IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN: No.S 55 of 2015

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
SECOND APPELLANT

10 **ACTAVIS PHARMA PTY LTD**
(FORMERLY WATSON PHARMA PTY LTD)
ACN 147 695 225
RESPONDENT

BETWEEN: No.S 56 of 2015

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
20 SECOND APPELLANT

ASCENT PHARMA PTY LTD
ACN 118 734 795
RESPONDENT

APPELLANTS' REPLY

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Introduction

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

2. The appellants (**AstraZeneca**) reply as follows to the respondents' submissions in Proceedings S 54 of 2015 (**Apotex**) and S 55 and S 56 of 2015 (**Actavis**). References to "**AS**" are to AstraZeneca's submissions on the appeal.

Inventive step (s 7(3)) and entitlement

3. AstraZeneca repeats its submissions on the issues of inventive step (s 7(3)) and entitlement made in its reply in Proceeding S 54 of 2015.

Other grounds of contention

The "starting point" argument

4. The primary judge held on the evidence that rosuvastatin was not part of the CGK before the priority date.[1] Her Honour also observed that there was no concession by the patentee that rosuvastatin was to be treated as a "given" in assessing inventive step.[2] Nevertheless, her Honour held that the skilled person should be assumed to have knowledge of rosuvastatin as a "starting point" for that assessment. This was because, in her Honour's view, the description in the 051 Patent indicated that the invention "pre-supposed" the existence of rosuvastatin: at [210], [220], [221]. Thus her Honour held that the invention would have been obvious under s 7(2) of the Act, despite the finding that rosuvastatin was not CGK, and without the need to resort to any s 7(3) information.

5. The respondents now seek to support that approach on the basis that her Honour correctly "assessed the inventiveness of the inventive concept described in the specification": Apotex [68]; see also [51], [56] – [58], [60], [61], [64], [66], [67].

6. The Full Court correctly rejected the approach as being contrary to the provisions of the Act. As submitted below, the Act imposes an objective test which involves asking whether the invention as claimed would have been obvious in the light of the CGK and any s 7(3) information. There are no words in the Act that can be used to support the approach of the primary judge. None have been identifed by the respondents. It is not possible to graft onto the Act an approach involving an assumed "starting point" that was neither CGK nor s 7(3) information, based on the description the specification. As the plurality said at [209]:

> *The statutory test for determining whether an invention is patentable under s 18(1)(b)(ii) involves asking whether the claimed methods of treatment would have been obvious to the hypothetical person skilled in the art in light of the common general knowledge and any s 7(3) information. It does not involve asking whether such methods would have been obvious to the hypothetical person skilled in the art armed not merely with the common general knowledge and any available s 7(3) information, but also some additional knowledge*

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[1] (2013) 100 IPR 285 at [195], [218].
[2] (2013) 100 IPR 285 at [219].

> *concerning the existence of rosuvastatin, its chemical properties or its potential role in the treatment of hypercholesterolemia based upon a description in the specification of the problem that the inventor was seeking to solve.*

7. Section 18(1) of the Act sets out the requirements for a patentable invention, including inventive step: s 18(1)(b)(ii). It does so by reference to "the invention, so far as claimed in any claim". This means the invention defined by the claims, as distinct from the description in the body of the specification: see s 40(2)(a) and (b) of the Act. These provisions reflect the fundamental distinction between the two parts of a patent specification – the description and claims – which has long been recognised in patent law. It is the claims that define the invention; the function of the description is to describe the invention in sufficient detail to enable a skilled person to perform it.[3] There is no requirement that the description identify any problem to be solved, any "starting point", or any "inventive concept".

8. Section 7(2) deems an invention to involve an inventive step "unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim", whether that knowledge is considered separately or with any s 7(3) information. As the plurality held, the "invention" in s 7(2) is the invention so far as claimed in any claim. This follows from a reading of s 7(2) and s 18(1)(b)(ii) together, and is confirmed by the reference in s 7(2) to "the priority date of the relevant claim". It is that invention which must be compared with, and compared only with, the CGK and any available s 7(3) information.[4]

