IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY **No S 54 of 2015**

BETWEEN:

ASTRAZENECA AB
First Appellant

ASTRAZENECA PTY LIMITED
ACN 009 682 311
Second Appellant

10 **AND:**

APOTEX PTY LTD
ACN 096 916 148
Respondent

RESPONDENT'S (APOTEX'S) SUBMISSIONS

Part I: Suitable for publication

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1. This submission is in a form suitable for publication on the internet.

Part II: Issues

2. Whether the primary Judge and the Full Court were correct in holding[1] that, in terms of s18(1)(b)(ii) of the *Patents Act 1990* (the **Act**), the invention claimed in each of the claims of Australian patent No 769897 (the **Patent**), when compared with the prior art base as it existed before the priority date of the claims, did not involve an inventive step.

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3. Whether, as Apotex contends, the invention claimed in each of the claims did not involve an inventive step on the alternative basis, upheld by the primary Judge, that the inventive concept described in the Patent, properly characterised, is the discovery of a dosage range for rosuvastatin.[2]

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[1] Per the primary Judge [2013] FCA 162, at [327]-[344]; Full Court [2014] FCAFC 99, per Jessup J at [516]-[552]; Besanko, Foster, Nicholas and Yates JJ agreeing at [228]-[229].
[2] At [2013] FCA 162 [218]-[223]. Apotex's Notice of Contention ground 2.

AB1929-AB1935
AB2584-AB2597
AB2497
AB1892-AB1893
AB2637

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4. Whether the Court should grant the leave necessary for the Appellants to rely on an assignment to cure the deficiency in their entitlement to the Patent.

5. The additional issues raised by Apotex's notice of contention, referred to in **Part VII**, below. Apotex does not press ground 3. AB2636-2639 AB2637

Part III: ***Judiciary Act 1903***

6. Apotex considers that no notice should be given in compliance with s78B of the *Judiciary Act 1903* (Cth).

Part IV: **Material facts**

7. Subject to the following, Apotex agrees with AstraZeneca's statement of facts. The arguments in paragraphs 26-32 are answered in Part VI, below.

8. Apotex would add to **AS** para 23 the fact that the recommended doses for statins were common general knowledge,[3] including the fact that the recommended starting dose of atorvastatin was 10mg (a dose within the claims).

9. The "many trillions of compounds" of the 471 Patent was not a reason for the Full Court's holding that it did not anticipate the Patent. See Full Court at [309]: AB2517 cf **AS** para 32. *Watanabe* disclosed the fact that "the clinical trial of S-4522 [rosuvastatin] is in progress". Dr *Reece* assumed from this that "*there was comparative data showing that S-4522 was both safe and potent from animal studies and, possibly Phase I studies in humans and that this data supported the further development of S-4522 in Phase II trials*".[4]

10. There has never been a patent in Australia for the compound rosuvastatin.[5]

Part V: **Applicable provisions**

11. The Appellants' statement of applicable constitutional provisions, statutes and regulations is accepted.

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[3] Primary Judge at [103]-[104]. AB1855
[4] See affidavit of *Philip Andrew Reece* para 173. AB971
[5] Primary Judge at [3]. AB1814

Part VI: Argument on the Appeal

Entitlement

12. The entitlement issue arises on the appeal and on the notice of contention. For the reasons given below, Apotex submits that the decision below to revoke the Patent for lack of inventive step should stand. That would confirm the correctness of the manner in which the Full Court disposed of the entitlement ground. Independently of the result on the s18 issues, however, the appeal should be dismissed solely on the entitlement ground.[6]

13. **AS** paras 3, 67 and 69 fail to confront the Full Court's acceptance of the generic parties' "*very persuasive case for refusing leave to amend on discretionary grounds*", including that they would suffer prejudice if the interlocutory application were allowed: Full Court at [189]. The Full Court would have been "*minded to refuse* [the proposed amendments] *on discretionary grounds*": Full Court at [190]. AB2484 AB2485

14. Apotex's pleading at the trial asserted a lack of entitlement by reason of the contribution of 13 named individuals from whom the Appellants derived no title.[7] Apotex pleaded that these had engaged in unpublished work, including in relation to preclinical and clinical trials, that amounted to a substantial contribution to any invention disclosed and/or claimed in the Patent.[8] In particular, two of them did not work for Shionogi. For example, the Chief Investigator on Shionogi's first trial[9] was *Akira Yamamoto*, the Deputy Head of the National Cardiovascular Centre Research Institute. His or her contribution to the "inventive concept"[10] of the Patent is unknown.

