IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN: **No. S55 of 2015**

ASTRAZENECA AB
First Appellant

ASTRAZENECA PTY LIMITED
ACN 009 682 311
Second Appellant

ACTAVIS PHARMA PTY LTD
(FORMERLY WATSON PHARMA PTY LTD)
ACN 147 695 225
Respondent

BETWEEN: **No. S56 of 2015**

ASTRAZENECA AB
First Appellant

ASTRAZENECA PTY LIMITED
ACN 009 682 311
Second Appellant

ASCENT PHARMA PTY LTD
ACN 118 734 795
Respondent

RESPONDENTS' (ACTAVIS') SUBMISSIONS

Part I: Suitable for publication

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

PART II: Issues presented by the Appeal

2. What is the proper construction of ss 7(2) and (3) of the *Patents Act 1990* (Cth) (the **Act**) in determining the question of obviousness in light of the common general knowledge (**CGK**) considered with a single document which meets the requirements of s 7(3)?

Date of document: 22 April 2015
Filed on behalf of the Respondent in No. S55 of 2015 / No. S56 of 2015 by:
Minter Ellison
525 Collins Street
MELBOURNE VIC 3000
Tel: (03) 8608 2598
Fax: (03) 8608 1598
Ref: Wayne McMaster
Email: wayne.mcmaster@minterellison.com

3. Should the Appellants (**AstraZeneca**) be granted leave to rely on the affidavit of Grant William Fisher sworn 13 June 2013 to support an argument that AstraZeneca is entitled to cure the deficiency in its entitlement to Australian Patent No. 200023051 (the **051 Patent**)[1] as at grant?[2]

4. What is the correct starting point for the consideration of obviousness under s 7(2) of the Act?[3]

5. Whether the 051 Patent is an invention or, in the alternative, a manner of manufacture within the meaning of s 6 of the Statute of Monopolies?[4]

6. Whether each of claims 1, 2 and 3 of the 051 Patent is novel when considered in light of European Patent Application No. 0521471 (the **471 Patent**)?[5]

7. Whether 20mg dosage of rosuvastatin is a staple commercial product within the meaning of s 117(2)(b) of the Act?[6]

8. Whether AstraZeneca established at trial that the Respondents had reason to believe that some consumers would put the Respondents' 20mg rosuvastatin product to an infringing use?[7]

PART III: Judiciary Act 1903

9. The Respondents in proceedings No. S55 of 2015 and No. S56 of 2015 (together, **Actavis**) have considered whether notice should be given in compliance with s 78B of the *Judiciary Act 1903* (Cth). It is not necessary in their view.

PART IV: Relevant facts

10. Actavis accepts the factual background to the proceedings at AstraZeneca Submissions (**AZ**) [7] – [22] insofar as it sets out a brief summary of some of the issues ventilated before the trial Judge (Jagot J)[8] and on appeal in the Full Federal Court (Besanko, Jessup, Foster, Nicholas and Yates JJ)[9] (the **Full Court**).

---

1 The 051 Patent bears the application number AU200023051 and the patent number 769897.
2 This arises on both the appeal and ground 1 of the notices of contention dated 2 April 2015 filed by each of the respondents (the **Notice of Contention**).
3 Ground 2 of the Notice of Contention.
4 Grounds 4 and 5 of the Notice of Contention.
5 Ground 6 of the Notice of Contention.
6 Ground 7 of the Notice of Contention.
7 Ground 8 of the Notice of Contention.
8 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285.
9 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324.

11. Further, Actavis agrees with AZ [23] – [25] in broad terms. However, Actavis does not agree with AZ [26] – [32]. The approach of the person skilled in the art is more appropriately discussed further below and the following additional facts are relevant to disposition of the appeal.

12. The trial of these proceedings related to a compound called "*rosuvastatin*", which is an active pharmaceutical ingredient from a known class of compounds known as statins or HMG CoA Reductase Inhibitors.[10]

13. Rosuvastatin was the subject of patents filed in other jurisdictions including Europe and the United States by a company called Shionogi.[11] Those patents specifically disclosed and claimed rosuvastatin in a pharmaceutical composition useful as an HMG-CoA reductase inhibitor.[12] They were filed in 1992 and published shortly thereafter. There was no equivalent patent for rosuvastatin filed in Australia. The European patent is the 471 Patent, which is one of the key pieces of prior art relied upon by Actavis.

14. Relevantly, the 471 Patent provides at page 2 lines 9-11:

> "*The compounds of the present invention inhibit HMG-CoA reductase, which plays a major role in the synthesis of cholesterol, and thus they suppress biosynthesis of cholesterol. Therefore, they are useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis.*"

15. The 471 Patent then states further at page 4 lines 25-28:

> "*The dosages may vary with the administration route, age, weight, condition, and the kind of disease of the patients, but are usually 0.5 – 200 mg/day, preferably 1-100 mg/day for oral administration and 0.1-100 mg/day, preferably 0.5-50mg/day for parenteral administration. They may be used in single or divided doses.*"

16. The patent in suit, the 051 Patent, was filed by AstraZeneca approximately seven years later, claiming an earliest priority date of 6 February 1999. It relates to a starting dosage of between 5mg and 10mg of rosuvastatin for the treatment of hypercholesterolemia.

