IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

BETWEEN: No. S 54 of 2015

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
SECOND APPELLANT

10 **APOTEX PTY LTD**
ACN 096 916 148
RESPONDENT

BETWEEN: No.S 55 of 2015

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
SECOND APPELLANT

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

BETWEEN: No.S 56 of 2015

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
30 SECOND APPELLANT

ASCENT PHARMA PTY LTD
ACN 118 734 795
RESPONDENT

APPELLANTS' SUBMISSIONS

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Part I: Suitable for publication

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

Part II: Issues presented by the appeal

2. What is the proper construction of ss 7(2) and (3) of the *Patents Act 1990* (Cth) (the **Act**) where multiple sources of prior art information are relied on to allege lack of inventive step under s 7(3)? In particular:

   (a) In assessing whether an invention would have been obvious in the light of the common general knowledge (the **CGK**) and any s 7(3) information, is it permissible to treat sources of s 7(3) information that teach towards the invention as the only avenue available to a skilled person?

   (b) In assessing whether a source of prior art information which was not part of the CGK can be taken into account under s 7(3), is it permissible to combine information in that source with other sources of prior art information which were also not part of the CGK?

3. Would it have been futile to grant the appellants leave to rely on an assignment and s 22A of the Act to cure the deficiency in their title to the patent in suit?

Part III: *Judiciary Act 1903*

4. The appellants have considered whether notice should be given in compliance with s 78B of the *Judiciary Act 1903* (Cth). In their view this is not necessary.

Part IV: Citations

5. The reasons for judgment of the primary judge are published as *Apotex Pty Ltd v AstraZeneca AB (No 4)* (2013) 100 IPR 285; [2013] FCA 162.

6. The reasons for judgment of the Full Court are published as *AstraZeneca AB v Apotex Pty Ltd* (2014) 312 ALR 1; (2014) 107 IPR 177; [2014] FCA 99.

Part V: Relevant facts

The 051 Patent

7. The appellants (together, **AstraZeneca**) are the patentee and exclusive licensee of Australian Patent No 200023051 (the **051 Patent**). 6 February 1999 is the priority date of the 051 Patent. The patent relates to a method of treating hypercholesterolemia, or high blood cholesterol, involving the administration of a compound called rosuvastatin.[1] Claim 1 is in the following terms:[2]

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

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[1] (2014) 312 ALR 1 at [2] – [3].
[2] (2014) 312 ALR 1 at [28].

8. AstraZeneca supplies rosuvastatin products under the brand name Crestor, which are widely used in the claimed method of treatment. The 5 mg and 10 mg Crestor products have achieved "blockbuster" commercial success in what is, and was before the priority date, a crowded statin market.[3]

9. Relevant passages of the specification of the 051 Patent are reproduced in the Full Court's reasons at [23] to [29]. Consistently with the terms of claim 1, the specification discloses that a starting dose of 5 to 10 mg per day of rosuvastatin has a superior efficacy, and a comparable or better safety profile, than starting doses of other statins, and is thus particularly advantageous.[4]

10 ***The first instance proceedings***

10. The respondents now supply generic rosuvastatin products, which are also used in the claimed method of treatment. In a series of decisions, AstraZeneca obtained interlocutory injunctions to restrain the supply of the respondents' products on the basis that this would infringe the 051 Patent and two other patents which are no longer in issue (referred to as the 842 Patent and the 165 Patent).

11. The primary judge held that the 051 Patent was invalid on three grounds as outlined below, but that, if valid, infringement of claims 1 to 3 was threatened in respect of the respondents' 5 mg and 10 mg products. Her Honour dissolved the interlocutory injunctions and ordered the revocation of the 051 Patent,[5] the orders
20 for revocation being stayed pending these appeals.[6]

12. *First*, her Honour held that AstraZeneca was not entitled to the 051 Patent because the claimed method of treatment was invented by employees of Shionogi & Co Ltd (**Shionogi**). Shionogi had invented rosuvastatin and granted a licence to AstraZeneca, which carried out research and development work including clinical trials to develop its use to treat hypercholesterolemia. Her Honour accepted that neither Shionogi nor its employees claimed any entitlement to the method of treatment claimed in the 051 Patent.[7]

13. *Secondly*, her Honour held that the claimed invention was not novel in the light of two prior publications referred to as Watanabe and the 471 Patent.[8]

30 14. *Thirdly*, her Honour held that the invention did not involve an inventive step. In this regard, her Honour held that rosuvastatin was not part of the CGK at the priority date of the 051 Patent. However, her Honour took rosuvastatin as the "starting point" for assessing inventive step, relying on *Apotex Pty Ltd v Sanofi-Aventis* (2009) 82 IPR 416 (***Sanofi-Aventis (2009)***). This led her Honour to find that the invention was obvious in the light of the CGK alone. Her Honour also held that, even without rosuvastatin as the "starting point", the invention was obvious in

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[3] (2014) 312 ALR 1 at [64]; Bull 20.09.12, paras 18 – 19; Confidential Annexure MBH-41; Confidential Annexure MBH-43.
[4] 051 Patent, page 10, lines 14 – 16.
[5] (2013) 100 IPR 285 at [514], [522] – [523]; Orders made on 5 and 19 March 2013.
[6] Orders made on 10 September 2014.
[7] (2013) 100 IPR 285 at [274], [287], [291] – [292].
[8] (2013) 100 IPR 285 at [315], [323].

the light of the CGK together with either of two non-CGK publications, namely Watanabe and the 471 Patent, which disclosed the existence of rosuvastatin and its potential utility in treating hypercholesterolemia. Her Honour found that each publication could be reasonably expected to be ascertained, understood and regarded as relevant to work in the relevant art under s 7(3) of the Act.[9]

The "Raising the Bar" amendments

15. On 15 April 2013, after the primary judge's reasons and orders, a suite of amendments to the Act came into effect. These were introduced by the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) (the **Raising the Bar Act**). A new s 22A was introduced in the following terms:

> *22A 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.*

16. The transitional provision for this amendment provided that the section would apply from the date of commencement of the amendment, being 15 April 2013, "in relation to patents granted before, on or after" that date.[10]

17. The Raising the Bar Act also made other amendments to the Act. These included the introduction of a new s 138(4), which provided that the Court "must not make an order [for revocation] 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". The transitional provision for s 138(4) provided that it applied to applications for orders made on or after the day it commenced, whether the patent was granted before, on or after that day.[11]

The appeal before the Full Court

18. AstraZeneca appealed to the Full Court against the primary judge's findings of lack of entitlement, lack of novelty and lack of inventive step.

19. AstraZeneca also sought to rely on s 22A of the Act. On 11 June 2013, it entered into a deed with Shionogi pursuant to which Shionogi assigned to AstraZeneca any and all right, title and interest Shionogi may have had in and to the invention claimed in the 051 Patent. By interlocutory application before the Full Court, AstraZeneca sought to adduce evidence of that assignment and to amend its grounds of appeal in order to rely on the assignment and s 22A. AstraZeneca argued that s 22A overcame the prevailing law at the time of the primary judge's decision, and that the Full Court, in an appeal by way of rehearing, should apply the law in force as at the date of the appeal.

