Federal Court of Appeal

Cour d'appel fédérale

Date: 20111219

Dockets: A-9-11
A-11-11

Citation: 2011 FCA 363

CORAM: EVANS J.A.
GAUTHIER J.A.
STRATAS J.A.

A-9-11

BETWEEN:

APOTEX INC.

Appellant

and

MERCK & CO. INC. and
MERCK FROSST CANADA LTD.

Respondents

APOTEX FERMENTATION INC.

Respondent

A-11-11

BETWEEN:

APOTEX FERMENTATION INC.

Appellant

and

MERCK & CO. INC. and
MERCK FROSST CANADA LTD.

Respondents

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on November 28, 2011.

Judgment delivered at Ottawa, Ontario, on December 19, 2011.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

CONCURRED IN BY: EVANS J.A.
STRATAS J.A.

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REASONS FOR JUDGMENT

GAUTHIER J.A.

[1] These appeals are from a judgment of Justice Snider of the Federal Court who found that Apotex Inc. (Apotex) and Apotex Fermentation Inc. (AFI) had infringed Merck & Co. Inc.'s (Merck) Canadian Patent Number 1,161,380 (the '380 Patent).

[2] This patent, which expired in 2001, covered a method for making lovastatin using a microorganism of the genus *Aspergillus terreus* (AFI-1). More specifically, the judge found that the appellants were liable for damages with respect to the Apo-lovastatin products made from the first commercial batch produced in Canada by AFI (batch CR0157) and from the 294 batches of lovastatin produced by Blue Treasure (BT) in China after March 1998.

[3] The judge's reasons (2010 FC 1265) are detailed and comprehensive (226 pages). It is clear that she had a firm grasp of the voluminous and complex evidence presented to her during the 35-

day trial where she also dealt with Apotex' own action against Merck pursuant to section 8 of the *Patented Medicine (Notice of Compliance) Regulations*, SOR/93-133 as amended in SOR/98-166.

[4] The judge based her conclusion that the process used to produce AFI batch CR0157 was infringing on the expert evidence of Dr. Davis. She found that his test results, which indicated that the Apo-lovastatin tablets made from this batch contained AFI-1 DNA, were reliable and credible. She expressly rejected Apotex' experts' theory of contamination (paragraph 454).

[5] With respect to the 294 batches of lovastatin produced in China by BT, she considered, under the general title "Infringement – the Circumstantial Case", the six points enumerated at paragraph 209 of her reasons. The judge indicated that she was persuaded that:

a. The documents presented as BT batch records were not business records and were not reliable and trustworthy evidence of the use of AFI-4 (*C. fuckelii* microbe used in another method then recently patented by Apotex), because they had been fabricated at least with respect to "any information that could identify the strain of [microbe] used" [emphasis added] (paragraph 242).

b. The evidence before her established that BT had enough of the media ingredient referred to as Polyglycol P-2000 (P-2000) to carry out the AFI-1 process. However, on the assumption that there was no further evidence available in that respect, there was insufficient evidence to establish that BT had a quantity of P-2000 sufficient to carry out the non-infringing AFI-4 process which required 10-20 times more of this ingredient.

c. BT had a financial motivation not to use the non-infringing process. It had the means to produce lovastatin with the infringing AFI-1 process and the opportunity to use that process as soon as Dr. Jerry Su, an AFI representative, left China at the end of October 1997.

d. Mr. Luo, the Deputy Plant Manager at BT, lied in two articles published in 2000 and 2002 and fabricated his testimony to cover up the use of the AFI-1 process at a time when BT was supposed to be using only the AFI-4 process. His behaviour supports Merck's contention that BT was using the AFI-1 process at least at the time when BT made the experiments referred to in the above-mentioned articles (paragraphs 327 and 335).

[6] Apotex and AFI make particular submissions concerning these findings. I deal with these submissions below. For present purposes, I find that each of these findings is supported by the evidence before the judge and was open to her to make.

[7] In addition, the judge made conditional findings responding to Merck's alternative arguments made in the event that a reviewing court found the BT batch records to be reliable evidence. The alternative nature of these arguments appears clearly from paragraph 244 of her reasons. It is not unusual in long and complex cases such as this one for judges to make findings in the alternative. However, as the judge ruled the batch records to be unreliable and the appellants have not contested this finding, all her comments on this alternative argument are *obiter*.

[8] Merck argued that it was not necessary to discuss the appellants' various arguments if the Court accepts its position that the judge erred in her interpretation of section 55.1 of the *Patent Act*, RSC 1985, c P-4 (or section 39.2 of the old Act) by refusing to place upon Apotex the burden of persuading her that BT's process did not infringe the '380 patent.