15. At trial, the Appellants' case was that Dr *Raza* was the sole inventor of the invention described in the Patent: primary Judge at [287]; Full Court at [105], [107]. In those circumstances, Apotex did not pursue any broader inquiries AB1916 AB2466 AB2466

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[6] Apotex's notice of contention, ground 1. AB2636
[7] Fourth Further Amended Particulars of Invalidity: Low Dose Patent, para 43. AB88
[8] Fourth Further Amended Particulars of Invalidity: Low Dose Patent, para 43.4 AB89
[9] **Ex A**, tab 3; Dr Yamamoto is named in particular in para 43(j). AB1671-1688
[10] Per French J in *University of Western Australia v Gray (No 20)* (2008) 76 IPR 222; [2008] FCA 498, at [1419]-[1443]. AB88

directed to establishing the identity, in fact, of the real inventor of the Patent: Full Court at [107]. It was sufficient for Apotex to confine its argument at trial to the proposition that employees of Shionogi contributed sufficiently to the invention: primary Judge at [273], [283]-[284]. AB2466 AB1912 AB1915

16. It was Apotex's evidence on the Appellants' interlocutory application in the Full Court that, if the Appellants had notified Apotex at any point prior to or during the trial that it intended to rely on an assignment from Shionogi to the First Appellant, Apotex's solicitors would have advised it to take one or more procedural steps in the proceeding. These included seeking to join Shionogi to the proceeding and applying for discovery orders in respect of documents "*relating to who at Shionogi or elsewhere conceived of the idea to use 5 and 10mg doses of rosuvastatin including ... as starting doses*" (emphasis added).[11] Further potential avenues for discovery included correspondence with Japanese regulatory agencies in relation to clinical trials and documents relevant to Shionogi's own entitlement to rights in the claimed invention.[12] The subsequent assignment from Shionogi to the First Appellant could not establish that Shionogi in fact possessed all necessary rights to confer clear title on the First Appellant.

17. The Full Court correctly noted that the Appellants could have flagged their intention to raise an argument based on an assignment from Shionogi and sought an adjournment of the hearing or a delay in the delivery of judgment at any time from the passing of the *Intellectual Property Laws Amendment (Raising the Bar Act) 2012*,[13] 6 months before the trial, such that upon commencement of the Act, the point was ready to be run: Full Court at [189]. No evidence was adduced by the Appellants on the interlocutory application to suggest otherwise. AB2484

18. Thus, in the absence of notice that the Appellants would rely on an assignment from Shionogi, Apotex did not pursue the other limb of its entitlement case, that people other than Shionogi employees contributed sufficiently to the invention,

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[11] Affidavit of *Patrick Richard Sands*, affirmed 2 July 2013, para 28(a), (b)(iv). AB2212 AB2212

[12] *Sands*, para 28(b)(v), (vii). AB2212 AB2212

[13] The Act had received Royal Assent on 15 April 2012.

and it was denied the opportunity to pursue forensic avenues to help prove that other limb. Similarly, discovery from Shionogi might have advanced Apotex's case on obviousness, including with respect to the adoption of 5 to 10 mg dosages: see, e.g., **AS** para 32. The Full Court's observations on discretionary issues at [189] reflect an acceptance of Apotex's evidence in this respect. AB2484

19. The assignment now sought to be relied on can only possibly save the Patent because the primary Judge made a finding, at [291], that "if there is any invention claimed by the patent, it was invented by Shionogi not Dr *Raza*". Of course, the Appellants led no evidence from Shionogi to establish Shionogi's entitlement to grant the rights that it now purports to assign. In light of this lost forensic opportunity, it would be open to Apotex to apply to re-open its case on lack of entitlement and to seek discovery and other orders, if leave were granted to the Appellants to rely on the Shionogi assignment. This would require remitter to the trial judge and is plainly undesirable. AB1917

20. The High Court is entitled to give effect to the Full Federal Court's clear opinion that the Appellants' interlocutory application should be refused on discretionary grounds. That would dispose of the appeal. If the Court were not disposed to that course, and the Appellants were successful on the s18 grounds, the interlocutory application should be remitted to the Full Court.

Lack of inventive step

Appellants' Issue 2(a) – s7(3) information and s7(2)

21. The issue advanced at **AS** para 2(a) is a question that does not arise on the statute. Further, the Appellants' answer to that question is inconsistent with the proposition it advances in answer to **AS** para 2(b).

22. It is common ground that the introduction of ss7(2) and (3) of the Act raised the threshold of inventiveness: cf **AS** para 35. In the form relevant to this proceeding, these provisions did so, when read with s18(1)(b)(ii), by permitting recourse to the "*prior art base*" (as defined in Schedule 1) subject to the conditions identified in ss7(2) and (3). The enquiry mandated by the text of s7(2) is whether the invention would have been obvious to a person skilled in

the art in the light of the common general knowledge (**cgk**). That enquiry may be answered with respect to the cgk "*considered separately*", or "*together with*" prior art information as described in s7(3).