9. Obviousness is an objective test.[5] The fact that the inventor found something difficult or easy is only relevant to the extent that this might reflect on the approach of the hypothetical skilled person; the same position obtains for any information used by the inventor. Indeed, an invention may be "stumbled upon by accident" or "remembered from a dream".[6] Consistently with this, there is no requirement for an inventor to state what he or she regards as the inventive step (or "inventive concept") that has been taken.[7] Further, while admissions of fact can be made in a specification, for example as to CGK, such admissions can be contradicted by evidence. As this Court said in *Lockwood (No 2)* (emphasis added):[8]

> *Admissions in a specification about any problem said to be overcome by an invention are made from the vantage point of knowing the solution. When used as evidence, they would always need to be weighed with evidence, if it exists, from persons skilled in the relevant art of their perception of any problem at the time before the priority date, before their exposure to any solution contained in the invention.*

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[3] See *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 1)* (2004) 217 CLR 274 at [44]; *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1 at [25]; *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588 at 610.

[4] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [148], [149].

[5] *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 280; *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [34], [54], [56].

[6] *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 286.

[7] *Rose Holdings v Carlton Shuttlecocks* (1957) 98 CLR 444 at 449; see also *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 1)* (2004) 217 CLR 274 at [50] – [54].

[8] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [105].

10. The respondents' approach would cast aside these cautionary observations by treating a problem said to be identified in the specification as an assumed "starting point" for the assessment of inventive step, without regard to the evidence, and contrary to the unchallenged finding of the primary judge that rosuvastatin, and thus the problem, was not part of the CGK. Moreover, in this case, the specification on its face does not admit that any problem identified was CGK.

11. The invention claimed in claim 1 of the 051 Patent is a method of treating hypercholesterolemia comprising administration as a starting dose of a single, once daily, oral dose of 5 to 10 mg of rosuvastatin; claim 2 is directed to a method of treatment comprising administration of a single, once daily, oral dose of 5.2 to 10.4 mg of the calcium salt of rosuvastatin. The use of rosuvastatin is an essential integer of each claim. Rosuvastatin was not part of the CGK or any assumed "starting point" for the objective assessment that is called for by s 7(2) of the Act. Accordingly, the primary judge's approach was in error.

12. Contrary to Apotex [49] – [50], the decision in *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411 does not sanction such an approach. As the plurality observed below at [218] – [219], the patentee in *Aktiebolaget Hässle* conducted that case on the basis that omeprazole was the appropriate starting point, and the issue was not addressed by this Court. Absent such a concession here, it provides no support to the respondents. Nor does the decision of French J (as the Chief Justice then was) in *University of Western Australia v Gray (No 20)* (2008) 76 IPR 222 provide any assistance: cf Apotex [56] – [57]. That case concerned questions of inventorship and entitlement. Reference to an "inventive concept" may be appropriate where a person's actual contribution to an invention is in issue. By contrast, as submitted, s 7(2) poses an objective test that depends not on what the inventor actually did, or on where he or she started from, but rather on whether the invention as claimed would have been obvious to the hypothetical skilled person in the light of the CGK and any s 7(3) information.

13. Further, contrary to Apotex [53] – [54] and [62], references to the problem faced by the inventor in *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 286 and *Lockwood (No 2)* at [127] provide no support for a "starting point" approach. In each case, the Court emphasised that the assessment of inventive step was to be conducted looking forward from the prior art, meaning the CGK and (in the latter case) any s 7(3) information. The problem is only relevant if it forms part of those sources of information.

14. AstraZeneca submits that the decision of the Full Court in *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 is distinguishable on the basis that it was decided under the different provisions of the *Patents Act 1952* (Cth).[9] In any event, for reasons similar to those outlined above, the decision was plainly wrong, and should not be applied in relation to the current Act: cf Apotex [59].

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[9] *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 at [145]. See also *Sanofi-Aventis v Apotex Pty Ltd* [2010] HCA Trans 59, refusing special leave to appeal from the Full Court's decision on the basis that the case was one "respecting the operation of section 100(1)(e) of the *Patents Act* 1952 (Cth)".

15. Finally, the respondents' characterisation of the "inventive concept" involves a misreading of the 051 Patent. The specification does not assume rosuvastatin as a "starting point". The "problem", as stated, was to find "dosages of alternative statins". The use of rosuvastatin in the claimed method of treatment is presented as a solution to that problem: see the reasons of the plurality at [208].

