Federal Court of Appeal | Cour d'appel fédérale

Date: 20100922

Docket: A-451-09

Citation: 2010 FCA 240

CORAM: **SEXTON J.A.**
EVANS J.A.
SHARLOW J.A.

BETWEEN:

ELI LILLY AND COMPANY and
ELI LILLY CANADA INC.

Appellants

and

APOTEX INC.

Respondent

Heard at Ottawa, Ontario, on September 22, 2010.

Judgment delivered from the Bench at Ottawa, Ontario, on September 22, 2010.

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

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REASONS FOR JUDGMENT OF THE COURT
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EVANS J.A.

A. INTRODUCTION

[1] Eli Lilly and Eli Lilly Canada Inc. (Lilly) have appealed a decision of the Federal Court (2009 FC 991) in which Justice Gauthier (Judge) held that Lilly had failed to prove that Apotex Inc. had infringed any of eight process patents owned by Lilly when Apotex imported into Canada, after June 3, 1998, approximately 7,500 kg of the compound cefaclor for use in its antibiotic medicines.

[2] The Judge held that Lilly had not proved that Apotex' Indian supplier, Lupin Laboratories Inc. (Lupin), had produced the bulk cefaclor from an intermediate compound (7-ACCA) made by a process covered by any of the Lilly patents. The compound cefaclor itself is no longer protected by a patent.

[3] She also held that Apotex had infringed Lilly patents by importing bulk cefaclor before June 3, 1998, which had been produced outside Canada from an intermediate compound that Apotex' suppliers had made by a patented process. Apotex has cross-appealed this aspect of the Judge's decision.

B. LILLY'S APPEAL

[4] The issue in Lilly's appeal is essentially factual: did Lupin change from using a patented to a non-patented process when it made the intermediate compound needed to supply Apotex with the bulk cefaclor imported after June 3, 1998?

[5] Whether a party has discharged its burden of proof is a question of fact. Appellate courts only interfere with a trial judge's finding of fact when the appellant can point to a palpable and overriding error in the judge's findings, or when the judge was wrong in law in, for example, admitting or excluding evidence that was material to the result.

[6] We are not persuaded that the Judge in this case, who rendered careful and comprehensive reasons for her decision after a six months' trial, committed any error that warrants our intervention.

[7] In arguing that the Judge erred in concluding that Lilly had not discharged its burden of proving infringement on a balance of probabilities Lilly did not identify any obvious and significant error in the Judge's analysis of the evidence. Particularly in light of the Judge's credibility findings, there was an ample evidential basis for her conclusion.

[8] Lilly effectively invited us to reweigh the evidence and to draw our own inferences from it, particularly the fact that the Drug Master File (DMF) filed with Health Canada, as well as regulatory filings with the United States' Food and Drug Administration, showed that Lupin was using an infringing process in the manufacture of the intermediate. This is an invitation that an appellate court should not accept. To do otherwise would usurp the role of the trial judge and unnecessarily burden public and private resources alike.

[9] Nor are we persuaded that the Judge committed legal errors in admitting certain oral and documentary evidence. Evidential rulings often require the trial judge to weigh competing factors. They thus involve an exercise of discretion to which an appellate court should afford considerable deference and not simply substitute its opinion for that of the trial judge who was immersed in the matter.

[10] Lilly says that the Judge erred in law in admitting the oral evidence of Mr Satpute, Lupin's Vice President, Active Pharmaceutical Ingredient Manufacturing, and, at the relevant time, the senior manager of Lupin's factory in India where 7-ACCA was manufactured. Lilly argues that Mr Satpute's evidence respecting the process used to produce the intermediate was inadmissible

hearsay because it was based on information given to him by Lupin scientists. The Judge did not address this issue in her reasons.

[11] We do not agree that the Judge erred by not excluding Mr Satpute's testimony as hearsay. It was based largely on his direct knowledge of the manufacturing process used to produce the 7-ACCA to fill Apotex' large order for bulk cefaclor. That he may have relied on others' notes to refresh his memory or for some of the technical detail of the process used does not warrant characterizing his evidence as hearsay. In any event, hearsay evidence is not automatically barred. The Judge found (at para. 252) that Mr Satpute's evidence was "very credible", an impression that she said was confirmed when she read and reread the transcript of his testimony.

