Federal Court of Appeal  Cour d'appel fédérale

Date: 20140314

Dockets: A-192-12

Citation: 2014 FCA 69

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

BETWEEN:

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

Appellants

and

TEVA CANADA LIMITED

Respondent

Heard at Toronto, Ontario, on October 16 and 17, 2013.

Judgment delivered at Ottawa, Ontario, on March 14, 2014.

REASONS FOR JUDGMENT BY: MAINVILLE J.A.

CONCURRED IN BY: SHARLOW J.A.
DAWSON J.A.

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REASONS FOR JUDGMENT

MAINVILLE J.A.

[1] These reasons concern an appeal brought by Sanofi-Aventis Canada Inc. and Sanofi-Aventis Deutschland GmbH ("Sanofi") from a judgment of Snider J. of the Federal Court ("Trial Judge") dated May 11, 2012 and issued for reasons whose neutral citation is 2012 FC 551 and publicly released on May 23, 2012 (the "Validity Judgment") which dismissed Sanofis's submissions with respect to the validity, applicability or operability of section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*NOC Regulations*").

[2] The Trial Judge issued another judgment concurrently with the Validity Judgment, the reasons for which are cited as 2012 FC 552 (the "*Teva Liability Judgment (FC)*"). That judgment ordered Sanofi to compensate Teva pursuant to section 8 of the *NOC Regulations* for its net lost profits with respect to capsules of Teva-ramipril during the period commencing December 13, 2005 and ending April 27, 2007.

[3] In similar proceedings involving Sanofi and Apotex Inc. ("Apotex") the Trial Judge also issued on the same day a judgment, the reasons for which are cited as 2012 FC 553 (the "*Apotex Liability Judgment (FC)*"), which also ordered Sanofi to compensate Apotex pursuant to section 8 of the *NOC Regulations* for its net lost profits in respect to capsules of Apo-ramipril during the period commencing April 26, 2004 and ending December 12, 2006.

[4] The *Teva Liability Judgment (FC)* and the *Apotex Liability Judgment (FC)* have been appealed to our Court. These appeals have resulted in judgments issued concurrently with these reasons and cited as 2014 FCA 67 (the "*Teva Liabily Judgment (FCA)*") and 2014 FCA 68 (the "*Apotex Liability Judgment (FCA)*").

General Background

[5] For the purposes of this appeal, it is sufficient to note that Teva and Apotex sell generic versions of ramipril in Canada. Ramipril is a drug mainly used to treat hypertension but also has other medical uses. Sanofi asserts patent rights to this drug and to some of its uses. It has for many years held a patent monopoly over this drug which it sold in Canada under the brand name ALTACE.

[6] To market a drug in Canada, a regulatory approval known as a notice of compliance ("NOC") must first be obtained under the terms of the *Food and Drug Regulations*, C.R.C., c. 870. Teva and Apotex could have received their NOCs earlier from the Minister of Health to market their generic versions of ramipril in Canada. However, they were delayed as a result of Sanofi applying for various orders under subsection 6(1) of the *NOC Regulations*, thus prohibiting the Minister from issuing the NOCs on the ground of its alleged patent rights.

[7] By virtue of section 8 of the *NOC Regulations*, the dismissal of Sanofi's applications under subsection 6(1) gave Teva and Apotex the right to assert claims against Sanofi for losses suffered for the delay as determined in accordance with the *NOC Regulations*. Teva and Apotex both took the view that they were entitled to such compensation and, after long trials, the Trial Judge agreed. Except with respect to some issues, our Court has largely confirmed the Trial Judge's decisions ordering Sanofi to compensate both Teva and Apotex.

[8] In the proceedings before the Federal Court involving both Teva and Apotex, Sanofi challenged the validity of section 8 of the *NOC Regulations*. The validity issues were essentially identical to those raised in another Federal Court case (*Apotex Inc. v. AstraZeneca Canada Inc.* Federal Court file T-2300-05), heard by Hughes J. With the agreement of all parties involved, the validity issues were argued simultaneously before both the Trial Judge and Hughes J., leading to the Validity Judgment by the Trial Judge and to a separate judgment by Hughes J. in which the validity issues were dealt with.

[9] Hughes J. rendered his decision in *Apotex Inc. v. AstraZeneca Canada Inc.*, 2012 FC 559, 410 F.T.R. 168 rejecting all challenges to the validity of the *NOC Regulations*. He relied notably on *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187, 76 C.P.R. (4th) 1 ("*Alendronate*"). The judgment of Hughes J. was appealed on a number of grounds, but not on the question of the validity of the *NOC Regulations*. The appeal was dismissed on March 11, 2013 (2013 FCA 77).