Manner of manufacture

16. Both the primary judge and the Full Court correctly rejected the respondents' argument that the invention claimed in the 051 Patent did not have the "threshold quality of inventiveness". The limits of that concept were considered by the Court in *Lockwood (No 2)* at [106] – [107], [111]. If the objection is available, it requires that it be apparent on the face of the specification alone that there is no invention. In this case, the 051 Patent does not disclose that a method of treatment having the integers in the claims was not new or inventive. To the contrary, it positively identifies the claimed method of treatment as something "surprising" which did not exist previously: see the reasons of the plurality at [378].

17. Contrary to Apotex [79], the plurality did consider the whole of the specification, including the passages relied on by the respondents. As their Honours said, "given what was known, as revealed only by what is stated on the face of the complete specification ... it could not be said that the invention as claimed was obvious and did not involve an inventive step": at [391]. Further, and contrary to Actavis [77] – [80], the plurality correctly held that Watanabe and the 471 Patent were not incorporated by reference into the 051 Patent, and that it could make no difference to the argument even if they were: at [389] – [390].

18. The respondents' assertions that the claimed invention was obvious on the face of the specification are made with hindsight, knowing the solution. They invite the Court to strike down the invention as obvious on that basis, contrary to the expert evidence, and in circumstances where neither the primary judge nor the Full Court were prepared to do so. As the Court emphasised in *Lockwood (No 2)* at [111], "[a] court cannot substitute its own deduction or proposition for that objective touchstone, except in the rarest of circumstances, such as where an expressly admitted matter of common general knowledge is the precise matter in respect of which a monopoly is claimed". That is plainly not this case.

Novelty

19. The Full Court was right to hold that the 471 Patent did not deprive the invention claimed in the 051 Patent of novelty. As the plurality observed at [292], the disclosure in the 471 Patent concerning dosage was made with respect to a vast number of compounds, without refinement as to particular compounds. The range for oral administration was a broad range of "usually 0.5-200 mg/day, preferably 1-100 mg/day". The 471 Patent did not disclose that each compound within the broad class could or should be administered at every dose within that range. To the contrary, it made plain that the doses may vary depending on a number of factors, including the kind of disease to be treated, and it raised but did not distinguish between single or divided doses: see the plurality at [290] – [292].

20. In these circumstances, as the plurality held at [293] – [306], the 471 Patent did not disclose the invention claimed in the 051 Patent. In particular, it did not contain a clear description of, or clear instructions to use, a method of treating hypercholesterolemia by administering as a starting dose a single, once daily, oral dose of 5 to 10 mg of rosuvastatin. It did not "plant the flag" at the precise destination of the patentee.[10] The submissions in Actavis [52] – [62] demonstrate no error in the Full Court's approach. Further, and contrary to Actavis [63], claim 3 does not stand or fall with claims 1 and 2 on this issue. This issue was raised before the Full Court and acknowledged by the plurality at [307].

10 ***Infringement***

21. The respondents' contention is limited to the Full Court's finding of infringement in respect of their 20 mg doses of rosuvastatin based on s 117(1) and (2)(b) of the Act. There is no challenge to the findings in respect of their 5 and 10 mg doses, or the finding against Watson Pharma Pty Ltd in respect of its 20 mg dose based on s 117(2)(c): see the reasons of the plurality at [424], [426] – [427].

22. As the plurality held at [428] – [431], the respondents' rosuvastatin products are not "staple commercial products" in any sense of those words. They are prescription pharmaceutical products indicated for the treatment of specific diseases. Such products are not "staples" on any sensible construction. They are
20 quite unlike like the raw timber considered in *Northern Territory v Collins* (2008) 235 CLR 619, which was supplied and used for multiple purposes (including to make other products). Accordingly, s 117(2)(b) was applicable.

23. Further, as the plurality held at [434] – [439], the evidence established that the respondents had reason to believe that persons to whom their 20 mg tablets were supplied would use those products in a manner that would infringe the 051 Patent, by splitting them into two 10 mg doses. As the plurality recognised at [440] – [444], the fact that only some consumers might do so might be relevant to the form of relief, but does not avoid infringement under s 117(1) and (2)(b). The question of relief would be a matter for remitter to the Federal Court.

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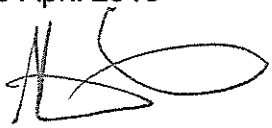

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[10] *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 at 485 – 486.