

AstraZeneca AB v Apotex Pty Ltd [2014] FCAFC 99

FEDERAL COURT OF AUSTRALIA

BESANKO, JESSUP, FOSTER, NICHOLAS AND YATES JJ

BESANKO, FOSTER, NICHOLAS AND YATES JJ:

INTRODUCTION

- 1 There are three appeals before the Court. The appellants in the case of each appeal are AstraZeneca AB and AstraZeneca Pty Limited (together referred to as “AstraZeneca”). The respondent to the first appeal is Apotex Pty Ltd (“Apotex”), the respondent to the second appeal is Watson Pharma Pty Ltd (“Watson”) and the respondent to the third appeal is Ascent Pharma Pty Ltd (“Ascent”). Each respondent has filed a notice of contention (Watson and Ascent filing jointly) seeking to uphold the primary judge’s orders on grounds other than those relied upon by her. Where it is appropriate to refer to the respondents as a group, we will refer to them as the generic parties.
- 2 AstraZeneca AB and AstraZeneca Pty Limited are the registered proprietor and exclusive licensee respectively of two Australian patents. The first patent is Australian Patent No. AU200023051, entitled “Use of cholesterol-lowering agent”, and it was referred to at the trial and on the appeals as the “051 patent” or “low dose patent”. The second patent is Australian Patent No. AU200051842 entitled, “Pharmaceutical compositions”, and it was referred to at the trial and on the appeals as the “842 patent” or “cation patent”. A third Australian patent (“the HeFH patent”) was in issue at the trial before the primary judge and it was the subject of orders made by her. However, those orders are not the subject of an appeal to this Court and this third Australian patent need not be considered any further.
- 3 There are three claims of the 051 or low dose patent and they relate to the use of a compound called rosuvastatin for the treatment of hypercholesterolemia, or what is commonly known as high cholesterol. There are 25 claims of the 842 or cation patent and they relate to pharmaceutical compositions which include rosuvastatin as the active pharmaceutical ingredient.
- 4 Each of the generic parties wishes to supply generic versions of rosuvastatin products. Each wishes to supply pharmaceutical products in the form of tablets of 5 mg, 10 mg, 20 mg and 40 mg in which the active ingredient is rosuvastatin. AstraZeneca claimed that the supply of

those tablets will infringe one or more claims of the patents and it sought relief against infringement. Each of the generic parties brought a claim against AstraZeneca seeking the revocation of the patents under s 138(3) of the *Patents Act 1990* (Cth) (“the Act”). They relied on a number of grounds of alleged invalidity.

5 On 19 March 2013, the primary judge made an order revoking the claims of the 051 or low dose patent and a number of claims of the 842 or cation patent. She also made an order dismissing AstraZeneca’s claims for infringement of each patent. On 11 June 2013, the primary judge made an order revoking the balance of the claims of the 842 or cation patent (*Apotex Pty Ltd v AstraZeneca AB (No 5)* [2013] FCA 560).

6 The orders for the revocation of the patents were stayed pending the resolution of the appeals.

7 The Court has sat as a court of five judges and the reason for that is set out below.

8 The priority date of the claims of the 051 or low dose patent is 6 February 1999. That was the finding of the primary judge and there is no challenge to that finding on the appeals.

9 The priority date asserted for the claims of the 842 or cation patent is 26 January 2000. In the alternative, AstraZeneca asserted a priority date of the claims of 4 August 2000. The generic parties claimed that the correct priority date of the claims of the 842 or cation patent is 31 January 2005. The primary judge found that the priority date of the claims of the 842 or cation patent is 31 January 2005. AstraZeneca challenges that finding on appeal and asks this Court to conclude that the priority date of the claims is 26 January 2000 or, if that is not correct, 4 August 2000.

10 The primary judge found that the two patents are not patents for the invention of the compound rosuvastatin and that there is not, and never has been, a patent in Australia for the invention of the compound rosuvastatin. The primary judge also made findings about the point in time at which rosuvastatin (then under a different description, namely ZD4522) became part of common general knowledge in Australia as that concept is used in s 7(3) of the Act. She found that the compound rosuvastatin was not part of common general knowledge in Australia before 30 June 2000. As we have said, the asserted priority date in the case of each patent is before 30 June 2000.

11 The primary judge, in assessing inventive step or obviousness in the case of the claims of each patent, treated rosuvastatin as a “given”, or, as she put it elsewhere in her reasons, “the invention pre-suppose[d] the existence of rosuvastatin”. Whether this was the correct approach

was referred to at trial and before this Court as the “starting point” issue and may be broadly described as a question of whether, in assessing inventive step or obviousness, the starting point is knowledge of rosuvastatin. In taking the approach she did, the primary judge relied on, among other matters, the decision of the Full Court of this Court in *Apotex Pty Ltd v Sanofi-Aventis and Others* (2009) 82 IPR 416 (“*Sanofi-Aventis* (2009)”). AstraZeneca submits that her Honour’s approach is erroneous and, should the decision of the Full Court stand in the way of the acceptance of its argument, it asks this Court, sitting as a court of five judges, to overrule that decision.

12 The principal conclusions of the primary judge with respect to the validity of the 051 or low dose patent and the 842 or cation patent were as follows.

13 First, the primary judge held that AstraZeneca was not entitled to the invention defined in the claims of the 051 or low dose patent and that the patent should be revoked on that ground (s 138(3)(a)). The inventor was Shionogi & Co., Ltd (“Shionogi”), not Dr Ali Raza on behalf of AstraZeneca as claimed in the patent.

14 Secondly, the primary judge rejected an argument advanced by the generic parties that the invention disclosed in the 051 or low dose patent and the invention disclosed in the 842 or cation patent were not patentable inventions because a manner of manufacture was not disclosed on the face of the respective specifications (s 18(1)(a)).

15 Thirdly, the primary judge held that the invention disclosed in the 051 or low dose patent was not a patentable invention because it was not novel when compared with the prior art base as it existed before the priority date of the claims. The novelty of the invention was defeated by either of two publications, being European Patent Application No. 0521471 (“471 patent”) filed by Shionogi on 30 June 1992 and an article published by Watanabe and Others in February 1997 in *Bioorganic & Medicinal Chemistry* 1997 (5)2, entitled “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” (“Watanabe”).

16 In the case of the invention disclosed in the 842 or cation patent, questions of novelty and inventive step could only be determined after a decision had been made as to the correct priority date of the claims. The primary judge found that the priority date of the claims was 31 January 2005. Having made that finding, her Honour then found that the invention

disclosed in the 842 or cation patent was not a patentable invention because it was not novel when compared with the prior art base as it existed before 31 January 2005. The novelty of the claimed invention was defeated by any one of the following: Australian Patent Application No. AU200051841 (“841 patent”), filed on 4 August 2000, claiming a priority date of 26 January 2000 and published on 2 August 2001, UK Patent Application GB 0001621, filed on 26 January 2000, International Publication No. WO 01/54669, published on 2 August 2001, and European Patent No. 1314425 published on 28 May 2003.

17 Fourthly, the primary judge held that the invention described in the 051 or low dose patent did not involve an inventive step when compared with the prior art base as it existed before the priority date of the claims. The primary judge reached a similar conclusion in relation to the 842 or cation patent.

18 Fifthly, the primary judge rejected an argument advanced by the generic parties that the claims of the 842 or cation patent were liable to be revoked on the basis that they were not fairly based on the matter described in the specification (s 40(3) and s 138(3)(f)).

19 Finally, the primary judge considered whether the supply of the generic parties’ products would infringe the patents had she held that they were valid. She found that the supply of the 5 mg and 10 mg doses would infringe the 051 or low dose patent, but the supply of the 20 mg and 40 mg doses would not do so. Her Honour found that the generic parties’ rosuvastatin products (other than the alternative product proposed by Apotex which does not use titanium dioxide or ferric oxide in the coating) would infringe claim 1 and the dependent claims of the 842 or cation patent.

20 Almost all of the primary judge’s principal conclusions are challenged, either in the appeals or by way of the notices of contention filed by the generic parties.

21 Before leaving this introduction, one further matter should be mentioned. Further, or in the alternative to its challenge to the primary judge’s findings and conclusion in relation to entitlement, AstraZeneca wishes to rely on amendments to the Act effected by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) (“the Raising the Bar Act”), which came into effect on 15 April 2013. AstraZeneca submits that, even if the primary judge’s findings of fact with respect to entitlement stand, the effect of the amendments to the Act is that the 051 or low dose patent should not be revoked on the ground of an alleged lack of entitlement. In each appeal, AstraZeneca has issued an interlocutory application seeking leave

to amend its notices of appeal to raise this contention and to adduce further evidence with respect to it.

22 The structure of these reasons is as follows:

- The Relevant Parts of the 051 or Low Dose Patent and the 842 or Cation Patent
- The Primary Judge's Findings as to the Hypothetical Skilled Addressee and Common General Knowledge
- Construction Issues
- Entitlement
- Inventive Step
- The Priority Date of Claims of the 842 or Cation Patent
- Novelty: The 051 or Low Dose Patent
- Novelty: The 842 or Cation Patent
- Manner of Manufacture: The 051 or Low Dose Patent
- Manner of Manufacture: The 842 or Cation Patent
- Fair Basis: 842 or Cation Patent
- Infringement: Section 117 of the Act
- Conclusions

THE RELEVANT PARTS OF THE 051 OR LOW DOSE PATENT AND THE 842 OR CATION PATENT

The 051 or low dose patent

23 As we have said, the 051 or low dose patent nominates Dr Ali Raza as the inventor. The priority date of the claims is 6 February 1999.

24 The specification of the 051 or low dose patent describes the invention as follows:

USE OF CHOLESTEROL-LOWERING AGENT

The present invention relates 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, [the formula for the compound rosuvastatin] ... and pharmaceutically acceptable salts thereof, hereinafter referred to as "the Agent" and illustrated (as the calcium salt) in formula I hereinafter. The invention further relates to the dosage range, start dose and dosage forms of the Agent.

The Agent is disclosed in European Patent Application, Publication No. 0521471, and in Bioorganic and Medicinal Chemistry, (1997), 5(2), 437-444 as an inhibitor of 3-hydroxy-3-methylglutaryl CoA reductase (HMG-CoA reductase) which is a major rate-limiting enzyme in cholesterol biosynthesis. The Agent is taught as 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.

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 lipoprotein 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.

Accordingly, one aspect of the present invention comprises a method of lowering LDL-C levels by 40% or more, and/or lowering total cholesterol levels by 30% or more, and/or lowering triglyceride levels by 10% or more, and/or lowering apolipoprotein B-100 levels by 30% or more, and/or raising HDL-C levels by 5% or more, in a patient in need thereof, by administration of 5 to 80 mg per day of the Agent.

A further aspect of the present invention comprises a method of ...

...

A particularly suitable starting dose of the Agent in the methods referred herein is 5 to 10 mg per day, especially 10 mg per day. After initiation and/or upon titration of the Agent, lipid levels may be analysed and the dosage adjusted accordingly. A further aspect of the invention is therefore a method as defined above when the Agent is administered at a starting dose of 5 or 10 mg per day, for example a method of lowering LDL-C levels in a patient in need thereof by 40% or more by administration of 5 or 10 mg per day ... A starting dose of 5 or 10 mg per day of the Agent unexpectedly has a

superior efficacy and a comparable or better safety profile compared to the starting doses of other statins, and is therefore particularly advantageous.

In carrying out the methods of the invention, the Agent will be administered to a patient in the form of a pharmaceutical composition. A further aspect of the invention is therefore a pharmaceutical composition which comprises 5 to 80 mg of the Agent together with a pharmaceutically acceptable excipient or diluent. Particular pharmaceutical compositions which themselves are further independent aspects of the invention comprise, for example, 5 mg, 10 mg, 20 mg, 40 mg and 80mg of the Agent together with a pharmaceutically acceptable excipient or diluent. The pharmaceutical compositions will be in the form of a conventional dosage unit form, for example, tablets or capsules. Accordingly, a further aspect of the invention comprises, a tablet or capsule containing the Agent in the amounts given above. The compositions of the invention may be obtained by conventional procedures using conventional pharmaceutical excipients, well known in the art. Preferably the Agent is administered as a single dose once daily.

...

25 The primary judge noted the following passages on pages 11A and 11B of the specification:

In a further aspect of the invention there is provided a pharmaceutical composition adapted for oral administration as a single, once daily dose which comprises 5 mg to 10 mg of [the Agent] ... in the form of the free acid or a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable diluent or carrier.

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Pharmaceutical compositions

The following Example illustrates, but is not intended to limit, pharmaceutical dosage forms which are suitable for use in the invention as defined herein:

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26 Her Honour noted that the patent referred to a trial in the following terms:

To illustrate the invention, a randomised, dose response parallel-group study with [the Agent] calcium salt (hereinafter referred to as ZD4522) and atorvastatin (ATORV) in subjects with primary hypercholesterolaemia was carried out.

Primary objectives

The primary objective of this trial was to estimate the dose-response relationship between the dose of ZD4522 and the percentage reduction of LDL-C from the baseline value with respect to placebo.

Secondary objectives

Secondary objectives of this trial included:

to estimate the effect of 10 and 80 mg doses of atorvastatin on LDL-C levels;

to estimate the effects of ZD4522 and atorvastatin on HDL-C, TG, TC, apolipoprotein A-1, apolipoprotein Lp(a), apolipoprotein B-100 levels and LDL-C (by indirect method);

to assess the pharmacokinetics of oral doses of 1, 2.5, 5, 10, 20, and 40 mg ZD4522 (capsule formulations) over a 6 week treatment period; and

to assess the tolerability and safety of ZD4522 in comparison with placebo.

Trial Design

After a 6-week dietary run-in, subjects were randomised to either atorvastatin doses (10 or 80 mg), supplied open labelled, or to placebo or 1 of 6 ZD4522 doses (supplied blinded). Analysis of the blinded portion of the trial addressed the primary objective. The open atorvastatin groups were included to obtain additional data on the starting and high doses, of a proven cholesterol-lowering agent in this patient population.

Trial Plan

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Number of Subjects

The primary endpoint on which the sample size is based is on percentage reduction from baseline in LDL-C (LDL cholesterol) values. A sample size of 9 in each group will have 90% power to detect a difference in means of 25% between 2 groups, assuming that the common standard deviation is 15%, using a 2 group t-test with a 0.05 two-sided significance level. This has been increased to 12 subjects per group to adjust for multiple comparisons of groups against placebo while preserving a power of at least 90% (based on simulations). This sample size also leads to an estimate of the dose-response curve for percentage decline in LDL-C with a width of the confidence band less than 10% for most of the dose range.

Inclusion Criteria

For inclusion in the dietary run-in period, subjects had to fulfil all of the following criteria:

- (1) fasting LDL cholesterol (>4.14 but <6.21 mmol/L);

...

Exclusion Criteria

Any of the following was regarded as a criterion for exclusion from the trial:

- (1) Subjects using cholesterol lowering drugs (this therapy must have been discontinued at least 4 weeks before the start of the dietary run-in period. Subjects taking probucol should have discontinued 12 months before inclusion in this study).
- (2) History of serious or hypersensitivity reactions to other HMG-CoA reductase inhibitors.

...

- (7) Known homozygous familial hypercholesterolaemia or known type III hyperlipoproteinemia (familial dysbetalipoproteinaemia).

27 The primary judge referred to page 21 of the specification, which contains the following paragraphs:

Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising”, will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

28 The three claims of the patent are in the following terms:

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 ... 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.
3. A methods [sic] as claimed in claim 1 or 2 wherein the patient has an LDL-C level of 160mg/dl or greater with no chronic heart disease or peripheral vascular disease and one or no risk factors for such a disease; an LCL-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.

29 The primary judge found that claim 3 was dependent on claims 1 and 2 and added limitations relating to the LDL-C (low density lipoprotein cholesterol) levels and other conditions of the patient receiving the treatment.

The 842 or cation patent

30 There is no issue about AstraZeneca’s entitlement to the 842 or cation patent. The patent claims a priority date of 26 January 2000. As we have said, the priority date was in dispute before the primary judge and is in issue on the appeals.

31 The specification of the 842 or cation patent describes the invention as follows:

The present invention relates to pharmaceutical compositions and more particularly to a pharmaceutical composition containing [the formula for the compound rosuvastatin] or a pharmaceutically-acceptable salt thereof (and referred to hereinafter as “the Agent”). In particular the sodium and calcium salts, and especially the calcium salt [of the Agent] (shown as Formula I below).

The Agent is disclosed as an inhibitor of 3-hydroxy-3-methylglutaryl CoA reductase (HMG CoA reductase) in European Patent Application, Publication No. 0521471 and in Bioorganic and Medicinal Chemistry, (1997), 5(2), 437-444 and is useful in the treatment of hypercholesterolemia, hyperlipidproteinemia and atherosclerosis.

A problem associated with the Agent is that it is particularly sensitive to degradation under certain conditions. The major degradation products formed are the corresponding (3R, 5S) lactone (hereinafter referred to as “the lactone”) and an oxidation product (hereinafter referred to as “B2”) in which the hydroxy group adjacent to the carbon-carbon double bond is oxidised to a ketone functionality. The potential for significant degradation of the Agent makes it difficult to formulate and provide a pharmaceutical composition with acceptable storage life for a marketed product.

Pharmaceutical formulations of certain 7-substituted-3,5-dihydroxy-6-heptenoic acid salts, which are HMG CoA reductase inhibitors, are disclosed in UK Patent 2 262 229, and that they are sensitive to pH degradation. These formulations require the presence of an alkaline medium (such as a carbonate or bicarbonate) capable of imparting a pH of at least 8 to an aqueous solution or dispersion of the composition.

However, we have found that for the Agent it is not sufficient to improve stability by solely controlling pH in the formulation.. We have found that with the Agent stability is improved by selection of an inorganic salt to be added to the composition which contains one or more multivalent inorganic cations. Whilst not wishing to be bound by theory we believe that the multivalent inorganic cation stabilises the structure of the Agent and makes it less susceptible to oxidation and/or lactonization.

We present as aspects of the invention

- (1) A pharmaceutical composition comprising the Agent or a pharmaceutically acceptable salt thereof as the active ingredient and an inorganic salt in which the cation is multivalent, provided that: the inorganic salt is not hydrotalcite or synthetic hydrotalcite and the counter anion to the inorganic salt is not a phosphate.
- (2) The use of an inorganic salt in which the cation is multivalent to stabilise the Agent or a pharmaceutically acceptable salt thereof, provided that: the inorganic salt is not hydrotalcite or synthetic hydrotalcite and the counter anion to the inorganic salt is not a phosphate.

Preferred features of the invention are:

- (1) wherein the Agent is present in the composition is more than 5 mg, preferably more than 10mg. Excluded compositions are those wherein the Agent is present at 1mg, 2mg, 5mg and 10mg. Preferred compositions are those where the amount of Agent is 20mg, 40mg or 80mg.
- (2) wherein the stabilising compound is not hydrotalcite or synthetic hydrotalcite.

(3) the pharmaceutical composition formed is a tablet or powder.

Preferably the pharmaceutical composition of the invention is a tablet.

The multivalent cation found in the inorganic salt may be selected from the following, calcium, magnesium, zinc, aluminium and iron or a mixture thereof. Preferred multivalent cations are calcium, aluminium and magnesium or a mixture thereof. Especially preferred multivalent cations are aluminium and magnesium or a mixture thereof.

The counter anion in the inorganic salt may be selected from a phosphate, a carbonate, a silicate, an oxide and a metasilicate. Preferred counter anions are selected from a carbonate, a silicate, an oxide or a metasilicate. Especially preferred counter anions are selected from a silicate, an oxide or a metasilicate.

Individual aspects of the invention include an inorganic salt comprising a multivalent cation selected from any of the above and a counter anion also selected from any of the above.

Preferred inorganic salts for use in the present invention are; aluminium magnesium metasilicate (NeusolinTM, Fuji Chemical Industry Limited), dibasic or tribasic calcium phosphate, tribasic magnesium phosphate and tribasic aluminium phosphate. Aluminium magnesium metasilicate and tribasic calcium phosphate are especially preferred.

It is also preferable that such a composition has a good flow rate to assist processing into unit dosage forms for oral administration, for example into tablets, and good disintegration and dissolution characteristics when processed into tablets for oral administration, which tablets can be in different dosage strengths.

The ratio of inorganic salt to Agent in the pharmaceutical composition is, for example, within the range of 1:80 to 50:1 by weight, for example 1:50 to 50:1 by weight, such as 1:10 to 10:1 by weight, and more particularly 1:5 to 10:1 by weight.

Preferably the pharmaceutical composition of the invention is formulated into an oral dosage form, such as a tablet. Accordingly a further aspect of the invention comprises a pharmaceutical composition comprising the Agent, an inorganic salt in which the cation is multivalent, and one or more fillers, binders, disintegrants or lubricants. A still further aspect of the invention relates to a pharmaceutical composition for oral administration comprising the Agent, one or more fillers, one or more binders, one or more disintegrants, one or more lubricants and an inorganic salt in which the cation is multivalent.

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The pharmaceutical composition of the invention may be prepared, using standard techniques and manufacturing processes generally known in the art, for example by dry blending the components. For example, the Agent and an inorganic salt in which the cation is multivalent, one or more fillers, one or more binders and one or more disintegrants, as well as other additional excipients if desired are blended together. The components of the blend prior to blending, or the blend itself, may be passed through a mesh screen, for example a 400-700 μm mesh screen. A lubricant, which may also be screened, is then added to the blend and blending continued until a homogeneous mixture is obtained. The mixture is then compressed into tablets. Alternatively, a wet granulation technique can be employed. For example, the Agent and an inorganic salt

in which the cation is multivalent, one or more fillers, one or more binders and a portion of a disintegrant, as well as other additional excipients if desired, are blended together, for example by using a granulator, and the powder blend is granulated with a small volume of purified water. The granulate is dried and passed through [sic] a mill. The remainder of the disintegrant and a lubricant are added to the milled granulation and after blending the resultant homogeneous mixture is compressed into tablets. It will be appreciated that modifications of the dry blending and wet granulation techniques, including the order of addition of the components and their screening and blending prior to compression into tablets, may be carried out according to principles well known in the art.

A tablet coating may then be applied, for example by spray-coating, with a water-based film coating formulation. The coating may comprise, for example, lactose, hydroxypropyl methylcellulose, triacetin, titanium dioxide and ferric oxides. Coating ingredient combinations are commercially available, such as those described in the Examples hereinafter. The coating may comprise, for example, 0.5 to 10% by weight of the tablet composition, particularly 1 to 6%, and preferably 2 to 3%. Coatings containing ferric oxides are especially preferred as they reduce the rate of formation of photodegradation products of the Agent.

Accordingly we present as a feature of the invention a pharmaceutical composition comprising the Agent, the composition having a ferric oxide light protective coating.

A further aspect of the present invention comprises a method of preparing a stabilised pharmaceutical composition which comprises admixing the Agent with an inorganic salt in which the cation is multivalent. A further aspect of the present invention comprises a method of producing a stabilised pharmaceutical composition which comprises incorporating an inorganic salt in which the cation is multivalent in a pharmaceutical composition containing the Agent.

32 Four Examples are given in the specification as follows:

Example 1

The Agent	2.50 mg
Tribasic calcium phosphate	20.0 mg
Microcrystalline cellulose	47.0 mg
Lactose monohydrate	47.0 mg
Sodium starch glycollate	3.00 mg
Butylated hydroxytoluene	0.05 mg
Magnesium stearate	1.00 mg

The Agent, microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, tribasic calcium phosphate, and butylated hydroxytoluene were blended together for 10 minutes. Magnesium stearate was screened through a #40 mesh (425 µm) screen and added to the blend and blending continued for a further three minutes. The resulting homogeneous mixture was compressed into tablets.

The tablets were stored at 70°C/80% relative humidity for one week. After one week there was found to be only 0.11%w/w of the oxidation product B2 formed and only

0.50%w/w of the lactone.

Example 2

The Agent	2.50 mg
Povidone	2.50 mg
Tribasic calcium phosphate	20.0 mg
Microcrystalline cellulose	47.0 mg
Mannitol	47.0 mg
Sodium starch glycollate	3.00 mg
Butylated hydroxytoluene	0.05 mg
Magnesium stearate	1.00 mg

The Agent, povidone, mannitol, microcrystalline cellulose, butylated hydroxytoluene, tribasic calcium phosphate and sodium starch glycollate (in the amounts given below) were blended for 5 to 60 minutes. Magnesium stearate was screened through a #40 mesh (425 μ m) screen and added to the blend and blending continued for a further three minutes. The resulting homogeneous mixture was compressed into tablets. The compressed tablets were coated by spraying with a mixture of hydroxypropyl methylcellulose, polyethylene glycol 400, titanium dioxide and ferric oxide (sold as Spectrablend™ by Warner-Jenkinson)) and water in a coating pan. The weight gain provided by the coating was 1 to 6%w/w, and preferably 2 to 3%w/w.

The tablets were stored at 70°C/80% relative humidity for one week. After one week there was found to be only 0.06%w/w of the oxidation product B2 formed and only 2.22%w/w of the lactone.

Example 3

The Agent	2.60 mg
Crospovidone	3.75 mg
Tribasic calcium phosphate	5.66 mg
Microcrystalline cellulose	15.5 mg
Lactose monohydrate	46.5 mg
Magnesium stearate	0.94 mg

The Agent and crospovidone were blended together for 5 minutes and the blend then passed through a 400-700 μ m screen. A small portion of the microcrystalline cellulose was passed through the screen afterwards. The screened material was blended with the other ingredients, excluding the lubricant, for 10 minutes. Magnesium stearate was passed through a #40mesh (425 μ m) screen and added to the blend and the mixture was blended for a further 3 minutes. The resulting homogeneous mixture was compressed into tablets. The compressed tablets were coated by spraying with a mixture of lactose monohydrate, hydroxypropyl methylcellulose, triacetin and ferric oxide (sold as Opadry II™ by Colorcon) and water in a coating pan. The weight gain provided by the coating is 1 to 6%w/w, and preferably 2 to 3%w/w.

The tablets were stored at 70°/80% relative humidity for one week. After this time

only 0.19%w/w of the oxidation product B2 had formed and only 2.71%w/w of the lactone.

Example 4

The Agent	2.50 mg
Povidone	2.50 mg
Tribasic calcium phosphate	20.0 mg
Microcrystalline cellulose	34.5 mg
Lactose monohydrate	34.0 mg
Sodium starch glycollate	6.00 mg
Magnesium stearate	1.00 mg
Butylated hydroxytoluene	0.05 mg

A portion of the tribasic calcium phosphate and butylated hydroxytoluene were blended for 30 seconds in a bag. The Agent, povidone, remainder of the tribasic calcium phosphate, microcrystalline cellulose, lactose monohydrate, tribasic calcium phosphate, microcrystalline cellulose, lactose monohydrate, tribasic calcium phosphate/butylated hydroxytoluene mixture and a portion of the sodium starch glycolate were blended in a granulator for 30 seconds. The powder blend was granulated with purified water for 1 minute at the addition rate of 70 mg/tablet/minute. The granulation is dried in a fluidized bed drier at 50°C until the loss on drying is less than 2% w/w. The dried granulation is passed through a mill (e.g. Comil™). The milled granulation and the remainder of the sodium starch glycolate was blended for approximately 5 minutes. Magnesium stearate was screened through a #40 mesh (425 µm) screen and added to the blend and blending continued for a further three minutes. The resulting homogeneous mixture was compressed into tablets.

The tablets were stored at 70°C/80% relative humidity for one week. After this time only 0.23% w/w of the oxidation product B2 had formed and only 0.28%w/w of the lactone.

33 The primary judge noted that page 10 of the specification contains the following statements:

Throughout this specification and the claims which follow, unless the context required otherwise, the word “comprise”, and variations such as “comprises” and “comprising”, will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

34 Finally, the claims defining the invention included the following claims:

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A pharmaceutical composition comprising [rosuvastatin] or a pharmaceutically acceptable salt thereof as the active ingredient and an

inorganic salt in which the cation is multivalent, provided that:

- (i) the inorganic salt is not hydrotalcite or synthetic hydrotalcite; and
 - (ii) the counter anion to the inorganic salt is not a phosphate.
2. A pharmaceutical tablet comprising [rosuvastatin] or a pharmaceutically acceptable salt thereof as the active ingredient and an inorganic salt in which the cation is multivalent, provided that the counter anion to the inorganic salt is not a phosphate.
 3. A pharmaceutical composition according to claim 1 or claim 2 wherein the cation of the inorganic salt is selected from calcium, magnesium, zinc, aluminium and iron.
 4. A pharmaceutical composition according to any one of claims 1 to 3 wherein the counter anion of the inorganic salt is selected from a carbonate, a silicate, an oxide and a metasilicate.
 5. A pharmaceutical composition according to any one of claims 1 to 3 wherein the counter anion of the inorganic salt is selected from a silicate, an oxide or a metasilicate.
 6. A pharmaceutical composition according to claim 1 or claim 2 wherein the inorganic salt is aluminium magnesium metasilicate.
 7. A pharmaceutical composition according to claim 1 which is a tablet or powder.

35 The primary judge noted that claim 8 was dependent on claims 1 or 2. Claim 9 was dependent on any of claims 1 to 8. Claims 10 to 18 inclusive were also dependent claims.

THE PRIMARY JUDGE'S FINDINGS AS TO THE HYPOTHETICAL SKILLED ADDRESSEE AND COMMON GENERAL KNOWLEDGE

36 The primary judge heard evidence from a number of witnesses, many of whom were experts. In her reasons, she sets out details of each witness' qualifications and experience. It is not necessary for us to summarise that aspect of her Honour's reasons. The primary judge then made a number of findings as to the hypothetical skilled addressee of each patent and the relevant common general knowledge at the relevant dates. It is not necessary for us to traverse a lot of this detail because there are very few challenges to her Honour's conclusions with respect to these matters. Where there is a dispute, we will identify its nature and how we resolve it.

37 The primary judge referred to the relevant authorities about what constitutes common general knowledge and the attributes of the hypothetical skilled addressee. It is not suggested that there is any error in her Honour's statement of the relevant principles.

38 In *Minnesota Mining and Manufacturing Company and Another v Beiersdorf (Australia) Limited* (1980) 144 CLR 253, Aickin J (with whom the other members of the High Court agreed) described the notion of common general knowledge in the following terms (at 292):

The notion of common general knowledge itself involves the use of 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.

39 In *Aktiebolaget Hässle and Another v Alphapharm Pty Limited* (2002) 212 CLR 411 (“*Alphapharm*”) (at 426 [30], 434 [55]), Gleeson CJ, Gaudron, Gummow and Hayne JJ referred to the hypothetical non-inventive worker in the field and said that, in the case before them, such persons would be highly qualified pharmaceutical chemists with, usually, a demonstrated capacity for original research. Their Honours noted that there are conceptual difficulties in applying what is said in some of the older authorities respecting “workmen” and the like to modern conditions in the pharmaceutical and other industries. Their Honours said that what might be found by conducting computer searches and the like was not a part of the common general knowledge in Australia in the absence of evidence of its general acceptance and assimilation by the hypothetical non-inventive worker in the field.

40 In *General Tire & Rubber Co Ltd v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 (“*General Tire*”), the Court of Appeal said (at 485):

If the art is one having a highly developed technology, the notional skilled reader to whom the document is addressed may not be a single person but a team, whose combined skills would normally be employed in that art in interpreting and carrying into effect instructions such as those which are contained in the document to be construed. We have already described the composite entity deemed to constitute the notional skilled addressee.

41 The primary judge found that the hypothetical skilled addressee of the 051 or low dose patent were medical practitioners with specialised expertise in treating hypercholesterolemia and particular expertise in lipidology.

42 At one point in her reasons, the primary judge said that the hypothetical skilled addressee of the 842 or cation patent were likely to have been pharmaceutical formulators. Later in her reasons, her Honour said that the hypothetical skilled addressee of the 842 or cation patent was not limited to pharmaceutical scientists or formulators, but also included treating physicians such as Professors Tonkin and O’Brien.

43 AstraZeneca challenges the primary judge's identification of the hypothetical skilled addressee in the case of both patents and her related finding that rosuvastatin (under the description ZD4522) was part of the common general knowledge of the hypothetical skilled addressee on or about 30 June 2000.

44 As far as the 051 or low dose patent is concerned, AstraZeneca submitted that the primary judge erred in defining the class too narrowly. AstraZeneca submitted that, although the class included medical practitioners with specialised expertise in treating hypercholesterolemia and particular expertise in lipidology, it also included "medical practitioners involved in treating patients suffering from hypercholesterolemia (whether or not the practitioner has specialist expertise in lipidology) and scientists involved in drug development including pharmacologists, biochemists, medicinal chemists, formulation chemists, analytical chemists, toxicologists and statisticians".

45 This submission was not developed in any way and nor was it explained how it was relevant to any issue on the appeals. In the circumstances, we see no reason to interfere with her Honour's finding.

46 As far as the 842 or cation patent is concerned, AstraZeneca submitted that the primary judge defined the class too broadly. The class should have been confined to pharmaceutical formulators having regard to the nature of the patent. AstraZeneca submitted that her Honour erred in including in the class treating physicians such as Professors Tonkin and O'Brien. Her Honour found that pharmaceutical formulators were not aware of rosuvastatin in 2000. The significance of this challenge relates to her Honour's findings as to when rosuvastatin became part of common general knowledge in Australia. That question is relevant to one of the issues concerning the 842 or cation patent. It is not relevant to the 051 or low dose patent as rosuvastatin was clearly not part of common general knowledge at the priority date of the claims of that patent. We deal with the issue below.

47 We turn now to the primary judge's findings as to common general knowledge before the claimed priority dates.

Hypercholesterolemia and statins

48 The primary judge accepted Professor O'Brien's description of cholesterol and the various types of cholesterol. It is as follows:

Cholesterol is a chemical that is made by the liver and is an important component of

cell walls. It is also an important precursor to steroid hormones and brain tissue. Cholesterol is insoluble in blood and therefore exists as a complex of phospholipid, cholesterol and a type of protein called apoprotein. This complex, known as a lipoprotein, is the transport vehicle for lipids in the bloodstream. Lipoproteins are characterised by density and are divided into four main classes; chylomicrons, very low density lipoproteins (“VLDL”), low density lipoproteins (“LDL”) and high density lipoproteins (“HDL”). Low density lipoproteins are the main carrier of cholesterol in the bloodstream.

In Australia, cholesterol is measured in millimoles per litre which is denoted as “mmol/L”. In other parts of the world (such as the USA), milligrams per decilitre (“mg/dL”) is the measurement used. These are both measurements of the total amount of cholesterol in the blood. Lipoprotein metabolism is briefly detailed below:

- (a) VLDL cholesterol (“VLDL-C”) refers to cholesterol packaged in VLDL particles which also contain triglyceride. VLDL-C is the form in which cholesterol is secreted from the liver, where most cholesterol is made.
- (b) Once it enters the bloodstream, VLDL-C is converted to LDL cholesterol (“LDL-C”) by the removal of triglyceride. LDL-C refers to cholesterol which is packaged in LDL. These particles use the bloodstream to transport cholesterol from the liver to all the tissues of the body. This form of cholesterol is often termed “bad cholesterol” and is indicative of an increased risk of heart disease.
- (c) HDL cholesterol (“HDL-C”) refers to the cholesterol which is packaged in HDL particles. The HDL-C complex returns cholesterol from the tissues or organs to the liver, where cholesterol is excreted or recycled. HDL-C is often referred to as “good cholesterol” and higher levels indicate a decreased risk of heart disease.
- (d) Total cholesterol (“TC”) refers to cholesterol in all of the lipoprotein-cholesterol complexes in the blood. Total cholesterol is what the lay person understands by their cholesterol level. This includes VLDL-C, LDL-C and HDL-C.

49 The primary judge also accepted, as part of common general knowledge before the claimed priority dates, Professor O’Brien’s description of hypercholesterolemia and the guidelines established by the US National Cholesterol Education Program and the targets expressed in relation to LDL cholesterol and total cholesterol. It is as follows:

Hypercholesterolemia is an elevated level of cholesterol in the blood. The broadest definition is where cholesterol is too high for a particular patient, taking into account that patient’s risk factors. For example, a TC level of 5.5 mmol/L is excessive for a patient with a previous heart attack but acceptable in somebody with no cardiovascular risk factors. A more traditional definition of hypercholesterolemia is where the patient has a level of cholesterol that is higher than that of the average population by more than two standard deviations from the mean.

Hypercholesterolemia may be defined either by considering the total cholesterol (TC) or, more accurately, by the cholesterol in the low density lipoprotein fraction (the LDL-C). There have been a number of treatment guidelines published which recommend

target levels for cholesterol based on LDL-C. These targets vary depending on the risk that high cholesterol will likely pose to a particular patient. This risk assessment takes into account risk factors such as whether the patient has previously had a heart attack, has diabetes, has high blood pressure etc. Essentially, the target levels are adjusted so as to set a level which is desirable for a particular group of patients. If a patient has a LDL-C level higher than the target level then I would define the patient as suffering from hypercholesterolemia.

...

Guidelines referred to as “**NCEP ATP II**” were produced by the US National Cholesterol Education Program (“**NCEP**”) and published in 1993. ... The guidelines express targets both in terms of TC and LDL-C. There were also similar guidelines published by learned Australian bodies although these were published after February 1999.

50 The primary judge found that the most common form of hypercholesterolemia is primary hypercholesterolemia, which is the disease where it is not caused by any other illness or disease and may have a number of causes. Her Honour found that patients with other diseases may also have elevated cholesterol levels and that condition is known as secondary hypercholesterolemia. That occurs where another illness, typically poorly controlled diabetes, hyperthyroidism, or renal or liver diseases, causes elevation in cholesterol levels.

51 The primary judge accepted Professor O’Brien’s description of how hypercholesterolemia increased the risk of atherosclerosis. It is as follows:

Hypercholesterolemia is a problem because elevated cholesterol levels are associated with an increased risk of atherosclerosis. Atherosclerosis is a build-up of cholesterol in the arteries.

Typically, atherosclerosis first occurs in the coronary arteries (the arteries which supply blood to the heart muscles) and then sometimes progresses to the arteries of the brain and legs, and occasionally other areas of the body as well. Cholesterol is the biggest risk factor in damage to the arteries. Generally, the degree of build-up of cholesterol is related to the level of cholesterol in the blood, as well as other risk factors.

Atherosclerosis increases a patient’s risk of coronary heart disease (“**CHD**”), stroke and peripheral vascular disease (“**PVD**”). Consequently, patients with hypercholesterolemia might also suffer from coronary heart disease, peripheral vascular disease and/or stroke. PVD refers to blockages of arteries in the legs such that leg muscles do not get enough blood. PVD is particularly common in patients who smoke and have high cholesterol.

52 The primary judge found that patients with severe or complicated lipid problems were usually referred to an endocrinologist, although such patients may also be referred to a clinical biochemist or cardiologist. Her Honour found that many general practitioners also treat people

with elevated cholesterol levels. The primary judge found that these practitioners knew that drugs that were available to treat hypercholesterolemia as at February 1999 included the following classes of drugs: statins; fibrates; bile acid binding resins (such as colestipol and cholestyramine); and nicotinic acid (niacin). The primary judge found that statins were the most common drug chosen and almost always the first choice.

53 The primary judge found that medical practitioners knew that a class of compounds known as statins (or HMG-CoA reductase inhibitors) were useful in lowering low density lipoprotein cholesterol (LDL-C), and were commonly used for that purpose in treating patients with cardiovascular disease, patients at risk of cardiovascular disease (including diabetics), or patients with elevated cholesterol levels. The primary judge accepted Professor O'Brien's description of how statins work. That description is as follows:

Statins were known to inhibit the process of cholesterol synthesis by inhibiting the enzyme HMG-CoA reductase. HMG-CoA reductase is the rate-limiting step in the pathway of cholesterol synthesis. It converts HMG-CoA to mevalonic acid which is a critical precursor molecule to cholesterol.

The enzyme HMG-CoA reductase, like all enzymes, is a complex three dimensional molecule which has a specific site at which it binds to its substrate, HMG-CoA. This binding site on the enzyme complements the shape of an area of the HMG-CoA molecule so that the enzyme and its substrate "fit" together and this allows a reaction which transforms HMG-CoA to mevalonic acid to take place. The substrate is said to have an "affinity" for the enzyme; that is, the substrate and the enzyme are attracted to one-another by inter-molecular forces which act to hold the two together while the reaction takes place.

Statins are molecules which have a similar structure to HMG-CoA (the natural substrate for the enzyme HMG-CoA reductase) but have greater affinity for the enzyme than HMG-CoA – the statin "competes" for the binding site with HMG-CoA. As a result, a statin molecule will be more likely to bind to the enzyme than an HMG-CoA molecule, and the statin will likely remain bound to the enzyme for longer than HMG-CoA would. When a statin is bound to the enzyme, HMG-CoA is unable to bind to it and thus cannot be converted to mevalonic acid which, in turn, cannot be synthesised into cholesterol.

