Federal Court of Appeal

Cour d'appel fédérale

Date: 20110502

Docket: A-473-10

Citation: 2011 FCA 149

CORAM: **NOËL J.A.**
SHARLOW J.A.
DAWSON J.A.

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

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

Respondents

Heard at Ottawa, Ontario, on May 2, 2011.

Judgment delivered from the Bench at Ottawa, Ontario, on May 2, 2011.

REASONS FOR JUDGMENT BY: DAWSON J.A.

CONCURRED IN BY: NOËL J.A.
DISSENTING REASONS BY: SHARLOW J.A.

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REASONS FOR JUDGMENT
(Delivered from the Bench at Ottawa, Ontario, on May 2, 2011)

DAWSON J.A.

[1] The respondents to this appeal have sued the appellant, Teva Canada Limited (Teva), for patent infringement. In response to the statement of claim Teva filed a statement of defense and counterclaim. Among other things, Teva counterclaimed for compensation under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR 93/-133 (*Regulations*). The claim was for losses suffered during the period Teva (formerly Novopharm Limited) was not in receipt of a Notice of Compliance (NOC) for its drug Novo-ramipril as a result of proceedings commenced

under section 6 of the *Regulations*. Included in the claim for compensation was a claim for damages for Teva's permanent loss of market share. At paragraphs 135, 136 and 143 of its third amended statement of defense and counterclaim Teva asserted:

> 135. The commencement of the NOC Proceedings resulted in lost sales and a permanent loss of market share to Novopharm for Novo-Ramipril capsules.
>
> 136. In addition, Novopharm was denied the opportunity to significantly enhance its reputation for the introduction of new products in advance of its competitors. As a result of this delay, Novopharm was prevented from obtaining increased sales and market share for its non-ramipril products.
>
> […]
>
> 143. Furthermore, during the periods in which Novopharm was being delayed by the Defendants by Counterclaim, Apotex received an NOC for its 1.25, 2.5, 5 and 10 mg ramipril capsules. If Novopharm had been approved on the same day as Apotex and ratiopharm, Novopharm would have had a greater share in the marketplace than it currently has. Moreover, Novopharm will be unable to capture a larger percentage of the market share over time due to its late entry. Accordingly, Novopharm claims its damages for lost market share as well.

[2] Relying upon this Court's decision in *Apotex Inc. v. Merck & Co.*, 2009 FCA 187, [2010] 2 F.C.R. 389 (leave to appeal refused [2009] S.C.C.A. No. 347) a Prothonotary of the Federal Court struck out the reference to the permanent loss of market share in paragraph 135 of the pleading, struck out paragraph 136 in its entirety and struck out the last two sentences of paragraph 143 of the pleading (2010 FC 150, 364 F.T.R. 122).

[3] On an appeal from that decision, a Judge of the Federal Court, in a *de novo* decision, agreed that the impugned portions of the counterclaim that referred to loss incurred after the period defined in section 8 of the *Regulations* should be struck out (2010 FC 1210, 88 (C.P.R. (4th) 465). On

consent, an order issued reinstating portions of the counterclaim that had been struck out to the extent they referred to damages incurred within the statutory period. In the Judge's view, this Court's decision in *Merck* made it plain and obvious that the claim for loss of a permanent market share was hopeless and disclosed no reasonable cause of action. In the words of the Judge, a "second person may claim damages resulting from a loss of market share, but only for losses actually incurred within the period [of liability defined in subsection 8(1) of the *Regulations*]. Section 8 does not provide any entitlement to damages in respect of losses incurred outside the period."

[4] We agree. The present pleading cannot be distinguished from that considered by this Court in *Merck*. As both the Prothonotary and the Judge recognized, the *Merck* decision is binding upon the Federal Court.

[5] In argument, Teva submitted that the decision in *Merck* should not be followed. However, in *Miller v. Canada (Attorney General)*, 2002 FCA 370, 293 N.R. 391, at paragraph 10, this Court held that it will not depart from the decision of a previous panel unless "the previous decision is manifestly wrong, in the sense that the Court overlooked a relevant statutory provision, or a case that ought to have been followed." See also *Eli Lilly and Co. v. Novopharm Ltd.* (1996), 67 C.P.R. (3d) 377 (F.C.A.) at page 380; *Glaxo Group Ltd. v. Canada (Minister of National Health and Welfare)* (1995), 64 C.P.R. (3d) 65 (F.C.T.D.) at pages 67 and 68; *Janssen Pharmaceutica Inc. v. Apotex Inc.*, [1997] F.C.J. No. 169 (F.C.A.) at paragraph 2; *Aventis Pharma Inc. v. Apotex*, 2005 FC 1283 at paragraphs 361 to 368.