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[9] (2013) 100 IPR 285 at [218], [220] – [223], [325] – [326], [328], [334].
[10] Raising the Bar Act, Schedule 6, Part 1, item 31; Schedule 6, Part 2, item 133(3).
[11] Raising the Bar Act, Schedule 6, Part 1, item 75; Schedule 6, Part 2, item 133(14).

20. The Full Court overturned the primary judge's findings that the invention claimed in the 051 Patent was not novel and was obvious in the light of the CGK alone. The Full Court held that it was impermissible to take rosuvastatin as a "starting point" in assessing obviousness under s 7(2) when it was not part of the CGK. The plurality of the Full Court disapproved of the reasoning in *Sanofi-Aventis (2009)*. Jessup J reached the same result by a different path.[12]

21. On the other hand, the Full Court upheld the primary judge's finding that the claimed invention was obvious in the light of the CGK and either Watanabe or the 471 Patent under s 7(3), with the plurality agreeing with the reasons of Jessup J on that issue.[13] The Full Court also upheld the primary judge's finding that AstraZeneca was not entitled to the 051 Patent. The plurality, with whom Jessup J agreed, found that the further evidence sought to be adduced by AstraZeneca "prove[d] that ... Shionogi assigned to AstraZeneca [AB] any and all right, title and interest that Shionogi may have had in and to the invention described and claimed in the 051 ... patent".[14] Nevertheless, their Honours held that AstraZeneca's interlocutory application should be dismissed, so that it was not permitted to rely on the assignment or s 22A of the Act.[15] The basis upon which the Full Court refused such leave was that it was futile to grant leave when the finding of obviousness was upheld.[16]

22. In the result, the appeal against the primary judge's orders for the revocation of the 051 Patent was dismissed. By the present appeal, AstraZeneca seeks to reverse the holdings of the Full Court that (a) the claimed invention was obvious in the light of the CGK, considered together with either Watanabe or EP 471 under s 7(3), and (b) the finding of lack entitlement should be upheld, because it was futile to grant AstraZeneca leave to rely on the assignment and s 22A.

The problem in light of the CGK

23. The CGK before the priority date included the knowledge that statins (or "HMG-CoA reductase inhibitors") were administered to patients to lower their low-density lipoprotein cholesterol (**LDL-C**) levels.[17] The four CGK statins used in such treatment in Australia before the priority date were fluvastatin, pravastatin, simvastatin and atorvastatin.[18] Each of these statins had differing efficacy, in terms of their ability to reduce cholesterol relative to each other. The most efficacious and market-leading statin was atorvastatin.[19]

24. To minimise the risk of side effects, doctors typically prescribed the lowest possible "starting dose" of a statin with a view to titrating the dose up if needed.[20]

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[12] (2014) 312 ALR 1 at [192]-[227], [454] – [504].
[13] (2014) 312 ALR 1 at [228]-[229], [516] – [553].
[14] (2014) 312 ALR 1 at [159].
[15] (2014) 312 ALR 1 at [137] – [143], [179] – [191], [447].
[16] (2014) 312 ALR 1 at [188].
[17] (2014) 312 ALR 1 at [53].
[18] (2014) 312 ALR 1 at [55].
[19] (2013) 100 IPR 285 at [103], [107]; (2014) 312 ALR 1 at [59].
[20] (2014) 312 ALR 1 at [61].

But dose titration required ongoing management and supervision and often did not occur. This left patients on their starting dose, even though cholesterol target levels were not achieved.[21] Further, and more generally, there remained patients who could not effectively be treated by the existing statins.[22]

25. The problem that existed in the CGK, as noted by the primary judge, was thus to develop a new statin treatment that could bring more patients to their target level blood cholesterol parameters (particularly LDL-C) without dose titration.[23] Such a statin would be considered "more effective" than the existing statins and offer a real "competitive advantage" over those statin treatments.[24]

The approach of the skilled person

26. The finding of obviousness was based principally on the evidence of Dr Reece and Professor O'Brien, which the primary judge and the Full Court accepted. The effect of this evidence was that the person skilled in the art (the **PSA**), faced with the problem in the CGK as at the priority date, would have engaged in a four-step process. *First*, the PSA would have undertaken or caused to be undertaken "routine and conventional literature searches" to discover "alternative" statins. *Secondly*, the PSA would have compared the results of those searches. *Thirdly*, the PSA would have selected from that comparison what he or she regarded as the best candidate to solve the problem. *Fourthly*, the PSA would have undertaken or caused to be undertaken relevant trials using that candidate statin to test its suitability at relevant dosages.[25]

27. Dr Reece and Professor O'Brien gave evidence of the computer searches they would have conducted according to this process, and as part of this, generated documents incorporating hundreds of abstracts of scientific papers. They read or further searched their abstracts documents and, on the basis of reading those documents or narrowed versions of those documents, identified a subset as abstracts of interest. Dr Reece obtained full copies of 19 of the papers uncovered by his searches and, as a result of reading them, identified three as "relevant", namely Watanabe, Aoki and Thompson.[26] A similar process was undertaken by Professor O'Brien. It resulted in him identifying as "relevant" documents Watanabe, the 471 Patent (via a reference in Watanabe) and Aoki.[27]

28. The two experts identified these documents as relevant based on comparisons they made with other documents identified in their searches and referred to in the abstracts documents. Such a comparison was necessary because: *first*, the problem being addressed was to find an improvement over existing statin

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[21] (2013) 100 IPR 285 at [109]; (2014) 312 ALR 1 at [61].
[22] (2013) 100 IPR 285 at [123]; (2014) 312 ALR 1 at [66].
[23] (2013) 100 IPR 285 at [123].
[24] (2013) 100 IPR 285 at [123].
[25] (2013) 100 IPR 285 at [327], [328]; (2014) 312 ALR 1 at [519], [522] – [526], [528]-[531], [536]; O'Brien 27.07.12, paras 13.9 to 13.46; T293.12 - 308.10; Reece 25.07.12, paras 148 – 166; T730.43-47; T731.45 – 732.7; T733.24 – 734.29; T761.1-42.
[26] (2014) 312 ALR 1 at [528]; Reece T761.1-42.
[27] (2014) 312 ALR 1 at [531]; O'Brien 27.07.12, paras 13.9 - 13.33.

treatments, so the comparative potential of drug candidates was important;[28] and, *secondly*, the process of drug development was so expensive and time-consuming that a single clinical candidate (showing the most promising signs of efficacy) would have been selected for development.[29] There was no finding, and the evidence did not support any finding, that the PSA would have contemplated developing two discrete statin candidates at the same time.