Statins are all based on the structure of the molecule compactin (which occurs naturally in some fungi), with differing side chains. The differences in the side chains affect the length of time that a statin remains inside a cell. The longer a statin remains inside a liver cell, the greater the reduction in cholesterol it is able to achieve. Differences in side chains also affect the affinity of a statin for the enzyme HMG-CoA reductase and, therefore, the ability of that statin to bind to and inhibit the enzyme. Variations in side chains can also affect the solubility of a statin, which can affect whether a particular statin is able to enter into the brain or a specific type of tissue. All of the above factors will have an effect on the percentage by which a statin is able to reduce a patient's cholesterol levels and also potentially the side effects of the statin.

Statins and HMG-CoA compete for the binding site of the enzyme HMG-CoA

reductase, and although statins have greater affinity for the enzyme, sometimes a molecule of HMG-CoA will successfully bind to the enzyme and be converted into mevalonic acid which, in turn, will go on to become cholesterol. Statins therefore do not completely inhibit the production of cholesterol by the liver, but they do act to decrease the amount of cholesterol produced.

Although statins reduce the production of cholesterol in liver cells, they have only a very minor effect on the release of cholesterol from the liver into the bloodstream. The primary method by which blood cholesterol is reduced is via the increased clearance of cholesterol (LDL-C particles) from the bloodstream. If a liver cell is unable to manufacture sufficient cholesterol (because of statin treatment), it expresses more LDL receptors so that it can take up more cholesterol from the bloodstream, reducing a patient's LDL-C level. This process is particularly important in the liver because the liver is the main organ which clears cholesterol from the bloodstream. This mechanism was known to me prior to February 1999.

54 The primary judge found that by the late 1990s statins were recognised as the primary class of drug available for lowering LDL cholesterol. She found that simvastatin had been commonly used for that purpose. Atorvastatin was also released and quickly became known in Australia and throughout the world. It was a more potent statin than simvastatin, and quickly replaced it as the most commonly prescribed statin in Australia. Statins available in Australia by 1999 also included fluvastatin and pravastatin.

55 The primary judge found that, according to the MIMS Annual 1998, the following statins were available in the following doses in Australia:

- (a) fluvastatin (Lescol and Vastin) – 20 mg and 40 mg tablets;
- (b) pravastatin (Pravachol) – 5 mg, 20 mg and 40 mg tablets;
- (c) simvastatin (Lipex and Zocor) – 5 mg, 10 mg, 20 mg and 40 mg tablets; and
- (d) atorvastatin (Lipitor) – 10 mg, 20 mg and 40 mg tablets.

56 Her Honour also found that the MIMS Annual 1998 recorded the recommended starting and maximum doses of each statin available in Australia as follows:

STATIN	RECOMMENDED STARTING DOSE	RECOMMENDED MAXIMUM DOSE
Fluvastatin	20 mg or 40 mg	40 mg
Pravastatin	10 mg or 20 mg	40 mg
Simvastatin	10 mg or 20 mg	40 mg
Atorvastatin	No starting dose for atorvastatin is listed in MIMS Annual 1998, rather a range of 10 mg to 80 mg	80 mg

	is stated. I typically used a starting dose of 10 mg.	
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57 The primary judge found that by 2000 cerivastatin was also available in Australia, but that it was not commonly used.

58 The primary judge found that all statins available in Australia as at 2000 were in tablet form and were typically dosed once a day at night because most cholesterol is synthesised by the liver during the night.

59 The primary judge found that between 1996 and 2000 in Australia a study comparing the efficacy of simvastatin and atorvastatin in general practice was carried out, with clinical trials taking place in 1998 and 1999. The study results were published in 2000. From this and other information, medical practitioners with a particular interest in treating hypercholesterolemia knew that the available statins had different efficacy in terms of the drug's ability to reduce cholesterol across its dosage range, with atorvastatin being the most efficacious, followed by simvastatin, then pravastatin, and then fluvastatin. The primary judge accepted Professor O'Brien's description of the dose-response pattern of statins. It is as follows:

For any given statin, the starting dose will result in a significant decrease in LDL-C, which varies depending on the efficacy of the statin. Thereafter, each doubling of the dose produces approximately a further 6% reduction in LDL-C. If this is represented graphically, the dose administered, when compared to reduction in LDL-C levels, produces a curve with a sharp initial fall in LDL-C which then begins to flatten out at subsequent higher doses. All known statins follow this dose-response pattern.

There is a limit to the practical cholesterol reduction that can be achieved with a statin, because side effects increase with dose. Fewer side effects are observed at lower doses of statins. Therefore a balance needs to be achieved between effective cholesterol reduction and the likely side effects of a given dose. The maximum marketed dose of a statin represents the upper limit of efficacy that maintains an acceptable side effect profile.

60 It was also understood that:

... the relationship between the dose administered and the reduction in LDL-C observed is non-linear for statins. This non-linear relationship affects prescribing practices, particularly if a patient's cholesterol levels are well above target levels when they are prescribed the starting dose of a statin. In such a case one may increase the dose beyond the next dose level in one step. For example, if a patient is on 10 mg and has an LDL-C level well above target, one may increase the dose to 40 mg in one step.

61 The primary judge found that medical practitioners typically prescribe patients, or at least patients who are not high risk, the lowest dosage of statin to begin with so as to minimise the

risk of adverse events such a myalgia (muscle pain), liver dysfunction and rhabdomyolysis (more severe muscle toxicity), which are potential side effects associated with statins. Her Honour found that, if the target level was not reached and the dose had been well tolerated, the dose would be increased over months. The increase in the dose was no more than dose titration. Dose titration aims to increase the dose until the patient reaches their target in as safe a manner as possible, but this practice increases costs and adversely affects patient compliance in that patients do not wish to repeatedly visit their doctor and have blood tests and/or change their dose. The primary judge found that for these reasons dose titration often does not occur and the patient remains on their starting dose even though their target levels have not been achieved. Patients with a significant risk profile are more likely to be placed on a higher dose of statins from the outset.

Perceived need for statins

62 The primary judge found that there were a number of statins available in Australia before the claimed priority dates and that many people were achieving their target cholesterol levels as a result of treatment by statins. However, medical practitioners in the field were aware that a material number of patients did not achieve their target levels because of either inadequate ongoing management of their condition and the need for dose titration or difficulty in achieving the required reduction of their cholesterol levels having regard to their risk profiles. These potentially “difficult to treat” patients included, but were not limited to, those suffering from HeFH, which is a severe form of hypercholesterolemia. The primary judge found that medical practitioners recognised before the claimed priority dates that there was room for improvement in the field of statins in terms of the development of new statins or improvement of existing statins so as to enable more patients to achieve their target cholesterol levels at doses where side effects could also be minimised. Furthermore, because it was also recognised that dose titration frequently did not occur due to the ongoing management required, medical practitioners in the field also appreciated that it was desirable to have available new or improved statins which enabled more people to achieve their target level at the first dose given which, in accordance with ordinary prescribing practices, would be a dose at the lower end of the approved range unless specific risk factors indicated a higher dosage was warranted.

63 The primary judge rejected AstraZeneca’s contention that the inventions claimed in the patents met an “unfelt want”. Her Honour did not think that the facts could be characterised in that way merely because there were a number of existing statins in the market before the claimed

priority dates, and she noted that none of the witnesses had suggested that the existing statins were perceived as incapable of being improved upon whether by a new drug or otherwise. In fact, her Honour considered that the evidence was to the contrary and that it was clear that those involved in the treatment of hypercholesterolemia were aware that the existing statins, while an enormous advancement on previously available treatments, still did not enable all patients to be effectively treated whether due to tolerance issues or the difficulty of ensuring appropriate dose titration or otherwise.

64 The primary judge found that atorvastatin was considered efficacious but it was not effective for all people, there being “a subset that require either other agents or require more potent agents, particularly patients with familial hypercholesterolemia”. The primary judge said that there were existing statins and the market for statins might well have warranted the description “crowded” before the claimed priority dates, but those involved in the treatment of hypercholesterolemia knew that existing statins did not effectively treat all patients.

65 The primary judge noted that the experts who gave evidence were not, in fact, looking for a new statin therapy at the claimed priority dates, but said that that was unsurprising because the evidence indicated that large scale clinical trials were time consuming and expensive and not usually initiated in Australia in the ordinary course. She found that the fact that none of the experts involved in treating hypercholesterolemia were looking for new statin therapy before the claimed priority dates did not mean that those involved in the field, including in Australia, failed to recognise that a new statin therapy, which was better at bringing more patients to their target level without dose titration, would be other than highly desirable.

66 The primary judge summarised her conclusions with respect to common general knowledge as to the perceived need for statins as follows. It was common general knowledge for those involved in treating hypercholesterolemia before the claimed priority dates that statins were an effective and safe treatment for hypercholesterolemia but, despite the existence of a number of statins, there remained patients who could not be effectively treated by them. It was common general knowledge at that time that one issue with the prescription of statins was that many patients did not achieve their target cholesterol level because they were not effectively subject to dose titration as this process involved ongoing management and supervision by a medical practitioner. It was common general knowledge for those involved in treating hypercholesterolemia that a statin that could bring more patients to their target level without dose titration than the existing statins would be highly desirable. Such a statin would be

considered to be “more effective” than existing statins and to offer a “competitive advantage” over those statins. There was no “unfelt want” but, to the contrary, there was a conscious perception that a new statin which could bring more patients to their target level without dose titration than the existing statins would be highly desirable.

Clinical trials

67 The primary judge considered the evidence before her with respect to pre-clinical trials and clinical trials. She accepted Professor O’Brien’s description of such trials. It is as follows:

A drug is initially chosen based on its efficacy in treating a specific condition or disease. Once a promising drug candidate has been screened for toxicology and therapeutic potential, pre-clinical trials are conducted. These pre-clinical trials test a drug candidate in order to assess the pharmacological effect and any gross side effects associated with administering the drug candidate. Such tests will be conducted on animals such as mice and rats, and then possibly on primates. These tests may involve testing of a range of doses, including even very high doses, well beyond those that would be administered to humans, to test safety. If the drug is considered to be safe and efficacious then it can then be considered a candidate for clinical trials.

Generally speaking, once the animal studies have been conducted, the researcher has an indication of safety and efficacy. By safety, I mean whether or not the drug is safe to administer and whether or not it has any side effects, as well as the severity of those side effects. When I refer to efficacy I am referring [to] how effectively the drug treats the condition or disease intended to be treated.

Whether or not a drug moves into a clinical trial (on humans) from pre-clinical trials (on animals) involves multiple considerations: not only safety and efficacy but also potential cost-effectiveness. The clinical trial process is very expensive and therefore the decision to go ahead with clinical trials is based on an expectation that the drug is going to be successful, both therapeutically and economically.

68 The primary judge found that a clinical trial is an experiment or a series of experiments investigating the use of a promising drug candidate and its use in humans. She said that it was common ground that clinical trials are more often than not time consuming and expensive, with many new drug candidates failing at some or other point in the trial process in terms of safety or efficacy or both. She found that pre-clinical and clinical trials were the subject of detailed prescriptive protocols and regulatory requirements, including ethical and safety requirements.

69 The primary judge found that the object of pre-clinical testing is to obtain an indication of the safety and efficacy of the drug candidate including in animal models so as to support progression to human trial. *In vitro* tests give an indication whether the drug has the desired activity against the drug target and its selectivity to the target. Animal studies are used to 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. Ideally the margin of safety is at least tenfold. As pre-clinical tests progress, information is gathered about safety and therapeutic efficacy, as well as the pharmacokinetics (what the body does to the drug in terms of absorption, distribution, metabolism and excretion) and pharmacodynamics (what the drug does to the body in terms of biochemical and physiological effects) of the drug. The primary judge found that, because human doses are not yet known, doses in animals often exceed that which would be used in humans to enable comprehensive evaluation of the safety indications of the drug. If the safety and therapeutic efficacy of these tests warranted further examination of the drug, clinical trials would then be considered involving testing in humans.

70 The primary judge found that the object of clinical trials was to establish the safety and efficacy of the drug in humans. They generally involved three phases. Phase I trials for new drugs usually involve a small number of healthy subjects, the purpose being to ensure that the drug is safe in humans and to consider dosage ranges, the pharmacodynamics of the drug being a secondary purpose. Phase I trials for reformulated versions of known drugs focus on the pharmacodynamics of the drug, ensuring that the reformulation interacts with the body in the same way as the original formulation. Phase II trials involve studying the drug in a larger number of patients with the relevant condition, the primary objective being to ascertain the pharmacodynamic effect of the drug. Early studies in Phase II are sometimes called Phase IIa studies. Phase III trials involve studying the effectiveness of the drug in a large number of patients over a long period of time. The primary judge accepted that Phase III clinical trials were “pivotal” for the reason (among others) that generally it was the first time that efficacy could be demonstrated in the long term and in a statistically significant number of participants. There is also a fourth phase, which involves long-term post-marketing observation of the drug in the target population. There is often a great deal of uncertainty, particularly in the early stages, as to whether a drug will work. Regulatory approval to market the drug may be given on the basis of Phase III trials, and Phase IV trials are undertaken after the drug has been launched onto the market and can be several years in duration.

71 The primary judge found that, in the case of statins, short term efficacy can be confirmed in Phase I trials because statins have an effect even in healthy humans. That was the evidence of Professor O’Brien and, her Honour said, it was not in dispute.

Drug formulation

72 The primary judge explained aspects of pharmaceutical formulations and formulating processes, including active pharmaceutical ingredients, excipients, standard mixing techniques of dry blending and wet granulation, degradation of pharmaceutical compositions, including oxidation and lactonisation reactions, the coating of tablets, and the compounds used thereafter. It is not necessary for us to set out the details.

Inorganic salt

73 The primary judge found that the hypothetical skilled addressee of the 842 or cation patent, being formulators of pharmaceutical compositions, understood the traditional meaning of a “salt” to be the compounds formed by the neutralisation of an acid and a base. Within this meaning, oxides, including ferric oxide and titanium dioxide, would not be considered to be a salt, whereas calcium sulphate would be. Within this meaning carbonate, silicate and metasilicate are counter anions of inorganic salt.

74 There is a wider meaning – compositional definition – of inorganic salt to mean an inorganic compound which is electrically neutral. Ferric oxide and titanium oxide would be “inorganic salts” within this definition, that is, they are an inorganic compound with a neutral net ionic charge, in which the cation is multivalent. A multivalent cation is one with more than one positive charge.

75 The primary judge noted that the compositional meaning of “inorganic salt” appeared in the International Union of Pure and Applied Chemistry (IUPAC), *Nomenclature of Inorganic Chemistry*, 1990 (GJ Leigh ed.). She also noted the large body of expert evidence which favoured the traditional meaning.

76 The correct meaning of the term “inorganic salt” turned on the proper construction of the specification of the 842 or cation patent, and the primary judge dealt with it in that context. She accepted that the broader meaning was the appropriate one, that is to say, a class of compounds in which a negatively charged ion (an anion) is ionically bonded to a positively charged ion (a cation) to form an electronically neutral molecule.

Awareness of rosuvastatin

77 The primary judge considered whether rosuvastatin, either under that name or referred to as ZD4522, was part of the common general knowledge of the hypothetical addressees of the patents in 1999 and 2000.

78 As we have said, the primary judge said that she considered that the skilled addressee of the 051 or low dose patent to be those with a particular expertise in lipidology. Accordingly, it was the knowledge of Professors Tonkin and O'Brien and Dr Colquhoun which was relevant.

79 The primary judge noted that Professor Tonkin attended and presented a paper at the International Society of Atherosclerosis meeting in Stockholm in June/July 2000, known as the 12th International Symposium on Atherosclerosis. At that meeting, a paper about rosuvastatin or ZD4522 was presented by Olsson and others. The abstract for that article, coincidentally, was posted next to the abstract of the paper in which Professor Tonkin was involved. The Olsson article published at the Stockholm symposium is in the following terms:

ZD4522 – a new HMG-CoA reductase inhibitor – causes rapid and profound reductions in plasma LDL-C levels in patients with primary hypercholesterolaemia

...

Effects of once-daily oral doses of ZD4522 (rosuvastatin) and atorvastatin – both synthetic inhibitors of HMG-CoA reductase – on plasma LDL-C levels were assessed in patients with mild-to-moderate hypercholesterolaemia.

Design/Methods: randomised, placebo-controlled, parallel-group dose-ranging trial (4522[L/0008). After a 6-wk dietary run-in, men (18-70yr) and post-menopausal women (50-70yr) received double-blind placebo or ZD4522 (1, 2.5, 5, 10, 20 or 40mg) or open-label atorvastatin (10 or 80 mg) during a 6 wk treatment period. Percentage change in LDL-C from baseline to wk 6 was analysed by ANOVA for ZD4522 and placebo groups only.

Results: 142 patients entered the 6-wk treatment period (124 provided data in efficacy analysis). Compared with placebo, all doses of ZD4522 significantly lowered LDL-C in a dose-dependent manner ($p < 0.001$). At wk 6, reductions in LDL-C from baseline ranged from 36% (1mg) to 63% (40mg) after treatment with ZD4522; reductions of 44% (10mg) and 59% (80mg) were seen with atorvastatin. Informal comparisons showed ZD4522 produced numerically greater reductions in LDL-C than did atorvastatin on a mg-per-mg basis. Approximately 90% of LDL-C reduction occurred within the first 2 wks of randomised treatment with ZD4522 (Figure), indicating ZD4522 had a rapid onset of efficacy. ZD4522 was well tolerated across all doses; occurrence of adverse events was similar across placebo and active treatments, with no increase in adverse events or withdrawals noted with increasing doses of ZD4522. No patients had clinically significant elevations in ALT ($>3 \times \text{ULN}$) or CK ($>10 \times \text{ULN}$).

80 The primary judge found that a version of the Olsson article was subsequently published in the European Heart Journal in 2000 and that that version contained an additional statement as follows:

ZD4522 – a new HMG-CoA reductase inhibitor – causes rapid and profound reductions in plasma LDL-C levels in patients with primary

hypercholesterolaemia

...

...

ZD4522 showed rapid, clinically relevant, dose-related reductions in LDL-C. The safety profile of ZD4522 compared favourably with those of atorvastatin and placebo.

[**European Heart Journal** 2000;21 Suppl p156 Abs P975].

- 81 The primary judge made the following findings. In April 1998, the predecessor of AstraZeneca, Zeneca Ltd, publicised its licence with the inventor of ZD4522, Shionogi, for the “world-wide development, marketing and commercialization of this very promising lipid-lowering agent to be known as ZD4522 ... with a ‘superstatin’ profile”. In April 1999, AstraZeneca was created from a merger between Zeneca Ltd and Astra Ltd. At that time, AstraZeneca’s new executive director of research and development gave an interview to Reuters in which he referred to “Zeneca’s superstatin used in heart disease”. On 6 December 1999, AstraZeneca issued its first R&D presentation referring to Phase II trials data stating that “ZD4522 superstatin confirms better lipid lowering efficacy than any existing product and tolerability equivalent to the best in the class”.
- 82 The presentation of the results at the 12th International Symposium on Atherosclerosis in Stockholm gained attention. An article published on the same day as the presentation on 28 June 2000 referred to the AstraZeneca trials as showing a 65% reduction in LDL cholesterol. Another article was published the following day in a free newsletter called Heartwire. The newsletter contained information of interest to cardiologists and clinicians interested in the area. The article was entitled “Rosuvastatin – the most powerful statin yet”. The article referred to Dr Olsson as having represented that the 65% reduction of LDL cholesterol achieved by rosuvastatin “surpasses the maximum responses of all other statins when used as monotherapy”. The results were reported under the by-line in bold “Faster than a speeding bullet? More powerful than a locomotive?” The article also reported that the drug showed “adverse events similar to placebo, [with a] lower risk of interactions with other drugs”. Another AstraZeneca researcher, Dr McTaggart, was reported as saying that rosuvastatin is more lipophilic than any of the other statins and, as it is not metabolised in the liver as with other statins, it should be free of interactions with other drugs. On the same day, a similar article appeared in the UK newspaper, The Guardian, which was available online.

83 On 31 July 2000, AstraZeneca issued a statement about its decision to spend £28.5m to construct a new plant to manufacture ZD4522 following the “recent publication of clinical data from Phase II trials demonstrating the potential of ZD4522, a HMG-CoA reductase inhibitor, to be a highly effective and well-tolerated alternative to currently available statins”.

84 The primary judge found that, on and from 30 June 2000 but not before, the skilled addressee, such as clinicians like Professors O’Brien and Tonkin and Dr Colquhoun, who had practices focusing on lipid reducing therapies, were aware that there was a new statin which had been the subject of Phase II clinical trials and that, by reason of the results presented at the symposium and subsequent publicity, the trials showed the drug’s potential to be the most potent yet in terms of capacity to reduce LDL cholesterol at doses which were as well-tolerated as the best of the existing statins. Although the Heartwire article referred to the statin as rosuvastatin, as we have said, the primary judge found it more likely that it was known as ZD4522 as at 30 June 2000.

85 The primary judge found that rosuvastatin was part of common general knowledge in Australia from on or about 30 June 2000. However, its chemical name and structure were not part of common general knowledge at that time, nor, presumably, on 4 August 2000.

86 AstraZeneca challenged the primary judge’s conclusion that rosuvastatin was part of common general knowledge in Australia from on or about 30 June 2000. In light of the priority date of the 051 or low dose patent of 6 January 1999, the point is only of potential significance in relation to the 842 or cation patent.

87 AstraZeneca challenged the primary judge’s finding about when rosuvastatin became part of common general knowledge in Australia on two grounds. First, it challenged her definition of the class of the hypothetical skilled addressee of the 842 or cation patent and, secondly, it challenged her conclusion that knowledge of rosuvastatin, without knowledge of its chemical name and structure, was sufficient to make the compound part of common general knowledge in Australia on 4 August 2000. In their written submissions, the generic parties sought to support the primary judge’s conclusion making submissions to the effect that knowledge of rosuvastatin without knowledge of its chemical name and structure was sufficient. However, during oral submissions on the hearing of the appeals, the generic parties abandoned those submissions. They accepted that, if rosuvastatin was not a “given”, then they did not pursue their submissions that the invention defined in the claims of the 842 or cation patent was obvious. The precise basis upon which this was done is not entirely clear. In any event, it does

not avail AstraZeneca. Although we conclude that the primary judge erred in treating rosuvastatin as a given, we also conclude that the primary judge did not err in concluding that the priority date of the 842 or cation patent was 31 January 2005. Furthermore, even if we are wrong and the correct priority date was 4 August 2000, we conclude that at least claims 1, 2, 4, 5 and 7 of the 842 or cation patent were not novel in light of the 841 patent. In any event, contrary to the conclusion of the primary judge, we are also satisfied that the claims of the 842 or cation patent are invalid for lack of fair basis.

CONSTRUCTION ISSUES

88 Initially, there were four construction issues, two raised by AstraZeneca on their appeals in relation to the 051 or low dose patent, and two raised by the generic parties in their notices of contention in relation to the 842 or cation patent. One of the construction issues raised by the generic parties, i.e., the meaning to be attributed to “inorganic salt”, was abandoned during the course of the submissions.

The 051 or low dose patent

89 First, AstraZeneca submitted that the primary judge misconstrued the phrase “method of treating” in the 051 or low dose patent.

90 The primary judge set out the principles governing the construction of the claims and body of a specification of a patent. Her statement of the relevant principles was uncontroversial and was not challenged by either party. There is no need for us to repeat what her Honour said.

91 The primary judge said that the words “method of treating” imported some degree of efficacy and safety, but not to the level of that necessary for regulatory approval.

92 AstraZeneca submitted that the primary judge erred and that she ought to have held that the claims imported the notion of a method of treating hypercholesterolemia that is sufficiently safe and efficacious to be administered by medical practitioners to patients requiring treatment for that condition. AstraZeneca submitted that it is not clear where her Honour set the bar in terms of safety and efficacy.

93 The primary relevance of this issue seems to be in relation to entitlement and, in particular, to whether employees of Shionogi, or Dr Raza, was the inventor of the 051 or low dose patent. We will deal with it in that context.

94 Secondly, AstraZeneca submitted that the primary judge misconstrued the term “starting dose”
in the 051 or low dose patent. The submission was not developed in any great detail and it was
not made clear how it related to the issues raised on the appeals.

95 The primary judge said that where an initial dose was varied, the starting dose was the initial
dose. Where it was not varied, it was a question of fact to be determined on a case-by-case
basis as to when the starting dose became a maintenance dose.

96 We think the primary judge’s construction is correct. It is the natural and ordinary meaning of
starting dose and we note that the specification itself refers to titration of rosuvastatin. We do
not think the fact that the specification makes claims of efficacy and safety at low dosages such
that patients may remain on the starting dose is sufficient to displace the natural and ordinary
meaning of the term.

The 842 or cation patent

97 Although the term “pharmaceutical composition” is used in the claims of both patents, it is the
proper construction of the term in claim 1 of the 842 or cation patent which is controversial.

98 At the trial, AstraZeneca contended that the term means the means by which the active
pharmaceutical ingredient is administered or delivered to a patient in whatever form and that it
followed from that that, if the form is a coated tablet, then that is the pharmaceutical
composition. The generic parties disputed this construction and contended that the term
“pharmaceutical composition” should be construed as excluding the coating on a tablet and as
including only compositions in which the cation is multivalent where the inorganic salt is
admixed or in intimate contact with the active pharmaceutical ingredient, being the
rosuvastatin.

99 The primary judge decided this point of construction in favour of AstraZeneca and the generic
parties challenge her Honour’s conclusion in their notices of contention.

100 The primary judge set out the principles relevant to the construction of claims of a patent in a
manner which was not the subject of criticism by any of the parties to the appeals. Of particular
significance was her Honour’s reference to *Welch Perrin and Company Proprietary Limited v
Worrel and Another* (1961) 106 CLR 588 at 610 per Dixon CJ, Kitto and Windeyer JJ and the
following passage from the decision of the Full Court of this Court in *Kinabalu Investments
Pty Ltd v Barron & Rawson Pty Ltd* [2008] FCAFC 178 at [44]:

When determining the nature and extent of the monopoly claimed, the specification must be read as a whole. But as a whole it is made up of several parts which have different functions. The claims mark out the legal limits of the monopoly granted. The specification describes how to carry out the process claimed and the best method known to the patentee of doing that. Although the claims are construed in the context of the specification as a whole, it is not legitimate to narrow or expand the boundaries of monopoly as fixed by the words of a claim, by adding to those words glosses drawn from other parts of the specification. If a claim is clear and unambiguous, it is not to be varied, qualified or made obscure by statements found in other parts of the document. It is legitimate, however, to refer to the rest of the specification to explain the background of the claims, to ascertain the meaning of technical terms and resolve ambiguities in the construction of the claims.

101 The primary judge then addressed nine reasons which had been advanced by the generic parties in support of their contention that the term “pharmaceutical composition” should be construed so that it was restricted to compositions where there is an admixing or blending of rosuvastatin and the inorganic salt with the multivalent cation. It is not necessary for us to set out these reasons. The reasons involve reliance on a number of matters, including the structure of the specification and various passages in it, including the four Examples, expert evidence about inorganic salt and organic salt and the reasons the stability of rosuvastatin might be improved by its association with inorganic salt with a multivalent cation, evidence about the conventional formulation approach, the contents of the priority document, evidence from AstraZeneca’s discovered documents to the effect that AstraZeneca always mixed the inorganic salt with the rosuvastatin, the composition of AstraZeneca’s own commercial product (Crestor), and the contents of a related application being a divisional of the 842 or cation patent.

102 We think that there were two matters critical to her Honour’s decision to reject the arguments advanced by the generic parties. First, her Honour considered the words in claim 1 of the 842 or cation patent to be clear and unambiguous and, furthermore, she relied on the fact that claim 1 said nothing about stability. Secondly, her Honour did not think that the language of the specification was as supportive of the generic parties’ submissions as they argued.

103 On the appeals, the submissions of the generic parties focused on the body of the specification and the effect it had on the proper construction of claim 1. In other words, they did not reiterate their arguments which relied on matters outside the body of the specification and the claims. In particular, their submission was that the body of the specification referred to the benefit of improved stability and that that could only be achieved where the rosuvastatin and inorganic salt in which the cation is multivalent are mixed together. When we come to consider the related issue of fair basis (at [413] and following) it will be seen that we take a different view

from her Honour as to the proper reading of the body of the specification as a whole. We think it describes an invention consisting of a pharmaceutical composition, the active ingredient of which has been mixed or blended with certain inorganic salts. However, we agree with the primary judge that the words of claim 1 are clear and that the claim makes no reference to stability. Claim 2 refers to a pharmaceutical tablet. Claim 3, to the extent it is dependent on claim 2, describes this tablet as a pharmaceutical composition. Thus, the claims specifically contemplate that a pharmaceutical composition includes a tablet. There is no reason to construe claim 2 as excluding any coating or other constituent part of the tablet. It is well established that it is not legitimate to narrow (or expand) the boundaries of monopoly as fixed by the clear words of a claim by adding to those words glosses or limitations drawn from other parts of the specification. We reject the challenge to her Honour's construction of the term "pharmaceutical composition".

ENTITLEMENT

104 At [292] of her reasons, the primary judge held that the 051 or low dose patent should be revoked under s 138(3)(a) of the Act because AstraZeneca as patentee was not entitled to the patent.

105 At trial, AstraZeneca claimed that Dr Ali Raza was the sole inventor of the invention described in the 051 or low dose patent (*viz* the use of 5 mg to 10 mg daily dose of rosuvastatin) and that it had properly claimed entitlement to the patent through him (see s 15 of the Act).

106 The generic parties, on the other hand, contended that employees of Shionogi were the inventors. None of those persons had been named as inventor.

107 Although the generic parties put their entitlement case in their pleadings on the basis that employees of Shionogi had sufficiently contributed to the alleged invention as to be inventors of the invention in the 051 or low dose patent, the issue at trial in respect of entitlement was whether the inventor was Dr Raza, as argued by AstraZeneca, or employees of Shionogi, as argued by the generic parties. The parties' respective contentions on this point were advanced on an all or nothing basis. It was not contended by any party that the invention was the result of any collaboration between Dr Raza and employees of Shionogi or the result of joint contributions from Dr Raza, on the one hand, and employees of Shionogi, on the other hand. In those circumstances, the generic parties did not raise or pursue any broader inquiries directed to establishing the identity, in fact, of the real inventor of the 051 or low dose patent.

108 AstraZeneca challenged the primary judge’s conclusion that AstraZeneca was not entitled to the patent. In each notice of appeal, it specified three grounds of appeal directed to her Honour’s finding in respect of entitlement. Those grounds are:

The primary judge erred in holding, and in finding or proceeding on the basis that it was common ground between the experts, that “*the efficacy of statins (unlike some other drugs) is disclosed by use in healthy volunteers*” (at [278]; see also [142]).

The primary judge erred in holding that the work conducted by Shionogi & Co Ltd (**Shionogi**) involved the discovery that rosuvastatin, at 5 mg and 10 mg once a day doses, reduced lipid levels by a significant extent and was tolerated by humans for that purpose (at [291]) and that Shionogi “*invented the idea of progressing rosuvastatin through a series of conventional trials, in conformity with the Japanese Guidelines*” (at [408]).

The primary Judge erred in holding that the invention described and claimed in the 051 Patent was invented by Shionogi and that the first appellant (**AstraZeneca**) was not entitled to the invention (at [291], [292]).

The primary judge’s findings and reasons

109 At [274], the primary judge noted that there was no dispute that Shionogi invented the compound rosuvastatin. She said that there was also no dispute that Shionogi had granted AstraZeneca a licence in respect of rosuvastatin. Her Honour then quoted from the inventorship record for the 051 or low dose patent as follows:

During the licence negotiations for ZD4522, Shionogi provided Zeneca with data from a Japanese Phase IIa study (dose of ZD4522 up to 4 mg) in hyperlipidaemic patients, showing 41% lowering at the 4 mg dose level. However, the effect of higher doses of ZD4522 to lower LDL had not been investigated.

At a meeting on 23rd December 1997 at Mereside, Alderley Park, between Ali Raza (AR), Brent Vose, Nigel Finch and Tony Clarke, AR suggested, as part of a proposed clinical plan, that a Phase II clinical trial be carried out to estimate the dose-response relationship between the dose of ZD4522 and the percentage reduction of LDL-C in hyperlipidaemic patients, including two open label arms of atorvastatin start dose of 10 mg and max dose of 80 mg, with secondary objectives of estimating the effects of ZD4522 on other lipoprotein levels, and assessing tolerability and safety.

110 At [276] to [277], the primary judge said:

This is consistent with the documentary record which shows that by October to December 1993, Shionogi began clinical trials for rosuvastatin. The first “Early Phase single dose tolerance study” involved doses of 0.25 2.5, 5, 10 and 20mg doses with healthy volunteers (a Phase I study). By February to April 1994, Shionogi’s second Phase I study had begun. The doses were:

Doses of 5 mg/day and 10 mg/day which were among the doses administered in the early phase single dose tolerance study and which were within the

estimated clinical dose range as well as 20 mg/day which correspond to twice the estimated maximum clinical dose were set in this study.

In June to July 1994, a further Phase I study, or “one-week repeated administration study”, was conducted. The report of this study said:

Estimated from the results of preclinical studies, the usual dose of S-4522 is 5 mg and the maximum dose 10 mg. Since one of the objectives of this study is to evaluate the accumulation of S-4522, the dose was set at 10 mg, a high dose among the estimated clinical doses.

111 At [278], her Honour held that it was common ground between the experts that the efficacy of statins is disclosed by use in healthy volunteers. Her Honour went on to observe that it was common ground between the experts that, even in a healthy person, statins reduce cholesterol levels.

112 At [279] to [281], her Honour said:

Shionogi conducted another study in September to October 2004 [the correct date is 1994], being a “two-week repeated administration study in subjects with mild hyperlipidemia” in which doses of at 0.5, 1, 2 and 4 mg were used.

From June 1995 to June 1996, Shionogi conducted an “Early Phase II clinical study of S-4522”. This tested rosuvastatin’s efficacy at doses from 1 to 4 mg daily. The report concluded:

In the Phase II clinical studies of the existing HMG-CoA reductase inhibitors, about 20% and 30% reductions in TC and LDL-C, respectively, have been reported (Table 14).

In the present study, we expected greater reductions in these lipids than those achieved with the conventional drugs and actually obtained the results as expected.

All of Shionogi’s work was disclosed to AZ as part of the licence arrangement.

113 At [275], her Honour held that, by April 1998, Shionogi had reached the development stage of the compound known as ZD4522 recorded in a press release issued at that time. Her Honour extracted the relevant parts of that press release at [275] in the following terms:

- (a) that ZD4522 [Shionogi’s S4522] had a “superstatin” profile;
- (b) that it “had the potential at well-tolerated doses” [i.e., as to safety] of lowering LDL-C and TG “to a much greater extent than the first generation of ‘statins’” [i.e., as to efficacy];
- (c) that “Phase IIa clinical trial results in Japan had shown very encouraging results” [i.e., in dose ranging studies, as to safety and efficacy]; and

- (d) that “first regulatory submission is anticipated in approximately 3 years’ time” and that “ZD4522 offers Zeneca the opportunity of entering the market for lipid lowering medicines” [i.e., that a full clinical trial program was contemplated, and was expected to succeed].

114 At [282] to [283], her Honour recorded the essence of the generic parties’ submissions directed to the question of entitlement. Those parties had submitted that not only had Shionogi invented rosuvastatin, but also that its scientists had conceived of a method of treating hypercholesterolemia comprising administration of 5 mg and 10 mg in daily doses of rosuvastatin, including as a starting dose. The generic parties had submitted that Shionogi had invented the invention claimed in the claims of the 051 or low dose patent. They argued that Dr Raza did not invent rosuvastatin and that he was not the first person to conceive of the use of a 5 mg dose or a 10 mg dose on a daily basis. They submitted that Dr Raza was not the inventor at all. Alternatively, he was only one of a number and AstraZeneca does not derive title from the others.

115 At [284], her Honour dealt with an objection raised by AstraZeneca to the effect that the case as run by the generic parties at trial was not open to them on the pleadings. Her Honour rejected that argument.

116 At [285] to [288], her Honour summarised AstraZeneca’s submissions in support of its case that Dr Raza was, in fact, the inventor. In those paragraphs, her Honour noted that AstraZeneca argued that Shionogi’s work had stopped in 1996 and that rosuvastatin had been identified as nothing more than a promising candidate for development. AstraZeneca submitted that the method of treatment and its constituent elements (a patient suffering from a particular condition being hypercholesterolemia, the administration of particular doses of the compound, being 5 mg to 10 mg, once daily, orally, as the starting dose daily in claim 1 or as a single daily dose in claim 2) are the inventive concept. The inventive concept resided in the combining of those elements to produce the relevant effect for the benefit of patients. AstraZeneca emphasised that Shionogi was not in a position to be categorical about the efficacy and safety of administering rosuvastatin in the doses said to form part of the ultimate invention.

117 At [289] to [291], her Honour set out the essence of her reasoning for the conclusion which she reached at [292] in the following terms:

One difficulty with these submissions is that they place too much of a load on the reference to a “method of treatment” in the claims. AZ appears to equate the reference to a “method of treatment” to a promise of efficacy and safety. Yet analysis of this exposes the difficulty. It cannot be the case that absolute efficacy and safety is inherent

in the assumed promise. Nor is there a proper basis to assume efficacy and safety relative to existing therapies in the sense that the method will be as efficacious and as safe as existing therapies. As it was put for the generic parties (albeit in a different context):

... that safety will never be assured or completely verified... The assessment of safety is a continuous process and even now rosuvastatin is marketed with a range of safety warnings in its product information including rhabdomyolysis.

It may be acknowledged that the claims do assert a “method of treating” hypercholesterolemia which must involve notions of at least some degree of efficacy and safety; otherwise there would be no method of “treating” at all. AZ’s case, however, appears to depend on efficacy and safety having been proved to a standard equivalent to that sufficient for regulatory approval before it can be said that the method of treatment exists. Nothing to that effect appears in the claims and it cannot be sustained merely by the invention being a method of treating hypercholesterolemia.

Whatever the contemporaneous debate about potential differences between Japanese and Western responses to statins (which I accept did exist at the time, it apparently being thought that Japanese were less tolerant of statins than Westerners) the work conducted by Shionogi had involved the discovery that rosuvastatin, at 5 and 10mg once a day doses, reduced lipid levels by a significant extent and was tolerated by humans for that purpose, even if its safety at various doses required further work. Given that the reference to a “method of treating” cannot mean anything more than some degree of efficacy and safety, if there is any invention claimed by the patent, it was invented by Shionogi not Dr Raza. This conclusion applies to both claims 1 and 2 and as claim 3 is dependent on either of those claims it too must fail.

The parties’ submissions on the appeals

118 AstraZeneca submitted that the reasoning of the primary judge involved three errors.

119 First, AstraZeneca submitted that her Honour erroneously held that it was “common ground” that the efficacy of statins was disclosed by use in healthy volunteers. This finding is found at [278] of her Honour’s reasons.

120 It was submitted on behalf of AstraZeneca that it had made no such concession and that the finding made by her Honour was contrary to the evidence. AstraZeneca submitted that the evidence at trial showed that the most that could be taken from Phase I trials of statin drugs was an indication of the short term efficacy of the drug in lowering plasma cholesterol levels in healthy patients. In context, so it was submitted, when her Honour spoke of the efficacy of statins being demonstrated by use in healthy volunteers at [278] of her reasons, her Honour was bringing to mind Phase I trials. It was then submitted that the primary purpose of such trials is to assess the tolerability of a candidate drug in healthy human volunteers in order to determine whether it is sufficiently safe to proceed to further development. Phase I trials do

not determine the efficacy of a drug in patients suffering from the target medical condition. It was said that, while an indication of short term efficacy in healthy patients may be gleaned from Phase I trials, Phase II testing must be undertaken in order to obtain information about the efficacy and safety of the drug in patients suffering from the relevant condition.

121 The second error identified by AstraZeneca was her Honour's holding that the invention was invented by Shionogi and not by Dr Raza because the work conducted by Shionogi had involved the discovery that rosuvastatin, at 5 mg and 10 mg once a day doses, reduced lipid levels significantly and was tolerated by humans for that purpose (see [291] of the reasons). AstraZeneca submitted that it was clear on the evidence that Shionogi made no such discovery.

122 AstraZeneca submitted that Shionogi had never tested, let alone treated, any patient suffering from hypercholesterolemia with any 5 mg to 10 mg dose of rosuvastatin. For this reason, so it was submitted, Shionogi did not determine and could not have determined that the administration of 5 mg and 10 mg doses to patients suffering from hypercholesterolemia was a useful or effective or safe method of treatment. The only Phase II study conducted by Shionogi demonstrated that it had pursued different combinations of doses. The particular study in question marked the end point of Shionogi's clinical trials. It was the study which considered the effect of administering 1 mg, 2 mg and 4 mg doses of rosuvastatin to Japanese patients with hyperlipidemia. No 5 mg or 10 mg doses were ever tested or progressed by Shionogi in Phase II clinical testing.

123 Shionogi never reached a point where it had in its possession a method of treatment. It certainly never reached a point when it had a method of treatment for patients with hypercholesterolemia which involved the administration of daily doses of 5 mg or 10 mg of rosuvastatin. AstraZeneca submitted that the primary judge's holding that Shionogi had discovered that rosuvastatin at 5 mg and 10 mg once a day doses reduced lipid levels by a significant amount and was tolerated by humans for that purpose (at [291] of the reasons) was not supported by the Phase I trial evidence obtained by Shionogi that apparently underpinned that finding. In any event, that finding could not be equated, as apparently the primary judge thought, to Shionogi being in possession of the invention in the patent. Shionogi tested a range of possibilities which may have included relevant potential clinical doses. But they did not test the invention.

