Federal Court of Appeal | Cour d'appel fédérale

Date: 20101026

Docket: A-13-10

Citation: 2010 FCA 282

CORAM: **NADON J.A.**
PELLETIER J.A.
STRATAS J.A.

BETWEEN:

HOSPIRA HEALTHCARE CORPORATION

Appellant

and

ELI LILLY CANADA INC. and
ELI LILLY AND COMPANY

Respondents

Heard at Ottawa, Ontario, on October 19, 2010.

Judgment delivered at Ottawa, Ontario, on October 26, 2010.

REASONS FOR JUDGMENT BY: PELLETIER J.A.

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

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REASONS FOR JUDGMENT

[1] This is an appeal from the decision of Mr. Justice Lemieux of the Federal Court dismissing an appeal from a decision of Prothonotary Tabib who granted an order for the further and better production of documents in an infringement action.

[2] Eli Lilly Canada Inc. and Eli Lilly and Company (Eli Lilly) hold the patent for an intermediate process step used in the seven step process by which the drug gemcitabine is produced. The patented process is known as the S_N2 reaction. It is an improvement on an earlier process known as the S_N1 reaction. Eli Lilly has no claim to the other steps in the fabrication process nor to

the drug gemcitabine itself. Hospira sells in Canada gemcitabine manufactured in China by Jiangsu Hansen Pharmaceutical Co. Ltd (Hansen). The allegation in Eli Lilly's infringement action is that Hansen uses the S_N2 reaction in its manufacturing process.

[3] Hospira filed an affidavit of documents in which it listed redacted copies of its Abbreviated New Drug Submission, and of a batch report for the manufacture of the drug.

[4] Prothonotary Tabib ordered the appellant Hospira to prepare and serve a further affidavit of documents including "the open part and the closed part of its Drug Master File, the relevant parts of its Abbreviated New Drug Submission as they relate to Hospira's process for manufacturing bulk gemcitabine, as well as amendments thereto, and Batch Records and certificates of analysis for the bulk gemcitabine imported and sold in Canada by Hospira."

[5] The standard of review of the Prothonotary's order concerning disclosure and production in this case is that it must be "clearly wrong" before the Federal Court or this Court can intervene. An example of "clearly wrong" is where the Prothonotary's discretion was founded upon a wrong principle or a misapprehension of the facts. See *Merck & Co. Inc. et al. v. Apotex Inc.*, 2003 FCA 488; *Novopharm Limited v. Eli Lilly Canada Inc.*, 2008 FCA 287, at paragraphs 52 and 57.

[6] Before this Court, Hospira raised two arguments. The first is that the Prothonotary erred in principle in accepting the expert evidence of Dr. Kjell, a chemist employed by Eli Lilly who had

worked on the glycosylation process for a number of years and who was listed as one of the inventors of the S_N2 reaction. Hospira argued that Dr. Kjell's evidence should be automatically rejected because he was an employee of Eli Lilly and, therefore, lacked the independence and the impartiality required of an expert witness

[7] Counsel for Hospira was unable to cite any authority for the proposition that an employee cannot give opinion evidence on behalf of his or her employer merely because of the employee's lack of independence from the employer. I am unaware of any basis for such a sweeping proposition which would have wide ranging consequences.

[8] While there has been judicial commentary on the desirability of experts being independent of the parties and impartial in their opinions (see, for example, *National Justice Campania Naveria SA v. Prudential Assurance Co. Ltd. ("The Ikarian Reefer")*, [1993] 2 Lloyd's Rep. 68, at pp. 81-82), one must distinguish between independence and impartiality. There is a corpus of law dealing with the question of independence as a bar to the admissibility of an expert's evidence, as opposed to a factor to be considered in assessing the weight to be given to that evidence. Those cases are reviewed in *United City Properties v. Tong*, 2010 BCSC 111. It is not necessary for us to settle this debate in order to dispose of this case. I would say though, that a review of many of those cases suggests that that which is being attacked under the name of lack of independence is often, in fact, lack of impartiality. Lack of impartiality is the mischief which has given rise to the recent amendments to the *Federal Courts Rules*, SOR/98-106, to which reference was made by counsel for Hospira.

