Federal Court of Appeal | Cour d'appel fédérale

Date: 20111102

Dockets: A-390-09
A-386-09
A-389-09
A-387-09

Citation: 2011 FCA 300

Toronto, Ontario, November 2, 2011

CORAM: **NOËL J.A.**
PELLETIER J.A.
LAYDEN-STEVENSON J.A.

A-390-09

BETWEEN:

SANOFI-AVENTIS CANADA INC., and SANOFI-AVENTIS DEUTSCHLAND GmbH

Appellants

and

APOTEX INC.

Respondent

and

SCHERING CORPORATION

Respondent

A-386-09

AND BETWEEN:

SCHERING CORPORATION

Appellant

and

APOTEX INC.

Respondent

and

SANOFI-AVENTIS CANADA INC., and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Respondents

A-389-09

AND BETWEEN:

SANOFI-AVENTIS CANADA INC., and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Appellants

and

NOVOPHARM LIMITED

Respondent

and

SCHERING CORPORATION

Respondent

A-387-09

AND BETWEEN:

SCHERING CORPORATION

Appellant

and

NOVOPHARM LIMITED

Respondent

and

SANOFI-AVENTIS CANADA INC., and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Respondents

Heard at Toronto, Ontario, on October 31, November 1 and 2, 2011.

Judgment delivered from the Bench at Toronto, Ontario, on November 2, 2011.

REASONS FOR JUDGMENT OF THE COURT BY: LAYDEN-STEVENSON J.A.

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A-387-09

AND BETWEEN:

SCHERING CORPORATION

Appellant

and

NOVOPHARM LIMITED

Respondent

and

SANOFI-AVENTIS CANADA INC., and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Respondents

REASONS FOR JUDGMENT

LAYDEN-STEVENSON J.A.

[1] These reasons relate to Court File Numbers A-390-09, A-386-09, A-389-09 and A-387-09. The original of the reasons will be filed in A-390-09, the lead file, and copies will be placed in the other three files.

[2] The appeals are from the judgment of Justice Snider of the Federal Court (the judge). The judge dismissed patent infringement actions against Apotex Inc. (Apotex) and Novopharm Limited (Novopharm) and declared Claims 1, 2, 3, 6 and 12 of Canadian Patent No. 1,341,206 (the '206 Patent) to be invalid, void, unenforceable and of no force or effect. The judge's reasons (2009 FC 676) contain a lengthy and detailed review of the background, the evidence, the law and the judge's findings.

[3] The basis of the judge's conclusion is her finding, on a balance of probabilities, that the inventors of the '206 Patent could not soundly predict, as of the filing date of the patent application, that all eight compounds of Claim 12 of the '206 Patent would have the utility promised by the patent. Claim 12 comprises eight compounds and describes compounds with five stereocentres (or chiral centres) that can have either an S or R configuration (stereochemistry). It prescribes the S configuration for two chiral centres and allows for the other three to be either S or R. When all five sterocentres are in the S configuration, the compound is ramipril. The judge found, of the eight compounds, only ramipril could be soundly predicted (judge's reasons at paragraph 194). Consequently, the claim failed for want of utility.

[4] Since Claims 1, 2, 3 and 6 include the same compounds as Claim 12, it followed that Claims 1, 2, 3, and 6 of the '206 Patent are also invalid. The judge stated, at paragraph 230 of her reasons, that the prediction of the appellant, Schering Corporation (Schering), at the date of the patent application, was not sound because it "failed on all three requirements making up the test for sound prediction – factual basis, articulable line of reasoning and disclosure."

[5] Despite the detailed and capable arguments of the appellants' counsel, we are of the view that the appeals must be dismissed. The soundness of a prediction is a question of fact: *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paragraph 71 (*AZT*). The appellants contend that the judge erred in law by elevating the legal test for sound prediction to a level requiring near certainty. More particularly, they submit that the judge required positive test results and ignored the common general knowledge of the person skilled in the art. Although we agree that, if the judge applied the wrong legal test, it would constitute an error of law, we do not believe that is what the judge did.

[6] Rather, the judge correctly identified the test for sound prediction set out in *AZT*. Indeed, she applied the test to arrive at her conclusion regarding ramipril. The appellants' submissions ignore the fundamental factual finding that underpins and informs the judge's analysis. That is, in the stereochemistry context, even a small change to a molecule can yield profound effects on activity (judge's reasons at paragraphs 160-162). The judge's references to testing related to that specific factual context of volatility.

[7] The thrust of the appellants' attack on the trial judge's findings is that she applied a purely subjective test to the issue of sound prediction, basing her conclusion on the inventor's state of mind

without reference to the common general knowledge attributable to the person of ordinary skill in the art. This attack cannot be sustained in light of the judge's reasons. She did focus on the work done by the inventor (judge's reasons at paragraphs 164 to 188) and found that, taken by itself, it did not provide a factual basis for a sound prediction. She then went on to consider the common general knowledge. After reviewing the state of the art she found that the common general knowledge, applied to Schering's own investigations, did not suffice to provide a factual basis for a sound prediction (judge's reasons paragraphs 199-200).