124 The primary judge's third error identified by AstraZeneca is her Honour's finding that the reference to a method of treating in the 051 or low dose patent cannot mean anything more than some degree of efficacy and safety (at [291] of the reasons).

125 AstraZeneca submitted that the invention or inventive step found in the patent resides in the combining of the various elements described at [116] to [117] above to produce a method of treatment that is efficacious, i.e., safe and effective in treating the patient's hypercholesterolemia. The search for the inventor, according to AstraZeneca, is a search for the person who in substance conceived of the idea of making that particular combination of elements. AstraZeneca submitted that Shionogi's Phase I trials never brought together all of the critical elements of the combination. AstraZeneca went on to submit that the pivotal study for the purposes of the 051 or low dose patent was AstraZeneca's first Phase II study (Study 8) which was conducted between August 1998 and January 1999. That study examined, *inter alia*, the effects on various lipid parameters of administering 1 mg, 2.5 mg, 5 mg, 10 mg, 20 mg and 40 mg doses of rosuvastatin, compared with 10 mg and 80 mg doses of atorvastatin. The results and methodology of Study 8 are presented over 10 pages of the 051 or low dose patent in order to illustrate the invention. AstraZeneca emphasised that the combination of elements, as claimed in the patent, had not existed previously.

126 AstraZeneca submitted that the evidence established that the person who was responsible for the claimed combination was Dr Raza. It then contended that there was no argument advanced by the generic parties that AstraZeneca does not derive title from the work of Dr Raza. Accordingly, the relevant choice being between Dr Raza and Shionogi employees, her Honour ought to have found that it was Dr Raza who was responsible for conceiving the claimed combination.

127 Apotex commenced its submissions by emphasising that the entire contribution made by Dr Raza to the invention in the patent is found in the inventorship record which her Honour extracted at [274] of her reasons. That contribution was to suggest a clinical plan in the terms documented in the inventorship record. Apotex made much of the fact that Dr Raza did not give evidence at the trial. Apotex had tendered one part of an affidavit which he had made prior to the trial. Apotex submitted that the idea advanced by Dr Raza as recorded in the inventorship record was an idea which had already occurred to Shionogi. The primary judge's unchallenged finding that, as at April 1998, "Phase IIa clinical trial results in Japan had shown very encouraging results" (i.e., in dose ranging studies as to safety and efficacy) (at [275] of

the reasons) was critical to her Honour's ultimate conclusions and was an important step in reaching the final combination of elements in the invention.

128 Early Shionogi reports of its progression through Phase I and Phase II trials included references to 5 mg and 10 mg as "within the estimated clinical dose range".

129 Apotex submitted that AstraZeneca was making too much of and exaggerating the import of the primary judge's finding at [278] of her reasons to the effect that, even in a healthy person, statins reduce cholesterol levels.

130 Apotex submitted that AstraZeneca's fundamental argument that the claims of the 051 or low dose patent define a method of treating hypercholesterolemia that is sufficiently safe and efficacious to be administered by medical practitioners to patients requiring treatment for that condition seeks impermissibly to read into the words of the claims of the patent such a limitation. Apotex contended that the primary judge rightly rejected this at [290] because nothing to that effect appears in the claims themselves. No level of efficacy is defined by the claims.

131 In any event, Shionogi had conceived although not yet proved a method of administering the claimed doses to patients suffering from hypercholesterolemia.

132 Apotex also submitted that, while Phase III trials are needed to obtain regulatory approval, there is no limitation in the claims of the patent to this effect. Still less is there any limitation to "western populations".

133 Watson and Ascent adopted the submissions of Apotex made in respect of entitlement. Those parties also submitted that the primary judge's findings of fact concerning inventorship were based upon a significant body of evidence and other findings littered throughout her Honour's reasons.

134 In reply, AstraZeneca repeated its submission that the claims made in the patent do require a method of treating hypercholesterolemia that is sufficiently safe and efficacious to be administered by medical practitioners to patients requiring treatment for that condition. It submitted that Shionogi never had any such method in its possession.

135 AstraZeneca submitted that no adverse inference should be drawn against it by reason of the fact that it did not call Dr Raza. It submitted that the onus was on the generic parties to establish that Dr Raza was not the inventor and that the state of the evidence was such that it was not

necessary for AstraZeneca to call Dr Raza in order to meet the generic parties' contentions in this regard.

136 AstraZeneca went on to submit that Shionogi's development work ceased at the point of the identification of rosuvastatin as a promising candidate for development. At that point, there was no method of treatment. The compound then apparently sat idle on Shionogi's shelf for another two years. It was AstraZeneca which thereafter progressed to Phase I and Phase II clinical trials and it was AstraZeneca which conceived of the combination which is reflected in the patent.

Consideration

137 AstraZeneca does not challenge any of the primary judge's findings found at [274] to [277] of her reasons. Those paragraphs contain findings which form the basis of her Honour's conclusions expressed at [291] of her reasons.

138 In addition to the findings made by her Honour, we note that:

1. In Attachment 1 to the February to April 1994 study referred to by her Honour at [276] of her Honour's reasons, the objective of the study was specified in the following terms:

The objective of study is to investigate the safety and pharmacokinetics of drug by starting from the estimated normal clinical dose of 5 mg/day and by gradually increasing the dose to 20 mg/day which corresponds to twice the estimated maximum clinical dose (10 mg/day) while checking the safety and pharmacokinetics at each step. At the dose of 5 mg/day, the effect of meal on the pharmacokinetics of this drug will also be investigated.

5 mg/day is described as the "normal clinical dose" and 10 mg/day is described as "estimated maximum clinical dose".

2. The evidence demonstrated that the Early Phase II study conducted in the period from June 1995 to June 1996 referred to by the primary judge at [280] of her reasons involved the daily administration of doses of 1 mg, 2 mg and 4 mg for a period of eight weeks.

139 No particular or specific standard of efficacy and safety is specified in the claims of the 051 or low dose patent. The suggested standard repeatedly advanced by AstraZeneca in its submissions is that the method of treating a patient must be sufficiently safe and efficacious to be administered by medical practitioners to patients requiring treatment. That requirement does not appear anywhere in the consistory clauses, claims or specification of the 051 or low dose patent.

140 We do not think that the primary judge misunderstood the difference between Phase I and Phase II trials of a candidate drug. Indeed, a fair reading of [274] to [280] demonstrates that her Honour well understood the distinction. Furthermore, her Honour also appreciated that Phase I trials involved healthy individuals. At the level at which her Honour's findings at [278] are expressed, we have no difficulty in accepting the correctness of those findings.

141 Secondly, when the work of Shionogi is compared with the invention as described in the 051 or low dose patent in the broad terms in which we have mentioned, her Honour's findings at [291] of her reasons are amply supported by the evidence. The work of Shionogi culminated in the June 1995 to June 1996 study referred to by her Honour at [280] in which the efficacy of rosuvastatin was tested at doses from 1 mg to 4 mg daily. The Phase I studies had established that the normal clinical dose range of rosuvastatin, when tested on healthy volunteers, was 5 mg to 10 mg per day. In particular, as her Honour found, the work conducted by Shionogi involved the discovery that rosuvastatin, at 5 mg and 10 mg once a day doses, reduced lipid levels by a significant extent and was tolerated by humans for that purpose, even if its safety at various doses required further work. Given the breadth of the claims of the patent, that finding was sufficient to support her Honour's ultimate finding that the 051 or low dose patent should be revoked because of a lack of entitlement to the invention claimed therein by AstraZeneca, its claim to entitlement being sourced in the nominated inventor, Dr Raza, who, as her Honour found, was not the inventor.

142 Before leaving this issue, it is not irrelevant to note that, albeit in a different context, it is well established that the fact that it is contemplated that there will be further experiments for checking and testing is not fatal to a conclusion that there is an existing invention (*The Wellcome Foundation Limited v V.R. Laboratories (Aust.) Proprietary Limited* (1981) 148 CLR 262 ("Wellcome") at 281 per Aickin J (with whom Gibbs, Stephen and Mason JJ agreed); and *Merck & Co Inc v Arrow Pharmaceuticals Ltd* (2006) 154 FCR 31 ("Merck") at 59-60, [104] to [108]).

143 For these reasons, we are of the view that the challenges to her Honour's findings in respect of entitlement have not been made out.

AstraZeneca's interlocutory application

144 By interlocutory application dated 13 June 2013, AstraZeneca applied to the Full Court for orders that:

1. The Appellants be granted leave pursuant to r 36.11 to file in each proceeding Amended Notices of Appeal in the form annexed as Annexure GWF-C to the affidavit of Grant William Fisher sworn on 13 June 2013.
2. The Appellants be granted leave pursuant to r 36.57 to file and adduce the following evidence:
 - (a) the affidavit of Benjamin C McDonald affirmed on 11 June 2013, with its Annexure BCMC-A; and
 - (b) the affidavit of Shinya Matsuzawa affirmed on 12 June 2013, with its Annexure SHI-A.

145 The interlocutory application was supported by an affidavit sworn by Grant William Fisher on 13 June 2013.

146 The amendments sought by AstraZeneca to each notice of appeal is embodied at proposed paragraph 15A which is in the following terms:

- 15A Further or alternatively to paragraphs 13 to 15 above, the Full Court should find that:
- (a) by operation of s 22A of the Act, as in force with effect from 15 April 2013, the 051 Patent is not invalid merely because it was granted to AstraZeneca AB or because it was not granted to Shionogi;
 - (b) by deed dated 6 June 2013 [sic], Shionogi assigned any and all right, title and interest it may have had in and to the invention described and claimed in the 051 Patent to AstraZeneca AB; and
 - (c) in the premises, AstraZeneca AB is entitled to the 051 Patent, and the 051 Patent is not invalid and is not liable to be revoked on the ground [specified in] s 138(3)(a) of the Act.

147 It is obvious from the terms of the proposed amendment that the basis for the ground of appeal specified in proposed paragraph 15A is an amendment made to the Act which came into effect on 15 April 2013, a date which is after the primary judge delivered judgment and made orders with respect to the 051 or low dose patent.

148 The proposed amendments also affect the orders made in June 2013, including the orders for costs made at that time.

149 If permitted to amend its notices of appeal in the manner sought by its interlocutory application, AstraZeneca will rely upon the evidence contained in two further affidavits, being the affidavit of Benjamin C McDonald affirmed on 11 June 2013 and the affidavit of Shinya Matsuzawa affirmed on 12 June 2013.

150 The generic parties oppose the relief sought by AstraZeneca in its interlocutory application. In support of their opposition to that relief, the generic parties relied upon an affidavit affirmed by Patrick Richard Sands on 2 July 2013.

151 At the commencement of the hearing before this Court, the Court informed the parties that it would entertain AstraZeneca's interlocutory application and then reserve its decision in respect of that interlocutory application. The Court said that that decision would be delivered as part of its reasons in respect of the appeals generally. In aid of that course, the affidavits of Messrs Fisher and Sands were admitted provisionally.

152 The parties directed detailed written and oral submissions to the issues raised by AstraZeneca's interlocutory application.

153 Before turning to those submissions, it is necessary to refer to the amendments to the Act which have led to AstraZeneca's interlocutory application.

154 The relevant amendment was introduced by Item 31 of Sch 6 to the Raising the Bar Act, which inserted a new s 22A immediately before s 22 in the Act. The new s 22A is in the following terms:

22A Validity not affected by who patent is granted to

A patent is not invalid merely because:

- (a) the patent, or a share in the patent, was granted to a person who was not entitled to it; or
- (b) the patent, or a share in the patent, was not granted to a person who was entitled to it.

155 At the same time, a new subsection (4) was added to s 138. That new subsection is in the following terms:

- (4) A court must not make an order under subsection (3) on the ground that the patentee is not entitled to the patent unless the court is satisfied that, in all the circumstances, it is just and equitable to do so.

156 Item 133(3) of Pt 2 of Sch 6 to the Raising the Bar Act contains the following transitional provision with respect to s 22A:

- (3) The amendments made by items 31 and 79 of this Schedule apply on and after the day those items commence in relation to patents granted before, on or after that commencement.

157 Item 133(14) of Pt 2 of Sch 6 to the Raising the Bar Act contains the following transitional provision with respect to the amendment to s 138:

- (14) The amendment made by item 75 of this Schedule applies in relation to applications for orders made on or after the day that item commences, whether the patent was granted before, on or after that day.

158 Prior to the introduction of s 22A into the Act, it had been held that the ground of revocation under s 138(3)(a) was established where the patentee was not entitled to the patent as at the time of the grant of the patent, regardless of the impact of any later assignment (*Stack and Another v Davies Shephard Pty Ltd and Another* (2001) 108 FCR 422 (“*Stack*”) at 435 [34] per Whitlam, Sundberg and Dowsett JJ; and *University of British Columbia v Conor Medsystems, Inc* (2006) 155 FCR 391 (“*Conor Medsystems, Inc*”)).

159 The evidence of Messrs McDonald and Matsuzawa proves that, on 11 June 2013, Shionogi assigned to AstraZeneca any and all right, title and interest that Shionogi may have had in and to the invention described and claimed in the 051 or low dose patent. If allowed to amend its notices of appeal and to argue the ground embodied in paragraph 15A, AstraZeneca will rely upon s 22A and the fact that the deed of assignment has been entered into as perfecting the entitlement of AstraZeneca to the 051 or low dose patent. AstraZeneca will only need to rely upon its proposed amendments if this Court dismisses its other challenges to the primary judge’s findings in respect of entitlement. In light of the conclusions which we have otherwise reached in respect of entitlement, we must now consider AstraZeneca’s interlocutory application.

The parties’ submissions on the application

160 AstraZeneca submitted that s 22A applies in relation to the 051 or low dose patent. It then argued that, as the present appeals are by way of rehearing, the Court is obliged to apply the law as it stands as at the date of the appeals and can substitute its own decision for that of the primary judge based on the facts as they now stand (*The State of Western Australia v Ward and Others* (2002) 213 CLR 1 at 87 [71] per Gleeson CJ, Gaudron, Gummow and Hayne JJ; and *Allesch v Maunz* (2000) 203 CLR 172 at 180 to 181 [23] per Gaudron, McHugh, Gummow and Hayne JJ).

161 The amendment to s 138 of the Act is also relevant. However, that amendment requires the Court to consider the position as at the date upon which an application for orders is made.

162 AstraZeneca submitted that the reference to applications for orders in that transitional provision is a reference to that which occurs when the Court is actually asked to make a relevant order, whether this be an order at first instance under s 138(3) for revocation of the patent, or an order on appeal by way of rehearing either upholding or overturning such an order. AstraZeneca submitted that the critical date is the date of the relevant hearing, not the date upon which the proceedings were instituted by way of an application or other process seeking the relevant orders. It also submitted that, in any event, if leave is granted to amend its notices of appeal, AstraZeneca's amended notices of appeal will have been filed after subs (4) of s 138 of the Act came into effect.

163 In support of its contentions concerning s 22A and s 138(4) of the Act, AstraZeneca relied upon various passages from the relevant Explanatory Memorandum to the Raising the Bar Act. Those references did not provide an obvious answer to the questions which we have to decide. However, the Explanatory Memorandum did make clear that the amendments were intended to overturn the consequences of *Stack* and *Conor Medsystems, Inc.*

164 AstraZeneca submitted that it was plainly the Parliament's intention that a patent should no longer be revoked under s 138(3)(a) of the Act in circumstances where the party found to be entitled does not seek the revocation of the patent and is prepared to assist in order to perfect the patentee's title. AstraZeneca referred to the judgment of Rares J in *Reckitt Benckiser Healthcare (UK) Ltd and Another v GlaxoSmithKline Australia Pty Ltd* (2013) 103 IPR 405 as supporting its submissions.

165 In oral submissions, AstraZeneca supported its contention that the transitional provision concerning the operation of s 138(4) of the Act referred to the date when orders are actually sought (not the date of filing) with a number of submissions. The first was that, when the Act is addressing the question of the institution of a proceeding or the filing of a document, it uses the word "filing". Secondly, the generic parties' argument would totally subvert the purpose of the amendment because it would lead to quirky and absurd results. Thirdly, the Court must decide the matter before it according to the law as it exists at the time that the Court makes its decision.

166 Apotex submitted that the use of the phrase "merely because" in s 22A indicates that a patent will not be invalid if the sole reason for lack of entitlement is a lack of title at grant. That phrase appears in other provisions of the Act, including s 23 and s 26. Each of these provisions

contemplates the continuing possibility of invalidity because of something other than the circumstances dealt with by each of those sections.

167 Apotex commenced the proceedings below on 18 May 2011. It applied for orders under s 138(1) that the 051 or low dose patent be revoked. Its particulars of invalidity provided at the commencement of the proceedings below included lack of entitlement. At that time, and at all times thereafter until very recently, the particulars of invalidity drew no distinction between lack of entitlement as at the date of grant and lack of entitlement as at the date when the application under s 138(1) was made. If AstraZeneca is permitted to rely upon the 11 June 2013 assignment and its proposed new ground of appeal, then this distinction needs to be addressed.

168 In each of *Stack* and *Conor Medsystems, Inc*, the Full Court was dealing with the question of entitlement at grant. On its face, s 138(3)(a) deals also with the lack of entitlement at the time an application under s 138(1) is made. In support of this proposition, Apotex relied upon the dissenting judgment of Bennett J in *Conor Medsystems, Inc* at 408 [79] to [80].

169 Accordingly, Apotex submitted that s 22A alone cannot save AstraZeneca, despite the fact, as Apotex accepts, it applies retrospectively. Section 138(4) is not retrospective and applies only to applications for orders under s 138(3)(a) which are made on and after 15 April 2013.

170 Apotex submitted that leave to argue the new ground of appeal should be refused because an assignment after a patent has been revoked in an application under s 138(1) cannot resurrect the patent.

171 The proposed new ground of appeal does not rely upon s 138(4) nor is that section mentioned in AstraZeneca's interlocutory application.

172 Apotex submitted that, in respect of applications under s 138(1) and s 138(3)(a) commenced before 15 April 2013, the present case being one such application:

- (a) Section 22A operates so that "merely because" there was no entitlement of grant, the patent is not invalid;
- (b) If the patentee has perfected or obtained title before the application for an order is made, then s 138(3)(a) has no application; and
- (c) If the patentee has not perfected or obtained title before the application for an order was made, then the patent is liable to be revoked and s 138(4) does not apply.

- 173 Apotex also made the obvious submission that AstraZeneca is not able to demonstrate error on the part of the primary judge in respect of the subject matter of its proposed new ground of appeal.
- 174 Apotex submitted that AstraZeneca must have been well aware for some time prior to 15 April 2013 when the Raising the Bar Act came into force that there were to be the significant changes to the Act. AstraZeneca must have been well aware long before the trial of the likelihood that s 22A would be introduced into the Act and that s 138 would be amended to incorporate s 138(4). Rather than obtain an assignment from Shionogi at the earliest possible time, AstraZeneca ran the trial on the basis that it, not Shionogi, was the inventor. It was only after it lost on this point that it decided to seek resort in the amendments to the Act brought about by the Raising the Bar Act. This has disadvantaged Apotex and the other respondents in the preparation for, and conduct of, the trial. For example, AstraZeneca has not given discovery on issues which will now be introduced at the appellate level.
- 175 Apotex submitted that it would definitely suffer real and substantial prejudice if AstraZeneca is permitted to raise the new ground of appeal. Following publication of the primary judge's reasons, and before notice of the interlocutory application, Apotex launched its rosuvastatin product in Australia, as it was entitled to do. Had it known that AstraZeneca would seek to rely upon s 22A, it may have acted differently. Apotex submitted that the problem feeds into other issues in the case such as obviousness and the state of common general knowledge.
- 176 Watson and Ascent also made detailed submissions in respect of AstraZeneca's interlocutory application.
- 177 Watson and Ascent submitted that the introduction of an entirely new argument on appeal such as that which is now sought to be introduced in the present case, raising for the first time a matter of real substance, ought generally not be permitted.
- 178 Watson and Ascent also submitted that, had AstraZeneca taken an assignment at an earlier point in time and relied upon that assignment at trial, the circumstances in which it had been agreed and the nature of the rights now claimed to be held by Shionogi could have been fully investigated. Those opportunities have now been lost. These parties submitted that the effect of the amendments is to move revocation from being a default remedy to being a discretionary remedy.

Consideration

179 The difficulty posed for patentees by the decisions of this Court in *Stack* and *Conor Medsystems, Inc* was that a patent may be subject to revocation on the ground specified in s 138(3)(a) of the Act simply because of some technical problem with ownership which, although in play as at the date of grant, was only discovered after grant. Serious consequences could be visited upon patentees as a result of honest mistakes. Section 22A is intended to alleviate those consequences by providing that a patent is not invalid merely because of a lack of entitlement as at the date of grant. In a revocation proceeding based upon, *inter alia*, lack of entitlement, the question of whether the Court will revoke a patent on the ground specified in s 138(3)(a) will nonetheless need to be considered notwithstanding the enactment of s 22A.

180 After the 2013 amendments, where lack of entitlement is raised as a ground for revoking a patent, the Court will be obliged to consider whether it is just and equitable to revoke the patent (s 138(4)).

181 In the present case, there is a dispute between AstraZeneca and the generic parties as to whether s 138(4) applies at all. That dispute concerns the application of the transitional provision referable to the amendment which inserted s 138(4) into the Act.

182 The relevant transitional provision (Item 133(14) of Pt 2 of Sch 6 to the Raising the Bar Act) makes clear that s 138(4) may be required to be applied in respect of patents granted before the subsection came into effect. The touchstone for the application of the subsection is “an application for [a revocation] order” made on or after 15 April 2013 (the day that the Item commenced).

183 We think that that phrase applies to the time when revocation orders are actually applied for in Court and not when an application for such orders is filed in the Registry.

184 The text of s 138(3)(a) is more consistent with this view than with the proposition that the date of filing of an application seeking orders for revocation is the date to which Item 133(14) is directed. Section 138(3) uses the present tense in the words “is not entitled” and addresses lack of entitlement as at the date that the Court is called upon to make the revocation order which, according to the language of s 138(3), is “after hearing the application ...”. In other words, s 138(3)(a) requires the Court to consider the question of entitlement after it has heard the application and as at the time when it proposes to determine that application. We see no

particular reason why the date of the filing of an application for revocation should be the relevant cut-off date.

185 The more difficult question is whether the phrase applies to an appeal from a first instance determination of an application for a revocation order which was determined prior to 15 April 2013. The problem is brought into sharp focus by the present case. At the time that the primary judge heard the proceedings below, she was not obliged to apply s 138(4). This is because the subsection had not yet come into force. Even if AstraZeneca's construction of the transitional provision is correct, her Honour was not obliged to consider the requirement specified in s 138(4) because, at the time when she heard and determined the proceeding below, s 138(4) had not yet come into force and thus was not law.

186 In the events which have happened, this Court is not being called upon to make an order under s 138(3)(a) in respect of the 051 or low dose patent. The primary judge made such an order but did so at a time when she was not required to consider either s 22A or s 138(4). Even though AstraZeneca's appeals are by way of rehearing, there is no possibility that, in determining those appeals, this Court will make an order revoking the 051 or low dose patent. The only possible orders that might be made on the appeals in the present case are that the appeals be allowed in respect of her Honour's order revoking the 051 or low dose patent or that the appeals be dismissed. If the appeals are dismissed, the Court will not make any order other than an order for dismissal. The only circumstance in which this Court will allow the appeals and, as a result, interfere with her Honour's order that the 051 or low dose patent be revoked is if this Court comes to the view that none of the grounds of revocation found by her Honour can be sustained. For reasons explained elsewhere, that is not the view of this Court. Therefore, even if this Court was minded to overturn her Honour's conclusion that the generic parties had made out a good case for revoking the 051 or low dose patent on the ground of lack of entitlement, this Court would not make any consequential orders dealing with her Honour's order for revocation. For these reasons, in the circumstances of this case, there is no application for an order for revocation before this Court and this Court will not ever need to hear and determine such an application whether the appeals are dismissed or allowed. This Court does not proceed on appeal upon the basis that the primary judge's orders and findings are to be ignored. Rather, it is the making of those findings and orders which constitute the starting point for our consideration of the appeals. In the present case, all that this Court will do in order to address AstraZeneca's challenges to her Honour's findings in respect of entitlement is to add its conclusions in relation to those challenges to the list of reasons why the appeals

should be dismissed, if that were to be the appropriate consequence of this Court's reasoning, or to take them into account when considering the appropriate order to make in the event that all other challenges to her Honour's findings in support of the order for revocation which she made are going to be upheld. All of this simply means that it is only her Honour who has been called upon to address and determine an application for an order for revocation and not this Court. At most, this Court is being asked to affirm her Honour's order for revocation but not to make such an order itself.

187 Whatever be the correct construction of s 138(4) and the relevant transitional provision, in our view, this Court is not obliged to take into account s 138(4) in the present appeals, whether or not the new ground of appeal is allowed to be advanced.

188 For reasons which we have explained elsewhere in these reasons, the 051 or low dose patent is invalid, not solely because of a lack of entitlement on the part of AstraZeneca but for other reasons as well. In those circumstances, to allow AstraZeneca to amend its notices of appeal in order to raise s 22A would serve no useful purpose as the 051 or low dose patent is invalid in any event.

189 In addition, in addressing AstraZeneca's interlocutory application, the generic parties brought forward a very persuasive case for refusing leave to amend on discretionary grounds. AstraZeneca must be taken to have been well aware of the provisions of the Raising the Bar Act at least from the time of its passing but almost certainly from an earlier point in time. While it must be accepted that AstraZeneca could not have litigated before the primary judge the arguments which it now wishes to bring forward by amending its notices of appeal, it could have flagged its intention to raise these arguments at the earliest opportunity and could have even gone so far as to seek an adjournment of the hearing or, alternatively, a delay in the delivery of judgment in order to accommodate its desire to run these arguments. No steps of that kind were taken. Also, AstraZeneca could have taken the assignment which it later took on 11 June 2013 and argued that *Stack* and *Conor Medsystems, Inc* had been wrongly decided thus preserving the point for later determination on appeal. It did not do so. Had any of these steps been taken, the nature of the issues concerning entitlement at trial would have changed markedly. There is considerable force in the submissions made on behalf of the generic parties that they would have conducted investigations of a different character and sought more extensive discovery from AstraZeneca had these points been in the ring.

190 Even if we are wrong as to the utility of the proposed amendments, we would be minded to refuse them on discretionary grounds.

191 We will incorporate into the orders made as a result of our determination of these appeals orders admitting into evidence on the interlocutory application filed by AstraZeneca the affidavit of Mr Fisher and the affidavit of Mr Sands. For the reasons which we have explained, that interlocutory application will be dismissed with costs.

INVENTIVE STEP

The starting point issue

192 The question that has been referred to by the parties in this and other cases as the “starting point” issue is whether a valid patent may be obtained for an invention that comprises a solution to a problem in the relevant art where the solution is obvious, but where the problem is neither common general knowledge nor information to which regard may be had pursuant to s 7(3) of the Act. This is the first time the Full Court has considered the issue. The Full Court in *Sanofi-Aventis* (2009) (Emmett, Bennett and Middleton JJ) considered similar arguments to those presented in these appeals. However, in that case their Honours were concerned with the application of s 100(1)(e) of the *Patents Act 1952* (Cth) (“the 1952 Act”) and their reasons for decision do not address the starting point issue with reference to the provisions of the 1990 Act.

193 In the present case, the resolution of the “starting point” issue turns on the proper construction of s 18(1)(b)(ii) and related provisions including s 7(2) and (3) of the Act as it stood immediately prior to its amendment by the *Patents Amendment Act 2001* (Cth).

194 Section 18(1)(b)(ii) of the Act provides that an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim, involves an inventive step when compared with the prior art base as it existed before the priority date of that claim.

195 The words “the invention, so far as claimed in any claim” as they appear in s 18(1)(b)(ii) also appeared in s 100(1)(e) of the 1952 Act. Their purpose is to direct attention to the invention as defined by the claim. In assessing novelty or obviousness, the focus is on the claim as construed in light of the complete specification read as a whole and the common general knowledge as it stood at the priority date of the claim. In particular, in assessing whether or not an invention was obvious and, consequently, lacking an inventive step, the relevant inquiry

is whether anything within the claim (not merely embodiments described in the complete specification) would have been obvious to the hypothetical person skilled in the art: Blanco White TA, *Patents for Inventions* (5th ed, Stevens & Sons, 1983) at [4-201]; see also *Grove Hill Pty Ltd v Great Western Corporation Pty Ltd* (2002) 55 IPR 257 at [364] per Gyles J. The position in Australia and United Kingdom is no different in this respect. It is the claimed invention that must involve an inventive step: *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] RPC 28 at [17] to [19] per Lord Hoffman.

196 Broadly speaking, the expression “patent area” is defined in Sch 1 to mean Australia. As originally enacted, the expression “prior art base” was relevantly defined in Sch 1 of the Act to mean:

- (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; and
 - (iii) where the invention is the subject of a standard patent or an application for a standard patent—information in a document publicly available outside the patent area ...

197 The Act originally provided (as did the 1952 Act at the time of its repeal) for the grant of petty patents. For petty patents, the prior art base was as specified in subparagraph (a)(i) and (ii) of the definition. For standards patents, the prior art base was as specified in subparagraph (a)(i)-(iii) of the definition. Petty patents were abolished and replaced by innovation patents as a result of the *Patents Amendment (Innovation Patents) Act 2000* (Cth) and subparagraph (a) of the definition of prior art base was amended so that the prior art base for standard patents and innovation patents was the same. For a time, the prior art base for both standard patents and innovation patents referred to in subparagraph (a) of the definition consisted of information in a document publicly available whether *in or out* of the patent area and information made publicly available through the doing of an act *in* the patent area. However, subparagraph (a) of the definition was further amended by the *Patents Amendment Act 2001* (Cth) to bring subparagraph (a)(i) and (ii) into complete alignment so that each now refers to information that is or was made publicly available *in or out* of the patent area. What is apparent from these changes is that the legislature has expanded the definition of prior art base over time both in

relation to information in documents (for innovation patents) and information made available through doing an act (for both types of patents).

198 At the relevant times (i.e., the date that each of the patents in suit is taken to have been applied for) s 7(2) and (3) of the Act provided:

- (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.

The expression “prior art information” is defined in Sch 1 to mean information that is part of the prior art base for the purposes of subsection 7(3) in relation to deciding whether an invention does or does not involve an inventive step.

199 A central purpose of the relevant provisions is to delineate the information that the Court may have regard to for the purposes of determining whether an invention, so far as claimed, is a patentable invention. In particular, the purpose of s 7(3) was explained by the High Court in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173 (“*Doric No 2*”) at [49]:

Previously, only common general knowledge was taken into account when assessing an inventive step. Now, additional information which was publicly available as at the priority date must also be taken into account. Broadly speaking, s 7(3) has as its purpose the specification of the additional publicly available information (s 7(3) 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.

200 To be patentable, an invention, so far as claimed, must involve an inventive step when compared with the prior art base as it existed before the priority date: s 18(1)(b)(ii). Section 7(2) requires that the question whether the invention involves an inventive step be assessed by reference to the common general knowledge as it existed in Australia before the priority date of the claim supplemented by the prior art information (if any) available for that purpose in accordance with s 7(3) (“s 7(3) information”). In particular, s 7(2) requires that an invention be taken to involve an inventive step when compared with the prior art base unless it would be obvious to the hypothetical person skilled in the relevant art in light of the common general knowledge and any s 7(3) information. Put another way, the invention is *deemed* to involve an inventive step when compared with the prior art base unless it would be obvious to the hypothetical skilled addressee having regard to such knowledge and information.

201 Except to the extent that any two or more documents or acts may be treated as a single source of information pursuant to s 7(3)(b), the combining of individual documents or acts that constitute s 7(3) information is prohibited. There may be many documents and acts that qualify as s 7(3) information in any particular case. However, unless s 7(3)(b) is engaged, the question arising under s 7(2) must be addressed by reference to the common general knowledge considered separately from, or together with, what will necessarily be a single piece of prior art information.

202 Accordingly, whether a claim of a patent is invalid for lack of inventive step is to be determined by comparing the invention, so far as claimed, against the common general knowledge and any s 7(3) information. The question is then whether the invention would have been obvious to the hypothetical person skilled in the art in light of that knowledge considered separately from, or together with, the s 7(3) information. So understood, it is apparent that the relevant provisions of the Act do not expressly or impliedly contemplate that the body of knowledge and information against which the question whether or not an invention, so far as claimed, involves an inventive step is to be determined may be enlarged by reference to the inventor’s (or patent applicant’s) description in the complete specification of the invention including, in particular, any problem that the invention is explicitly or implicitly directed at solving.

203 If the problem addressed by a patent specification is itself common general knowledge, or if knowledge of the problem is s 7(3) information, then such knowledge or information will be attributed to the hypothetical person skilled in the art for the purpose of assessing obviousness. But if the problem cannot be attributed to the hypothetical person skilled in the art in either of

these ways then it is not permissible to attribute a knowledge of the problem on the basis of the inventor's "starting point" such as might be gleaned from a reading of the complete specification as a whole. There are a number of reasons why this should be so.

204 First, the inventor's "starting point" as ascertained from the complete specification might not be one that would suggest itself to the hypothetical person skilled in the art who, for the purpose of assessing inventiveness, is taken to be in possession of the common general knowledge and any s 7(3) information but who lacks the capacity for invention. It is true the contents of the complete specification may have an evidentiary significance, for example, as an admission (see *Doric No 2* at [105] to [111]), which might lead to a finding that a piece of information referred to is common general knowledge or s 7(3) information. But that is quite different to supplementing the knowledge and information available for the purposes of s 7(2) with any knowledge or information that is, *ex hypothesi*, not common general knowledge and not s 7(3) information.

205 Secondly, although the complete specification must describe the invention fully, including the best method known to the inventor of performing the invention, it does not follow that the inventor must explain how he or she arrived at the invention. It is the invention itself that must be fully described, not the route that was travelled by the inventor to arrive at it. Again, the way in which the inventor came to the invention described and claimed may also have an evidentiary significance. However, an invention may be the result of chance or luck as much as long experiment and the question whether an invention, or an alleged invention, involves an inventive step is an objective one: *Wellcome* at 279 per Aickin J.

206 Thirdly, there are still many standard patents in force (including those in suit in this case) in which the prior art base for the purpose of assessing obviousness is, in relation to information made publicly available by doing an act, confined to acts done in the patent area. The inventor's starting point may consist of information that was made publicly available by an act that took place outside Australia. It would be inconsistent with the statutory scheme to treat such information as knowledge which must be attributed to the hypothetical person skilled in the art for the purpose of assessing obviousness in such a case. Not only is such knowledge not common general knowledge or s 7(3) information, it does not form part of the prior art base (as that expression was defined at the relevant time) to which s 18(1)(b)(ii) refers.

207 Fourthly, if inventiveness may be assessed by reference to a piece of information that is not common general knowledge or s 7(3) information on the basis that it constitutes the inventor's starting point, then there does not appear to be any logical reason why that information must be publicly available. And yet the notion that the question of inventive step can be answered by reference to knowledge or information that has not been made publicly available is antithetical to patent law. The definition of prior art base, through all its previous iterations, ensures that information that is not or was not publicly available must be disregarded when deciding whether or not the invention, so far as claimed, involves an inventive step.

208 Fifthly, there is a difficulty with the starting point approach in that it will often give rise to a debate as to where the inventor's "inventive journey" began. Of course, it is not suggested by the generic parties that this involves a factual inquiry as to what the inventor actually did. Rather, the inventor's starting point, according to the generic parties' submission, is something that is to be ascertained from a reading of the complete specification. Nevertheless, in the case of the 051 or low dose patent, the problem addressed by the patent may be formulated in at least three different ways: Is it possible to devise a new method for the treatment of (i) hypercholesterolemia; (ii) hypercholesterolemia using a statin; or (iii) hypercholesterolemia using rosuvastatin? Any of these three formulations of the problem is open based upon a reading of the complete specification but it is perhaps the second of them that finds the most support in the body of the specification (especially at page 1, lines 16 to 23). In any event, the validity of the claims should not turn on distinctions of this kind unless they are reflected in the claims.

209 In the case of the 051 or low dose patent, the inventor's contribution to the art was to conceive of new methods of treatment for hypercholesterolemia using rosuvastatin. Whether or not the inventor discovered rosuvastatin is not a question that arises in considering whether each of the claimed methods involved an inventive step when compared to the prior art base as it existed at the priority date of the claim. The statutory test for determining whether an invention is patentable under s 18(1)(b)(ii) involves asking whether the claimed methods of treatment would have been obvious to the hypothetical person skilled in the art in light of the common general knowledge and any s 7(3) information. It does not involve asking whether such methods would have been obvious to the hypothetical person skilled in the art armed not merely with the common general knowledge and any available s 7(3) information, but also some additional knowledge concerning the existence of rosuvastatin, its chemical properties or its

potential role in the treatment of hypercholesterolemia based upon a description in the specification of the problem that the inventor was seeking to solve.

210 It should also be remembered that many patent applications filed in Australia are Convention applications or PTC applications (see generally Ch 8, ss 88-96, of the Act). These applications often include specifications written with respect to applications for a European Patent made under the European Patent Convention (“EPC”) and the national laws of the EPC contracting states where it is common practice to assess inventive step by applying a problem-and-solution approach that takes as its starting point the “closest prior art”: see, for example, *Actavis UK Ltd v Novartis AG* [2010] FSR 18 at [25]. An applicant for a European patent is generally required to identify the background art known to him or her preferably by mentioning or quoting documents which reflect it. For this purpose the background art includes every document in the public domain. Such documents will not always be common general knowledge or s 7(3) information.

211 In *Pfizer Ltd’s Patent* [2001] FSR 16 Laddie J was concerned with an application to revoke a European patent on various grounds including obviousness. His Lordship, contrasting the qualities of the skilled but non-inventive worker with those of the real worker, said at [62]:

A real worker in the field may never look at a piece of prior art – for example he may never look at the contents of a particular public library – or he may be put off because it is in a language he does not know. But the notional addressee is taken to have done so. This is a reflection of part of the policy underlying the law of obviousness. Anything which is obvious over what is available to the public cannot subsequently be the subject of valid patent protection even if, in practice, few would have bothered looking through the prior art or would have found the particular items relied on. Patents are not granted for the discovery and wider dissemination of public material and what is obvious over it, but only for making new inventions. A worker who finds, is given or stumbles upon any piece of public prior art must realise that that art and anything obvious over it cannot be monopolised by him and he is reassured that it cannot be monopolised by anyone else.

The position in the United Kingdom and other countries bound by the EPC was then quite different to the position in Australia. As the High Court pointed out in *Doric No 2* at [57] to [58], the *Patents Act 1977* (UK) provides that the “state of the art” for the purpose of determining obviousness includes everything in the public domain.

212 The Act was amended by the Raising the Bar Act to better align the approach to inventive step in Australia with the approach taken in the United Kingdom and other major jurisdictions by (*inter alia*) assessing inventive step against all information made publicly available before the priority date: see the Explanatory Memorandum to the *Intellectual Property Laws Amendment*

(Raising the Bar) Bill 2011 (Cth) at 40 to 43. However, these important amendments do not apply in the present case.

213 In conclusion, in our respectful opinion, the “starting point” approach to obviousness adopted by the Full Court in *Sanofi-Aventis* (2009) in relation to s 100(1)(e) of the 1952 Act is incompatible with the essentially objective comparison that must be undertaken under the Act between the invention as claimed and the relevant prior art (i.e., the common general knowledge and any available s 7(3) information) and should not be followed in situations where the provisions of the 1952 Act do not apply.

214 As to s 100(1)(e) of the 1952 Act, the Full Court in *Sanofi-Aventis* (2009) placed considerable emphasis upon Aickin J’s statement of the test of obviousness in *Wellcome* at 286 to the following effect:

The test is 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.

(Emphasis added).

215 The Full Court’s approach reflects the view that in expressing the test for obviousness in *Wellcome* at 286 in this way, Aickin J was intending that it apply to situations in which the problem awaiting solution would not be known to the hypothetical skilled addressee. And yet that seems unlikely given the context in which his Honour’s statement of the test appears. Aickin J said at 270 to 271:

It is as well to bear in mind that the question of obviousness involves asking the question whether the invention would have been obvious to a non-inventive worker in the field, equipped with the common general knowledge in that particular field as at the priority date, without regard to documents in existence but not part of such common general knowledge. The question is not whether it was or would have been obvious to the inventor or to some other particular worker in the field: *Minnesota Mining and Manufacturing Co. v. Beiersdorf (Aust.) Ltd.* [(1980) 144 CLR 253].

Aickin J also observed at 286 (in the same passage in which his statement of the test appears) that a valid patent may be obtained from something “stumbled upon by accident” or “imported from abroad” (c.f., the remarks of Laddie J quoted at [211] above) and that “[w]hat is important is that the patent itself should involve an inventive step, whether or not it was consciously taken by the patentee and whether or not it appeared obvious to the patentee himself.”

