e)].

8. Abbey places particular reliance on the numbered paragraphs beginning on page 69 of the 984 Patent. These correspond to the claims beginning on page 76. Paras 1, 10, 12 and 13 are of particular relevance to Abbey's appeal. The primary judge identified para 1's shortcomings at J [171] (not challenged on appeal). There are 16 possible anthelmintic agents[9] identified in para 10 (J [174]), any one of which might be used in the composition of para 1.[10] Only one of these is levamisole. There are 27 pharmaceutical carriers or solvents identified in para 12 (J

[6] See J [37]; and for example J [53]; J [62]; J [71]; J [111]-[112].
[7] J [186]; Bunt 1 (AB Part C Tab 34), [281], [463(a)], [552].
[8] J, [160].
[9] The last two "agents" are in fact classes of agents of an unknown number.
[10] The calculations that follow are a continuation of those raised at trial: Day 4, T15.38-T16.19; T78.24-T80.40 (AB Part C Tab 242).

[176]), each of which might be used in the composition of para 1 either singly or in any combination. This amounts to 134,217,727 possible choices.[11] DMI and DMA are included in the list. Para 13 identifies 4 carriers or solvents (J [177]), any one of which might be used alone or in a mixture, one of which is DMI. This amounts to 15 possible combinations.[12] Putting aside all other integers, there are 2,147,483,632 possible combinations of anthelmintic agents and carriers/solvents via paras 1, 10[13] and 12.[14] Para 13 read with paras 1 and 10 discloses 240 possible combinations of agents and carriers/solvents.[15]

D. <u>Ground 1</u> – A false premise; the novelty principles were correctly applied

9. Ground 1 proceeds on the premise that the primary judge rejected the novelty case because the skilled addressee would need to make "*choices*" (see too AS [14]). This is a reductive reading of the primary judge's reasons. There is no attack on any of the primary judge's findings of fact or law from J [148] to J [193]. The first two sentences of J [194], and the first sentence of J [195] are important. There is simply no disclosure of the specific claimed combinations of the Patent in the 984 Patent nor any directions which, if followed, would inevitably result in such combinations. That is sufficient to dispose of the appeal.

10. ***Relevant novelty principles.*** The primary judge correctly summarised the relevant principles at J [189]-[193]. As the primary judge recognised, the statements of principle from *General Tire* have been described by the Full Court in *AZ FC* as the "*touchstone*": J [190]. In short, the prior art document must contain clear and unmistakable directions to do what the patentee claims to have invented: J [190]-[191].

> If, on the other hand, **the prior publication contains a direction which is capable** of being carried out in a manner which would infringe the patentee's claim, **but would be at least as likely to be carried out in a way which would not do so**, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness.[16]

11. Critically, a prior disclosure must provide information "*equal to*" the invention claimed, in the sense of being both specific and complete: *Hill v Evans* (1862) 4 DeG., F & J. 288; 1A IPR 1 at 6-7 (Lord Westbury); ***Mylan*** *Health Pty Ltd v Sun Pharma ANZ Pty Ltd* (2020) 279 FCR 354 at [82], [87], [89]. For example, a compound or combination "buried" among many is not clearly disclosed,[17] or where, as Burley J observed in *Hanwha Solutions Corp v REC*

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[11] Any combination of 27 options, including single use but excluding no use at all, is $2^{27} – 1$.
[12] $2^4 – 1$.
[13] Inaccurately treating the last two "agents" of para 10 as single agents. The real number is higher.
[14] 16 x 134,217,727.
[15] 16 x 15. The same qualification about para 10 applies.
[16] *General Tire* at 486.
[17] *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2010] RPC 9 at [26], [28]; *AZ FC* [285]-[286].

Solar Pte Ltd (2023) 180 IPR 315 at [505],[18] a range with a set of variables that is so broad, the disclosure will be "*a far cry from a clear and unmistakable direction*".

12. Whether a document that discloses a range of possibilities anticipates a particular claim is a question of fact and degree, sensitive to the breadth of the range and the number and significance of the variables: *AZ FC*, [285]-[290]; J [193]. One must examine each claimed combination as a whole, and consider, on an application of orthodox principles, whether each combination was disclosed in the prior art.