23. Each of the "kinds" of information in s7(3) must:

(a) be "*considered separately*" for s7(2), that is, each single document[14] (s7(3)(a)) or each set of related documents (s7(3)(b)) must be considered separately from other s7(3) documents; and

(b) be information that the skilled person could be "*reasonably expected to have ascertained, understood and regarded as relevant to work in the relevant art*" in Australia (the **pertinence criteria**).

24. To meet the definition of "*prior art information*", s7(3) information must be information in a document publicly available in, or outside, Australia.[15] The requirement that documents meeting the pertinence criteria be considered separately from each other is an express statutory recognition that more than one document (or set of related documents) might meet the pertinence criteria in any given case. It may be that different disclosures in different s7(3) documents lead to different lines of enquiry, each of which is, or some of which are, obvious in light of the document, together with cgk. The Act prohibits "mosaicing" of s7(3) documents; it does not assume or require that there can only be one obvious course for the person skilled in the art to take. The Appellants, rightly, have conceded as much. See, e.g., the Appellants' Reply on their Application for Special Leave, para 9.

25. These conditions give rise to a straightforward enquiry for the tribunal of fact, prior to the application of s7(2), where a revoker wishes to rely on information that is not within the cgk:

(a) is the information publicly available anywhere in the world; and

(b) does it meet the pertinence criteria?

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[14] Section 7(3) also refers to information made publicly available through "doing of a single act" but for clarity these submissions focus on documents, corresponding to the instant facts.
[15] For a standard patent. See "*prior art information*" and "*prior art base*" in Schedule 1.

26. In respect of any documents, or sets of related documents, satisfying those conditions, the tribunal must apply them one at a time to the s7(2) question. A revoker may rely on multiple documents in the alternative. If the s7(2) question is answered in the revoker's favour on any one of the s7(3) documents, the claim is invalid. It follows that the question at **AS** para 2(a) does not arise. One does not attempt to shoe-horn ss7(2) and (3) into preconceived notions of available "avenues", whether "teaching towards" the invention or away from it. The word "obvious" in s7(2) is an ordinary English word and the question of obviousness is classically a jury question: is there "*some difficulty overcome, some barrier crossed*", is the invention "*beyond the skill of the calling*".[16] The reference points for the determination of that question are the cgk and information from a s7(3) document.

27. The above approach is required by the statutory text. Nothing in the statutory context requires a different approach. It is completely consistent with the construction approved in *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816; [2002] HCA 21 at [36] and *Lockwood [No 2]* at [150]-[153]. In the latter at [166], the Court said that once information satisfies the s7(3) conditions, the question is, "*If the* [s7(3)] *information had been considered by a person skilled in the relevant art together with common general knowledge would the invention ... have been obvious?*"

28. The Courts below took precisely this approach in the present case. The Appellants had submitted that the modified "Cripps question" of *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411; [2002] HCA 59, at [53] should be applied. This is reflected at [543]. The primary Judge did this at [328], as did Jessup J at [539]-[549]. Accommodated to s7(2) of the 1990 Act, the question is "*Would the notional research group at the relevant date in the light of common general knowledge considered together with either Watanabe or the 471 Patent directly be led as a matter of course to try 5 and 10mg doses of rosuvastatin ...*". This is the same question as *Lockwood [No 2]* at [166]. AB2594 AB1930 AB2593-AB2596

[16] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173; [2007] HCA 21 at [51]-[52].

29. In its response to the IPAC report,[17] the Commonwealth Government expressly approved an expansion in the prior art base for obviousness, limited to the use of a single document that satisfied the pertinence criteria,[18] on the basis that "*higher requirements*" for patentability apply in Australia's major trading partners.[19] The UK approach is encapsulated in the observations of Laddie J in *Pfizer Ltd's Patent* [2001] FSR 16 at [62], extracted by the Full Court at [211]. AB2491 In particular, "*Anything which is obvious over what is available to the public cannot subsequently be the subject of valid patent protection*". Parliament intended that the Act would operate as if the words "to the public" were replaced with "to the skilled addressee under s7(3)". Steps three and four in the structured UK approach to obviousness[20] are, having identified the inventive concept embodied in the patent in suit, to identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the invention, and then to ask whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the person skilled in the art: *Pozzoli Spa v BDMO SA* [2007] FSR 37; 2007 EWCA (Civ) 588 at [14]. In Australia, the "state of the art" of the UK approach is read as "the cgk taken together with any s7(3) information".

30. Similarly, in *KSR International Co v Teleflex Inc* 550 U.S. 398 (2007), at 1729 the United States Supreme Court continued the approach laid down in *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966), at 17:

> *"the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or non-obviousness of the subject matter is determined."*

31. Thus two of Australia's major trading partners with a common patent heritage with Australia ask whether the invention as claimed is obvious over the prior art

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[17] Report of the Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, 1984 (**IPAC Report**)

[18] Department of Science (1986), Statement by the Minister for Science, Government Response to the IPAC Report, p 4, Response to Recommendation 13(ii).