[9] At the hearing, Apotex suggested that it would not be appropriate for this Court to decide this issue in this case, for the judge did not have the benefit of full arguments on this issue. In particular, Apotex notes that the reference to subsection 1709(11) of *NAFTA* and section 3 of the *North American Free Trade Agreement Implementation Act*, SC 1993, c 44 were not brought to her attention.

[10] I agree that this issue is better left for another day. The burden of proof is not determinative of this appeal. However, nothing in these reasons should be taken as endorsing the judge's analysis of section 55.1 which, as mentioned, was made on an incomplete record.

AFI's CR0157 Batch

[11] AFI submits that the judge erred in concluding that the AFI-1 DNA detected by Dr. Davis was not the result of contamination during this expert's experiments because she failed to consider substantial relevant evidence (their own expert evidence, their lay witnesses' evidence, as well as their batch records which were accepted as business records).

[12] Essentially, AFI invites this Court to reweigh all the evidence with respect to this particular batch. It did not point to any particular error in the 36 pages devoted to the analysis of all the expert evidence.

[13] Even though the judge refers to the testimony of AFI's lay witnesses in other parts of her judgment, AFI appears to suggest that it can be inferred from her "failure" to state specifically that the evidence of Dr. Davis convinced her, on a balance of probabilities, "despite the evidence of these lay witnesses and AFI batch records", that she did not consider this evidence.

[14] In *Housen v Nikolaisen*, 2002 SCC 33, [2002] 2 SCR 235 [*Housen*] (at paragraph 46) the Supreme Court of Canada made it clear that the trial judge is presumed to have considered all the information on the record and that the simple failure to rely expressly on, or to mention, some of the contradictory evidence in the reasons is insufficient proof to reverse such presumption.

BT's Post-February 1998 Batches

(i) AFI's Submissions

[15] I am not persuaded that AFI demonstrated the existence of a palpable and overriding error in this finding of fact of the judge.

[16] Turning now to the finding with respect to the batches made in China for exportation to Canada starting in March 1998, AFI raises two issues which, in its view, vitiate the judge's ultimate finding of fact that this material was more likely than not to have been made using the AFI-1 process. First, it states that the judge erred in not finding that the RC-14 impurity levels of the batches made during that period were consistent with the continued use of AFI-4 to make this lovastatin. Second, AFI argues that the judge erred in her assessment of Mrs. Hu's evidence which supported the use of AFI-4 during the said period. More particularly, AFI states that the judge gave no weight to the testimony of this witness and failed to adequately explain why she disbelieved Mrs. Hu, especially considering that, contrary to the rule in *Browne v Dunn* (1893), 6 R 67 (HL), the credibility of this witness with respect to the microorganism use for the fermentation at BT at that time was not challenged on this point and she was given no opportunity to explain her position.

[17] I do not agree. As to the RC-14 levels, not only has AFI failed to rebut the presumption that this evidence was considered, but it is clear from the reasons (paragraphs 194-198) that the judge was alert and alive to this issue. As noted in *Waxman v Waxman* (2004), 186 OAC 201 (CA), 44 BLR (3d) 165, [*Waxman*] at paragraph 344, the fact that a judge does not re-discuss particular evidence presumably means that she did not find it significant enough to warrant further discussion. AFI failed to demonstrate a palpable error, let alone an overriding one.

[18] The principles applicable to the review of credibility findings by an appellate court were recently summarized in *Corlac Inc v Weatherford Canada Inc*, 2011 FCA 228 at paragraphs 89-91. The judge explained in sufficient detail why she did not find Mrs. Hu's testimony to be credible.

AFI has not established that the judge misapprehended her testimony or that this is one of those rare cases that warrant this Court's intervention on a credibility finding.

(ii) Apotex' Submissions

[19] Before discussing the many issues raised by Apotex with respect to the finding of infringement based on the post-February 1998 batches of lovastatin manufactured by BT, I shall reiterate some basic principles.

[20] First, to succeed in their attack, the appellants had to establish that the errors they raised, individually or taken together, constitute not only a clear and obvious error (palpable) but more importantly, one that is overriding.

[21] The following statement of the Ontario Court of Appeal in *Waxman* at paragraph 297 is particularly apposite here:

> An "overriding" error is an error that is sufficiently significant to vitiate the challenged finding of fact. Where the challenged finding of fact is based on a constellation of findings, the conclusion that one or more of those findings is founded on a "palpable" error does not automatically mean that the error is also "overriding". The appellant must demonstrate that the error goes to the root of the challenged finding of fact such that the fact cannot safely stand in the face of that error [reference omitted].