216 The Full Court’s reasoning in *Sanofi-Aventis* (2009) requires that inventive step be assessed not merely by reference to what was “known and used” (i.e., the common general knowledge) as at the priority date of the claim, but also by reference to what might be a quite different body of knowledge based upon the inventor’s own knowledge and understanding of the problem (as described in the complete specification) he or she was seeking to solve. This in turn gives rise to the possibility that a claim for an invention by one inventor might be invalid as lacking any inventive step while a claim by a different inventor might still be valid as involving an inventive step, even though both claims are in the same terms, have the same meaning and the same priority date, and where the common general knowledge against which obviousness is to be assessed is in each case also precisely the same. That seems to be a very odd result.

217 It is not strictly necessary to express a view as to the correctness of the Full Court’s decision in *Sanofi-Aventis* (2009). Whatever may be the correct position under the 1952 Act, the position under the Act is, in our view, as previously described.

218 There is a further matter we should refer to before leaving this topic. The generic parties submitted that their position with respect to the starting point issue found support in the decision of the High Court in *Alphapharm* because the High Court’s obviousness analysis took omeprazole as the relevant starting point even though it did not form part of the common general knowledge.

219 The appellants in *Alphapharm* appear to have conducted the appeal on the basis that the obviousness analysis should begin with an assumed knowledge of omeprazole and its physical and chemical properties: see the appellants’ submissions in *Alphapharm* at 415. The focus of the High Court’s consideration of obviousness was on what might constitute a “matter of routine” as those words were used by Aickin J in *Wellcome* at 286 in the passage referred to at [214] above: see, in particular, the joint judgment of Gleeson CJ, Gaudron, Gummow and Hayne JJ in *Alphapharm* at [50] to [53]. What we have described as the starting point issue was not addressed by the High Court in *Alphapharm*.

The s 7(2) argument

220 The generic parties submitted that the law as it stood under the 1952 Act was altered with the introduction of the Act to bring the law of obviousness in Australia substantially into line with the laws of the United Kingdom and other major jurisdictions where obviousness is tested against any information made publicly available in a single document in or outside the patent area irrespective of whether such information is common general knowledge or s 7(3)

information. The submission focuses on the language of s 7(2) which the generic parties contend requires a comparison between the invention and the prior art base (as defined) that is conducted in the light of the common general knowledge and any available s 7(3) information.

221 The generic parties also submitted that their construction of s 7(2) is consistent with the relevant analysis and recommendation contained in the Industrial Property Advisory Committee's ("IPAC") report in 1984 entitled "Patents, Innovation and Competition in Australia". The topic of obviousness was considered by IPAC at [7.2] where the following appears:

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.

This is followed by a recommendation in these terms:

[13] WE RECOMMEND –

- (i) that novelty and obviousness for standard patents be determined against a prior art base consisting of –
 - 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;
- (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
- (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 should reasonably have been expected to find, understand, and regard as relevant.

222 The Federal Government's official response to the IPAC report was published in 1986 (reproduced in the *Official Journal of Patents, Trade Marks and Designs*, 18 December 1986, Vol 56, No 47, at 1462 to 1471). There are two things apparent from this response. First, the Government did not accept recommendation 13(iii) that the concept of common general knowledge be expanded to include disclosures in recorded form publicly available anywhere in the world which the person skilled in the art would reasonably be expected to find, understand and regard as relevant. Secondly, and most relevantly for present purposes,

although recommendation 13(ii) was said to have been accepted, it is clear that, so far as obviousness is concerned, this was subject to the following qualification at 1471:

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.

The qualification is significant because it involves a rejection of the proposal that obviousness be considered against the universe of publicly available documentary disclosures and instead favours the more limited approach reflected in language that appears in s 7(3).

223 The first reported case in which s 7(2) and (3) of the Act was considered is *Tidy Tea Ltd and Another v Unilever Australia Ltd* (1995) 32 IPR 405. In that case Burchett J said at 414:

These provisions in s 7 seem to be designed to overcome the rejection in *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 295; 29 ALR 29 of the availability, when obviousness is being considered, of specifications of prior patents not actually proved to be part of common general knowledge at the relevant time. But it is one thing to say that the rule forbidding the use of such a specification is relaxed; it would be another to say that in all circumstances such a specification may be used to some relevant effect. The new provisions are limited by the words “being information that the skilled 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”. And if a prior specification passes those tests, it must still be able to be said that, if that specification had been considered by the hypothetical skilled person together with the common general knowledge at the relevant time, “the invention would have been obvious”.

His Honour’s observations make clear that a published patent specification that is not common general knowledge is only relevant to any consideration of obviousness if it constitutes s 7(3) information.

224 Burchett J also referred to the Explanatory Memorandum that was circulated when the *Patents Bill 1990* (Cth) was before the Senate. The Explanatory Memorandum included the following statement at 3:

In assessing whether an invention involves an inventive step, publicly available information from a prior document or prior use may be considered together with the common general knowledge, provided that the information would have been ascertainable, understandable and seen as relevant by a person skilled in the relevant art.

This statement is consistent with the Government’s qualified response to the relevant IPAC recommendation and is inconsistent with the generic parties’ construction of s 7(2) and (3).

225 In their submissions the generic parties fixed upon the following passage in the High Court judgment in *Doric No 2* at [126]:

What is obvious under Australian law is to be determined by the combined operation of ss 7(2), 7(3), 18(1)(b)(ii) and Sch 1 to the Act. These provisions are all directed to determining whether an invention “is to be taken to involve an inventive step when compared with the prior art base” (s 7(2)). *Schedule 1 defines “prior art base” and s 7(3) contains the statutory test for enlarging the prior art base beyond common general knowledge.*

(Emphasis added).

The generic parties submitted that the last sentence of this passage supports the argument that s 7(3) does not operate to reduce the scope of the prior art base for the purpose of determining obviousness.

226 There may be a difficulty with the way in which the last sentence in the passage from *Doric No 2* relied on by the generic parties is expressed. This is because s 7(3) does not enlarge the “prior art base” as that expression is defined in the Schedule. And yet, however the sentence is to be interpreted, the generic parties do not themselves suggest that s 7(3) operates to enlarge the prior art base: on the contrary, their position is that the prior art base is no more and no less than that which is defined in the Schedule.

227 The High Court approved Burchett J’s construction of s 7 of the Act in *Firebelt Pty Ltd v Brambles Australia Ltd (t/as Cleanaway) and Others* (2002) 188 ALR 280 at [36] and again in *Doric No 2* at [150]. In our view the generic parties’ construction of s 7(2) must be rejected because it is inconsistent with Burchett J’s construction of s 7 of the Act as approved by the High Court.

The 051 or low dose patent

228 We agree with Jessup J for the reasons given by his Honour that the primary judge’s finding of obviousness with respect to the 051 or low patent was open on the evidence. The evidence established that each of the publications referred to in the 051 patent (the 471 patent and the Watanabe article respectively) was a document which the hypothetical skilled addressee could, before the priority date of the claims, be reasonably expected to have ascertained, understood and regarded as relevant to work in the relevant art in the patent area.

229 We also agree with Jessup J that the primary judge’s finding that the claims of the 051 or low dose patent would be obvious to the hypothetical skilled addressee armed only with the

common general knowledge as at the priority date and either the 471 patent or the Watanabe article. In particular, the evidence established, as the primary judge found, that the hypothetical skilled addressee, armed only with the common general knowledge and the information in the 471 patent or the Watanabe article would have been led, as a matter of course, to try the methods of treatment claimed in the 471 patent, in the expectation that they might well produce a useful or better alternative to those that were known and used at the priority date.

The 842 or cation patent

230 For reasons which will be explained, the priority date of the claims of the 842 or cation patent is deferred to 31 January 2005 and each of them is invalid for lack of novelty. If, however, the priority date was not deferred, then we would have allowed AstraZeneca's appeals insofar as they relate to the primary judge's conclusion that the claims of the 842 or cation patent are invalid for lack of inventive step. In our opinion, the primary judge's conclusion is only open if the question of obviousness is approached on the basis that knowledge of rosuvastatin and its properties was, at the earliest of the asserted priority dates, something that should be regarded as a given based upon the inventor's starting point, even though it was not common general knowledge, and not s 7(3) information. For reasons previously explained, we do not think that is a permissible approach to take under the Act.

THE PRIORITY DATE OF CLAIMS OF THE 842 OR CATION PATENT

231 The 842 or cation patent was granted on the basis of a patent application ("the 842 application") filed on 4 August 2000. The 842 application claimed priority from UK Patent Application No 1621 ("the priority document") filed on 26 January 2000.

The 2005 amendments

232 On 29 August 2003, AstraZeneca amended claim 1 of the 842 application to exclude synthetic hydrotalcite as the relevant inorganic salt. Nothing turns on this amendment. On 31 January 2005, AstraZeneca amended claims 1, 2 and 19 and, by implication, their dependent claims ("the 2005 amendments") to exclude inorganic salts where the counter anion is a phosphate. The words which first introduced this exclusion were added both to the claims and the consistory statement at page 2, lines 8 to 16.

233 The pharmaceutical composition of the invention as described at page 2, lines 8 to 9 of the specification in the form it took at the time it was filed, and immediately before the 2005 amendments were made, was said to include with the active ingredient "an inorganic salt

in which the cation is multivalent.” The specification includes a list of “multivalent cations” and “counter anions” which are suitable for the inorganic salt. The specification states at page 3, lines 1 to 7:

The counter anion in the inorganic salt may be selected from a phosphate, a carbonate, a silicate, an oxide and a metasilicate. Preferred counter anions are selected from a carbonate, a silicate, an oxide and a metasilicate. Especially preferred counter anions are selected from a silicate, an oxide or a metasilicate.

Individual aspects of the invention include an inorganic salt comprising a multivalent cation selected from any of the above and a counter anion also selected from any of the above.

(Emphasis added).

234 Accordingly, while the specification clearly indicated that phosphate may be used as the counter anion in the compositions of the invention, the claims in their amended form made it clear that compositions that use phosphate for that purpose are not within the scope of the claimed invention.

235 Section 114(1) of the Act, as it stood at relevant times, provided as follows:

Where a claim of a complete specification claims matter that was in substance disclosed as a result of amending the specification, the priority date of the claim must be determined under the regulations.

Regulation 3.14 of the *Patent Regulations 1991* (Cth), as it stood at relevant times, relevantly provided:

If subsection 114(1) of the Act applies to a claim of a specification, the priority date of the claim is:

(a) ...

(b) in any other case – the date of filing of the statement of proposed amendments that resulted in the disclosure referred to in subsection 114(1) of the Act.

These provisions complement s 102(1) of the Act which provides that an amendment of a complete specification is not allowable if, as a result of the amendment, the specification would claim matter not in substance disclosed in the specification as filed.

236 The language of s 102(1) directs attention to the effect of the *proposed* amendment on the specification as filed. In *RGC Mineral Sands Pty Ltd v Wimmera Industrial Minerals Pty Ltd* (1998) 89 FCR 458, Carr and Goldberg JJ (with whom Burchett J agreed) observed (at 466)

that s 102(1) "... focuses on the amendment proposed and it must be *that* amendment which has the result of pushing the claimed matter over the line defined by the expression 'matter not in substance disclosed in the specification as filed'". Their Honours also observed (at 466) that the application of s 102(1) includes a two stage process:

... The first stage, which requires a comparison between the specification as it stands and how it would stand after amendment, enables the identification of what matter results from the amendment. It is only after one determines what matter results from the amendment that one turns to a consideration of, or comparison with, the specification as filed.

237 Unlike s 102(1), s 114(1) (as it stood at relevant times) does not refer to the specification "as filed". Whether or not the omission of those words from s 114(1) has a material effect upon the operation of the provision does not need to be decided in this case. None of the parties suggested that anything turned on the question of whether the relevant comparison was with the specification as filed or the specification as it stood immediately prior to the making of the relevant amendment (in which case the specification would by that time incorporate the 23 August 2003 amendments).

238 In the present case the primary judge held that s 114(1) was engaged because the claims of the 842 or cation patent claimed matter that was in substance disclosed as a result of the 2005 amendments and that the priority date of the claims was therefore 31 January 2005.

239 AstraZeneca challenged the primary judge's finding that the priority date of the claims was deferred. It submitted that the 2005 amendments resulted in a narrowing of existing claims which were to matter that was, in substance, disclosed in the specification as filed on 4 August 2000. This submission was put to and rejected by the primary judge. The primary judge said at [425]:

... an exclusion from a claim may or may not result in a matter in substance being disclosed in the amendment containing the exclusion. It does not indicate that, as a matter of principle, an exclusion from a claim can never so result. It indicates that what is required is a case-by-case consideration to ascertain whether the relevant disclosure is in substance disclosed in the specification or in the subsequent amendments. Labelling an amendment as an exclusion only may distract from the required task; inventions may be defined by both inclusion and exclusion and changes to either may change the substance of what is disclosed.

Her Honour went on to hold at [426] that "[t]he limitations (or at least one of them) specified in the amendments are part of the invention as claimed ... [and] are essential in defining the alleged invention ...". She added at [428] that all of the claims of the 842 or cation patent

involve at least one limitation introduced by the amendments (presumably, the exclusion of inorganic salts where the counter anion is a phosphate) and:

... [a]ccordingly every form of the invention claimed travels beyond the disclosure in the specification before amendment and every form thus takes the priority date of 31 January 2005, being the date of the making of the amendment application.

240 On appeal it was accepted by the parties that the issue arising under s 114(1) and reg 3.14 required the Court to apply a test that is closely related to, if not quite the same as, the test for fair basis under s 40(3) of the Act: *ICI Chemicals & Polymers Ltd v The Lubrizol Corporation Inc* (2000) 106 FCR 214 (“*ICI Chemicals*”). None of the parties propounded any different test which might be applied under s 114(1), although the generic parties submitted that in deciding whether s 114(1) was engaged, assistance might be gained from the approach taken by Lloyd-Jacob J in *Re Mond Nickel Company Ltd’s Application for a Patent* [1956] RPC 189 at 194.

241 In *Lockwood Security Products Pty Limited v Doric Products Pty Limited* (2004) 217 CLR 274 (“*Doric No I*”) the High Court observed at [68] that in seeking to determine whether or not a claim is fairly based upon matter disclosed in the body of the specification, it is not appropriate to engage in an “over meticulous verbal analysis” or “to seek to isolate in the body of the specification ‘essential integers’ or ‘essential features’ of an alleged invention and ask whether they correspond with the essential integers of the claim in question.” The High Court held (at [69]) that s 40(3) requires that there be a “real and reasonably clear disclosure” in the body of the specification of what is claimed.

242 The generic parties submitted that the effect of the 2005 amendments was to “change the basis and the characterization and the description of the invention.” In support of this submission the generic parties relied upon a comparison of the description of the invention in the priority document with the claims introduced as a result of the 2005 amendments. However, this is not the correct comparison. For the purposes of s 114(1) the question is whether the specification, in the form it took before amendment, made a real and reasonably clear disclosure of what was claimed as a result of the 2005 amendments. If the specification before amendment did make such a disclosure, then s 114(1) is not engaged and there is no deferral of the priority date due to the operation of that provision. What is in the priority document is irrelevant to that question.

243 AstraZeneca’s submissions on the s 114(1) issue are well summarised in the following passage from its written submissions before the primary judge:

Once it is understood that the effect of the amendments was to narrow the scope of the

claims, there is no basis for any conclusion that the claims “claim matter that was in substance disclosed as a result of amending the specification”. All of the matter that is within the scope of the claims as they stand now was already disclosed, and indeed was already claimed, as and from the date of filing of the specification of the 842 Patent on 4 August 2000. It is just that there is some additional matter (compositions in which the counter anion is phosphate, for example) which is no longer claimed but is nevertheless disclosed in the specification. That circumstance provides no basis for a deferral of the priority date pursuant to s 114(1) and reg 3.14.

244 We do not accept that s 114(1) can never be engaged in circumstances where the claim in question claims less than what was described in the specification immediately prior to the amendment. A very general description of an invention in a specification before amendment might not contain a real and reasonably clear disclosure of more specific embodiments of the invention subsequently disclosed and claimed after amendment. Similarly, in the case of a claim to a pharmaceutical formulation, the description of the invention in the specification before amendment might allow for the use of particular classes of chemicals with which to make the formulation, while the amended claim might positively exclude their use for that purpose. Whether or not there is a real and reasonably clear disclosure in the specification before amendment of what is claimed in such circumstances is the question that arises in this case.

245 It is true, as AstraZeneca submitted, that the compositions claimed in claims 1, 2 and 19 as a result of the 2005 amendments were already disclosed in the body of the specification as filed. The effect of the 2005 amendments was to disclaim any composition that used phosphate as the counter anion. The logical consequence of the amendment was that the amended claims claimed something less, not more, than previously described.

246 It is also true, as AstraZeneca submitted, that there is nothing in the unamended specification to indicate that the use of a phosphate as the counter anion was an essential aspect of the invention described. The specification shows that phosphates were but one of a number of possible substances that might be used as the counter anion. Other substances recommended for this purpose were carbonates, silicates, oxides and metasilicates. Nor are phosphates one of the “[e]specially preferred counter anions” referred to at page 3, lines 3 to 4 of the specification.

247 However, the specification states that dibasic calcium phosphate and tribasic calcium phosphate are preferred inorganic salts, and tribasic calcium phosphate is the inorganic salt used in each of the Examples (Examples 1 to 4) of the pharmaceutical compositions of the

invention described in detail in the specification. In each of these compositions the phosphate is the counter anion to the inorganic salt. This is fundamentally inconsistent with the revised form of claims and the additional matter introduced as a result of the 2005 amendments. Not only does the specification before amendment not suggest that phosphate not be used as the counter anion in the inorganic salts used in the pharmaceutical compositions of the invention, it positively recommends that it be used for that purpose. We are satisfied that the unamended specification does not contain a real or reasonably clear disclosure of what was claimed as a result of the 2005 amendments.

248 AstraZeneca also relied upon s 43(3) of the Act. Section 43(3) provides:

Where a claim defines more than one form of an invention, then, for the purposes of determining the priority date of the claim, it must be treated as if it were a separate claim for each form of the invention that is defined.

249 AstraZeneca's submission was as follows. The unamended specification describes pharmaceutical compositions which do not include phosphates as the salt forming anion. This is because the salt forming anions recommended for use include carbonates, silicates, oxides and metasilicates. This disclosure would therefore provide a fair basis for claim 1 to the extent that it claimed a pharmaceutical composition in which rosuvastatin was stabilised with an inorganic salt that did not include phosphate, for example, aluminium magnesium metasilicate. Most relevantly for this case, it would also extend to a claim for pharmaceutical compositions that used titanium dioxide or ferric oxide as the counter anion to the inorganic salt used to stabilise rosuvastatin. According to AstraZeneca's submission, a claim to such a pharmaceutical composition would be "one form of the invention" already defined by claim 1 which must be treated as if it were the subject of a separate claim, and which would be entitled to a priority date of 4 August 2000 or earlier.

250 Section 43(3) of the Act is in similar terms to s 44(2) of the 1952 Act. Section 44(2) of the 1952 Act was introduced by s 8 of the *Patents Act 1969* (Cth) which made two amendments to s 44 as it then stood. These amendments were not referred to in the Attorney General's Second Reading Speech for the *Patents Bill 1968* (Cth) (see Hansard, House of Representatives, 16 May 1968 at pp 1540 to 1544). However, the purpose of the relevant amendment as we understand it was to overcome a problem under the 1952 Act which was first identified in the context of the relevant UK legislation in *Thornhill's Application* [1962] RPC 199 ("*Thornhill's Application*") where it was pointed out that the *Patents Act 1949* (UK) made no provision for the attribution of different priority dates to different alternatives comprised in a single claim.

The relevant claim in that case (reproduced at 202 to 203) had been drafted in a manner that embodied two alternatives only one of which was fairly based on the provisional specification relied upon by the patent applicant to establish the priority date of the claim.

251 In our view, claim 1 of the 842 or cation patent does not define more than one form of the invention. Unlike the claim in issue in *Thornhill's Application*, claim 1 of the 842 or cation patent does not by its terms allow for any alternatives or, adopting the language of s 43(3), different forms of the same invention. Claim 1 *defines* only one form of the invention even though there will be any number of potential variants that are within its scope. We do not think s 43(3) is intended to treat every potential variant of the defined invention as if it was a form of the invention that must be treated as a separate claim which is to be given its own priority date. Rather, it is intended to deal with very different situations such as that which arose in *Thornhill's Application* or where, to take a slightly different example, a claim is dependent on one or more independent claims (claim 3 of the 842 or cation patent takes this form) each of which has a different priority date. We therefore reject AstraZeneca's submission based upon s 43(3) of the Act.

252 Subject to the outcome of the argument based upon s 43(3), AstraZeneca accepted that if s 114(1) is engaged, then the priority date of claims 1, 2 and 19 (and their dependent claims) would be deferred to 31 January 2005. It also accepted that if the priority date was deferred to 31 January 2005 then each and every claim of the 842 or cation patent was invalid for lack of novelty.

253 Given the foregoing, we agree with the primary judge that s 114(1) is engaged. It follows that the priority date of the claims of the 842 or cation patent was deferred to 31 January 2005 and the claims of the 842 or cation patent are invalid for lack of novelty.

The priority document

254 In light of our conclusion based upon the effect of the 2005 amendments, it is unnecessary for us to decide whether the claims of the 842 or cation patent are entitled to a priority date of 26 January 2000 based upon the filing of the priority document. But if we are wrong in our view that s 114(1) is engaged, then we would have held that the claims of the 842 or cation patent were not entitled to a priority date based upon the filing of the priority document, and that the earliest possible priority date of all claims was 4 August 2000. Our reasons for finding that the claims of the 842 or cation patent would not be entitled to priority dates based upon the filing of the priority document may be shortly stated.

255 The priority document describes a pharmaceutical composition comprising “[rosuvastatin] and a tribasic phosphate salt in which the cation is multivalent.” The requirement that the pharmaceutical composition described in the priority document include a tribasic phosphate salt in which phosphate is the counter anion is fundamental to the invention described and yet the claims of the 842 or cation patent do not include any such requirement. On the contrary, the 842 or cation patent makes clear that the pharmaceutical compositions of the invention may include a range of inorganic salts including some in which the counter anion is a carbonate, a silicate, an oxide or a metasilicate. Moreover, while the priority document requires that the inorganic salt include a tribasic phosphate salt in which phosphate is the counter anion, the claims of the 842 or cation patent expressly disclaim the use of a phosphate for that purpose. In our opinion, the invention described in the priority document and the invention claimed in each of the claims of the 842 or cation patent are fundamentally different. There is no disclosure of the invention defined by the claims of the 842 or cation patent in the priority document.

NOVELTY: THE 051 OR LOW DOSE PATENT

The 471 patent

256 The invention disclosed in the 471 patent is expressed to be one that relates to HMG-CoA reductase inhibitors. After noting the development of “first” and “second” generation drugs for the treatment of atherosclerosis by inhibiting the activity of HMG-CoA reductase, the 471 patent states:

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

257 The 471 patent identifies the compounds of the invention by a Markush formula. This formula covers what AstraZeneca described as “over 57 trillion compounds”. The generic parties did not demur. One of those compounds is rosuvastatin. More importantly, Examples 1 and 7 in the 471 patent disclose, respectively, the sodium salt and the calcium salt of rosuvastatin.

258 Apart from other disclosures, the 471 patent states:

... Pharmaceutical compositions comprising the compounds of the present invention can be administered orally or parenterally. For example, the compound of the present invention may be orally administered in the form of tablets, powders, capsules, and granules, aqueous or oily suspension, or liquid form such as syrup or elixir, and

parenterally in the form of aqueous or oily suspension.

259 With respect to dosage, the 471 patent states:

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. They may be used in single or divided doses.

The primary judge's findings and reasons

260 The primary judge discussed and rejected four principal submissions advanced by AstraZeneca as to why the 471 patent could not be an anticipatory disclosure of the invention claimed in claims 1 to 3 of the 051 or low dose patent.

261 The first submission concerned the fact that that the Markush formula discloses “a practically infinite number of compounds”, albeit that rosuvastatin was encompassed by that formula. The primary judge acknowledged this fact, but noted that the 471 patent disclosed the two salt forms of rosuvastatin. Her Honour found at [301]:

... There cannot be any real doubt that the 471 patent is a sufficient disclosure of the compound rosuvastatin given the terms of the patent as a whole. The fact that many other compounds might also fall within the class, at least insofar as the sufficiency of disclosure of rosuvastatin is concerned, is immaterial given the examples. Hence, to the extent that AZ's submission might suggest that the 471 patent does not disclose the integer rosuvastatin by reason of the breadth of the class of compounds disclosed, the submission cannot be accepted.

262 The second submission concerned the fact that the 471 patent described the disclosed compounds as useful for treating three different conditions, only one of which is hypercholesterolemia, the condition to which the claims of the 051 or low dose patent are directed. AstraZeneca submitted that “what compound should be used to treat which disease is not identified”.

263 The primary judge rejected that submission, essentially on the basis that the 471 patent disclosed that the class of compounds are useful for treating each condition. After referring to the disclosure concerning dosages, quoted at [259] above, the primary judge found (at [304]):

This is a clear disclosure that the compounds, or at least the specific examples given, are useful for treating each of the three diseases in the dosage ranges identified. The fact that the dosage range may vary depending on each of the factors described (disease, age, weight etc) does not undermine the sufficiency of this disclosure. It is a specific disclosure, and would be understood as such by the skilled addressee, of the usefulness of rosuvastatin (a specific example given of the compound) for treating

hypercholesterolemia (a specific disease associated in the context of compounds which are HMG-CoA reductase inhibitors, itself indicative of usefulness of treating hypercholesterolemia to the skilled addressee), in specific dosage ranges (preferably 0.1-100 mg per day for oral administration) in either a single daily dose or a split daily dose.

264 The third submission was that the 471 patent did not state that the disclosed compounds can be safely administered to humans. AstraZeneca submitted that the 471 patent disclosed the biological activity of the compounds by an experiment carried out *in vitro* on rat liver microsomes, but there was no mention of the compounds (and rosuvastatin in particular) having been tested on humans, let alone humans suffering from hypercholesterolemia. AstraZeneca submitted that the statement in the 471 patent that the compounds were “useful in the treatment” of, amongst other things, hypercholesterolemia “cannot make up for this lack of disclosure”. AstraZeneca also submitted that safety and efficacy of administration cannot be predicted in the absence of appropriate and extensive human testing.

265 The primary judge rejected those submissions. Her Honour found that the lack of any reference in the 471 patent to testing in humans did not undermine the disclosure that at least the compounds identified in the Examples were useful for treating the three nominated conditions in humans.

266 After discussing AstraZeneca’s proposition that “safety and efficacy cannot be predicted in the absence of appropriate and extensive testing” – the correctness of which the primary judge accepted as a general statement – her Honour referred to the disclosures of the 471 patent, saying (at [308]):

The question remains, however, whether the “prior disclosure is sufficient to enable the skilled addressee to perceive, understand and, where appropriate, apply the prior disclosure necessarily to obtain the invention” (*Lundbeck* at [190]). In the face of a document which specifically identifies rosuvastatin as useful for treating three diseases in humans, where rosuvastatin belongs to a known drug class with a known set of side effects and dose profile, the submissions of AZ lack persuasive force.

267 The fourth submission was to the effect that the 471 patent did not identify how any of the broad class of compounds should be administered to humans, including the appropriate dose.

268 The primary judge did not consider that this submission accurately reflected the actual terms of the 471 patent concerning doses. The relevant disclosure is quoted at [259] above. At [310], her Honour found:

... Read as a whole it is clear that the 471 patent at least discloses that the identified

compounds of the broader class, which specifically include rosuvastatin, are useful in treating all three identified diseases (one of which is hypercholesterolemia) by, relevantly, oral administration in a preferred dosage range of 1 to 100 mg, either once or twice daily. As such, AZ's contention that the 471 patent is "far from a disclosure, for novelty purposes, of the invention of the 051 Patent, which claims a method of treatment involving, amongst other things, the safe and efficacious treatment of hypercholesterolemia by administering a particular dose (5 mg to 10 mg of rosuvastatin) at a particular frequency (one daily) to treat a particular condition (hypercholesterolemia)" cannot be accepted. *The 471 patent discloses precisely the method of treatment claimed in the 051 or low dose patent.*

(Emphasis added).

269 The primary judge found (at [315]) that each of the integers of claims 1 and 2 of the 051 or low dose patent are disclosed in and anticipated by the 471 patent. The primary judge reasoned that, as claim 3 was a dependent claim, it was also anticipated.

The parties' submissions on the appeals

270 AstraZeneca contended that the primary judge erred in finding that the invention claimed in each of claims 1 to 3 of the 051 or low dose patent was not novel (ground 16 in the notices of appeal) by:

- failing to consider whether the 471 patent disclosed the integers of each of claims 1 to 3 in combination (ground 17); and
- misapplying s 7(1) of the Act by treating common general knowledge as part of the prior art base and relying on that information to assess whether the 471 patent anticipated the invention as claimed (ground 18).

271 AstraZeneca also contended (ground 19) that the primary judge erred by finding that the 471 patent disclosed:

- the compound rosuvastatin;
- that each compound identified in the Examples (including rosuvastatin) was useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis in humans and sufficiently safe to be administered to patients for that purpose; and
- that each compound (including rosuvastatin) identified in the Examples was useful to treat hypercholesterolemia, hyperlipoproteinemia and atherosclerosis when administered at any dose between 0.5 mg to 200 mg, including in the doses specified in the 051 or low dose patent.

272 In its submissions, AstraZeneca focused on three aspects of these grounds.

273 The first aspect was the contention that the primary judge erred by failing to consider whether each combination of integers claimed, respectively, in claims 1 to 3 of the 051 or low dose patent was disclosed in the 471 patent. This attack was directed to the primary judge's finding, quoted at [268] above, that the 471 patent disclosed "precisely the methods of treatment claimed in the 051 or low dose patent". AstraZeneca submitted, in specific reliance on evidence given by Dr Reece and Dr O'Brien in cross-examination, that:

... no person skilled in the art read the 471 Patent to disclose any particular compound – including rosuvastatin – was an effective and safe medical treatment at each dose identified in the broad range of dosages claimed for each of the three diseases, or at 5 mg or 10 mg specifically.

274 It should be noted that the primary judge specifically referred to this evidence in her reasons (at [311]), but did not consider that it provided support for AstraZeneca's case.

275 The second aspect was the contention that the primary judge wrongly held that the 471 patent anticipated the invention as claimed, notwithstanding the absence of any disclosure of safety data in humans. AstraZeneca submitted that the claims in suit define a method of treating hypercholesterolemia that was sufficiently safe and efficacious to be administered by medical practitioners to patients requiring treatment for that condition. AstraZeneca submitted that no such method is disclosed in the 471 patent.

276 The third aspect was the contention that the primary judge erred by treating information within common general knowledge as part of the prior art base under s 7(1) of the Act, and thereby impermissibly added integers from the common general knowledge about the known effects and known dose profile of different statins to find that there had been an anticipation by the 471 patent of the invention as claimed.

277 In this connection, AstraZeneca submitted:

... Section 7(1) and the long-established principles that govern the law of novelty do not permit the hindsight process of adding integers, even if they be perceived to be part of the common general knowledge, to find that there is a disclosure. Further, the missing integers of the invention as claimed were not in any event present in common general knowledge, because the safety and efficacy of rosuvastatin at 5 mg or 10 mg or indeed any dose was not part of common general knowledge. ... no class effect between different statin molecules could be assumed.

278 The generic parties supported the primary judge's findings and reasons.

279 Apotex submitted that the primary judge was correct to find that the 471 patent disclosed that rosuvastatin was useful in treating all three conditions (one of which was hypercholesterolemia) by oral administration, preferably in a dose range of 1 mg to 100 mg. Apotex submitted that this clearly included doses of 5 mg and 10 mg, including as a starting dose. Apotex submitted that this was particularly so when the 471 patent was “considered in light of the common general knowledge that the available statins at the priority date were all given in doses of 5, 10, 20 and/or 40 mg”.

280 Further in this regard, Apotex submitted that the primary judge’s reasons show that her Honour did consider whether all the integers of each claimed method of treatment were disclosed in the 471 patent in combination. It submitted that it was “irrelevant that combinations involving other doses were also disclosed”.

281 As to whether the primary judge impermissibly took into account common general knowledge when considering the disclosures of the 471 patent, Apotex submitted that at [297] of the reasons, the primary judge clearly distinguished between reading a prior art document through the eyes of the person skilled in the art with the benefit of common general knowledge, and the impermissible mosaicing of publications. Apotex submitted that this recognition by the primary judge showed that her Honour did not misapply s 7(1) of the Act by adding common general knowledge to what was disclosed by the 471 patent itself. Specifically, Apotex submitted that the primary judge relied on common general knowledge to understand, in a conventional way, the nature and the adequacy of the disclosures in the 471 patent, not to supply a missing integer.

282 Watson and Ascent made submissions to similar effect. They submitted that, at trial, the primary judge correctly considered AstraZeneca’s submissions concerning the need for an anticipatory document to disclose the combined features of the invention as claimed. They submitted that a prior art document is to be considered as a whole. According to Watson and Ascent, such a document may, and frequently does, teach more than one thing. They submitted, however, that it is not to the point that the 471 patent refers to other compounds, conditions and dosages, because “the anticipatory disclosure is clear”.

283 Watson and Ascent submitted that the “requirement of efficacy” does not limit the claims in suit. They submitted further that, even if the claims were so limited, this would not change the analysis in the present case because the 471 patent expressly discloses and teaches a method of

treating hypercholesterolemia. In this connection they submitted that, relevantly, “it is not a requirement for anticipation” that there be disclosure of safety data in humans.

284 As to the disclosure of dosages, Watson and Ascent submitted that it was unsurprising that the primary judge rejected the contention that 5 mg and 10 mg doses were not disclosed in the 471 patent. They submitted that, by specifying a range, the 471 patent was merely adopting a short-hand way of indicating that “all dosages in the range are contemplated”.

Consideration

285 It may be accepted that the present case is not one where the prior disclosure is simply in relation to a large class of compounds of which the subject matter of the invention in suit is but one of such compounds. Dealing with disclosures of that nature, Jacob LJ in *Dr Reddy’s Laboratories (UK) Ltd v Eli Lilly and Co Ltd* [2010] RPC 9 at [26] said:

... An old question and answer runs as follows: “Where does a wise man hide a leaf? In a forest.” It is, at least faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves.

286 Later at [28], his Lordship said:

I would add that I would regard the listing out of a great number of compounds as opposed to the use of a Markush formula in the same way. To say a particular book is identified by saying “the books in the Bodleian” is no different from saying it is identified by providing access to the catalogue of the Bodleian.

287 In the present case, the primary judge correctly distinguished the disclosures in the 471 patent on the basis that two salts of rosuvastatin were exemplified as useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis. The primary judge also correctly held that this disclosure was one of usefulness in the treatment of each condition, not one or more of such conditions. It should be noted that the disclosure of the calcium salt of rosuvastatin is particularly important because that salt falls within each of the claims of the 051 or low dose patent.

288 The real question is whether the primary judge erred in concluding (at [310]) that the 471 patent disclosed “precisely the method of treatment claimed in the 051 or the low dose patent” with respect to the treatment of hypercholesterolemia, using:

- a starting dose of a single, once daily, oral dose of 5 mg to 10 mg of rosuvastatin or a pharmaceutically acceptable salt thereof, in the form of a pharmaceutical composition (claim 1); or
- a single, once daily, oral dose of 5.2 mg to 10.4 mg of the calcium salt of rosuvastatin in the form of a pharmaceutical composition (claim 2).

289 There can be no question that each of the above dosage regimens falls within the broad description in the 471 patent as to formulation (“a pharmaceutical composition”), route of administration (“orally or parenterally”), drug dose (“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”) and dosing interval (the dose may be “single or divided”).

290 However, the 471 patent makes plain that the dosages may vary depending on a number of factors, including the kind of disease to be treated. In context, this means that the dose may vary depending on whether or not the disease to be treated is hypercholesterolemia, hyperlipoproteinemia or atherosclerosis. Further, the range given for oral administration is a broad range. Even then, the disclosed dosage is no more particular than that the dosage “usually” falls within that broad range. The 471 patent also raises the possibility of single or divided doses, although it does not descend to describe the conditions in which or circumstances under which a divided dose should be given or, indeed, how the dose should be divided.

291 It is also important to note the following additional matters.

292 First, the disclosure in the 471 patent concerning dosage is made with respect to a vast number of compounds, without refinement as to particular compounds. Although Examples 1 and 7 identified two salt forms of rosuvastatin, nothing is there said about dosage or dosage regimen. Secondly, the disclosure in the 471 patent concerning dosage is not that each compound in the broad class, or indeed each exemplified compound, could be administered or should be administered at every dosage or according to every dosage regimen contemplated by the broad disclosure made.

293 The touchstone for determining whether a prior publication, such as the 471 patent, anticipates a claimed invention, is stated in *General Tire* at 485 to 486:

When the prior inventor’s publication and the patentee’s claim have respectively been construed by the Court in the light of all properly admissible evidence ... the question whether the patentee’s claim is new ... falls to be decided as a question of fact. If the

prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated. The prior inventor, however, and the patentee may have approached the same device from different starting points and may for this reason, or it may be for other reasons, have so described their devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor's publications will inevitably result in something being made or done which, if the patentee's patent were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated.

If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented ... a signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee.

294 The metaphor of planting the flag has been taken up in this Court. For example, in *ICI Chemicals*, the Full Court at [51], after noting the metaphor, remarked that, in that case, the appellant's argument involved the skilled addressee rummaging through a "flag locker" to find a flag which the prior art document possessed and could have planted. In *Apotex Pty Ltd and Another v Sanofi-Aventis and Another* (2008) 78 IPR 485 ("*Sanofi-Aventis* (2008)"), Gyles J at [91] adopted a different metaphor, remarking that "anticipation is deadly but requires the accuracy of a sniper, not the firing of a 12 gauge shotgun". Each metaphor underlines the importance of the specificity required in order for a prior art document to anticipate an invention as claimed.

295 What the 471 patent discloses is that, somewhere within the broad range given, there will usually be a suitable dosage and dosage regimen for, for example, the sodium salt or the calcium salt of rosuvastatin for the treatment of hypercholesterolemia, which may not be the same dosage or dosage regimen of that compound for the treatment of hyperlipoproteinemia or for the treatment of atherosclerosis. Absent specific disclosure of the appropriate dosage and dosage regimen for the use of the sodium salt or, more particularly, the calcium salt of rosuvastatin to treat hypercholesterolemia, the 471 patent does not disclose all of the combined features of either claim 1 or claim 2 of the 051 or low dose patent.

296 The sufficiency of the disclosure given by the 471 patent in this regard can be assessed by considering whether, in following that disclosure, either claim 1 or claim 2 of the 051 or low dose patent would inevitably be infringed. In this connection, it is important to note the cautionary observations of Bennett and Yates JJ in *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd and Others (No 2)* (2012) 204 FCR 494 (“*Sanofi-Aventis* (2012)”) at [165] that there is a question whether the unyielding logic of the “inevitable result” cases can be applied uncritically in every case of alleged anticipation, particularly where the invention in suit is claimed as a new method of medical treatment involving the administration of a known compound for a hitherto unknown and unexpected, but nevertheless useful, therapeutic use. Similarly, in *Actavis UK Ltd v Janssen Pharmaceutica NV* [2008] FSR 35 (“*Actavis*”), Floyd J at [90] noted the possibility of an exception to “the rule about inevitable results” when considering the correctness of a submission that unadvertised technical effects which underlie new uses of known materials can lead to an invention satisfying the requirement for novelty. In that connection, his Lordship considered the decision of the Enlarged Board of Appeal of the European Patent Office in *G02/88 Mobil/Friction reducing additive* [1990] EPOR 73, which held that novelty of purpose coupled with an undisclosed technical effect is enough to confer novelty on a claimed invention, even if the undisclosed technical effect would inherently have occurred alongside the known technical effect when using the known substance for its known purpose. His Lordship further observed (at [90]) that:

No doubt when an old medicine (known for disease X) is found to treat a new disease, Y, it could be said that it is inevitable that some of the patients treated to date with this medicine for X may have had disease Y, and inherently been treated for it. Yet the novelty of purpose, using it for making a medicine for Y is enough. That principle is now definitely part of our law: see *EISAI/Second Medical Indication (G05/83)* [1985] OJ EPO 64; [1979-85] EPOR B241 and *Wyeth (John) and Brother Ltd’s Application, Schering AG’s Application* [1985] RPC 545.

297 The problematic element in the cases to which Bennett and Yates JJ referred in *Sanofi-Aventis* (2012), and to which Floyd J referred in *Actavis*, is not present in the instant case.

298 Here, relying only on the disclosures of the 471 patent, and not imputed common general knowledge concerning the administration of prior art statins, the person skilled in the art might seek to use one or any number of different dosages and dosage regimens for administering a pharmaceutical composition containing either the sodium salt or the calcium salt of rosuvastatin to treat hypercholesterolemia. It is possible that, out of a very large number of possibilities, the person skilled in the art might, based only on the disclosures of the 471 patent,

use the dosage and dosage regimen of claim 1 or claim 2 of the 051 or low dose patent. But it is at least equally possible that such a dosage and dosage regimen might not be used. It cannot be said, therefore, that, by following the directions – such as they are – in the 471 patent, the person skilled in the art would inevitably do something that would inevitably infringe either claim 1 or claim 2 of the 051 or low dose patent.

