AstraZeneca AB v Apotex Pty Ltd [2015] HCA 30

HIGH COURT OF AUSTRALIA

FRENCH CJ, KIEFEL, GAGELER, KEANE AND NETTLE JJ

FRENCH CJ:

Introduction

1 AstraZeneca AB, the first appellant, is the registered proprietor of Australian Patent Number AU200023051 ("Patent 051") entitled "Use of Cholesterol-Lowering Agent". AstraZeneca Pty Ltd, the second appellant, is the exclusive licensee of the Patent. The term "AstraZeneca" is used in these reasons to designate either or both appellants. The term "the Agent" used in the title of Patent 051 is defined in the specification as a compound called "rosuvastatin" and its pharmaceutically acceptable salts. Rosuvastatin is one of a class of compounds called statins which can reduce health threatening cholesterol levels in the human body by blocking the action of an enzyme called HMG-CoA reductase. The enzyme binds to a substrate HMG-CoA and mediates a reaction which transforms the substrate to mevalonic acid, a precursor of cholesterol. Statins interfere with that process by preferentially binding to the substrate, thus limiting the sites available for the enzyme and thereby reducing the production of cholesterol.

2 Patent 051 is a method patent defining low dosage levels at which rosuvastatin is said to be efficacious in lowering cholesterol with less need for upward titration of doses over time and associated patient supervision and management than other statins existing at the priority date of the patent. The patent sets out three claims defining the invention:

1. A method of treating a patient suffering from hypercholesterolemia which comprises administration as a starting dose of a single, once daily, oral dose of 5 to 10 mg of the compound [rosuvastatin][1] or a pharmaceutically acceptable salt thereof, in the form of a pharmaceutical composition.

2. A method of treating a patient suffering from hypercholesterolemia which comprises administration of a single, once daily, oral dose of 5.2 to 10.4 mg of the calcium salt of the compound [rosuvastatin] in the form of a pharmaceutical composition.

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1 The generic designation rosuvastatin has been inserted in lieu of the full technical name of the chemical compound used in the claims.

3. A method as claimed in claim 1 or 2 wherein the patient has an LDL-C level[2] of 160 mg/dl or greater with no chronic heart disease or peripheral vascular disease and one or no risk factors for such a disease; an LDL-C level of greater than 130 mg/dl with no chronic heart disease or peripheral vascular disease and two or more risk factors for such a disease; or an LDL-C level of greater than 100 mg/dl with clinically evident chronic heart disease or peripheral vascular disease.

The priority date of Patent 051 was 6 February 1999.

3 The Full Court of the Federal Court, in a judgment delivered on 12 August 2014[3], dismissed appeals by AstraZeneca against a decision of Jagot J[4] in which her Honour revoked the patent on a number of grounds. Her Honour held that AstraZeneca was not entitled to the patent because the claimed method of treatment had been invented by employees of Shionogi & Co Ltd ("Shionogi")[5]. She held that the invention as claimed lacked novelty[6] and that it involved no inventive step having regard to the common general knowledge at the priority date whether considered by itself or in conjunction with either of two prior art publications extant at the priority date and not forming part of the common general knowledge[7]. The two prior art publications were a European patent, referred to as Patent 471, which claimed the invention of the compound rosuvastatin and methods of preparing it and a technical journal article referred to as the "Watanabe Article".

4 The Full Court held that the primary judge had erred in finding want of novelty[8]. It also found, contrary to the primary judge, that the invention as claimed did not lack an inventive step having regard to the common general knowledge considered alone[9]. However, it agreed with the primary judge that

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2 LDL-C refers to low density lipoprotein cholesterol.

3 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324.

4 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285.

5 (2013) 100 IPR 285 at 365 [291]–[292].

6 (2013) 100 IPR 285 at 373 [323].

7 (2013) 100 IPR 285 at 373–375 [324]–[334].

8 (2014) 226 FCR 324 at 402 [357] per Besanko, Foster, Nicholas and Yates JJ, Jessup J agreeing at 421 [447].

9 (2014) 226 FCR 324 at 371–372 [202]–[203], 373 [209] per Besanko, Foster, Nicholas and Yates JJ, 441 [503]–[504] per Jessup J. The Court essentially rejected the premise of her Honour's conclusion that it was possible to assume the existence and nature of rosuvastatin even though it did not form part of the

(Footnote continues on next page)

the invention as claimed lacked inventive step by reference to common general knowledge considered with either of the two prior art publications[10]. The decision of the Full Court on that question involved the application of ss 7(2) and 7(3) of the *Patents Act* 1990 (Cth) ("the 1990 Act") as that Act stood at the priority date and when the Patent was applied for.

5 Sections 7(2) and 7(3) are central to these appeals against the decision of the Full Court. They defined the condition on satisfaction of which an invention would not be taken to involve an inventive step. Relevantly, that condition was satisfied if the invention would have been obvious to a person skilled in the relevant art in light of the common general knowledge considered separately or together with prior art information publicly available in a single document before the priority date of the patent. The single document had to contain prior art information which could reasonably be expected to have been ascertained, understood and regarded by the skilled person, before the priority date, as relevant to work in the relevant art in the patent area. In this Court, AstraZeneca's primary argument was for a construction of ss 7(2) and 7(3) which would preclude the use, in the imputed ascertainment of the relevant single document, of other prior art information not forming part of the common general knowledge. Its second argument was that the Court could not decide the question of want of inventive step on the basis of a single avenue of approach based on common general knowledge and the relevant single document.

6 AstraZeneca also challenged the conclusion by the Full Court that the appeals against the primary judge's finding of want of entitlement failed. An interlocutory application, seeking to amend the notices of appeal to invoke an assignment by Shionogi to AstraZeneca which post-dated the primary judgment and to invoke relieving provisions of the 1990 Act in relation to entitlement which came into force after that judgment[11], was dismissed[12].

7 The grounds of each appeal to this Court by special leave granted on 13 March 2015[13] were:

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common general knowledge: see (2013) 100 IPR 285 at 346 [220]–[221], 373 [325].

10 (2014) 226 FCR 324 at 452 [545] per Jessup J, Besanko, Foster, Nicholas and Yates JJ agreeing at 378 [228]–[229].

11 *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012 (Cth), Sched 6, Item 31. Section 22A of the 1990 Act commenced on 15 April 2013.

12 (2014) 226 FCR 324 at 368–369 [188]–[191] per Besanko, Foster, Nicholas and Yates JJ, Jessup J agreeing at 421 [447].

13 [2015] HCATrans 058 (French CJ and Hayne J).

"The Full Court erred in upholding the finding of the primary judge that Australian Patent 200023051 (the **051 Patent**) was invalid on the ground that the claimed invention was obvious in the light of the common general knowledge (the **CGK**) considered together with each of the documents referred to as Watanabe and the 471 Patent under the provisions of s 7(2) and (3) of the *Patents Act 1990* (Cth) (the **Act**).

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The Full Court erred in upholding the finding of the primary judge that the 051 Patent was invalid on the ground that the first appellant was not entitled to the 051 Patent and in refusing to grant leave to the appellants to amend their notices of appeal and adduce further evidence directed to that issue."

8 The first ground depended primarily upon constructions of ss 7(2) and 7(3) which their text will not bear. On their correct construction and application, the invention as claimed lacked an inventive step having regard to the common general knowledge and each of the Watanabe Article and Patent 471 considered separately with the common general knowledge. The failure of the first ground of appeal is sufficient to dispose of the appeals, which should be dismissed. Neither the second ground of appeal nor issues raised on the notices of contention filed by the respondents need to be determined. Before turning to the factual findings and evidence relating to the first ground, it is necessary to consider the construction and application of ss 7(2) and 7(3).

The inventive step requirement

9 Patent 051, being the subject of Letters Patent granted under s 61 of the 1990 Act, is a standard patent as defined in the Dictionary set out in Sched 1 to the Act. As a standard patent, it had to meet the requirement of s 18(1)(b)(ii) of the 1990 Act that "[the] invention ... so far as claimed in any claim ... when compared with the prior art base as it existed before the priority date of that claim ... involves an inventive step". The relevant part of the definition of "prior art base" set out in the Dictionary provided:

"(a) in relation to deciding whether an invention does or does not involve an inventive step:

(i) information in a document, being a document publicly available anywhere in the patent area; and

(ii) information made publicly available through doing an act anywhere in the patent area".

10 Sections 7(2) and 7(3) of the 1990 Act set out the condition upon which an invention would not be taken to involve an inventive step when compared with the prior art base:

"(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base 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 together with either of the kinds of information mentioned in subsection (3), each of which must be considered separately.

(3) For the purposes of subsection (2), the kinds of information are:

(a) prior art information made publicly available in a single document or through doing a single act; and

(b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art in the patent area would treat them as a single source of that information;

being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood and regarded as relevant to work in the relevant art in the patent area."

This case does not involve the use of two or more related documents. Section 7(3)(b) is therefore not material for present purposes.

11 Sections 7(2) and 7(3), read with s 18(1)(b)(ii), take their place in the long history of the concept of the inventive step necessary to attract patent protection[14] and are to be read in that context[15]. Section 6 of the Statute of Monopolies[16], upon which British patent law was based after 1624, did not refer to an "invention". It excepted from the declaration that all monopolies were void "any Letters Patents and Grants of Privilege" for the "Making of any Manner of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the Time of Making such Letters Patents and Grants shall not use". Section 6 did not contain a requirement for an inventive step. Before the enactment of the *Patents, Designs, and Trade Marks Act* 1883

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14 Beier, "The Inventive Step in Its Historical Development", (1986) 17 *International Review of Industrial Property and Copyright Law* 301.

15 *Network Ten Pty Ltd v TCN Channel Nine Pty Ltd* (2004) 218 CLR 273 at 280–281 [10]–[12] per McHugh ACJ, Gummow and Hayne JJ; [2004] HCA 14.

16 21 Jac I c 3 (1624).

(UK), scrutiny of patent applications in the United Kingdom was largely concerned with compliance with formalities unless the patent was challenged[17]. Want of novelty or utility or "lack of subject matter" could be raised in proceedings for the repeal of a patent taken by action of *scire facias*, brought in the name of the Crown pursuant to the fiat of the Attorney-General. The action was abolished by the 1883 Act but the grounds upon which it could be brought became grounds of revocation under that Act and were also available as defences to infringement proceedings[18]. They also became, under s 86(3) of the *Patents Act* 1903 (Cth), grounds for the revocation of a patent by petition to the High Court or the Supreme Court of a State[19]. The ground of want of inventive step, distinct from want of novelty and want of utility, as a basis for revoking a patent, was a product of case law under the rubric of "lack of subject matter"[20]. The term "obvious" emerged from the common law in relation to lack of subject matter in the late 19th century[21]. Lord Herschell, in an early use of the term in *Vickers, Sons & Co Ltd v Siddell*[22], said:

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17 Monotti, "Divergent Approaches in Defining the Appropriate Level of Inventiveness in Patent Law", in Ng, Bently and D'Agostino (eds), *The Common Law of Intellectual Property: Essays in Honour of Professor David Vaver*, (2010) 177 at 179.