[22] Second, the deference accorded to a trial judge with respect to simple findings of facts also applies to inferences she draws from the evidence. In *Housen*, the Supreme Court of Canada describes the numerous reasons why this is so, including that where evidence exists that may

support the inference, a review of the inference involves a reweighing of the evidence (paragraphs 19-25).

[23] Third, as Apotex spent some time trying to explain how the proceeding and the trial evolved, most of which was disputed by Merck, it is useful to reiterate, as was done in *Waxman* at paragraph 293, the wisdom of the policy favouring appellate deference, especially in long trials where:

> [t]he trial judge saw the witnesses and heard the evidence unfold in a narrative with a beginning, a middle, and an end. Our system of litigation is predicated on the belief that it is through the unfolding of the narrative in the testimony of witnesses that the truth will emerge. This court is not presented with a narrative, but instead with a description or summary of that narrative from the trial judge in her reasons, and from counsel in their written and oral arguments. The descriptions provided by counsel are not designed to tell a story, but rather to support an argument. Of necessity, and in keeping with their forensic role, counsel's description of the narrative at trial is selective and focuses on parts of the narrative or on a particular interpretation of a part of the narrative.

[24] Apotex submits that the judge made several errors in processing the evidence before her. First and most important, it says the judge made a fundamental error of law by relying on the BT batch records that she had already rejected to reach certain conclusions. She then relied on these conclusions to make her final finding that it could be inferred from the totality of the evidence that BT was using the infringing process (paragraphs 339-340). According to Apotex, this error is extricable from the facts and vitiates her conclusion with respect to the fermentation duration and recorded titres, the availability of P-2000, as well as her determination that BT had the means to produce lovastatin with the infringing process commencing in March 1998.

[25] In the same vein, Apotex argues that the judge also improperly relied on other documents that had never been filed to establish the truth of their content, including one that she had expressly refused to rely upon to support one of its arguments with respect to the titres (paragraph 292 of the reasons).

[26] Second, Apotex submits that the judge erred in law when she drew an adverse inference that there was no further evidence supporting AFI's suggestion that BT could have bought more P-2000 from other sources because she did not have evidence that Mr. Zhou, the BT general manager in March 1998, was within the appellants' exclusive control. According to Apotex, there was no evidence that the appellants could even bring Mr. Zhou to testify, especially considering that as of 2009 he was no longer the general manager of BT. He had been replaced by Mr. Xu who Merck should have been able to compel to testify when he came to Canada at some point during the trial. Also, Mr. Luo was equally available to Merck for questioning.

[27] Thirdly, Apotex says that the judge erred in law by reaching a conclusion of fact as to the attributes of the microorganism used for the production of lovastatin from March 1998 onward, as well as by drawing technical inferences in the absence of expert evidence permitting her to do so. According to Apotex, Merck's own expert, Dr. Lazure, had mentioned in her report that she could not establish from the BT batch records which microorganism was used in the process.

[28] Apotex raises other errors described in its memorandum and its outline of arguments that need not be summarized here for, in general, they simply amount to an invitation to reweigh the

evidence. It argues that once all of the judge's errors are corrected, the evidence only supports a finding of continued use of the AFI-4 process, since all that is left from the judge's reasons is an opportunity to infringe, and what Apotex refers to as the "Chinese articles".

(iii) Analysis

[29] Apotex' first argument is based on the premise that the judge misconstrued Merck's arguments. As mentioned earlier at paragraph 7 above, her comments in paragraph 244 of her reasons clearly indicate that she did not. She repeated, at paragraph 270, that her conclusions with respect to fermentation duration were conditional on the acceptance of the batch records. She did not need to repeat this each and every time she referred to the said batch records and dealt with the parties' position based on this documentary evidence, which she had so clearly and definitely put aside as unreliable.

[30] I am not persuaded that the judge based her ultimate finding of infringement on her alternative findings, especially those dealing with the fermentation duration and titres reflected in the batch records and on which Apotex put a particular emphasis.

[31] That said, and even though the transfer of technology with respect to the AFI-1 process to BT clearly establishes that BT had the means to make lovastatin using the infringing process, the judge's finding with respect to the "means" is the most vulnerable of her findings. After dealing with the parties' arguments based on the batch records, as well as exhibits TX-76 and TX-94 (her

final conclusion in that respect is at paragraph 315), she does not explain her conclusion at paragraph 316.

[32] However, I am not satisfied that this is an overriding error. Putting aside an erroneous finding that Merck had established on a balance of probabilities that BT had the "means" is not the same as a finding that BT did not have such means. There was ample other evidence on which it was open to the judge to find that BT was using the infringing process from March 1998 onward.