Watanabe, the 471 Patent, Aoki and Thompson

29. Of the four key documents thrown up by the literature searches, Watanabe and the 471 Patent disclosed, *inter alia*, rosuvastatin as potentially useful in the treatment of hypercholesterolemia. Aoki disclosed another statin compound, NK-104, as potentially useful in such treatment. Thompson disclosed rosuvastatin and NK-104, together with two further alternative statin candidates. Of the four statin candidates in Thompson, NK-104 was singled out as "[o]ne of the more interesting compounds ... [a] statin that is reportedly more potent and longer acting than simvastatin and pravastatin".[30]

30. Dr Reece did not opine as to whether he would have chosen rosuvastatin over NK-104 at the priority date, if he had been seeking to solve the problem. Professor O'Brien's evidence was that a relevant addressee could just as reasonably have pursued NK-104 as the candidate of choice as rosuvastatin, armed with knowledge of both.[31] This was apparent from the following evidence that Professor O'Brien gave in cross-examination:[32]

> *Q. But you reasonably expect others might have gone for the NK-104 in a similar position? A. Possibly, yes. Q. Just hard to say which? A. Exactly, yes. I mean, I wouldn't be critical of somebody that went for the other.*

31. NK-104 was ultimately developed and marketed by a competitor as the compound pitavastatin. It was not a success like Crestor (rosuvastatin). To the contrary, it was found to be unsafe at doses above 4mg per day.[33] There was no finding, and the evidence did not support any finding, that the PSA armed with NK-104 (Aoki) in one hand, and rosuvastatin (Watanabe or the 471 Patent) in the other, would have chosen rosuvastatin over NK-104 as the candidate to try to develop.

32. While Watanabe and the 471 Patent disclosed the potential utility of rosuvastatin as a treatment for hypercholesterolemia, neither document was held by the Full Court to be novelty-destroying. In the case of the 471 Patent, this was because the preferred dosage range (1 to 100 mg) for the many trillions of compounds it disclosed (two of which were salt forms of rosuvastatin, identified in examples 1 and 7) was so broad and non-specific that any PSA could just as likely adopt

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[28] (2013) 100 IPR 285 at [119], [121] – [123]; (2014) 312 ALR 1 at [66].
[29] (2013) 100 IPR 285 at [121] – [122], [124] – [125]; (2014) 312 ALR 1 at [65], [67] – [68].
[30] Reece Annexure PAR-13, Section 3.1.
[31] O'Brien 27.07.12, paras 13.31-13.32; O'Brien T297.42 – T298.5; T301.29-30; see also T296.45 – 297.25.
[32] O'Brien T298.1-5. Jessup J referred indirectly to this evidence at (2014) 312 ALR 1, [536].
[33] Ex 27, p 97, col 1 and footnote 47; Ex 28, p 453; O'Brien T280.15-16.

dosages other than 5 to 10 mg.[34] In the case of Watanabe, no dosage range at all was disclosed.[35] The only dosage expert called by the respondents, Dr Reece, confirmed that neither Watanabe nor the 471 Patent contained any animal or human trial safety data, which was essential before any treatment dosage could be selected and tried.[36]

Part VI: Argument

The statutory provisions

33. In the form applicable to the 051 Patent, s 7(2) of the Act provided that an invention was to be taken to involve an inventive step unless it "... would have been obvious to a person skilled in the relevant art in the light of the [CGK] 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". Section 7(3) as applicable to the 051 Patent referred to:

> *(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.*

34. The purpose of s 7(3) is to allow the CGK to be supplemented by an additional source of prior art information that was not part of the CGK. It permits reliance on a "single" source of such information in accordance with sub-paragraph (a) or (b) (the latter was not engaged in this case) where the information could "be reasonably expected to have [been] ascertained, understood and regarded as relevant" by the PSA. As this Court has held, if that threshold is met, it remains to be assessed whether the invention would have been obvious in the light of the CGK, together with that single source of information.[37]

35. Section 7(3) falls to be construed by reading the statutory text in the light of its legal and historical context.[38] The *Patents Act 1952* (Cth) prohibited the use of any publication that was not CGK when assessing obviousness, alone or in

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[34] (2014) 312 ALR 1 at [259], [288] – [306], [447].
[35] (2014) 312 ALR 1 at [343], [344], [353], [447].
[36] (2014) 312 ALR 1 at [547]; (2013) 100 IPR 285 at [320]; Reece 25.6.12 paras [75], [84], [96], [132], [134], [135]; Reece T740.28 – 741.2; T753.45 – 754.19; T757.32-40.
[37] See *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 188 ALR 280 at [36] and *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [150], both citing *Tidy Tea Ltd & Lyons Tetley Ltd v Unilever Australia Ltd* (1995) 32 IPR 405 at 414 per Burchett J.
[38] *Network Ten Pty Ltd v TCN Channel Nine* (2004) 218 CLR 273 at [10] – [12].

combination with others. Thus, it was impossible to say "you may take one or two, or twenty-one or twenty-two, prior publications and then select from them appropriate extracts or pieces of information, which will add up to the invention claimed and so demonstrate that it was obvious".[39] It was also illegitimate to take into account the results of a "routine literature search" as a step towards the conclusion that a patent was bad for obviousness.[40] The enactment of s 7(3) as part of the Act raised the threshold of inventiveness, but in a limited way. It permitted consideration of the CGK together with a single source of information, but only if the PSA "could be reasonably expected to have ascertained, understood and regarded" the source as "relevant", and on the proviso that each such single source was "considered separately".

36. Section 7(3) was never intended, in the form applicable to the 051 Patent, to allow multiple different sources of non-CGK information to be considered together as a step along the path to finding an invention obvious. Thus the extrinsic material stated that it should not be possible "... to combine two disclosures, two uses, or a disclosure and a use, where neither is within the common general knowledge of the art, except where one disclosure refers to another disclosure or use".[41] The words "each of which must be considered separately" in s 7(2), read with the text of s 7(3), give effect to that statutory purpose. They preclude a finding of obviousness where the PSA could never have been seized of the invention without combining the information in multiple non-CGK sources.

37. Nor was s 7(3) intended to radically alter the law by sanctioning hindsight reasoning or "ex post facto" analyses of the kind this Court has warned must be avoided.[42] To the contrary, as the Court said in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 (***Lockwood (No 2)***):[43]

> *... the idea remains that the prior disclosures to be taken into account, even as enlarged by s 7(3), are being considered for a particular purpose. That purpose is the purpose of looking forward from the prior art base to see what a person skilled in the relevant art is likely to have done when faced with a similar problem which the patentee claims to have solved with the invention.*

38. Thus the effect of s 7(3) is not to dictate that the single added source of information be treated as the only path available to the PSA to solve the relevant problem. Section 7(3) simply adds one single source of information (e.g. a publication) to the CGK. It does not alter the test to be applied once that single source is added. The test is governed by the words "... would have been obvious to a person skilled in the relevant art" in s 7(2). If other pathways remain available to the PSA to solve the problem "looking forward" from the prior art base, the

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[39] *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 293.
[40] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at [55].
[41] See *Firebelt Pty Ltd v Brambles Australia Ltd* (2002) 188 ALR 280 at [35], citing the report by the Industrial Property Advisory Committee (29 August 1984) entitled "*Patents, Innovation and Competition in Australia*" at 45.
[42] See *Wellcome Foundation Ltd v VR Laboratories (Aust) Pty Ltd* (1980) 148 CLR 262 at 286; *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 293; *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at [21]; *Graham Hart (1971) Proprietary Limited v S. W. Hart & Company Proprietary Limited* (1978) 141 CLR 305 at 332.
[43] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [127].

existence of those pathways remains a relevant matter that must be taken into consideration. The choice of what path of discovery to follow is a matter that remains at the heart of the obviousness inquiry.