18 Edmunds and Stevens, *The Law and Practice of Letters Patent for Inventions*, 2nd ed (1897) at 484–486; Monotti, "Divergent Approaches in Defining the Appropriate Level of Inventiveness in Patent Law", in Ng, Bently and D'Agostino (eds), *The Common Law of Intellectual Property: Essays in Honour of Professor David Vaver*, (2010) 177 at 179–180.

19 Reflecting similar provisions in the pre-federation legislation of the Australian colonies: *Patents, Designs, and Trade Marks Act* 1884 (Q), s 29(3); *Patents Act* 1884 (Vic), s 15(3); *Patents Act* 1888 (WA), s 31(3); *Patents, Designs, and Trade Marks Act* 1893 (Tas), s 38(2); *Patents Act* 1899 (NSW), s 19(3).

20 *Sunbeam Corporation v Morphy-Richards (Aust) Pty Ltd* (1961) 180 CLR 98 at 110–111 per Windeyer J; [1961] HCA 39. See, for example, *Gadd v The Mayor of Manchester* (1892) 9 RPC 516 at 525–526 per Lindley LJ. See also Terrell, *The Law and Practice Relating to Letters Patent for Inventions*, 7th ed (1927) at 57–58.

21 *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1981) 148 CLR 262 at 272 per Aickin J, Gibbs ACJ, Stephen and Mason JJ agreeing at 268, Wilson J agreeing at 288; [1981] HCA 12 citing Fox, *Monopolies and Patents*, (1947) at 214–243.

22 (1890) 15 App Cas 496 at 501–502. See also *Longbottom v Shaw* (1891) 8 RPC 333 at 337.

> "the question remains, whether this ... was so obvious that it would at once occur to anyone acquainted with the subject, and desirous of accomplishing the end, or whether it required some invention to devise it."

12 In *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]*[23] this Court adverted to the historical development of want of inventive step at common law and the statutory ground, referring to obviousness, first created in the United Kingdom by the *Patents and Designs Act* 1932 (UK) ("the 1932 UK Act"), which the Court described as[24]:

> "a different formulation of the old ground of 'want of subject matter' with the test becoming an overtly qualitative test rather than a quantitative one."

Australia followed the 1932 UK Act with the enactment of s 100(1)(e) of the *Patents Act* 1952 (Cth) ("the 1952 Act") providing as a ground of revocation that a claim "was obvious and did not involve an inventive step, having regard to what was known or used in Australia on or before the priority date of that claim". Section 100(1)(e) was "the first legislative recognition in Australia that obviousness, or lack of inventive step, constituted a ground of revocation which was independent of lack of novelty"[25].

13 Under the 1952 Act, a prior disclosure did not support a conclusion of obviousness unless there was evidence that the disclosure was part of the "common general knowledge" at the relevant time[26]. The term "common general knowledge" did not appear in s 100(1)(e). It was derived from the words "what was known or used in Australia". It had its origin in the common law of patents and was used in connection with want of novelty and want of subject matter. The relevant aspect of the latter objection was that the invention was "not proper subject-matter in view of the common knowledge of the time when it was patented"[27]. The content of common general knowledge, applied for the

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23 (2007) 235 CLR 173; [2007] HCA 21.

24 (2007) 235 CLR 173 at 192 [43].

25 (2007) 235 CLR 173 at 193 [45].

26 *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 295 per Aickin J, Barwick CJ agreeing at 259, Stephen and Mason JJ agreeing at 260, Wilson J agreeing at 298; [1980] HCA 9; *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816 at 822 [35]; 188 ALR 280 at 288; [2002] HCA 21.

27 Terrell, *The Law and Practice Relating to Letters Patent for Inventions*, 5th ed (1909) at 340.

purposes of the 1952 Act, was explained by Aickin J in *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* as[28]:

> "that which is known or used by those in the relevant trade. It forms the background knowledge and experience which is available to all in the trade in considering the making of new products, or the making of improvements in old, and it must be treated as being used by an individual as a general body of knowledge."

Importantly, under Australian law, it was not to be constructed out of a mosaic of prior publications[29].

14 Publications existing before the priority date of a patent, in order to be relevant to want of inventive step under the 1952 Act, had to have become part of the common general knowledge. In *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd*, Aickin J wrote the leading judgment, with which Gibbs ACJ, Stephen, Mason and Wilson JJ agreed, and said[30]:

> "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*." (emphasis added)

The same requirement applicable to the 1952 Act was reflected in the discussion of *Minnesota Mining* in the joint judgment in *Aktiebolaget Hässle v Alphapharm Pty Ltd* ("*AB Hässle*")[31].

15 Relevant content was given to the term "obvious" by Aickin J in *Wellcome Foundation Ltd*, posing as the test[32]:

> "whether the hypothetical addressee 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."

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28 (1980) 144 CLR 253 at 292.

29 (1980) 144 CLR 253 at 292–293.

30 (1981) 148 CLR 262 at 270.

31 (2002) 212 CLR 411 at 430–431 [43]–[45] per Gleeson CJ, Gaudron, Gummow and Hayne JJ; [2002] HCA 59.

32 (1981) 148 CLR 262 at 286.

The idea of steps taken "as a matter of routine" did not, as was pointed out in *AB Hässle*, include "a course of action which was complex and detailed, as well as laborious, with a good deal of trial and error, with dead ends and the retracing of steps"[33]. The question posed in *AB Hässle* was whether, in relation to a particular patent, putative experiments, leading from the relevant prior art base to the invention as claimed, are part of the inventive step claimed or are "of a routine character" to be tried "as a matter of course"[34]. That way of approaching the matter was said to have an affinity[35] with the question posed by Graham J in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd*[36]. The question, stripped of references specific to the case before Graham J, can be framed as follows:

> "Would the notional research group at the relevant date, in all the circumstances, which include a knowledge of all the relevant prior art and of the facts of the nature and success of [the existing compound], directly be led as a matter of course to try [the claimed inventive step] in the expectation that it might well produce a useful alternative to or better drug than [the existing compound]?"

That question does not import, as a criterion of obviousness, that the inventive step claimed would be perceived by the hypothetical addressee as "worth a try" or "obvious to try"[37]. As was said in *AB Hässle*, the adoption of a criterion of validity expressed in those terms begs the question presented by the statute[38].

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33 (2002) 212 CLR 411 at 436 [58] per Gleeson CJ, Gaudron, Gummow and Hayne JJ.

34 (2002) 212 CLR 411 at 433 [52] per Gleeson CJ, Gaudron, Gummow and Hayne JJ.

35 (2002) 212 CLR 411 at 433 [53] per Gleeson CJ, Gaudron, Gummow and Hayne JJ.

36 [1970] RPC 157 at 187–188. The question posed was described in *AB Hässle* as a "reformulation of the 'Cripps question'" — a reference to the question set out in *Sharp & Dohme Inc v Boots Pure Drug Company Ltd* (1928) 45 RPC 153 at 173.

37 (2002) 212 CLR 411 at 441 [72] per Gleeson CJ, Gaudron, Gummow and Hayne JJ.

38 See the discussion of that observation, particularly with respect to the decisions of United States courts, in McRobert, "Inventive step: Obvious to try again?", (2009) 20 *Australian Intellectual Property Journal* 237.

16 The enactment of ss 7(2) and 7(3) followed a report and recommendations by the Industrial Property Advisory Committee ("IPAC") which proposed that[39]:

> "For the purpose of determining inventiveness, any single prior disclosure or use should be capable of being considered against the background of all that is common general knowledge in the relevant field of art. On this basis the requirement of inventiveness will not be fulfilled if the knowledge imparted by the disclosure or use, combined with what is common general knowledge in the art, would render the claimed invention obvious to a person reasonably skilled in the art.
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> However, it should not be possible for this purpose to combine two disclosures, two uses, or a disclosure and a use, where neither is within the common general knowledge of the art, except where one disclosure refers to another disclosure or use."

IPAC recommended[40]:

> "(i) that novelty and obviousness for standard patents be determined against a prior art base consisting of—
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> - disclosures in recorded form publicly available anywhere in the world;
> - disclosures openly made, by oral communication, in Australia; and
> - what has been openly done and used in Australia;
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> (ii) that, for these purposes (except where there is cross-referencing) it not be permissible to combine any two disclosures, or a disclosure and a use, or any two uses, save that in determining obviousness any single disclosure or use should be capable of being viewed in the light of the common general knowledge in the relevant field of art, at the relevant time; and
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> (iii) that the common general knowledge in the art be treated as including disclosures in recorded form publicly available anywhere in the world which a skilled person working in the art at the time

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39 Commonwealth of Australia, Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, (1984) at 45.

40 Commonwealth of Australia, Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, (1984) at 46, Recommendation 13.

should reasonably have been expected to find, understand, and regard as relevant."

The latter recommendation was not accepted and was not reflected in ss 7(2) and 7(3). The qualification it contained, however, was found in the government's response to Recommendation 13(ii)[41]:

> "It is to be understood, however, for the purpose of determining whether an invention is obvious, that it be permissible only to consider, in the light of the common general knowledge, a single disclosure or use which a skilled person working in the art in Australia at the time should reasonably have been expected to find or uncover, understand, and regard as relevant."

17 In the 1990 Act, as the Court said in *Lockwood [No 2]*, the threshold of inventiveness was raised compared with that set by the 1952 Act. The new threshold reflected the two IPAC recommendations which were accepted with the qualifications mentioned in the previous paragraph[42]. The change effected by s 7(2) was that information publicly available at the priority date, but not part of common general knowledge, could be taken into account in addition to common general knowledge. The purpose of s 7(3) was broadly speaking[43]:

> "the specification of the additional publicly available information ... which must be added to common general knowledge for the purposes of deciding whether an alleged invention is obvious when compared with the prior art base."

While the range of disclosures that could support a finding of obviousness was widened, the content of the "inventive step" requirement was not changed. The test was still that posed under the 1952 Act by Aickin J in *Wellcome Foundation Ltd* in terms of the hypothetical addressee taking, as a matter of routine, steps which might lead from the prior art to the invention[44]. That said, it was the text of ss 7(2) and 7(3) which governed the prior art information which could be invoked and how it could be invoked.

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41 "Government Response to the Report of the Industrial Property Advisory Committee, 'Patents, Innovation and Competition in Australia'", *Official Journal of Patents, Trade Marks and Designs*, 18 December 1986, vol 56, No 47, 1462 at 1471.

