Federal Court of Appeal | Cour d'appel fédérale

Date: 20140303

Docket: A-208-13

Citation: 2014 FCA 54

CORAM: **GAUTHIER J.A.**
STRATAS J.A.
WEBB J.A.

BETWEEN:

PFIZER CANADA INC.

Appellant

and

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on February 25, 2014.

Judgment delivered at Ottawa, Ontario, on March 3, 2014.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

CONCURRED IN BY STRATAS J.A.
WEBB J.A.

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REASONS FOR JUDGMENT

GAUTHIER J.A.

[1] Pfizer Canada Inc. ("Pfizer") appeals from the judgment of Justice O'Reilly of the Federal Court ("the Judge") regarding Apotex Inc.'s ("Apotex") claim for compensation under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. The Judge held that Apotex was entitled to claim compensation for the loss, if any, resulting from its inability to sell its Apo-azithromycin tablets ("the Apotex product") before it obtained a notice of compliance after the

dismissal of Pfizer's application for a prohibition order. By virtue of a bifurcation order, issues relating to the quantum of compensation were left to be determined in a further proceeding.

[2] Before the Judge, Pfizer alleged that the Apotex product actually put on the market infringed Canadian Patent No. 1,314,876 ("the '876 patent"), owned by Pfizer, which expired on March 23, 2010. The judge disagreed. He found that the evidence before him "supports only the *possibility* that Apotex's [product] may have contained some small amount of infringing material before the expiry of the '876 patent. It is insufficient to support a conclusion, on a balance of probabilities, that Apotex's [product] did contain infringing material" [emphasis in original] (reasons of the Judge reported at 2013 FC 493 at paragraph 78).

[3] Pfizer submits that the Judge relied heavily on the evidence of Apotex's expert, Dr. Zaworotko, evidence that should not have been admitted. Pfizer argues that Dr. Zaworotko conjectured that the results of the routine tests undertaken by Pfizer were not what they appeared to be, but rather revealed some new and unidentified compound, unknown to science, that happened to have a profile similar to that of azithromycin dihydrate ("AD"). In Pfizer's view, the Judge erred in law by accepting the so-called "Zaworotko hypothesis" without considering and applying the test set out in *R. v. J.-L.J.*, 2000 SCC 51, [2000] 2 S.C.R. 600 (*J.-L.J.*) as to the admissibility of expert scientific evidence, including particularly, the factors to be considered when dealing with novel scientific theories or techniques. Had he applied the test, he would have found that the novel scientific theory advanced by Dr. Zaworotko failed to meet the required threshold of reliability.

[4] In any event, Pfizer adds that even if the Zaworotko hypothesis were found to be admissible, it was so inherently unreliable that no weight should have been given to it. The Judge committed a palpable and overriding error by attributing any weight to the Zaworotko hypothesis.

[5] With respect to the admissibility issue, there are two problems with Pfizer's reliance on the Supreme Court of Canada's decision in *J.-L.J.*

[6] First, as noted by Apotex, this case refers to threshold reliability – is the evidence capable of forming the subject matter of expert testimony? Is the proposed evidence "science"? (*R. v. Dimitrov*, 2003 CanLII 50104 (ONCA) at paragraph 37). In my view, Dr. Zaworotko was doing nothing more than interpreting results of recognized tests relying upon the expertise for which he was tendered as an expert. There is no doubt that the interpretation of results of recognized tests is "science". In fact, this is exactly what Pfizer's own expert, Dr. Atwood, also did in his affidavit. In my view, Dr. Zaworotko was not trying to establish the exact nature of the compound depicted in the various tests carried out by Pfizer, but rather was raising concerns about whether the testing conducted by Dr. Atwood was as conclusive as Pfizer contends in the particular circumstances of this case. Pfizer bore at all times the burden of persuading the Judge that this compound was AD, Dr. Zaworotko raised concerns based on his expertise, and, in the end, the Judge found that Pfizer had not discharged its burden in part because of the concerns raised. I say in part because the Judge had other concerns about Dr. Atwood's evidence.

[7] Second, unlike as in *J.-L.J*, Pfizer never raised at trial the admissibility of Dr. Zaworotko's opinion.