17. Professor O'Brien was an independent expert cardiologist called by Actavis. The trial Judge accepted Professor O'Brien's description of hypercholesterolemia and the common treatments prescribed at the priority

---

[10] (2013) 100 IPR 285 at [102].
[11] (2013) 100 IPR 285 at [299].
[12] Claim 8 of the 471 Patent.

date.[13] Relevantly, the following facts were part of the CGK at the priority date:

(a) Hypercholesterolemia is an elevated level of cholesterol in the blood, which is assessed by considering the level of cholesterol in the low density lipoprotein fraction (the **LDL-C**) of a patient's blood.[14]

(b) Statins were recognised as the primary class of drugs, and the most commonly used treatment, for patients with hypercholesterolemia.[15] There were a number of statins available in Australia.[16] In particular, atorvastatin had recently been released and it quickly became the most commonly known and prescribed statin in Australia.[17]

(c) Medical practitioners prescribing statins would typically provide the lowest dose of the compound to begin with, so as to minimise side effects, with the dosage increased at later consultations if necessary (dose titration).[18] The typical starting dose for atorvastatin was 10mg.[19]

18. The evidence from those in the field, which the trial Judge accepted, was that there was an established need for a new statin that was superior to atorvastatin.[20] Dose titration required ongoing management, and it was appreciated that it was desirable to have new or improved statins which enabled more patients to achieve their target LDL-C levels at the first dose given.[21]

19. Faced with the problem that, at the priority date, treatments with statins achieved less than optimal results in reducing blood cholesterol in patients, Professor O'Brien's evidence was that, armed with the CGK, he would have conducted routine and conventional literature searches.[22] Professor O'Brien nominated resources to be searched, as well as keywords that he would have used to effect the searches.[23] The searches were subsequently conducted and Professor O'Brien reviewed the results in order to identify abstracts of potential relevance to the problem.[24]

20. Professor O'Brien requested copies of both Watanabe and the US equivalent of the 471 Patent.[25] He identified Watanabe as the most

---

[13] (2013) 100 IPR 285 at [97]; (2014) 226 FCR 324 at [49].
[14] (2013) 100 IPR 285 at [97]; (2014) 226 FCR 324 at [49].
[15] (2013) 100 IPR 285 at [103]; (2014) 226 FCR 324 at [52] and [54].
[16] (2013) 100 IPR 285 at [103]-[104]; (2014) 226 FCR 324 at [55]-[56].
[17] (2013) 100 IPR 285 at [103]; (2014) 226 FCR 324 at [54].
[18] (2013) 100 IPR 285 at [109] and [119]; (2014) 226 FCR 324 at [61].
[19] (2013) 100 IPR 285 at [104]; (2014) 226 FCR 324 at [56].
[20] (2013) 100 IPR 285 at [119]; (2014) 226 FCR 324 at [62].
[21] (2013) 100 IPR 285 at [119]; (2014) 226 FCR 324 at [62].
[22] O'Brien #1 at [13.11] and [13.14].
[23] O'Brien #1 at [13.13]-[13.18].
[24] O'Brien #1 at [13.24] and [13.33].
[25] O'Brien #1 at [13.29], [13.33] and [13.40].

relevant document. Both Watanabe and the 471 Patent led Professor O'Brien to the solution to the problem, namely to treat the patient with rosuvastatin at a starting dose of 10mg per day. Professor O'Brien expected that such a solution might well produce a useful or better result.[26]

21. This solution fell directly within the claims of the 051 Patent and subsequently the trial Judge found, and the Full Court agreed, that the 051 Patent was invalid for lack of inventive step under s 7(2) of the Act.

PART V: Applicable provisions

22. The Appellants' statement of applicable statutes and regulations is accepted.

PART VI: Argument in response on the Notice of Appeal

Statutory provisions: Section 7(2) and (3)

23. The application of ss 7(2) and (3) of the Act requires a two-stage analysis.[27] The first stage involves identifying what document or documents the skilled addressee would have ascertained, understood and regarded as relevant at the priority date of the patent, as per the criteria in s 7(3).

24. The second stage, as directed by s 7(2), involves (so far as presently relevant) considering obviousness in the light of the CGK and the information disclosed in any single prior art document identified in the first stage process.

25. The second stage is undertaken by means of the test set out by this Court in *Aktiebolaget Hässle v Alphapharm Pty Ltd* [2002] 212 CLR 411 at [51]–[53] (the **Cripps Question**).