42 (2007) 235 CLR 173 at 193 [45].

43 (2007) 235 CLR 173 at 194 [49].

44 (1981) 148 CLR 262 at 286, quoted at [15] above.

18 The text of s 7(2) required, in unambiguous language, that "the onus to establish the absence of an inventive step rests upon the party challenging validity."[45] It was, as Jessup J correctly observed in the Full Court, a deeming provision[46]. Section 7(2) would defeat a claim for want of inventive step unless one of the alternative conditions set out in s 7(2), read with s 7(3), was satisfied. Those conditions involved the following elements:

1. An hypothetical person skilled in the relevant art.

2. The person being, therefore, notionally possessed of the common general knowledge as it existed in the relevant area before the priority date of the impugned claim.

3. The invention being obvious to that person in the light of the common general knowledge.

4. Alternatively, that person being provided with prior art information made publicly available in a single document or through doing a single act, or made publicly available in two or more related documents or through doing two or more related acts if the relationship between them satisfied the requirement of s 7(3)(b).

5. That prior art information, as defined by s 7(3), being information that the person could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood and regarded as relevant to work in the relevant art in the patent area ("the relevance requirement"). "Ascertained", in this context, means "discovered or found out". "Understood" means that, having discovered the information, the person would have "comprehended it" or "appreciated its meaning or import"[47].

6. The invention being obvious to the person in the light of the common general knowledge considered together with either of the classes of prior art information defined in s 7(3).

The judicial determination whether want of inventive step is established pursuant to s 7 is mediated through the legal construct of the hypothetical person skilled in the relevant art. The construct is of a kind well-known to the law and used for

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45 *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816 at 821 [31]; 188 ALR 280 at 287.

46 (2014) 226 FCR 324 at 424 [458].

47 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 at 219 [132].

setting parameters for evaluative judgments[48]. It is a tool of analysis and is given statutory recognition, for that limited purpose, in s 7.

AstraZeneca's constructional arguments

19 Expert evidence at trial, as to the process by which prior art information is identified for the purposes of s 7(3), may assist the court in deciding whether that information meets the relevance requirement and whether it is thereby available for consideration under the alternative operation of s 7(2). Expert evidence may also inform the court's judgment as to obviousness, albeit mediated by the notional person skilled in the relevant art. In this case, the finding by the Full Court of want of inventive step was informed principally by the expert evidence of the respondents' witnesses, Professor Richard O'Brien and Dr Phillip Reece[49], which is considered later in these reasons. They gave evidence of searches they carried out leading to identification of the prior art information invoked against the patent. In identifying that prior art information they had regard to other prior art publications disclosed by their searches. That approach, which was accepted by the primary judge and in the Full Court, was challenged in two constructional arguments about ss 7(2) and 7(3) which lay at the heart of AstraZeneca's case on its first ground of appeal.

20 The first of the constructional arguments concerned satisfaction of the relevance requirement. AstraZeneca submitted in its outline of oral argument that:

> "A process of satisfying the 'regarded as relevant' requirement which involves considering by way of comparison non-cgk publications subverts the purpose of s 7(3) and is impermissible; *a fortiori* if the effect of the

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48 See, for example, the hypothetical fair-minded person used in determination of a reasonable apprehension of bias discussed in *British American Tobacco Australia Services Ltd v Laurie* (2011) 242 CLR 283; [2011] HCA 2 and *Isbester v Knox City Council* (2015) 89 ALJR 609; 320 ALR 432; [2015] HCA 20; the hypothetical referee in determining whether particular material is defamatory discussed in *Radio 2UE Sydney Pty Ltd v Chesterton* (2009) 238 CLR 460; [2009] HCA 16 and *Harbour Radio Pty Ltd v Trad* (2012) 247 CLR 31; [2012] HCA 44; the hypothetical reasonable person referred to in s 471.12 of the *Criminal Code* (Cth) considered in *Monis v The Queen* (2013) 249 CLR 92; [2013] HCA 4; the hypothetical reasonable person invoked to determine whether a representation to the public constitutes misleading or deceptive conduct discussed in *Campomar Sociedad, Limitada v Nike International Ltd* (2000) 202 CLR 45; [2000] HCA 12.

49 Professor O'Brien was the expert witness of Watson Pharma Pty Ltd (now Actavis Pharma Pty Ltd) and Ascent Pharma Pty Ltd. Doctor Reece was the expert witness of Apotex Pty Ltd.

comparison is to identify the publication as 'the' relevant course to pursue."

In its written submissions it contended that:

> "The clear words of s 7(2) require that non-CGK sources must be 'considered separately'. This requires each non-CGK source to be considered separately at each stage of the obviousness inquiry, including (i) when assessing whether the invention is obvious in the light of the CGK and a single source of s 7(3) information and *(ii) at the anterior step of assessing whether or not any given source of information satisfies the 'ascertained, understood and regarded as relevant' requirement in s 7(3)*." (emphasis added)

21 The reasons of the Full Court on that argument were given by Jessup J, with whom the other Judges agreed[50]. His Honour, directing his remarks to s 7(3), said[51]:

> "It is, in my view, wholly within the scheme of the subsection that [the skilled person] might well sort through all manner of information with a view to finding something that is 'regarded as relevant'. There is nothing in the provision which would place an embargo upon the skilled person using combinations of sources of information along the road to that destination."

That approach was correct. The words "considered separately" in s 7(2) qualify the way in which prior art information complying with s 7(3) must be used, in conjunction with common general knowledge, in determining obviousness under the alternative operation of s 7(2). They preclude the use of a combination of unrelated documents, not forming part of the common general knowledge, for the purposes of that determination. Section 7(2) says nothing about how the relevance requirement in s 7(3) is to be satisfied.

22 AstraZeneca argued that the construction adopted by the Full Court led to incongruity in that a comparative assessment of the prior art information against other located publications was permitted for the purpose of determining whether the relevance requirement was satisfied under s 7(3), but not permitted when applying the obviousness test under s 7(2). There is no incongruity. The relevance requirement is a threshold criterion for consideration, by the court, of a prior art publication in conjunction with common general knowledge for the

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50 (2014) 226 FCR 324 at 447–448 [529]–[532], Besanko, Foster, Nicholas and Yates JJ agreeing at 378 [228]–[229].

51 (2014) 226 FCR 324 at 448 [530].

purpose of determining obviousness. The process leading to its identification plays no role in that determination.

23 There was a tendency in AstraZeneca's arguments to confer upon the "person skilled in the relevant art" more human characteristics of volitional and purposive action than are necessary for its function. The notional person is not an avatar for expert witnesses whose testimony is accepted by the court. It is a pale shadow of a real person — a tool of analysis which guides the court in determining, by reference to expert and other evidence, whether an invention as claimed does not involve an inventive step.

24 AstraZeneca's second constructional argument was that, even if it were wrong on its first argument, s 7(2) did not allow the court to decide the question of want of inventive step on the basis that "the only course available to the skilled person [was] that identified in the s 7(3) document [a]dded to the prior art base." It submitted that the "single avenue approach" allowed by the Full Court created "a new revoker's starting point with the benefit of hindsight" and avoided false routes suggested by other documents which might have met the relevance requirement. One such document, referred to as the "Aoki Article" and located by both expert witnesses, had identified a promising compound other than rosuvastatin, known as NK-104. It suffices to say that the text of s 7(2) simply does not offer a constructional choice imposing the limitation for which AstraZeneca contends. The second argument must be rejected.

25 AstraZeneca also argued that the "single avenue approach" led the Full Court to find obviousness despite the non-disclosure in the Watanabe Article or Patent 471 of animal safety data which was essential to any human dosage selection, including 5-10 mg, on the basis that the relevant range would be discovered by tests. This was effectively an attack on the merits of the obviousness finding considered later in these reasons. The rejection of the constructional arguments and consideration of the challenge to the merits of the obviousness finding should be placed in the concrete context of the terms of the patent, the relevant common general knowledge, the prior art information relied upon and the expert testimony in the case.

Patent 051

26 The invention was described in Patent 051 as relating to the use of a cholesterol lowering agent and, more particularly, to the administration of a particular dose or dosage range of the HMG-CoA reductase inhibitor rosuvastatin[52] and its pharmaceutically acceptable salts. The specification acknowledged that rosuvastatin had been disclosed in the European Patent Application, Publication No 0521471, which claimed it and methods for its preparation as inventions ("Patent 471"). That patent was one of the documents

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52 Described in the specification by its technical chemical name.

contained in prior art information which grounded the finding of a want of inventive step under the alternative operation of s 7(2). The specification also acknowledged disclosure of rosuvastatin in an article published in 1997[53]. The article, whose lead author was Masamichi Watanabe, is the other prior art information, referred to in these reasons as "the Watanabe Article". In each of Patent 471 and the Watanabe Article, rosuvastatin was disclosed as an inhibitor of HMG-CoA reductase. However, the primary judge found, and it is not in dispute, that neither the chemical name nor structure of rosuvastatin was part of the common general knowledge of persons skilled in the relevant art before the priority date of Patent 051[54].

27 The specification referred to a number of HMG-CoA reductase inhibitors marketed under the collective designation of "statins". A "problem" was then identified:

> "Despite the benefits of statin therapy, less than optimal results may be achieved in patients, due to the level of efficacy and safety achieved at the recommended dosages of the currently marketed statins. Accordingly it is important to find dosages of alternative statins which beneficially alter lipid levels to a significantly greater extent than similar dosages of currently used statins and which have a similar or improved safety profile."

A solution was set out:

> "Surprisingly it has now been found that when dosed orally to patients with hypercholesterolemia at particular dosages or in a particular dosage range the Agent lowers total cholesterol (TC) and low-density lipoprotein cholesterol (LDL-C) by an unexpected degree, and without any significant adverse side effects. When dosed at the same dosages or in the same dosage range, the Agent also modifies other lipoprotein levels (such as raising high density lipid cholesterol (HDL-C) levels, lowering triglyceride (TG) levels and lowering apolipoprotein B-100 (Apo-B) levels) to an unexpected and beneficial extent, without any significant adverse side effects. Elevations of alanine aminotransferase (ALT) liver enzyme levels are reported for other HMG-CoA reductase inhibitors. Surprisingly it has now been found that when the Agent is dosed at the dosages or in the dosage ranges discussed herein, clinically significant rises in these levels are less frequently observed."

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53 Watanabe et al, "Synthesis and Biological Activity of Methanesulfonamide Pyrimidine- and *N*-Methanesulfonyl Pyrrole-Substituted 3,5-Dihydroxy-6-heptenoates, a Novel Series of HMG-CoA Reductase Inhibitors", (1997) 5 *Bioorganic and Medicinal Chemistry* 437.