Reasons of the Trial Judge

[10] In light of the limited issue raised by Sanofi in this appeal, it is not necessary to summarize in any great detail the reasons of the Trial Judge. It suffices to note that the validity issues raised by Sanofi were a moving target in the Federal Court, with claims of constitutional invalidity being raised and later abandoned, and numerous other claims being either abandoned, modified or unsuccessfully pursued by this litigant.

[11] The Trial Judge found that she need not address Sanofi's submissions involving the validity issues with respect to (a) the start and end dates of the liability period under section 8 of the *NOC Regulations* (Reasons at paras. 32, 33 and 41), (b) competition and causation (Reasons at paras. 44 and 45), and (c) patent infringement (Reasons at para. 49).

[12] With respect to Sanofi's claims concerning the inconsistency of section 8 of the *NOC Regulations* with the *Agreement on Trade-Related Aspects of Intellectual Property Rights* and the *North American Free Trade Agreement*, the Trial Judge essentially relied on paragraphs 102 to 119 of the reasons of Hughes J. in *Apotex Inc. v. AstraZeneca Canada Inc.*, cited above: Trial Judge's Reasons at paras. 53 to 55.

[13] Finally, with respect to Sanofi's claims concerning the invalidity of the recovery of compensation under section 8 of the *NOC Regulations* for so-called "unapproved" indications, the Trial Judge found that Sanofi's submissions were not supported by a proper factual record: Trial Judge's Reasons at para. 47.

The Issue in Appeal

[14] Sanofi appeals to this Court solely on the question of whether section 8 of the *NOC Regulations* can validly allow compensation to be paid to a generic drug manufacturer for lost sales attributable to so-called "unapproved" indications, such as the HOPE indications referred to below.

Analysis

[15] Ramipril is a drug that is mainly used to treat hypertension, but whose medical use has expanded over the years to include heart related health issues following a "Heart Outcomes Prevention Evaluation" ("HOPE") study published in the year 2000 which found that "[t]reatment with ramipril reduced the rates of death, myocardial infarction, stroke, coronary revascularization, cardiac arrest, and heart failure as well as the risk of complications related to diabetes and of diabetes itself": HOPE study at p. 150 as cited in the *Teva Liability Judgment (FC)* at para. 307 and in the *Apotex Liability Judgment (FC)* at para. 277. The term "HOPE indications" has come to be associated with the patient profiles from the HOPE study where vascular protection was demonstrated: *Ibid*.

[16] The initial Canadian patent for ramipril was Patent No. 1,187,087 issued May 14, 1985 and which expired May 14, 2002, after 17 years of patent monopoly as the *Patent Act*, R.S.C. 1985, c.

P-4 then provided. With the pending expiration of this initial patent, many generic drug manufacturers, including Teva and Apotex, became interested in marketing their own generic versions of ramipril. The Trial Judge found that "Sanofi, in efforts to extend patent protection for ramipril, proceeded to obtain a further series of patents and protect those patents through listing on the Patent Register": *Teva Liability Judgment (FC)* at para. 30 and *Apotex Liability Judgment (FC)* at para. 26. Sanofi described these efforts as "Altace Lifecycle Management", while the generic manufacturers referred to these efforts as "evergreening": *Ibid*. A considerable amount of litigation under the *NOC Regulations* ensued with respect to these subsequent patents.

[17] Two of these patents are of particular relevance for the purposes of this appeal: Canadian Patent number 2,382,549 (the '549 Patent) issued March 15, 2005 concerning the use of ramipril in the prevention of cardiovascular events, and Canadian Patent number 2,382,387 (the '387 Patent) concerning the use of ramipril in the prevention of stroke, diabetes and congestive heart failure. The '549 Patent and the '387 Patent are referred to as the HOPE patents, and both these patents were registered by Sanofi on the patent list maintained under the *NOC Regulations* with respect to ramipril.

[18] The Trial Judge found that, in the hypothetical markets she constructed to determine the compensation owed respectively to Teva and Apotex under section 8 of the *NOC Regulations*, both Teva and Apotex would not have included in their product monographs for their respective generic versions of ramipril reference to anything other than hypertension, but that nevertheless, some sales of those generic drugs would have related to HOPE indications: *Teva Liability Judgment (FC)* at paras. 302 and 310 and *Apotex Liability Judgment (FC)* at paras. 280 and 281.

[19] The Trial Judge refused to discard these sales from the calculation of Teva's and Apotex's section 8 compensation on the grounds that (a) generic products are not promoted for specific uses, but rather sold as drug products; (b) off-label prescribing and substitution commonly take place and there appears to be nothing illegal about this practice; (c) in the real market, Sanofi has not opposed the listing of Teva's or Apotex's generic version of ramipril as fully interchangeable with its own product ALTACE; and (d) the fact that Sanofi could have commenced an action for patent infringement with respect to the HOPE patents but had not done so: *Teva Liability Judgment (FC)* at para. 312 and *Apotex Liability Judgment (FC)* at para. 283.

