Date: 20090129

Docket: A-565-08

Citation: 2009 FCA 24

Present: **EVANS J.A.**

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

ELI LILLY CANADA INC.,
ELI LILLY and COMPANY LIMITED
and THE MINISTER OF HEALTH

Respondents

Dealt with in writing without appearance of parties.

Order delivered at Ottawa, Ontario, on January 29, 2009.

REASONS FOR ORDER BY: EVANS J.A.

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REASONS FOR ORDER

EVANS J.A.

[1] This is a motion in writing under rule 369 of the *Federal Courts Rules* by the Canadian Generic Pharmaceutical Association (CGPA) requesting leave to intervene in an appeal by Novopharm Ltd. from a decision of the Federal Court. The motion is supported by Novopharm, and opposed by the respondents, the Minister of Health, and Eli Lilly Canada Inc. and Eli Lilly and Co. Ltd. (Eli Lilly).

[2] In the decision under appeal (2008 FC 1221), Justice Martineau dismissed a motion by Novopharm for

> (i) a declaration that sections 2, 3, and 4 of the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2008-211 (*2008 Amendments*) are *ultra vires* the enabling provision of the *Patent Act*, R.S.C. 1985, c. P-4; and
>
> (ii) an order under paragraph 6(5)(*a*) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*PMNOC Regulations*), dismissing Eli Lilly's application for an order of prohibition restraining the Minister of Health from issuing a Notice of Compliance (NOC) to Novopharm with respect to its olanzipine drug until the expiry of Canadian Patent No. 2,214,005.

[3] Justice Martineau concluded that neither the *NOC Regulations*, nor the *Patent Act*, conferred jurisdiction on the Court, a statutory court, to grant a declaration that provisions of the *PMNOC Regulations* (and any amendments) are invalid. Further, he held, even if the Court had jurisdiction to grant the declaration sought, he would decline in his discretion to exercise it, in part because Novopharm had a more suitable remedy available to it, namely, an application for judicial review in which it could seek the declaratory relief requested in its motion. Justice Martineau supported this latter proposition (at para. 34) by reference to a recent case, *Canadian Generic Pharmaceutical Association v. Canada (Governor in Council)*, 2007 FCA 375 (*CGPA v. Canada*), in which the CGPA had sought a declaration in an application for judicial review that regulations were invalid.

[4] In its Notice of Motion, the CGPA states that the "central issue" to be decided in Novopharm's appeal is whether Justice Martineau erred in refusing to determine the validity of the impugned provisions of the *2008 Amendments* on the ground that he either lacked jurisdiction in that proceeding to grant the relief sought or, if he had jurisdiction, it was not appropriate for him to exercise it. Novopharm goes on to say that, if the Court agrees with its position on this point and concludes that the validity of the *2008 Amendments* can properly be determined in the appeal, it must then decide if they are invalid.

[5] The Court may grant leave to intervene in a proceeding under rule 109 if the proposed intervener (i) has an interest in the outcome of the litigation, (ii) has rights that may be adversely affected by the outcome, and (iii) will assist the court by bringing a perspective to the proceedings different from that of the parties: *Abbott v. Canada*, [2000] 1 F.C. 482 (F.C.).

[6] CGPA is the trade association representing manufacturers of generic drugs in Canada, including Novopharm. It has been consulted in the NOC regulation-making process, it is very familiar with regulatory scheme and the pharmaceutical industry in Canada, and it has been granted leave by the Supreme Court of Canada to intervene in litigation involving the *PMNOC Regulations*, including their validity.

[7] Even if the CGPA were to satisfy the first two branches of the *Abbott* test, it has not, in my opinion, demonstrated that it will bring to the appeal a sufficiently different perspective on the

questions likely to be in issue as to warrant being granted intervener status. I say this for two reasons.

[8] First, even if the Court agrees that Justice Martineau had, and should have exercised, jurisdiction to declare the impugned sections of the *2008 Amendments* to be invalid, it is unlikely, in my view, that the Court would proceed to determine the validity of the *2008 Amendments* in this appeal. When exercising an appellate jurisdiction, this Court is always reluctant to decide controversial, difficult, and important questions of law at first instance, without the benefit of a reasoned decision by the judge whose decision is under appeal. Hence, the only question likely to be at issue in the appeal is whether a declaration that the regulations are invalid is properly made in an interlocutory motion under the *PMNOC Regulations*. The Court is unlikely to decide the substantive question of whether the *2008 Amendments* are *ultra vires* the power conferred by the *Patent Act*, a question on which the CGPA may have a stronger claim to an expertise that would be valuable to the Court.

[9] Second, CGPA submits that it has a valuable perspective to bring to the Court even on the remedial issue, because it was a party in one of the cases relied on by Justice Martineau in support of the proposition that an application for judicial review is a more suitable proceeding than an interlocutory motion under the *PMNOC Regulations* for seeking a declaration that provisions of the *2008 Amendments* are invalid. Counsel argues that that case, *CGPA v. Canada*, is distinguishable from the present litigation.

[10] In my view, CPGA is no better placed than Novopharm to present to the Court reasons why the validity of the regulatory regime considered in *CPGA v. Canada* was properly examined in the context of an application for judicial review, but the validity of the *2008 Amendments* is not.

[11] Finally, I would note that the limited scope of the issues likely to be decided by the Court on Novopharm's appeal also reduces the seriousness of any harm that the CGPA and its members may sustain if the appeal is dismissed.

[12] In short, I am not persuaded that the interests of justice would be advanced by granting leave to the CGPA to intervene in this appeal.

[13] For these reasons, the CGPA's motion is dismissed. Eli Lilly shall be awarded its costs.

"John M. Evans"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-565-08
STYLE OF CAUSE:	Novopharm Limited and Eli Lilly Canada Inc., Eli Lilly and Company Limited, and the Minister of Health

MOTION DEALT WITH IN WRITING WITHOUT APPEARANCE OF PARTIES

REASONS FOR ORDER BY:	Evans J.A.
DATED:	January 29, 2009

WRITTEN REPRESENTATIONS BY:

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