DEC-16-2015 10:00 P.04/07

Hederal Court of Appeal



Cour d'appel fédérale

Date: 20151215

Docket: A-139-15

Citation: 2015 FCA 286

CORAM:

DAWSON J.A.

NEAR J.A. BOIVIN J.A.

BETWEEN:

ELI LILLY CANADA INC. and ICOS CORPORATION

Appellants

and

MYLAN PHARMACEUTICALS ULC and THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT OF THE COURT (Delivered from the Bench at Ottawa, Ontario, on December 15, 2015).

DAWSON J.A.

[1] In comprehensive and thoughtful reasons cited as 2015 FC 178 a judge of the Federal Court dismissed an application for prohibition brought by Eli Lilly Canada Inc. and ICOS Corporation (together Eli Lilly) under the *Patented Medicines (Notice of Compliance)*Regulations, SOR/93-133. In the prohibition application Eli Lilly sought to prohibit the issuance

of a Notice of Compliance to Mylan Pharmaceuticals ULC for a generic version of the drug tadalafil until after the expiration of Canadian Patent 2,379,948.

- [2] In the Federal Court Mylan alleged that it would not infringe the '948 Patent and that, in any event, the '948 Patent was invalid because it was obvious. The Judge agreed and found the allegations of non-infringement and invalidity were each justified. This is an appeal from that decision. The Minister of Health did not take part in the appeal.
- [3] On this appeal Eli Lilly asserts numerous legal and factual errors on the part of the Judge.

 Notwithstanding counsel's submissions, we are all of the view that the appeal should be dismissed. We reach this conclusion for the following reasons.
- First, Eli Lilly asserts that the Judge erred in law in his obviousness analysis by applying an incorrect test for obviousness when he wrote, at paragraph 150 of his reasons, that the "test, rather, is whether the skilled person had good reason to pursue predictable solutions or solutions that provide a 'fair expectation of success'". We agree that the correct test, and the test that ought to be applied by the Federal Court, is that articulated by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, at paragraph 66: "For a finding that an invention was 'obvious to try', there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough." This said, the Judge went on, at paragraph 151 of his reasons, to note that it was "more or less self-evident" that the invention ought to work. The Judge then concluded "even if the standard is not 'fair expectation of

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success', I find that the invention was 'obvious to try' according to the test in' Sanofi-Synthelabo. It follows that any error by the Judge in his initial articulation of the test for assessing obviousness was not material to the Judge's decision.

- [5] Second, with respect to the balance of the issues asserted by Eli Lilly, we are of the view that the appeal should be dismissed substantially for the reasons given by the Judge.
- [6] It follows that the appeal will be dismissed with costs.

"Eleanor R. Dawson"

J.A.

DEC-16-2015 10:00 P.07/07

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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ICOS CORPORATION v. MYLAN PHARMACEUTICALS ULC and THE MINISTER OF HEALTH

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DATE OF HEARING: DECEMBER 15, 2015

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NEAR J.A. BOIVIN J.A.

DELIVERED FROM THE BENCH BY: DAWSON J.A.

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