The Full Court's approach to s 7(3)

39. The conclusion of Jessup J (with whom the plurality agreed) that the claimed invention was obvious in the light of the CGK plus Watanabe or the 471 Patent was dependent on two markedly different approaches being taken to treatment of non-CGK information at different stages of the obviousness inquiry.

40. *First*, his Honour held that ss 7(2) and (3) did not preclude the PSA from using combinations of sources of non-CGK information "along the road to [the] destination" of assessing whether or not any single piece of prior art information could reasonably be expected to have been "ascertained, understood and regarded as relevant" to solving the problem, and was therefore available as prior art information under s 7(3). The critical reasoning was set out at [530]:

> *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.*

41. *Secondly*, having held that combinations of sources of non-CGK information could be utilised to establish that Watanabe and the 471 Patent fell within s 7(3), his Honour then construed s 7(2) as mandating "a wholly notional exercise" in which those documents were to be treated as the only relevant sources of non-CGK information when assessing whether the invention was obvious. His Honour's reasoning was that, although Aoki (and hence NK-104) was found and identified as "relevant" in the same search process that identified Watanabe and the 471 Patent (and hence rosuvastatin), this was irrelevant to the question under ss 7(2) and (3), because s 7(2) required each document identified in the searches to be "considered separately" when assessing obviousness.

42. Jessup J said, at [536]:

> *... 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. 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.*

43. There is no dispute that the above choice between competing drug candidates is a choice that any PSA addressing the problem at the priority date would have in fact confronted and in fact have been required to make.

Errors in the Full Court's approach

44. That the Full Court's approach involved error is exposed by considering the implications of the reasoning process encapsulated at [536]. An essential step in the Full Court's conclusion that each of Watanabe and the 471 Patent could be added to the CGK by the s 7(3) mechanism was the acceptance of the four-step approach of the PSA to solving the problem. A critical step for the PSA in attempting to solve the problem was to compare the new statin candidates found in the search process and make a selection. Yet, in the same stroke as accepting this methodology, the Full Court denied its applicability once an individual publication was identified by that methodology.

45. The effect of this is to allow the party challenging a patent to identify the correct path (or "starting point") *ex post facto*, in this case rosuvastatin, based upon a consideration of multiple sources of non-CGK information, *and then* have the question of obviousness determined on the basis of "obvious to try with an expectation of success" by reference to that path only, and not the choices the PSA would in fact have faced. If the question is confined to whether it was obvious to try one path only, being the pathway known many years later to lead to the invention, the tendency for the question to answer itself is high.

46. Let it be assumed, for example, that there are ten non-CGK documents available for consideration under s 7(3), one of which teaches towards the invention, and nine of which teach away from it, and that the evidence does not demonstrate that the PSA would have been directly led as a matter of course to pursue the one document that teaches towards the invention, instead of the others that teach away. On the Full Court's approach, the invention must nevertheless be held to be obvious by reference to the one combination of the CGK with a document that teaches towards the invention, while disregarding the others on the basis that they do not form part of the CGK. This cannot have been the intention when s 7(3) was introduced. To construe the statue this way is unfair to inventors. It is also inconsistent with the principle that it is the selection of the integers of an invention out of "perhaps many possibilities" that must be shown to be obvious, "bearing in

mind that the selection of the integers in which the invention lies can be expected to be a process necessarily involving rejection of other possible integers".[44]

47. The Full Court's approach meant that there was no consideration of whether it was obvious to select rosuvastatin as the candidate to be tried to solve the problem, as distinct from some other statin candidate (e.g. NK-104) or another approach entirely. If the choice between the drug candidates had been considered, the invention could not have been held obvious on the evidence – see [29] to [31], above. The outcome of the Full Court's approach is that the patentee would have been better served if all of the search publications had been part of the CGK, because then the PSA would have been faced with a non-obvious choice between the different publications. Again, this is a counter-intuitive outcome that cannot have been the intention when s 7(3) was introduced.

48. The Full Court was correct to reject the "inventor's starting point" as the relevant approach to assessing obviousness elsewhere in its reasons.[45] However, it has introduced a new variant, which amounts to the revoker selecting its "starting point" under the guise of s 7(3) with the benefit of knowing the outcome. This involved at least the following four species of error, although there may in truth be one error considered from different perspectives.

49. *First*, let it be assumed that the Full Court was correct in concluding that Watanabe or the 471 Patent could be added to the CGK under s 7(3). That having been done, the test for obviousness did not alter. Applying *Lockwood (No 2)* to the Full Court's own findings, the task would then be to look forward to see what the PSA would have done to solve the problem. Here, the PSA's approach was to conduct a literature search and compare the results. This was necessary to identify the candidate for selection to be tried. There was no evidence that providing the PSA with any single s 7(3) document would have altered the PSA's approach. Once the PSA had Watanabe, that would have saved a search for that article, but could not have avoided the PSA's accepted desire to complete the search and compare that disclosure with the other search results. With only the Watanabe article and the CGK, the PSA could not have moved forward: he or she would not have known whether rosuvastatin was the candidate of choice. The same analysis applies to the 471 Patent.

50. It is no answer to hold, as Jessup J did, that the other search results must be ignored, because they (like Watanabe and the 471 Patent) were not part of the CGK. The CGK included knowledge that routine searches could be undertaken designed to uncover relevant information for consideration before any decision to move forward with the prior art was made. Again, there was no finding, and the evidence did not support any finding, that the PSA would have been directly led to try a statin disclosed in one of the publications added to the CGK, without first searching for other statins and comparing them. In this way, the Full Court's approach involved error in not applying the relevant test for obviousness, which it

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[44] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at [41].
[45] (2014) 312 ALR 1 at [192] – [227], [454] – [504].

itself had accepted after determining that Watanabe and the 471 Patent were each a s 7(3) publication. The Full Court's conclusion that a finding of obviousness was dictated by the "wholly notional exercise" of assessing Watanabe and the 471 Patent, divorced from any consideration of the CGK that other relevant publications were likely to exist, is not supported by the text, history or purpose of those sub-sections. There are no words in the section that support that outcome or approach. Nor does the statutory purpose or context.