[12] Lilly also says that the Judge erred in law by not excluding Mr Satpute's testimony under rule 248 of the *Federal Courts Rules*. On discovery, an officer of Apotex had stated that he had no knowledge of the process actually used by Lupin, when in fact, unknown to Lilly, Lupin had written a letter, dated July 4, 2000, to Mr Ivor Hughes as Apotex' lawyer advising him that it was willing to cooperate in the litigation.

[13] We do not agree with Lilly's submission. It is apparent from the paragraphs in the Judge's reasons dealing with the admissibility of the disputed evidence (paras. 235-56) that she was alive to Lilly's underlying concern, namely that Apotex' litigation tactics had resulted in "ambushing" Lilly and thus deprived it of an opportunity to effectively probe the evidence on which Apotex based its defence.

[14] However, the Judge decided to admit the disputed evidence after having both considered the lengthy submissions of the parties on these issues, and offered to suspend the trial to enable Lilly to try to obtain more information or reopen discovery after it became aware that Apotex intended to call witnesses from India, an offer that Lilly declined. Of Mr Satpute's evidence in particular, she said (at para. 256) that, "in this case", it would not be in the best interests of justice to "totally put aside" his testimony, and that she would exercise her residual discretion to admit it.

[15] In so concluding, the Judge, in our view, made no error of principle warranting the intervention of this Court.

[16] In reaching this decision, we should not be taken to condone Apotex' unexplained failure to provide timely responses to questions, to correct erroneous responses, and to produce documents in a timely fashion. In the circumstances of the present case, the Judge properly exercised her discretion when she accepted the late tendered evidence. It should, however, never be considered good practice for a party to fail to comply with the rules of discovery, and parties cannot expect that such conduct will always be excused at trial.

C. APOTEX' CROSS-APPEAL

[17] Apotex cross-appeals the Judge's finding that it infringed Lilly's patents when, prior to June 3, 1998, it imported bulk cefaclor from overseas suppliers who had produced it from an intermediate compound made by processes covered by Lilly patents. Apotex says that, by finding that the importation of cefaclor breached Lilly's rights under the *Patent Act*, the Judge extended the

scope of protection beyond the use of the claimed invention (here, the processes for making the intermediate product), and gave an extraterritorial reach to the Act that Parliament should not be taken to have intended.

[18] After thoroughly canvassing the relevant jurisprudence, the Judge rejected Apotex' argument, holding that it has been settled law in Canada for over a hundred years that a process patent can be infringed by the importation, and use and sale in Canada, of a product manufactured abroad by another person using the patented process. She pointed out that the Supreme Court of Canada had recently endorsed the rule, known as the "*Saccharin* doctrine" (*Saccharin Corporation Ltd. v. Anglo-Continental Chemical Works*, [1901] 1 Ch. 414 (Eng. Ch. D.): see *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 especially at para. 44.

[19] The Judge also rejected Apotex' alternative argument that, if relevant at all, the *Saccharin* doctrine should not apply if "material changes" are made to the article produced by the patented process prior to the importation of the ultimate product. She applied (at paras. 326-329) the present law, which requires only that the patented process played an "important part" in the manufacture of the imported product, and concluded that it did.

[20] We see no legal error in the Judge's analysis of the state of the law in Canada on either of these issues.

D. CONCLUSIONS

[21] For these reasons, Lilly's appeal and Apotex' cross-appeal will be dismissed, both with costs.

"John M. Evans"

J.A.

EDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-451-09
APPEAL FROM A DECISION OF THE HONOURABLE JOHANNE GAUTHIER OF THE FEDERAL COURT DATED OCTOBER 1, 2009, DOCKET NO. T-1321-97	
STYLE OF CAUSE:	Eli Lilly and Company and Eli Lilly Canada Inc. v. Apotex Inc.
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	September 22, 2010
REASONS FOR JUDGMENT OF THE COURT BY:	(SEXTON, EVANS, SHARLOW JJ.A.)
DELIVERED FROM THE BENCH BY:	EVANS J.A.

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