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

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APOTEX PTY LTD
ACN 096 916 148
RESPONDENT

APPELLANTS' REPLY

Date of document: 29 April 2015

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Introduction

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

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

The appeal on inventive step (s 7(3))

Alternative avenues and obviousness

3. Apotex submits that AstraZeneca seeks to "shoe-horn" a consideration of the "avenues" available to the skilled person into the inquiry under s 7(2) and (3): Apotex [26]. But s 7(2) asks: was the invention "**obvious**"? That word takes its meaning from the case law.[1] It has long been recongised that an invention may not be obvious where alternative avenues existed that the skilled person might well have pursued instead, which would never have led to the invention.

4. The significance of this aspect of the law on obviousness was recognised by the adoption in *Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411 at [53] of the reformulated "Cripps question" posed by Graham J in *Olin Mathieson Chemical Corporation v Biorex Laboratories Ltd* [1970] RPC 157 at 187 – 188. In the passage cited, Graham J had said (emphasis added):[2]

> *Would the notional research group at the relevant date, in all the circumstances, which include a knowledge of all the relevant prior art and of the facts of the nature and success of chlorpromazine, directly be led as a matter of course to try the -CF_3 substitution in the '2' position in place of the -Cl atom in chlorpromazine or in any other body which, apart from the -CF_3 substitution, has the other characteristics of the formula of claim 1, in the expectation that it might well produce a useful alternative to or better drug than chlorpromazine or a body useful for any other purpose?*

5. *Olin Mathieson* was a case where the evidence showed that literature searches would have produced documents teaching towards the claimed invention.[3] But, as here, such documents formed only part of the picture; there was a "large amount of prior material [the skilled team would have had] before it, leading as it does in a number of different directions".[4] Graham J pointed out that the availability of leads in different directions told against a finding of obviousness.[5] In reformulating the Cripps question, Graham J said (emphasis added):[6]

> *... The word "obvious", as Sir Lionel agreed, and as its derivation implies, means something which lies in the way, and in the context of the* [Patents Act 1949 (UK)] *is used in its normal sense of something which is plain or*

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[1] See *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 173 at [50].
[2] [1970] RPC 157 at 187 – 8.
[3] [1970] RPC 157 at 187.
[4] [1970] RPC 157 at 192.
[5] [1970] RPC 157 at 185.
[6] [1970] RPC 157 at 188.

> *open to the eye or mind, something which is perfectly evident to the person thinking on the subject.*
>
> *In the question here I have tried to incorporate this meaning by using the words "led directly as a matter of course to try".*

6. The submission that the choice of the drug candidate to be tried is "a red herring" disregards this aspect of the inquiry: Apotex [35]. The choice of which candidate to try, in the face of prior art leading in different directions, required skill and judgment. It differentiated between success and failure. Section 7(3) does not avoid the statutory task of assessing whether that choice was "obvious" under s 7(2); it merely expands the information that can be taken into consideration for the purpose of that assessment. Once the s 7(3) information is taken into account, it still remains to be asked: was the claimed invention something that the skilled person would have been "led directly as a matter of course to try"?

The statement at [330] of the primary judgment

7. Actavis relies on a statement of the primary judge at [330]: Actavis [38]. In the passage relied on, her Honour said that the existence of eleven "other potential statin candidates" (including NK-104) did not "detract from the fact that the information in each of the 471 Patent and the Watanabe article would have led the skilled person as a matter of course to try the claimed invention ...". This was not a finding that the skilled person, faced with a choice between competing drug candidates, would have chosen rosuvastatin over NK-104 or any other candidate. It was not expressed in that way, and her Honour did not refer to any evidence to support such a finding. In light of her Honour's reasons on this issue as a whole, it is apparent that her Honour considered the "other potential statin candidates" to be irrelevant, on the basis that each of the 471 Patent and Watanabe, considered separately with the CGK pursuant to s 7(3), provided rosuvastatin as the starting point, or a "given". For the reasons already submitted, that approach was in error.