[33] To conclude my assessment of Apotex' arguments relating to the batch records, I note that the reference to the quantity of P-2000 required to run the fermentation batches in paragraph 253 does not vitiate the judge's findings under the heading of "P-2000". There was sufficient evidence in the file for the judge to conclude that the quantity of P-2000 necessary to complete the production of lovastatin, using the AFI-4 process, was vastly superior to the quantity shipped to BT by AFI. There was simply no need for the judge to quantify the exact amount required.

[34] Apotex' second argument is also ill-founded. In my view, this issue does not raise an extricable error of law, but at best a question of mixed fact and law. The law with respect to such adverse inferences is well settled. The principle applied by the Supreme Court of Canada in *Levesque v Comeau*, [1970] SCR 1010 was not new (*Blatch v Archer* (1774), 1 Cowp 63, 98 ER 969 at page 65) and was recently discussed by the Supreme Court of Canada in *R v Jolivet*, 2000 SCC 29, [2000] 1 SCR 751 at paragraphs 25-28. It must be applied with caution and depends

entirely on the specific facts of the case. Such inference is not mandated and remains a matter of discretion for the trier of facts.

[35] The judge notes at paragraph 258 of her reasons that "there are obviously people associated with [BT] who could have provided evidence of additional purchases of P2000, if such purchases had taken place." She viewed that evidence as particularly important and relevant to determine whether, as argued by the appellants, the AFI-4 process had been used.

[36] In the unique circumstances of this case, I am not persuaded that such witnesses (Mr. Zhou was only an example and was not meant to limit the statement) were not under the exclusive control of AFI who was the largest shareholder in the joint venture with BT. It is clear that BT had provided documentary evidence as well as witnesses (Mr. Luo and Mrs. Hu) to support the appellants' case and they were willing to assist them: see Alan W. Bryant, Sydney N. Lederman and Michelle K. Fuerst, *Sopinka, Lederman & Bryant: The Law of Evidence in Canada*, 3rd ed. (Toronto: LexisNexis Canada Inc., 2009) at paragraph 6.449.

[37] Apotex did not adduce any evidence establishing that under Chinese law these witnesses or BT's documentary evidence, not already in the possession of the appellants, could be compelled.

[38] The judge was better acquainted with all these issues than this Court and she was clearly of the view that, at least with respect to other relevant facts, the appellants – AFI in particular – had presented obstacles to uncovering those facts (paragraph 201 of the reasons). As noted at the

hearing, Mr. Luo, despite his senior position at BT, claimed to be unaware of any matter that did not fall directly under his supervision (paragraph 229 of the reasons). There is no indication that Merck knew or ought to have known that he was in charge of purchases, if indeed he was.

[39] Apotex has not demonstrated a palpable and overriding error in the judge's inference-finding process or in her conclusion in that respect.

[40] Turning now to the third error of law alleged by Apotex, it is clear that Dr. Lazure's comments did not support Apotex' point of view in any way. In fact, these comments reinforce the conclusion that the BT batch records were unreliable for they should have contained information enabling an expert to identify which microorganism was used in the process. Be it as it may, this evidence is not particularly relevant, nor is the alleged error, given that the judge's findings with respect to the titres, fermentation durations, and the "means" need not be discussed further for they are *obiter*. In my view, they had no impact on the judge's ultimate finding at paragraphs 339 and 340.

[41] Leaving aside the judge's alternate findings, as well as her conclusion with respect to the "means", I am of the opinion that the judge could reasonably infer from the totality of the evidence before her that BT had manufactured lovastatin using the infringing AFI-1 process during the relevant period. The appellants have not demonstrated any overriding error in that respect. There was sufficient evidence to support the judge's finding.

[42] For these reasons, I would dismiss the appeal with costs.

"Johanne Gauthier"

J.A.

"I agree
John. M. Evans J.A."

"I agree
David Stratas J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-9-11
(APPEAL FROM A JUDGMENT OF THE FEDERAL COURT (SNIDER J.) DATED DECEMBER 22, 2010, T-1272-97)	
STYLE OF CAUSE:	APOTEX INC. v MERCK & CO. INC. and MERCK FROSST CANADA LTD. and APOTEX FERMENTATION INC.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	November 28-30, 2011
REASONS FOR JUDGMENT BY:	GAUTHIER J.A.
CONCURRED IN BY:	EVANS J.A. STRATAS J.A.
DATED:	December 19, 2011

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PLACE OF HEARING:	Toronto, Ontario
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CONCURRED IN BY:	EVANS J.A. STRATAS J.A.
DATED:	December 19, 2011

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