[6] In *Merck* this Court neither overlooked a relevant statutory provision nor failed to have regard to a prior decision that ought to have been followed. The decision in *Merck* has not been shown to be manifestly wrong. The Judge made no error in its application to the pleading before her.

[7] For these reasons, the appeal will be dismissed with costs.

"Eleanor R. Dawson"
J.A.

"I agree
Marc Noël J.A."

SHARLOW J.A. (Dissenting Reasons)

[8] I respectfully disagree with the disposition of this appeal proposed by my colleagues. I reach that conclusion for the following reasons.

[9] Teva sought in its pleadings compensation under section 8 of the *Regulations* for the permanent loss of market share it suffered during the period defined by that provision because, during that period, other generic producers of ramipril entered the market ahead of Teva. In this Court, Teva argues that it should not be barred from asserting that claim merely because the quantification of that loss necessarily takes into account an estimate of sales that Teva would have made after the end of the period.

[10] In my view, Teva's allegations are based on an interpretation of section 8 that its words can reasonably bear, and that is consistent with the purpose of section 8 as reflected in the Regulatory Impact Analysis Statements published when the *Regulations* were first enacted in 1993, and when the current version of section 8 was enacted in 1998.

[11] The *Regulations* establish a legal procedure that amounts to a mandatory injunction for a period of time during which the Federal Court must assess, on a *prima facie* basis, an allegation that a listed patent is not valid or will not be infringed by a particular generic product. Section 8 of the *Regulations* is a counter balance to the power of an innovator drug company to cause this mandatory injunction to be imposed in a particular case, merely by commencing a prohibition

application. If it is determined that an innovator was not justified in causing the mandatory injunction to be imposed, the innovator must compensate the generic drug producer.

[12] The damages contemplated by section 8 are intended to be analogous to the undertaking a party is normally required to offer when seeking an interlocutory injunction in ordinary commercial litigation. An interlocutory injunction is an extraordinary remedy because it imposes a potentially onerous burden on a party before any wrong is proved. For that reason, an undertaking in damages is normally broad enough to cover all losses resulting from the injunction, in the event it is determined that the injunction should never have been imposed.

[13] In my view, section 8 of the *Regulations* was intended to be similarly broad, and should be so interpreted. Nothing within section 8 or in the Regulatory Impact Analysis Statements discloses an intention on the part of the Governor in Council to impose an artificial limitation on the normal method of computing damages that would result from the analogous situation of an interlocutory injunction imposed without justification.

[14] Thus, it is arguable that the losses Teva has been barred from claiming are within the scope of the phrase “loss suffered during the period”, in the context of section 8 of the *Regulations*. I am not persuaded that the narrow interpretation of section 8 adopted in *Merck*, which turns on a literal interpretation of the word “suffered”, is correct, or that *Miller* should preclude this Court from permitting the interpretation of section 8 adopted in *Merck* to be reconsidered in the context of Teva’s claim.

[15] I express no opinion on whether the facts of this case are distinguishable from the facts in *Merck*.

[16] For these reasons, I would have allowed this appeal and made an order permitting Teva to amend its pleadings accordingly.

"K. Sharlow"

J.A.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-473-10
STYLE OF CAUSE:	TEVA CANADA LIMITED v. SANOFI-AVENTIS CANADA INC., and SANOFI-AVENTIS DEUTSCHLAND GmbH
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DISSENTING REASONS BY:	SHARLOW J.A.
DATED:	May 2, 2011

APPEARANCES:

Mr. Jonathan Stainsby Mr. Mark Edward Davis	FOR THE APPELLANT
Mr. J. Sheldon Hamilton Mr. Andrew E. Mandlsohn	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Heenan Blaikie LLP Lawyers Toronto, Ontario	FOR THE APPELLANT
Smart & Biggar Barristers & Solicitors Toronto, Ontario	FOR THE RESPONDENTS