[19] Department of Science (1986) Statement by the Minister for Science, Government Response to the IPAC Report, p 4, Response to Recommendation 13(i).

[20] Referred to in *Lockwood [No 2]* at [61]-[62].

that is available to be considered for the enquiry. That prior art is to be considered in light of the cgk. The scope of the available prior art differs; the Act was narrower, before the amendments of the *Raising The Bar Act*, than the UK and US tests permitted. But the nature of the enquiry is the same. It reflects precisely the formulation of the question in *Lockwood [No 2]* at [166]. The Appellants' complaint that the Full Court's approach to s7(3) was "*unfair to inventors*", **AS** para 46,[21] merely begs the question as to the proper construction of the Act. The Act as it then stood was considerably more favourable to inventors than the law in jurisdictions having larger economies and where more pharmaceutical research takes place.

32. The Appellants attempt to deflect simple factual questions by misconceiving the effect of s7(3). They do not confront the concurrent findings of fact that each of *Watanabe* and the 471 Patent met the pertinence criteria: Jagot J at [329], AB1931 FCAFC at [228], [229], [532].[22] There was no debate as to public availability, AB2497 AB2497 AB2590 this was admitted by the appellants.

33. The Appellants contend that the Full Court's reasoning on the s7(3) issue revealed "*at least four species of error*" (emphasis added), although this indeterminate genus might comprise only one error: **AS** para 48. The errors propounded by the appellants are predicated on an internally inconsistent argument: on the one hand, the Full Court inappropriately confined the enquiry to a single s7(3) document in light of the cgk (the first three errors); on the other hand, the Full Court erred by taking multiple documents into account (the fourth error): cf **AS** paras 39-41.

34. The first three alleged errors (**AS** paras 49 to 54) pick up **AS** para 2(a). These proceed on the assumption that the concurrent findings, that each of *Watanabe* and the 471 Patent were s7(3) documents, were correct. This assumption was correct as a matter of fact, as submitted below. They also proceed on the assumption that a person skilled in the art was constrained to proceed along a single "pathway", which was to pursue a single drug candidate that could not be chosen until **all** of the results of a literature search had been considered: see **AS**

[21] See too **AS** para 53, referring to "*a measure of protection to inventors*".
[22] See also *Firebelt* at [57].

paras 49, 51, 54. This second assumption has no support in the Act. It is directly contrary to the command in s7(2) that non-cgk documents be considered separately.

35. As noted, the Appellants accept that more than one thing can be obvious. The question of a choice to be made between rosuvastatin and NK-104 is a red herring. As it happens, NK-104 was also developed: **AS** para 31. In another enquiry, it might well be established that the selection of NK-104 was also obvious. Section 7(2) requires that each s7(3) document be considered separately. The question of assessing multiple s7(3) documents simultaneously in answering the s7(2) question cannot arise. At [536], Jessup J simply applied s7(2), in terms: cf **AS** paras 41-43. AB2591-2592

36. Ultimately, as posed in *Lockwood [No 2]* at [166], the question is whether the invention as claimed is inventive in light of *Watanabe* or the 471 Patent, considered together with the cgk. The cgk included the desirability of a new statin that "could bring more patients to their target level without dose titration than the existing statins"[23] and that statin dosages in the range of 5-10 mg were conventional, including as starting doses.[24]

37. Once the skilled person is armed with either of *Watanabe* or the 471 Patent and in light of the cgk as to the need for a new statin and as to dosages, the only remaining issue was that of dose.[25] On the evidence, the Full Court held that the Appellants' challenge to the primary judge's finding that the administration of rosuvastatin at 5-10 mg once daily would have been tried as a matter of course was "*unsustainable*": Jessup J at [545]. That conclusion should be upheld. AB2595

Appellants' issue 2(b) – combining information from multiple documents

38. The submissions on this issue, under "Fourthly" at **AS** paras 55-60 do not specify the multiple sources said to have been wrongly combined or compared. Presumably the facts asserted at **AS** paras 26-28 are relied on. The Appellants' assertions that the process was one of combining information (**AS** para 2(b)) or

[23] Full Court at [538], primary Judge at [119], [123].
[24] Primary Judge at [103]-[104], [325]; Jessup J at [542]-[545].
[25] Jessup J at [544].

AB2592 AB1859-AB1860 AB1861-AB1862 AB1855 AB1929 AB2593-AB2595 AB2594

comparing documents (**AS** paras 26-28) are not correct. **AS** para 28 also conflates the pre-conditions of s7(3) with the ultimate question under s7(2).