26. In determining whether a document satisfies s 7(3), "ascertained" simply means that it would be found.[28] This prevents resort to a document which, *albeit* published, might never have been found, for example, because it was only contained in an obscure publication.

27. "Understood" means that, having discovered the information, the addressee would have comprehended it, or appreciated its meaning or import.[29]

---

[26] O'Brien #1 at [13.39] and [13.46].

[27] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [151].

[28] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [132].

[29] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2005)68 IPR 459 at [179] per curiam. This observation by the Full Court was approved by this Court in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [132].

Finally, the relevance of the document is established by reference to the problem posed, and is to be determined on the evidence.[30]

28. In the present case, the trial Judge found, and the Full Court agreed, that a skilled addressee would readily have found the Watanabe article and the 471 Patent and considered each of them relevant to the problem.[31] In accepting the evidence of Professor O'Brien and Apotex's independent expert witness, Professor Reece, the trial Judge held that:[32]

> *"[t]he skilled addressee, attempting to find dosages of alternative statins, would have discovered the 471 patent (or its US equivalent as Professor O'Brien found) and the Watanabe article by routine and conventional literature searches that necessarily would have been carried out by reason of the posited attempt... Each document, on the evidence, would have been ascertained, understood and regarded as relevant to the skilled addressee as required by s 7(3) as applicable to the 051 or low dose patent. "*

29. The introduction of s 7(3) into the Act was intended to and did alter the law in relation to obviousness as it then stood, by providing an "expanded prior art base" against which obviousness would be assessed; that is, expanded from CGK alone. This Court in *Lockwood Security Products Pty Ltd v Doric Pty Ltd (No. 2)* (2007) 235 CLR 173 (***Lockwood (No 2)***) stated:[33]

> *"... 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. ..."*

30. This legislative change reflected the balance of policy considerations in patent law of encouraging and rewarding inventors without impeding advances and improvements by skilled, non-inventive persons.[34] This Court described the legislative change as a "*rebalance*" of the competing policy considerations.[35]

31. However, the introduction of s 7(3) of the Act only enlarged the prior art base in as much as it enabled one single source of information (for

---

[30] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [153].

[31] (2013) 100 IPR 285 at [328]-[329]; (2014) 226 FCR 324 at [518]-[520] per Jessup J, with whom the plurality agreed at [228]-[229].

[32] (2013) 100 IPR 285 at [328].

[33] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [127].

[34] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [48].

[35] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [48].

example, a document, or in very limited circumstances, which are not relevant here, a combination of documents under s 7(3)(b)) to be considered with the CGK as the baseline for assessing obviousness. In other words, under s 7(2) of the Act, the person skilled in the art is only permitted to consider what paths might be available to him or her in light of the CGK plus that single document and no other document.

32. As mentioned by Jessup J in the Full Court, the exercise undertaken in enquiring as to obviousness is a "*wholly notional*" exercise requiring the Court to place itself in the position of the hypothetical skilled worker armed with the CGK and one document only.[36]

33. The statutory purpose or context does not suggest a contrary construction. In fact, the regime in s 7 of the Act was specifically introduced to raise the level of inventiveness from that which existed when only the CGK was taken into account. The legislative intention was to ensure that monopolies are only granted where there is something more than a routine advance over a relevant document which, although able to be ascertained and understood by the person skilled in the art, has not made its way into the CGK.

Response to the Appellants' submissions

34. In light of the legal principles set out above, the submissions at AZ [44] to [64] must be rejected.

35. AstraZeneca at AZ [47] objects to the approach of the trial Judge and the Full Court because it means that, in assessing obviousness, only:

(a) Watanabe plus the CGK; or

(b) the 471 Patent plus the CGK,

is relevant information. This means putting the Aoki publication to one side and ignoring the possibility of going forward with the compound it disclosed, NK-104, in place of rosuvastatin.

36. However, as mentioned above, this is precisely the approach called for under s 7.

37. The provision does not require that all information which could be ascertained, understood and regarded as relevant be considered when assessing obviousness. On the contrary, it mandates consideration of a single piece of such information (plus CGK) only. Thus, as NK-104 was not part of the CGK, it could not be part of the assessment based on the 471 patent or the assessment based on Watanabe.