54 (2013) 100 IPR 285 at 339 [195].

Various aspects of the invention were described essentially by reference to the objective of treatment and the dosage range. The claims defining the invention have been set out in the introduction to these reasons.

Common general knowledge

28 The primary judge defined the hypothetical skilled addressee of Patent 051 as a medical practitioner with specialised expertise in treating hypercholesterolemia[55]. It was common general knowledge for such persons before the priority date that:

- statins were an effective and safe treatment for hypercholesterolemia but despite the existence of a number of statins there were patients who could not be treated with them[56];
- simvastatin had been commonly used for lowering LDL-C. Atorvastatin, being more potent than simvastatin, had replaced it as the most commonly prescribed statin in Australia. Other statins available were fluvastatin and pravastatin[57];
- statins on the market as at the priority date were available in the following doses, listed in the MIMS Annual 1998[58]:
  (a) fluvastatin — 20 mg and 40 mg tablets;
  (b) pravastatin — 5 mg, 20 mg and 40 mg tablets;
  (c) simvastatin — 5 mg, 10 mg, 20 mg and 40 mg tablets; and
  (d) atorvastatin — 10 mg, 20 mg and 40 mg tablets[59];
- medical practitioners would typically prescribe patients the lowest dose of statin to begin with to minimise the risk of adverse events, such as muscle pain, liver dysfunction and more severe muscle toxicity, side effects potentially associated with statins. If the target cholesterol level was not reached and the dose had been well tolerated it would be increased by a

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55 (2013) 100 IPR 285 at 314 [94].

56 (2013) 100 IPR 285 at 323 [123].

57 (2013) 100 IPR 285 at 318 [103].

58 An acronym derived from a publication originally called Monthly Index of Medical Specialties.

59 (2013) 100 IPR 285 at 318 [103].

process known as "dose titration" over a period of months. Dose titration aimed to increase the dose until the patient reached the target in as safe a manner as possible[60];

- one issue with the prescription of statins was that many patients did not achieve their target cholesterol levels because dose titration required ongoing management and supervision by a medical practitioner[61];

- consequently a statin which could bring more patients to their target level without dose titration than the existing statins would be highly desirable[62].

The existence, the name and the chemical structure of rosuvastatin and the fact that it had been subject to clinical trials were not part of the common general knowledge before the priority date of Patent 051. The primary judge found they were not part of the common general knowledge before 30 June 2000[63].

29 Under the heading "Common general knowledge" the primary judge also considered evidence with respect to pre-clinical trials and clinical trials of promising new drugs. Her findings, which were summarised by the Full Court, involved the following propositions:

- A clinical trial is an experiment or a series of experiments investigating the use of a promising drug candidate and its use in humans. Clinical trials are time consuming and expensive with many new drug candidates failing in the trial process in terms of safety or efficacy, or both[64].

- Pre-clinical in-vitro tests give an indication of whether the drug has the desired activity against the drug target and its selectivity to the target[65].

- Pre-clinical animal studies establish the margin of safety of the drug which is the dosage or blood plasma concentration at which the first signs of toxicity are seen compared to the dose or plasma concentration required for efficacy. They provide information about safety and therapeutic efficacy, as well as pharmacokinetics — ie what the body does to the drug in terms of its absorption, distribution, metabolism and excretion. They

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60 (2013) 100 IPR 285 at 319 [109].

61 (2013) 100 IPR 285 at 323 [123].

62 (2013) 100 IPR 285 at 323 [123].

63 (2013) 100 IPR 285 at 338–339 [190]–[197].

64 (2014) 226 FCR 324 at 348 [68].

65 (2014) 226 FCR 324 at 348 [69].

also provide information about pharmacodynamics — ie what the drug does to the body in terms of biochemical and physiological effects[66].

- Clinical trials establish the safety and efficacy of the drug in humans and are done in three sequential phases. Phase I trials use a small number of healthy subjects to ensure that the drug is safe in humans and to consider dosage ranges — the pharmacodynamics being a secondary purpose. Phase II trials involve studying the drug in a large number of patients, typically involving 50–300, suffering from the relevant condition, the primary objective being to ascertain the pharmacodynamic effects of the drug. Phase III trials involve studying the effectiveness of the drug in a large number of patients (up to 5,000) over a long period of time. Phase III trials are pivotal because generally it is in such trials that long term efficacy can be demonstrated for the first time and in a statistically significant number of participants. A fourth class of investigation involves long term post-marketing observation of the drug in a target population[67].

30 The primary judge's findings as to the common general knowledge at the priority date of Patent 051 were not challenged on the appeal to the Full Court[68].

Prior art information — Patent 471

31 The first in time of the two prior art publications relied upon by the respondents was Patent 471, which had a priority date of 1 July 1991. The compound the subject of the patent was rosuvastatin although that name was not used in the specification or claims. The applicant for the patent was Shionogi. One of the co-inventors was Masamichi Watanabe. The title of the patent was "Pyrimidine derivatives as HMG-CoA reductase inhibitors". A first generation of HMG-CoA reductase inhibitors, used for the treatment of atherosclerosis, was identified. They were the fungal metabolites, mevinolin, pravastatin sodium and simvastatin and their chemical derivatives. A second generation, of synthetic inhibitors of HMG-CoA reductase, including fluvastatin, was also identified.

32 The compound claimed in Patent 471 was said, in the specification, to inhibit HMG-CoA reductase and to be useful in the treatment of hypercholesterolemia and other conditions. The specification set out methods for its preparation and stated that it could be administered orally in the form of

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66 (2014) 226 FCR 324 at 348 [69].

67 (2014) 226 FCR 324 at 349 [70].

68 See especially (2014) 226 FCR 324 at 450 [538] per Jessup J. See generally (2014) 226 FCR 324 at 342–352 [47]–[86] per Besanko, Foster, Nicholas and Yates JJ.

tablets, powders, capsules and granules or parenterally in the form of an aqueous or oily suspension. Dosages were mentioned:

> "The dosages may vary with the administration route, age, weight, condition, and the kind of disease of the patients, but are usually 0.5-200 mg/day, preferably 1-100 mg/day for oral administration and 0.1-100 mg/day, preferably 0.5-50 mg/day for parenteral administration."

There was no reference to clinical trials.

33 The claims in the patent identified rosuvastatin (albeit not by that name), variants of it and processes for its preparation. Its biological activity was described by reference to its HMG-CoA reductase inhibitory effect on rat liver microsomes. The specification also stated:

> "The test data demonstrates that the compounds of the present invention exhibit HMG-CoA reductase inhibition activities superior to mevinolin."

Prior art information — the Watanabe Article

34 The Watanabe Article was published in 1997. It was co-authored by Masamichi Watanabe and others. Watanabe's affiliation was described as Shionogi Research Laboratories, Shionogi and Company Ltd. The title of the article referred to the synthesis and biological activity of a series of compounds identified as HMG-CoA reductase inhibitors. In the introductory section, mention was made of lovastatin, pravastatin and fluvastatin as potent hypocholesterolemic agents widely used clinically. Much effort was said to have been expended to obtain more potent reductase inhibitors. The article reported on the synthesis and biological activity of particular compounds, one of which was rosuvastatin, designated not by that name but as S-4522. The authors stated:

> "During this study, we found that [rosuvastatin] possesses greater enzyme inhibitory activity than lovastatin (1a) and pravastatin (1b)."

S-4522 was tested for its ability to inhibit cholesterol biosynthesis in hepatocytes isolated from rat livers. It was approximately 100-fold more potent than pravastatin sodium salt. The results of testing on cultured human hepatoma cells suggested it could lead to a greater decrease in serum cholesterol than pravastatin. As a liver-selective HMG-CoA reductase inhibitor, it indicated a potent cholesterol lowering and reduced side effects in clinical use because the liver is a major site of cholesterol biosynthesis. It reduced the plasma cholesterol levels of beagle dogs by 26 per cent, compared with 18 per cent for pravastatin at a repeated dose for 14 days of 3 mg/kg per day. It also reduced the plasma cholesterol levels of the cynomologus monkey by 22 per cent at a dosage of 12.5 mg/kg whereas pravastatin reduced them by 19 per cent at a dosage of 50 mg/kg. It was said to be approximately four times more potent than lovastatin sodium salt in inhibiting HMG-CoA reductase in-vitro and was the most potent

cholesterol biosynthesis inhibitor in isolated rat liver hepatocytes. The article noted that a clinical trial of S-4522 was in progress.

Expert evidence — ascertainment of relevant prior art information

35 The expert evidence relevant to inventive step, which was the focus of attention in this Court, was that of the respondents' witnesses, Dr Reece and Professor O'Brien. Their expertise was not in issue. Prior to trial Dr Reece had been instructed as follows in relation to the preparation of his opinion:

> "You are given a new statin and are told that it is useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis. HMG-CoA reductase inhibitors are the most widely used prescription medication for the treatment of hypercholesterolaemia. A number of HMG-CoA reductase inhibitors are marketed, namely lovastatin, pravastatin, simvastatin, fluvastatin, atorvastatin and cerivastatin, and are collectively referred to as 'statins'. Despite the benefits of statin therapy, less than optimal results may be achieved in patients, due to the level of efficacy and safety achieved at the recommended dosages of the currently marketed statins. Accordingly it is important to find dosages of alternative statins which beneficially alter lipid levels to a significantly greater extent than similar dosages of currently used statins and which have a similar or improved safety profile."

36 The instructions given to Professor O'Brien in effect set out only so much of the preceding passage as commenced with the words "Despite the benefits"[69]. He was not told that there was "a new statin" that was not part of the common general knowledge. Jessup J took the view, however, that even in the case of Dr Reece the setting in which he prepared his opinion did no more than create an incentive to discover whether there was such a molecule. His Honour concluded that the utility of Dr Reece's evidence was not compromised because of the premise, in his instructions, that there was a new statin in existence[70].

37 In response to the problem set for him, Dr Reece searched for published articles which had the potential to provide information about a new statin with the characteristics referred to in his instructions. He acquired 19 abstracts of articles that appeared to fall within his terms of reference. He obtained the full texts of the articles concerned. He concluded that only three were relevant to his terms of reference. The lead authors were respectively Aoki, Watanabe and Thompson. The Aoki Article referred to an HMG-CoA reductase inhibitor called NK-104. The Watanabe Article, as already outlined, contained a report on a series of compounds including rosuvastatin which Dr Reece recognised as "a

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69 (2014) 226 FCR 324 at 445 [522] per Jessup J.