[9] None of the cases relied upon by Hospira are authority for the proposition that the testimony of a properly qualified expert may be rejected solely on the basis of the latter's lack of independence. *Merck & Co v. Apotex Inc.*, 2004 FC 567, [2004] F.C.J. No. 684, deals with the issue of the appropriateness of a protective order. No decision was made as to the admission or rejection of expert evidence. In *Biovail Pharmaceuticals Inc. v. Canada (Minister of National Health and Welfare)*, 2005 FC 9, [2005] F.C.J. No. 7, the Court, after repeating the often quoted passage from *The Ikarian Reefer*, accepted as an expert witness the applicant's Vice-President, Pharmaceutical Technology, over the objections of the respondents who questioned his financial interest in the outcome of the litigation. In *Lundbeck Canada Inc. v. Canada (Minister of Health)*, 2009 FC 146, [2009] F.C.J. No. 249, the Court rejected a challenge to the qualification of a certain witness as an expert on the basis that the witness had testified for the same party 20 times in the past 30 years. The Court accepted his evidence after a reading of his cross-examination disclosed his objectivity.

[10] The Prothonotary assessed Dr. Kjell's evidence in the light of his cross-examination and of the expert opinion tendered on behalf of Hospira. It cannot be said that she was clearly wrong to have embarked on that exercise, or that she misdirected herself in the course of it.

[11] Hospira's second argument is that the Prothonotary erred in her application of the test for relevance. The Prothonotary applied the broad relevance test which asks whether a document is likely to undermine a party's own case, to advance its opponent's or to lead its opponent to a train of

inquiry which may do either of the above. If the disclosure of a document is likely to lead to any of these results, it is relevant and must be disclosed and produced.

[12] Hospira argued that the presumption of veracity which attaches to its regulatory filings raised the bar in terms of whether it was likely that the documents sought by Eli Lilly would advance its case, impair Hospira's or suggest a train of inquiry which might lead to either result. In effect, Hospira's argument was addressed to the requirement that a document be "likely to" produce one of these effects in order to be considered relevant. In Hospira's view, it was unlikely that the documents requested would contradict its regulatory filings.

[13] It is true that regulatory filings provide a basis for administrative action, and to that extent can be taken to be true unless and until some basis for disbelieving them is made out. That said, this practical reality is without consequences for the course of an infringement action. A party cannot resist production of documents on the basis that, in a regulatory context, it has filed documents which are inconsistent with the plaintiff's allegations in an infringement action. The likelihood that the requested documents are relevant is not dependent upon a party's good faith but upon the content of those documents.

[14] The best example of this proposition is the batch records whose production Hospira resisted. Once Hospira conceded that the batch records in issue "would constitute direct evidence of the process actually used by Hansen in manufacturing gemcitabine" (see the 2nd full paragraph on page 3 of the Prothonotary's order), their relevance was obvious, notwithstanding any of Hospira's

regulatory filings. As for the scope of the order for production, the Prothonotary's order is limited to lots of gemcitabine imported into Canada and does not have the unlimited reach which counsel for Hospira attributed to it, even though it may amount to a continuing obligation.

[15] Hospira also opposed production of its unredacted regulatory filings. Hospira argued that since Eli Lilly's only interest was in a single step of a multi-step fabrication process, its demand for disclosure of Hospira's entire unredacted regulatory file amounted to a fishing expedition. As the Prothonotary pointed out at page 10 of her order, "as Lilly has succeeded in establishing some grounds for doubting the reliability of that part of the regulatory filings on which Hospira intends to rely, it follows that the remaining portions of the regulatory filings may point to other grounds upon which the disclosed portions may be undermined; they are accordingly relevant." I am unable to say that the Prothonotary erred in applying the broad relevance principle to the facts in the way she did. As a result, there is no basis on which we could intervene.

[16] As a result, I would dismiss the appeal with costs.

"J.D. Denis Pelletier"

J.A.

"I agree.
M. Nadon J.A."

"I agree.
David Stratas J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-13-10
STYLE OF CAUSE:	HOSPIRA HEALTHCARE CORPORATION and ELI LILLY CANADA INC. AND ELI LILLY AND COMPANY
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	OCTOBER 26, 2010
REASONS FOR JUDGMENT BY: **CONCURRED IN BY:**	PELLETIER J.A. NADON J.A. STRATAS J.A.
DATED:	OCTOBER 26, 2010

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