[20] The Trial Judge concluded that in each of the hypothetical markets, Teva and Apotex would have been able to make sales for HOPE indications during the relevant periods without any serious objection from Sanofi, and that consequently Teva's and Apotex's losses with respect to such sales should be taken into account in determining the compensation owed to them under section 8 of the *NOC Regulations*: *Teva Liability Judgment (FC)* at paras. 319 to 322 and *Apotex Liability Judgment (FC)* at paras. 292 and 293.

[21] The Trial Judge however added that a generic drug manufacturer may not always recover monetary compensation for unapproved indications, noting that another section 8 claim could provide a clear defence in the pleadings and a different set of facts that would warrant, pursuant to subsection 8(5) of the *NOC Regulations*, a different finding or a downward adjustment to the generic drug manufacturer's compensation: *Teva Liability Judgment (FC)* at para. 322 and *Apotex Liability Judgment (FC)* at para. 295.

[22] These conclusions were confirmed by this Court in both the *Teva Liability Judgment (FCA)* and the *Apotex Liability Judgment (FCA)*, principally because, in the real market, Sanofi had taken no measure to enforce its HOPE patents. Consequently, if Sanofi is not enforcing its HOPE patents in the real market, and is allowing the sale of generic versions of ramipril for HOPE indications without any serious opposition, there is no reason to find that the situation would be different in the hypothetical markets involving Teva and Sanofi.

[23] Sanofi nevertheless submits that, as a matter of jurisdiction, section 8 of the *NOC Regulations* cannot allow compensation to be paid to generic drug manufacturers with respect to sales for unauthorized indications such as the HOPE indications. It refers to no authority to support its submission. Sanofi essentially argues that since section 6 of the *NOC Regulations* only gives an innovator drug manufacturer the right to apply for a prohibition order with respect to a listed patent where that patent is worked on by the generic drug manufacturer for the purposes of securing its NOC, the generic drug manufacturer's right to compensation under section 8 of the Regulations should therefore be limited to the lost sales arising from the uses identified in the patent which the generic drug manufacturer must deal with under the Regulations: Sanofi's Memorandum at para. 30.

[24] With respect, Sanofi's submission is a misguided attempt to transform a factual issue into a question of jurisdiction. Moreover, its position is completely at odds with the decision of this Court in *Alendronate* which confirmed the validity of the *NOC Regulations*.

[25] It is important to place Sanofi's submissions in context. Sanofi listed the HOPE patents on the patent list maintained with respect to ramipril under section 4 of the *NOC Regulations* with the clear objective of forcing generic drug manufacturers, such as Teva and Apotex, to deal as "second persons" with those patents under the machinery of those Regulations. Moreover, Sanofi availed itself of subsection 6(1) of the *NOC Regulations* to initiate prohibition proceedings involving both Teva and Apotex with respect to the HOPE patents, thus obtaining the benefit of the statutory stay provided under those Regulations.

[26] The purpose of section 8 of the *NOC Regulations* is precisely to ensure that when an innovator drug manufacturer reaps the benefits of those Regulations by initiating unfounded prohibition proceedings, the generic drug manufacturer can then seek appropriate compensation for having been impeded from entering the market earlier as a result of those proceedings.

[27] As found by the Trial Judge, compensation under section 8 of the *NOC Regulations* for sales related to unauthorized indications may be precluded if the facts so justify. However, in the case of Sanofi, the facts did not justify such preclusion for the reasons set out by the Trial Judge in the *Teva Liability Judgment (FC)* and in the *Apotex Liability Judgment (FC)* and referred to above.

[28] In the case of both Teva and Sanofi, the Trial Judge simply determined as a matter of fact that "any loss suffered during the period" as referred to in subsection 8(1) of the *NOC Regulations* (emphasis added), included the sales related to the HOPE indications. She reached that conclusion by "taking into account all matters that [the court] considers relevant to the assessment of the

amount" of compensation, as she was entitled to do under subsection. 8(5) of the *NOC Regulations* (emphasis added).

[29] In *Alendronate*, this Court found the *NOC Regulations* to be valid, including its subsections 8(1) and 8(5) on which the Trial Judge relied to reach her conclusions. In my view, *Alendronate* is a complete answer to Sanofi's validity submissions, once these submissions are placed in their proper context.

Conclusion

[30] I would therefore dismiss this appeal, with costs in favour of Teva.

"Robert M. Mainville"
J.A.

"I agree.
Karen Sharlow J.A."

"I agree.
Eleanor R. Dawson J.A."

FEDERAL COURT OF APPEAL
NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-192-12

(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED MAY 11, 2012, DOCKET NUMBER T-1161-07.)

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