70 (2014) 226 FCR 324 at 445 [522].

very potent inhibitor of cholesterol biosynthesis" and as "definitely a candidate for further development". The Thompson Article referred to a number of "the more promising looking compounds in the pipeline", including NK-104 and rosuvastatin[71]. Doctor Reece's assessment of the relevance of the Watanabe Article involved his assumption that the unknown compound with the characteristics for which he was searching was at the stage of phase II trials at least. As noted above, the Watanabe Article stated that rosuvastatin was in clinical trials. Doctor Reece took that to mean either phase I or phase II trials. The Thompson Article told him that rosuvastatin was in phase II trials[72]. Consistently with his approach to the construction of s 7(3), which has been accepted as correct earlier in these reasons, Jessup J, in effect, concluded that Dr Reece's use of the Thompson Article did not prevent his evidence from supporting a finding that the Watanabe Article met the relevance requirement[73].

38 Professor O'Brien's search and elimination process led him to the Watanabe and Aoki Articles and, via a footnote in Watanabe, to a Japanese patent equivalent to Patent 471. He was subsequently provided with a copy of the equivalent United States patent. He identified five abstracts of articles, two of which related to the statin cerivastatin. Those two abstracts suggested it was less efficacious than atorvastatin. Another article by Betteridge was a general reference which did not describe any new statin. Professor O'Brien preferred rosuvastatin, designated as S-4522 in the Watanabe Article, over NK-104, the subject of the Aoki Article. Rosuvastatin appeared to be more effective than pravastatin, fluvastatin and lovastatin and had progressed to clinical trials. The Watanabe Article also indicated that it had high potency with reduced side effects in clinical use. It appeared to be further along the line of development than NK-104. Professor O'Brien therefore regarded rosuvastatin as the most relevant compound in relation to the defined problem.

39 As appears from his description of the search process, Professor O'Brien regarded the Watanabe Article as the most relevant one as a result of comparing it with other publications. His decision thus involved a choice between the publications. Again, consistently with the correct construction of s 7(3), Jessup J rejected the proposition that the Watanabe Article thus ascertained could not be said to have met the relevance requirement necessary for the purposes of s 7(2)[74].

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71 (2014) 226 FCR 324 at 447 [528].

72 (2014) 226 FCR 324 at 447 [529].

73 (2014) 226 FCR 324 at 447–448 [530].

74 (2014) 226 FCR 324 at 448 [532].

Want of an inventive step

40 In approaching the question of inventive step for the purposes of s 7(2), Jessup J asked[75]:

> "whether the invention (in the 051 patent) would have been obvious to the skilled addressee in the light of the common general knowledge when considered together with the information brought in under s 7(3), namely, the information to be found in either the Watanabe article or the 471 patent (but not both)."

His Honour adopted as the correct approach to "obviousness" that approved in *AB Hässle*[76] and derived from the judgment of Graham J in *Olin Mathieson*, paraphrased earlier in these reasons. His Honour posed the question thus[77]:

> "whether the notional skilled person would have directly been led as a matter of course to try the invention as claimed in the expectation that it might well produce a better method of treating a patient suffering from hypercholesterolemia than existing statins and doses."

The primary judge had answered that question in the affirmative.

41 His Honour referred to the evidence of Professor O'Brien and Dr Reece. Both were aware of the existing statin known as atorvastatin which, it was common general knowledge, was the most efficacious of the existing statins on the market[78]. His Honour cited Professor O'Brien's evidence that he would have expected rosuvastatin "to have a similar or better efficacy than atorvastatin" but that would need to be confirmed by direct comparison. Rosuvastatin looked to him to be "an exciting molecule". Its data were "impressive" and it "may well be better than atorvastatin"[79]. His Honour also referred to Dr Reece's evidence that the new statin which he was asked to identify would have to be neither less potent nor less safe than atorvastatin. Doctor Reece drew the conclusion from the Watanabe Article that rosuvastatin was "a very potent agent in reducing plasma cholesterol concentrations". The Full Court's attention was not drawn to any passage in his cross-examination in which he was tested on the extent to

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75 (2014) 226 FCR 324 at 448 [533].

76 (2002) 212 CLR 411 at 433 [53].

77 (2014) 226 FCR 324 at 448–449 [533].

78 See (2014) 226 FCR 324 at 345 [54] per Besanko, Foster, Nicholas and Yates JJ.

79 (2014) 226 FCR 324 at 450–451 [540].

which he could have inferred that rosuvastatin would be likely to be at least as efficacious as atorvastatin[80].

42 Jessup J concluded that the primary judge had not erred in concluding that a person skilled in the art would have been led directly and as a matter of course to try rosuvastatin at a dosage of 5-10 mg/daily in the expectation that it might well be an efficacious treatment for a patient suffering from hypercholesterolemia. The evidence of Professor O'Brien and of Dr Reece was sufficient to sustain the conclusion that the skilled person, having read the Watanabe Article in the light of the common general knowledge, would have entertained the expectation that rosuvastatin might well be at least as efficacious a treatment as atorvastatin. No error was involved in that reasoning. In the light of the evidence it would be a routine step to test rosuvastatin at the lowest efficacious dose.

43 Jessup J rejected a submission by AstraZeneca that the primary judge's conclusion that the skilled person would have proceeded to try rosuvastatin at any dose, let alone a 5 or 10 mg dose, with any reasonable expectation of success was not open on the evidence before her. That rejection was plainly correct. As his Honour said[81]:

> "Whether an invention is obvious is a question to be answered by the Court."

The question posed by this Court in *Wellcome Foundation Ltd* and *AB Hässle* does not require that, in order to sustain an obviousness case, a party has to lead evidence which echoes the terms of that question. A similar conclusion was open, as the primary judge found, on Patent 471.

44 AstraZeneca submitted in this Court that the "claimed invention" is a treatment using a once daily, 5-10 mg dosage of rosuvastatin. The only dosage expert, Dr Reece, confirmed that neither the Watanabe Article nor Patent 471 contained animal or human trial safety data. He had given evidence that such data were essential to determining what dosage should be tested in clinical trials. The person skilled in the art would never have chosen the dose to be tested simply by trying the doses that worked for other statins. That evidence was referred to by Jessup J, who said[82]:

> "But that evidence also made it quite clear that such trials would conventionally be carried out. They would fall within the concept of

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80 (2014) 226 FCR 324 at 451 [541].

81 (2014) 226 FCR 324 at 451 [543].

82 (2014) 226 FCR 324 at 452 [547].

working towards the invention with an expectation of success referred to in *AB Hassle*."

No error is disclosed in that reasoning.

45 Finally, AstraZeneca submitted that the approach by Jessup J to s 7(3) led his Honour to disregard secondary evidence of inventiveness, namely, the failure of others to produce the invention and its substantial commercial success. AstraZeneca said that Jessup J held such evidence was irrelevant to a case based on s 7(3) information because the inquiry was a notional one "which need not correspond with reality"[83]. That approach was said to be contrary to the reasoning in *Lockwood [No 2]*. What the Court in *Lockwood [No 2]* said was that an Australian court should be slow to ignore secondary evidence or to rely on its own assumed technical expertise to reach conclusions contrary to such evidence[84]. Their Honours added, however, that Australian courts have long recognised that the importance of such evidence and its weight will vary from case to case and it will not necessarily be determinative.

46 Jessup J's treatment of the secondary evidence arose in the context of the alternative operation of s 7(2). He said[85]:

> "the extended form of s 7(2) sets up a notional inquiry which need not correspond with reality. We know that, as a matter of common general knowledge, the notional non-inventive worker was not aware of the Watanabe article or the 471 patent. The fact that no-one proceeded to the point of making the invention claimed in claim 1 of the patent in suit is, therefore, beside the point. Once we equip the notional worker with the Watanabe article or the 471 patent, the whole setting in which the Cripps question must be asked is altered. The conclusion that the invention under the 051 patent would *then* be obvious is, therefore, not foreclosed by the failure of any flesh and blood research worker to have reached that point in fact." (emphasis in original)

47 In dealing with the substantial commercial success of the drug in which rosuvastatin was the active ingredient administered conformably with claim 1 in Patent 051, the primary judge had said[86]:

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83 (2014) 226 FCR 324 at 453 [551].

84 (2007) 235 CLR 173 at 216 [116] citing *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816; 188 ALR 280; *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (2000) 97 FCR 524.

85 (2014) 226 FCR 324 at 453 [551].

86 (2013) 100 IPR 285 at 375 [332].

> "The problem with this approach in the present case is that the commercial success of AZ's rosuvastatin product, on the evidence, is due to its potency at lower doses than other statins. But as the generic parties pointed out, these are qualities of the compound rosuvastatin. AZ did not invent rosuvastatin. As Apotex put it, 'the commercial success of Crestor is due to the quality of the drug itself, not to the entirely conventional doses of 5 mg and 10 mg'."

The treatment of the "secondary evidence" in this case was tied to the particular statutory context of the alternative operation of s 7(2) and the efficacy of the drug itself. No error is disclosed in the reasoning of Jessup J in this respect.

Conclusion

48 For the preceding reasons AstraZeneca's appeals fail on the first ground and must be dismissed. It is therefore not necessary to consider the questions raised on the notices of contention. In particular, it is not necessary to consider the question on which the Commonwealth was granted leave to intervene, namely, the correctness of the decision of the Full Court of the Federal Court in *Apotex Pty Ltd v Sanofi-Aventis*[87]. The appeals should be dismissed with costs.

KIEFEL J:

49 For some time, HMG-CoA reductase inhibitors, which are referred to as "statins", have been prescribed by medical practitioners for the treatment of conditions such as hypercholesterolemia and for the lowering of low density lipoprotein ("LDL") cholesterol. The statins are typically taken once a day as tablets.

50 The primary judge in the Federal Court of Australia (Jagot J)[88] noted that according to the MIMS Annual 1998, recommended starting doses of statins were typically 10, 20 or 40 milligrams. Medical practitioners usually prescribed the lowest dose of statins to begin with, to minimise the risk of adverse side-effects associated with statins[89]. If the target level of LDL cholesterol was not met and the dose had been well tolerated, it would be increased ("dose titration") over months. Dose titration aimed to increase the dose until the patient reached his or her target safely, but the practice was costly, because it necessitated a number of visits to the doctor and blood tests. It therefore risked patient non-compliance. As a result, titration often did not take place and the patient remained on the starting dose even though his or her target level was not reached.

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87 (2009) 82 IPR 416.

88 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285 at 318 [104].

89 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285 at 319 [109].