38. In any event, the fact that there might be other potential candidates disclosed by other documents (which may also have met the s 7(3) criteria)

---

[36] (2014) 226 FCR 324 at [536] per Jessup J, with whom the plurality agreed at [228]-[229].

does not detract from the trial Judge and the Full Court's findings. The trial Judge correctly held that:[37]

> *"The fact that there were other potential statin candidates ... for development at the time, ... which the skilled addressee would also have located as a matter of course, does not detract from the fact that the information in each of the 471 patent and the Watanabe article would have led the skilled addressee as a matter of course to try the claimed invention ..."*

39. In this respect, the position internationally is no different, even in jurisdictions where the combining of prior art documents is permitted. For example in the United Kingdom, in Pfizer Ltd's Patent [2001] FSR 16, Laddie J said:[38]

> *"The fact that there are alternative routes is no answer to a case of obviousness based on a particular piece of prior art. On the contrary, the notional skilled addressee is expected to have read the pleaded prior art carefully and to bring to it his interest in the field. If he does that and finds the patented step was an obvious one to make, it is no answer to say that if he had started with other prior art other solutions would have come to mind."*

40. AZ [49] and [50] proceeds upon the assumption that because the CGK "included knowledge that routine searches could be undertaken" and that such searches would have exposed the Aoki article, then NK-104 (as disclosed in the Aoki article) must be included in the information against which the Cripps Question is posed. This is quite contrary to the statutory scheme. It equates the results of routine searches with the CGK, an approach which was rejected by this court in *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411.[39]

41. AZ [51] and [53] asserts that the Full Court "in effect, treated the words 'considered separately' in s 7(2) as a statutory injunction to treat each of Watanabe and the 471 patent as 'the' only relevant information". It is not the words "considered separately" that dictates that approach; rather, it is the abundantly clear reference to "**single document**" in s 7(3)(a).

42. The assertions, again at AZ [51], that "[n]either the primary judge nor the Full Court found that Watanabe or the 471 Patent was 'the' relevant prior art information" (emphasis added) and "the PSA could not move forward without knowing what other results might be available" overstate the position. The question is whether the notional skilled person would directly have been led as a matter of course to try the invention in the expectation

---

[37] (2013) 100 IPR 285 at [330].
[38] [2001] FSR 16 at [78].
[39] *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at [21], [54] and [57].

that it might well produce a useful alternative or better method of treating a patient suffering from hypercholesterolemia than existing statins and doses.[40] It is not necessary in order to answer that question affirmatively that all other possible paths be eliminated. The issue is whether the notional skilled person might well have a useful alternative or better method than the existing method, not whether he or she has identified the single best possible method.

43. At AZ [52] AstraZeneca asserts that "there was no finding, and the evidence did not support any finding, that the PSA would have chosen rosuvastatin over NK-104". This also overstates the position. Professor O'Brien had no difficulty in selecting rosuvastatin over NK-104, since Watanabe disclosed that rosuvastatin could be tolerated by humans whereas Aoki did not disclose the same for NK-104.[41]

44. At AZ [53] AstraZeneca again misinterprets the words "considered separately" in s 7(2).

45. As to AZ [55] to [60], the fact that the experts regarded Watanabe and the 471 Patent separately as relevant after reviewing other documents or abstracts thereof in the typical search procedure does not take the information in Watanabe and the 471 Patent outside the scope of s 7(3)(a). All that is important for the obviousness analysis is that, *when asking the question posed by s 7(2)* – was it obvious? – one must be careful to deploy only the CGK plus the information in a single document that meets the requirements of the last four lines of s 7(3). The Full Court correctly found this to be the position.[42] It would be strange if the position were otherwise, because in all areas of science where practitioners advance knowledge by means of papers published in learned journals, ascertaining information and assessing its relevance involves undertaking sophisticated searches, which produce many documents that need to be considered for their comparative significance.

46. As to AZ [62], this simply disregards the evidence of Professor O'Brien referred to by the Full Court.[43]

47. AZ [63] and [64] relate to the failure by others to produce the invention and the commercial success of rosuvastatin. It is not an answer to an obviousness case to contend that because the compound of the alleged invention had not been marketed before, then it follows that it was not obvious. The question is whether the statutory test for inventive step is

---

[40] (2014) 226 FCR 324 at [533] per Jessup J, with whom the plurality agreed at [228]-[229].

[41] O'Brien T296.45 – T297.45.

[42] (2014) 226 FCR 324 at [530] per Jessup J, with whom the plurality agreed at [228]-[229]. See also the trial Judge's finding that Professor O'Brien "is the representative of the skilled addressee": (2013) 100 IPR 285 at [320].

[43] (2014) 226 FCR 324 at [544] per Jessup J, with whom the plurality agreed at [228]-[229].

met[44] rather than whether another person did, in reality, develop the invention in the sense of bringing a product to market.

48. For the fact that others had not found the claimed solution to the problem at hand to be of any significance in the present case, much more would need to have been known about the actual landscape facing third parties at the priority date. This would include the patent protection available to Shionogi and AstraZeneca in jurisdictions where manufacture could be expected to occur and the extent to which and time at which third parties may in fact have been aware of Watanabe and the 471 Patent.

