Federal Court of Appeal  Cour d'appel fédérale

Date: 20131204

Docket: A-400-10

Citation: 2013 FCA 282

CORAM: **EVANS J.A.**
STRATAS J.A.
WEBB J.A.

BETWEEN:

APOTEX INC.

Appellant

and

ELI LILLY CANADA INC.

Respondent

and

ELI LILLY AND COMPANY LIMITED

Respondent/Patentee

and

MINISTER OF HEALTH

Respondent

Heard at Toronto, Ontario, on December 4, 2013.

Judgment delivered from the Bench at Toronto, Ontario, on December 4, 2013.

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

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REASONS FOR JUDGMENT OF THE COURT
(Delivered from the Bench at Toronto, Ontario, on December 4, 2013).

EVANS J.A.

[1] This is an appeal by Apotex Inc. (Apotex) from a decision of Justice Gauthier (Judge) when a Judge of the Federal Court dismissing a motion by Apotex under rule 399 of the *Federal Courts Rules*, SOR/98-106. The decision is reported at 2010 FC 952.

[2] In its motion Apotex had requested the Court to set aside an order granted to Eli Lilly Canada Inc. (Lilly), the respondent in this appeal, prohibiting the Minister of Health (Minister) from issuing a Notice of Compliance (NOC) to Apotex with respect to its olanzaprine products until the expiry of Lilly's Canadian Letters Patent No. 2,041,113 ('113 patent). In addition, Apotex requested that the Judge dismiss the application that resulted in the order of prohibition.

[3] The nub of the Judge's decision was that, even if the '113 patent were ultimately held invalid in an action impeaching its validity, which at that time had not been finally resolved, that would not be a matter arising after the order of prohibition for the purpose of rule 399(2)(*a*). Following the hearing of the motion, the Federal Court of Appeal held in *Apotex Inc. v. Syntex Pharmaceuticals International Inc.*, 2010 FCA 155 (*Syntex*) that "there is no need to set aside the prohibition order when the patent expires through a declaration of invalidity" (para. 30 of the Judge's reasons).

[4] In appealing the Judge's order Apotex acknowledges that it is asking the Court reconsider a question that it has already decided, and that if the Court declines this request its appeal cannot succeed.

[5] The question at issue is whether a declaration that a patent is invalid enables the Court to vary its earlier order and dismiss an application for a prohibition under subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (Regulations) in which the Court had granted an order prohibiting the Minister from issuing a NOC pending the expiry of a patent on the list submitted by an applicant in respect of a new drug, and listed by the Minister on the patent register in respect of that drug.

[6] This Court has unequivocally held on several occasions that a finding that a patent is invalid does not enable the Court to reach back and retroactively dismiss an application for an order of prohibition granted earlier on the ground that an allegation of non-infringement or invalidity in a Notice of Allegation was not justified: see, in particular, *Syntex* at para. 36; *Pfizer Canada Inc. v. Ratiopharm*, 2011 FCA 215 (*Ratiopharm*).

[7] The practical significance of this issue is that a generic pharmaceutical manufacturer may claim damages under section 8 of the Regulations if an application for an order of prohibition under subsection 6(1) is withdrawn or discontinued, dismissed, or reversed on appeal. Since a subsequent declaration that a patent listed on the register is invalid is none of these, it does not give rise to a claim by the generic manufacturer for damages for loss of profits sustained during the time that the prohibition order kept its product off the market.

[8] Because this Court is normally bound by its own decisions, Apotex can only succeed in this appeal if it satisfies us that *Syntex* and *Ratiopharm* should not be followed because they are "manifestly wrong" within the narrow meaning of *Miller v. Canada (Attorney General)*, 2002 FCA

370 at paras. 8, 10, and 22 (*Miller*). They were not *per incuriam*, nor subsequently overruled or seriously attenuated by decisions of the Supreme Court of Canada.

[9] We would emphasize that an important basis of *Miller* is the public interest in avoiding the waste of scarce judicial, and other, resources through the re-litigation of decided questions.

[10] The principal argument advanced by Apotex in the present appeal for our revisiting the issue decided in *Syntex* and *Ratiopharm* is that the Court relied on a decision of the English Court of Appeal, *Unilin Beheer BV v. Berry Floor N V*, [2007] EWCA Civ. 364 (*Unilin*), which was subsequently overruled by the Supreme Court of the United Kingdom in *Virgin Airways Limited v. Zodiac Seats UK Limited*, [2013] UKSC 46.

[11] We do not agree that this argument establishes that *Syntex* and *Ratiopharm* were "manifestly wrong" in the *Miller* sense. In particular, we are not satisfied that they, or the decision in the present appeal, were based on *Unilin* to such an extent that they should be reconsidered by this Court. They involved the interpretation of the very particular statutory regime created by the Regulations, including the statutory cause of action under section 8. *Unilin* did not. Subsequent decisions of foreign courts that may be somewhat analogous do not normally demonstrate that a contrary decision by a Canadian court was "manifestly wrong".

[12] Whatever the merits of Apotex' arguments that *Syntex* and *Ratiopharm* are bad law and inconsistent with the overall scheme and purposes of the Regulations, they are more appropriately addressed in an application for leave to appeal to the Supreme Court of Canada.

[13] For these reasons, and despite the very able arguments of counsel for Apotex, we are not persuaded that the Judge committed any reviewable error in exercising her discretion to deny the motion. Accordingly, the appeal will be dismissed with costs.

"John M. Evans"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET: A-400-10

APPEAL FROM A ORDER OF THE HONOURABLE JUSTICE GAUTHIER OF THE FEDERAL COURT OF CANADA, DATED SEPTEMBER 24, 2010, DOCKET NO. T-156-05 & T-787-05

STYLE OF CAUSE:	APOTEX INC. v. ELI LILLY CANADA INC. AND ELI LILLY AND COMPANY LIMITED AND MINISTER OF HEALTH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	DECEMBER 4, 2013
REASONS FOR JUDGMENT OF THE COURT BY:	EVANS J.A. STRATAS J.A. WEBB J.A.
DELIVERED FROM THE BENCH BY:	EVANS J.A.

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