51 AstraZeneca AB and AstraZeneca Pty Limited (together "AstraZeneca") are respectively the registered proprietor and exclusive licensee of Australian Patent No 200023051 (which has been referred in the proceedings in the Federal Court as the "051 patent" and the "low dose patent", but is here referred to as "the Patent"). The specification for the Patent identifies the problem which the claimed invention seeks to overcome as finding dosages of alternative statins which have a similar or improved safety profile and are more efficacious in altering lipid levels than dosages of statins then being marketed. It discloses a method of treatment by the administration of what is called "the Agent" in a particular dose or dosage range. The Agent is rosuvastatin and pharmaceutically acceptable salts thereof. The method involved a starting dosage of rosuvastatin of 5-10 milligrams per day. The Patent's specification claimed that at these dosages LDL cholesterol is lowered "by an unexpected degree, and without any significant adverse side effects."

52 The method of treatment described in the Patent, using rosuvastatin at the nominated dosages, has proved effective and commercially successful. The respondents to these appeals, Apotex Pty Ltd, Watson Pharma Pty Ltd (now Actavis Pharma Pty Ltd) and Ascent Pharma Pty Ltd ("the generic parties"), supplied generic compounds using rosuvastatin at like dosages. AstraZeneca claimed infringement of the Patent by that supply and obtained interlocutory injunctions. The generic parties sought revocation of the Patent.

53 Her Honour the primary judge found the Patent to be invalid on three grounds: that AstraZeneca was not entitled to the Patent; that the invention disclosed in the Patent was not novel in light of two prior publications; and that the invention disclosed in the Patent did not involve an inventive step and was obvious within the meaning of s 7(2) of the *Patents Act* 1990 (Cth).

54 A Full Court of the Federal Court (Besanko, Jessup, Foster, Nicholas and Yates JJ) overturned only the finding of lack of novelty and dismissed the appeals from her Honour's decision[90].

55 On its appeals to this Court, AstraZeneca sought to agitate all of the grounds of invalidity which had been upheld by the Full Court. The generic parties raised other issues by notice of contention.

56 One issue which arises in connection with the test of obviousness under s 7(2) of the *Patents Act* 1990 concerns her Honour the primary judge's approach to the characterisation of the invention disclosed by the Patent specification. Her Honour considered[91] that although rosuvastatin was not part of the common

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90 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324.

91 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285 at 345 [218], 346 [220]-[221], 348 [229].

general knowledge at the priority date, the invention presupposed its existence. Rosuvastatin could therefore be taken as a given in applying the test of obviousness.

57 The reasons of the Full Court on the question of obviousness were given by Jessup J, with whom the other members of the Court agreed. His Honour observed[92] that the primary judge's approach to characterising the invention had regard to the specification rather than the claims of the Patent. That approach appeared to follow the decision of a Full Court of the Federal Court in *Apotex Pty Ltd v Sanofi-Aventis*[93], although her Honour eschewed the use of the term "starting point", which had been used in that case, to describe the significance of rosuvastatin in testing the invention for obviousness. The decision in that case, his Honour observed, was at odds with a decision of another Full Court in *Insta Image Pty Ltd v KD Kanopy Australasia Pty Ltd*[94], which his Honour considered to have been correctly decided.

58 The Commonwealth was granted leave to intervene in this matter. It submitted that this Court need not, and should not, deal with this aspect of the primary judge's reasons. A determination of the correctness of her Honour's approach may have significant effects for the Commonwealth as a party in pending proceedings concerning undertakings made to it as to damages, and which were brought by the Commonwealth upon an acceptance of the correctness of the decision in *Apotex Pty Ltd v Sanofi-Aventis*.

59 Were it necessary to the determination of the real issues in this matter for that issue to be addressed, the consequences for other litigation would not be a weighty, or even a relevant, consideration. However, it is not necessary to consider this issue in order to determine the question of obviousness. The evidence shows that a person skilled in the art would have discovered the existence of rosuvastatin in any event. In its reply submissions, AstraZeneca conceded as much.

60 The conclusion of invalidity on the ground of obviousness which was reached by the primary judge and by the Full Court is correct, for the reasons which follow. It is unnecessary to consider the other issues raised. The appeals should be dismissed with costs.

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92 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324 at 440-441 [497]-[500].

93 (2009) 82 IPR 416.

94 (2008) 78 IPR 20.

Obviousness – the *Patents Act* 1990 provisions

61 Section 18(1)(b) of the *Patents Act* 1990 provides that an invention is patentable if, so far as claimed in any claim, it is novel and involves an inventive step when it is compared with the prior art base existing before the priority date of the claim. In relation to deciding whether an inventive step was involved, "prior art base" is defined in the Dictionary to the Act to mean information in a document that is publicly available and information made publicly available through doing an act. However, s 7(2) makes plain that, subject to the effect of the provisions of s 7(3), what is spoken of as the prior art base in the assessment of an inventive step is the common general knowledge, which is to say, the general body of knowledge and experience which is available to all those who might consider making a new product or improving existing products in order to meet an identified need[95].

62 At the priority date and the time the Patent was applied for, s 7(2) provided that:

> "an invention is to be taken to involve an inventive step when compared with the prior art base 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 together with either of the kinds of information mentioned in subsection (3), each of which must be considered separately."

Sub-section (3) relevantly provided:

> "For the purposes of subsection (2), the kinds of information are:
>
> (a) prior art information made publicly available in a single document ...
>
> being information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have ascertained, understood and regarded as relevant to work in the relevant art in the patent area."

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95 *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 292 per Aickin J; [1980] HCA 9.

63 The prior art information referred to in s 7(3) is information which is not part of the common general knowledge. The effect of permitting the use of this additional information is to raise the threshold for inventiveness in s 7(2)[96].

The s 7(2) question

64 The primary judge considered the hypothetical person skilled in the relevant art for the purposes of s 7(2) (hereafter "the skilled person") to be a medical practitioner with specialised expertise in treating hypercholesterolemia and particular expertise in lipidology. The Full Court saw no reason to interfere with this finding[97]. No party to these appeals challenged this aspect of her Honour's decision.

65 The primary judge accepted the evidence of Professor Richard O'Brien and another witness as to the awareness of medical practitioners of the fact that a significant number of patients were not reaching their target levels of LDL cholesterol. Because of the ongoing management involved in dose titration, it was thought by practitioners to be desirable to have available new or improved statins which enable more people to achieve their target level at the first dose, which, according to ordinary prescribing practices, would be a dose at the lower end of the approved range.

66 *Aktiebolaget Hässle v Alphapharm Pty Ltd*[98] ("*Alphapharm*") stated the question to be answered to determine obviousness under the *Patents Act* 1952 (Cth). Section 100(1)(e) of that Act was in relevantly similar terms to s 7(2) of the 1990 Act except for the latter's addition to the matters to be considered, together with the common general knowledge, the prior art information referred to in s 7(3), which does not form part of the common general knowledge.

67 Modifying the question stated in *Alphapharm* to allow for that further information and to be referable to the invention claimed in the Patent, the relevant enquiry is:

> Would a medical practitioner who specialises in treating hypercholesterolemia and who has particular expertise in lipidology, alone or in a notional research group, at the relevant date in all the circumstances, which include the common general knowledge considered separately or together with prior art information publicly available in a document relevant to the problem that many patients are unable to achieve

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96 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 at 218 [127]; [2007] HCA 21.

97 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324 at 341 [45].

98 (2002) 212 CLR 411 at 433 [53]; [2002] HCA 59.

their target LDL cholesterol level using available statins at currently prescribed dosages, directly be led as a matter of course to try rosuvastatin with a starting dosage of 5-10 milligrams in the expectation that it might well produce a useful alternative to or better drug than the most effective statin then available?

68 Before a document containing prior art information can be used along with the common general knowledge for the purposes of the s 7(2) enquiry, it is necessary that it meet the requirements of s 7(3). In *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]*[99] it was explained that prior art information which is publicly available in a single document is "ascertained" if it is discovered or found out, and "understood" means that, having discovered the information, the skilled person would have comprehended it or appreciated its meaning or import. The Court also explained[100] that the phrase "relevant to work in the relevant art" is directed to publicly available information, not part of the common general knowledge, which the skilled person could be expected to have regarded as relevant to solving a particular problem, or meeting a long-felt want or need, as the patentee claims to have done.

69 *Lockwood [No 2]* also explains[101] that, in answering the question of obviousness, the information referred to in s 7(3), like that part of the prior art base which is the common general knowledge, is considered for a particular purpose. That purpose is to *look forward* from the prior art base to see what the skilled person is likely to have done when faced with a problem similar to that which the patentee claims to have solved with the claimed invention. It is this aspect of the s 7(2) enquiry which assumes particular importance on these appeals.

70 In addressing s 7(2), it is to be borne in mind that the skilled person is an artificial construct, intended as an aid to the courts in addressing the hypothetical question of whether a person, with the same knowledge in the field and aware of the problem to which the patent was directed, would be led directly to the claimed invention. The statute's creation of the skilled person construct for this purpose is not to be taken as an invitation to deal with the question posed by s 7(2) entirely in the abstract. Whilst the question remains one for the courts to

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99 (2007) 235 CLR 173 at 219 [132].

100 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 at 222-223 [152].

101 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 at 218 [127].

determine, the courts do so by reference to the available evidence[102] including that of persons who might be representative of the skilled person.

The evidence in this case

71 The Patent had a priority date of 6 February 1999. The primary judge accepted that the existence of rosuvastatin was not part of the common general knowledge of the skilled person at that date. However, it was disclosed in two documents, which were referred to by the primary judge as the "471 Patent" and the "Watanabe article".

72 The 471 Patent was filed by Shionogi, from whom AstraZeneca later obtained a licence in an endeavour to overcome the finding that it was not entitled to the Patent because it was not the inventor of rosuvastatin. The 471 Patent is the European patent for the compound rosuvastatin, which has an equivalent US patent. The specification for the Patent itself states that "the Agent" to which it refers, but not by the name rosuvastatin, is disclosed in European Patent Application, Publication No 0521471. The primary judge found that the 471 Patent is a sufficient disclosure of the compound rosuvastatin.

73 The Watanabe article contains a reference to a range of new compounds, but it is the compound there referred to as S-4522 that is rosuvastatin, which is identified on the first page of the article and referred to as "the selected compound". It is described as having greater potency than some other statins then marketed and as having been tested on animals. It was said to be a promising candidate for development.

74 The primary judge took Professor O'Brien to be representative of the skilled person who is the addressee with respect to the Watanabe article, which he found in the course of his searches for prior art information. Professor O'Brien's expertise qualified him as representative of the skilled person according to the primary judge's description. It is evident that Professor O'Brien's evidence in particular was considered by her Honour to be of the most assistance on the question of obviousness.

75 Professor O'Brien gave evidence that a person in his position faced with the problem of patients not reaching their target LDL cholesterol levels would engage in a four-stage process. In the first place, the person would undertake, or cause to be undertaken, routine and conventional literature searches to discover any alternative statins. Secondly, the person would compare the results of those searches. Thirdly, the person would select from that comparison the best candidate to solve the problem. Lastly, the person would undertake, or cause to be undertaken, trials using that candidate statin to test its suitability at relevant

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102 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 at 223 [153].

dosages. All drugs must be subjected to animal studies and then clinical trials involving humans before they can be marketed and these trials are very expensive.

