ASTRAZENECA AB & ANOR v APOTEX PTY LTD (S54/2015)
ASTRAZENECA AB & ANOR v WATSON PHARMA PTY LTD (S55/2015)
ASTRAZENECA AB & ANOR v ASCENT PHARMA PTY LTD (S56/2015)

Court appealed from: Full Court of the Federal Court of Australia [2014] FCAFC 99

Date of judgment: 12 August 2014

Special leave granted: 13 March 2015

The Appellants ("AstraZeneca") own Australian Patent Number 200023051 ("the Patent"). The Patent is over a method of treating high cholesterol using the compound rosuvastatin, which is contained in AstraZeneca's pharmaceutical product known as "Crestor". Rosuvastatin itself is not patented in Australia.

Rosuvastatin was invented by Shionogi & Co Ltd ("Shionogi"), whose employees also discovered that low doses of rosuvastatin reduced lipid levels in the blood. Shionogi granted AstraZeneca an exclusive licence for the use of rosuvastatin. AstraZeneca then conducted further trials to ensure the efficacy and safety of rosuvastatin, before obtaining both the Patent and regulatory approval for Crestor.

The Respondents, each wishing to supply generic products similar to Crestor, challenged the validity of the Patent.

On 19 March 2013 Justice Jagot ordered that the Patent be revoked, after holding all three of its claims invalid. Her Honour held that AstraZeneca was not entitled to the Patent, as any invention claimed by it had in fact been invented by Shionogi. Justice Jagot found that the claimed invention was not novel when compared with the art base in existence before the priority date of the Patent's claims. This was because the integers of the claims were disclosed in both a European patent application filed in 1992 and a scientific article published in 1997 (together, "the Publications"). After finding that rosuvastatin was not part of common general knowledge ("CGK") at the relevant time, her Honour held that the invention lacked an inventive step. This was upon finding that the invention would have been obvious to a suitably skilled person, in light of the CGK in conjunction with either of the Publications.

AstraZeneca appealed.

On 15 April 2013, s 22A of the *Patents Act* 1990 (Cth) ("the Act") commenced operation. It provides that a patent is not invalid merely because it was granted to a person who was not entitled to it. Pursuant to transitional provisions of the amending legislation, s 22A applies to patents granted before 15 April 2013.

In June 2013 AstraZeneca entered into a deed with Shionogi ("the Deed"), under which Shionogi assigned to AstraZeneca any rights it had to the invention

claimed in the Patent. AstraZeneca then argued on appeal that it did not lack entitlement, on account of s 22A of the Act along with the Deed.

The Full Court of the Federal Court (Besanko, Jessup, Foster, Nicholas & Yates JJ) unanimously dismissed AstraZeneca's appeal. Their Honours held that although Justice Jagot had erred in finding that the integers of the Patent's claims were disclosed in the Publications, her Honour's finding of the lack of an inventive step was nevertheless open on the evidence. In particular, the evidence established obviousness in that a hypothetical skilled person would have tried the methods claimed in the European patent application to produce a useful alternative, if armed only with the CGK and either of the Publications. In respect of AstraZeneca's claimed capacity of entitlement to the Patent, the Full Court held that Justice Jagot had not erred. Their Honours then refused AstraZeneca leave to rely on its argument founded upon s 22A of the Act, because the Patent was invalid in any event.

In each of these matters the grounds of appeal include:

- The Full Court erred in upholding the finding of the primary judge that the Patent was invalid on the ground that the claimed invention was obvious in the light of the CGK considered together with each of the documents referred to as Watanabe and the 471 Patent under the provisions of sections 7(2) and (3) of the Act (at [228] - [229], [516] - [552]).

In each of these matters a notice of contention has also been filed, the grounds of which include:

- The Full Court ought to have exercised its discretion to refuse to allow the Appellants to amend their notice of appeal to that Court in order to raise s 22A of the Act on the additional ground that the Respondent would have conducted the trial differently, if the intended reliance on an assignment from Shionogi had been raised in a timely manner, and the Respondent would therefore have been disadvantaged if the amendment were permitted.