10 49. In relation to the commercial success of rosuvastatin, this is at best only a secondary indicator of obviousness and can never of itself be decisive.[45] There must be a nexus between the commercial success relied on and the merits of the invention; here, 5mg and 10mg dosages of rosuvastatin.[46] Thus there was no error in the Full Court upholding the trial Judge's finding that the commercial success claimed was not attributable to the claimed dosage regime but to the properties of the compound *per se*.[47] The trial Judge found that AstraZeneca knew it would achieve commercial success even before testing dosages.[48] Commercial success can be achieved by a range of factors including marketing or, in this case, the compound itself.

20 ***The entitlement issue***

50. Actavis relies on the submissions of Apotex Pty Ltd (**Apotex**) in proceeding No. S 54 of 2015 on the Notice of Appeal issue of entitlement.

PART VII: Argument on Notice of Contention

51. Actavis adopts the submissions of Apotex in proceeding No. S 54 of 2015 made in respect of ground 1 (entitlement) and ground 2 (obviousness) of the Notice of Contention. It also abandons ground 3 of the Notice of Contention.

---

[44] (2014) 226 FCR 324 at [551] per Jessup J, with whom the plurality agreed at [228]-[229].

[45] See *Conor Medsystems Inc v University of British Columbia* (2005) 223 ALR 74 at [8]; *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 188 ALR 280 at [50] per Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ; *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228 at 239 per Aickin J; *Winner v Ammar Holdings Pty Ltd* (1993) 25 IPR 273 at 282 per Davies and Morling JJ.

[46] *Garford Pty Ltd v Dywidag Systems International Pty Ltd* (2015) 110 IPR 30 at [85] per Dowsett, McKerracher and Nicholas JJ; see also *Eli Lilly & Co Ltd v Apotex Pty Ltd* (2013) 100 IPR 451 at [668].

[47] (2013) 100 IPR 285 at [333]; (2014) 226 FCR 324 at [552] per Jessup J, with whom the plurality agreed at [228]-[229].

[48] (2013) 100 IPR 285 at [333].

Novelty[49]

52. The trial Judge found that the 471 Patent discloses each and every essential integer of the claims of the 051 Patent.[50] Her Honour's analysis of the teaching of that document is summarised in the following terms:[51]

> "*This is a clear disclosure that the compounds, or at least the specific examples given, are useful for treating each of the three diseases in the dosage ranges identified. The fact that the dosage range may vary depending on each of the factors described (disease, age, weight etc) does not undermine the sufficiency of this disclosure. It is a specific disclosure, and would be understood as such by the skilled addressee, of the usefulness of rosuvastatin (a specific example given of the compound) for treating hypercholesterolemia (a specific disease identified in the context of compounds which are HMG – CoA reductase inhibitors, itself indicative of usefulness of treating hypercholesterolemia to the skilled addressee), in specific dosage ranges (preferably 0.1-100mg per day for oral administration) in either a single daily dose or a split daily dose.*"

53. Thus the 471 Patent teaches a single dosage regimen comprising the ranges specified, which apply to each compound and each condition referred to. The reference to a preferred dosage range of 1 to 100mg is a shorthand means of disclosing that any dosage within that range may be selected. This is consistent with the evidence of Professor O'Brien, who understood this to mean that the range encompasses all numerical dosages.[52]

54. This was not a case where the disclosure was so broad that the person skilled in the art could not readily understand or appreciate exactly what was being taught, as, for example, where there is a formulaic disclosure of many millions of compounds so that the person skilled in the art cannot identify any particular one of them. This contrast was noted by the Full Court.[53] Here, it is clear that the person skilled in the art, looking at the 471 Patent, would see that 1-100mg discloses 5mg and 10mg dosages, as was Professor O'Brien's evidence.[54]

55. It was not necessary to look beyond this disclosure and further ask what dosage, from the disclosed dosing regimen, would then in fact be chosen by the person skilled in the art in a particular scenario to treat a particular

---

[49] Ground 6 of the Notice of Contention.
[50] (2013) 100 IPR 285 at [299]-[333].
[51] (2013) 100 IPR 285 at [304].
[52] O'Brien #1 at [16.12]; see also [13.41]. AstraZeneca did not lead any evidence from an expert disputing the teaching of the 471 Patent.
[53] (2014) 226 FCR 324 at [285].
[54] O'Brien #1 at [16.12]; O'Brien T307.5-10.

patient. The Full Court in *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 46 IPR 553 (***Bristol Myers***) concluded:[55]

> "*What all those authorities contemplate, in our view, is that a prior publication, if it is to destroy novelty, must give a direction or make a recommendation or suggestion which will result, if the skilled reader follows it, in the claimed invention.*" (emphasis added)

56. The Full Court correctly cited *Bristol Myers* but erred in its application by unnecessarily asking whether the skilled reader would follow the recommendation. This error is encapsulated in the following paragraph:[56]

> "*... It is possible that, out of a very large number of possibilities, the person skilled in the art might, based only on the disclosures of the 471 Patent, use the dosage and dosage regimen of claim 1 or claim 2 of the 051 or low dose patent. But it is at least equally possible that such a dosage or dosage regimen might not be used.*"

57. There are a number of recommendations in the 471 Patent. The finding that a person skilled in the art might use a dosage within the claims follows because there is a sufficient recommendation to do that thing; that is, to adopt as a starting point a dosage of 5mg or 10mg. Whether or not there is a sufficient disclosure is assessed at this point of identifying the relevant recommendation/s made in the document.