8. This is how the Full Court understood the primary judge's reasons, and their Honours approached the matter in the same way.[7] AstraZeneca submitted that it was not possible on the evidence to conclude that the skilled person would have been directly led as a matter of course to try rosuvastatin on the basis of Watanabe or the 471 Patent, as distinct from NK-104, having regard to Aoki and Thompson: see AS [30]; cf Actavis [43]. The sole basis upon which the Full Court rejected that submission was the holding of Jessup J that NK-104 was not CGK and that the "wholly notional exercise" under s 7(2) avoided "a choice of the kind which is implicit" in the submission.[8] That is to say, his Honour reasoned that the Act (and not the evidence) required Aoki (and thus NK-104) to be put to one side, and disregarded in the analysis, as Actavis and Apotex now urge: Actavis [35] – [36]; Apotex [35]. But no skilled person would in fact have done this. There is no dispute that Aoki and Thompson were highly relevant sources of information that would have been ascertained and understood by the skilled person.

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[7] (2014) 312 ALR 1 at [534] – [535] per Jessup J, with whom the plurality agreed.
[8] (2014) 312 ALR 1 at [536].

9. AstraZeneca does not contend that the Court was required to assess "multiple s 7(3) documents simultaneously": cf Apotex [35]. The point is that it is wrong to assume that any single source of s 7(3) information is "the" relevant source that the skilled person would have been directly led to follow as a matter of course, when the evidence indicates otherwise. Here, the CGK included the knowledge that routine searches had to be conducted in order to solve the problem. It is not necessary to consider the search results "simultaneously" to conclude that the invention was not obvious; it is enough that the skilled person would not have been directly led to take any step based on the CGK and a single publication alone. The search had to be conducted, and the results assessed comparatively, before any step would have been taken: see AS [49] – [51].

The combining of information

10. Contrary to Apotex [38], the Full Court found that both Dr Reece and Professor O'Brien had combined and compared information in multiple non-CGK documents for the purpose of assessing the "relevance" of those documents: at [529] and [531]. This was the only finding open on the evidence. Thus, Dr Reece gave the following evidence: "Q. And you took into account that Thompson information to come to your conclusion that each of the Watanabe article and the Aoki article were relevant? A. Yes."[9] Similarly, Dr O'Brien said: "Q. ... your decision to say you would have gone with Watanabe on this artifical – hypothetical exercise ... is based on ... [i]n effect, putting them in front of you ... and reading them together, and then working out which is the best one? A. Yes."[10]

11. Apotex's contention that the four species of error identified by AstraZeneca are "internally inconsistent" reflects a misunderstanding of AstraZeneca's submissions: cf Apotex [33]. The inconsistency lies in the Full Court permitting multiple non-CGK sources of information to be considered in combination for the purpose of identifying a source as "relevant", but then requiring other sources obtained in that process to be put to one side, and disregarded, when applying the obviousness test. Both approaches cannot be correct: see AS [60].

12. The problems with the Full Court's treatment of Watanabe are not overcome by pointing to the 471 Patent as an independent source of s 7(3) information: cf Apotex [46]. The route by which the skilled person could reasonably be expected to have ascertained and understood the 471 Patent and regarded it as "relevant" depended upon them first finding and regarding Watanabe as relevant by the comparative search process, and using information in Watanabe to find the 471 Patent.[11] This exercise was again outside the scope of ss 7(2) and (3).

Other matters

13. The respondents rely on the decision of Laddie J in *Pfizer Ltd's Patent* [2001] FSR 16 to submit that "the position internationally is no different": Actavis [39]; Apotex [29]. But as this Court has observed, the Australian and UK patent systems have

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[9] Reece T733.24 – 734.29.
[10] O'Brien T296.45 – 297.17.
[11] O'Brien 27.07.12, para 13.33.

diverged in their treatment of obviousness.[12] One aspect of that divergence is that the "state of the art" in the UK includes everything in the public domain. This is a "much broader and quite different formulation" to the prior art base contemplated by s 7(3), as it does "not depend on the standard of a skilled person's opinion of the relevance of the information".[13] The divergence is underscored by the fact that, in the corresponding Australian litigation to that before Laddie J, the Full Court of the Federal Court held that the invention was not obvious in light of the CGK and two sources of s 7(3) information.[14] This was despite a finding by the trial judge that the s 7(3) information "provided an unusually powerful indication" that the claimed invention was "worth trying".[15] The passage quoted at Actavis [39] was part of the reasoning that led Laddie J to reach the opposite conclusion, finding the same invention obvious in the light of the same prior art.

