Date: 20090504

Docket: A-565-08

Citation: 2009 FCA 138

CORAM: **DÉCARY J.A.**
LINDEN J.A.
SEXTON J.A.

BETWEEN:

NOVOPHARM LIMITED

Appellant

and

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

Respondents

Heard at Toronto, Ontario, on May 4, 2009.

Judgment delivered from the Bench at Toronto, Ontario, on May 4, 2009.

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

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Toronto, Ontario, on May 4, 2009)

SEXTON J.A.

[1] This is an appeal by Novopharm from a decision of Justice Martineau of the Federal Court, dismissing its motion for a declaration that certain sections of the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2008-211 ("the *Amending Regulations*") were *ultra vires* the powers of the Governor in Council, and other consequential relief (2008 FC 1221). The motions judge found that he did not have jurisdiction to grant the declaratory

relief sought by Novopharm, and alternatively would have exercised his discretion not to grant it if he did have jurisdiction. It was therefore unnecessary to consider the other relief sought.

[2] Novopharm brought its motion in response to an application brought by the respondent, Eli Lilly Canada ("Lilly") pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("the *NOC Regulations*"). Eli Lilly and Company Limited was issued Canadian Patent 2,214,005 ("the '005 Patent") on July 3, 2001 for olanzapine, and Lilly markets orally disintegrating olanzapine tablets in Canada. Lilly's application sought an order prohibiting the Minister of Health ("the Minister") from issuing a notice of compliance (NOC) to Novopharm for its generic orally disintegrating olanzapine tablets.

[3] Generally, paragraph 6(5)(a) of the *NOC Regulations* allows a generic drug manufacturer to bring a motion for the court to dismiss an innovator's application for prohibition on the ground that the relevant patent is not eligible for inclusion on the register. Novopharm claims that the '005 Patent is not eligible for inclusion on the register because it is not relevant to Lilly's supplemental new drug submissions and the corresponding NOCs against which it is listed.

[4] However, the *NOC Regulations* were amended on June 12, 2008 by the *Amending Regulations*, made pursuant to subsection 55.2(4) of the *Patent Act*, R.S.C. 1985, c. P-4. Subsection 6(5.1) of the *NOC Regulations*, as enacted by section 3 of the *Amending Regulations*, states that an application may not be dismissed solely on basis that the patent is not eligible for inclusion on the

register where the patent was listed prior to June 17, 2006. The ‘005 Patent was listed prior to this date, and is therefore a “grandfathered patent”.

[5] Further, section 2 of the *Amending Regulations* amended the *NOC Regulations* to provide that the Minister may not refuse to add a grandfathered patent to the register solely on the basis that it is not relevant to a new drug submission or supplemental new drug submission. Further, the Minister may not delete a grandfathered patent from the register, subject to a few “common sense” exceptions. Section 4 of the *Amending Regulations* provided transitional provisions in this regard concerning grandfathered patents.

[6] As stated in subsection 4(8) of the *Amending Regulations*, the new subsection 6(5.1) does not apply if the generic’s motion to dismiss was brought prior to the publication of the *Amending Regulations* in Part I of the *Canada Gazette*, which occurred on April 26, 2008. However, since Novopharm’s motion was brought after this date, it could not benefit from this exception.

[7] Had the *Amending Regulations* not been made, the ‘005 Patent would not be protected from the potential application of paragraph 6(5)(a). Novopharm therefore requested that the motions judge declare that sections 2, 3, and 4 of the *Amending Regulations* were *ultra vires* the regulation-making powers of the *Patent Act* and therefore of no force or effect.

[8] We are of the view that the motions judge did not err when he said (at para. 23):

> Accordingly, for this Court to make some general and binding judicial declaration that the *2008 Amending Regulations* are *ultra vires* and of no force and effect would go well beyond

> the limited scope of the herein summary proceeding under the *NOC Regulations*. See *Eli Lilly & Co. v. Novopharm Ltd.; Eli Lilly & Co. v. Apotex Inc.*, [1998] 2 S.C.R. 129 at paras. 93, 95 and 97.

We are of the view that the Supreme Court's decision in *Eli Lilly* (as cited by the motions judge) rejected the possibility of interlocutory declaratory relief being available in a NOC proceeding. Although the particular declarations sought in that case concerned private rights, the court emphasized that NOC proceedings are summary in nature and generally intended to produce rulings binding only on the parties to the litigation. Granting a declaration of the *vires* of legislation is incompatible with this limited type of proceeding.

[9] Further, as the motions judge noted, declarations generally cannot be sought by way of motion (*Pacific Salmon Inc. v. The Queen*, [1985] 1 F.C. 504 at 510 (T.D.)). None of the cases referred to by Novopharm in this regard state otherwise. In *Rocois Construction Inc. v. Quebec Ready Mix*, [1980] 1 F.C. 184 (T.D.), rev'd [1985] 2 F.C. 40 (C.A.), aff'd [1989] 1 S.C.R 695 and *Canadian Assn. of Broadcasters v. Canada*, 2005 FC 1217, 50 Admin. L.R. (4th) 26, aff'd 2006 FCA 208, 353 N.R. 12, the court made orders that preliminary questions of law be determined prior to trial, in the context of actions. This is a procedure expressly provided for by the *Federal Courts Rules*.

[10] This court recently affirmed in *Canadian Council for Refugees v. Canada*, 2008 FCA 229, 74 Admin L.R. (4th) 79 at para. 55, that an application for judicial review brought under section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, is the proper procedure for challenging the validity of a regulation made by the Governor in Council. While paragraph 18(1)(a) of the *Federal Courts*

Act gives the court jurisdiction to grant declaratory relief against a federal board, commission, or tribunal, subsection 18(3) states that this remedy "may be obtained only on an application for judicial review made under section 18.1". An innovator's application for an order or prohibition, which is brought pursuant to subsection 55.2(4) of the *Patent Act* and section 6 of the *NOC Regulations*, is not such an application.

[11] We therefore conclude that declaratory relief related to the validity of a law is not available in the context of an application brought under to the *NOC Regulations*. The proper course is for Novopharm to commence an application for judicial review under section 18.1 of the *Federal Courts Act* seeking a declaration that the *Amending Regulations* are *ultra vires*. We are not satisfied by Novopharm's arguments that it would be impractical or unworkable for it to proceed in this fashion.

[12] For these reasons, the appeal is dismissed, with costs to the respondents.

"J. Edgar Sexton"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-565-08

(AN APPEAL FROM THE ORDER OF THE HONOURABLE MR. JUSTICE MARTINEAU, OF THE FEDERAL COURT, DATED NOVEMBER 3, 2008, IN FEDERAL COURT FILE NO. T-703-08.)

STYLE OF CAUSE:	NOVOPHARM LIMITED v. ELI LILLY CANADA INC., ELI LILLY AND COMPANY LIMITED, AND THE MINISTER OF HEALTH
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