13. ***AZ FC was correctly applied.*** Contrary to AS [6]-[15], there was no error in the primary judge's application of *AZ FC*. Consistently with *AZ FC*, the primary judge compared the claims of the Patent against the disclosure in the 984 Patent and found there was insufficient disclosure of the *specific* claimed *combinations*. Abbey's approach of trying to shoe-horn the facts of *AZ FC* into the primary judge's analysis should be rejected. The last sentence of J [193] is apt; see too *Mylan* at [109]. Abbey's parsing of the Full Court's reasoning in AS [6]-[13] is again focused on an integer-by-integer analysis, failing to observe the overriding concern of the Full Court as to whether there is a specific disclosure of "*all of the combined features*" of the claims: *AZ FC,* [295]. Ultimately, it must be remembered that the anticipation argument in *AZ FC* **failed**, because the entirety of the claimed combination was not disclosed with sufficient specificity.

14. The facts here are not analogous to the "*disease state*" or "*compound*" integers of *AZ FC* referred to in AS [6]-[13]. In *AZ FC,* two salts of rosuvastatin were **exemplified** as useful in the treatment of **each** of the three diseases in the prior art: AZ FC [287]. That was an express disclosure of the particular integers in question. There is no equivalent disclosure of the claimed combination here, indeed the examples teach away. The failure of the argument in *AZ FC* based on the dosage integer is more telling. Oral doses in the range of 1-100 mg per day were disclosed as preferred. The claim required 5 or 10 mg per day. A 5 mg or 10 mg dose were each clearly possibilities within that range but there were many possibilities outside the claim: *AZ FC* [288], [289].[19]

15. ***The primary judge's approach is consistent with recent UK authority.*** In *ModernaTX, Inc v Pfizer Inc* [2025] EWCA Civ 1032, the Court of Appeal affirmed that prior disclosure is "*a strict test*", and considered that while the whole of a document must be considered, that "*does not mean that it is a reservoir from any part of which a feature can be taken to combine with*

[18] Referring also to *AZ FC* and *Apotex Pty Ltd v **ICOS** Corp (No 3)* (2018) 135 IPR 13.
[19] If doses were considered in 5 mg increments, there were 18 choices outside the claim. In 1 mg increments, there were 98 choices outside the range, far fewer than the possibilities in the present case.

a feature from some other part, in the absence of a clear teaching to do so": [40], [41]. And further, a feature is not novelty-destroying merely because selecting it from a list would have been an obvious choice, that is "*emphatically not*" the test: [56]-[57].[20] See too *Laboratorios Almirall S.A. v Boehringer Ingelheim Pharma GmbH & Co KG* [2009] FSR 12 at [222] (a "*bewildering list of choices*" from which no "*individualised combination*" falling within the patent had been disclosed), and *GlaxoSmithKline UK Ltd v Wyeth Holdings LLC* [2016] EWHC 1045 (Ch) at [156]-[169].

E. Ground 2 – Claim 1 not anticipated

16. The first two sentences of AS [17] highlight a major vice in Abbey's approach. Abbey states that 984 para 1 directs the reader to make a composition "*containing the majority*" of the integers of claim 1 (i.e., not ***all***). Abbey concedes that the skilled addressee must then *find* the remaining integers in the paras that follow 984 para 1 or otherwise earlier within the 80-page document. Further, Abbey's repeated use of "*thus*" in AS [17] betrays its fallacious reasoning on the appeal. Treating an "*animal*" does not disclose integer 1.4, which is specific to cattle; "*another anthelmintic agent*" does not disclose integer 1.1(a) which is specific to levamisole; a "*pharmaceutically acceptable carrier*" does not disclose the specific solvents of integer 1.2; and of course it is disclosure of the integers in the specific combination that is critical.

17. Reading the document "*as a whole*" is not permission to jigsaw pieces together from different parts of a document, nor does it obviate the requirement for a "*clear and unmistakable direction*" of the specific combination. Similarly, Abbey's contention that 984 para 1 supplies "*the **starting point** by which the skilled reader would understand the recommendations in the whole of 984*" only serves to confuse the novelty inquiry which must be kept separate from any type of obviousness analysis: AS [17]. This was the error correctly characterised by the primary judge at J [195].

18. ***Choice of animal.*** Claim 1 of the Patent requires that the specific combination be formulated for use in cattle. At trial, Abbey and Dr Alawi relied on 984 para 1, however, that para does not specify any particular target animal, and would include treatments for several animals other than cattle, each requiring different formulation considerations.[21] Further, "animal" is defined very broadly in the 984 Patent, including humans.[22] All of the examples in the 984 Patent are to cats.[23] Abbey relies on a reference to cattle at the end of a list of nine "*livestock*

[20] Relatedly, in *Celltrion Inc v Genentech, Inc* [2025] EWHC 174 (Pat) at [66], [72], the Court held that where claimed subject matter is reached by selection from two or more independent lists, regard must be had to the effective size of the total number of alternatives across those lists, and to whether the prior document indicates any preference among them.
[21] T254.39-43 (AB Part C Tab 240).
[22] See page 9:23-27; J [196].
[23] J [186(j)]; Bunt 1 (AB Part C Tab 34) [292].

and companion animals" on page 5: AS [18]. Not only do the ellipses in Abbey's extracted quote obscure the nature of the disclosure, Abbey fails to confront the need for the relevant integer to appear in the claimed combination. Neither on page 5, nor on any other page of the 984 Patent, is there a clear and unmistakable direction to make a composition for cattle with each of the essential integers of claim 1.