58. A prior art document may, and frequently does, teach more than one thing. The fact that the 471 Patent also refers to other compounds, conditions and dosages is not to the point, as the anticipating disclosure is clear.

59. The test in *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457[57] (***General Tire***), referred to by the Full Court,[58] provides for a lack of novelty by either:

(a) description; or

(b) instructions which would lead to a product or process otherwise not disclosed in terms.

60. The 471 Patent falls into the former category as the trial Judge correctly found.[59] Situations in the latter category frequently arise, for example, where a prior art document gives instructions which of themselves do not

---

[55] *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 46 IPR 553 at [67].
[56] *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 46 IPR 553 at [298].
[57] *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457, 485-486.
[58] (2014) 226 FCR 324 at [293].
[59] (2013) 100 IPR 285 at [310].

anticipate a product claim but, if followed, would result in a product within the claims.[60]

61. The effect of the Full Court requiring that the invention be the inevitable outcome of following the claimed method, as in [296], is to conflate the two ways by which a lack of novelty can be shown. This means that any publication which contains more than one recommendation could never deprive a patent of novelty if one of the other recommendations leads to something outside the claimed invention. This is inconsistent with the proper application of the test in *General Tire* and established authority such as *Bristol-Myers*.

62. Actavis does not dispute that the 471 Patent also recommends methods which are outside the claims of the 051 Patent. However this does not detract from the fact that there is a recommendation to do something within the scope of the claims. It follows that the trial Judge was correct and the Full Court erred in overturning her Honour's findings on novelty in respect of claims 1 and 2 of the 051 Patent.

63. The remaining issue on novelty relates to claim 3 of the 051 Patent. The Full Court considered the validity of claim 3 together with claims 1 and 2. Claim 3 simply describes a patient who is suffering hypercholesterolemia by reference to cholesterol levels and risk factors rather than by reference to the condition itself.[61] AstraZeneca made no separate submission in respect of this claim at trial. The reasoning of the trial Judge was prefaced on the fact that the scope of this claim was, in practical terms, no different to that of claims 1 and 2.[62] It, therefore, stood or fell based on the fate of those claims.

Infringement[63]

64. AstraZeneca maintained a contention at trial that 20mg dosages of rosuvastatin infringed the claims of the 051 Patent under ss 117(1) and (2)(b) of the Act. A necessary precondition for operation of this provision is a finding that 20mg dosages of rosuvastatin are "not a staple commercial product".

65. The phrase "staple commercial product" is not defined in the Act and determining its meaning requires resort to the context and purpose of s 117.[64] Section 117 had no equivalent in the *Patents Act 1952* (Cth). The implementation of that section represented a policy change recommended in the Industrial Property Advisory Committee's 1984 report entitled

---

[60] See, for example, *Novozymes A/S v Danisco A/S* (2013) 99 IPR 417 at [144]; *Abbott GmbH & Co KG v Apotex Pty Ltd (No 2)* (2010) 87 IPR 561 at [12] and [55]-[56].
[61] O'Brien #1 [6.5], [6.6], [16.30] and [16.48].
[62] (2013) 100 IPR 285 at [315].
[63] Grounds 7 and 8 of the Notice of Contention.
[64] *CIC Insurance v Bankstown Football Club* (1997) 187 CLR 384 at 408.

"Patents, Innovation and Competition in Australia"[65] (the **IPAC Report**) which adopted the term from United States jurisprudence. The explanatory memorandum to the Patents Bill 1990 confirmed that clause 117 was intended to implement the Government's response to IPAC's recommendation.[66]

66. This Court in *Northern Territory of Australia v Collins* (2008) 235 CLR 619 (***Collins***) dealt with the issue. At [144] Crennan J said as follows:

> *"The legislative intention evinced in the statutory language, and apparent also from the relevant secondary materials, is to except from liability, the supply of products with significant non-infringing uses, or as has been put in relation to the American provisions, products with 'lawful as well as unlawful uses'. A preference for such a construction has also been essayed in respect of section 60(3) of the Patents Act 1977 (UK) by a writer who states 'the intention is to stop material particularly adapted to the use of an invention being made available to a putative infringer, but that material which has and, importantly, had, a general purpose of more than de minimis utility, falls within the [UK] exception. The phrase 'staple commercial product' means a product supplied commercially for various uses. This does not mandate an inquiry into whether there is 'an established wholesale or retail market' or into whether the product is 'generally available' even though evidence of such matters may well be sufficient to show that a product is a 'staple commercial product'. The relevant inquiry is into whether the supply of the product is commercial and whether the product has various uses."* (emphasis added)