299 It is here that the true setting for using the notion of reverse infringement in assessing anticipatory disclosure must be recognised. In *Meyers Taylor Pty Limited v Vicarr Industries Limited and Others* (1977) 137 CLR 228 Aickin J (at 235) said:

The basic test for anticipation or want of novelty is the same as that for infringement and generally one can properly ask oneself whether the alleged anticipation would, if the patent were valid, constitute an infringement.

300 But it is important to note that the reverse infringement test is not applied by simply asking whether something within the prior art document would, if carried out after the grant of the patent, infringe the invention as claimed. In *Flour Oxidizing Company Ltd v Carr & Co. Ltd* [1908] 25 RPC 428, Parker J (at 457) observed:

... where the question is solely a question of prior publication, it is not, in my opinion, enough to prove that an apparatus described in an earlier Specification could have been used to produce this or that result. It must also be shown that the Specification contains clear and unmistakable directions so to use it.

301 These observations are the wellspring of a long line of cases that recognise that, in order for a prior art document to be anticipatory, there must be (to adopt the language in *General Tire*) a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent. In *Bristol-Myers Squibb Company v F H Faulding & Co Limited* (2000) 97 FCR 524 ("*Bristol-Myers*"), Black CJ and Lehane J reviewed the relevant authorities and concluded (at [67]):

What all of those authorities contemplate, in our view, is that a prior publication, if it is to destroy novelty, must give a direction or make a recommendation or suggestion which will result, if the skilled reader follows it, in the claimed invention. A direction, recommendation or suggestion may often, of course, be implicit in what is described and commonly the only question may be whether the publication describes with sufficient clarity the claimed invention or, in the case of a combination, each integer of it. But in this case medical practitioners hardly needed to be told that it was possible to infuse a particular dose of taxol over three hours, or how to do it. Nor, equally obviously, is that the point of the claims. The claims of the earlier of the petty patents are for a method for administration of taxol to a patient suffering from cancer; the claims of the later one are for a method of treating cancer. In each case the method involves a particular regimen for the infusion of taxol. The context was that great

difficulties had been encountered in using taxol, despite its known anti-carcinogenic properties, in the treatment of cancer, because of the drug's side effects. Each of the trials reported in the articles referred to was an investigation directed towards finding a solution of the difficulties: directed, particularly, to ascertaining safe dosage levels. But, though methods falling within the claims of the patents were used in each trial, none of the reports can be said to teach (a word which in this context encompasses direct, recommend and suggest) that which the petty patents claim.

302 Sufficiency of disclosure is a cardinal anterior requirement in the analysis of whether a prior art document anticipates a claimed invention. It is only after the stage of assessing the sufficiency of disclosure – which involves a determination about whether a prior document has “planted the flag” as opposed to having provided merely “a signpost, however clear, upon the road” or, perhaps, something less – that the notion of reverse infringement comes into play as the final and resolving step of the required analysis. It is not the first step of the required analysis; nor is it the only step.

303 When dealing with AstraZeneca's submissions concerning the disclosure of dose variability in the 471 patent, the primary judge (at [313]) said:

... Construed in context, there is a clear direction in the 471 patent that rosuvastatin at a dose of anywhere between 0.5 to 200 mg (which includes doses as specified in the 051 or low dose patent) will be useful in treating hypercholesterolemia in an oral once or twice daily administration. This necessarily encompasses the integer of a starting dose in claim 1 of the 051 or low dose patent as there will always be a starting dose to treat a disease by oral administration and the 471 patent directs the starting dose and the continuing doses to be in the range specified.

304 If, by that finding, the primary judge was saying that the 471 patent directs that any dosage within the stipulated range for oral administration would be suitable for treating hypercholesterolemia, then we would respectfully disagree with her Honour. In our view, the 471 patent is clear that the dose will vary depending on a number of factors, including importantly the disease to be treated. Further in our respectful view, the 471 patent discloses the possibility of different dosage regimens, including those involving single or divided doses.

305 If, on the other hand, the primary judge was finding only that the 471 patent directs that a suitable dosage will usually be found within the range stipulated for oral administration, then in our respectful view such a direction will be insufficient to disclose the invention claimed in claims 1 and 2 of the 051 or low dose patent, notwithstanding the disclosure in the 471 patent that the sodium and calcium salts of rosuvastatin are useful for treating hypercholesterolemia.

306 The same conclusion follows in respect of claim 3. The primary judge correctly noted that claim 3 is dependent, separately, on claims 1 and 2. If claims 1 and 2 are not anticipated, claim 3 cannot be anticipated. However, the inverse is not true: it does not follow from the fact that claim 1 or claim 2, or both claims, lack novelty that claim 3, as a dependent claim, also lacks novelty.

307 AstraZeneca advanced a separate ground of appeal (ground 31) that the primary judge erred in holding that claim 3 of the 051 or low dose patent was invalid merely by reason of its dependency on claims 1 and 2. It does appear that the primary judge may have found against claim 3 on this basis. If so, her Honour erred in that regard. However, in light of the findings above with respect to claims 1 and 2, it is not now necessary to consider, independently, whether the 471 patent anticipates claim 3.

308 The above conclusions derive from the first aspect of AstraZeneca's submissions on the appeals. Although it is not necessary to deal with the second and third aspects of its submissions (see [275] and [276] above), it is desirable to say something about them.

309 First, it is not necessary, as AstraZeneca submitted, for the 471 patent to make a disclosure of safety data in humans with respect to the two salts of rosuvastatin – or for that matter, with respect to any of the compounds falling within the Markush formula – in order for the 471 patent to be anticipatory of the invention claimed in claims 1 and 2 of the 051 or low dose patent. The 471 patent plainly discloses that the sodium salt of rosuvastatin, and the calcium salt of rosuvastatin, are useful in the treatment of, amongst other things, hypercholesterolemia in humans. That is all that is required in that regard. AstraZeneca has not demonstrated error in the primary judge's conclusion in that regard.

310 Secondly, with respect to the question of common general knowledge, it is undoubtedly correct that the prior art information referred to in s 7(1) of the Act is not the same, conceptually, as the common general knowledge: *ICI Chemicals* at [43]. As the definition of “prior art information” in the Act makes clear, it is particular information in the prior art base, namely information in a document or through doing an act that is made publicly available, including, where relevant, a published specification filed in respect of a complete application. The distinction between this information and the common general knowledge, as categories of information, is important and must be maintained for the purpose of analysis when considering challenges to validity based on lack of novelty. That is not to say, as a matter of fact, that certain published information may not also be part of the common general knowledge. Indeed,

it is difficult to conceive of the common general knowledge as being anything but information that has been made publicly available. But the mere fact that information has been made publicly available, does not qualify that information as being part of the common general knowledge.

311 Section 7(1) of the Act sets the precise boundaries of the information that is to be taken into account when assessing novelty. Common general knowledge, as a notionally organised body of information possessed by the person skilled in the art, does not fall within those boundaries. We will return to discuss that matter further when considering AstraZeneca's appeals with respect to the primary judge's finding that Watanabe anticipates the invention claimed in claims 1 and 2 of the 051 or low dose patent.

312 AstraZeneca contended that, when assessing the generic parties' challenge to novelty with reference to the 471 patent, the primary judge deployed the common general knowledge as part of the prior art base under s 7(1) of the Act. Essentially, AstraZeneca submitted that the primary judge supplemented the disclosures of the 471 patent with information drawn from the common general knowledge about the known effects and known dose profile of different statins.

313 There are indications in the primary judge's reasons that her Honour did take into account the common general knowledge as a complementary source of information. For example, in rejecting AstraZeneca's contention concerning the necessity for the 471 patent to disclose the safe administration of rosuvastatin, the primary judge (at [306]) referred not only to the explicit statement in the 471 patent that the relevant compounds are useful for treating the identified diseases:

... but also ... the fact that the compounds are part of a class, statins, which from the expert evidence I am satisfied had known side effects before the priority date, primarily myalgia (muscle pain), liver dysfunction and rhabdomyolysis (more severe muscle toxicity) and a known dose-efficacy-side effect relationship (in that lower doses were associated with fewer side effects and achieve the greatest reduction in LDL-C levels, which thereafter flattened out with increased doses.

314 Perhaps less clearly, at [308] the primary judge identified rosuvastatin as belonging "to a known drug class with a known set of side effects and dose profile ...".

315 There is some force in AstraZeneca's contention that these references went beyond the use of the common general knowledge to construe the 471 patent. However, the primary judge's reliance on these matters could not have affected the correctness of her Honour's conclusion

that it was not necessary for the 471 patent to make a disclosure of the safety of the compounds (and, in particular, the two salts of rosuvastatin) beyond the disclosure that the compounds are useful in the treatment of, amongst other things, hypercholesterolemia in humans.

Watanabe

316 In general terms, Watanabe reports on the synthesis of a series of (then) novel compounds and an evaluation of their ability to inhibit HMG-CoA reductase. Rosuvastatin was one of the compounds that was synthesised and evaluated.

317 Watanabe commences with a statement that hypercholesterolemia is well-recognised as a primary risk factor in coronary heart disease and that decreasing elevated serum cholesterol levels by lipid-lowering agents reduces the risk of cardiovascular mortality. It identifies lovastatin, pravastatin and fluvastatin as potent hypercholesterolemic agents that are widely used clinically and that these agents belong to a class of compounds that inhibit HMG-CoA reductase and induce the expression of LDL receptors, which mediate the clearance of LDL cholesterol from plasma.

318 In these introductory passages, Watanabe discloses that, during the evaluation on which it reports, rosuvastatin was found to possess greater enzyme inhibitory activity than lovastatin and pravastatin.

319 Within the article, rosuvastatin is identified as compound 3a or compound S-4522. It was evaluated, along with some other compounds in the series, for its ability to partially inhibit purified rat liver HMG-CoA reductase *in vitro*. As the “selected compound”, rosuvastatin was further evaluated for its ability to inhibit cholesterol biosynthesis in rat liver isolated hepatocytes, to increase the m-RNA of LDL receptors and liver tissue selectivity, and to decrease plasma cholesterol levels in normolipemic male beagle dogs and cynomolgus monkeys *in vivo*.

320 When discussing these tests, Watanabe discloses that rosuvastatin acted more potently in liver tissue than in peripheral tissue. Watanabe says that this was an expected outcome, given rosuvastatin’s lipophilicity value, which suggested good liver selectivity. This selectivity indicated to the authors that rosuvastatin was potent in lowering cholesterol, with reduced side effects in clinical use.

321 Watanabe concludes that the series of compounds that were synthesised and investigated were found to exceed lovastatin sodium salt, pravastatin, and fluvastatin in their ability to inhibit

HMG-CoA reductase *in vitro* and to decrease plasma cholesterol levels *in vivo*. Watanabe also concludes that rosuvastatin was 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 rat isolated hepatocytes. In this connection, Watanabe reports that rosuvastatin was 100 times more potent than pravastatin.

322 Watanabe concludes by stating that the synthesised compounds “are promising candidates for development of antiarteriosclerotic agents”. It also reports that rosuvastatin was in the course of clinical trials.

The primary judge’s findings and reasons

323 At trial, AstraZeneca’s principal submission was that Watanabe did not describe a method of treatment (in particular, the treatment of humans suffering from hypercholesterolemia), but only the synthesis and characterisation of a range of compounds, including rosuvastatin, by reference to biological activity revealed by certain *in vitro* and *in vivo* animal tests. It pointed to the conclusion that all these synthesised compounds were described as merely “promising candidates”, with the clinical trials of rosuvastatin “in progress”.

324 In considering this submission, the primary judge noted the introductory discussion in Watanabe about hypercholesterolemia and its implications for coronary heart disease; the use of lovastatin, pravastatin and fluvastatin; and the specific identification of rosuvastatin as the “selected compound”.

325 The primary judge also noted the discussion of the biological results obtained from animal testing, including that rosuvastatin was “liver selective”. The primary judge found that these matters provided the context in which the conclusion concerning “promising candidates” should be considered. At [319], the primary judge said:

The conclusion in the Watanabe article, emphasised by AZ, that the compounds (that is, all of 3a to 3g) “are promising candidates for development of antiarteriosclerotic agents”, with the “clinical trials” of S-4522 “in progress”, is to be read in this context. While it is true that the experimental section of the Watanabe article identifies the potency of all of the compounds 3a to 3g and all are encompassed by the “promising candidates” reference, it is only one which is described as the “selected compound” and which is reported in detail in the text and said to be in clinical trials. *Read against the common knowledge that the skilled addressee would have about how statins function, available statins, the dose range and response activity of statins, and their dose-side effect relationships, Watanabe is an effective disclosure of a new statin capable of treating hypercholesterolemia having greater potency than existing statins (the dose-response range of existing statins being well-known), albeit without safety and efficacy having been proven by the extensive clinical trials and ongoing*

monitoring required to obtain regulatory approval. In terms of the doses of existing statins, it should be noted that cerivastatin, which involved far smaller doses than all other statins, was not available in Australia until 2000 and was not commonly prescribed. The commonly prescribed statins involved a dosage range of between 10mg and 80mg, with dose titration from a lower starting dose to a higher dose a well-understood process.

(Emphasis added).

326 AstraZeneca advanced a submission that the data on animal testing presented in Watanabe was incomplete and insufficient to provide guidance “when moving from animals to humans”. At [320], the primary judge said:

AZ said that the “data presented from animal testing is also hopelessly incomplete and insufficiently detailed to be of any use to provide any guidance when moving from animals to humans”. It is correct that the Watanabe article does not disclose the maximum tolerated dose in any animal, toxicological effects, if any, that were observed in any animals and at what dose or the minimum effect dose that first caused plasma cholesterol lowering in any animal model. But the Watanabe article does report on relative potency of compound 3a, the relativity measured against known compounds with (to the skilled addressee) a known dose-response range in humans. In this regard, the cross-examination of Dr Reece, a formulator, about the lack of information in the Watanabe article was not particularly helpful. Dr Reece (or at the least Dr Reece alone) is not the skilled addressee. *Dr O’Brien is representative of the skilled addressee and on his reading of the Watanabe article he expected S-4522 to have similar or better efficacy than atorvastatin and to be effective in doses lower than the commonly used doses of pravastatin (10 to 40 mg). Given what the skilled addressee knew about statins at the time and what the Watanabe article reports as set out above, this expectation is unsurprising. Read against the common general knowledge of the skilled addressee the Watanabe does teach that there is a new statin, rosuvastatin, which is a class of drugs used to treat hypercholesterolemia, which due to its structure, is relatively more potent than the nominated existing statins in reducing cholesterol (that is, by inference, greater cholesterol lowering effect at the same doses) and exhibits liver selectivity which indicates a potential for reduced side effects in clinical use compared to the existing statins. Given common knowledge of the dose-response range of existing statins, including the frequent administration of a starting dose within a fairly narrow dosage range for the then existing statins which is then dose-titrated, the Watanabe article teaches each of the integers of the 051 or low dose patent. As Apotex submitted:*

A piece of prior art does not have to persuade the reader to abandon his or her currently preferred drug. It has to disclose something within the claims “with sufficient clarity”.

(Emphasis added).

327 Later, at [322], the primary judge said:

AZ’s references to Professor O’Brien’s evidence concerning the potency of rosuvastatin as compared to atorvastatin do not undermine these conclusions. *Given the results reported in respect of lovastatin and pravastatin, and the common*

knowledge of the skilled addressee about the relative potency of statins, it is hardly surprising that on reading the Watanabe article Professor O'Brien expected rosuvastatin to be more potent than atorvastatin. The results overwhelmingly pointed in that direction.

(Emphasis added).

328 The primary judge found (at [323]) that each of the integers of claims 1 and 2 of the 051 or low dose patent were disclosed in and anticipated by Watanabe. Once again, the primary judge reasoned that, as claim 3 was a dependent claim, it was also anticipated.

The parties' submissions on the appeals

329 AstraZeneca contended that the primary judge erred in finding that the invention claimed in claims 1 to 3 of the 051 or low dose patent was not novel (ground 20 of the notices of appeal) by:

- failing to consider whether Watanabe disclosed the integers of each of claims 1 to 3 in combination (ground 21); and
- misapplying s 7(1) of the Act by treating common general knowledge as part of the prior art base and relying on that information to assess whether Watanabe anticipated the invention as claimed (ground 22).

330 These grounds are similar to those raised with respect to the primary judge's findings in relation to whether claims 1 to 3 of the 051 or low dose patent were anticipated by the 471 patent.

331 AstraZeneca also contended (ground 23) that the primary judge erred by finding that Watanabe disclosed:

- rosuvastatin;
- that rosuvastatin was capable of treating hypercholesterolemia and had greater potency than existing statins; and
- the integers of claims 1 to 3 of the 051 or low dose patent, including the administration of rosuvastatin by the route, dose and frequency identified in the claims.

332 In its submissions, AstraZeneca focused on three aspects of these grounds. Those aspects were essentially the same as those on which it relied when arguing its appeal in relation to the primary judge's findings concerning the disclosures of the 471 patent.

333 Thus, the first aspect was the contention that the primary judge erred by failing to consider whether each combination of integers claimed, respectively, in claims 1 to 3 of the 051 or low dose patent was disclosed in Watanabe. AstraZeneca pointed to the fact that there was no disclosure of any dosage, and therefore no basis for finding that the relevant integers were disclosed in combination.

334 The second aspect was the contention that the primary judge wrongly held that Watanabe anticipated the invention as claimed, notwithstanding the absence of any disclosure of safety data in humans. AstraZeneca criticised the primary judge's reliance (see the passage quoted at [326] above) that Watanabe reports on the relative potency of rosuvastatin measured against known compounds with a known dose-response in humans. In this part of the reasons, the primary judge relied on evidence given by Professor O'Brien concerning his expectations that rosuvastatin would be effective at dosages lower than those commonly used for pravastatin. AstraZeneca submitted that Professor O'Brien's "expectations" were not part of the disclosure made by Watanabe. AstraZeneca also submitted that this evidence should not be given weight in any event because it was not based on relevant specialised knowledge or experience. In AstraZeneca's submission, Professor O'Brien's evidence, in that regard, was based on an assumption that the data reported in Watanabe would "translate into human studies". In cross-examination, Professor O'Brien accepted that the determination involved in moving from dosages for animals to dosages for humans was something that "would have been undertaken by others".

335 The third aspect was the contention that the primary judge erred by treating information within the common general knowledge as part of the prior art base under s 7(1) of the Act, and thereby impermissibly added integers from the common general knowledge to find that there had been an anticipation by Watanabe of the invention as claimed.

336 In this connection, AstraZeneca pointed to the passages in the primary judge's reasons quoted at [325] and [326] above. AstraZeneca submitted that there was no disclosure in Watanabe of any dosage range. Moreover, there was no disclosure that rosuvastatin was a safe and efficacious treatment in humans. AstraZeneca also advanced the submission, quoted at [277] above, as equally applicable to the primary submission of whether Watanabe was an anticipatory disclosure of the invention as claimed.

337 Once again, the generic parties supported the primary judge's findings and reasons.

338 Apotex submitted that the primary judge was right to find that Watanabe anticipated the invention as claimed. It submitted that the primary judge's reasons did not treat the common general knowledge as part of the prior art base. According to Apotex, the primary judge's use of the common general knowledge was to gain a correct reading of Watanabe through the eyes of the person skilled in the art. Apotex also submitted that, in order to be anticipatory, it was not necessary for Watanabe to show "a level of safety and efficacy required at the regulatory level".

339 Watson and Ascent submitted that, although Watanabe does not state a dosage range, "it still gives sufficient direction to the person skilled in the art as to dosage". In this connection, Watson and Ascent relied on Professor O'Brien's evidence in chief given in the context of him being asked to address a hypothetical problem as at 6 February 1999 by finding "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". This is the evidence referred to by the primary judge at [320] of her Honour's reasons.

340 In this evidence, Professor O'Brien used information of animal trials taken from Watanabe, with information of dosages used for other statins, to recommend, with a reasonable expectation of success, a starting dose of rosuvastatin for the treatment of hypercholesterolemia in humans. Professor O'Brien said:

My expectation of a starting dose would be around 10 mg once daily, based on its relative efficacy compared to pravastatin in the monkey model. More specifically, and assuming the monkey studies translate into human studies, I would consider that a dose of around 10 mg of S-4522 may achieve around a 35% LDL-C lowering. However, this would need to be confirmed in human subjects. As stated above at paragraph 12.11, at least a 35% LDL-C reduction at its starting dose is desirable if S-4522 is to compare favourably with atorvastatin.

341 Although it is clear that this evidence was given in the context of the generic parties' case on obviousness, and not in the context of their case on novelty, Watson and Ascent submitted that Professor O'Brien's stated expectation was "a shorthand reference to what the document teaches the person skilled in the art". Watson and Ascent submitted that "something less than a full description of an effective means by which the combination claimed in the patent may be produced may be sufficient to a reader having common general knowledge in the art". In so submitting, they relied on passages in *H Lundbeck A/S and Another v Alphapharm Pty Ltd and Another* (2009) 177 FCR 151 at [173] which refer more specifically to observations made by Gummow J (when in this Court), with whom Jenkinson J agreed, in *Nicaro Holdings Pty*

Ltd and Others v Martin Engineering Co and Another (1990) 91 ALR 513 (“*Nicarо Holdings*”) at 531.

342 Further in this regard, Watson and Ascent submitted that, when considering Watanabe, the primary judge did not add common general knowledge to supplement a missing integer. They submitted that Watanabe disclosed the effectiveness of rosuvastatin in treating hypercholesterolemia. They submitted that “the only question was the dosage”. They further submitted that the primary judge was entitled to consider Watanabe in light of the common general knowledge, which included “how statins function, available statins, the dose range, response activity and their dose-side effect relationships, to disclose a dosage range of 5 mg to 10 mg per day”.

Consideration

343 In our respectful view, the primary judge erred in concluding that each of the integers of claims 1 and 2 of the 051 or low dose patent are disclosed in and anticipated by Watanabe.

344 It is not in dispute that Watanabe does not, in terms, disclose dosages for the administration of rosuvastatin in humans and, more specifically, for the administration of rosuvastatin in humans for the treatment of hypercholesterolemia. As we have noted, on appeal Watson and Ascent, in reliance on evidence given by Professor O’Brien, advanced a submission directed to implicit disclosure.

345 Although an implicit disclosure may constitute a sufficient disclosure for finding that information in a prior art document anticipates a claimed invention, the limits of implicit disclosure must be borne in mind. In *Nicarо Holdings*, Gummow J surveyed a number of authorities concerning the nature of the disclosure required in order for a prior art document to constitute an anticipation of a claimed invention. His Honour quoted the following observations of Lord Reid in *Van Der Lely NV v Bamfords Ltd* [1963] RPC 61 (“*Van Der Lely*”) at 71 to 72:

The law regarding anticipation derives from Lord Westbury’s statement of it in *Hills v. Evans* (1862) 4 DeG., F & J. 288. There are two branches of this statement. The first is that “a person of ordinary knowledge of the subject would at once perceive and understand and be able practically to apply the discovery without the necessity of making further experiments.” The appellants maintain that even if the skilled man could perceive in the photograph all the integers in claim 1 he could not apply the discovery without making further experiments. But Lord Westbury must have meant experiments with a view to discovering something not disclosed. He cannot have meant to refer to the ordinary methods of trial and error which involve no inventive step and are generally necessary in applying any discovery to produce a practical result.

That view appears to have been generally accepted, and I need only refer to the speech of Lord Maugham in *No-Fume Limited v Pitchford* (1935) 52 R.P.C. 231. The other requirement is that “the information given by the prior publication must for the purposes of practical utility be equal to that given by the subsequent patent.” There may be cases where the skilled man has to have the language of the prior publication translated for him or where he must get from a scientist the meaning of technical terms or ideas with which he is not familiar, but once he has got this he must be able to make the machine from what is disclosed by the prior publication. This part of Lord Westbury’s statement appears to have been universally accepted, and I need only refer to the latest authority in this House, *Martin v. Millwood* [1956] R.P.C. 125.

346 After referring to other United Kingdom authorities, and their consideration by the High Court in *N Guthridge Limited v The Wilfley Ore Concentrator Syndicate Limited* (1906) 3 CLR 583 and *Broken Hill South Silver Mining Co. No Liability v N Guthridge Limited* (1908) 8 CLR 187, Gummow J at 531 to 532 said:

It follows from the English authorities as they have been applied in Australia that, whilst *Hill v Evans* does not require a literal disclosure and something less may suffice, and whilst an alleged paper anticipation is to be treated as read by a skilled addressee, a disclosure will fall short of an anticipation by description of an effective means by which the combination claimed in the patent in suit might be produced, if what is required of the skilled addressee is the exercise of any inventive ingenuity and the taking of any inventive step.

Any references in this context to workshop improvements or variations should not be understood as importing into this field of novelty concepts of obviousness. There may be room for disagreement upon the English authorities as to what degree of activity by the skilled addressee may be called for in respect of an alleged anticipation for it still to suffice to destroy novelty. *In my view, the way in which the English authorities have been treated by the High Court supports the position as stated by Lord Reid in Van der Lely's case, supra. It is also to be borne in mind that the notional addressee of the alleged anticipation is a skilled addressee with common general knowledge of the art. But his Lordship was not saying that an alleged anticipation of a combination claim, which did not include an integer thereof, nevertheless would constitute an effective disclosure if what was required of a skilled addressee to produce that claimed combination was the taking of an obvious and non-inventive step by way of workshop improvement.*

(Emphasis added).

347 Lord Reid’s discussion of implicit disclosure in *Van Der Lely* was also commented on by the Full Court in *Ramset Fasteners (Australia) Pty Ltd v Advanced Building Systems Pty Ltd and Another* (1999) 164 ALR 239 (“*Ramset*”), where (at [23]) the Full Court said:

... It is important to appreciate that what Lord Reid was prepared to infer was the actual existence of a feature (referred to as “ground drive”) in the combination alleged to be an anticipation, although that feature was not visible in the photograph which was relied on as a publication. What is not permissible is to draw from a disclosure of one thing a conclusion that a different thing, different by the addition of an essential

integer, would clearly be a good idea.

348 In that case, the Full Court also quoted, with approval, the following passage in *Hoechst Celanese Corp v BP Chemicals Limited* [1998] FSR 586 at 600 to 601:

[I]f what is said to be implicit in a document is given too much scope you will be blurring the distinction between lack of novelty and obviousness. On the other hand it must be right to read the prior document with the eyes of a skilled man. So if he would find a teaching implicit, it is indeed taught. The prior document is novelty-destroying if it explicitly teaches something within the claim or, as a practical matter, that is what the skilled man would see it is teaching him.

349 In *Ramset*, the invention was the use of a ring clutch used as a hoisting attachment for tilt-up walls. As claimed, the invention required, as an essential feature, a “release cable” attached to the distal end of a lever arm. It was alleged that the invention as claimed was anticipated by the prior publication of photographs of a ring clutch used in a hoisting application, which did not have a release cable. The Full Court held that the claimed combination was not disclosed by the photographs. The Full Court (at [25]) said:

... Whether or not a skilled worker might deduce the desirability of adding such a feature, it cannot be said that any of the pictures in the advertisements, or anything said in them, infers that the device to which they relate involved the presence of this feature. The appellant argued that the alleged invention makes no “difference in substance from that which was known”, presumably by virtue of these advertisements. But this way of putting the matter, which departs from an investigation as to whether the essential integers of the combination were revealed, risks a coalescence between considerations of novelty and obviousness so as to create an amorphous test on which the modern law of patents has turned its back.

350 *Nicaro* and *Ramset* were cases dealing with the question of lack of novelty arising under the 1952 Act. They nevertheless make clear the general proposition that the notion of implicit disclosure is confined to what is in fact disclosed by the prior art document. If the prior art document does not disclose explicitly or implicitly an essential feature of a claimed invention, the prior document cannot constitute an anticipation of that invention.

351 Further, under the 1952 Act, a clear distinction existed between the test for want of novelty and the test for want of subject matter (obviousness): *Sunbeam Corporation and Another v Morphy-Richards (Aust.) Pty Ltd* (1961) 180 CLR 98 at 111 to 112. That distinction is maintained in the present Act, as a comparison between the test for novelty under s 7(1) and the test for inventive step under s 7(2) read with s 7(3) makes clear. In *N V Philips Gloeilampenfabrieken and Another v Mirabella International Pty Limited* (1995) 183 CLR 655

(“*N V Philips*”), Brennan, Deane and Toohey JJ observed (at 660) that s 7 and the definitions of “prior art base” and “prior art information” identify the reference points for the comparisons required by s 18(1)(b) of the Act.

352 Although the common general knowledge can be used in a limited way to construe a prior art document, s 7(1) does not permit the common general knowledge to be used as a resource that can be deployed complementarily to arrive at a disclosure which the document alone, properly construed, does not make. If it were otherwise, the separate requirement of an inventive step to support a patentable invention (see s 18(1)(b)(ii) of the Act) would be otiose. The test of novelty would encompass the test for inventive step, without the need to satisfy the threshold requirements of s 7(3) (as it then stood) that the information in the document be information that the person skilled in the art 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. All that would be required is that the information in the prior art document be publicly available.

353 In our view, Professor O’Brien’s evidence, on which Watson and Ascent in particular relied, does not establish that Watanabe would implicitly disclose to the person skilled in the art a method of treating a patient suffering from hypercholesterolemia using a starting dose of a single, once daily, oral dose of 5 to 10 mg of rosuvastatin (or a pharmaceutically accepted salt thereof) in the form of a pharmaceutical composition or administering a single, once daily, oral dose of 5.2 to 10.4 mg of the calcium salt of rosuvastatin in the form of a pharmaceutical composition. All that Watanabe discloses in that connection, and would disclose to the person skilled in the art, is what the authors state in their conclusion: rosuvastatin, and the other compounds synthesised in the evaluation carried out by them, are promising candidates for the development of antiarteriosclerotic agents, based on the results of the tests on which they report and their findings regarding comparative potency. For the purpose of assessing novelty, this is, in the language of *General Tire*, no more than a “signpost ... along the road” to the invention as claimed.

354 In our respectful view, the passages at [319] and [320] of the primary judge’s reasons, which we have quoted above (see at [325] and [326] above), reveal that her Honour did impermissibly supplement the disclosures of Watanabe by reference to information that was part of the common general knowledge, but not part of the disclosure which Watanabe itself made, in arriving at her conclusion that each of the integers of claims 1 and 2 of the 051 or low dose

patent were disclosed in and anticipated by Watanabe. These passages show that the primary judge had regard to the common general knowledge about the available statins, including the dosage range and response activity of statins and their dose-side effect relationships. In this connection, the primary judge noted that the commonly prescribed statins had a dosage range of between 10 mg and 80 mg. This information, together with Professor O'Brien's evidence – which itself was based on a synthesis of the information disclosed in Watanabe, aspects of the common general knowledge and an assumption about the translation of the results from animal to humans – was used to complement the prior art information comprised in Watanabe.

355 The above conclusions derive from the first and third aspects of AstraZeneca's submissions on the appeals. As to the second aspect, it is enough to say that Watanabe falls short of disclosing the use of rosuvastatin for the treatment of hypercholesterolemia in humans. It simply points to it being a promising candidate as an antiarteriosclerotic agent.

356 With respect to claim 3, it appears that, once again, the primary judge may have found against its validity on the basis that it was a dependent claim. If so, her Honour erred in that regard. However, in light of the findings above with respect to claims 1 and 2, it is not now necessary to consider, independently, whether Watanabe anticipates claim 3. As claims 1 and 2 are not anticipated, claim 3 cannot be anticipated.

Conclusion

357 For these reasons, we would allow the appeals insofar as they concern the primary judge's findings that the invention claimed in claims 1 and 2 of the 051 or low dose patent were disclosed in and anticipated by the 471 patent and Watanabe, considered separately. We would also allow the appeals insofar as they concern the primary judge's finding that, consequently, claim 3 was also anticipated.

NOVELTY: THE 842 OR CATION PATENT

358 As we have already said, if the priority date of the claims of the 842 or cation patent is deferred to 31 January 2005 then the claims of the 842 or cation patent are invalid for lack of novelty.

359 If, contrary to our previous conclusion, the priority date of the claims of the 842 or cation patent is not 31 January 2005, but 4 August 2000, a question arises as to whether the claims are in any event invalid for lack of novelty based upon s 18(1)(b)(i), when read with s 7(1)(c), and subparagraph (b)(ii) of the definition of "prior art base" in Sch 1 of the Act. These provisions, when read together, provide for what is commonly referred to as the "whole of contents"

ground of objection (or invalidity). The “whole of contents” objection under the Act replaced the “prior claiming” objection under the 1952 Act (see s 100(1)(f)) which IPAC accepted was unduly limited in its scope (see IPAC report at [7.3]).

360 The primary judge upheld the generic parties’ whole of contents objection in relation to all claims of the 842 or cation patent or at least those on which AstraZeneca relied to assert infringement. As her Honour observed, the whole of contents objection depended on whether the application for the 841 patent, filed by AstraZeneca on the same day as the 842 application (i.e., on 4 August 2000), contained information that satisfied the following requirements of subparagraph (b)(ii) of the definition of prior art base:

information contained in a published specification filed in respect of a complete application where:

- (A) if the information is, or were to be, the subject of a claim of the specification, the claim has, or would have, a priority date earlier than that of the claim under consideration; and
- (B) the specification was published after the priority date of the claim under consideration; and
- (C) the information was contained in the specification on its filing date and when it was published.

361 Example 2 and Example 3 in the specification of the 842 or cation patent are precisely the same as Example 2 and Example 3 in the specification of the 841 application as filed and published. Thus, the specification of the 841 application contains information which either was, or at least could have been, the subject of a claim (e.g., “A formulation made in accordance with Example 2”). The question is then whether such a claim would have been entitled to a priority date earlier than the priority date of each of the claims for the 842 or cation patent. For the purpose of addressing this question, we shall assume that the postulated claim is based upon Example 2 and that 4 August 2000 is the true priority date of the claims of the 842 or cation patent. If the claim is entitled to a priority date of 26 January 2000 based upon the filing of the priority document (the 841 application also claimed priority from the priority document i.e., UK Patent Application No. 1621) then the primary judge was correct to uphold the whole of the contents objection at least with respect to some claims. In circumstances where Example 2 also appears in the priority document, there is no reason to think that the postulated claim would not be entitled to a priority date of 26 January 2000.

362 In our view the 841 application anticipates each of claims 1, 2, 4, 5 and 7 of the 842 or cation patent. This is because Example 2 comprises a pharmaceutical composition including a coating containing ferric oxide and titanium dioxide, each of which is an inorganic salt (as that expression is used in the 842 or cation patent) the counter anion of which is not a phosphate and which pharmaceutical composition is otherwise within the scope of each of these claims. Whether or not any other claims of the 842 or cation patent is anticipated by the 841 application was not the subject of any detailed submission (whether by reference to relevant expert evidence or otherwise) by AstraZeneca and in those circumstances we do not propose to express a view one way or the other in relation to the remaining claims except to say that when Example 2 is read together with other parts of the relevant disclosure then it seems likely that at least some of them would also be anticipated.

363 We should add that AstraZeneca sought to rely upon an argument based upon s 43(3) of the Act which would, if accepted, have the consequence that the forms of the invention claimed in the claims of the 842 or cation patent corresponding to those falling within the scope of any available claim (whether it be actual or notional) based upon the contents of the 841 application would also be entitled to a priority date of 26 January 2000. The problem with this argument is that it assumes that each of the independent claims of the 842 or cation patent “defines more than one form of the invention” so as to engage the operation of s 43(3) of the Act. For reasons previously explained, this assumption is incorrect.

MANNER OF MANUFACTURE: 051 OR LOW DOSE PATENT

364 This challenge to the validity of the 051 or low dose patent rested on two bases.

365 The first was that the invention claimed in claims 1 to 3 is not a manner of manufacture for the purposes of s 18(1)(a) of the Act because those claims claim methods of treatment of the human body. The primary judge found that the generic parties’ contention in that regard could not be accepted given the then state of authority, which held that such inventions are patentable.

366 The High Court has since held, by majority, that a method of treatment of the human body which involves a hitherto unknown therapeutic use of a pharmaceutical (having prior therapeutic uses) is a manner of manufacture within the meaning of s 18(1)(a) of the Act: *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* (2013) 103 IPR 217 (“*Sanofi-Aventis* (2013)”). The invention in the present case is not precisely of that character. It is one directed to a method of treatment of the human body involving the administration of a pharmaceutical composition under a hitherto unknown dosage regimen for that composition. However, as a

method of treatment of the human body, the invention as claimed is of the same general character as the invention considered by the High Court.

367 The generic parties expressed a desire to make further submissions, if considered necessary, should the decision in the present appeals be reserved at the time that the High Court delivered its judgment in *Sanofi-Aventis* (2013). In submissions, Apotex expressed its expectation that the High Court judgment would almost certainly bind this Full Court on the point of principle involved, which was whether methods of treatment of the human body are patentable inventions for the purposes of the Act. As events have transpired, none of the generic parties has sought leave to make supplementary submissions following the delivery of the High Court's judgment.

368 At the level of generality at which the relevant point of principle has been expressed, the present case is indistinguishable from that considered by the High Court in *Sanofi-Aventis* (2013). Thus this particular challenge is foreclosed to the generic parties.

369 The second basis was that it was apparent on the face of the specification that the quality of inventiveness for there to be a manner of manufacture within the meaning of s 18(1)(a) of the Act was absent, having regard particularly to the reference in the complete specification of the 051 or low dose patent to the 471 patent and Watanabe.

The primary judge's findings and reasons

370 At trial, the generic parties placed reliance on *N V Philips, Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1998) 194 CLR 171 ("*Advanced Building Systems*") and *Merck*, when advancing the second basis of their challenge.

371 The primary judge found (at [343]) that there was no express statement of incorporation of the 471 patent or Watanabe into the complete specification of the 051 or low dose patent. The primary judge reasoned that the complete specification was, therefore, similar to that considered in *Sanofi-Aventis* (2008). In that connection, the primary judge appears to have accepted AstraZeneca's submission that the 471 patent and Watanabe are referred to in the complete specification briefly, to assist in identifying rosuvastatin rather than to describe the invention. The primary judge concluded (at [344]) that the 471 patent and Watanabe are properly considered to be "external to the specification" and that the conclusion of lack of a manner of manufacture could not be reached.

The parties' submissions on the appeals

- 372 Watson and Ascent submitted that an express statement of incorporation is not required. They submitted – apparently on the basis that the 471 patent and Watanabe had been incorporated into the complete specification of the 051 or low dose patent – that the complete specification, especially page 1, lines 10 to 23, failed to teach any advance over the 471 patent and Watanabe.
- 373 Watson and Ascent also submitted that the primary judge erred by failing to consider “the remaining teaching of the specification”. However, as this submission came to be advanced, “the remaining teaching of the specification” appears to be no more than a reference to the disclosures on page 1, lines 10 to 23 of the complete specification, already addressed by Watson’s and Ascent’s submission noted immediately above.
- 374 Relying on a finding made by the primary judge in respect of the generic parties’ case on obviousness, Watson and Ascent submitted that the primary judge was correct to find that the invention involved nothing more than the identification of a conventional starting dose for a compound within a known class for a known purpose (see [325] of the primary judge’s reasons). They submitted that this reasoning, if applied to a consideration of manner of new manufacture, supports the contention that “there is insufficient newness or inventiveness on the face of the specification”.
- 375 Finally, Watson and Ascent submitted that *Merck* is an analogous case in which the Full Court found that the complete specification disclosed no new substance, no new characteristic of a known substance, no new use and no new method, thereby supporting the conclusion that there was no manner of new manufacture. Watson and Ascent submitted that a similar analysis should be adopted in the present case concerning AstraZeneca’s “nomination” of the 5 to 10 mg dosage of rosuvastatin. They submitted that “such a claim is in the nature of a direction for a known use and not a manner of manufacture”.
- 376 Apotex adopted Watson’s and Ascent’s submissions on this ground. In addition, it submitted that 10 mg is “a conventional dose” and that this fact is disclosed by the clinical trial reported in the complete specification in which atorvastatin was evaluated, along with rosuvastatin, at doses which included a 10 mg dose. Apotex also submitted that the primary judge should have held that the invention claimed in the 051 or low dose patent did not involve a manner of manufacture on a basis similar to that on which her Honour held that another patent under consideration in the case, the HeFH patent, did not involve a manner of manufacture, namely that each of the claims is nothing more than a claim for the use of a known pharmaceutical

substance for a use for which its known properties make it suitable, namely the treatment of hypercholesterolemia in patients with HeFE.

377 AstraZeneca submitted that the primary judge was plainly right to hold that neither the 471 patent nor Watanabe was incorporated into the complete specification of the 051 or low dose patent. AstraZeneca submitted that the decision in *Merck* is distinguishable from the present case.