[8] I note that, as it has become customary in complex cases of this nature, Pfizer received Dr. Zaworotko's affidavit filed in response to the report of its expert, Dr. Atwood, several months before the trial. At the time, it knew that the case manager had ordered that it make its decision to file reply evidence on or before July 2, 2012. Pfizer did not tender any such evidence. Further, at a trial management conference, the parties were ordered that if they objected to the admissibility of an expert's evidence, they must make that clear by August 20, 2012. Pfizer did not file any such objection, nor did it object at any time during trial. In fact, Dr. Zaworotko was qualified as an expert on consent and his two reports were filed as exhibits, without any objection. Instead, Pfizer chose to vigorously cross-examine Dr. Zaworotko on his opinion that Dr. Atwood's testing did not provide conclusive information that Apotex's product actually contained AD (A.B., Vol. 21, Tab 55, pages 6016 and following). Pfizer used Dr. Zaworotko's responses to some of its questions in its closing submissions to question Dr. Zaworotko's *objectivity* and credibility (A.B., Vol. 23, Tab 59, pages 6890-6895, in particular page 6892). In those closing submissions, Pfizer did not object to the admissibility of any of the evidence of Dr. Zaworotko.

[9] The Supreme Court of Canada in *J.-L.J.* at paragraph 28 observed that the admissibility of expert evidence should be scrutinized "at the time it is proffered". There is an important rationale behind the preclusion of objections to the admissibility of evidence on appeal: had the objection been made in a timely way before or at trial, the parties would have been able to conduct examinations of the person presented as an expert, the trial judge would have made all appropriate

factual and credibility findings on the matter, after the ruling of the trial judge the parties might call other evidence or adjust their examinations of other witnesses accordingly, and the appellate court would have the reasons of the trial judge.

[10] It is also material to consider that nowadays, complex civil cases like pharmaceutical patent cases are court managed from the start to ensure that there is full disclosure of all the evidence and of all the issues to be determined before the trial or at the trial in a manner that will ensure the most efficient prosecution of the case and use of court resources. In this context, trial judges should generally be allowed to rely on experienced counsel who have the assistance of their technical experts to raise admissibility issues, especially those regarding the reliability of scientific evidence. The court must be especially vigilant to prevent tactical conduct: *Apotex Inc. v. Bristol-Myers Squibb Company*, 2011 FCA 34 at paragraph 37.

[11] However, there are cases where appellate courts will use their discretion to consider admissibility issues despite the absence of an objection at first instance. Pfizer referred to a few such cases. But considering all the circumstances of this case, especially those set out in paragraph 8 above, this Court should refuse to consider the admissibility issue for the first time on this appeal.

[12] I now turn to Pfizer's argument that the Judge made a palpable and overriding error in giving weight to Dr. Zaworotko's expert evidence.

[13] It is trite law that it is not the role of an appellate court to retry cases. Nor is it its role to reassess expert evidence and substitute its own view for that of the trial judge (*Aventis Pharma Inc.*

v. Apotex Inc., 2006 FCA 64 at paragraph 22; *AB Hassle v. Canada (Minister of National Health and Welfare)*, 2002 FCA 421 at paragraph 30).

[14] I agree with Apotex that Pfizer puts too much emphasis on the weight given by the Judge to certain portions of Dr. Zaworotko's evidence. Pfizer appears to assume that the main if not the sole reason why the Judge concluded that it had not met its burden of persuasion was because this expert "hypothesized" on a whim an unproven and untested theory that the Pfizer test results were also consistent with the presence of an unknown compound that was not AD.

[15] In fact, the judge summarizes and reviews the various categories of evidence before him at paragraphs 56 to 76 of his reasons. He then notes at paragraph 77:

> In my view, Pfizer has not established infringement of the '876 patent. The evidence, in summary, amounts to the following:
>
> - The bulk material Apotex used to manufacture tablets did not contain any AD.
> - The bulk material that Apotex kept as retained samples, in screw-top bottles, may have contained AD. If it did, the most likely explanation for its appearance was the exchange of isopropanol for water through the permeable cap.
> - Tests of tablets reveal that:
>   - in 2006, Apotex's tablets contained no AD;
>   - in 2008, 2009, and 2012, Apotex's tablets contained AIM and a small amount of crystal that is probably not AD.