67. Hayne J at [41] agreed with Crennan J that a staple commercial product is one that is supplied commercially for various uses and noted at [42] that the expression should not be given a narrow meaning "because to do so would expand the classes of supply which are reached by section 117, thus expanding the rights of the patentee where, by hypothesis, the act of supply

---

[65] Australian Industrial Property Advisory Committee & Australian Department of Science and Technology 1984, "Patents, Innovation and Competition in Australia", Industrial Advisory Committee, Canberra. The IPAC Report, in turn, adopted the report by Ms Ann Dufty entitled "Report to the Industrial Property Advisory Committee", Vol 1, Monash University Law School, (1983). Ms Dufty considered the position at common law and the United States, United Kingdom and Japanese positions and recommended, *inter alia*, goods should be defined as "non-staple" or "goods which have no substantial infringing use".

[66] Government Response to the IPAC Report, (1986) 56(47) *Official Journal of Patents, Trade Marks and Designs* 1468; EM Patents Bill 1990, paragraphs 170-171; *Patents Bill 1990*, Senate Second Reading Speech, 29 May 1990. See also *Patents Bill 1989* (of which the 1990 Bill was a reincarnation), House Second Reading Speech, 1 June 1989.

is not otherwise an infringement of the patentee's monopoly". At [48] his Honour said:

> *"To read 'staple commercial product' as identifying a product that is supplied commercially for various uses does not reflect the notion of principal or chief importance sometimes conveyed by the adjective 'staple'. But as Crennan J concludes: 'staple', used adjectivally in the compound expression 'staple commercial product', should not be read as directing attention to the economic significance of the product concerned. Rather, it should be read as inviting attention to the variety of uses to which the product both can be, and is in fact, put. It is that variety of uses which, when the product is supplied commercially, makes the product a staple commercial product."* (emphasis added)

68. And then at [50], his Honour said:

> *"... the question posed in section 117(2)(b) is: To what uses is the product* in fact *put? If it is in fact supplied commercially for various uses, it is a staple commercial product and the supplier of such products is not to be held liable as an infringer because the person to whom the product is supplied uses it in a way that infringes, even if the supplier has reason to believe that it may be used in that way."* (emphasis in original)

69. The trial Judge and the Full Court rejected the contention that rosuvastatin is a staple commercial product. The Full Court said:[67]

> *"We are not satisfied that rosuvastatin is a staple commercial product. The fact that it may be used for both infringing and non-infringing purposes is not conclusive. There are many products capable of being used for both infringing and non-infringing purposes that cannot be characterised as either raw materials or basic products commonly used for a variety of purposes. The uses to which rosuvastatin may be put appear to us to be limited to the prevention or treatment of cardiovascular disease and its associated risk factors (e.g., high cholesterol)."*

70. The last sentence is wrong in fact: the evidence at trial showed that rosuvastatin had a number of medical uses other than the treatment of hypercholesterolemia.[68] Further, Actavis respectfully submits that the Full

---

[67] (2014) 226 FCR 324 at [431].

[68] Rosuvastatin is used for treating pleomorphic (anti-inflammatory) effects to reduce the incidence of plaque rupture and heart attacks: Hay T158.14-29; diabetes: Hay 158.31-35; stroke: Hay T158.46-159.4; chronic renal disease: Hay T159.13-19; coronary artery disease or peripheral vascular disease: Bull T203.29-206.3. The evidence of Dr Wilson

Court's approach is incorrect. It focuses on the notion of principal or chief importance sometimes conveyed by the word "staple", which was the very approach expressly rejected by Hayne J at [48] of *Collins,* rather than the issue identified by Crennan J at [144], namely, whether rosuvastatin has significant non-infringing uses. A 20mg dosage of rosuvastatin can be used in a non-infringing way even if split into 10mg dosages, where it is used for the treatment of conditions other than hypercholesterolemia. Where it is used to treat hypercholesterolemia but not as a starting dose (for example) it may also be used in a non-infringing manner.

71. Even if, contrary to the above submission, rosuvastatin is not a staple commercial product, it remains necessary for the Court to accept that the supplier of rosuvastatin has reason to believe that "the person" to whom the product is supplied, referred to in s 117(2)(b), would put the product to an infringing use.

72. The evidence at trial showed that the prevalence of pill splitting was, at its highest, 2.75%.[69] Given the proportion of tablets likely to be split, the use relied upon by AstraZeneca is an "unlikely" use in the context of all possible uses of rosuvastatin. In *Generic Health Pty Ltd v Otsuka Pharmaceutical Co Ltd* (2013) 100 IPR 240 ***(Generic Health)***, Bennett J referred to the authority of *Grimme Landmaschinenfabrik GmbH & Co KG v Scott* (2010) 89 IPR 631 (***Grimme***) and held: "Grimme suggests that s 117(2)(b) cannot apply where there is unlikely, freak or maverick use."[70] That is the case here.

