Federal Court of Appeal  Cour d'appel fédérale

Date: 20150603

Docket: A-299-14

Citation: 2015 FCA 137

CORAM: **DAWSON J.A.**
WEBB J.A.
BOIVIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

ALLERGAN INC. AND ALLERGAN, INC.
and
THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on May 26, 2015.

Judgment delivered at Ottawa, Ontario, on June 3, 2015.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: WEBB J.A.
BOIVIN J.A.

Federal Court of Appeal  Cour d'appel fédérale

Date: 20150603

Docket: A-299-14

Citation: 2015 FCA 137

CORAM: **DAWSON J.A.**
WEBB J.A.
BOIVIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

ALLERGAN INC. AND ALLERGAN, INC.
and
THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT

DAWSON J.A.

[1] For reasons cited as 2014 FC 567, a judge of the Federal Court issued a judgment prohibiting the Minister of Health from issuing a notice of compliance to Apotex Inc. in respect of its generic version of the drug LUMIGAN RC until the expiration of Canadian patent 2,585,691 (691 patent). The prohibition order was issued to Allergan Inc. and Allergan, Inc.

(Allergan) pursuant to subsection 6(1) of the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133. In the Judge's view, Apotex' allegations of obviousness, lack of utility and anticipation were not justified (reasons of the Federal Court, at paragraphs 2, 36, 45 and 51).

[2] On this appeal from the judgment of the Federal Court, Apotex largely re-argues the issues it raised in the Federal Court. It also argues that the reasons of the Federal Court as to why the 691 patent was not obvious were inadequate.

[3] I am of the view that the appeal cannot succeed for the following reasons.

[4] With respect to the adequacy of the reasons of the Federal Court, Apotex submits that the reasons ignored substantial portions of its evidence, arguments and the authorities it relied upon and did not explain why the Judge preferred the evidence of Allergan's witnesses over those of Apotex.

[5] In oral argument, Apotex acknowledged that it did not assert that any finding made by the Judge was unsupported by evidence. Instead, it argued that there was conflicting evidence and that the Judge did not explain why he preferred one version over another. However, a reviewing court is entitled to presume that a judge reviewed all of the evidence; reliance on the evidence of some witnesses over others cannot by itself demonstrate that the Judge forgot, ignored or misconceived the evidence in a manner that affected his conclusion (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, at paragraph 46). Read fairly, in light of the extensive record

before the Federal Court, and in light of the fact that the Judge was alive to all of the issues and that all of his findings were supported by evidence, the reasons are adequate.

[6] Apotex next submits that, while the Federal Court accurately recited the four-step test for the obviousness inquiry articulated in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, it erred in law and in fact when applying each stage of the analysis.

[7] Dealing with each asserted error, I am satisfied that:

i. The Federal Court did not err in its construction of the inventive concept of the 691 patent. The nub of Apotex' argument is that the Federal Court inferred the inventive concept from data found in the 691 patent. In *Sanofi*, at paragraph 77, the Supreme Court found that the inventive concept of the claims there in issue was not readily discernible from the claims themselves. It was therefore acceptable to read the specification in the patent to construe the inventive concept. In the present case, the relevant claims related to a chemical composition and the use of the composition for treating glaucoma or intraocular hypertension in a mammal. The Federal Court found the composition claimed did not determine the claims' inventive concept and so it construed the inventive concept by reading the patent as a whole. In doing so, the Federal Court considered the inventive concept in light of the disclosure of the patent from the viewpoint of the skilled reader. This was not an error of law and no palpable and overriding error has been shown in the Federal Court's conclusion as to the inventive concept.

ii. The Federal Court did not err when determining the state of the art as of the claim date. As noted above, Apotex argues that the Court ignored or misapprehended evidence, drew

unreasonable inferences and reached a conclusion that was unsupported by the evidence. The Federal Court's analysis of the state of the art is reviewable on the deferential standard of palpable and overriding error, and Apotex acknowledged that the findings of the Federal Court were all supported by the evidence.

iii. The Federal Court did not err in finding there were differences between the state of the art and the inventive concept. This finding is again one entitled to deference. Based on the Federal Court's conclusions about the state of the art and the inventive concept, Apotex has not demonstrated any palpable or overriding error in the finding that there were differences between the two.

iv. The Federal Court did not err in finding that the differences between the state of the art and the inventive concept were not obvious to try. It found: the significant differences between the claims in issue and the state of the art would not have been obvious to the skilled person; the formulation of LUMIGAN RC required experimentation and inventive steps; extensive, expensive testing was required before arriving at the claimed invention; and the result was a commercially successful product. These factual findings were based on admissible evidence and they support the conclusion that the composition at issue was not obvious to try. These findings have not been shown to be palpably and overridingly wrong.