14. Similarly, the US approach as laid out in *KSR International Co v Teleflex Inc* 550 U.S. 398 (2007) does not assist the respondents: cf Apotex [30]. The Supreme Court recognised in that case that it is relevant to consider prior art that teaches away from the invention,[16] which is precisely what was avoided by the Full Court's approach to s 7(3). In any event, the statutory provisions that govern this appeal differ from those in other jurisdictions, including the UK and the US. The resolution of the appeal turns upon the proper construction of the Act.

15. Actavis [46] highlights the error below in the assessment of the obviousness of the dose range. Dr Reece gave evidence which established that the dose range was not obvious in light of either Watanabe or the 471 Patent: AS [62]. The primary judge preferred Professor O'Brien's evidence on the mistaken basis that Dr Reece was a "formulator" and "not the skilled addressee".[17] In fact, Dr Reece was a pharmacologist and the only witness called by the respondents with relevant dose selection experience. At [548], Jessup J accepted that Professor O'Brien did not have expertise in dose selection. But Jessup J then wrongly assumed that the dose range would have been obvious to another member of the "skilled team". This was not supported by the evidence; the only relevant member of the team (Dr Reece) gave evidence that selecting dose based on other statin doses was "not ... an appropriate scientific way to approach this problem";[18] cf [544].

The entitlement issue

16. The Full Court did not decide the discretionary issues: see [190]; cf Apotex [13]. The discretionary factors raised by respondents fall away on proper analysis. There is no doubt that it would have been futile for AstraZeneca to obtain and rely on any assignment of the invention at the time of trial, because s 22A was not then in force, and the law at that time meant that any defect in title at the time of

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[12] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 172 at [46].
[13] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) 235 CLR 172 at [152].
[14] *Pfizer Overseas Pharmaceuticals v Eli Lilly & Co* (2005) 225 ALR 416 at [278] – [310].
[15] *Pfizer Overseas Pharmaceuticals v Eli Lilly & Co* (2005) 225 ALR 416 at [305].
[16] 550 U.S. 398 at 416; 127 S.Ct. 1727 at 1740 (2007).
[17] (2013) 100 IPR 285 at [320].
[18] Reece T740.45 – T741.2.

grant could not be cured: see AS [65] – [66]. The suggestion that any assignment should have been obtained in those circumstances is unsound: AS [71].

17. The suggestion that AstraZeneca should have sought an adjournment of the trial until after s 22A had come into force is equally unsound. Its case was that it, not Shionogi, was entitled to the 051 Patent at the time of grant. Further, there is no prospect that any such adjournment would have been granted even had it been sought: at the respondents' urging, the case was brought on for urgent final hearing less than 12 months after interlocutory injunctions had been granted against them, restraining them from launching their products.

10 18. The respondents speculate that they might have sought to mount a different case that someone other than Shionogi was entitled to the 051 Patent: Apotex [14], [16]. This is misconceived. They had extensive discovery of documents recording the clinical trials Shionogi conducted. They tendered and relied on that discovery for the very purpose of proving that Shionogi was the party entitled to the 051 Patent, which the primary judge accepted. The documents referred to in Apotex [14] provide no basis for believing or suspecting, let alone pleading, that Shionogi's title was defective. Discovery would never have been ordered for that speculative purpose. There was no basis for joining Shionogi to the proceeding in circumstances where it claimed no entitlement to the invention. The only "different
20 case" the respondents could have run in the face of an assignment was to abandon their entitlement challenge altogether. Any prejudice to them can fairly be remedied, if necessary, by an appropriate costs order. Such prejudice is wholly disproportionate to that which AstraZeneca would suffer from denial of the opportunity to remedy the defect in its title to the 051 Patent.

Other grounds of contention

19. AstraZeneca repeats its submissions on the respondents' other grounds of contention made in its reply in Proceedings S 55 and S 56 of 2015.

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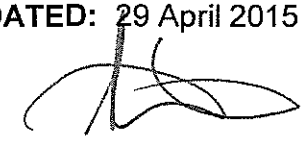

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