19. ***Choice of anthelmintic agent.*** The limitations of the levamisole disclosure have been addressed above. Abbey submits (AS [19]) that 984 para 10 is a "clear **direction** to use levamisole as **the** anthelmintic of the composition" (emphases added). This is not a fair reading of the text or context. To submit that para 10 "*recommended each*" of the 16 options is to misapply *Bristol-Myers Squibb Co v FH* ***Faulding*** *& Co Ltd* (2000) 97 FCR 524 in the manner warned against by the Full Court in *Mylan* at [102] and correctly applied by the primary judge here (without challenge on appeal): J [192]. Abbey also misconstrues Professor Bunt's evidence. At T 261.3-7, he agreed that he "*might*" use levamisole as one of his active ingredients. It was not put to him that he was directed to use it.

20. Importantly, when the 984 Patent does specifically identify an anthelmintic agent in combination with specific solvents, it identifies praziquantel <u>not</u> levamisole. The ambivalence of the 984 Patent about levamisole is palpable – it is not mentioned anywhere in the detailed description of the invention or the examples. Praziquantel is the anthelmintic agent selected for each of the formulations in the examples in the 984 Patent.[24] This is a direction ***away*** from levamisole. It cannot be said that the skilled addressee "*would inevitably*" make a composition using levamisole (*AZ FC*, [298]), much less using levamisole in combination with the other essential integers of claim 1.

21. ***Choice of mode of administration.*** Claim 1 requires the composition to be a topical formulation, and one that is a solution (requiring "*both of said actives being dissolved*" (J [198])). Dr Alawi agreed that compositions within 984 para 1 need not be in solution, and include emulsions, gels and pastes, confirming that 984 para 1 is "*a general one*".[25] Nothing in the 984 Patent directs the skilled reader to a solution in preference to any of those other forms. As to AS [20], the "*pour-on solution*" passage on page 47 concerns one embodiment, presented as an option alongside the emulsions, gels and pastes contemplated by para 1. The 984 Patent does not disclose an unmistakable direction to this embodiment, nor does it direct that a solution be made with the specific actives, solvent system and target animal of claim 1.

[24] 984 Patent page 63 to 69; Bunt 1 (AB Part C Tab 34), [321]-[371]; Alawi 3 (AB Part C Tab 25) [23].
[25] T256.21-25, T257.3-23; T258.10-16.

22. ***Choice of aqueous versus non-aqueous system.*** Claim 1 of the Patent requires a non-aqueous solvent system, i.e., no water used.[26] There is no requirement in the 984 Patent that the solvent system be non-aqueous: J [158]. Indeed, water is referred to throughout the 984 Patent.[27] Dr Alawi accepted that the composition of 984 para 1 could include an aqueous system.[28] As to AS [22], the mere omission of water from the lists of solvents in paras 12 and 13 in the 984 Patent is far from a clear and unmistakable direction to exclude water altogether from the composition, particularly in the context where para 1 permits an aqueous system and the specification expressly contemplates aqueous embodiments.

23. ***Choice of specific solvents.*** The limitations of the solvent disclosures in the 984 Patent paras 12 and 13 are addressed above. Dr Alawi accepted that rather than "*defining*" a composition, paras 12 and 13 merely "*identify ... potential candidates*", giving "*many options ... of carriers"*.[29] AS [23] reveals further misuse of *Faulding* by elevating the DMI disclosure to a "*direction*", and characterising the other candidates as "*recommended*". 984 para 13 does not differentiate between the possible solvents.

24. Each of paras 12 and 13 refers to the composition of 984 para 1, not 984 para 10. That is, the terms of the 984 Patent do not require that a para 12 or para 13 solvent be combined with levamisole. Contrary to AS [23], that drafting is not a technicality to be brushed aside. It is the clearest available evidence of what the 984 Patent itself does, and does not, disclose as a combination. The primary judge's reliance on the absence of cross-reference between paras 10 and 13 was not "*akin to claim construction*" impermissibly imported into the anticipation inquiry as Abbey suggests; it was a conventional and necessary step of asking what the prior publication, read in context, actually discloses. Reading "*cumulatively*" is another way of asking the Court to retrospectively unite passages which the 984 Patent's own authors separated. Contrary to AS [23], this approach is not inconsistent with *AZ FC.* DMI's inclusion among several unranked solvent candidates in para 13 is far from the complete and specific disclosure of exemplified rosuvastatin salts: e.g. *AZ FC,* [287].