[8] Apotex next argues that the utility of the invention was not soundly predicted because the line of reasoning from which the desired result can be inferred was not explicitly disclosed in the patent. As the Federal Court correctly noted, citing *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153, at paragraph 70, a patent will be valid based on a sound

prediction of utility if the inventor has an articulable and sound line of reasoning available at the date of the patent application from which the predicted utility can be inferred from the factual basis and there is proper disclosure to the public.

[9] The Federal Court identified the factual basis for the prediction (the minimum inhibitory concentration values of several compounds tested against a number of bacteria species together with comparative data) and the line of reasoning that would, to the skilled reader, flow from that data. As this Court observed in *Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2013 FCA 219, 449 N.R. 111, at paragraphs 152 and 153, the factual basis, line of reasoning and level of disclosure required by the doctrine of sound prediction are to be assessed as a function of both the knowledge that the skilled person would have to base that prediction on and what the skilled person would understand as a logical line of reasoning leading to the utility of the invention. Those elements of the doctrine of sound prediction that would be self-evident to the skilled person need not be explicitly disclosed in the patent.

[10] Finally, in the Federal Court, Apotex argued that the claims in issue were anticipated by Canadian patent 2,144,967 (967 patent). The Federal Court, assuming without deciding that the 691 patent was a selection patent, held that, if the 967 patent, as the asserted genus patent, did not describe the special advantages of the invention of the 691patent, the genus patent did not anticipate the 691 patent. This was a correct statement of the law articulated by the Supreme Court in *Sanofi* at paragraph 32. The Federal Court then made two findings: first, the prior patent did not disclose the special advantage of the 691 patent and, second, the prior patent would not

have enabled the skilled patent to perform the invention of the 691 patent because an inventive step was required. These are findings of fact.

[11] On this appeal, Apotex has not shown these findings to be palpably and overridingly wrong. This is fatal to its argument that the 691 patent was anticipated by the 967 patent.

[12] Central to the reasons of the Federal Court were its construction of the inventive concept and its conclusion with respect to a sound prediction of utility found in the 691 patent. These conclusions were based upon the Court's finding that the opinion of Dr. Stella was persuasive (Federal Court reasons, at paragraph 42) and its rejection of Apotex' concerns (Federal Court reasons, at paragraphs 43 and 44). These findings have not been shown to be wrong in a manner that justifies intervention by this Court.

[13] It follows that I would dismiss the appeal with costs.

"Eleanor R. Dawson"

J.A.

"I agree.
Wyman W. Webb J.A."

"I agree.
Richard Boivin J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-299-14
STYLE OF CAUSE:	APOTEX INC. v. ALLERGAN INC. AND ALLERGAN, INC. and THE MINISTER OF HEALTH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	MAY 26, 2015
REASONS FOR JUDGMENT BY:	DAWSON J.A.
CONCURRED IN BY:	WEBB J.A. BOIVIN J.A.
DATED:	JUNE 3, 2015

APPEARANCES:

Andrew Brodkin Dino Clarizio Michel Shneer	FOR THE APPELLANT
Andrew Reddon Steven Mason Steven Tanner Sanjaya Mendis	FOR THE RESPONDENTS (ALLERGAN INC. AND ALLERGAN, INC.)
No appearance	FOR THE RESPONDENT (THE MINISTER OF HEALTH)

SOLICITORS OF RECORD:

Goodmans LLP Barristers & Solicitors Toronto, Ontario	FOR THE APPELLANT
McCarthy Tétrault LLP	FOR THE RESPONDENTS

Toronto, Ontario	(ALLERGAN INC. AND ALLERGAN, INC.)
William F. Pentney Deputy Attorney General of Canada	FOR THE RESPONDENT (THE MINISTER OF HEALTH)