Federal Court of Appeal | Cour d'appel fédérale

Date: 20131015

Dockets: A-123-13

Citation: 2013 FCA 244

CORAM: **EVANS J.A.**
GAUTHIER J.A.
NEAR J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

NOVARTIS PHARMACEUTICALS CANADA INC., THE MINISTER OF HEALTH, NOVARTIS AG AND BOEHRINGER MANNHEIM GMBH

Respondents

AND BETWEEN:

TEVA CANADA LIMITED

Appellant

and

NOVARTIS PHARMACEUTICALS CANADA INC., THE MINISTER OF HEALTH, NOVARTIS AG AND ROCHE DIAGNOSTICS GMBH

Respondents

Heard at Toronto, Ontario, on October 15, 2013.

Judgment delivered from the Bench at Toronto, Ontario, on October 15, 2013.

REASONS FOR JUDGMENT OF THE COURT BY: GAUTHIER J.A.

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Toronto, Ontario, on October 15, 2013)

GAUTHIER J.A.

[1] Teva Canada Limited (Teva) appeals from the Order of prohibition of Hughes J. of the Federal Court (the Judge) issued in respect of two applications under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 which were heard together on the basis of common evidence and arguments in respect of Teva's allegations that the Canadian Letters Patent No. 1,338,937 (the '937 Patent) and Patent No. 1,338,895 (the '895 Patent) were invalid.

[2] Teva only appeals those parts of the Order allowing the application in respect of the '937 Patent and prohibiting the Minister of Health from issuing a Notice of Compliance to Teva for 4mg/5ml (court file number T-1420-11) and 5mg/100 ml (court file number T-288-12) strengths of zoledronic acid I.V. infusion until after the expiration of the '937 patent.

[3] Teva submits that the Judge erred in his obviousness analysis of the '937 Patent. More particularly, it argues that the Judge:

i) Substituted a higher standard for determining obviousness based on the excerpt he cites at paragraph 161 of his reasons from a United Kingdom decision (*MedImmune Limited v. Novartis Pharmaceuticals UK*, [2012] EWCA Civ 1234 at paragraph 90);

ii) Failed to properly ascertain the state of the art and to identify the differences between the inventive concept and the state of the art as required by step 3 of the "*Sanofi* test" (*Apotex Inc. v. Sanofi Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265);

iii) Having failed to properly analyse step 3 or having done so incorrectly, improperly applied step 4 of the analysis.

[4] Teva adds that the Judge's factual inference that there was "too much uncertainty as to whether any particular combination [would] be useful" is also flawed because it is the result of the above-mentioned legal errors in the analysis.

[5] According to Teva, the Judge misconstrued and misapprehended the evidence and appears to have ignored some important evidence in respect of the prior art.

[6] We cannot agree that the Judge applied a higher standard than that set out in *Sanofi* to determine whether or not the '937 Patent was obvious. It is clear in our view that the Judge's conclusion at paragraph 159 is based on the test set out by the Supreme Court of Canada. The comments in paragraph 161 of his reasons are simply rhetorical embellishments and added nothing to the statement already made by Rothstein J. in *Sanofi* at paragraph 64 that:

> The patent system is intended to provide an economic encouragement for research and development. It is well known that this is particularly important in the field of pharmaceuticals and biotechnology. [emphasis added]

[7] With respect to the allegations regarding the Judge's failure to apply step 3 of the "*Sanofi* test", it is clear from *Sanofi* and from the jurisprudence post-*Sanofi* that there is no single or mandatory approach for the conduct of this inquiry (see, for example, *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*, 2012 FCA 333 at paragraph 105, *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228 at paragraphs 67-68.

[8] Furthermore, in this particular case, although we agree that the Judge could have said more in his reasons about the differences between the inventive concept as he defined it and the state of the art, we are satisfied that he did indeed conduct this analysis. This is apparent from paragraphs 148 to 154 of his reasons. Most importantly at paragraph 154, he noted that:

> 154 Having read the evidence of all the expert witnesses, both in their affidavits and in cross-examination, I am left with the view that, even given a broad number of choices for atoms or molecules or compounds that could be attached, even using one carbon linker, to the geminal carbon backbone of a bisphosphonate, there is still too much uncertainty as to whether any particular combination will be useful.

[9] All this to say that we have not been persuaded that the Judge erred in law in his approach to his factual findings in respect of obviousness. There is therefore no basis to for the appellant's argument that the purported failure to apply the "*Sanofi* test" led to the wrong inference of uncertainty mentioned above.

[10] Despite the appellant's efforts to convince us by selecting items from the evidence that one could reach a different conclusion than that reached by the Judge, the appellant has failed to establish that the Judge made an overriding and palpable error in his appreciation of the evidence.

[11] The following passages by Stratas J. in *Yukon Forest Corporation v. Canada*, 2012 FCA 165, 431 N.R. 286 at paragraphs 46 and 51 are apposite:

> [46] Palpable and overriding error is a highly deferential standard of review: *H.L. v. Canada (Attorney General)*, 2005 SCC 25, [2005] 1 S.C.R. 401; *Peart v. Peel Regional Police Services* (2006) 217 O.A.C. 269 (C.A.) at paragraphs 158-59; *Waxman, supra*. "Palpable" means an error that is obvious. "Overriding" means an error that goes to the very core of the outcome of the case. When arguing palpable and overriding error, it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall.

> [51] Sometimes appellants attack as palpable and overriding error the non-mention or scanty mention of matters they consider to be important. In assessing this, care must be taken to distinguish true palpable and overriding error on the one hand, from the legitimate by-product of distillation and synthesis or innocent inadequacies of expression on the other.

[12] The Judge is presumed to have considered all the evidence before him. This presumption is not rebutted simply because the Judge does not refer to particular pieces of prior art (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 SCR 235 at paragraph 46). Moreover, in this case, there are clear indications that the Judge was alert and alive to the issues raised, but in the end, simply did not agree with the appellant's analysis of the evidence.

[13] For these reasons, the appeal will be dismissed with costs.

"Johanne Gauthier"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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