51. *Secondly*, and again assuming that the Full Court was correct in concluding that Watanabe or the 471 Patent could be added to the CGK, the "relevance" of each document, as determined by the search and comparison process, was that it was "a" (i.e. one) relevant publication, among others. Neither the primary judge nor the Full Court found that Watanabe or the 471 Patent was "the" relevant prior art information. On the contrary, the respondents did not attempt to prove, and did not seek a finding, that either of those publications was any more than "a" relevant piece of prior art information. No such finding that either publication was "the" relevant publication was possible on the evidence. At best, each publication suggested "a" possible path, among others, including Aoki and Thompson. Yet the Full Court, in effect, treated the words "considered separately" in s 7(2) as a statutory injunction to treat each of Watanabe and the 471 Patent as "the" only relevant information. As this Court held in *Lockwood (No 2)* at [152], what is "relevant" under s 7(3) "depend[s] on the standard of a skilled person's opinion of the relevance of the information". The PSA's assessment of the relevance of Watanabe and the 471 Patent as "a" (but not "the") relevant publication was directly relevant to the obviousness inquiry. The Full Court erred in failing to recognise and consider this. Again, the PSA could not move forward without knowing what other results might be available. That is enough to conclude that the invention was not obvious.

52. If one needed to go further, there was no dispute that at least Aoki and Thompson would have been found and regarded by the PSA as highly "relevant" alternative sources of information in the search process. The two publications, together with the 471 Patent and Watanabe, positioned the choice between NK-104 and rosuvastatin as a critical juncture in any effort to solve the problem. As noted above, there was no finding, and the evidence did not support any finding, that the PSA would have chosen rosuvastatin over NK-104. Only with hindsight is it simple now to see that rosuvastatin was the right path to follow.

53. *Thirdly,* the holding of Jessup J that the choice between competing drug candidates was avoided by the words "considered separately" in s 7(2) was antithetical to the statutory purpose, as revealed by the legal and historical context. The purpose of the words "considered separately" in s 7(2) is to offer a measure of protection to inventors, by forbidding the hindsight practice of combining information in multiple sources of non-CGK information to arrive at the invention. In this respect, the words retain the position that applied under the *Patents Act 1952* (Cth), as elucidated by Aickin J in *Minnesota Mining and Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253 at 293:

> *When once an idea or an object or a process or a combination, admittedly novel, has been published, it is very easy to say after perhaps months of search and study in the Patent Office and the public libraries that the integers into which the patent might be dissected could be found scattered amongst the prior documents by a person who already knew the solution to the problem and therefore knew what to look for and what to discard. But that process does not demonstrate lack of an inventive step. The opening of a safe is easy when the combination has been already provided.*

54. To construe the words "considered separately" as forbidding one species of hindsight (the mosaicing of prior art) but requiring a new species of hindsight (the assessment of obviousness by reference to combinations of the CGK and s 7(3) information that teach towards the invention only, in disregard of all sources of the CGK and s 7(3) information that teach away from the invention) is to defeat the statutory purpose.

55. *Fourthly,* and consistently with this, on the proper construction of s 7(2) and (3), the Full Court erred in accepting that Watanabe and the 471 Patent were s 7(3) publications. The issue here is that the PSA's assessment of whether any given document was "relevant" involved, on the evidence of the experts, a comparative assessment of the information in multiple non-CGK sources: each candidate's "relevance" to the problem depended in part on its apparent potential in comparison with other candidates disclosed in non-CGK publications produced by the search process. However, s 7(2) and (3) specify that obviousness must be assessed by reference to the CGK alone, or in combination with any single additional source of s 7(3) information, "each of which must be considered separately". They do not permit multiple sources of information to be considered as a step in the reasoning that leads to a finding of obviousness.

56. The error of the Full Court is captured in the following statement of Jessup J:[46]

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

57. The effect of the above reasoning is to construe the words "each of which must be considered separately" in s 7(2) as inoperative on the last 40 words of s 7(3), which requires any single (non-CGK) source of information to be information that the PSA "could ... be reasonably expected to have ascertained, understood and regarded as relevant ..." before it may be taken into account when assessing obviousness under s 7(2). AstraZeneca submits that this is wrong, having regard to both the text and statutory purpose. The clear words of s 7(2) require that non-CGK sources must be "considered separately". This requires each non-CGK source to be considered separately at each stage of the obviousness inquiry, including (i) when assessing whether the invention is obvious in the light of the CGK and a single source of s 7(3) information and (ii) at the anterior step of

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[46] (2014) 312 ALR 1 at [530]; see also [527] – [532].

assessing whether or not any given source of information satisfies the "ascertained, understood and regarded as relevant" requirement in s 7(3).

58. The Full Court's approach required the taking of starkly inconsistent positions on this issue. At [523], Jessup J said (emphasis added):

> *It was submitted* [on behalf of the appellants] *that an important question arises with respect to the construction of s 7(3), namely, in what factual environment is the skilled person notionally 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. That subsection permits an extension to the common general knowledge only when certain conditions are satisfied [i.e., the requirement to ascertain, regard as relevant (etc) under s 7(3)]. In determining whether those conditions are satisfied in a particular case, it would be circular, and contrary to the scheme of the provision [i.e., s 7(3)], notionally to provide the skilled person with access to information which was not part of the common general knowledge.*

59. AstraZeneca submits that the reasoning in the underlined passages is correct. Yet, in contrast, at [530], his Honour erred by holding (emphasis added):

> *The question is whether he or she could reasonably be 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'.*

60. The problematic nature of this construction culminates at [536] in the incongruity of a comparative assessment with other located publications being a necessary step in finding that Watanabe and the 471 Patent met s 7(3), but those publications then being put to one side and ignored when applying the obviousness test. Where the PSA could only attempt to solve the problem by a process that required multiple non-CGK sources of information to be searched and considered in combination with each other, s 7(3) could not be usefully employed to advance the attack of obviousness.

Other difficulties with the Full Court's reasoning

61. The assumption that s 7(2) required either Watanabe or the 471 Patent to be treated as the only pathway appears to have infected the Full Court's upholding of the primary judge's finding that either Watanabe or the 471 Patent would have led the PSA "as a matter of course to try the claimed invention" in the expectation that it might well produce a useful alternative, in at least two other ways.[47]

62. *First*, the "claimed invention" is the treatment using a once daily 5 to 10 mg dosage of rosuvastatin. As noted above, the only dosage expert called by the respondents, Dr Reece, confirmed that neither Watanabe nor the 471 Patent

[47] (2013) 100 IPR 285 at [330]; (2014) 312 ALR 1 at [228] – [229] and [547].

contained any animal or human trial safety data.[48] He gave evidence that such data were essential to determining what dosage should be tested in clinical trials; the PSA would never have chosen the dose to be tested by simply trying the doses that worked for other statins.[49] Elsewhere, the Full Court correctly rejected the manner of new manufacture ground on the basis that the invention was not obvious on the face of Watanabe or the 471 Patent, as further experimentation would be required to ascertain the appropriate dosage range and regimen.[50] The obviousness conclusion of Jessup J is, in effect, that a PSA would be directly led to try experiments which may or may not reveal information on which the claimed dosage regime could be based. But "the statute does not ask whether a particular avenue of research was obvious to try so that the result claimed therefore is obvious".[51] The Full Court erred approaching the matter that way.