[16] The so-called unreliable opinion of Dr. Zaworotko regarding an unknown form of azithromycin can only be relevant to the last finding in respect of the 2008, 2009 and 2012 tests on tablets that the Judge mentions were "probably not AD". The Judge notes that there was no expert evidence interpreting the results of the 2008 and 2009 tests except for that of Dr. Zaworotko, evidence provided after he had been given only a few minutes to review these results (Judge's

reasons at paragraph 58). Although Dr. Zaworotko acknowledged that these results could be consistent with the presence of AD, this did not add much as he had already acknowledged in his affidavit (at paragraph 11(b)) that similar results of tests in 2012 were also consistent with the presence of AD. His issue was that there were too many unexplained discrepancies to draw a definite conclusion especially given the type of compound involved. This is why he found his alternative interpretation more probable.

[17] The Judge had the benefit of hearing all the evidence including the responses given during cross-examination as well as Dr. Zaworotko's very clear assertion as to why, contrary to what Pfizer's counsel was suggesting, his opinion was not speculation (for example see A.B., Vol. 21, Tab 55, page 6021). This witness, the only expert who testified on this point, affirmed that he did not need further experimentation to opine as he did.

[18] Pfizer made the same arguments it now raises before us when it urged the Judge to give no weight to Dr. Zaworotko's hypothesis because it was unreliable .The Judge clearly did not agree that this expert had no reliable grounds to question Pfizer's assertion that the test results were only consistent with one conclusion – the presence of some AD (see for example the Judge's reasons at paragraphs 57 and 70).

[19] Having considered the evidentiary record before him, this conclusion was open to him. In that respect, it is worth reproducing some of the Judge's observations on this point:

> 73 Dr Zaworotko disputed Dr Atwood's results, particularly whether Apotex's tablets had been shown to contain AD. Given that azithromycin is known for its tendency to form a variety of polymorph crystals, Dr Zaworotko believes that

> what Dr Atwood may have detected was a previously unidentified polymorph of AIM, not easily distinguished from AD. The tablets contained a significant amount of AIM and isopropanol, and only a small amount of some other crystal. In fact, the PXRD patterns, SSNMR spectra, and ^{1}H NMR data for the tablets were consistent with a large quantity of isopropanol in the tablets, which would be inconsistent with any significant transformation to AD. Rather, it is likely that any conversion would be to another crystalline form that, despite a similar PXRD pattern and SSNMR spectrum to AD, is, in fact, a polymorph of AIM or another solvate.
>
> 74 Dr Zaworotko points out that Dr Atwood's opinion does not include any explanation as to how the tablets could acquire water in order to convert to AD. The exchange of isopropanol for water could occur in the bulk material that Dr Atwood tested because it was stored in screw-cap bottles whose seal was permeable. However, that material was not used to make tablets. The bulk material used for manufacture, according to all the evidence, was pure AIM and the tablets produced were placed into impermeable blister packs. In order for AD to form in the tablets, a source of water would be required.
>
> 75 Again, in Dr Zaworotko's opinion, it is therefore more likely that the transformation observed by Dr Atwood was from AIM to another type of azithromycin, not AD. He also found support for this explanation in Pfizer's own 2006 testing of AIM, in which the analyst noted the presence of other forms of azithromycin, not AD, in Apotex's tablets.
>
> 76 Pfizer tendered no evidence in response to Dr Zaworotko's evidence.

[20] Furthermore, as mentioned by the Judge, there was no direct evidence that Apotex used any bulk material that contained AD or that it manufactured or sold any product that contained AD. Pfizer's case was based primarily on *inferences to be drawn* from tests made of bulk material not intended to be used for manufacturing and of tablets made from non-infringing material (Judge's reasons at paragraph 55). I have not been persuaded that the Judge made a palpable and overriding error in refusing to draw the inference put forth by Pfizer. There was an evidentiary basis to support his conclusion that it was only *possible* that the Apotex product contained AD before the expiry of the '876 patent.

[21] In view of the foregoing, the appeal should be dismissed with costs.

"Johanne Gauthier"

J.A.

"I agree
David Stratas J.A."

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

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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APPEARANCES:

Mr. Orestes Pasparakis Ms. Allyson Whyte Nowak Mr. Chris Cummins	FOR THE APPELLANT
Mr. H. B. Radomski Mr. Jerry Topolski	FOR THE RESPONDENT

SOLICITORS OF RECORD:

NORTON ROSE FULBRIGHT CANADA LLP Toronto, Ontario	FOR THE APPELLANT
GOODMANS LLP Toronto, Ontario	FOR THE RESPONDENT