73. The fact that a small proportion of the patient population might:

    (a) split the 20mg dosage;

    (b) further, use it as a starting dose; and

    (c) still further, use it for the treatment of hypercholesterolemia,

    is not sufficient to lead to the conclusion that the supplier has reason to believe that "the person" to whom it is supplied would put the product to an infringing use.

74. Actavis contends that it is not enough to show that as a matter of statistics there is merely a slight chance that some unidentified individual might perform those actions for it to be said that the generic parties have "reason to believe that the person would put it to that [infringing] use". The consequences of there being only a slight chance that the product would be

---

was also to the effect that patients with vascular disease and diabetes are two of the classes of patients most commonly prescribed statins independently of whether they have hypercholesterolemia: Wilson T169.21-28. The product information for Crestor (rosuvastatin) recommended the drug for cardiovascular events: Crestor product information at page 12 and page 24.

69 (2014) 226 FCR 324 at [437].

70 *Generic Health Pty Ltd v Otsuka Pharmaceutical Co Ltd* (2013) 100 IPR 240 at [105] per Bennett J.

put to an infringing use were discussed by Bennett J in *Generic Health* in the following terms:[71]

> "*A reasonable belief that an event would happen arises from a belief in the likelihood of that event. That likelihood must be significant. A belief that an event is of a low likelihood would amount to a reasonable belief that the event* may *happen. The word used by s 117(b) is that that a person* would *put the product to that use.*" (emphasis in original)

75. Her Honour's reasoning is directly applicable in this case. The regime mandated by ss 117(1) and 117(2)(b) requires supply of the product to a particular person who would put the product to an infringing use. This arises from the definite article being used in paragraph (b) to identify "the person" and the use of the word "would" in that paragraph.

76. It would have been a simple matter for Parliament instead to have referred to a supplier having reason to believe that the product may be put to an infringing use, but it did not do so. The reason for this lies in Parliament's apparent intention not to require suppliers of products which have more than one reasonable use to be responsible for policing the activities of third parties who might decide to put the product to an infringing use, unless there is some degree of certainty that this will occur (and of course, save for the situation covered by s 117(2)(c) where instructions are given to use the product in an infringing manner).

Manner of manufacture[72]

77. The Full Court correctly summarised the principles relevant to whether an invention constitutes a manner of manufacture.[73] However, in considering the 051 Patent, the Court erred at paragraph [389] in failing to hold that both the 471 Patent and Watanabe were incorporated in the specification.

78. Actavis submits that the relevant passages in the 051 Patent referring to those documents were there to direct the person skilled in the art to their teaching as part of the description of the invention. It was necessary for the patentee to show the best method of performing the invention and to fully describe the invention in order to comply with s 40 of the Act and this included, on AstraZeneca's case, identifying and obtaining the compound rosuvastatin. The 471 Patent and Watanabe enabled that to be done. Accordingly, the documents must be read as incorporated into the specification.

79. Being prior publications and identified as such, they thus constitute admissions that rosuvastatin was not new and its utility for the treatment of

---

[71] *Generic Health Pty Ltd v Otsuka Pharmaceutical Co Ltd* (2013) 100 IPR 240 at [106] per Bennett J.

[72] Grounds 4 and 5 of the Notice of Contention.

[73] (2014) 226 FCR 324 at [379]-[386].

hypercholesterolemia was known. All that remained to achieve the claimed combination was selecting the starting dosage. The 471 patent taught a single oral dosage range for rosuvastatin of 1 to 100mg per day. Atorvastatin is admitted in the 051 Patent as a proven cholesterol-lowering statin with a starting dose of 10mg.[74]

80. Thus, all the alleged inventor has done is adopt the starting dosage of atorvastatin. It is respectfully submitted that this "does not involve the quality of inventiveness necessary for there to be a proper subject of letters patent."[75] Contrary to the holding of the Full Court at [391], no further experimentation is required to move from the disclosures in 471 and Watanabe when one takes into account the admission of the starting dose for atorvastatin.

Part VIII: Oral argument

81. Actavis estimates that approximately 4 hrs (taken together with Apotex) will be required for its oral argument.

DATED: 22 April 2015

A J RYAN
Tel: (03) 9225 8523
Fax: (03) 9600 0320
Email: ajryan@vicbar.com.au

I P HORAK

Counsel for the Respondents in No. S55 of 2015 and No. S56 of 2015

---

[74] 051 Patent at page 1 line 17 and page 12 lines 15-20.

[75] Per this court in *N V Philips Gloeilampenfabrieken v Mirabella International Pty Limited* (1995) 183 CLR 655 at 663 to 664 per Brennan, Deane and Toohey JJ; cited by the Full Court in (2014) 226 FCR 324 at [379].