63. *Secondly*, Jessup J's approach to s 7(3) led his Honour to disregard evidence of inventiveness. AstraZeneca pointed to the failure of others to produce the invention and its substantial commercial success. Jessup J held that such evidence was irrelevant to a case based on s 7(3) information, since the inquiry was a notional one "which need not correspond with reality":[52]

> *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.*

64. This is contrary to the reasoning in *Lockwood (No 2)* at [115] – [116], where this Court held, in a case in which s 7(3) was relied on, that secondary evidence of the above kind has an "important role" to play in the assessment of obviousness. If Watanabe or the 471 Patent is merely "a" relevant publication, but not understood as the "only" relevant source of information, the evidence of commercial success becomes particularly relevant. It reflects satisfaction of a community need which the patent system has classically rewarded for the extraordinary time and cost risked by the claimant for a patent in choosing a path which, as one of other available choices, could not be said to be obvious. The Full Court's approach is antithetical to that statutory purpose.

The entitlement issue

65. At trial, the prevailing law was that the ground of revocation under s 138(3)(a) was established where the person to whom a patent was granted was not entitled to be

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[48] Reece T753.42 to T754.19; T757.32-42.
[49] (2014) 312 ALR 1at [547]; (2013) 100 IPR 285 at [320]; Reece 25.6.12 paras [75], [84], [96], [132], [134], [135]; Reece T740.28 – 741.2.
[50] (2014) 312 ALR 1 at [391], [447].
[51] *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at [72].
[52] (2014) 312 ALR 1 at [551]; see also [552] in relation to the issue of commercial success.

granted the patent in accordance with s 15(1) of the Act *as at the time of the grant*, regardless of any later assignment of rights in the patent.[53] This was despite s 138(3)(a) using language in the present tense. This aspect of the law was said to stem from the common law principle that deception of the Crown as to entitlement to the invention or the identity of the true inventor destroys the foundation on which the patent is granted.[54]

66. By the time of the appeal to the Full Court, s 22A had come into effect. It provided that the 051 Patent was "not invalid merely because ... the patent ... was granted to a person who was not entitled to it". The extrinsic material confirms what is already apparent from the provision itself: s 22A was enacted to do away with the old law concerning entitlement, and allow a patentee's chain of title to be rectified after grant where the person entitled at the time of grant is willing to assist. The text of the Explanatory Memorandum accompanying the proposed s 22A included the following explanation (emphasis added; footnote omitted):[55]

> *The courts have clarified that grant of a patent to a person named in the patent application as an applicant or inventor, who is not entitled to it, or to some but not all persons who are entitled to it, renders the patent void. This creates difficulties because patent ownership issues can be complicated, and it can be unclear, even to the parties involved, who has entitlement to particular patent claims. In particular, amendments to a complete specification during prosecution can change the parties who are entitled.*
>
> *The Act provides several mechanisms for correcting ownership and resolving ownership disputes. However, some of these mechanisms are unnecessarily complicated, making it onerous or difficult to correct ownership details. These remedies may also be ineffective if the error is only discovered after grant, and can leave the parties who can demonstrate entitlement to the invention without effective patent rights. Patentees are therefore exposed to serious consequences from what may have been an honest mistake in the first instance.*

67. The sole basis upon which the Full Court concluded that leave to rely on the assignment and s 22A should be refused was that this would be futile because the finding of obviousness was upheld.[56] Accordingly, if this Court holds that the finding on obviousness should be overturned, the basis for the Full Court's refusal of leave to rely on the assignment and s 22A will fall away.

68. Further, if AstraZeneca had been given leave to rely on the assignment and s 22A, it is clear that s 22A would have required the Full Court to overturn the primary judge's finding of lack of entitlement. It appears that the Full Court

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[53] *Stack v Davies Shephard Pty Ltd* (2001) 108 FCR 422 at [34] per Whitlam, Sundberg and Dowsett JJ. See also *University of British Columbia v Conor Medsystems Inc* (2006) 155 FCR 391 at [23] – [24] per Emmett J; at [54] per Stone J, agreeing; cf [79]-[80] per Bennett J, dissenting; *JMVB Enterprises Pty Ltd v Camoflag Pty Ltd* (2005) 67 IPR 68 at [129] – [131] per Crennan J.

[54] See *JMVB Enterprises Pty Ltd v Camoflag Pty Ltd* (2005) 67 IPR 68 at [129] per Crennan J, referring to *Stack v Davies Shephard Pty Ltd* (2001) 108 FCR 422 at 428 – 433.

[55] Explanatory Memorandum to *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* (Cth), at p 118.

[56] (2014) 312 ALR 1 at [188].

accepted this, as did at least one of the respondents on the special leave application.[57] As this Court has held, the Full Court is bound to "decide the rights of the parties upon the facts and in accordance with the law as it exists at the time of hearing the appeal".[58] The law that existed at the time of the appeal included s 22A, which removed any basis for the finding of lack of entitlement.

69. The respondents have filed notices of contention seeking to raise discretionary factors in opposition to the grant of such leave. These were raised before the Full Court and referred to in the plurality's *obiter* remarks at [189]-[190], although they did not form the basis for the Full Court's decision. If this Court holds that the finding on obviousness should be overturned, AstraZeneca respectfully submits that the Court would not refuse AstraZeneca leave to rely on the assignment and s 22A. Alternatively, it would be open to this Court to remit the matter to the Full Court to exercise that discretion.

70. The usual preconditions for the grant of such leave are made out: (a) s 22A and the evidence of the assignment arise out of matters occurring since the primary judge's decision, in the form of the amendments to the Act that took effect from 15 April 2013; (b) neither was available to AstraZeneca at trial;[59] and (c) s 22A, coupled with the assignment, would lead to an opposite result on the question of entitlement to that reached by the primary judge and the Full Court. Further, this would be consistent with the statutory intent, evident from the amendments and the extrinsic material, that a patent should no longer be revoked under s 138(3)(a) in circumstances where the party found to be entitled does not seek such revocation and is prepared to assist to rectify the patentee's title. It would also be consistent with the provision that s 22A, in particular, is to have retrospective effect. A refusal of leave would deprive AstraZeneca of intellectual property rights that have extraordinary value.

71. AstraZeneca will respond in due course to any submissions on these matters on the notices of contention, but in the meantime makes the following points. *First,* AstraZeneca never conceded at trial, nor before the Full Court, that Shionogi or its employees were entitled to the 051 Patent.[60] AstraZeneca's position at all times was that it, not Shionogi, was entitled to the 051 Patent at the time of grant. *Secondly,* at the time of the trial, AstraZeneca did not have any assignment from Shionogi. There was thus no assignment in existence that could have been relied upon even had s 22A been in force. *Thirdly,* any suggestion that an assignment should have been obtained earlier and brought forward at trial is unsound. Such reasoning depends upon the fallacy that AstraZeneca should have engaged in a commercial transaction, the utility of which was denied, in circumstances where the consideration (an assignment) would have been worthless, because the law in

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[57] The respondent in Proceeding Nos. S 240 of 2014 and S 54 of 2015 (Apotex Pty Ltd).
[58] *CDJ v VAJ* (1998) 197 CLR 172 at [111]; *Western Australia v Ward* (2002) 213 CLR 1 at [70] – [71]; see also *Allesch v Maunz* (2000) 203 CLR 172 at [23].
[59] Fisher 13.06.13, paras [24] – [25].
[60] Fisher 13.06.15, Annexure GWF-B, p 21, recital 6.

force at the time required AstraZeneca to have been the person entitled to the 051 Patent at the time of grant.

