Date: 20061011

Docket: A-589-05

Citation: 2006 FCA 328

CORAM: **LÉTOURNEAU J.A.**
NOËL J.A.
EVANS J.A.

BETWEEN:

SANOFI-AVENTIS CANADA INC. and
SANOFI-AVENTIS DEUTSCHLAND GmbH

Appellants

and

APOTEX INC. and
THE MINISTER OF HEALTH

Respondents

Heard at Toronto, Ontario, on October 11, 2006.

Order delivered from the bench at Toronto, Ontario, on October 11, 2006.

REASONS FOR ORDER OF THE COURT BY: NOËL J.A.

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REASONS FOR ORDER
(Delivered from the Bench at Toronto, Ontario, on October 11, 2006)

NOËL J.A.

[1] This is a motion by Apotex Inc. ("Apotex") to dismiss, on the ground of mootness, an appeal brought by Sanofi-Aventis Canada Inc. ("Aventis"). The appeal is from the Order of Tremblay-Lamer J. dated November 4, 2005 (2005 FC 1504), dismissing an application by Aventis for the issuance of an Order pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*NOC Regulations*"), prohibiting the Minister of Health from issuing a

Notice of Compliance ("NOC") to Apotex in respect of its drug product ramipril until after the expiration of Canadian Letters Patent No. 1,246,457 ("the '457 patent").

[2] It is by reason of the expiration of '457 patent on December 13, 2005, that Apotex seeks the dismissal of the appeal on the ground of mootness.

Background

[3] In August of 2003, Apotex filed a first Notice of Allegation with respect to the '457 patent and its ramipril product. Invalidity on the ground of obviousness was argued only on a conditional basis, and as the stated condition did not materialize, this ground was not addressed in the decision disposing of the first allegation.

[4] By that decision, rendered on October 11, 2005, (2005 FC 1381) Simpson J. prohibited the Minister from issuing an NOC to Apotex until after the expiry of the '457 Patent, on the basis that Apotex' allegation that its proposed drug would not be used to treat heart failure – a patented use under the '457 patent – had not been made out.

[5] The application below was commenced further to a second Notice of Allegation filed by Apotex on November 10, 2003, which alleged invalidity based on, *inter alia*, obviousness. Tremblay-Lamer J. dismissed the ensuing application for prohibition. She concluded that Apotex' allegation of invalidity based on obviousness was justified. In coming to this conclusion, she dismissed Aventis' argument that Apotex' Notice of Allegation amounted to an abuse of process and was, as such, invalid.

[6] This is the decision that is currently under appeal and which Apotex moves to dismiss.

[7] In support of its motion, Apotex argues that, as a result of the expiry of the '457 patent, and given its undertaking to abandon its appeal from the decision of Simpson J. in the event that the present application succeeds, there is no longer a statutory obstacle preventing the issuance of an NOC and therefore nothing left to decide. It adds that a decision on appeal cannot change the result.

[8] Apotex relies on the current line of jurisprudence, and in particular this Court's decision in *Pfizer Canada Inc. v. Apotex Inc.* (2001), 11 C.P.R. (4th) 245 ("*Pfizer*"), which stand for the general proposition that this Court should not hear appeals arising under the *NOC Regulations* once they become moot.

[9] Aventis, for its part, argues that the appeal is not academic since mootness arises only once an NOC has been issued (Written Representations of the Appellants, para. 25). In this case an NOC has yet to issue. Hence, Aventis takes issue with Apotex' submission that the within appeal is moot.

[10] Aventis also emphasizes that in the proceeding before Tremblay-Lamer J., it sought a declaration that the Notice of Allegation was invalid because it constituted an abuse of process. According to Aventis, this particular issue is not rendered moot by the expiry of the '457 patent.

[11] In any event, Aventis submits that this is a case where the Court should exercise its discretion to hear the appeal even if it is moot. In this respect, Aventis relies on this Court's

decision in *Bayer AG v. Apotex Inc*. (2004), 32 C.P.R. (4th) 449 ("*Bayer*"), which allowed an appeal to be heard despite the fact that the case was clearly moot.

[12] In that case, Rothstein J.A. (as he then was), writing for the Court, followed the test developed in *Borowski v. Canada (Attorney General)*, [1989] 1 S.C.R. 342 ("*Borowski*"). Applying this test, the Court decided to hear the appeal despite its mootness, in order to preserve Apotex' entitlement to damages pursuant to section 8 of the *NOC Regulations*.

[13] Subsection 8(1) of the *NOC Regulations* provides:

8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period	**8.** (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :
(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court is satisfied on the evidence that another date is more appropriate; and	*a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal estime d'après la preuve qu'une autre date est plus appropriée;
(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.	*b*) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

Decision

[14] We are satisfied that the appeal became moot as a result of the expiration of the patent in issue. The relief that can be granted under the *NOC Regulations* can only remain in effect until the patent that forms the subject matter of the prohibition proceedings has expired (see, in particular, subsection 6(1) of the *NOC Regulations*). In other words, once the patent has expired, there is no basis upon which the Minister could be the subject of an order of prohibition. The fact that the relevant NOC has yet to issue changes nothing in this regard.

[15] The fact that Aventis also sought a declaration invalidating the Notice of Allegation that gave rise to the proceeding before Tremblay-Lamer J. is also of no assistance to Aventis. The purpose of such a declaration was to prevent Apotex from entering the market pending the expiration of the '457 patent. Since the patent has expired, nothing can flow from a decision on appeal on this point.

[16] The only issue, therefore, is whether this Court should nevertheless exercise its discretion to hear the appeal. In this respect, Aventis claims that, absent a favourable decision on appeal, it will be exposed to damages pursuant to section 8 of the *NOC Regulations*, and that, as a result, it finds itself in the same position as Apotex in the *Bayer* case. As such, Aventis urges the Court to exercise its discretion in the same way.

[17] We first note that unlike Apotex in the *Bayer* case, Aventis has, as a patentee the right to undertake a patent infringement action (circumstances permitting) and, if successful, obtain compensation either in the form of damages or loss of profits.

[18] In addition, Aventis' potential exposure to damages under section 8 is too remote and speculative to justify our hearing the appeal.

[19] Under that provision, a first person is liable for any loss suffered during the period beginning on the date on which a Notice of Compliance would have been issued in the absence of the *NOC Regulations*. This provision is intended to allow a second person to be compensated with respect to an application made by a first person that is shown to have been unsuccessful by reason of, *inter alia*, a dismissal at first instance or a reversal of a prohibition order on appeal.

[20] In this case, Apotex chose to first proceed with its conditional allegation before Simpson J.. It did not seek to accelerate its appeal from that decision with the result that, insofar as this decision is concerned, none of the events mentioned in section 8 have taken place. Simpson J.'s prohibition order has remained in effect until the expiration of the '457 patent. Based on the limited record that we have, and without pre-judging the issue, if it should arise in the context of a section 8 application, the section 8 exposure is in our view speculative.

[21] In order to satisfy us that the appeal ought to be heard despite its mootness, it was incumbent upon Aventis to show, on a balance of probabilities that a decision on appeal will have a practical effect on the rights of the parties (*Borowski*, at 358-62 as applied in *Bayer*, *supra*). This demonstration has not been made.

[22] The motion will be allowed with costs and the appeal will be dismissed with costs on the ground of mootness.

"Marc Noël"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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