76 Professor O'Brien explained that, to address the problem, he would be looking for a statin that would lower LDL cholesterol more efficaciously across its safe dose range than the most effective statin being marketed, atorvastatin. To be more efficacious, the statin must have greater efficacy than existing statins at the maximum safe dose to assist in treating patients with very high LDL cholesterol levels. It would be advantageous to have greater efficacy with at least similar safety at the lowest recommended starting dose as this would benefit patients who were intolerant of higher doses.

77 Professor O'Brien conducted what the primary judge described as "routine and conventional literature searches"[103] and identified five abstracts of documents of potential relevance to the problem. He requested a full text copy of those documents, which he identified by reference to their authors. One of them, the "Aoki article", disclosed a statin referred to as NK-104, which he considered to be promising. But it was the Watanabe article and the compound S-4522 which seemed to him more interesting because it suggested that the statin S-4522 had high potency with reduced side-effects and it had progressed to clinical trials. He regarded this as the most likely compound to solve the problem. As mentioned above, S-4522 was in fact rosuvastatin.

78 Having selected this compound, Professor O'Brien gave evidence that the skilled person would have conducted further searches for other articles concerning it, including a patent search for the Japanese patent referred to in the Watanabe article. This was the Japanese Shionogi patent, which is to say the Japanese equivalent of the 471 Patent. He received an English language equivalent of the Japanese patent, which indicated that the author of that patent expected the compound to be effective across the typical dosage range of existing statins marketed in Australia.

79 The information contained in the Watanabe article led Professor O'Brien to expect that this new statin would have a similar, or better, efficacy than atorvastatin. He expected it to be effective in lower dosages and considered that a starting dosage would be around 10 milligrams. The English language equivalent of the Japanese patent led him to expect that the starting dose would be 5-10 milligrams once daily, though he said that this would need to be confirmed by studies of human subjects. The Watanabe article indicated to him that the compound had been successful in both safety and efficacy on the pre-clinical animal trials, because it was not usual to commit to a clinical trial process, as the author reported, unless these trials were successful.

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103 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285 at 374 [328].

80 The primary judge found[104], by reference to the evidence of Professor O'Brien, and of Dr Reece, another expert witness, that the skilled person would have found each of the Watanabe article and the 471 Patent, would have understood them and would have regarded each as relevant. The information in each of them would have led that person, as a matter of course, to undertake clinical trials in the expectation that the compound might produce a better result than was currently achieved in the field.

AstraZeneca's contentions as to obviousness

81 AstraZeneca's contentions as to obviousness may be divided into two stages. The first concerns the application of the s 7(3) stipulations and in particular the determination of whether a document is relevant and therefore eligible to be considered as part of the s 7(2) process. The second concerns the s 7(2) process for determining the question of obviousness. Here AstraZeneca submits that there is an evidentiary gap, because the skilled person would be faced with a number of alternative routes to follow and there was no evidence as to what that person would do. There must be alternative routes available because there is more than one document satisfying the test of relevance and each must be considered. Alternatively, if the Watanabe article can be relied upon alone, the skilled person could not be led by it to the dosage amounts that are part of the invention disclosed in the Patent.

82 AstraZeneca submitted that in addressing the questions as to whether a document could reasonably be expected to be ascertained, understood and regarded by the skilled person as relevant to the problem, s 7(3) does not permit a process of comparison as between the documents in question and other documents not within the common general knowledge in order to select the document to be used in answering the question of obviousness under s 7(2). It submitted that, for the purposes of s 7(3), and in particular to determine its relevance, each document must be looked at independently.

83 Although this point concerns the stipulations of s 7(3), AstraZeneca drew upon the concluding words of s 7(2) – "each of which must be considered separately" – in aid of the suggested prohibition on comparison in order to select a s 7(3) document. A consequence of its argument would appear to be that if a search for prior art information reveals more than one document, none of them could qualify as relevant to the problem if identifying a single document as relevant involved a process that required disregarding all other documents.

84 The purpose of the requirements of separate consideration in s 7(2) is to prevent mosaicking, which is to say, selecting pieces of information from a number of prior publications or objects and assembling them such that the

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104 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285 at 374-375 [329]-[330].

mosaic achieved reveals what is claimed in the patent in suit[105]. This is reinforced by the stipulation in s 7(3)(b) that two documents not within the common general knowledge may be used for the purposes of s 7(2) only if the skilled person would treat them as a single source of information. AstraZeneca's submissions are not directed to the mosaicking of information.

85 AstraZeneca's submissions elide the stipulations of ss 7(2) and 7(3), when the purposes of those sub-sections are quite distinct. The purpose of s 7(3) is to identify documents which may be used for the s 7(2) question of obviousness. The sub-section does so by reference to attributes of a document and the information contained in it, as seen through the eyes of the skilled person. So long as the information in the document has those attributes stipulated by s 7(3) it may be used for the purposes of the enquiry under s 7(2). This is essentially a question of evidence, not statutory construction.

86 The evidence of Professor O'Brien and Dr Reece clearly showed that the Watanabe article, and other documents, could be expected to be ascertained by the skilled person, by routine and conventional searches. In oral argument in this Court, AstraZeneca conceded that the Watanabe article, and the 471 Patent, could be regarded as capable of ascertainment so that the question became one as to the application of s 7(2). In that event the fact that the information contained in those documents could be appreciated as relevant to solving the problem at hand would also appear necessarily to be conceded.

87 Regardless, there can be no doubt, having regard to Professor O'Brien's evidence, that the Watanabe article conveyed sufficient information about the compound it referred to in order for him to appreciate the compound's usefulness. In some cases there may be an issue about the extent to which the information in the document in question may be supplemented or explained by other information. This is not such a case. Professor O'Brien understood from the Watanabe article, as the skilled person would, that the compound there referred to, being rosuvastatin, would be useful for the treatment of hypercholesterolemia and might be more potent than statins then being marketed.

88 The limited comparison Professor O'Brien undertook of the compound in the Watanabe article with that disclosed in the Aoki article was not done with a view to determining the Watanabe article's relevance. It was by way of selecting the best candidate for the solution to the problem. It was necessary for him to select the *best* candidate because the clinical trials which would follow are extremely expensive. The difficulty for AstraZeneca with respect to this aspect of his evidence is that selecting the Watanabe article leads inevitably to the complete invention. This is why AstraZeneca challenges the selection of the Watanabe article over others.

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105 *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 292-293.

89 AstraZeneca accepts that the Watanabe article discloses the route to the invention, but it submits that this is not the only route to be considered. It argues that not only must each document qualifying as relevant be considered separately, but that each must be considered under s 7(2). None may be discarded. The situation which would then be achieved would be that the skilled person would have a number of routes to choose from. It is at this point that AstraZeneca submits that the claim of obviousness must fail, because witnesses such as Professor O'Brien did not say what they would do in such a situation.

90 There is a level of unreality about the situation AstraZeneca seeks to create. Professor O'Brien did not need to comment upon what he would do faced with alternative routes, because that hypothetical did not arise, given the selection he had made of rosuvastatin. This evidence of Professor O'Brien that he would select rosuvastatin is sufficient to conclude that the skilled person would have selected the route that led to the invention of rosuvastatin.

91 AstraZeneca further submitted that even if the Watanabe article was selected or preferred, it was not obvious that the skilled person would actually pursue that route to reach the invention. However, this submission was premised upon the information in that article being regarded as relevant and no more. This ignores the effect of Professor O'Brien's evidence which went further than to identify the compound disclosed as relevant.

92 There is no step towards the invention unaccounted for in the evidence of Professor O'Brien. His evidence not only identified rosuvastatin as relevant to solving the problem to which the Patent is addressed; both he and Dr Reece identified rosuvastatin as warranting clinical trials. This evidence also provides the answer to AstraZeneca's final submission.

93 The final submission was that, armed with the Watanabe article and the common general knowledge, the skilled person would not have been led directly to the invention because the starting dosages are an essential element of the invention and were not revealed by that article or by any other prior art document.

94 This may be accepted. The dosages were revealed to AstraZeneca by clinical trials on humans, as inevitably they would be if undertaken. The point is that the Watanabe article contained sufficient information, including as to the results of the pre-clinical trials on animals, for Professor O'Brien to consider that clinical trials were warranted. Dr Reece was of the same view.

95 Professor O'Brien's evidence about what the right dosages might be, although accurate, was largely speculative and this was not his area of expertise. However, Dr Reece, who has a background in clinical pharmacology and research, gave evidence that dose sizes which would be trialled could be expected to start from 5 milligrams, 10 milligrams and 20 milligrams. I do not understand AstraZeneca to contend that the starting dosages disclosed in the Patent would not be identified by normal clinical trials, which utilise certain

standards and procedures. The evidence therefore shows that the skilled person would be led to the invention.

Orders

96 I agree with the orders proposed by the Chief Justice.

GAGELER AND KEANE JJ:

97 We agree, for the reasons given by the Chief Justice and by Kiefel J, that the issue on which these appeals turn was correctly decided by the courts below. We wish only to make some brief comments upon the lack of merit in AstraZeneca's challenge to those decisions.

98 In this case, special leave to appeal was granted principally to allow this Court to address difficulties said to attend the interpretation of s 7(2) and (3) of the *Patents Act* 1990 (Cth). The arguments advanced by AstraZeneca on these issues in this Court were without substance; they were also distinctly elusive in their presentation. The shifts which occurred in AstraZeneca's position during the course of argument should not be allowed to obscure the reality that these provisions give rise to no difficulties of interpretation material to the outcome of this case. The deference due to the plain and ordinary meaning of statutory language is not diminished because that language regulates intellectual property rights[106].

99 Both courts below were right to conclude that the putative invention did not involve an inventive step. Given that conclusion, the other arguments on which the parties lavished much time, resources and enthusiasm are unnecessary to resolve.

The patent

100 The priority date of the patent in suit ("the Patent") is 6 February 1999. Before this date it was part of the common general knowledge that statins were administered to patients to lower their low-density lipoprotein (LDL) cholesterol levels. The problem in the common general knowledge at the priority date was to develop a new statin treatment that could bring more patients to their target blood cholesterol level without the need to resort to dose titration. AstraZeneca claimed that it solved this problem by inventing the method of treatment claimed in the Patent.

101 Claim 1 of the Patent defined the method of treatment as:

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106 *Alphapharm Pty Ltd v H Lundbeck A/S* (2014) 89 ALJR 1 at 10 [42], 20 [104]; 314 ALR 182 at 193, 207; [2014] HCA 42.