378 Secondly, AstraZeneca submitted that the “crucial feature of this type of objection” is that it must be apparent on the face of the specification that there is no invention, without reference to “what might be described as external evidence”, including the disclosures in the 471 patent and Watanabe, and the common general knowledge. According to AstraZeneca, it cannot be said that the complete specification “on its face” shows that the invention claimed is not a manner of new manufacture. In this connection, AstraZeneca submitted that, although the complete specification includes the statement that rosuvastatin is useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis, nothing is said about how to administer rosuvastatin in a way that it safe and effective, including the method of administration, dosage range, starting dose or the dosage form that should be used. To the contrary, AstraZeneca submitted, the claimed method of treatment is identified on the face of the specification as something “new”, particularly by the words (at page 1, lines 24 and following) “[s]urprisingly, it has now been found ...”

Consideration

379 In *N V Philips*, the majority in the High Court held (at 663) that the opening words of s 18(1) of the Act (“... a patentable invention is an invention that ...”) imposes a threshold requirement which must be satisfied before reaching the requirement of s 18(1)(a). Further, the majority held that those words refer to “an alleged invention” – that is, an “alleged” “manner of new manufacture” within the meaning of s 6 of the *Statute of Monopolies*. Their Honours said (at 663 to 664) that, notwithstanding an assertion of “newness”, the threshold requirement will:

... remain unsatisfied if it is apparent on the face of the relevant specification that the subject matter of the claim is, by reason of absence of the necessary quality of inventiveness, not a manner of new manufacture for the purposes of the *Statute of Monopolies*. That does not mean that the threshold requirement of “an alleged invention” corresponds with or renders otiose the more specific requirements of novelty and inventive step (when compared with the prior art base) contained in s 18(1)(b). It simply means that, if it is apparent on the face of the specification that the quality of inventiveness necessary for there to be a proper subject of letters patent under the *Statute of Monopolies* is absent, one need go no further ...

380 Although in *N V Philips* special leave to appeal was granted solely to enable the construction of s 18(1)(a) of the Act to be considered, the majority's finding with respect to the existence of a threshold requirement, taken with the conclusions of the primary judge and majority in the Full Court below, meant that the threshold requirement could not be met and that the patent was properly revoked on the ground that the alleged invention was not a "patentable invention". In the event, the proper construction of s 18(1)(a) of the Act did not arise for determination (see at 666).

381 Nevertheless, the majority went on to make the following observations (at 666 to 667):

Strictly speaking, it is unnecessary to answer the question whether a process which could not be a proper subject matter for a patent according to traditional principle, for the reason that it is merely a new use of a known product, can nonetheless be a "manner of manufacture within the meaning of section 6 of the Statute of Monopolies" for the purposes of s 18(1)(a). However, in view of the fact that the argument in this court and the judgments in the Full Court were primarily directed to that question, it is appropriate that we indicate that we consider that the above construction of s 18(1)'s threshold requirement of "an invention" goes a long way towards answering it since it would border upon the irrational if a process which was in fact but a new use of an old substance could be a "patentable invention" under s 18 if, but only if, that fact were not disclosed by the specification. In the context of that construction of s 18(1)'s threshold requirement of an "invention", the preferable conclusion is that the phrase "manner of manufacture within the meaning of section 6 of the Statute of Monopolies" in s 18(1)(a) should be understood as referring to a process which is a proper subject matter of letters patent according to traditional principle.

382 These observations suggest that s 18(1)(a), considered separately from the threshold requirement, has an operation that would deny patentability to a claimed invention that is in truth nothing more than a "new use of an old substance" (properly understood) where that fact is not apparent on the face of the specification. However, the majority did not examine that prospect in any more detail.

383 In *Bristol-Myers*, Black CJ and Lehane J (with whom Finkelstein J at [161] expressed general agreement on these matters) observed (at [27]) that *N V Philips* does not provide a comprehensive answer to the question: by reference to what body of knowledge is inventiveness [under s 18(1)(a), including the threshold requirement] judged? Nevertheless, as Black CJ and Lehane J recognised, the majority in *N V Philips* clearly held that the requirement of inventiveness will not be satisfied where the claims are for nothing more than the use of a known material in the manufacture of known articles for a purpose for which that material's known properties make it suitable.

384 After referring to certain passages from *Commissioner of Patents v Microcell Limited and Others* (1959) 102 CLR 232 (“*Microcell*”) at 250 to 251, Black CJ and Lehane J held (at [30]):

... In our view, in the light of the authorities to which we have referred, *Philips* stands for the proposition (as a matter of construction of the 1990 Act) that if, on the basis of what was known, as revealed on the face of the specification, the invention claimed was obvious or did not involve an inventive step - that is, would be obvious to the hypothetical non-inventive and unimaginative skilled worker in the field (*Minnesota* (at CLR 260) per Barwick CJ) - then the threshold requirement of inventiveness is not met. Some elaboration, however, is required in relation to what the specification reveals as “known”. If a patent application, lodged in Australia, refers to information derived from a number of prior publications referred to in the specification or, generally, to matters which are known, in our view the court — or the Commissioner - would ordinarily proceed upon the basis that the knowledge thus described is, in the language of s 7(2) of the 1990 Act, part of “the common general knowledge as it existed in the patent area”. In other words, what is disclosed in such terms may be taken as an admission to that effect. In substance, we think, that is what happened, both in *Microcell* and in *Philips*. If, however, the body of prior knowledge disclosed by the specification is insufficient to deprive what is claimed of the quality of inventiveness, then the only additional knowledge or information which will be taken into account is knowledge or information of a kind described in s 7(2) of the 1990 Act. That again, in our view, is consistent with the approach taken in *Microcell*. It is also, with respect, the only approach which does not, in practical terms, render s 18(1)(b)(ii) otiose. Of course, once that additional knowledge is taken into account, one is applying s 18(1)(b)(ii), not the opening words of s 18(1) - unless, perhaps, one might apply either, there being, in this respect, no difference between them.

385 It is evident that the same approach to the same ground of invalidity was adopted by the Full Court in *Merck* at [22], [66] and [72] to [75], and in *Novozymes A/S and Another v Danisco A/S and Another* (2013) 99 IPR 417 at [215] and [221] per Jessup J (Greenwood J at [37] and Yates J at [241] agreeing) namely, an assessment of newness and inventiveness by reference only to what is disclosed on the face of the specification.

386 A substantially similar approach has been followed in relation to the corresponding ground of invalidity arising under the 1952 Act: see s 100(1)(d) and *Advanced Building Systems*. In that case, the majority in the High Court gave s 100(1)(d) an operation that was distinct from s 100(1)(e) (obviousness) and s 100(1)(g) (lack of novelty). The majority held (at [33]) that “novelty and obviousness are dealt with specifically and exhaustively in pars (e) and (g)” and (at [40]) that the Full Court below (*Ramset Fasteners (Aust) Pty Ltd v Advanced Building Systems Pty Ltd* (1996) 66 FCR 151) was in error in taking into account matters that could only have arisen under the grounds of obviousness and lack of novelty.

387 The parties did not suggest that we should depart from the Full Court’s approach to applying *N V Philips* in the authorities to which we have referred. Further, as is evident from the

summary above, the generic parties' submissions on the appeals were, in the main, directed to considering the application of s 18(1)(a) of the Act on the basis of what was disclosed on the face of the complete specification of the 051 or low dose patent.

388 In that connection, page 1, lines 10 to 23 of the complete specification, after stating that rosuvastatin is disclosed in the 471 patent and Watanabe, notes the following:

- Rosuvastatin is an inhibitor of HMG-CoA reductase which is a major rate-limiting enzyme in cholesterol biosynthesis.
- Rosuvastatin 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 hypercholesterolemia.
- A number of HMG-CoA reductase inhibitors are marketed 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.
- 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.

389 We are not persuaded that the primary judge was in error in concluding that the 471 patent and Watanabe are not incorporated into the complete specification. Those publications are only referred to in the complete specification as the source of the statement that rosuvastatin has been disclosed as an inhibitor of HMG-CoA reductase that is useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis. That being the case, the generic parties' contention cannot succeed for this reason alone. By way of contrast, the National Cholesterol Education Program – Adult Treatment Panel II target LDL-C levels are expressly and specifically incorporated into the complete specification. However, the fact that these data have been incorporated does not advance the generic parties' case. They say nothing about the dosage range or dosage regimen of the therapeutic agent. Rather, they concern the target levels of LDL-C to be achieved by administration of the agent.

390 In any event, it could make no difference to the fate of this challenge to the validity of the 051 or low dose patent even if the 471 patent and Watanabe were to be taken as incorporated in full into the complete specification. The invention as claimed is directed to methods of treatment of hypercholesterolemia using rosuvastatin or the calcium salt of rosuvastatin under specific dosage regimens. These regimens are not disclosed in the 471 patent or Watanabe. They are only disclosed, for the first time, in the complete specification as “the invention”. The 471 patent gives no more than a broad indicative dosage range which is, in any event, dependent on the disease being treated. Watanabe does not teach a dosage regimen in the treatment of human subjects.

391 Moreover, given what was known, as revealed only by what is stated on the face of the complete specification (including, on this argument, the 471 patent and Watanabe), it could not be said that the invention as claimed was obvious and did not involve an inventive step: *Bristol-Myers* at [30]. The person skilled in the art, on reading the complete specification, and using it as the sole body of information, would understand from the 471 patent and Watanabe, if incorporated in full, that further experimentation would be required to ascertain the appropriate dosage range and dosage regimen for the administration of rosuvastatin or its salts to treat hypercholesterolemia.

392 Further in this connection, the generic parties rely on the primary judge’s findings on the question of obviousness. They contend that if the same reasoning were to be applied when considering the present challenge to validity, then “there is insufficient newness or inventiveness on the face of the specification”. The difficulty with this contention is that “the same reasoning” takes into account the common general knowledge and, thus, cannot apply in relation to this ground. As the authorities referred to above make clear, the present challenge to validity can only be based on what the complete specification itself discloses.

393 Finally, the present case is clearly distinguishable from that in *Merck*, where it was found that two prior art documents (referred to as “Strein” and “Goodship”) were incorporated in the specification there under consideration. The Full Court in *Merck* (at [62]) observed:

When Strein and Goodship are read as part of the Patent specification, the available ground for the currently claimed invention is significantly narrowed. Strein teaches weekly administration of effective amounts of alendronate for the treatment of osteoporosis, an advantage being reduced GI side effects. By analogy to the treatment of osteoporosis, Goodship teaches weekly administration of alendronate in therapeutically effective amounts for treatment of prosthesis loosening and prosthesis migration. The range of dosages includes those identified in the Patent claims. All that can be said of the Patent, as against Strein, is that the former does not teach rest periods.

As against Goodship, the Patent additionally teaches use of alendronate for the treatment of osteoporosis (which the Goodship application assumes) and expressly identifies the advantages of weekly, over daily, dosing. The question is whether the Patent specification (including Strein and Goodship), on its proper construction, demonstrates a claim for a manner of new manufacture for the purposes of s 6 of the Statute of Monopolies. The meaning of that expression emerges from the cases.

394 Later, the Full Court concluded (at [75]):

At the most, it might be said, in the words of the Lord Chancellor in *Windover*, that Merck, by applying well-known and well-understood things to an analogous case, achieved advantages not previously thought of or practised. In the words of Lord Herschell in the same case, Merck saw or realized advantages inherent in an existing substance and practice. However this may be too generous, given Strein and Goodship. The claims in the Patent are analogous to the use of alendronate as taught in those documents. The Patent specification discloses no new substance, no new characteristic of a known substance, no new use and no new method. There is, therefore, no manner of new manufacture.

395 In the present case, the disclosures of the 471 patent and Watanabe are plainly different from, and fundamentally more limited than, the disclosures of Strein and Goodship in *Merck*, which taught specific dosage regimens in the treatment of humans using the agent in question (alendronate) closely corresponding to the claims in suit, such as to reveal, in truth, no more than an analogous method of administration.

396 For these reasons, we are of the view that the generic parties' challenge to the 051 or low dose patent on this ground should be rejected.

MANNER OF MANUFACTURE: 842 OR CATION PATENT

397 It is convenient to repeat, for ease of exposition, certain passages in the complete specification of the 842 or cation patent.

398 The complete specification discloses that a problem associated with rosuvastatin is that it is particularly sensitive to degradation under certain conditions. The major degradation products are a lactone and an oxidation product. The complete specification discloses that the potential for significant degradation makes it difficult to formulate a pharmaceutical composition containing rosuvastatin with acceptable storage life for a marketed product. The inventors found that it was not sufficient to improve stability by solely controlling pH in the formulation. They found that the stability of rosuvastatin is improved by adding to the pharmaceutical composition a selected inorganic salt containing one or more multivalent inorganic cations.

399 The complete specification states:

The pharmaceutical composition of the invention may be prepared, using standard techniques and manufacturing processes generally known in the art, for example by dry blending the components. For example, the Agent and an inorganic salt in which the cation is multivalent, one or more fillers, one or more binders and one or more disintegrants, as well as other additional excipients if desired are blended together. The components of the blend prior to blending, or the blend itself may be passed through a mesh screen, for example a 400-700 μm mesh screen. A lubricant, which may also be screened, is then added to the blend and blending continued until a homogeneous mixture is obtained. The mixture is then compressed into tablets. Alternatively, a wet granulation technique can be employed. For example, the Agent and an inorganic salt in which the cation is multivalent, one or more fillers, one or more binders and a portion of a disintegrant, as well as other additional excipients if desired, are blended together, for example by using a granulator, and the powder blend is granulated with a small volume of purified water. The granulate is dried and passed through [sic] a mill. The remainder of the disintegrant and a lubricant are added to the milled granulation and after blending the resultant homogeneous mixture is compressed into tablets. It will be appreciated that modifications of the dry blending and wet granulation techniques, including the order of addition of the components and their screening and blending prior to compression into tablets, may be carried out according to principles well known in the art.

400 This disclosure is followed by the following passage on which the generic parties place particular emphasis:

A tablet coating may then be applied, for example by spray-coating with a water-based film coating formulation. The coating may comprise, for example, lactose, hydroxypropyl methylcellulose, triacetin, titanium dioxide and ferric oxides. Coating ingredient combinations are commercially available, such as those described in the Examples hereinafter. The coating may comprise, for example, 0.5 to 10% by weight of the tablet composition, particularly 1 to 6%, and preferably 2 to 3%. Coatings containing ferric oxides are especially preferred as they reduce the rate of formation of photodegradation products of the Agent.

401 For completeness, the complete specification then states:

Accordingly we present as a feature of the invention a pharmaceutical composition comprising the Agent, the composition having a ferric oxide light protective coating.

402 The complete specification discloses that in Example 2 compressed tablets were formed from a particular pharmaceutical composition containing rosuvastatin. The tablets were then coated with a mixture, sold commercially as Spectrablend™, which contained ferric oxide and titanium dioxide. In Example 3, the compressed tablets were formed from a different composition containing rosuvastatin. These tablets were then coated with a mixture, sold as Opadry II™, which also contained ferric oxide.

The primary judge's findings and reasons

403 At trial, the generic parties advanced a submission to the effect that if, as the primary judge ultimately found, the claims of the 842 or cation patent encompass a pharmaceutical composition in which rosuvastatin is coated with commonly available coatings, such as Spectrablend™ or Opadry™, then, on the face of the specification, the invention as claimed is not a manner of new manufacture. They submitted that it is not an invention to take a known substance (rosuvastatin) and apply to it (that is, tablets containing rosuvastatin) a known pharmaceutical tablet coating.

404 The primary judge rejected that submission. The primary judge accepted (at [462]) AstraZeneca's submission that the complete specification of the 842 or cation patent:

... does not admit or disclose on its face that it was known, before the priority date, that such coatings could be used to address the stability issues with rosuvastatin which are discussed in the specification.

The parties' submissions on the appeals

405 Apotex relied on the aphorism that "a [mere] new use of an old substance" is not an invention. It submitted that, insofar as the claims of the 842 or cation patent include the use of a coating containing ferric oxide on a tablet, it is clear on the face of the complete specification that the claimed invention does not involve a manner of new manufacture because using a coating containing ferric oxide is a known substance being used for precisely the same purpose for which the "utility of the substance is already known" (that is, coating a tablet). It can be seen that this submission focuses on the use of ferric oxide coatings as stabilisers.

406 Watson and Ascent made a submission to similar effect. They submitted that there is no need to identify an express admission on the face of the specification that there is no invention. Rather, in their submission, it is sufficient that the specification shows in fact that the alleged invention is not new and inventive, even if there is a promise or assertion to the contrary. They submitted that it is not an invention to apply a commercially available coating known to protect against light, moisture and oxygen. Similarly, they submitted that it is not an invention to claim a known substance (rosuvastatin) with a known coating. They submitted that the use of the known coating in the present case is analogous to the use of known reinforced plastic material referred to in *Microcell*.

407 AstraZeneca submitted that, although the complete specification discloses the commercial coatings identified above, the invention claimed is a combination comprising rosuvastatin or a

pharmaceutically acceptable salt thereof and an inorganic salt in which the cation is multivalent. The complete specification does not admit or disclose that the combination is not new or inventive. The passage in the complete specification on page 6, lines 6 to 13, which refers to the commercial availability of coatings (see [400] above) does not admit or disclose on its face that it was known before the priority date that they could be combined with rosuvastatin to address the issue of stability discussed in the specification.

Consideration

408 In our respectful view, the primary judge was correct to conclude that the complete specification of the 842 or cation patent does not admit or disclose on its face that it was known, before the priority date, that the disclosed commercial coatings, containing ferric oxide, could be used to address the stability issues that are discussed in the specification.

409 Importantly in this regard, it is not admitted or disclosed that it was known that rosuvastatin was particularly sensitive to degradation or, indeed, sensitive to degradation of the particular kind described. The fact that rosuvastatin was sensitive to degradation of that particular kind appears to be a disclosure made by the complete specification itself. Here the complete specification is not merely reporting on an antecedent disclosure made by others. The position is far removed from that in *Microcell*.

410 Further, the invention as claimed is not a method of stabilising pharmaceutical compositions by the use of known tablet coatings. Rather, the invention as claimed is directed to pharmaceutical compositions containing rosuvastatin, the use of inorganic salts with multivalent cations to stabilise rosuvastatin and its pharmaceutically acceptable salts, and methods of producing a stabilised pharmaceutical composition containing rosuvastatin or its pharmaceutically acceptable salts.

411 The product claims were the focus of the submissions advanced on the appeals. Plainly, those claims were directed to specific combinations involving rosuvastatin and its pharmaceutically acceptable salts. The passage in the complete specification on which the generic parties place significant reliance (see [400] above) does not admit or disclose that it was known that, for example, ferric oxide could be used in pharmaceutical compositions containing rosuvastatin or its pharmaceutically acceptable salts to successfully overcome a known stability problem with rosuvastatin. That passage is, in fact, part of the description of the invention itself. It cannot be used by the generic parties to argue that the patentee has “recited himself out of Court”:

Chapman and Cook and Lectro Linx Ltd v Deltavis Ltd (1930) 47 RPC 163 at 173, quoted in *Doric No 2* at [106].

412 For these reasons, we are of the view that the generic parties' challenge to the 842 or cation patent on this ground should be rejected.

FAIR BASIS: 842 OR CATION PATENT

413 We have previously rejected the generic parties' appeals against the primary judge's finding that the claims of the 842 or cation patent, properly construed, are broad enough to encompass a pharmaceutical composition in which the relevant inorganic salt is present only as a coating. Before the primary judge the generic parties contended that, so construed, the claims of the 842 or cation patent lack fair basis and are therefore invalid for lack of compliance with s 40(3) of the Act ("[t]he claim or claims must be ... fairly based on the matter described in the specification") as it stood prior to amendment by the Raising the Bar Act. Her Honour rejected this challenge to the validity of the claims of the 842 or cation patent.

414 In fact, the primary judge at [463] to [468] of her reasons rejected a number of different contentions as to why the claims of the 842 or cation patent lacked fair basis. However, the only such contention that the generic parties still press is that recorded at [463] of the primary judge's reasons which was:

The only real and reasonably clear disclosure is of the inorganic salt and the rosuvastatin being mixed or blended together in the pharmaceutical composition. There is no disclosure whatsoever of a formulation in which the inorganic salt is a component of the coating only ... Accordingly, if the claims are broad enough to include a pharmaceutical composition in which the inorganic salt is only in the coating, then the claims are not fairly based on the specification.

The primary judge rejected this contention at [465] on the basis that it:

... [d]epends on construing the specification as if it limited relevant pharmaceutical compositions to those in which the inorganic salt is present in the tablet core when, as discussed in the context of the construction issues above, this limitation is not apparent from the specification.

Her Honour's reference in this paragraph to her previous discussion of construction issues is to [239] to [266] of her reasons. It is there that her Honour explains why claim 1, in referring to a pharmaceutical composition comprising rosuvastatin and a relevant inorganic salt, includes

such pharmaceutical composition “in any form” including a tablet made from rosuvastatin coated with a relevant inorganic salt.

415 The generic parties submitted that the primary judge erred in rejecting their contention. They submitted that her Honour failed to consider whether there was a disclosure, as an invention, of a pharmaceutical composition where the relevant inorganic salt is not mixed with the rosuvastatin but is present only in a coating. They submitted that, contrary to her Honour’s finding, none of the claims of the 842 or cation patent was fairly based because there is no real and reasonably clear disclosure in the specification of a pharmaceutical composition in which the relevant inorganic salt is not mixed with the active ingredient, but is instead contained solely within the coating of the pharmaceutical composition.

416 The generic parties also submitted that every disclosure in the 842 or cation patent of the use of a relevant inorganic salt with a multivalent cation, including in each of the Examples, involves the salt being mixed or blended with rosuvastatin. They further submitted that the only theory advanced in the specification to explain how the multivalent cation improves the stability of rosuvastatin is that it stabilises its structure, which the experts’ evidence confirmed required intimate mixing. On the appeals, AstraZeneca did not dispute the correctness of either of these propositions. Rather, it placed reliance upon the consistory clause in the specification, the relevant language of which mirrors the language of claim 1.

417 Thus, while the generic parties contended that the consistory clause was insufficient to provide fair basis for claim 1 and (in this particular respect) its dependent claims, AstraZeneca submitted that the consistory clause was itself sufficient for this purpose, relying on statements in *Doric No 1* at [38] and [91] to [93].

418 The test for fair basis that should be applied under s 40(3) of the Act was explained by the High Court in *Doric No 1* at [68] to [69] as follows:

... The comparison which s 40(3) calls for is not analogous to that between a claim and an alleged anticipation or infringement. It is wrong to employ “an over meticulous verbal analysis”. It is wrong to seek to isolate in the body of the specification “essential integers” or “essential features” of an alleged invention and to ask whether they correspond with the essential integers of the claim in question.

... Section 40(3) requires, in Fullagar J’s words, “a real and reasonably clear disclosure”. But those words, when used in connection with s 40(3), do not limit disclosures to preferred embodiments.

“The circumstance that something is a requirement for the best method of performing an invention does not make it necessarily a requirement for all

claims; likewise, the circumstance that material is part of the description of the invention does not mean that it must be included as an integer of each claim. Rather, the question is whether there is a real and reasonably clear disclosure in the body of the specification of what is then claimed, so that the alleged invention as claimed is broadly, that is to say in a general sense, described in the body of the specification.”

Fullagar J’s phrase serves the function of compelling attention to the construction of the specification as a whole, putting aside particular parts which, although in isolation they might appear to point against the “real” disclosure, are in truth only loose or stray remarks.

(Footnotes omitted).

In that case the High Court held (at [38]) that there was nothing in the body of the specification to suggest that the description of the invention to be found in the consistory clause was wider than the invention actually was. The consistory clause was held to provide fair basis for the invention claimed. However, the High Court went on to acknowledge (at [87]) that “to couch a claim ‘in the same terms as the description of the invention in the specification’ did not of itself, by that mere ‘coincidence of language’, establish fair basing”. Their Honours added:

A ‘coincidence of language’ between a claim and part of the body of a specification does not establish fair basing if that part of the language of the specification does not reflect the description of the invention in the light of the specification as a whole.

The High Court also observed (at [91]) that the requirements of s 40(3) would only be satisfied by the inclusion of a consistory clause if the specification, when read as a whole, corresponded with the consistory clause.

419 We are mindful that it is customary for the consistory clause to describe the invention in its broadest form and that a consistory clause may provide fair basis for a claim that uses the same language. We are also mindful that, in the case of the 842 or cation patent, the Examples given in the specification are merely examples of the invention described, and are not intended to be exhaustive or to traverse the full scope of the claims. However, it is our view that the specification, when read as a whole, describes an invention consisting of a pharmaceutical composition the active ingredient of which has been mixed or blended with certain inorganic salts. The specification does not suggest that the pharmaceutical composition of the invention might not consist of such a mixture or blend or that it might be prepared otherwise than by mixing or blending the active ingredient with the relevant inorganic salt.

420 It is true that the specification makes reference to coatings that may be applied to tablets. These coatings include ferric oxide and titanium dioxide both of which are inorganic salts (at least in the context of the 842 or cation patent) in which the cation is multivalent and the counter anion is not a phosphate. But these coatings are described in the specification in terms that make it clear that they are intended to provide an optional protective coating for tablets prepared with the relevant mixture of active ingredient and inorganic salt.

421 In our respectful opinion, the primary judge took an unduly narrow approach to the question of fair basis. The answer to the question whether the claims of the 842 or cation patent are fairly based does not depend upon whether one construes the specification as if it is limited to those pharmaceutical compositions in which the inorganic salt is present in the tablet core. The difficulty with framing the question in that way is that it merely brings one back to the question of what the expression “pharmaceutical composition” as used in both the claims and the specification means. This in turn brings one back to the consistency clause and the question whether the description of the invention in the specification, read as a whole, corresponds with the consistency clause. The question that must be addressed is whether there is a real and reasonably clear disclosure in the specification of an invention in which there might be no mixture of the active ingredient and inorganic salt. In our opinion, the specification, when read as a whole, does not make any such disclosure even in the most general sense.

422 We would therefore uphold the generic parties’ contention that the claims of the 842 or cation patent are invalid for lack of fair basis.

INFRINGEMENT: SECTION 117 OF THE ACT

423 Section 117 of the Act provides:

Infringement by supply of products

- (1) If the use of a product by a person would infringe a patent, the supply of that product by one person to another is an infringement of the patent by the supplier unless the supplier is the patentee or licensee of the patent.
- (2) A reference in subsection (1) to the use of a product by a person is a reference to:
 - (a) if the product is capable of only one reasonable use, having regard to its nature or design—that use; or
 - (b) if the product is not a staple commercial product—any use of the product, if the supplier had reason to believe that the person would put it to that use; or

- (c) in any case—the use of the product in accordance with any instructions for the use of the product, or any inducement to use the product, given to the person by the supplier or contained in an advertisement published by or with the authority of the supplier.

The word “supply” is defined in Sch 1 of the Act to include (*inter alia*) supply by way of sale and offer to supply by way of sale.

424 At trial AstraZeneca relied upon s 117 of the Act to establish that the supply by the generic parties of 5 mg, 10 mg, 20 mg and 40 mg dosages of rosuvastatin would constitute an infringement of the claims of the 051 or low dose patent. On the assumption that those claims were valid, the primary judge found for AstraZeneca in relation to the 5 mg and 10 mg dosages, but not the 20 mg and 40 mg dosages.

425 The primary judge considered and rejected an argument raised by AstraZeneca based upon s 117(2)(a) of the Act. That aspect of her Honour’s decision is not in issue in the appeals. What remains is a challenge to various findings made by the primary judge in relation to s 117(2)(b) and s 117(2)(c) of the Act. AstraZeneca has appealed against the primary judge’s rejection of the infringement case under s 117(2)(b) and (c) based upon the supply of the 20 mg dosage but has not appealed against her Honour’s rejection of the case based upon the supply of the 40 mg dosage.

426 As to s 117(2)(c), the primary judge rejected a submission by AstraZeneca founded upon the Watson product information document which included an express statement that “[t]he 10, 20 and 40 mg tablets can be divided into equal halves”. AstraZeneca contended this constituted an inducement to use their 20 mg and 40 mg products by splitting the tablets into two and four parts respectively so that they might then be taken as 10 mg dosages in a manner that would infringe one or more of the claims. The primary judge rejected this argument at [510] for the following reason:

... Despite the reference to the tablets being able to be divided in the Watson and Ascent product information, on the whole of the evidence, including the proposed communications with medical practitioners and pharmacists, it cannot be said that the generic parties will instruct or induce any person to split a 20 or 40 mg tablet into two or four.

427 We should say at once that, in our view, the Watson product information document provided a clear inducement to consumers of its 20 mg dosage product to engage in tablet splitting. Had we been of the opinion that the claims of the 051 or low dose patent were valid, we would have

found Watson (but not the other respondents) liable for infringement under s 117(1) when read with s 117(2)(c) of the Act. We respectfully disagree with the primary judge in so far as she was of a different opinion.

428 The generic parties also submitted to the primary judge, and again on the appeals, that s 117(2)(b) could have no application in this case because rosuvastatin is a “staple commercial product”. In support of this submission, they relied on the decision of the High Court in *Northern Territory of Australia v Collins and Another* (2008) 235 CLR 619 (“*Collins*”). The primary judge recorded the generic parties’ submission in these terms (at [502]):

The generic parties contend that rosuvastatin is a staple commercial product. Rosuvastatin, on the evidence, is “used to treat various different conditions or for other effects including (i) pleomorphic (anti-inflammatory) effects to reduce the incidence of plaque rupture and heart attacks; (ii) treatment of diabetes; (iii) treatment of stroke; (iv) treatment of chronic renal disease; and (v) coronary artery disease or peripheral vascular disease”. Further, the “most common group of patients seen by Dr Wilson appear not to be hypercholesterolemia patients but those requiring secondary prevention such [as] patients with coronary artery disease or peripheral vascular disease and diabetes independent of their cholesterol level”. As rosuvastatin can be used in various non-infringing ways, it is a staple commercial product by analogy to the reasoning in *Northern Territory v Collins* [citation omitted].

Her Honour was not persuaded that rosuvastatin is a staple commercial product. She said (at [511]):

Despite the fact that I accept that rosuvastatin has a number of medical uses, not just the treatment of hypercholesterolemia, I cannot accept that it should be characterised as a “staple commercial product”. The difficulty I have arises from the word “staple”, which does indicate something more than merely a “commercial product”. The reasoning in *Collins* does not lead me to the view that the fact that a product can be used in one or even a number of non-infringing ways is itself sufficient to make the product a staple commercial product. While “staple” is not concerned with the economic significance of uses, it is concerned with the variety of uses. The variety of uses in this case is confined by the nature of the product to a limited class, being the treatment of diseases of a particular kind or class (albeit different diseases) in humans. Rosuvastatin, despite its usefulness for a variety of disease conditions, is not able to be compared to timber (as in *Collins*) or, for example, types of pharmaceutical products which might be useful for many human conditions. It is for these reasons I conclude that the rosuvastatin products proposed to be supplied by the generic parties are not staple commercial products.

429 In argument before us, the generic parties placed considerable reliance on the judgment of Crennan J in *Collins* at [145]. Her Honour said that the phrase “staple commercial product” means “a product supplied commercially for various uses.” Hayne J (at [41]) and Heydon J (at [57]) agreed. However, Crennan J’s statement must be read in its proper context including the

factual setting in which it came to be made. *Collins* involved the supply of a species of timber which Crennan J acknowledged at [143] to [144] constituted “[a] basic product commonly used for various purposes.”

430 Whether a product meets that description is a question of fact. Considerations relevant to the question whether a product is a staple commercial product include how widely the product is used and for what range of purposes. In a passage in Thorley S, Miller R, Burkill G, Birss C and Campbell D, *Terrell on the Law of Patents* (16th ed, Thomson Sweet & Maxwell, 2006) at [8-37] referred to in a footnote to Crennan J’s judgment at [144] the learned authors, referring to the use of the expression “staple commercial product” in s 60(3) of the *Patents Act 1977* (UK), state:

The use of the word “staple” is presumably a reference to raw materials or other basic products commonly available and with a multitude of possible applications, and the purpose of the subsection is to protect the supplier of such products even if he has knowledge that they are to be put to an infringing purpose. The scope of the words is far from clear and the dividing line between protecting the supplier of raw materials on the one hand and giving a fair monopoly to the patentee must be a question of fact in each case.

The authors of the IPAC report referred (at paragraph 14.2) to the undesirability of preventing a person from selling “a staple commodity with a wide variety of possible uses” suggesting that they also considered that a staple commodity was one that had a wide range of uses.

431 We are not satisfied that rosuvastatin is a staple commercial product. The fact that it may be used for both infringing and non-infringing purposes is not conclusive. There are many products capable of being used for both infringing and non-infringing purposes that cannot be characterised as either raw materials or basic products commonly used for a variety of purposes. The uses to which rosuvastatin may be put appear to us to be limited to the prevention or treatment of cardiovascular disease and its associated risk factors (e.g., high cholesterol). This is apparent from the evidence of Dr Wilson, a cardiologist called by AstraZeneca, who said that he does not prescribe rosuvastatin (or any other statin) for any indication other than cardiovascular disease or its associated risk factors. It is true that Dr Hay, a general practitioner called by AstraZeneca, gave evidence that he also prescribes rosuvastatin for the treatment of conditions such as cerebrovascular disease, chronic renal disease and diabetes. However, as we read his evidence, rosuvastatin is prescribed by Dr Hay in order to prevent or treat cardiovascular disease in situations where there is increased risk of it occurring due to the existence of these conditions.

432 Although the primary judge was not satisfied that rosuvastatin is a staple commercial product, AstraZeneca's argument based on s 117(2)(b) was rejected by her Honour on other grounds. Her Honour said (at [512]):

I do not accept that s 117(1) and (2)(b) requires AZ to prove that any particular person will split a 20 mg tablet into two 10 mg doses. In the present case the evidence is sufficient to infer that whatever the instructions the generic parties give to medical practitioners and pharmacists there remains a risk that some people will obtain the 20 mg dose of the generic tablets for the purpose of dividing them into two 10 mg doses. Risk, however, is one thing. Proof on the balance of probabilities that any person "would" infringe the 051 or low dose patent is another. Given the steps proposed by the generic parties to instruct medical practitioners and pharmacists not to endorse or encourage tablet splitting, it is a long stretch on the currently available evidence to conclude that any person would split the tablets into 10 mg doses and thereby infringe the patent. I accept that AZ has proved a real risk that it might occur, given the economic incentives. But in terms of proof that is insufficient.

433 Her Honour's rejection of the first of the arguments referred to in [512] of her reasons was challenged in the generic parties' notices of contention but the point was not developed in submissions. In any event, the primary judge was right to reject it. Section 117 owes its existence, in large part, to the difficulties that patentees are likely to experience in enforcing their rights against consumers at the end of a supply chain who engage in infringing use of products supplied to them by others. The inability of the patentee to identify the particular person or persons who engage in such use is one of the very difficulties confronting patentees that s 117 was intended to ameliorate (see the IPAC report at paragraph 14.2). It is not necessary for a patentee to succeed under s 117 that he or she identify any particular person or persons who the supplier has reason to believe will use the product in question in an infringing manner.

434 The second argument relied upon by the generic parties in relation to s 117(2)(b), which was accepted by the primary judge, raises what is primarily a question of fact. In short, the primary judge was not satisfied, on the evidence, that any of the generic parties had reason to believe that consumers would engage in tablet splitting and use the generic parties' 20 mg or 40 mg products in a manner that would infringe the claims of the 051 or low dose patent.

435 So far as the economic incentive to engage in tablet splitting is concerned, the evidence showed that AstraZeneca's rosuvastatin product (whether it is in 5 mg, 10 mg or 20 mg dosages) comes in the same size pack and (at least for patients with PBS prescriptions) at the same price. This means that a patient who is directed by a doctor to take 10 mg dosages will have a financial incentive to purchase a pack of 20 mg tablets which he or she may then split into 10 mg dosages.

436 There was evidence from Mr Sanghvi, a pharmacist from Melbourne called by AstraZeneca, as to the widespread availability of “tablet splitting” devices used by patients in relation to many different kinds of prescription medicines. There was also evidence from Dr Wilson who said he was aware that some of his patients split their statin tablets. He said that he regularly agrees to requests from patients to prescribe a higher dosage of statin to permit them to engage in tablet splitting in order to save money. Dr Hay also gave evidence to much the same effect, although he was more specific in his evidence as to his prescribing practices in such situations than was Dr Wilson. Dr Hay said that if he wanted to prescribe a 10 mg dose of rosuvastatin to a patient who wants to split tablets (to save money) he would always write “20 mg, take half a tablet” on the script.

437 Market research data relied upon by AstraZeneca indicated that only a small percentage (2.75%) of prescriptions written by medical practitioners directed patients to take half a 20 mg tablet. AstraZeneca submitted that there are likely to be more patients who engage in tablet splitting who do so in circumstances where there is no relevant direction on their prescription. However, this submission is not supported by the evidence. It seems doubtful that doctors would prescribe rosuvastatin in 20 mg tablets to a patient who was to be treated in 10 mg dosages without taking the same precautions taken by Dr Hay. One can see why a doctor would feel the need to guard against the patient taking more than the prescribed dosage by making it clear on the prescription that the patient was to take half a tablet in order to ensure the patient received the correct dosage.

438 On the primary judge’s analysis of the evidence, AstraZeneca established that the generic parties were aware (or, objectively, should have been aware) that there was a risk that consumers would split the generic parties’ 20 mg tablets in order to save money. However, her Honour stopped short of holding that they had reason to believe that consumers would engage in such a practice.

439 It is difficult to draw any precise conclusions as to how widespread the practice of 20 mg tablet splitting might become (at the time of trial the generic parties’ products were not yet on sale) without knowing what developments might occur in the market place with respect to the pricing of both the generic parties’ 20 mg products and AstraZeneca’s 10 mg product. The more AstraZeneca’s 10 mg product costs relative to the generic parties’ 20 mg products, the more likely it is that consumers would buy and split the generic parties’ 20 mg products. However, in our view, contrary to the finding of the primary judge, the evidence established that the

generic parties had reason to believe that some consumers would put the generic parties' 20 mg products to an infringing use.

440 Section 117(2)(b) raises a special problem that was referred to by Hayne J in *Collins* (at [41] to [51]) in the context of his Honour's consideration of the meaning of the phrase "staple commercial product". His Honour drew attention to the potentially wide operation of s 117(1) when read with s 117(2)(b) in circumstances where the relevant product is one that may be used for both infringing and non-infringing uses. The facts of the present case highlight one aspect of the problem referred to by Hayne J.

441 It is important to note that the relief sought by AstraZeneca in respect of the 051 or low dose patent included a *quia timet* injunction that would have the effect of restraining the supply by the generic parties of their 20 mg rosuvastatin products to any person (in particular wholesalers and/or pharmacists) through whose hands such products may pass on their way to consumers including, but not limited to, the relatively small proportion of such consumers who the generic parties have reason to believe would engage in infringing use.

442 Section 117(2)(b) uses the expression "the person" which is the same person referred to in the opening words of s 117(1), viz "[i]f the use of a product by *a person* would infringe a patent". Section 117(1) when read with 117(2)(b) is therefore only engaged if the supplier has reason to believe that *the person* to whom the product is or may be supplied would put it to an infringing use. As we have said, it is not necessary for the patentee to identify any particular person or persons in order to successfully rely upon s 117(1) when read with s 117(2)(a), (b) or (c). But the application of s 117(1) when read with s 117(2)(b) may be particularly challenging for a patentee both in establishing an actual or threatened supply to which s 117(1) can apply and in fashioning appropriate injunctive relief in circumstances where there are many users of the product only some of whom are likely to put the product to an infringing use.

443 The first difficulty arises out of the fact that s 117(1) and s 117(2)(b) deem a supply of a product to be an infringement of a patent if, but only if, the supplier has reason to believe that *the person* to whom the product is or may be supplied will put it to an infringing use. It is not easy to apply s 117(1) and s 117(2)(b) literally in circumstances involving the supply of product in large quantities for use by a large number of consumers where the first supplier in the relevant supply chain has reason to believe that some, but not all, of the consumers to whom the product might ultimately be supplied will put it to an infringing use. If s 117(1) is engaged in such

circumstances then some consideration of proportionality as between the extent of the infringing use that is forecast and the scope of any injunctive relief is warranted.

444 It may be undesirable to impose a blanket restraint upon a supplier who has reason to believe that only some consumers, perhaps a very small minority, may put the product that is or may be supplied to them to an infringing use. This is because the effect of such an injunction may be to deny a supplier access to a market, and consumers' access to a product, in circumstances where the supplier could have no reason to believe that the majority of consumers would put the product to an infringing use. It seems to us that, all other things being equal, the more difficult it is for the patentee to establish that there is a likelihood of widespread infringing use, the more difficult it should be for the patentee to obtain injunctive relief in the broad terms restraining *any* supply of the relevant product. In the present case, even if AstraZeneca established that the generic parties had reason to believe that some consumers would engage in infringing use, the likely scale of that activity, were it to occur, was not shown to be such as would justify the grant of the wide injunction that AstraZeneca sought. Given our conclusion in relation to the validity of claims of the 051 or low dose patent, it is not necessary for us to consider what other injunctive relief, if any, might have been appropriate in lieu of that sought by AstraZeneca.

CONCLUSIONS

445 Each appeal must be dismissed. As we have said, we will receive in evidence, on the interlocutory application in each appeal, the affidavit of Mr Fisher and the affidavit of Mr Sands. However, each interlocutory application must be dismissed with costs.

