HIGH COURT OF AUSTRALIA

2 September 2015

ASTRAZENECA AB & ANOR v APOTEX PTY LTD; ASTRAZENECA AB & ANOR v WATSON PHARMA PTY LTD; ASTRAZENECA AB & ANOR v ASCENT PHARMA PTY LTD

[2015] HCA 30

Today the High Court unanimously held that a patent which disclosed a method of treatment for hypercholesterolemia was invalid because it lacked an inventive step within the meaning of s 7(2) and 7(3) of the *Patents Act* 1990 (Cth) ("the Act").

Section 18(1)(b)(ii) of the Act provided as a requirement for a patentable invention that the invention must involve an inventive step. Sections 7(2) and 7(3) defined the condition on satisfaction of which an invention would not be taken to involve an inventive step. Relevantly, that condition was satisfied if the invention would have been obvious to a person skilled in the relevant art in light of the common general knowledge considered separately or together with prior art information publicly available in a single document before the priority date of the patent. The single document had to contain prior art information which could reasonably be expected to have been ascertained, understood and regarded by the skilled person, before the priority date, as relevant to work in the relevant art in the patent area.

The first appellant in each appeal is the registered proprietor of Australian Patent Number AU200023051 ("the Patent"). The second appellant is the exclusive licensee of the Patent. The Patent disclosed as a method of treatment for hypercholesterolemia the administration of rosuvastatin and its pharmaceutically acceptable salts at a starting dosage of 5-10 milligrams per day. The respondents supplied generic compounds using rosuvastatin at like dosages.

The appellants commenced proceedings in the Federal Court of Australia claiming infringement of the Patent by that supply and obtained interlocutory injunctions. The respondents sought revocation of the Patent. The primary judge found the Patent invalid on three grounds: that the appellants were not entitled to the Patent; that the invention disclosed in the Patent was not novel in light of two prior art publications; and that the invention disclosed in the Patent did not involve an inventive step and was obvious within the meaning of s 7(2) of the Act. The Full Court of the Federal Court of Australia overturned only the finding of lack of novelty and dismissed the appeals from the primary judge's decision. On its appeals to the High Court, the appellants sought to agitate all grounds of invalidity which had been upheld by the Full Court. The respondents raised other issues by notice of contention.

The High Court unanimously dismissed the appeals on the basis that the invention claimed lacked an inventive step and was obvious in light of the common general knowledge together with either of the two prior art publications considered separately. It was unnecessary for the Court to consider the other ground of invalidity and issues raised in the notice of contention.

- *This statement is not intended to be a substitute for the reasons of the High Court or to be used in any later consideration of the Court's reasons.*

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