> "A method of treating a patient suffering from hypercholesterolemia which comprises administration as a starting dose of a single, once daily, oral dose of 5 to 10 mg of [rosuvastatin], or a pharmaceutically acceptable salt thereof, in the form of a pharmaceutical composition."

The decision of the primary judge

102 The primary judge held that the existence of the method of treatment was disclosed by two pieces of prior art. One was a European patent application ("the 471 patent"), which disclosed that various compounds, including rosuvastatin (within a certain dosage range), were useful in the treatment of hypercholesterolemia. Her Honour found that the 471 patent would have enabled a person skilled in the art to proceed to the method of treatment claimed in the Patent. The other piece of prior art information was an academic article (referred to by the parties as "the Watanabe article") that described a compound, S-4522 (rosuvastatin), as a "promising candidate for development" in relation to the treatment of hypercholesterolemia. Her Honour found that the Watanabe article would also have enabled a person skilled in the art to proceed to the method of treatment claimed in the Patent. These findings were based on the expert evidence of Professor O'Brien and Dr Reece.

103 There was no challenge to Professor O'Brien's qualification to give evidence in relation to how a person skilled in the art would have gone about solving the problem in the common general knowledge. Professor O'Brien's evidence was that a person skilled in the art who encountered the problem would have engaged in a four-step process to solve it. That process would have involved, as the first two steps, routine and conventional literature searches to discover alternative statins, and a comparison of the results of those searches. That comparison would have led to a selection of the best candidate to solve the problem. There would then have been trials using that selected statin to determine its efficacy at relevant dosages.

104 Professor O'Brien gave evidence that he conducted routine and conventional literature searches as the first step in this process. Those searches generated hundreds of abstracts of scientific papers. Professor O'Brien gave evidence that his comparison of these papers identified the Watanabe article and another paper, referred to as the Aoki article (which concerned an agent described as NK-104), as candidates to solve the problem.

105 The Watanabe article led Professor O'Brien to ascertain the Japanese equivalent of the 471 patent, the English language version of which led him to expect that an appropriate starting dose for treatment would be five to 10 milligrams once daily, although this expectation would need to be confirmed by studies of human subjects. In this regard, Dr Reece's evidence was to the same effect.

106 Professor O'Brien said he would have chosen rosuvastatin for treatment, although he would not have been critical of someone who chose NK-104.

107 This evidence led the primary judge to conclude that a person skilled in the art would have been led, as a matter of course, to try the method of treatment claimed in the Patent in the expectation of improved results for patients. Accordingly, the claimed method of treatment did not involve an inventive step.

The appeals to the Full Court

108 AstraZeneca appealed from the decision of the primary judge to the Full Court of the Federal Court of Australia (Besanko, Jessup, Foster, Nicholas and Yates JJ). In a separate concurring judgment, Jessup J dealt with the inventive step point.

109 Jessup J upheld the primary judge's conclusion that the claimed invention was obvious in light of the common general knowledge together with either the Watanabe article or the 471 patent. His Honour's consideration[107] of this issue involved two questions:

> "first, was there prior art information, of the kind referred to in [s 7(2)], which the skilled addressee 'could … be reasonably expected to have ascertained, understood [and] regarded as relevant' (within the meaning of [s 7(3)]); and secondly, if so, would the invention then have been obvious, in the light of the common general knowledge when considered together with that information, to the skilled addressee?"

110 In relation to the first question, Jessup J held that it was permissible under s 7(3) to have regard to multiple pieces of prior art information "along the road to [the] destination" of assessing whether any single piece of prior art information could reasonably be expected to have been regarded as relevant to solving a problem in the common general knowledge. As his Honour rightly said[108]:

> "It is true that, under s 7(2) ... the skilled person notionally knows nothing beyond the common general knowledge. But it is then assumed [by s 7(3)] that he or she will undertake the task of finding some additional information which is not part of the common general knowledge. The question is whether he or she *could* be reasonably expected to have ascertained (etc) the information. Such an assumed course of inquiry must necessarily take the person into the realm of information which is not within the common general knowledge. It is, in my view, wholly within the scheme of the subsection that he or she might well sort through all manner of information with a view to finding something that is 'regarded as relevant'. There is nothing in the provision which would place an embargo upon the skilled person using combinations of sources of

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107 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324 at 444 [516].

108 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324 at 447-448 [530].

> information along the road to that destination. … Ultimately, of course, there must be one document (or act) only which imparts the information which is to be added to the common general knowledge. But the sources which the skilled person would consult to decide what that document is, to come to an understanding of the information in it and to consider whether that information was relevant, are not confined to a single document." (original emphasis)

111 This was sufficient to resolve the first question against AstraZeneca. As Jessup J appreciated, the plain and ordinary meaning of the language of s 7(3) imposes no limitation on the search for information outside the common general knowledge other than that the information must be "reasonably expected to have [been] ascertained, understood and regarded as relevant to work in the relevant art in the patent area." Nothing in s 7(3) suggests that the notional skilled addressee may not trawl through multiple documents, discarding the irrelevant and retaining the useful, as part of the ascertainment of relevant information. AstraZeneca initially argued that s 7(3) precluded such a sorting process in the search for relevant information; but the pressure of argument led inevitably to the abandonment of that position.

112 Once relevant information has been ascertained in accordance with s 7(3), the second question posed by Jessup J may be addressed: would the invention be obvious if the information had been considered by a person skilled in the relevant art together with common general knowledge?

113 The inquiry contemplated by s 7(2) is whether the invention would have been obvious to a person skilled in the art in the light of the common general knowledge alone, or "together with" a single piece of prior art information ascertained pursuant to s 7(3). What s 7(2) requires, by the plain and ordinary meaning of its language, is that where multiple pieces of prior art information are available and capable of being regarded as relevant, each must be considered, one at a time, together with the common general knowledge to answer the question whether the invention is obvious. If the invention is obvious in light of the common general knowledge plus any one of the ascertained pieces of prior art information, then the patent is invalid for want of an inventive step.

114 AstraZeneca's contention seemed to be that a person skilled in the art, confronted by a choice between rosuvastatin and NK-104, would not be able to identify the pathway to a solution of the problem, and that this difficulty was not resolved by Professor O'Brien's evidence. It was said that the potential usefulness of *both* rosuvastatin *and* NK-104 meant that it would not have been obvious to a person skilled in the art at the priority date to choose rosuvastatin rather than NK-104 to treat hypercholesterolemia. On a fair view of Professor O'Brien's evidence, and indeed the view taken by the primary judge, Professor O'Brien's express preference for rosuvastatin means that this contention

cannot be sustained. In any event, AstraZeneca's contention pursues a red herring. As the primary judge rightly said[109]:

> "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 in the expectation that it might well produce a useful alternative to or a better result than currently achieved in the field."

115 The question is not whether it would have been obvious to the skilled addressee to choose rosuvastatin over NK-104; rather, it is whether a person skilled in the art would, in light of the common general knowledge plus *either* the Watanabe article *or* the 471 patent, have been directly led as a matter of course to try rosuvastatin in the expectation that it might well produce a solution to the problem which existed in the common general knowledge. Section 7(2) does not contemplate that a choice between apparently effective solutions must be attributed to the notional skilled addressee, much less that the notional skilled addressee might be so befuddled by an embarrassment of choices as to cease pursuit of the solution.

116 It is also wrong to suggest, as AstraZeneca did, that the need for further testing of human subjects was an obstacle to a conclusion that rosuvastatin would have been tried as a matter of course in the expectation of a solution to the problem in the common general knowledge. Section 7(2) does not invite a consideration of the notional addressee's motivation to carry out any tests that would need to be done. In particular, it does not contemplate consideration of whether the skilled addressee would be sufficiently encouraged by the available information to undertake the expense and inconvenience of further tests necessary to bring the solution to the stage of implementation.

117 AstraZeneca's appeals should be dismissed with costs.

NETTLE J:

118 With respect, I substantially agree with the reasons for judgment of French CJ and those of Kiefel J and wish to add only some brief observations on the meaning of ss 7(2) and 7(3) of the *Patents Act* 1990 (Cth).

119 As French CJ and Kiefel J observe, the issue of central importance in these appeals was the construction of those provisions: more precisely, whether the person skilled in the art who is referred to in s 7(2) is permitted to have regard to more than one document when deciding whether there is a single

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109 *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285 at 374-375 [330].

document within the meaning of s 7(3)(a) which discloses prior art that in the light of common general knowledge renders an invention obvious.

120 As French CJ and Kiefel J conclude, there is nothing in ss 7(2) or 7(3) which precludes the person skilled in the art from looking at more than one document (whether sequentially or comparatively or otherwise) for the purposes of determining the relevance of any single document. It is to be emphasised, however, that ss 7(2) and 7(3)(a) do not permit the person skilled in the art to combine information from other sources with the contents of the one document[110]. The plain and ordinary meaning of the words in s 7(2) – "each of which must be considered separately" – is that the single document referred to in s 7(3)(a) must be capable of standing alone without interpretative or corroborative assistance from another document or other source of information apart from common general knowledge. The rectitude of that meaning is supported by the legislative history of ss 7(2) and 7(3) which is essayed in French CJ's reasons.

121 One of the arguments advanced for the appellants was that, but for information that Dr Reece derived from the Thompson article that the trials referred to in the Watanabe article were Phase II trials, Dr Reece would not have concluded that rosuvastatin was an obvious choice to satisfy the need for an effective statin that did not require dose titration.

122 If that had been so, it would have been a valid point of objection. In contrast to the exercise involved in ascertaining the relevance of the Watanabe article – for which purpose it was permissible for a person skilled in the art to consider other documents – when the person skilled in the art came to deciding whether the Watanabe article rendered the invention obvious, it was necessary for that person to exclude from consideration any information derived otherwise than from common general knowledge and the prior art disclosed in the Watanabe article.

123 In fact, however, there is no basis in the objection. Both the primary judge and the Full Court approached the matter in accordance with that requirement. As Jessup J said[111], although Dr Reece's evidence was that the Watanabe article contained no safety data the result of either animal or human trials, the evidence also disclosed that trials of that kind would conventionally be carried out. Accordingly, carrying out the trials fell within the concept of

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110 Section 7(3)(b) of the *Patents Act* permits two or more related documents, or two or more related acts, to be considered against the common general knowledge "if the relationship between the documents or acts is such that a person skilled in the relevant art in the patent area would treat them as a single source of that information", but that provision is not here engaged.

111 *AstraZeneca AB v Apotex Pty Ltd* (2014) 226 FCR 324 at 452 [546]-[547].

working towards an invention with an expectation of success and that was consistent with the conclusion that the invention was obvious.

124 I agree with the orders proposed by French CJ.