39. The conditions of s7(3) were met in the experts' ascertaining of *Watanabe* and the 471 patent and in their understanding them and regarding them as relevant. As the High Court said in *Lockwood [No 2]* [530], "ascertained" means discovered or found out. Dr *Reece* ultimately selected three articles as being of relevance – *Aoki*, *Watanabe* and *Thompson*. He had ascertained them by conventional searches. Professor O'Brien's searches also were conventional.

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40. The Appellants' principal complaint before the Full Court on the topic of combining documents was that, in regarding *Watanabe* as relevant, Dr *Reece* used *Thompson* to reinforce the relevance of *Watanabe*. See per Jessup J at [529] and the quotation from [530], at **AS** paras 40, 56 and 59. AB2589 AB2589

41. The evidence was clear, however, that Dr *Reece* already regarded *Watanabe* as relevant, standing alone: per Jessup J at [528]. He said that the compound disclosed therein [rosuvastatin] was "*a very potent inhibitor of cholesterol biosynthesis*" and "*definitely a candidate for further development*".[26] This had been clear from the early stages of his searching process. At para 159, Dr *Reece* describes narrowing his search to 19 abstracts. Before reading *Thompson*, he already said of *Watanabe* that, "*one of the abstracts also contains blue highlighting by me to signify that the reported result of relative potency in that abstract* ***stood out from all the other abstracts***." (emphasis added) AB2588-AB2589 AB967

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42. Dr *Reece* also said that he understood from the statement in *Watanabe* that a clinical trial was in progress that "*the data supported the further development of* [rosuvastatin] *in Phase II trials*".[27]

30 43. Dr *Reece* was not challenged on that evidence. He agreed that the *Thompson* article told him that the clinical trials referred to in *Watanabe* were Phase II and not "*either Phase I or Phase II*". See [529]; T733.11-734.25. His not knowing whether *Watanabe* was in Phase I or Phase II trials would not have affected the AB2589 AB529-AB530

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[26] *Reece* para 165(b). AB969

[27] *Reece* para 173. AB971

question of its relevance for s7(3) because it already "*stood out*"; "*it was definitely a candidate*". See also [541], [547]. The primary Judge, at [330]-[331] and the Full Court per Jessup J at [542] and [547] and the plurality (as to novelty) at [309] rejected the Appellants' insistence on a certain level of trials. AB2593 AB2595 AB1931-AB1932 AB2593-AB2594 AB2595 AB2517

44. S7(3) postulates a process of "finding out" and the skilled addressee is entitled to "sort through all manner of information", although "ultimately, there must be one document": [530]. The "considered separately" command appears in s7(2). It is in that enquiry that it is applied. AB2589

45. The Appellants' criticisms cannot apply to the evidence of Professor O'Brien. See per Jessup J at [531]. His process of "comparison" was one of "whittling down" the articles of interest, at [531]. Any researcher would immediately recognise such a process as implicit in the determination of the relevance of a document obtained on a literature search. It is not foreclosed by s7(3). AB2590 AB2590

46. *AstraZeneca's* criticisms also do not apply to the 471 Patent – see per Jessup J at [532], Jagot J at [329]. This was a conventional process of location of information when answering the need that was common general knowledge: at [538]; **AS** paras 23-25. Contrary to **AS** paras 26 and 41, this was not a "comparative analysis of multiple sources", nor of combining them. AB2590 AB1931 AB2592-AB2593

Part VII: Argument on the Respondent's Notice of Contention

Obviousness and starting point – the inventive concept (ground 2)

47. Apotex submits that the approach of the primary Judge to this issue, at [207]-[215], [218]-[223] and [228]-[229] is correct. As her Honour said, at [210], AB1888-AB1891 AB1892-AB1893 AB1895 AB1889

> *The terms of the specification and claims inform the relevant starting point for the assessment of obviousness ... Characterisation of the invention depends on the terms of the claims construed in the context of the specification as a whole.*

48. At [220], her Honour then characterised the invention: AB1892-AB1893

> *The specification identifies the invention in a manner that pre-supposes the existence of rosuvastatin. It is not necessary to make use of the prior art disclosing the existence of rosuvastatin referred to in*

> *the specification to reach this conclusion. It is apparent from the terms of the specification as a whole. The invention relates to the dosage range for rosuvastatin. The inventive concept is in the dosage range alone. So much is plain from the opening paragraph of the specification. The subsequent reference to it being important to find dosages of alternative statins does not make knowledge of rosuvastatin any part of the inventive concept. For the purposes of the invention as disclosed the specification itself makes a rosuvastatin a given and locates the inventive concept in the discovery of a dosage range. If the language of problem-solution is apt, the problem is not finding dosages of alternative statins and rosuvastatin is not the answer to that problem. The problem is the dosage range of rosuvastatin itself to achieve the objective of lowering cholesterol without significant side effects and the answer to the problem is the dosage range of 5-80 mg of rosuvastatin. Claim 1, for example, then claims as an invention part only of that dosage range as a starting dose, being a single once daily dose of 5-10 mg of rosuvastatin.*

49. In *Alphapharm*, the Court adopted the same approach. The plurality's reasons at [218]-[219] in the present case oversimplify this. The High Court did not AB2493 proceed merely on the basis of the submission that appears at 212 CLR 415. After a discussion of the European "problem and solution approach", at [41], the plurality characterised the invention, as Jagot J did here, referring to the consistory clause, which "... *states that the invention claimed therein is designed to obtain a pharmaceutical dosage form of omeprazole which answers the problems referred to earlier in the body of the specification ...*".