72. Neither Shionogi nor its employees have ever claimed to be entitled to the 051 Patent, as the primary judge found.[61] There was a dispute at trial, and there would have been a dispute at trial irrespective of when the assignment had been taken, over whether Shionogi or AstraZeneca was the party entitled to the invention. Contrary to the Full Court's *obiter* remarks, there is no basis for finding that "the nature of the issues concerning entitlement at trial would have changed markedly" had the assignment been raised or foreshadowed at an earlier stage. Section 22A simply was not in force at the time of the trial. The respondents had discovery on the development of the invention. It was their case that Shionogi's employees invented it and that Shionogi was entitled to the 051 Patent on that basis. That case was accepted at both levels.

Conclusion

73. The Full Court erred in construing s 7(2) and (3) as (a) permitting a comparative analysis of multiple sources of non-CGK information to be conducted for the purpose of proving *ex post facto* that a single "relevant" source existed that set out a pathway to the invention, while at the same time (b) artificially constraining the obviousness inquiry to that pathway when other "relevant" sources obtained in the very same process provided alternative pathways that might well have been pursued instead, and would not have led to the invention. Applying s 7(2) according to its terms, this case is one in which the invention cannot be said to be obvious in the light of the CGK plus a "single" source of s 7(3) information, "considered separately" from all other such sources. In these circumstances, the Full Court was also wrong to hold that it would be futile to grant AstraZeneca leave to rely on the assignment and s 22A. The Full Court's orders should be set aside and orders made in the form set out in the Notices of Appeal.

Part VII: Applicable provisions

74. The applicable version of s 7 is that which existed prior to the amendments made by the *Patents Amendment Act 2001* (Cth). This provided 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*

[61] (2013) 100 IPR 285 at [287].

(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.

75. A copy of each later provision amending s 7(3) is set out in **Annexure A**.

76. Section 22A, as at the time of the appeal before the Full Court, provided:

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.

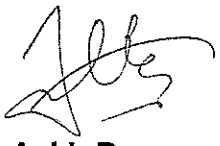
Part VIII: Orders sought

77. The appellants seek the orders set out in the **Annexure B**.

Part IX: Oral argument

78. The appellants estimate that approximately 3.5 hours (including their answer on the contentions, and reply) will be required for their oral argument.

DATED: 8 April 2015



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Patents Amendment Act 2001

No. 160, 2001

Patents Amendment Act 2001

No. 160, 2001

An Act to amend the *Patents Act 1990*, and for related purposes

Patents Amendment Act 2001

No. 160, 2001

An Act to amend the *Patents Act 1990*, and for related purposes

[*Assented to 1 October 2001*]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Patents Amendment Act 2001*.

2 Commencement

(1) Subject to this section, this Act commences on the day on which it receives the Royal Assent.

(2) Subject to subsection (3), Schedule 1 commences on a day to be fixed by Proclamation.

(3) If Schedule 1 does not commence under subsection (2) within the period of 6 months beginning on the day on which it receives the Royal Assent, it commences on the first day after the end of that period.

(4) Schedule 2 is taken to have commenced immediately after the commencement of the *Patents Amendment (Innovation Patents) Act 2000*.

3 Schedule(s)

Subject to section 2, each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Amendments commencing on Proclamation

Part 1—Amendments relating to novelty, inventive step and innovative step

Patents Act 1990

1 Paragraph 7(1)(b)

Omit "in the patent area".

3 Subsection 7(2)

Omit all the words from and including "either" to the end of the subsection, substitute ".".

4 Subsection 7(3)

Repeal the subsection, substitute:

(3) The information for the purposes of subsection (2) is:

(a) any single piece of prior art information; or

(b) a combination of any 2 or more pieces of prior art 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, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph.

6 Paragraph 7(5)(b)

Omit "in the patent area".

7 Subsection 45(1A)

Omit "anywhere in the patent area", substitute "(whether in or out of the patent area)".

8 Subsection 48(1A)

Omit "anywhere in the patent area", substitute "(whether in or out of the patent area)".

9 Subsection 98(2)

Omit "anywhere in the patent area", substitute "(whether in or out of the patent area)".

10 Subsection 101B(3)

Omit "anywhere in the patent area", substitute "(whether in or out of the patent area)".

11 Subsection 101G(5)

Omit "anywhere in the patent area", substitute "(whether in or out of the patent area)".

12 Schedule 1 (subparagraph (a)(ii) of the definition of *prior art base*)

Omit "in the patent area", substitute ", whether in or out of the patent area".

13 Application

The amendments made by this Part apply in relation to:

(a) patents for which the complete application is made on or after the day on which this Schedule commences; and

(b) the making of complete applications for patents on or after the day on which this Schedule commences.

Intellectual Property Laws Amendment (Raising the Bar) Act 2012

No. 35, 2012 as amended

Compilation start date: 15 April 2013

Includes amendments up to: Act No. 31, 2014

Prepared by the Office of Parliamentary Counsel, Canberra

An Act to amend legislation relating to intellectual property, and for related purposes

1 Short title

This Act may be cited as the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*.

2 Commencement

(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provision(s)	**Commencement**	**Date/Details**
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	15 April 2012
2. Schedule 1	The day after the end of the period of 12 months beginning on the day this Act receives the Royal Assent.	15 April 2013
3. Schedule 2	The day after this Act receives the Royal Assent.	16 April 2012
4. Schedules 3 to 5	The day after the end of the period of 12 months beginning on the day this Act receives the Royal Assent.	15 April 2013
5. Schedule 6, items 1 to 86	The day after the end of the period of 12 months beginning on the day this Act receives the Royal Assent.	15 April 2013
6. Schedule 6, item 87	The day after this Act receives the Royal Assent.	16 April 2012
7. Schedule 6, items 88 to 134	The day after the end of the period of 12 months beginning on the day this Act receives the Royal Assent.	15 April 2013

Note: This table relates only to the provisions of this Act as originally enacted. It will not be amended to deal with any later amendments of this Act.

(2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Raising the quality of granted patents

Part 1—Main amendments

Patents Act 1990

1 Section 3 (in the list of definitions)

Insert "preliminary search and opinion".

2 Subsection 7(2)

Omit "in the patent area", substitute "(whether in or out of the patent area)".

Note: The heading to section 7 is altered by omitting "**and inventive step**" and substituting "**, inventive step and innovative step**".

3 Subsection 7(3)

Repeal the subsection, substitute:

(3) The information for the purposes of subsection (2) is:

(a) any single piece of prior art information; or

(b) a combination of any 2 or more pieces of prior art information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have combined.

4 Subsection 7(4)

Omit "in the patent area", substitute "(whether in or out of the patent area)".

5 Section 7 (note 2)

Omit "subsection 98(1)", substitute "section 98".