25. ***Stability.*** Importantly, the Patent provides a specific definition of stability.[30] The patentee has acted as its own lexicographer and specifically defined a stable formulation for the purposes

[26] A "*non-aqueous system*" means that "*there is no water used*": Alawi 4 (AB Part C Tab 26), [30]; Bunt 1 (AB Part C Tab 34), [535]-[536].
[27] Including at pgs 15:5-10, 39:8-11, 41:28-29 (capsules), 41:31-32 (emulsions), 42:23-28, 43:9-24 (aqueous suspensions) and 44:23-31 (sterile injectable solutions); J [199].
[28] T257.29 - T258.4. Dr Alawi's reference to "our task" shows that he read the 984 Patent as if in an obviousness context.
[29] T259.39 - T260.12; J [200].
[30] Patent 6:20-23.

of the specification, including the claims defining the invention.[31] Contrastingly, as Abbey accepts, the paras describing the invention of the 984 Patent do not specifically require a stable formulation so defined. As to AS [25], the statement at page 36 of the 984 Patent that the compositions of the invention "*have been surprisingly discovered to be stable*" is a generalised statement in the body of the specification, untethered to the specific embodiments from page 69 onwards, let alone to any particular combination of animal, anthelmintic, solvent and mode of administration, or to any particular stability standard. The only worked example bearing on stability is Example 5, which uses praziquantel, not levamisole. Contrary to AS [25], the primary judge was entitled to give weight to the fact that the 984 Patent's own chosen illustration of a stable formulation does not use the anthelmintic on which Abbey's anticipation case otherwise depends. Professor Bunt's oral evidence was that the 984 Patent disclosure is "*too broad*" to disclose that every combination of every active ingredient and solvent referred to in the specification is stable,[32] and his CGK evidence of the stability characteristics is irrelevant to novelty: *cf* AS [25].

F. <u>Ground 3</u> – the dependent claims are not anticipated

26. Ground 3 suffers from the same defects as Ground 2. Abbey fails to identify a clear and unmistakable direction to the specific combination clamed in each of the dependent claims.

27. ***Claims 2, 7 and 10.*** Claim 2 requires one or more of the specific claim 1 solvents in a concentration range of 20% to 85% w/v. Abbey relies on the embodiment on page 50 of the 984 Patent, however, as correctly found by the primary judge, that embodiment does not refer to the claim 1 solvents (or indeed, any solvents at all), and does not require the use of levamisole: J [203]; c*f* AS [27]. In order to avoid that reality, Abbey contends that the skilled addressee would skip ahead thirty pages in the specification to the list of solvents in para 13 on page 89, and construe those two passages (without any cross-reference) as a clear and unmistakable direction. The Court should reject that contention. The same reasoning applies for claim 7 and claim 10: J [206], [208]; AS [28]-[29].

28. ***Claim 3*** requires the use of DMI **and also a second solvent** from the identified claim 1 solvents. On appeal, Abbey only relies on para 13 of the 984 Patent, asserting that the list in para 13 is not "*materially distinguishable from the disclosure of the 471 Patent in AZ FC*": AS [30]. However, para 13 is not of the same character. The use of DMI is not required, rather it is simply one of the solvents listed without preference. As to AS [30] (last sentence), Abbey's use of the Latin *inter alia* itself belies its contention of specificity.

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[31] *Danisco A/S v Novozymes A/S (No 2)* (2011) 91 IPR 209; [2011] FCA 282 at [37].
[32] T264.32; T265.1-3.

29. Further, para 13 does not require a mixture at all, far less a particular mixture of DMI with DGME (the only other candidate in para 13 that falls within claim 3 of the Patent). Again, the relationship of para 13 with para 1 (and not para 10) means that the solvents in para 13 need not be used with levamisole. Nor is any such combination disclosed as a composition for cattle in the form of a topical solution: J [204].

30. ***Claim 4*** requires a "*formulation for cattle in solution for topical administration, incorporating levamisole and a macrocyclic lactone, that includes DMI, DMA or a phthalate in addition to one of the co-solvents in claim 4*": J [205]. For the reasons given in respect of claim 3, there is no such clear and unmistakable disclosure in the 984 Patent of the specific combination of claim 4. Abbey's stated desire for the Court to read the paras of the 984 Patent "*cumulatively*" (AS [31]) is, again, an effort to impermissibly pick and choose parts of the disclosure.