50. Given the attention given by the plurality in *Alphapharm* to errors in the judgments below in relation to cgk and the application of *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 - at [31], [43]-[49], [55], [57] and [61] - it is unlikely that their Honours would, solely on the basis of a concession, have proceeded as they did if such an approach committed the heresy asserted by the Appellants. See *Firebelt* at [34]. Their Honours assessed whether the dosage form involved an inventive step, by reference to "routine steps" and "obvious to try", at [54]-[76]. The plurality plainly did not consider that the law of obviousness required the invention being considered to include the [re-]discovery of the compound, omeprazole itself. Omeprazole was not cgk. Thus, the plurality did not focus only on "the invention as claimed"; it considered the obviousness of the invention referred to in the specification and discussed at [2]-[3] and [41].

51. This approach does not involve the illegitimate use of prior publications that were not part of cgk. It depends on the full description of the invention in the specification and claims,[28] read in order to characterise the invention, or the inventive concept.

52. Jagot J pointed out at [228] that the Appellants' contrary approach is that the AB1895
invention of each of the three patents then in suit included the discovery of rosuvastatin, "*when the claimed invention suggests no such thing*". This would allow a multiplicity of patents involving the most trivial advances, each *ipso facto* involving an inventive step because rosuvastatin was not cgk.

53. Jagot J's approach is also consistent with *Wellcome Foundation Limited v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262. Aickin J, with whom the other members of the Court agreed, reiterated the holding of *Minnesota Mining* several times, e.g., at 270,

> *It is as well to bear in mind that the question of obviousness involves asking the question whether the invention would have been obvious to a non-inventive worker in the field, equipped with the common general knowledge in that particular field as at the priority date, without regard to documents in existence but not part of such common general knowledge.*

54. See also at 278.5 and 284-285. Having done this, Aickin stated at 286,

> *The test is whether the hypothetical address faced with the same problem would have taken as a matter of routine whatever steps might have led from the prior art to the invention, whether they be the steps of the inventor or not.*

55. Each of these passages focusses on "the invention". This is the central concept here. The reference in s18 to the invention "so far as is claimed in any claim" focusses attention of each of the claims vis-a-vis the other claims. It does not preclude consideration of the body of the specification. This is where the invention is fully described (s40(2)(a)). It provides the disclosure on which each claim must be fairly based (s40(3)). The claim or claims "must relate to one invention only", s40(4). The phrase in s18(1) (and in s100 of the *Patents*

[28] *Patents Act 1990*, s40(2).

Act 1952), "an invention is a patentable invention ... if the invention, so far as claimed in any claim ...", reflects the broad ranges of the meaning of the word "invention".

56. See the discussion, in the context of entitlement, per French J (as the Chief Justice then was) in *University of Western Australia v Gray (No 20)* (2008) 76 IPR 222, [1419]-[1427]. After referring to the multiple uses of the term "invention", discussed in *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, [2001] HCA 8 at [21], his Honour said, of the meanings there referred to, "*each is consistent with the proposition that an invention is essentially described by the inventive concept, albeit it may be manifested in the invention as variously claimed*": at [1424].

57. See, too, *Gray* at [1424]-[1441].[29] At [1425], French J referred to the discussion of inventive concept in *Lockwood [No 2]*. His Honour said that "*Lockwood did not reject the idea of 'inventive concept' but rather the problem and solution approach in the English cases*".

58. In *Lockwood [No 2]* at [60]-[66], the Court referred to the importance of identification of the "inventive concept" in the UK's "structured approach to obviousness". The Court expressed reservations about the problem and solution approach but regarded it as useful in some circumstances. See [63]-[65]. It was useful in the instant case – see [148], [152]-[153] and [127], discussed below. Footnote 221 to [148] refers to *Alphapharm* [41], referred to above.

59. It follows that, in the context of the 1952 Act, the Full Court of the Federal Court was right in *Apotex Pty Ltd v Sanofi-Aventis Pty Ltd* (2009) 82 IPR 416; [2009] FCAFC 134 in applying *Alphapharm* and *Lockwood [No 2]* to the instant facts.[30] The Court considered the terms of the specification, including "the problem addressed in the patent", at [160]. It concluded that "the invention of the patent starts with a biologically active racemate" (emphasis added), at [162].

