Date: 20071023

Docket: A-274-07

Citation: 2007 FCA 329

Present: **SEXTON J.A.**

BETWEEN:

ELI LILLY CANADA INC.

Appellant
(Applicant)

and

NOVOPHARM LIMITED

Respondent
(Respondent)

and

THE MINISTER OF HEALTH

Respondent
(Respondent)

and

ELI LILLY AND COMPANY LIMITED

Respondent/Patentee
(Respondent/Patentee)

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on October 23, 2007.

REASONS FOR ORDER BY: SEXTON J.A.

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REASONS FOR ORDER

SEXTON J.A.

[1] This appeal concerns a NOC proceeding in which *inter alia* an allegation of insufficiency of disclosure was made by Novopharm with respect to a selection patent owned by the appellant, Eli Lilly. The trial judge held that Eli Lilly had failed to demonstrate that such allegation was unjustified. As a result a NOC was issued to Novopharm which has precipitated a motion by Novopharm to dismiss the appeal as being moot.

[2] Four parties seek intervener status in this appeal and on the motion to dismiss the appeal as being moot. They are outlined below.

[3] The Canadian Chamber of Commerce with a membership of 170,000 businesses from every sector and region in Canada, supports the appellant, Eli Lilly, and seeks to intervene claiming that it can bring to the appeal the perspective of Canadian businesses as to how the decision negatively affect businesses and innovation in Canada.

[4] BIOTECanada – a national biotechnology industry association committed to ensuring the sustainable commercial development of biotechnology in Canada supports the appellant, Eli Lilly. BIOTECanada acts as an advocate for its members on intellectual property protection, and,

in particular, patent protection available in Canada, and wishes to intervene in the appeal as well as on the motion by Novopharm to quash the appeal as being moot.

[5] Canada's Research-Based Pharmaceutical Companies (Rx&D) is the incorporated trade associate for innovative pharmaceutical manufacturers in Canada which claims to foster the discovery, development and availability of new medicines and vaccines, and seeks to intervene to support the appellant, Eli Lilly.

[6] The Canadian Generic Pharmaceutical Association is a trade associate whose members include most generic drug manufacturers in Canada, seeks to intervene in Novopharm's motion with respect to mootness and on the appeal also. CGPA supports the position of Novopharm.

[7] To succeed on these motions, the proposed interveners must demonstrate how their participation in the proceedings will assist in the determination of a factual or legal issue related to the proceeding.

[8] This Court has set forth the factors to be considered on a motion to intervene.

See *CUPE v. Canadian Airlines* [2000] F.C.J. No. 220

Those factors are:

a) Is the proposed intervener directly affected by the outcome?

b) Does there exist a justiciable issue and a veritable public interest?

c) Is there an apparent lack of any other reasonable or efficient means to submit the question to the Court?

d) Is the position of the proposed intervener adequately defended by one of the parties to the case?

e) Are the interests of justice better served by the intervention of the proposed third party?

f) Can the Court hear and decide the case on its merits without the proposed intervener?

[9] In the present case:

a) None of the interveners are directly affected.

b) While there may be a justiciable issue, it is not clear that there is a veritable public interest.

c) There is no apparent lack of efficient means to submit the question to the Court. It is apparent that the appellant and respondents, through their memoranda of fact and law which have been filed, are quite able to adequately present the issues to the Court.

d) Three of the interveners wish to support the appellant. One of the interveners wishes to support the respondent, Novopharm. It appears to me, from their actions, that the appellant and the respondent, Novopharm, are quite able to defend their respective positions.

e) I cannot see how the interests of justice are better served by the interventions. Indeed the proceedings will certainly be lengthened with no apparent justification.

f) The Court is quite able to decide the appeal without the proposed interveners. The issues have been clearly framed by the appellant and the respondent, Novopharm.

[10] As mentioned previously, this appeal arises out of a proceeding under the NOC regulations.

The issue is a narrow one – was the trial judge wrong in holding that the disclosure in the patent was

insufficient. It has been said on a number of occasions that proceedings under the NOC regulations are intended to be summary and of short duration. Thus allowing interventions in NOC proceedings should be done only in the clearest of cases and only where it is obviously warranted. Such is not the case here. Sharlow J.A. in *AB Hassle v. Apotex Inc.* 2006 FCA 51 at paragraph 2 described what NOC proceedings are supposed to be:

> These are summary proceedings, intended to facilitate a relatively quick determination by the Federal Court of certain issues of patent construction, infringement and validity, but only for the limited purpose of making (or declining to make) an order prohibiting the Minister of Health from approving the sale in Canada of a new generic drug for which approval is sought on the basis of a comparison to an existing product whose producer has certain patent rights.

[11] It has not escaped the attention of this Court that litigants are ignoring the intended summary nature of NOC proceedings. As Noel J.A. recently stated in *Abbott Laboratories v. Canada (Minister of Health)* 2007 FCA 187 at paragraph 28:

> …[the 24-month statutory stay period provided in paragraph 7(1)(e) of the NOC Regulations] was no doubt intended to focus the minds of the parties and the Court on the summary nature of the proceedings and the need for their expeditious prosecution. It is the absence of focus on this time frame which has given these summary proceedings over time the ponderous character of patent infringement actions commonly known to last numerous days and sometimes weeks. The end result is that judicial resources are increasingly being consumed by these so called summary proceedings at the expense of other jurisdictions which advance more obvious public policy concerns.

[12] In considering whether to allow the motions to intervene, it is worth noting that the appellant has commenced an infringement action in the Federal Court where the same issues, relating to the sufficiency of its disclosure in the patent, may be raised. It has been held that decisions with respect

to infringement and validity in NOC proceedings are not ultimately adjudicative of the scope or validity of a patent. Actions for infringement still lie.

Novartis AGC v. Apotex Inc. (2002) 22 C.P.R. (4th) 450 (C.A.) at paragraph 9

AB Hassle, *supra*., at paragraphs 28-29.

[13] I am therefore of the view that the interests of justice would not be well served by allowing these interventions. I emphasize, however, that these reasons are not to be taken as expressing any view on whether the appeal is moot or whether, if the appeal is moot, the Court should agree to hear it anyway.

[14] For these reasons, all the applications for intervention will be dismissed.

"J. Edgar Sexton"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-274-07
STYLE OF CAUSE:	Eli Lilly Canada Inc. v. Novopharm Limited and The Minister of Health and Eli Lilly and Company Limited

MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY:	SEXTON J.A.
DATED:	October 23, 2007

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