6 After section 7

Insert:

Part 3—Application, savings and transitional provisions

55 Application of amendments

(1) The amendments made by items 2, 3, 4, 6, 8, 9 and 10 of this Schedule apply in relation to:

(a) patents for which the complete application is made on or after the day this Schedule commences; and

(b) standard patents for which the application had been made before the day this Schedule commences, if the applicant had not asked for an examination of the patent request and specification for the application under section 44 of the *Patents Act 1990* before that day; and

(c) innovation patents granted on or after the day this Schedule commences, if the complete application to which the patent relates had been made before that day; and

(d) complete patent applications made on or after the day this Schedule commences; and

(e) complete applications for standard patents made before the day this Schedule commences, if the applicant had not asked for an examination of the patent request and specification for the application under section 44 of the *Patents Act 1990* before that day; and

(f) complete applications for innovation patents made before the day this Schedule commences, if a patent had not been granted in relation to the application on or before that day; and

(g) innovation patents granted before the day this Schedule commences, if:

(i) the Commissioner had not decided to examine the complete specification relating to the patent under section 101A of the *Patents Act 1990* before that day; and

(ii) the patentee or any other person had not asked the Commissioner to examine the complete specification relating to the patent under section 101A of the *Patents Act 1990* before that day.

ANNEXURE B

B1

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No. 54 of 2015

BETWEEN:

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
SECOND APPELLANT

and

APOTEX PTY LTD
ACN 096 916 148
RESPONDENT

ORDERS SOUGHT BY THE APPELLANTS

1. An order that the appeal be allowed.

2. An order that orders 1, 3 and 4 made by the Full Court on 12 August 2014 in Federal Court of Australia Proceeding NSD 603 of 2013 be set aside and in lieu thereof:

   (a) orders in accordance with the appellants' interlocutory application to the Full Court dated 13 June 2013 in Federal Court of Australia Proceeding NSD 603 of 2013; and

   (b) an order that the appeal to the Full Court in Federal Court of Australia Proceeding NSD 603 of 2013 be allowed with costs insofar as it relates to the 051 Patent; and

   (c) an order that orders 1 (sub-paragraph (b) only) and 3 made by the primary judge on 19 March 2013 and order 1 made by the primary judge on 11 June 2013, each in Federal Court of Australia Proceeding NSD 673 of 2011, be set aside.

Date of document: 8 April 2015

Filed on behalf of the appellants by:

ASHURST AUSTRALIA
Level 26, 181 William Street
MELBOURNE VIC 3000

Tel (03) 9679 3000
Fax (03) 9679 3111
Ref: MLP GF 03 2018 9753
Contact: Grant Fisher

3. An order that the respondent pay the appellants' costs in this Court.

4. An order remitting the matter to the primary judge in Federal Court of Australia Proceeding NSD 673 of 2011 for:

   (a) the making of declarations and orders in the form sought in the appellants' further amended notice of cross-claim dated 8 May 2012 in Federal Court of Australia Proceeding NSD 673 of 2011 or such other form as may be appropriate;

   (b) the making of orders for the costs of the proceedings to date at first instance; and

10 (c) the hearing and determination of the appellants' claim for pecuniary relief.

5. Such further or other orders or relief as the Court thinks fit.

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No. 55 of 2015

BETWEEN:

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
SECOND APPELLANT

and

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

ORDERS SOUGHT BY THE APPELLANTS

1. An order that the appeal be allowed.

2. An order that orders 1, 3 and 4 made by the Full Court on 12 August 2014 in Federal Court of Australia Proceeding NSD 604 of 2013 be set aside and in lieu thereof:

   (a) orders in accordance with the appellants' interlocutory application to the Full Court dated 13 June 2013 in Federal Court of Australia Proceeding NSD 604 of 2013; and

   (b) an order that the appeal to the Full Court in Federal Court of Australia Proceeding NSD 604 of 2013 be allowed with costs insofar as it relates to the 051 Patent; and

   (c) an order that orders 1 (sub-paragraph (b) only) and 3 made by the primary judge on 19 March 2013 and order 4 made by the primary judge on 11 June 2013, each in Federal Court of Australia Proceeding NSD 2342 of 2011, be set aside.

Date of document: 8 April 2015

Filed on behalf of the appellants by:

ASHURST AUSTRALIA
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MELBOURNE VIC 3000

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Fax (03) 9679 3111
Ref: MLP GF 03 2018 9753
Contact: Grant Fisher

3. An order that the respondent pay the appellants' costs in this Court.

4. An order remitting the matter to the primary judge in Federal Court of Australia Proceeding NSD 2342 of 2011 for:

   (a) the making of declarations and orders in the form sought in the appellants' amended notice of cross-claim dated 8 May 2012 in Federal Court of Australia Proceeding NSD 2342 of 2011 or such other form as may be appropriate;

   (b) the making of orders for the costs of the proceedings to date at first instance; and

   (c) the hearing and determination of the appellants' claim for pecuniary relief.

5. Such further or other orders or relief as the Court thinks fit.

IN THE HIGH COURT OF AUSTRALIA
SYDNEY REGISTRY

No. 56 of 2015

BETWEEN:

ASTRAZENECA AB
FIRST APPELLANT

ASTRAZENECA PTY LIMITED
ACN 009 682 311
SECOND APPELLANT

and

ASCENT PHARMA PTY LTD
ACN 118 734 795
RESPONDENT

ORDERS SOUGHT BY THE APPELLANTS

1. An order that the appeal be allowed.

2. An order that orders 1, 3 and 4 made by the Full Court on 12 August 2014 in Federal Court of Australia Proceeding NSD 605 of 2013 be set aside and in lieu thereof:

   (a) orders in accordance with the appellants' interlocutory application to the Full Court dated 13 June 2013 in Federal Court of Australia Proceeding NSD 605 of 2013; and

   (b) an order that the appeal to the Full Court in Federal Court of Australia Proceeding NSD 605 of 2013 be allowed with costs insofar as it relates to the 051 Patent; and

   (c) an order that orders 1 (sub-paragraph (b) only) and 3 made by the primary judge on 19 March 2013 and order 4 made by the primary judge on 11 June 2013, each in Federal Court of Australia Proceeding NSD 208 of 2012, be set aside.

Date of document: 8 April 2015

Filed on behalf of the appellants by:

ASHURST AUSTRALIA
Level 26, 181 William Street
MELBOURNE VIC 3000

Tel (03) 9679 3000
Fax (03) 9679 3111
Ref: MLP GF 03 2018 9753
Contact: Grant Fisher

3. An order that the respondent pay the appellants' costs in this Court.

4. An order remitting the matter to the primary judge in Federal Court of Australia Proceeding NSD 208 of 2012 for:

   (a) the making of declarations and orders in the form sought in the appellants' amended originating application dated 8 May 2012 in Federal Court of Australia Proceeding NSD 208 of 2012 or such other form as may be appropriate;

   (b) the making of orders for the costs of the proceedings to date at first instance; and

   (c) the hearing and determination of the appellants' claim for pecuniary relief.

5. Such further or other orders or relief as the Court thinks fit.