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[29] The Full Court agreed with French J's reasoning in *University of Western Australia v Gray* (2009) 179 FCR 346, at [254]-[259].

[30] Special Leave to appeal on this point was refused in *Sanofi-Aventis Pty Ltd v Apotex Pty Ltd* [2010] HCA Trans 59.

60. The primary Judge was right to characterise the invention of the Patent in the manner set out above: "the specification itself makes rosuvastatin a given and locates the inventive concept in the discovery of a dosage range", at [220]. AB1892-1893

The reasoning of the Full Court

61. The plurality takes too narrow a view of "the invention", at [195]. The words of s18(1)(b) focus on whether, insofar as it is claimed in the claim being assessed, the invention involves an inventive step. The invention "*is the embodiment which is described and around which the claims are drawn. This is the sense used in the Act: cf the phrase of s32, 'the invention so far as claimed in any claim'*".[31] The invention, or the inventive concept, is to be found in the specification as a whole, including the claims. As submitted, there is one invention; this is defined in various ways in the claims. AB2485-AB248(

62. At [202], the plurality says that the question of inventive step is to be "*determined by comparing the invention, so far as claimed, against the common general knowledge and any s7(3) information*". As the High Court said in *Lockwood v Doric [No 2]* at [127], however, (emphasis added): AB2488

> *By enlarging the prior art base through including relevant prior disclosures beyond those disclosures proven to be part of the common general knowledge, these provisions raise the threshold for inventiveness. However, the idea remains that the prior disclosures to be taken into account, even as enlarged by s7(3), are being considered for a particular purpose. That purpose is the purpose of looking forward from the prior art base to see what a person skilled in the relevant art is likely to have done when faced with a similar problem which the patentee claims to have solved with the invention.*

63. The Full Court's error is to assume that the invention always involves a step from the cgk (perhaps enlarged by s7(3) information). The cgk is a skilled addressee's intellectual capital. *Minnesota Mining* and *Wellcome* do not say that the inventive step is the journey from that cgk to the claim. In some cases,

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[31] *Kimberly-Clark* at [21], quoting *Blanco White*, Patents for Inventions, 4th edn (1974), para 1-101, n33. In fn 52, the Court notes that s32 of the Patents At 1949 (UK) "used the same expression as s18(1) of the present Australian statute", the 1990 Act.

of course, the "problem which the patentee claims to have solved" will be cgk, such as a "long-felt want". In others, it will not.

64. The proper course is to characterise the invention, or the "inventive concept", and to assess this "in light of" the cgk and any s7(3) information. See *Lockwood [No 2]* at [59]-[65].

65. The plurality gives five reasons why, when a problem is not cgk, "*it is not permissible to attribute a knowledge of the problem on the basis of the inventor's 'starting point' such as might be gleaned from a reading of the complete specification as a whole*".

66. The essential foundation of the five reasons is that the specification cannot be used to identify the invention, or the inventive concept. In short, the plurality's approach is that the specification has no role in the assessment of inventive step except in the case of an admission, or to resolve ambiguity. See, e.g., [204]. AB2489

67. The first reason, at [204] assumes the truth of the premise that the inventive concept cannot be derived from the specification. The second reason, at [205], confuses the "route that was travelled by the inventor" with the inventive concept described in the specification. The third reason, at [206], confuses the information "in the light of" which the inventive step is assessed, with the invention that is described in the specification. AB2489 AB2489 AB2489-AB2490

68. The fourth reason, at [207], again begs the question. It demonstrates the plurality's error perhaps most starkly. The primary Judge did not assess inventiveness by reference to information that is not cgk or s7(3) information. Her Honour assessed the inventiveness of the inventive concept described in the specification, in the light of the cgk. AB2490

69. The fifth reason, at [208]-[209] is a question of the proper reading of the specification. It is clear, however, that the proper characterisation of the invention is set out at p1 lines 18-20. Only one "alternative statin" is mentioned in the Patent – "the Agent" – that is, ZD4522 or rosuvastatin. AB2490-AB2491 AB1083

70. At [210]-[213], the Court refers to the attempt by the *Raising the Bar Act* better to align the approach to inventive step with that in the UK and other jurisdictions. As submitted, that has been the purpose of the various attempts to reform the law of obviousness in Australia since the IPAC Report in 1984. See *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 54 IPR 449; [2002] HCA 21, at [31]-[35]. See also *Lockwood [No 2]* at [42]-[49], [125]-[127]. AB2491-AB2492

71. The controversy that was settled by *Minnesota Mining* was whether, "regard could be had to documents in existence but not part of such common general knowledge", as is the case in the UK and the US. The stringency of that decision has been ameliorated by the Act in 1990 and amendments in 2001[32] and 2012,[33] but the necessity to identify "the invention" has not changed: this is the single invention described in the specification and around which the claims are drawn. The primary Judge was right to characterise this as she did at [220]. AB1892-AB1893