31. ***Claim 5*** specifies particular macrocyclic lactones. While para 8 identifies those macrocyclic lactones, para 8 is dependent only on para 1, such that there is no disclosure of levamisole or the claim 1 solvents *in combination* with those macrocyclic lactones: J [206]. AS [32] seeks to deploy the adage of reading "*as a whole*" to reconstruct a combination of solvents, levamisole and macrocyclic lactones into a composition that is inconsistent with the 984 Patent's own internal guide as to what actives are directed to be used with which solvents and for which animals and method of administration.

32. ***Claim 6*** requires a specific stability metric, namely that the active ingredients of the relevant composition remain within 10% of their initial specification for at least 3 months while stored at 25 degrees and at ambient humidity. There is no clear and unmistakable direction in the 984 Patent for a composition of claims 1-5 satisfying the specific stability requirements of claim 6, particularly where, there is no stability data for any composition that includes levamisole as an anthelmintic agent, and no stability data at all consistent with the claimed metric in claim 6.

33. Example 5 does not assist Abbey, as the stability metrics are different: J [207]. Further, there is no stability data at all in respect of a composition with levamisole and DMI/DMA. As to Abbey's attempt to import the CGK into the 984 Patent disclosure at AS [33], Professor Bunt had, at best, a "*hope*" that the defined stability requirement may be satisfied, but pointed out that the disclosure is simply "*too broad*".[33]

34. ***Claims 8 and 9*** require a specific form of levamisole (i.e., base, hydrochloride or phosphate form). As found by the primary judge, "*there are numerous permutations of modes of*

[33] T264.27-32; T265.1-3.

administration, active ingredients (including but not limited to levamisole of any form), solvents (including aqueous solvent systems), and target animal": J [208]. Abbey's reading of "levamisole" as being a disclosure of levamisole in the base form is an exercise of importing from the CGK into a novelty document,[34] particularly in light of its own expert evidence that, "*the levamisole form is not specified in Patent 984, which allows the possibility of using any of these forms*".[35] Further, page 15 of the 984 Patent includes a definition for the term "*base*", indicating that such term was clearly within the drafters' contemplation and one that they decided not to use in conjunction with levamisole. In any event, levamisole is not specifically disclosed by the 984 Patent in the claimed combinations of the Patent: see [19] above.

35. ***Claim 13*** requires the composition to include antioxidants and/or stabilizers. While page 60 refers to antioxidants and stabilizers, that is not in the context of the specific combinations required by the claims, and the primary judge's approach discloses no error: J [209].

36. ***Claim 15*** is a method of treatment in respect of specific parasites by administering one of the claimed compositions. Abbey's approach ought to be rejected, in particular because there is no direction to treat cattle (in the context of a long list of animals in the next sentence), infected with those specific parasites with a composition having levamisole and DMI/DMA: J [210].

37. ***Claims 16 and 18*** are both method of preparation claims, and critically still require levamisole and the specific claim 1 solvents: J [211]-[212]. Abbey relies on the "mixing" passage at page 60, lines 2-4, but that passage does not identify any specific active, nor does it require a solution (the next sentence confirms that the resulting formulation could be one of "*tablets, pastes, pour-on, spot-on, collars, etc*").[36] Nothing in the page 60 passage clearly and unmistakably directs the reader to prepare a solution of levamisole, a macrocyclic lactone and a claim 1 solvent. Curiously, AS [38] suggests that this approach is "*unduly confined*", suggesting that the skilled addressee would serendipitously "*understand*" that the passage on page 60 pertains to a composition containing levamisole, a macrocyclic lactone and DMI in solution, in circumstances where the passage refers to none of those things.

38. The appeal should be dismissed with costs.

N.R. Murray J. M. Elks Counsel for the Respondent **29 July 2026**

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[34] As observed in J [195], "*while the prior art is to be read by the PSA in light of the CGK, it is impermissible to add CGK to fill gaps between what is disclosed in the prior publication and the claimed invention: BlueScope Steel Ltd v Dongkuk Steel Mill Co Ltd (No 2) [2019] FCA 2117; (2019) 152 IPR 195 at [1029] (Beach J); AstraZeneca v Apotex at [352]; Merck Sharp & Dohme Corporation v Wyeth LLC (No 3) [2020] FCA 1477; (2020) 155 IPR 1 at [230] (Burley J).*"

[35] See Formulators JER, [156]-[157], [160]-[161] (AB Part C Tab 226).

[36] See also Alawi T272.37 - T273.12.