[8] The appellants also find fault with the judge's treatment of Schering's test results. In their view, she mischaracterized inactive test results as evidence of inactivity as opposed to evidence of lack of potency at the stipulated test levels. This line of attack is misconceived. The appellants' position was that the patent promised utility with the R configuration at the various chiral centres, though at a reduced level. They took this from the patent's statement that S configurations were preferred ('206 Patent at pages 17, 18). When the trial judge's reasons are read as a whole, it is apparent that the conclusion she drew from Schering's test results was that an inactive test at a stipulated test level did not prove or allow one to predict activity at a different test level. Thus, to the extent that the appellants claimed a sound prediction of some activity in relation to molecules with the R configuration, inactive test results did not support their prediction. This is not an error.

[9] Indeed, in summarizing her conclusions, the judge reiterated the proposition that patent protection rests on the concept of a bargain between the inventor and the public. She noted that Schering included compounds in Claim 12 to cover off future possibilities. In this respect, she referenced an excerpt from the cross-examination of Dr. Smith, one of the inventors of the '206

Patent. Part of that excerpt is reproduced here; the entire excerpt may be found at paragraph 357 of the judge's reasons.

> Q. And I take it the reason you wrote that was to cover off the possibility that at some point down the road, a particular stereoisomer might surprisingly turn out to have a very good activity, because you didn't want to miss one and then have the patent department come back to you and say, "Dr. Smith, you missed a good one"?
>
> A. Right.
>
> Q. So you were just protecting yourself, and you wrote this down to just make sure in case there was an unexpected one down the road, you had it covered off?
>
> A. Yes, that would have it covered, and it's also what is done in patents.

[10] The remaining issues raised by the appellants involve questions of fact or mixed fact and law, which can be reversed on appeal only if palpable and overriding error is demonstrated. We are not persuaded that the appellants have demonstrated such errors.

[11] The judge rendered detailed and comprehensive reasons for her conclusions with respect to sound prediction. Her findings are grounded on her assessment of the evidence and are fulsomely explained. The appellants have not identified any reviewable error in the judge's assessment of the evidence although they question the judge's application of the legal principles to the facts before her. Essentially, the appellants' arguments constitute an invitation to this Court to reweigh the evidence and to draw our conclusions from it. That is not our function.

[12] To reiterate, absent palpable and overriding error, there is no basis upon which this Court can intervene. In our view, the judge properly cited the legal principles applicable to the doctrine of sound prediction, applied those principles to the evidence before her and arrived at her conclusions. The appellants have not demonstrated any error warranting this Court's intervention.

[13] Having concluded that Claims 1, 2, 3, 6 and 12 of the '206 Patent were invalid for want of utility, in the alternative, the judge addressed the issue of validity on the basis of obviousness. The judge's obviousness analysis is *obiter*. The matter was determined on the basis of sound prediction. These reasons should not be taken as an endorsement of the judge's conclusions regarding the issue of obviousness and do not constitute such an endorsement.

[14] The appeals will be dismissed with costs to the respondents in each appeal.

"Carolyn Layden-Stevenson"
J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS:	A-390-09, A-386-09, A-389-09, and A-387-09

(APPEAL FROM THE JUDGMENT OF THE HONOURABLE JUSTICE SNIDER, DATED JUNE 29, 2009, IN DOCKET NO. T-161-07)

STYLE OF CAUSE:

A-390-09 - SANOFI-AVENTIS CANADA INC., and SANOFI-AVENTIS DEUTSCHLAND GmbH v. APOTEX INC. and SCHERING CORPORATION

A-386-09 - SCHERING CORPORATION v. APOTEX INC. AND SANOFI-AVENTIS CANADA INC., and SANOFI-AVENTIS DEUTSCHLAND GmbH

A-389-09 - SANOFI-AVENTIS CANADA INC., and SANOFI-AVENTIS DEUTSCHLAND GmbH v. NOVOPHARM LIMITED and SCHERING CORPORATION

A-387-09 - SCHERING CORPORATION v. NOVOPHARM LIMITED AND SANOFI-AVENTIS CANADA INC., and SANOFI-AVENTIS DEUTSCHLAND GmbH

PLACE OF HEARING:	Toronto, Ontario
DATES OF HEARING:	October 31, November 1 & 2, 2011
REASONS FOR JUDGMENT OF THE COURT BY:	(NOËL, PELLETIER & LAYDEN-STEVENSON JJ.A.)
DELIVERED FROM THE BENCH BY:	LAYDEN-STEVENSON J.A.

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