72. Jessup J agreed with the plurality but for different reasons. At [503], his Honour said that the problem was the patient with hypercholesterolemia, not the appropriate dose for a known drug. Because rosuvastatin lay outside the cgk, the invention was not obvious. The above submissions apply to this reasoning. With the "cation patent", by contrast, Jessup J characterised the invention in a similar manner to the primary Judge, at [507]-[513]. This was because the claim was for a combination, not for rosuvastatin as such, at [512]. AB2581 AB2582-AB2584 AB2583-AB2584

73. This illustrates the too-narrow approach to the inventive concept adopted by the Full Court. It is the invention described by the patentee in the specification, insofar as it is claimed, whose inventive step is to be assessed. Here, that is the finding of an appropriate dosage range for rosuvastatin. As the primary Judge held, at [324]-[327], this was obvious in light of the cgk. AB1929-AB1930

Manner of Manufacture – ground 4

74. It is clear from High Court decisions since *Commissioner of Patents v Microcell Limited*[34] and *National Research Development Corporation v Commissioner of*

[32] *Patents Amendment Act 2001*, Schedule 1, Part 1 para 4. See **AS** Annexure A pA5.
[33] *Raising the Bar Act*, Schedule 1, Part 1, para 3. See **AS** Annexure A pA10.
[34] (1959) 102 CLR 233, at 246-251.

Patents[35] that the concept of a manner of manufacture, now in s18(1)(a) includes a requirement that there be a "quality of inventiveness", apparent on the face of the specification: *NV Philips Gloeilampenfabriken v Mirabella International Pty Ltd* (1995) 183 CLR 655, at 664. In *Advanced Building Systems Pty Limited v Ramset Fasteners (Aust) Pty Limited* (1997) 194 CLR 171, at [36]-[40], the Court referred to "*the category of cases, considered in Philips, where lack of an inventive step appears on the face of the specification*" and, in effect, confined the ratio of *Philips* to that category. The first two cases related to acceptance before grant. The last two related to revocation.

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75. In *Lockwood [No 2]* at [106] the Court referred to the circumstance "*where a specification 'on its face' shows the invention claimed is not a manner of new manufacture*". The reference at [106] to a "discrete threshold test" is to the introductory words of s18(1).

76. The Court continued, at [107], by referring to rare "*cases where the alleged subject-matter is 'so obviously not an invention that it is tempting to take an axe to the problem by dismissing the claim*'".[36] This is, in effect, what the primary Judge did with one of the other patents initially in suit, at [397]-[400]. AB1951-AB1952

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77. As the Court said in *Microcell* at 246, this does not depend on an "express admission contained in the specification"; to warrant rejection,"it should be clear on its face that the specification discloses no inventive step".

78. The Patent says at p1 lines 10-14 that "the Agent" (rosuvastatin) is disclosed in AB1083
the 471 Patent and *Watanabe* and is "taught as useful in the treatment of hypercholesterolemia". It then states that "*it is important to find dosages of alternative statins which beneficially alter lipid levels to a significantly greater extent than similar doses of currently used statins ...*" (at p1 lines 20-23). The AB1083
30 only alternative statin mentioned is rosuvastatin. Perception of the need for greater efficacy is not suggested to have been inventive. The "similar doses" of currently used statins are identified, for atorvastatin, at p12 lines 12 and 18-20: AB1096

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[35] (1959) 102 CLR 252, at 262-268.
[36] Quoting Lord Hoffman in *Biogen Inc v Medeva Plc* [1997] RPC 1 at 42.

10mg is the starting dose of "a proven cholesterol-lowering agent", atorvastatin. A method using 10mg of rosuvastatin falls within the claims.

79. On the face of the specification, there is no invention in the selection of the same dose as that for a proven agent, for a method of treatment using another agent already known to be useful in treating the disease, when the purpose is to examine superior efficacy (and equivalent safety) at "similar dosages" to currently used agents - and the claims include the same dose as the proven, currently used, agent. It follows that none of the claims complies with s18(1)(a). The plurality noted this submission at [376]. Its answer at [391]-[392] does not address the above passages of the specification. AB2533 AB2538

80. Apotex also adopts, in the alternative, Actavis/Ascent's additional submissions as to the incorporation by reference of *Watanabe* and the 471 Patent and the consequences of this: Apotex's notice of contention ground 5.

Novelty and infringement – grounds 6 and 7

81. Apotex adopts Actavis/Ascent's submissions on these issues.

Part VIII: Oral argument

82. If it is convenient to the Court, counsel for Apotex and Actavis/Ascent propose to divide the time for oral argument among themselves. They estimate that 4 hours will be required in answer and on their contentions.

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