446 As to the costs of the appeals, we note that the appellants have succeeded on two important issues in the appeals, namely, starting point and novelty in relation to the 051 or low dose patent. That would not necessarily be reflected in the order for costs where the order of the Court is that an appeal be dismissed. However, in this case the generic parties filed notices of contention which raised substantial issues. For the most part, they were unsuccessful in relation to these issues. We think that circumstance should be reflected in the order we make as to costs. We think one order is appropriate so as to avoid the complexity and time associated with linking the assessment of costs to particular issues. We have had regard to the way in which the appeals and notices of contention were argued before us and the extensive written outlines. We think the appropriate order in each appeal is that the appellants pay the respondent 80% of its costs of the appeal.

JESSUP J:

447 The reasons which follow deal only with so much of the present appeals as relates to the matter of obviousness. In other respects I agree with the reasons of Besanko, Foster, Nicholas and Yates JJ. I agree that the orders proposed by their Honours should be made.

THE SETTING

448 A ground upon which the primary judge held that each of the 051 patent and the 842 patent ought to be revoked under s 138 of the *Patents Act 1990* (Cth) (“the Patents Act”) was that for which para (b) of subs (3) provides, namely, that the invention was not a patentable invention. A respect in which her Honour held that each invention was not patentable was its failure to comply with one of the requirements set out in s 18(1)(b)(ii), namely, that –

... the invention, so far as claimed in any claim:

...
(b) when compared with the prior art base as it existed before the priority date of that claim:

...
(ii) involves an inventive step

449 Whether an invention, so far as claimed in any claim, complies with s 18(1)(b)(ii) is to be determined by reference to subss (2) and (3) of s 7, the relevant version of which, as the primary judge noted, is as follows:

(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.

450 In the application of these provisions to the circumstances of the 051 patent and the 842 patent there were three broad areas of controversy before the primary judge, and they remain contentious in the present appeal. Fundamental to each was the circumstance that neither patent was for the invention of rosuvastatin as such: the 051 patent was for a method of treating hypercholesterolemia by the use of rosuvastatin in certain doses and the 842 patent was for a pharmaceutical composition for the administration of rosuvastatin. In each case, however, rosuvastatin was an integer of the claims held by her Honour to be invalid. Further, at the priority date for the 051 patent, and at the earliest of three possible priority dates for the 842 patent, rosuvastatin was not part of the common general knowledge.

451 The first area of controversy involved what was essentially an issue of the construction of s 7(2) of the Patents Act. The respondents submitted that the comparison mandated by s 7(2) was between the prior art base on the one hand and the claimed invention on the other hand. Rosuvastatin as an entity was part of the prior art base, and was thus included in the range of information and artefacts against which the invention had to be compared. Common general knowledge, by contrast, was the skilled person's notional intellectual equipment and general understanding of the relevant area of discourse which enabled him or her to carry out the comparison required. Thus the fact that an item in the prior art base was not part of the common general knowledge was not disqualifying under s 7(2). Reference to such an item was, on the respondents' case, not to be confused with the permissibility of referring to a single additional source under s 7(3): the latter was to complement the notional skilled person's common general knowledge. The respondents' submission was rejected by the primary judge. That rejection is now challenged by way of a notice of contention filed on behalf of each of the respondents.

452 The second area of controversy related to what the primary judge described as the characterisation of the invention for the purposes of considering the matter of obviousness. That is to say, what was "the invention" as the term was used in s 7(2) of the Patents Act? The respondents submitted, and her Honour accepted, that it was necessary to discern from the terms of the specification as a whole what it was that the inventor had in fact invented, and, in the present case, that did not include rosuvastatin. Rosuvastatin was treated as a given, and was thus the "starting point" for the purposes of s 7(2). On the other hand, the appellants submitted, and submit on appeal, that that the result of this approach would be, and was as the case was decided below, that the inventions were measured against something that was not within the common general knowledge; and, moreover, that an entity which had been claimed

by the inventor (rosuvastatin) was excised from the relevant claim for the purpose of making the comparison which s 7(2) required.

453 The third area of controversy arose if the appellants were successful in their challenge to her Honour's decision to the extent that it involved the primary operation of s 7(2). In such an event, the appellants would still need to deal with the finding which her Honour made that, when the additional item of prior art brought in under subs (3) is considered, the invention under the 051 patent should be held to have been obvious at the relevant priority date. As I shall explain below, no such problem is now encountered by the appellants in relation to the 842 patent.

THE COMPARATOR ISSUE UNDER s 7(2)

454 It is convenient to commence with the point raised on the respondents' notices of contention. The point was said to be consistent with long-established principles of patent law. I would not accept that submission. Under s 100(1)(e) of the *Patents Act 1952* (Cth) ("the 1952 Act"), a ground of revocation was –

... that the invention, so far as claimed in any claim of the complete specification ... 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

In *Minnesota Mining and Manufacturing Company v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 ("*Minnesota Mining*"), Aickin J (with the assent of the other members of the court) held that the judgment of Williams J in *HPM Industries Pty Ltd v Gerard Industries Ltd* (1957) 98 CLR 424, to the effect that the 1952 Act had changed the pre-existing law insofar as the expression "known or used" permitted recourse to prior art which was not part of the common general knowledge, did not correctly state the position (144 CLR at 292). Aickin J held that that expression referred to the common general knowledge, and that nothing that was not part of that body of knowledge might be considered for the purposes of deciding the matter of obviousness, or want of an inventive step, under s 100(1)(e). Of course, "common general knowledge" was not as such a term used in the 1952 Act, but – as was clarified in *Minnesota Mining* – that concept, by then familiar to patent lawyers, was invoked by the words which the statute did use, "known or used in Australia". Aickin J described it as follows (144 CLR at 292):

The notion of common general knowledge itself involves the use of 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.

455 Far from being consistent with the law which predated the enactment of the Patents Act, therefore, the essence of the respondents' point is that that Act brought about a change in the law, a change which Aickin J had been at pains to stress had not been introduced in the 1952 Act. Undoubtedly the Patents Act did make substantive changes to the law in relation to obviousness, but did it do so in the presently material respect? That is to say, does it, in that setting, permit recourse to one or more items of the prior art which is or are not part of the common general knowledge?

456 An important change made by the Patents Act was to set out positively what were the requirements for a valid patent (ie as distinct from them having been grounds for revocation). Those requirements were the subject of s 18(1), the relevant terms of which have been set out above. At the same time, a special definition of "prior art base" was introduced in Sch 1 to the Patents Act, as follows:

"prior art base" means:

- (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; and
 - (iii) where the invention is the subject of a standard patent or an application for a standard patent – information in a document publicly available outside the patent area;

If nothing more had been enacted, s 18(1)(b)(ii) would have required a comparison between the invention and the prior art base as so defined.

457 However, and significantly in the present context, something more was enacted, namely, subs (2) and (3) of s 7, the relevant terms of which have also been set out above. Relevantly to s 7(3), "prior art information" was defined as "information that is part of the prior art base in relation to deciding whether an invention does or does not involve an inventive step". As previously stated, the expression "common general knowledge" was not defined in the Patents Act. However, as noted presently, the terminology of subs (2) is consistent only with the prospect that the newly-defined "prior art information" might well extend beyond information that constituted the common general knowledge.

458 Section 7(2) is a deeming provision. Absent a positive conclusion on the proposition following the word “unless”, the invention is taken to involve an inventive step for the purposes of the Patents Act. Perhaps most conspicuously, those purposes include the purposes of s 18(1)(b)(ii). Of itself, that proposition – that 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 – marks out no departure from the law as clarified in *Minnesota Mining*. It may be noted that the proposition does not refer to, and does not require recourse to, anything described as “the prior art base”. Rather, grammatically, the existence of “an inventive step when compared with the prior art base” is the thing that is deemed. To get to that point, the inquiry is concerned, and – subject to subs (3) in cases in which it is invoked – concerned only, with the common general knowledge. Presumptively, the information introduced under s 7(3) is not part of the common general knowledge. Thus subs (2) and (3) working together might be viewed, first, as requiring the matter of inventive step to be determined by reference to the common general knowledge, and then, secondly, as permitting, within tightly-prescribed limitations, recourse to some information in the prior art which is not part of the common general knowledge.

459 The respondents accepted that s 7(2) is a deeming provision, but their submission from that point cannot be understood as accepting the literal application of that provision. Although expressed in various ways, the essence of their point is that s 18(1)(b)(ii) as enacted in 1990 required the inventive step question to be resolved by reference, directly rather than via s 7(2), to the prior art base. Their answer to the problem that such an approach would have opened all manner of information, subject only to being “publicly available” somewhere in the patent area, to consideration was to propose that the exercise of comparison required by s 18(1)(b)(ii) permitted recourse to one item of information only. It was by reference to that item that a skilled worker in the relevant field would notionally consider the matter of inventive step, and would do so in the light of his or her understanding of everything that was part of the common general knowledge, either as such or as supplemented in the limited way permitted by s 7(3). Thus the s 7(3) information was not the point of comparison, but a permitted supplement to the common general knowledge; and the common general knowledge, in turn, was, as mentioned above, that skilled worker’s notional intellectual equipment and general understanding of the relevant area of discourse.

460 I would not accept the respondents’ case in these respects. As I have mentioned above, recourse to anything beyond what was common general knowledge was not, prior to the enactment of

the Patents Act, permissible in the determination of obviousness for the purposes of a revocation application. The very point of *Minnesota Mining* was to reject the possibility of obviousness being decided by reference to some document or act which, although publicly available, was not “known or used”, that is to say, was not part of the common general knowledge. The Patents Act altered that only to the extent of permitting recourse to be had to non-common general knowledge prior art information within the bounds of s 7(3). The purposes of that limited exception would be compromised if some other item of information, not part of the common general knowledge, could be used as the point of comparison under s 7(2). More importantly, the position for which the respondents contend gains no support from the text of the relevant provisions. Both as a matter of language and as a matter of purpose, therefore, that position should be rejected.

THE CHARACTERISATION ISSUE

461 In relation to the 051 patent, the primary judge set out, in her reasons, substantial passages from the specification, but the following will suffice to mark the differences between the positions taken by the parties, both before her Honour and on appeal:

The present invention relates 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, [the formula for the compound rosuvastatin]... and pharmaceutically acceptable salts thereof, hereinafter referred to as “the Agent” and illustrated (as the calcium salt) in formula I hereinafter. The invention further relates to the dosage range, start dose and dosage forms of the Agent.

The Agent is disclosed in European Patent Application, Publication No. 0521471, and in *Bioorganic and Medicinal Chemistry*, (1997), 5(2), 437-444 as an inhibitor of 3-hydroxy-3-methylglutaryl CoA reductase (HMG-CoA reductase) which is a major rate-limiting enzyme in cholesterol biosynthesis. The Agent is taught as 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.

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 lipoprotein 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.

Accordingly, one aspect of the present invention comprises a method of lowering LDL-C levels by 40% or more, and/or lowering total cholesterol levels by 30% or more, and/or lowering triglyceride levels by 10% or more, and/or lowering apolipoprotein B-100 levels by 30% or more, and/or raising HDL-C levels by 5% or more, in a patient in need thereof, by administration of 5 to 80 mg per day of the Agent....

462 Both in these passages and elsewhere, the specification for the 051 patent made it clear that the inventors had come up with something they described as “the use of a cholesterol-lowering agent, and more particularly ... the administration of a particular dose or dosage range” for that agent. The agent was rosuvastatin. There was no suggestion in the specification that the inventors had invented rosuvastatin: indeed, a fair reading of the specification justifies the primary judge’s observation that “the specification itself makes rosuvastatin a given and locates the inventive concept in the discovery of a dosage range”. So far as the specification itself is concerned, and subject possibly to such reservations as one might have about the non-technical term “inventive concept”, I do not understand the appellants to take issue with that.

463 Claim 1 in the 051 patent is expressed as follows:

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] or a pharmaceutically acceptable salt thereof, in the form of a pharmaceutical composition.

In terms, this claim is not for a method of administering rosuvastatin: it is for a method of treating a patient suffering from hypercholesterolemia, a method which includes the selection of rosuvastatin, or a pharmaceutically acceptable salt thereof (a first integer) and the administration as a starting dose of a single, once daily, oral dose of 5 to 10 mg of that compound (a second integer). On the respondents’ case, both integers are part of the claim and, therefore, part of the invention as defined (see s 40(2)(b) of the Patents Act). It was a mistake, they say, for her Honour to have “characterised” the invention without the first of these integers.

464 In the case of the 842 patent, the passages from the specification which the primary judge set out in her reasons included the following, which will suffice to mark out the points of difference between the parties:

The present invention relates to pharmaceutical compositions and more particularly to a pharmaceutical composition containing [rosuvastatin] or a pharmaceutically-acceptable salt thereof (and referred to hereinafter as “the Agent”). In particular the sodium and calcium salts, and especially the calcium salt ... (shown as Formula I below).

The Agent is disclosed as an inhibitor of 3-hydroxy-3-methylglutaryl CoA reductase (HMG CoA reductase) in European Patent Application, Publication No. 0521471 and in Bioorganic and Medicinal Chemistry, (1997), 5(2), 437-444 and is useful in the treatment of hypercholesterolemia, hyperlipidproteinemia and atherosclerosis.

The problem associated with the Agent is that it is particularly sensitive to degradation under certain conditions. The major degradation products formed are the corresponding (3R, 5S) lactone (hereinafter referred to as “the lactone”) and an oxidation product (hereinafter referred to as “B2”) in which the hydroxy group adjacent to the carbon-carbon double bond is oxidised to a ketone functionality. The potential for significant degradation of the Agent makes it difficult to formulate and provide a pharmaceutical composition with acceptable storage life for a marketed product.

Pharmaceutical formulations of certain 7-substituted-3,5-dihydroxy-6-heptenoic acid salts, which are HMG CoA reductase inhibitors, are disclosed in UK Patent 2 262 229, and that they are sensitive to pH degradation. These formulations require the presence of an alkaline medium (such as a carbonate or bicarbonate) capable of imparting a pH of at least 8 to an aqueous solution or dispersion of the composition.

However, we have found that for the Agent it is not sufficient to improve stability by solely controlling pH in the formulation. We have found that with the Agent stability is improved by selection of an inorganic salt to be added to the composition which contains one or more multivalent inorganic cations. Whilst not wishing to be bound by theory we believe that the multivalent inorganic cation stabilises the structure of the Agent and makes it less susceptible to oxidation and/or lactonization.

We present as aspects of the invention

- (1) A pharmaceutical composition comprising the Agent or a pharmaceutically acceptable salt thereof as the active ingredient and an inorganic salt in which the cation is multivalent, provided that: the inorganic salt is not hydrotalcite or synthetic hydrotalcite and the counter anion to the inorganic salt is not a phosphate.
- (2) The use of an inorganic salt in which the cation is multivalent to stabilise the Agent or a pharmaceutically acceptable salt thereof, provided that: the inorganic salt is not hydrotalcite or synthetic hydrotalcite and the counter anion to the inorganic salt is not a phosphate.

Preferred features of the invention are:

- (1) wherein the Agent is present in the composition is more than 5 mg, preferably more than 10mg. Excluded compositions are those wherein the Agent is present at 1mg, 2mg, 5mg and 10mg. Preferred compositions are those where the amount of Agent is 20mg, 40mg or 80mg.
- (2) wherein the stabilising compound is not hydrotalcite or synthetic hydrotalcite.
- (3) the pharmaceutical composition formed is a tablet or powder. Preferably the pharmaceutical composition of the invention is a tablet....

465 Here too there is no suggestion in the specification that the inventors had invented rosuvastatin: indeed, it was said in terms that rosuvastatin was disclosed in existing sources which were identified. What the inventors said they had done was to have invented a pharmaceutical composition with identified features that would enable rosuvastatin to be practically used without degradation.

466 The relevant claims in the 842 patent are expressed as follows:

1. A pharmaceutical composition comprising [rosuvastatin] or a pharmaceutically acceptable salt thereof as the active ingredient and an inorganic salt in which the cation is multivalent, provided that:
 - (i) the inorganic salt is not hydrotalcite or synthetic hydrotalcite; and
 - (ii) the counter anion to the inorganic salt is not a phosphate.
2. A pharmaceutical tablet comprising [rosuvastatin] or a pharmaceutically acceptable salt thereof as the active ingredient and an inorganic salt in which the cation is multivalent, provided that the counter anion to the inorganic salt is not a phosphate....

Under each of these claims, rosuvastatin is the first integer. As before, the appellants say that the primary judge was in error to have treated rosuvastatin as lying outside the invention as defined by the claims.

467 As I read the reasons of the primary judge, the resolution of an obviousness objection under the Patents Act requires, in effect, a 3-stage analysis: first, identify “the invention”, that is to say, what it was that, according to the specification, had actually been invented; secondly, identify the aspect of the invention which was claimed in the claim under consideration; and thirdly, apply s 7(2) to that aspect. It was critical in the case before the primary judge that a feature or characteristic which had been excluded as not being part of the invention under the first stage could not be re-introduced at the second stage.

468 The primary judge applied this reasoning first in relation to the 051 patent. Her Honour said (referring to the appellants as “AZ”):

[220] ... [T]he statute requires the invention as claimed to be compared with the common general knowledge. The invention is defined by the terms of the patent. In the case of the 051 or low dose patent AZ’s position that by reason of the terms of ss 7(2) and (3) the invention can somehow include discovering the existence of rosuvastatin is inconsistent with the terms of the patent. The specification identifies the invention in a manner that pre-supposes the existence of rosuvastatin. It is not necessary to make use of the prior art disclosing the existence of rosuvastatin referred to in the specification to reach this conclusion. It is apparent from the terms of the specification as a whole. The invention relates to the dosage range for rosuvastatin. The inventive

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

[221] Contrary to AZ's submissions I do not find it absurd to treat rosuvastatin as a given in respect of this invention when, as noted, I consider that knowledge of rosuvastatin did not become commonplace for the hypothetical skilled addressee of the patent in Australia until nearly 18 months after the asserted priority date. This is because the statute focuses on the invention and the invention is defined by the terms of the patent. In the case of the 051 or low dose patent the invention is the discovery of a dosage range of a compound assuming that the existence and nature of the compound is known. Nothing in the patent suggests any inventive activity in respect of rosuvastatin itself or its nature as a HMG-CoA reductase inhibitor. It is not possible to posit the claimed invention without knowing about the existence of rosuvastatin as an HMG-CoA reductase inhibitor.

....

[223] AZ's submission that the "identification, appreciation, development and use of rosuvastatin in the method of the invention is presented as the solution to that problem, not as part of the problem itself, or the 'starting point'", the problem being "the need for 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 greater safety profile", cannot stand with the terms of the patent. The patent recognises a fact that was part of the common general knowledge at the time, namely, that finding dosages of alternative statins is important because not all patients respond well to existing statins. But nothing suggests anything inventive about the identification of rosuvastatin as an HMG-CoA reductase inhibitor. The invention, as noted, lies in the identification of a dosage range of a compound assumed by the patent to be a known HMG-CoA reductase inhibitor.

469 With respect to the 842 patent, her Honour said:

[227] ... [T]he invention claimed in the 842 or cation patent has nothing to do with the discovery or, as AZ would have it, the synthesis of rosuvastatin. The invention is a pharmaceutical composition containing rosuvastatin as its active ingredient. The idea that finding or synthesising rosuvastatin has anything to do with the invention claimed is without foundation. Accordingly, the submission of AZ that the statute mandates the notion that obviousness is to be tested assuming that the skilled addressee has no knowledge of rosuvastatin or its chemical formula is misconceived. As discussed, AZ's approach seems to disregard the actual invention claimed, contrary to the terms of the statute. If the invention is not disregarded on AZ's approach then, at the least, it is

fundamentally recreated as an invention different from that actually claimed. For the 842 or cation patent, the invention becomes or includes discovering rosuvastatin and its chemical structure and being able to synthesise rosuvastatin. Yet, from the terms of the 842 or cation patent, it is clear that the discovery or synthesis of rosuvastatin has nothing to do with the claimed invention. The invention lies in the formulation of a particular pharmaceutical composition of rosuvastatin. The formulation, which requires the addition of an inorganic salt in which the cation is multivalent, involves improved stability than achieved for other similar compounds by raising the pH. It is that formulation and nothing else which constitutes the invention claimed.

470 Her Honour's conclusions, dealing with both of these patents, were in the following terms:

[228] As should be apparent, I consider AZ's approach to the inventions in each patent to be untenable. Whilst on the one hand stressing that strict observance must be paid to the terms of the statute (specifically, the common general knowledge requirements as defined in ss 7(2) and (3)) AZ also on the other hand disregarded the other key requirement of these provisions which involve the invention as claimed. Comparison between the inventions as claimed and the version of the inventions which underlies AZ's submissions exposes the discrepancy. Hence, on AZ's case, for the 051 or low dose ... [patent], the invention becomes or includes discovering rosuvastatin as an HMG-CoA reductase inhibitor when the claimed invention suggests no such thing. For the 842 or cation patent, the invention becomes or includes discovering rosuvastatin and its chemical structure and being able to synthesise rosuvastatin.

[229] I have referred to the version of the inventions which underlies AZ's submissions because AZ has described its argument as a result of the terms of ss 7(2) and (3). For this purpose, assume rosuvastatin never formed part of the common general knowledge as referred to in s 7(2). AZ would have it that it necessarily follows that in performing the tasks 7(2) requires, knowledge of rosuvastatin must be assumed not to exist because it did not form part of the common general knowledge. But the common general knowledge is only part of the statutory equation. Section 7(2) requires the invention to be compared with the prior art base. If, as here, the invention pre-supposes the existence of rosuvastatin as an HMG-CoA reductase inhibitor the required comparison would be distorted by assuming out of existence the factual predicate for the invention. The effect of doing so is necessarily to transform the invention into something which includes the discovery of rosuvastatin as an HMG-CoA reductase inhibitor when no such invention was claimed. In other words, the approach of the generic parties does not undermine the statutory element of the common general knowledge. AZ's approach undermines the statutory element of the invention.

471 Later sections of the primary judge's reasons, dealing with the validity of these two patents, were based upon the above reasoning, and conclusions. With respect to the 051 patent, her Honour said that the invention was "the discovery of a dosage range of a compound assuming that the existence and nature of the compound is known, the compound being rosuvastatin." Her Honour said the invention "would have been obvious to a person skilled in the relevant art

in light of the common general knowledge in the patent area as it existed before the asserted priority date ... because, against the common general knowledge, the invention involved nothing more than the identification of a conventional starting dose for a compound within a known class for a known purpose.” Her Honour accepted the submission of the respondents that –

... [t]he selection of a 5 to 10 mg dose is no more than the selection of a relatively low (but conventional) dose of rosuvastatin, by reference to the preferred prescribing practice of some, but not all, doctors – of starting patients on a relatively low dose and then titrating the dose upward.

Her Honour imputed to the skilled addressee a knowledge of rosuvastatin and of its membership of the “known class for a known purpose”. That is to say, not only would he or she know, as a matter of common general knowledge, that statins at conventional starting doses were efficacious in the treatment of hypercholesterolemia, but he or she would also know that rosuvastatin was a member of that class.

472 With respect to the 842 patent (and even if, contrary to her Honour’s holding, the priority date lay before rosuvastatin became part of the common general knowledge), her Honour held as follows:

[B]ecause I consider that the invention lies in the formulation of a particular composition of rosuvastatin, the invention pre-supposes the existence of the compound, with its particular chemical structure. In other words, no part of the invention lies in knowing about rosuvastatin or its chemical structure, it being common general knowledge in the art that such a structure might suffer from instability.

Her Honour rejected the submission of the appellant that “while the evidence is that coatings containing titanium dioxide and ferric oxide were well-known, that does not make their combination in a composition with rosuvastatin obvious”. Her Honour held that “the combination of the well-known coatings containing titanium dioxide and ferric oxide with rosuvastatin would have been obvious to the skilled addressee at and before the earliest asserted priority date”

473 The main authorities upon which the primary judge relied for her view that it was necessary first to characterise the invention from a reading of the specification as a whole were the judgment of the High Court in *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 (“*AB Hassle*”), the judgment of the Full Court in *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 (“*Apotex*”) and the judgment of Bennett J at first instance in *Danisco A/S v Novozymes A/S (No 2)* (2011) 91 IPR 209 (“*Danisco*”). Having considered those authorities, and concluding

by noting that Bennett J had said that ascertaining a starting point was particularly apposite where the specification was drafted to describe a problem and a solution to that problem, the primary judge continued:

In other words, the terms of the specification and claims inform the identification of the relevant starting point for the assessment of obviousness. Contrary to [the appellant]’s submission, this does not involve placing an impermissible gloss on the statutory provisions. Sections 7(2) and (3) of the Act (in their applicable form) presuppose the existence of “an invention”. Characterisation of the invention depends on the terms of the claims construed in the context of the specification as a whole. This point was made in *Apotex* at [152] in which the Full Court said the question “whether the invention, so far as claimed in the particular claim, is obvious and does not involve an inventive step...requires a determination of the invention, as described in the specification” (recognising that the claims may claim something less than the whole of the invention in the specification). Although this approach to the question of obviousness was involved in the provisions of the *Patents Act 1952* (Cth), the versions of ss 7(2) and (3) applicable in the present case also focus on the invention compared to the prior art base. It thus remains the case that, as the Full Court said at [152], “[t]he invention to be assessed for obviousness is ascertained from the patent and the obviousness or inventive step of the invention as claimed is then assessed by reference to common general knowledge in Australia at the priority date”.

474 The primary judge’s own conclusion, which is central to an appreciation of how her Honour decided the case before her, was expressed as follows:

It follows that references to the correct “starting point” and the “problem-solution” approach, expressed at the level of principle, are not particularly helpful. As the terms of the statute and the cases disclose close attention to the terms of the specification is required in order to characterise the invention. The relevant comparison is between the invention and the prior art base in order to determine obviousness.

As it seems to me, in this passage not only did her Honour place a consideration of the relevant “starting point” to one side in her treatment of the question of obviousness, she also held it to be in “the terms of the specification”, rather than in the terms of the particular claim, that one should identify (or “characterise”) what had been invented.

475 In the case of the appellants on appeal, the primary judge erred by –

... proceeding on the basis that the invention claimed in each of the 051 and the 842 Patents “presupposed” the existence of rosuvastatin, or in characterising the invention by reference to the contents of the description in the specification, including her Honour’s assessment of the inventive step as appearing from that description.

The appellants submitted that it was the claims as such which “defin[ed] the invention” (s 40(2)(b)), that the invention was patentable if, “so far as claimed in any claim”, it involved an inventive step (s 18(1)(b)(ii)) and that it was either wholly or “so far as it relates to a claim”

that the invention was susceptible to revocation on the ground of not being a patentable invention under s 138(3)(b). Thus, in the assessment required under s 7(2) as applied for the purposes of s 18(1)(b)(ii), one had to take the invention as defined in each relevant claim. It was not permissible to pick the claim apart, as it were, by reference to the court's understanding of what was really invented, as informed by the specification.

476 It must be said that the appellants' submission derives a deal of support from the text of the statute, but it would produce, in a case such as the present, what might be regarded as the counterintuitive result that the patentee may claim credit for the inventiveness involved in developing a compound which he or she did not invent. To see whether, and if so how, these positions may be reconciled, it will be necessary to turn to the authorities, the main ones of which have already been mentioned, but I would include also another Full Court authority which lay between *AB Hassle* and *Apotex, Insta Image Pty Ltd v KD Kanopy Australasia Pty Ltd* (2008) 78 IPR 20 ("*Insta Image*").

477 *AB Hassle* concerned an invention for "an oral pharmaceutical preparation in the form of a tablet, capsule or pellet containing omeprazole as the active ingredient" (212 CLR at 418 [2]). The main claim made in the patent, by reference to which the reasons of Gleeson CJ, Gaudron, Gummow and Hayne JJ proceeded, had been set out in the judgment of the primary judge as follows (*Aktiebolaget Hassle v Alphapharm Pty Ltd* (1999) 44 IPR 593, 599 [21]):

An oral pharmaceutical preparation in the form of a tablet or pellet containing omeprazole as the active ingredient, characterised in that it is composed of:

(A) core material containing omeprazole together with an alkaline reacting compound, or an alkaline salt of omeprazole optionally together with an alkaline reacting compound; (B) one or more inert reacting subcoating layer(s) on said core material; and (C) an outer layer, which is an enteric coating, said inert reacting subcoating layer(s) between said core material and said outer layer comprising tablet excipients which are soluble or rapidly disintegrating in water, or polymeric, water soluble, filmforming compounds, optionally containing pH-buffering, alkaline compounds.

The essence of that claim was stated by their Honours in the High Court as follows (212 CLR at 419 [5]):

The tablet or pellet claimed in claim 1 is a combination of three integers or elements. The first is the "core material" containing omeprazole as the active ingredient with an alkaline reacting compound; an alkali is a substance which neutralises or effervesces with acids. The second is one or more inertly reacting subcoating layer(s) on the core material, and the third an outer layer which is an enteric coating.

Their Honours proceeded to explain the correct approach to be taken to the determination of the inventive step requirement in the case of a combination invention. I shall return to that subject in more detail below.

478 At the core of the judgment in *AB Hassle* was the proposition that satisfaction of the inventive step requirement under s 100(1)(e) of the 1952 Act was not negatived by the circumstance that the invention would have eventually presented itself to a skilled worker in the field if he or she undertook the process of trying out various possibilities until the correct solution emerged: 212 CLR at 443 [78]. The quality of the inventive process was the essential issue in the case, in which respect their Honours endorsed the approach which had been favoured by Graham J in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd* [1970] RPC 157, 187-188 (212 CLR at 433 [53]) (“*Olin Mathieson*”). In this respect, the question which arises in the present case is different from that which arose in *AB Hassle*. However, their Honours in the High Court *were* concerned with the means by which the skilled addressee would move from the position of not knowing what the invention was to a position in which he or she had the invention. That movement was, of course, the “step” to which s 100(1)(e) referred, and the central question in *AB Hassle* was whether it would have been an inventive one; or, contrariwise, would have been an obvious step to take.

479 As it seems to me, it was in this setting that their Honours invoked the concept of a “starting point”. Of critical significance in their reasoning was the following passage in the speech of Lord Diplock in *Technograph Printed Circuits Ltd. v Mills & Rockley (Electronics) Ltd* [1972] RPC 346, 362 (212 CLR at 423-424 [21]):

Once an invention has been made it is generally possible to postulate a combination of steps by which the inventor might have arrived at the invention that he claims in his specification if he started from something that was already known. But it is only because the invention has been made and has proved successful that it is possible to postulate from what starting point and by what particular combination of steps the inventor could have arrived at his invention. It may be that taken in isolation none of the steps which it is now possible to postulate, if taken in isolation, appears to call for any inventive ingenuity. It is improbable that this reconstruction a posteriori represents the mental process by which the inventor in fact arrived at his invention, but, even if it were, inventive ingenuity lay in perceiving that the final result which it was the object of the inventor to achieve was attainable from the particular starting point and in his selection of the particular combination of steps which would lead to that result.

Their Honours in the High Court said that warnings such as this “are not to be repeated as but prefatory averments and statements of trite law”.

480 In the concluding section of their reasons, their Honours returned to this theme. They said of the view which had been taken by the Full Court in *AB Hassle*:

That view of the matter wrongly takes as the starting point the assumed result. It succumbs immediately to the seduction of hindsight.

That is to say, any consideration of the question whether an invention involved an inventive step, or (alternatively) would have been obvious, cannot start with an assumption about the result which is (by the time the court considers the matter) a known fact. That would not be a legitimate “starting point”.

481 In my opinion, the feature of *AB Hassle* which is of particular interest in the present context is their Honours’ holding that the invention then in suit was a combination one. The question of obviousness arose in relation to the combination, not in relation to one or more of the individual integers. One or more of the integers may have been “known” (to use the word in s 100(1)(e) of the 1952 Act), but that was not to the point. What *was* to the point was the “ingenuity of the combination”. In order to examine that point, a court would, inevitably in my view, be required to assume the existence of each of the integers claimed to have been inventively combined. In the present case, it was submitted on behalf of the respondents that *AB Hassle* supported the approach taken by the primary judge because “omeprazole was not part of the common general knowledge in Australia”. For my own part, I would not regard *AB Hassle* as authority for the proposition that a compound, thing or artefact which lies outside the common general knowledge would always qualify as a legitimate “starting point” for the comparison required by s 100(1)(e) – or by s 7(2) of the Patents Act, for that matter – but I would accept that the reasoning of their Honours, focussing as it did on the combination rather than on the individual integers, would be applicable whether or not any, or all, of those integers was or were in the common general knowledge.

482 I turn next to *Insta Image*, which was referred to only in passing in the submissions made in the present appeal. The invention there was an expandable and collapsible framework structure which might be used to support shelters of the kind seen, for example, in situations of camping, outdoor events, and the like. Several previous such structures had been invented – by the same inventor – and patented in the USA, each, it seems, involving some improvement on its predecessor. According to the patent in suit in *Insta Image*, notwithstanding these improvements, there remained a stability problem when such a structure was subjected to lateral forces when in use. The invention sought to overcome that problem by the use of a

particular means of attachment as between the uprights in the structure and the scissor means which operated co-operatively with the uprights when the structure was expanded or collapsed. The terms of the first claim are too lengthy to set out here (see 78 IPR at 26 [25]), but they covered every defining and functioning feature of the structure, including, but not limited to, those that had been most recently introduced in the course of inventing the version which was the subject of the patent there in suit.

483 The Full Court held (78 IPR at 35-36 [80]) that, in determining the issue of obviousness, it was necessary –

- (1) to identify the invention “so far as claimed in any claim”;
- (2) to identify the “person skilled in the relevant art”;
- (3) to identify the common general knowledge as it existed in Australia before the priority date;
- (4) to inquire under s 7(2) whether the invention referred to in (1) above would have been obvious to the person referred to in (2) above in light of the knowledge referred to in (3) above; and
- (5) to inquire whether that invention would have been obvious to that person in the light of that knowledge when that knowledge is considered together with either kinds of information mentioned in s 7(3) (additional prior art information).

Dealing with the first item on this list, their Honours noted (78 IPR at 36 [83]) that, in *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 12 [14], the High Court had said that the claims were as much a part of the specification of a patent as the “body” thereof, but added (207 CLR at 12 [15]) that “something like special principles apply where it is the scope of a claim that alone is in question”. Their Honours in the Full Court continued:

That is the case here because s 18(1) uses the language the invention “so far as claimed in any claim”, not, for example, the invention “as described in the complete specification”.

484 Their Honours referred to what had been a consensus amongst five experts who had given evidence that the invention related “to the provision of sockets having parallel side walls and the use of non-compressive pins”, that is to say, to the specific improvements which set the invention apart from previous versions of structures invented by the same inventor. Their Honours did not accept that as a sufficient identification of the artefact which had to be considered under s 18(1) of the Patents Act. They said (78 IPR at 37 [90]):

Regardless of what [the inventor] and the experts understood, s 18(1) requires us to identify *the invention* “so far as claimed in any claim”. A claim may claim less than the whole invention, but the subject matter of s 18(1) cannot be wider than the claims, and the provision demands that close attention be given to the claims.

Their Honours added (78 IPR at 37 [92]):

The product described in claim 1 was an entire expandable framework structure that had many features over and above the U-shaped mounts and non-compressive pins. We see no possibility of identifying the invention, as claimed, as being limited to the introduction of the novel mounts and non-compressive pins into an existing known structure.

485 The Full Court held that the references in the specification to the earlier versions of the structure did not amount to admissions that those versions had entered the common general knowledge in Australia at the priority date (78 IPR at 38 [99] and 39 [104]). Their Honours held, in concluding on this aspect, that the effect of the relevant evidence “was that the combination of all of the integers, including as one (or two) of them the U-shaped mount with non-compressive pin, was not obvious having regard to the common general knowledge in Australia before the priority date.” (78 IPR at 42 [113])

486 There is, in my view, much to be taken from the judgment of the Full Court in *Insta Image* which is germane to the issue presently before the court. Setting the case apart from *AB Hassle*, the invention in *Insta Image* was not for a combination. It was for a single, complete, structure. That is not to say that the structure was not made up of elements, but it is to stress that what was claimed was the single entity, rather than the combination of the parts. Their Honours in the Full Court also made it clear, in the first of their five stages, that the identification of the invention had to be done by reference to the terms of the relevant claim. They rejected the approach, which had been taken by the experts in the case, of discerning from the specification, *rather than* the relevant claim, what had been invented. Particularly given the circumstance that *Insta Image* arose under, and was decided specifically by reference to the provisions of, ss 18(1)(b)(ii) and 7(2) of the Patents Act, this distinction is of some importance in the resolution of the “characterisation” issue in the present case.

487 Another aspect of their Honours’ reasoning in *Insta Image* which is of some present interest is the following (78 IPR at 36 [84]-[85]):

[84] We referred (at [15]–[23]) to passages from the body of the specification. Through them, [the inventor] tells the story of his own inventive journey. Those passages may show that [the inventor] thought that his invention consisted of the introduction into collapsible canopies the subject of his earlier

patents of novel mounts having sockets with parallel side walls (U-shaped mounts) and non-compressive fastening pins.

[85] The question, however, is not what [the inventor] thought but what is “the invention, so far as claimed in any claim”?

In other words, it should not matter whether earlier parts of the inventive journey had been travelled by the particular inventor, by some other inventor, or by no-one. The question which arose in *Insta Image* would have been exactly the same (as would the answer) if there had been no earlier versions of the framework structure then invented. It would also have been exactly the same (and so would the answer) if the earlier versions had been invented by another person.

488 The patent in suit in *Apotex* claimed the dextro-rotatory isomer – referred to as the d-enantiomer – of a racemic mixture identified as PCR 4099, and its pharmaceutically acceptable salts. Bennett and Middleton JJ held that the d-enantiomer as such was not novel over the prior art: 82 IPR at 434 [106] and 436 [118]. However, the first claim in the patent was not limited to the d-enantiomer – it extended also to the salts. It may be important to note the actual terms of the claim itself, which appear in the reasons of the primary judge in that case, *Apotex Pty Ltd v Sanofi-Aventis* (2008) 78 IPR 485, 490 [15]:

Dextro-rotatory isomer of methyl alpha-5 (4,5,6,7-tetrahydro (3,2-c) thieno pyridyl) (2-chlorophenyl)-acetate and its pharmaceutically acceptable salts.

In the Full Court, Bennett and Middleton JJ found that the salts referred to in the prior art were the salts of the racemate (82 IPR at 436 [121]) and that the claim, to the extent that it related to the salts of the d-enantiomer, was novel (82 IPR at 438 [131]).

489 The question which then arose was whether the invention, so far as it involved the salts of the d-enantiomer, was obvious. In this area, their Honours’ reasons were organised under the subheadings of “the starting point for the assessment of obviousness”, “common general knowledge”, “the inventive step” and “consideration of obviousness of particular claims of the patent”. It is with the first of these sections of their Honours’ reasons that I am presently concerned. PCR 4099 was not part of the common general knowledge in Australia. Neither were the prior art patents by reference to which the patentee failed on novelty. Thus, as noted by their Honours (82 IPR at 442 [148]), “if common general knowledge is the starting point, the claims are not obvious”. The patentee contended that common general knowledge was indeed the starting point. That contention was rejected, their Honours holding (82 IPR at 444

[163]) that “[t]he invention of the patent starts with a biologically active racemate”, that is to say, with a chemical entity that was not part of the common general knowledge.

490 There were two main threads to their Honours’ reasoning in this regard. The first, as it seems to me, proceeded from a construction of s 100(1)(e) of the 1952 Act. Their Honours said (82 IPR at 442 [152]-[153]):

[152] Section 100(1)(e) makes it clear that the question to be addressed is whether *the invention*, so far as claimed in the particular claim, is obvious and does not involve an inventive step. That requires a determination of the invention, as described in the specification. What is claimed may then equate with, or be less than the totality of or scope of, the invention. The specification of the Patent makes it clear that the selection of PCR 4099 as the racemate to be resolved formed no part of this invention as described and claimed. From the primary judge’s reasons, no such claim was made. It was the process of separation of the enantiomers of that mixture to obtain the enantiomers, and, in turn, the pharmaceutically acceptable salts of the d-enantiomer, that broadly, were the subject matter of the claims. The invention to be assessed for obviousness is ascertained from the patent and the obviousness or inventive step of the invention as claimed is then assessed by reference to common general knowledge in Australia at the priority date. [Emphasis in original]

[153] This analysis of the invention assists in determining the correct starting point for the application of the common general knowledge of the hypothetical person of skill in the art in order to decide whether the invention as claimed in the claims was obvious or involved an inventive step. The invention presupposes that the hypothetical worker was in possession of the racemate and the knowledge that it had platelet aggregation inhibiting activity. As the primary judge said, the desire to separate the enantiomers should be taken for granted. Knowledge of the kind of activity was a prerequisite to testing the enantiomers for that activity which led to the asserted unexpected result that the l-enantiomer did not exhibit any such activity. However, the hypothetical skilled worker would not know the contents of the French prior art patent or, indeed, the other prior art patents, that were not part of common general knowledge.

491 To the extent that Bennett and Middleton JJ derived assistance from the decided cases in reaching this conclusion, that was, it seems, limited to the “general principles” laid out in the judgment of the High Court in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd [No 2]* (2007) 235 CLR 173, 195-197 [51]-[56] (“*Lockwood*”). Most of those principles are not germane to the issue here at hand, but they did include the proposition, derived from *Minnesota Mining*, that “for the purpose of determining inventiveness prior disclosures which were publicly available information, but which were not part of common general knowledge, were excluded from consideration” (235 CLR at 197 [55]). Here their Honours in the High Court were consciously speaking historically (ie with reference to s 100(1)(e) of the 1952 Act),

and they recognised that “reference to and use of prior disclosures, in existence but not part of the common general knowledge, has now been extended.” (235 CLR at 197 [56]) That was, of course, a reference to the concluding passage in subs (2), and to subs (3), of s 7 of the Patents Act (see 235 CLR at 217-218 [126]-[127]). In *Apotex*, Bennett and Middleton JJ set out the passage which I have quoted above (82 IPR at 441 [146]), but did not address what might have been perceived as a tension between that passage and the proposition, which their Honours ultimately accepted, that a conclusion as to obviousness might be reached by identifying the “starting point” in a way that imputed to the skilled addressee the possession of information that was not part of the common general knowledge.

492 The second thread proceeded from an acceptance of the “problem/solution approach” in the assessment of obviousness. Bennett and Middleton JJ referred to a number of judicial references to that approach, ending with *Lockwood*, where the High Court said (235 CLR at 211 [105]):

While not every invention constitutes a solution to a problem, it is commonplace so to describe an invention where it is appropriate to do so. Admissions in a specification about any problem said to be overcome by an invention are made from the vantage point of knowing the solution. When used as evidence, they would always need to be weighed with evidence, if it exists, from persons skilled in the relevant art of their perception of any problem at the time before the priority date, before their exposure to any solution contained in the invention.

493 To the extent that the problem/solution approach was appropriate in *Apotex*, Bennett and Middleton JJ noted that the problem described in the specification was “the difficulty of purifying the d-enantiomer and of obtaining suitable salts” (82 IPR at 444 [160]). Their Honours continued (82 IPR at 444 [160]):

Accordingly, the hypothetical skilled worker armed with common general knowledge would have that racemic mixture as the starting point. The question is then whether, from that starting point, the claimed invention was obvious; whether there was an inventive step, as assessed by reference to the common general knowledge, in resolving the enantiomers and obtaining pharmaceutically acceptable salts of the d-enantiomer. It should be emphasised that the base line or starting point may itself be part of the inventive step or inventive process but that is not the case here. The selection of PCR 4099 for resolution was not claimed to be inventive.

With respect to their Honours, the kind of case in which a starting point (in the sense of a base line by reference to which the obviousness question would be determined) might itself be “part of the inventive step or inventive process” is not readily apparent, but their Honours may have had in mind, for example, a combination patent in which one or more of the integers was

previously known. They might also have had in mind an invention for a method of using a known object or compound. Each would, in my view, qualify for consideration as inventive even if the previously-known integer, object etc was part of the common general knowledge. Likewise, the circumstance that the integer, object etc was not part of the common general knowledge would not, in my view, stand in the way of a conclusion, if otherwise proper to be drawn, that the combination or method (as the case may be) was obvious.

494 In *Apotex*, Bennett and Middleton JJ distinguished *Insta Image* in the following terms (82 IPR at 444 [162]):

As the Full Court said in *Insta Image Pty Ltd v KD Kanopy Australasia Pty Ltd* (2008) 78 IPR 20; [2008] FCAFC 139 (*Insta*), close attention should be given to the terms of the individual specification to understand what admissions are made and also to understand the invention. In *Insta*, previous patents of the same inventor were cited but this did not constitute an admission that the inventions the subject of those patents had become part of common general knowledge. Rather, the specification described the inventor's own inventive journey (at [84]) and his own familiarity with the inventions the subject of earlier US patents: at [104]. Importantly, the claim in that case was to an entire structure or construction, which included the subject matter of those earlier US patents with additional features described in the specification. The invention was not limited to the introduction of new features into an existing structure: at [92].

There are two strands of thought in this passage. The first involves what became, in effect, a limitation on the "starting point" approach: if close attention to the terms of the specification showed that what might otherwise stand as the "starting point" was in fact the point which the inventor himself or herself had reached before taking the "step" that was argued to be inventive in the case at hand, that point should be regarded as no more than part of his or her "inventive journey" and thus as disqualified from standing as the "starting point".

495 The second strand of thought in the above passage from *Apotex* marks out an important point of distinction between *Insta Image* and *Apotex*: in the former, unlike the latter, "the claim ... was to an entire structure or construction, which included the subject matter of those earlier US patents with additional features described in the specification". That is to say, it was the claim which defined the invention, but it was the specification which described in what respects the invention constituted an advance on what had gone before. Being an invention for an entire structure, it was impermissible to address the question arising under s 18(1)(b)(ii) of the Patents Act as though what had been invented was the advance only. Whatever the specification said, the invention as claimed could not have notionally excised from it all of the integers which had been drawn from previous versions. Those versions were not the "starting point" under

ss 18(1) and 7(2). By contrast, in *Apotex*, and effectively by definition, the racemate was not incorporated into what had been claimed. The racemate, therefore, stood outside the invention as claimed on any view. Further – and regardless of the inventor’s actual “inventive journey” – the d-enantiomer could be obtained only by starting with the racemate.

496 Turning finally to the judgment of Bennett J in *Danisco*, as the primary judge noted in the present case, her Honour’s reasons on inventive step were not the subject of appeal in *Novozymes A/S v Danisco A/S* (2013) 99 IPR 417. Although Bennett J said that the relevant legal principles were “not in issue”, she summarised them in a bulleted list which included the following (91 IPR at 278 [326]):

In assessing obviousness, it is necessary first to determine the nature of the claimed invention and the inventive step described in the patent. This may involve ascertaining the “starting point” of the inventive step, sometimes described in terms of an existing problem for which the inventor found a solution. The obviousness of the invention as claimed is then assessed by reference to common general knowledge in Australia at the priority date.

In the present case, the primary judge set out this passage from *Danisco*, as well as the following passage (91 IPR at 278-279 [329]):

The fact that a specification makes reference to earlier patents or patent applications does not necessarily amount to an admission that those documents were part of common general knowledge. It depends on the description of the invention in the patent under consideration. It may also reflect the inventor’s own journey, especially where the references are to the inventor’s own work (*Apotex* at [162], discussing *Insta Image* ...).

497 In the light of these authorities, I agree with the primary judge that references to a “starting point ... expressed at the level of principle, are not particularly helpful”. The idea of a “starting point” appears to have been mentioned first (in Australia at least) by the High Court in *AB Hassle*, but, as I have attempted to show, not in the same analytical setting as that in which the idea was used by Bennett and Middleton JJ in *Apotex*. Use in a setting of the latter kind tends to draw the mind towards the point at which the particular inventor “started”. But the result yielded by the application of s 7(2) of the Patents Act to the requirement set out in s 18(1)(b)(ii) does not depend upon the fortuitous circumstance of what the particular inventor had done on a previous occasion, or what he or she knew. The question is to be addressed by reference to the conclusion which would have been reached by the notional “person skilled in the relevant art”. In answering that question, he or she is assumed to be equipped with the common general knowledge. That the particular inventor might be ignorant of some part of the common general

knowledge is neither here nor there. It should likewise be the case that the fact that the particular inventor knew more than the common general knowledge is not to the point.

498 I would also agree with the primary judge in the present case that it is first necessary to “characterise” the invention, but, to the extent that her Honour proposed, following *Apotex*, that this should be done with primary reference to the specification as distinct from the relevant claim, I consider such an approach to be inconsistent with the terms of the statute and with the first stage referred to in *Insta Image*. There the Full Court rejected that approach, and did so as a matter of law. Their Honours’ emphasis upon so much of s 18(1) as required the question to be confined to the invention “so far as claimed in any claim” may be contrasted with the observation in *Apotex* that s 100(1)(e) of the 1952 Act required “a determination of the invention, as described in the specification” (82 IPR at 442 [152]). It is the claim which must be the primary point of reference for any exercise by way of identification (or “characterisation”) of the invention.

499 The court, however, should not read the claim in isolation. Just as it may refer to the specification for the resolution of any questions of ambiguity or uncertainty which arise from the terms of a claim, so too would it be appropriate to allow a reading of the specification as part of the process of coming to an understanding of what had been invented, as claimed. Here I do not mean that the court might reduce, expand or otherwise alter the scope of the invention as defined in the relevant claim. But the court could, and should where appropriate, refer to the specification to understand such matters as, for example, whether what was claimed was a new free-standing device, or was a combination, or was a method for using or applying something. Neither do I suggest that inquiries of this nature should be necessary in most or even in many cases. My point is simply that as in a situation where constructional issues arise, so too when the invention must be identified or characterised, each claim must be read practically and sensibly having regard to the audience to whom it is addressed and allowing for the realistic prospect that members of that audience would naturally read the specification in order to gain the kind of understanding of the claim that is necessary to undertake the first of the five tasks laid out by the Full Court in *Insta Image*.

500 If I am correct in my understanding of the stages of inquiry that were implicit in the analysis of the primary judge in the present case – see para 467 above – I would take the view that those stages are not responsive to the terms of the Patents Act. The correct framework of analysis, in my view, is that laid out by the Full Court in *Insta Image*. To the extent that Bennett and

Middleton JJ held in *Apotex* that the “starting point” must always be “a determination of the invention, as described in the specification”, I take the view, with respect, that their Honours’ test would misdirect the focus of the relevant inquiry away from the claim and thus cannot stand alongside *Insta Image*.

501 It is necessary now to apply the law as discussed above to the facts arising in the present case with respect to the 051 patent and the 842 patent.

SECTION 7(2) – PRIMARY OPERATION

502 Following the course marked out by s 7(2) of the Patents Act with respect to the invention claimed in the 051 patent, the first step is to identify the invention from the terms of the claim under consideration. The invention is for a method of treating hypercholesterolemia. We know immediately that this is a method patent and that no claim is made to have invented rosuvastatin. A reading of the specification – permitted at this stage – confirms this identification of the invention. However, we also know that the invention was not merely for a method of administering rosuvastatin in the treatment of hypercholesterolemia. The selection of rosuvastatin is an integer of the invention as claimed. The question implicitly posed by the Patents Act is not “given rosuvastatin, would the administration of it at the claimed doses be obvious?” Rather, the question is “given a patient suffering from hypercholesterolemia, would the treatment of him or her with rosuvastatin at the claimed doses be obvious?”

503 Under Claim 1 in the 051 patent, the “problem” was the patient with hypercholesterolemia, not the appropriate dose for a known drug. If the “starting point” approach is to be of value, such a point, too, would be the patient suffering from hypercholesterolemia, not the drug to be used in the treatment of him or her. Either way, the “solution” which the inventor proposed was the administration of rosuvastatin at stated doses. The question which arises under s 7(2) is “would that have been obvious to the skilled person”? Such a person would not have known of the existence of rosuvastatin. The inventor did, of course, but the skilled person would not have, for the reason that rosuvastatin lay outside the field of common general knowledge. The s 7(2) question must, therefore, be answered in the negative.

504 It follows that I would uphold the appeal to the extent that it relates to the 051 patent under the primary operation of s 7(2) of the Patents Act.

505 The situation arising with respect to the 842 patent is made somewhat more complex because of the dispute between the parties as to the correct priority date for the claims in this patent.

As to the resolution of that dispute, I agree with the reasons of Besanko, Foster, Nicholas and Yates JJ.

506 On the ruling of the primary judge that the invention in the 842 patent pre-supposed the existence of rosuvastatin, the skilled addressee was taken to be armed with that compound for the purposes of the exercise required by s 7(2) regardless of the correct priority date (ie even if it were 26 January 2000). Her Honour held that “[t]he combination of the well-known coatings containing titanium dioxide and ferric oxide with rosuvastatin would have been obvious to the skilled addressee at and before the earliest asserted priority date of 26 January 2000.” Her Honour continued:

The hypothetical skilled addressee, faced with the same problem disclosed in the 842 or cation patent, immediately would have taken the routine step of applying a conventional coating containing titanium dioxide and ferric oxide to a pharmaceutical composition containing rosuvastatin in the expectation that stability would be improved because improving shelf life, providing protection from degradation by external agents and enhancing tablet stability were three of the recognised potential functions of coatings at all material times. On the evidence, the skilled person would directly be led to try the step of stabilising a pharmaceutical composition of rosuvastatin by “slapping on a coating” containing titanium dioxide and ferric oxide in the expectation that it may achieve a useful result in terms of improved stability. The uninventive worker in the field would have taken such a step as a matter of course.

Although formally covered by grounds in the appellants’ Notice of Appeal, the submissions made on their behalf to challenge these findings were desultory at best. They provide no proper basis for us to overturn the findings.

507 For reasons which follow, I consider that the primary judge was correct in holding that the skilled person would have been armed with rosuvastatin on 26 January 2000, not because it was then in the common general knowledge (which it was not) but because of the characterisation of the invention.

508 Although, like the primary judge, I consider it important first to characterise an invention where issues of obviousness are in play, unlike her Honour I would, for reasons explained above, require that process to start in the claim, rather than in the specification. Significantly for present purposes, I intend a reference to the question whether the claim is for a product invention or for a combination invention. If the former, the question will be whether the development of the product involved an inventive step, and clearly the skilled addressee would not take the product as a starting point, or as a “given”. If the latter, the situation would be covered by the reasons of Aickin J in *Minnesota Mining* (44 CLR at 266):

The patent thus claimed is a combination patent in the proper sense of that term, i.e. it combines a number of elements which interact with each other to produce a new result or product. Such a combination may be one constituted by integers each of which is old, or by integers some of which are new, the interaction being the essential requirement.

509 This approach was confirmed by the Full Court of the High Court in *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 188 ALR 280, 285 [21] and applied, almost in terms, by Gleeson CJ, Gaudron, Gummow and Hayne JJ in *AB Hassle* (212 CLR at 419 [6]):

The tablet or pellet thus claimed is a combination in the proper sense of that term, combining three elements which interact with each other to produce the new product; it is the interaction which is the essential requirement of invention and such a combination may be constituted by integers each of which is old or some of which are new (*Commonwealth Industrial Gases Ltd v MWA Holdings Pty Ltd* (1970) 180 CLR 160 at 163; *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 266; *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 76 ALJR 816 at 819-820 [21]; 188 ALR 280 at 285). Thus, for example, in the present case, it is not to the point that of the three integers it may be said that omeprazole was known as an acid labile compound and that it was known that enteric coatings were resistant to acids. The question for decision concerns the ingenuity of the combination, not of the employment of any one or more integers taken individually. Astra complains that this analysis by dissection is what the Patent has wrongly been subjected to by the Full Court.

510 In a true combination patent in the above sense, a claim to inventiveness under s 18(1)(b)(ii) would not be defeated by the mere fact, if it were a fact, that each of the integers was, considered in isolation, part of the common general knowledge or was obvious in the light of the common general knowledge. Correspondingly, however, it will not avail the inventor to point out that some, or even all, of the integers were not in the common general knowledge and would not, in the light of the common general knowledge, have been obvious to the skilled addressee. If the inventor chooses not to claim the integers separately, the question of the obviousness of each of them, considered separately, will not arise.

511 Section 7(2) is in effect a reverse onus of proof provision. That circumstance, in my view, underlines the importance of determining first whether the claimed invention relates to a combination. If so, the assumption must be – inevitably as it seems to me – that the skilled addressee would then have before him or her each of the integers of the claimed combination, whether or not they are in the common general knowledge. The obviousness question must then be addressed in the light of the common general knowledge. I realise that this result may, on one way of looking at it, appear to some as an unlikely one, in that it might lead to a situation in which a combination invention would be held to be obvious even where none of its

constituent parts had previously entered the common general knowledge. However, in my view that is the inescapable result of the law as laid down by the authorities to which I have referred and by the inventor's own choice in claiming a combination rather than any one or more individual artefacts or things which are integers of the combination.

512 Returning to the 842 patent, the question is whether Claim 1 is for a combination or for rosuvastatin as such. As expressed, the claim is for a combination of integers, being (1) rosuvastatin or a pharmaceutically acceptable salt and (2) an inorganic salt in which the cation is multivalent, but subject to the provisos referred to (see para 466 above). Looking only at the claim, the position is, in my view, closely analogous to that which came before the High Court in *AB Hassle*. However, if there be some uncertainty as to whether this is a claim for a combination or a product, it is permissible to have resort to the specification for a deeper understanding of the matter and to resolve any such uncertainty. It is at this point that I would join forces with the primary judge. The specification makes it clear beyond argument that no claim to have invented rosuvastatin is being made in the 842 patent. The only claim is for the combination.

513 When the question of obviousness is addressed apropos the combination, it does not avail the appellants that rosuvastatin was not, on 26 January 2000, within the common general knowledge. As mentioned above, once rosuvastatin is placed within the skilled addressee's notional field of vision under s 7(2) of the Patents Act, there really is no serious argument but that the invention in the 842 patent, so far as claimed in Claim 1, was obvious.

514 Claim 2 in the 842 patent is relevantly indistinguishable and should be dealt with similarly under s 7(2) of the Patents Act.

515 It follows that I would dismiss the appeal to the extent that it relates to the 842 patent under s 7(2) of the Patents Act, without the need to bring in the additional information, if any, permitted under the extended operation of that subsection.

SECTION 7(2) – EXTENDED OPERATION

516 In relation to each of the 051 patent and the 842 patent, two questions arose under the extended operation of s 7(2) before the primary judge: first, was there prior art information, of the kind referred to in the subsection, which the skilled addressee "could ... be reasonably expected to have ascertained, understood [and] regarded as relevant" (within the meaning of subs (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? In relation to the 051 patent, her Honour resolved each of these questions favourably to the respondents. That resolution is challenged by the appellants.

517 In relation to the 842 patent, her Honour ruled that, if recourse to subs (3) were necessary, the evidence did not go the distance required by the respondents. Although it is not clear whether that ruling related to the availability of the subsection or to its operation, that distinction is now unimportant, for two reasons. First, as indicated above, I would uphold her Honour's ruling under the primary operation of s 7(2), in which event there would be no need to consider the extended operation. And secondly, each of the respondents filed a Notice of Contention which challenged her Honour's ruling, but no such contention was made on the hearing of the appeals. The respondents accepted that, in relation to the 842 patent, if they did not succeed on obviousness under s 7(2) as such, they could not succeed by reference to its extended operation invoking subs (3).

518 In relation to the 051 patent, there were two pieces of s 7(3) prior art information on which the respondents relied in their case on obviousness:

- Watanabe, M *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" *Bioorganic & Medicinal Chemistry*, 5(2): 437-444 (1997) ("the Watanabe article"); and
- European Patent Application No 521471 ("the 471 patent").

519 In her Honour's reasons, the primary judge said:

The skilled addressee, attempting to find dosages of alternative statins, would have discovered the 471 patent (or its US equivalent as Professor O'Brien found) and the Watanabe article by routine and conventional literature searches that necessarily would have been carried out by reason of the posited attempt. AZ's arguments to the contrary are not well-founded. Each document, on the evidence, would have been ascertained, understood and regarded as relevant to the skilled addressee as required by s 7(3) as applicable to the 051 or low dose patent. Each document, considered separately, 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 (*[Alphapharm]* at [53]).

And:

Whatever the issues with parts of the evidence, what the evidence did establish was that a skilled addressee would have readily found each of these two documents, understood each and regarded each as relevant. In this regard, the fact that Dr Wilson

and Dr Evans did not locate either document, in contrast to Professor O'Brien and Dr Reece, does not persuade me to the contrary.

520 Although there were, in the view of the primary judge, two documents which contained prior art information that brought s 7(3) into play, each was treated separately in answering the ensuing question whether, when taking the information into account, the invention would have been obvious to the skilled addressee. That is to say, no role was given to para (b) in the subsection: resort was had to para (a) only. However, the fact that there were two documents, and the means by which they were located by the expert witnesses called by the respondents, gave rise to one of the submissions made on appeal by the appellants to which I refer below.

521 The first of those submissions focussed on her Honour's assumption that, in considering whether the skilled addressee would have ascertained the information, understood it and regarded it as relevant, he or she would have notionally been "attempting to find dosages of alternative statins". Each of the experts whose searches produced information on which the respondents relied under subs (3) was set to a task of this nature. The appellants submitted that the experts "assumed as their starting point that some new and alternative statin molecule was in existence". However, "no new and alternative statin molecule was part of common general knowledge."

522 Factually, this submission on behalf of the appellants was only half right. Dr Reece had indeed been instructed as follows:

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.

But the instructions given to Prof O'Brien set out only so much of this passage as commenced "Despite the benefits ...". He was not told that there was "a new statin" that was not part of the common general knowledge. Even in the case of Dr Reece, although he was indeed told that there was a new statin, at the point where he described the searches which he would have undertaken in 1999, the setting was no more, on my reading of it, than that he had an incentive

to discover whether there was such a molecule. I deal with the searches which he in fact undertook below. In the result, I do not think that the utility of the evidence of Dr Reece was compromised because of the premise, given to him in his instructions, that there was a new statin in existence.

523 I would, if necessary, decide the present point conformably with what I have said in the previous paragraph. However, to so proceed would do less than justice to the appellants' submissions on appeal. It was submitted on their behalf that an important question arises with respect to the construction of s 7(3), namely, in what factual environment is the skilled person notionally to be placed when one enquires whether he or she "could reasonably be expected" to do the things referred to? That environment must, it seems to me, be limited to the common general knowledge. The subsection permits an extension to the common general knowledge only when certain conditions are satisfied. In determining whether those conditions are satisfied in a particular case, it would be circular, and contrary to the scheme of the provision, notionally to provide the skilled person with access to information which was not part of the common general knowledge. To this point, I would accept the appellants' argument.

524 However, one must then move to a consideration of the task which subs (3) allocates to the skilled person. Although it has been noted that inventions do not invariably come about by the development of a solution to a problem, the intellectual exercise for which s 7(3) provides does, in my view, require one notionally to have the skilled person giving attention to the subject concerned, in the sense of working upon, or at least thinking about, some possibilities for an improvement in the existing state of things, whether by the solution of a problem or otherwise. Whether the leading of expert evidence would in all cases be a necessary link in the chain which leads to the conclusion for which s 7(3) provides is a question which did not arise in the present case, and I would not want to enter upon it. However, if there is to be such evidence, I would perceive no difficulty in the provision to the expert of a statement of the nature of the task, problem or suboptimal situation in the context of which he or she proceeds to give evidence which may lead to such a conclusion. That was what happened in the present case, and I do not consider that the primary judge erred to the extent that she based her decision upon it.

525 The appellants' next submission was that the searches which led to the unearthing of the Watanabe article and the 471 patent were not such as any skilled addressee could reasonably be expected to have undertaken before the priority date. The appellants drew attention to the

evidence of Prof O'Brien that he had never undertaken a search of this kind before, and to that of Dr Reece, who accepted that it would be "bizarre" for him to have been asked what he would do when given a new, unidentified, statin. In the case of Prof O'Brien, however, the appellants' submissions substantially misrepresent the tenor of the evidence which he relevantly gave. He did agree that the steps which, in his evidence-in-chief, he stated that he would have taken were steps which he had in fact never previously taken. But he insisted that he would have taken those steps if confronted with the instructions which had been given to him. He said that the procedures which he outlined were "a standard sort of thing", and that the resources which, in his affidavit, he had indicated that he would have used "were the resources that were available" to him. He emphatically rejected the suggestion, put to him by counsel for the appellants, that he entertained any doubt on the subject. He added:

It's what I do now if I'm looking for new compounds. Just last week I was giving some talks overseas, and one of the titles was New Drugs and Diabetes. I took exactly those sorts of steps, purely to give an interesting talk for general practitioners, so very much along those lines. I've been doing that for many years.

526 The evidence of Dr Reece on this point also needs to be placed into context. It related to an aspect of the instructions given to him to which I have referred above, namely, that he was "given a new statin and told that it is useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis". Dr Reece agreed with cross-examining counsel that it would have been a "bizarre" situation for him to have been given a new compound in "a circumstance in which you weren't told what it was", that is to say, given to him "in some sort of black box". It may be accepted that that would have been bizarre in the normal run of professional work in which Dr Reece was engaged. But the kind of tasks with which experts called in support of an obviousness case are charged may often be regarded as bizarre against the example of more normal research or practice activities. More importantly, Dr Reece's answer did not, in my appreciation of it, derogate from his description of the steps which he would have taken to ascertain, and by which he did ascertain, the existence of information which the primary judge then took into account under s 7(3).

527 The final submission made by the appellants in this area (the activation of s 7(3)) was one which was given special emphasis in their oral address to the Full Court. It was said (and here I refer to the appellants' outline) that Dr Reece and Prof O'Brien "combined information they found in multiple sources", and that s 7(3) "made no provision for multiple sources to be

combined and read together in this fashion”. In order to deal with this submission, it will be convenient to commence with the evidence of these two expert witnesses.

528 In his affidavit, Dr Reece described the means by which, using only information that was available before the priority date, he searched for published articles which had the potential to provide information about a new statin which had the characteristics referred to in his instructions. He reached the point where he had 19 abstracts that appeared to fall within his terms of reference, and he obtained the articles concerned. Having reviewed those articles, he concluded that only three were relevant to the terms of reference. The lead authors of those articles were Aoki, Watanabe and Thompson. The Aoki article referred to an HMG-CoA reductase inhibitor referred to as NK-104. The Watanabe article contained a report on a series of compounds, including one described as S-4522 (which was rosuvastatin), which Dr Reece recognised as “a 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 both NK-104 and S-4522.

529 So far as the endeavours of Dr Reece were concerned, the respondents relied on the Watanabe article as satisfying the requirements of para (a) of s 7(3). It was the article with respect to which Dr Reece was asked to continue his work, once he had located the three articles referred to above. However, part of Dr Reece’s assessment of the relevance of the article was his assumption that the unknown compound for the characteristics of which he was searching was at the stage of Phase II trials at least. The Watanabe article informed him that S-4522 was in clinical trials, which Dr Reece took to mean either Phase I or Phase II trials. But it was the Thompson article which told him that S-4522 was in Phase II trials. Neither article was, of course, in the common general knowledge. The appellants say, therefore, that Dr Reece went beyond the common general knowledge in respects not permitted by para (a) of the subsection.

530 In my view, the appellants’ submission proceeds from a misreading of s 7(3). It is true that, under s 7(2) in its non-extended form, the skilled person notionally knows nothing beyond the common general knowledge. But it is then assumed 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 information along the road to that destination. As noted above, subs (3) assumes that the skilled person will commence with the common general knowledge, but, beyond that, the only requirement is that the information is within what he or she “could be reasonably expected to have ascertained [etc]”. 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.

531 In the case of Prof O’Brien, he too undertook searches and whittled down the articles of interest by reference to their abstracts. Ultimately, he requested a full copy of each of three articles, namely, the Aoki article, the Watanabe article and a third one. Under cross-examination – and this was the section of his evidence upon which the appellants rely here – Prof O’Brien agreed that he had come to the position of regarding the Watanabe article as the most relevant one as a result of his comparing it with what he had read in the other articles. His decision involved a choice between the articles in this way. The appellants’ criticism of the primary judge in this respect was the same as that with which I have dealt above, namely, that it was an error to have acted upon evidence of the means by which the witness came to an identification of the single document referred to para (a) of s 7(3) by a process which involved him looking at several documents in combination, or by way of comparison. For reasons which by now should be apparent, I would not accept that criticism.

532 For the above reasons, I would reject the appellants’ challenge to her Honour’s decision that it was proper to use the Watanabe article as the source of the information that would be added to the common general knowledge pursuant to the extended operation of s 7(2) of the Patents Act. Although there was, in the appellants’ grounds of appeal, a challenge to the primary judge’s holding that the 471 patent formed part of the prior art base under s 7(3) of the Patents Act, at the level of the availability of the subsection no separate submission was made in that regard. The appellants’ submissions were confined to the matters discussed above.

533 That brings me to the question 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). As to the “would have been obvious” aspect of this question, as mentioned previously the correct approach is that which was favoured by Graham J in *Olin Mathieson* ([1970] RPC at 187-188) and approved by Gleeson CJ, Gaudron, Gummow and Hayne JJ in *AB Hassle* (212 CLR at 433 [53]), namely, to ask 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. As mentioned above, her Honour answered that question – the “Cripps question” – in the affirmative.

534 The passages which I have set out at para 519 above came subsequently in her Honour’s reasons, and were necessarily informed by, the following passage in which her Honour had dealt with the issue of primary obviousness under subs (2) on the basis, which was her holding, that rosuvastatin was a given, and must be treated as the starting point from which the inventors’ work proceeded:

On this basis the invention in the 051 or low dose patent would have been obvious to a person skilled in the relevant art in light of the common general knowledge in the patent area as it existed before the asserted priority date. The invention would have been obvious because, against the common general knowledge, the invention involved nothing more than the identification of a conventional starting dose for a compound within a known class for a known purpose. As Apotex submitted:

The selection of a 5 to 10 mg dose is no more than the selection of a relatively low (but conventional) dose of rosuvastatin, by reference to the preferred prescribing practice of some, but not all, doctors - of starting patients on a relatively low dose and then titrating the dose upward.

The primary judge appears to have decided the alternative point involving the question of obviousness where subs (3) had an operation on the basis that, having consulted the Watanabe article or the 471 patent, the skilled person would have rosuvastatin as a compound before him or her. It would then be a “given” on any view. From that point to the invention in suit involved only the selection of appropriate dosages.

535 On appeal, the appellants submitted that the obviousness issue should be resolved by answering the question whether the skilled person, armed with the common general knowledge and the additional information permitted by s 7(3)(a) (the Watanabe article or the 471 patent), would directly be led as a matter of course to try the administration of rosuvastatin at starting daily dose of 5-10 mg in the expectation that it might well be an efficacious treatment for a patient

suffering from hypercholesterolemia: *AB Hassle* 212 CLR at 433 [53]. The appellants submitted that the primary judge had made a number of errors in dealing with that subject.

536 It was said first that her Honour had not explained why the skilled person, armed with the Watanabe article or the 471 patent, would necessarily have been led to try rosuvastatin rather than the NK-104 compound, the subject of the Aoki article turned up by the researches of Prof O'Brien and Dr Reece. We were taken, at some length, to the evidence of these witnesses (especially to that of Prof O'Brien) where it was accepted that, so far as they could see from the publications they consulted, NK-104 was a new compound of considerable potential in the treatment of hypercholesterolemia. It was submitted that there was nothing in the evidence to justify the conclusion that the notional skilled person would have been led directly to try the S-4522 (rosuvastatin) route, rather than the NK-104 route. The difficulty with this submission, however, is that her Honour did not find, and we were directed to no evidence which would have sustained a finding, that NK-104 was part of the common general knowledge as at the priority date. That being the case, the skilled person would not have had before him or her both the Watanabe article or the 471 patent, on the one hand, and the Aoki article on the other hand: it had to be Watanabe or 471 or Aoki. In this wholly notional exercise, the skilled person would never be faced with a choice of the kind which is implicit in this submission on behalf of the appellants.

537 The appellants' next submission related to what was, at the relevant time, a known, well-established, statin known as "atorvastatin". It was submitted that "no skilled addressee would have pursued any new statin unless they were satisfied that it was at least as effective as atorvastatin", and that he or she could not, at the priority date, have been so satisfied merely by reference to the information in Watanabe or the 471 patent, together with the common general knowledge. It was pointed out that "neither Watanabe nor '471 reported any test of any kind that compared the efficacy of rosuvastatin against atorvastatin", and that "there was no finding that any part of the common general knowledge, read together with either publication, would have enabled the necessary comparison to be made as a matter of course".

538 In considering this submission on behalf of the appellants, I would commence with some findings made by the primary judge which were not criticised in the appellants' case on appeal. Her Honour said:

Atorvastatin was considered efficacious but, as Professor O'Brien said, it was not effective for all people, there being "a subset that require either other agents or require more potent agents, particularly patients with familial hypercholesterolemia". There

were existing statins and the market for statins might well have warranted the description “crowded” before the asserted priority dates but those involved in the treatment of hypercholesterolemia knew that the existing statins did not effectively treat all patients for the reasons already identified.

And:

Insofar as the common general knowledge is concerned, accordingly, it was common general knowledge in those involved in treating hypercholesterolemia before the asserted priority dates that statins were an effective and safe treatment for hypercholesterolemia but, despite the existence of a number of statins, there remained patients who could not be effectively treated by them. It was also common general knowledge at that time that one issue with the prescription of statins is that many patients did not achieve their target cholesterol level because they were not effectively subject to dose titration as this process involves ongoing management and supervision by a medical practitioner. Accordingly, it was common general knowledge in those involved in treating hypercholesterolemia that a statin which could bring more patients to their target level without dose titration than the existing statins would be highly desirable.

539 Turning to the evidence, in his affidavit Prof O’Brien said that, in responding to the instructions which he had been given, he would, at the priority date, have been looking for a statin that yielded “at least a 35% reduction in LDL-C at the starting dose so that it could be said that the statin was as good as or better than atorvastatin”. Under cross-examination, Prof O’Brien confirmed that, unless he had (and here I use counsel’s words in his question to the witness) “a sufficient degree of confidence ... that [the hypothetical new drug] would be as good as or better than atorvastatin, at least [as] one of the reasonable possibilities, [he] would have said, well, sit back, we won’t waste our time on that, we will wait and see if something else comes along.”

540 But it was Prof O’Brien’s evidence that the Watanabe article disclosed a compound that had the very real potential to be at least as good as atorvastatin. Having read the article, Prof O’Brien said that he would have expected S-4522 “to have a similar or better efficacy than atorvastatin”, but that “[t]his would need to be confirmed by a direct comparison”. He made that qualification because the article compared S-4522 with other statins, but not directly with atorvastatin. When tested on his reading of the article under cross-examination, and (as counsel pointed out to him) in contradistinction to the more conservative assessments made by the authors of the article themselves, Prof O’Brien said that S-4522 looked to him to be “an exciting molecule”; that the data was “impressive”; that S-4522 “may well be better than atorvastatin”; and that S-4522 was “a promising candidate for being better than atorvastatin”.

541 In Dr Reece's affidavit, he said that the new statin which he had been asked to identify would have to be neither less potent nor less safe than atorvastatin. One of the conclusions which he drew from the Watanabe article was that S-4522 was "a very potent agent in reducing plasma cholesterol concentrations". Our attention was drawn to no passage in his cross-examination in which he was tested on the extent to which he could have inferred that S-4522 would likely be at least as efficacious as atorvastatin in this regard.

542 In my view, in this state of the evidence, it was no error for the primary judge to have found that the s 7(2) skilled person would have been led directly, and as a matter of course, to try S-4522 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. It is not necessary that he or she would have known, before the event, that the compound or method notionally being further investigated would in fact satisfy that test: the requirement is that it "might well" do so. The evidence of Prof O'Brien particularly, but also the evidence of Dr Reece to the limited extent that he dealt with the subject, 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 S-4522 might well be at least as efficacious a treatment as atorvastatin.

543 The appellants' next submission was that "neither Dr Reece nor Professor O'Brien gave evidence that they would have been directly led as a matter of course to try rosuvastatin as a treatment for hypercholesterolemia at any dose (let alone a 5 or 10 mg dose) with any reasonable expectation of success ...". The submission then drew attention to some aspects of the evidence of these witnesses. If this was intended as a submission that the primary judge's conclusion that the skilled person would have proceeded in this way was not open on the evidence before her, I would reject it. Whether an invention is obvious is a question to be answered by the court. The Cripps question is the touchstone by reference to which the High Court, in *AB Hassle*, gave content to the notion of "obvious". By no means were their Honours proposing that, in order to sustain an obviousness case, a party had to lead evidence which, in terms, echoed the formula. Indeed, there is a sense in which the recitation of the formula by an expert witness might be regarded as tendentious, if not objectionable.

544 In the context of Claim 1 of the 051 patent, the skilled person would, to use her Honour's term, be "armed" with the Watanabe article or with the 471 patent. That is to say, he or she would be armed with rosuvastatin. The only issue which would then arise would be whether he or

she would be directly led as a matter of course to try a dosage of 5-10 mg daily. Even before he had reviewed the Watanabe article and the 471 patent – that is to say, working only with the instructions given to him that there was a new statin at least as efficacious and safe as others with which he was familiar – Dr Reece expressed the expectation that the dose sizes used in the hypothetical Phase II trials would be 5 mg, 10 mg and 20 mg. Having reviewed those sources, Dr Reece adhered to his earlier evidence. Prof O’Brien’s corresponding evidence was given from the perspective of having reviewed Watanabe and the 471 patent. His expectations of starting doses were “around 10 mg once daily” and “5 to 10 mg once daily” respectively.

545 The submission that the primary judge was not justified in holding that the administration of rosuvastatin at 5-10 mg once daily would not have been something which the skilled person, armed with the Watanabe article or with the 471 patent and otherwise drawing upon the common general knowledge, would have tried as a matter of course is, in the light of this evidence, unsustainable.

546 It was next submitted on behalf of the appellants that the primary judge was in error to find (in the passage of her Honour’s reasons that I have set out in para 534 above) that “against the common general knowledge, the invention involved nothing more than the identification of a conventional starting dose for a compound within a known class for a known purpose”. It was submitted that “to adopt such a course would have been out of the ordinary”. It was said that “the dose that is known and marketed for other drugs is not the determining factor in dose selection”, and that “there was no animal (or human) safety data published in either Watanabe or ‘471” (emphasis in the applicant’s outline). It was further said that the only step that the skilled person “attempting to follow Watanabe or ‘471 could have taken was to conduct animal testing themselves to find out the necessary information and then select the dose to be tried in human testing”.

547 In my view, in the context of an inquiry as to the obviousness of an invention, these submissions would place the bar too high. For an invention to be obvious, it is not necessary that the single source of information admitted under s 7(3) disclose a completed invention to the extent that the notional skilled person would have little or nothing further to do. That he or she would need to work towards the invention is not inconsistent with the conclusion that the invention was obvious, in the sense of falling within the range of destinations that he or she would expect to reach after the investigations, tests, trials and the like that would be carried out as a matter of course. The evidence upon which the appellants relied in support of this submission –

wholly that of Dr Reece – did make it apparent that neither the Watanabe article nor the 471 patent contained safety data the result of either animal or human trials. But that evidence also made it quite clear that such trials would conventionally be carried out. They would fall within the concept of working towards the invention with an expectation of success referred to in *AB Hassle*. The primary judge’s conclusions in this area of her reasons were, in my view, unobjectionable.

548 The appellants’ next point related to Prof O’Brien. It was said that he had “never before selected human doses for human clinical trials on the basis of animal studies and had no expertise in that regard”. Thus his opinion as to the doses that he himself would have selected was “not based on any relevant specialised knowledge or expertise”. But the evidence of Prof O’Brien, given under cross-examination, was that, before 1999 or 2000, the determination of human doses from animal dosage by weight is something that “would have been undertaken by others”. As the primary judge noted, and as counsel for the appellants accepted, the skilled addressee is a “legal construct [who] may not be a single person but may be a team of persons ‘whose combined skills would normally be employed in that art in interpreting and carrying into effect instructions such as those which are contained in the document to be construed’ (*General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 at 485)”. Or, as put by Graham J in *Olin Mathieson* [1970] RPC at 187, the skilled addressee may be perceived as “the notional research group”. In the circumstances, there is nothing in this point raised by the appellants on appeal.

549 Finally, the appellants submitted that neither Prof O’Brien nor Dr Reece expressed the opinion that either the Watanabe article or the 471 patent “would solve or alleviate dose titration”. The appellants put the submission in these terms because the primary judge had said that there was “a conscious perception that a new statin which could bring more patients to their target level without dose titration than the existing statins would be highly desirable”. This would have provided the notional research group with an incentive to carry out their work. In that setting, it would then be asked whether rosuvastatin at 5 or 10 mg would have been within the range of things which the group would, as a matter of course, have tried. If an affirmative answer would otherwise be given to that question, it would, in my view, amount to no disqualification that the group would not read, in the information with which it was provided under s 7(3), an indication that the dose titration problem would necessarily be overcome.

550 The other argument which the appellants advanced in this area of the case related to what were said to be the secondary indicia of non-obviousness, of which there were two. The first was the absence of any worker in the field actually having reached a point equivalent to the patent in suit, notwithstanding the 471 patent specification having been published some six years before the priority date and the Watanabe article having been published some two years before that date. If the invention was so obvious, it was asked rhetorically, why did the relevant scientific community leave it to the appellants to make it?

551 The answer to this submission, in my view, is that 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.

552 The second asserted indicium of non-obviousness was the substantial commercial success of the drug in which rosuvastatin was the active ingredient, administered to patients conformably with Claim 1 in the 051 patent. The primary judge considered a submission along these lines, and dealt with it as follows:

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".

In their outline on appeal, the appellants reiterated their "starting point" submission but, under the extended form of s 7(2), one must take rosuvastatin as a given, as it was disclosed both in the Watanabe article and in the 471 patent. Recognising this, the appellants then returned to the submission dealt with most recently above, namely, that no skilled addressee had developed rosuvastatin (albeit that it was, as such, not patented in Australia) over a number of years before the priority date of the 051 patent. I have already provided an answer to that submission, which also deals with the present point.

CONCLUSION

553 For the above reasons, I would dismiss the appellants' inventive step appeal in relation to both patents.