Federal Court of Appeal | Cour d'appel fédérale

Date: 20111216

Dockets: A-172-11
A-173-11

Citation: 2011 FCA 358

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

A-172-11

BETWEEN:

APOTEX INC.

Appellant

and

ELI LILLY CANADA INC.

Respondent

A-173-11

BETWEEN:

APOTEX INC.

Appellant

and

NYCOMED CANADA INC. and
NYCOMED GmbH

Respondents

Heard at Toronto, Ontario, on December 12, 2011.

Judgment delivered at Ottawa, Ontario, on December 16, 2011.

REASONS FOR JUDGMENT BY:	NOËL J.A.
CONCURRED IN BY:	DAWSON J.A.
	TRUDEL J.A.

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REASONS FOR JUDGMENT

NOËL J.A.

[1] These are two appeals – heard together but not consolidated – involving Apotex Inc. as the appellant (Apotex or the appellant) which both raise the same issue, namely whether paragraphs claiming disgorgement profits in Apotex' statements of claim, pled in conjunction with others seeking damages pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (*PM(NOC) Regulations*), were properly struck by Prothonotaries Milczynski (A-173-11) and Tabib (A-172-11), as confirmed by Justice Heneghan of the Federal Court (the Federal Court judge) by decisions issued on April 18, 2011.

[2] The reasons which follow dispose of both appeals. The original will be filed in A-172-11 and a copy will be filed as reasons for judgment in A-173-11.

[3] The paragraphs which have been struck in each case are almost identical. They provide respectively:

> A-173-11
>
> 1. The Plaintiff, Apotex Inc. ("Apotex"), claims:
>
> …
>
> (b) disgorgement of the excess revenues realized by the Defendant by reason of the higher prices charged by it for its 20 mg and 40 mg pantoprazole tablets as a consequence of the delay in issuance to Apotex of its NOC as described in subparagraph (a);
>
> …

20. Furthermore, by reason of the delay in Apotex obtaining its NOC for 20 mg and 40 mg pantoprazole tablets, the Defendant was free from competition from Apotex for approximately 12 months.

21. Apotex states that, during this 12-month period, the Defendant generated revenue from sales which it would not otherwise have made.

22. Apotex states that the Defendant, by reason of its wrongful invocation of the *Patent Regulations*, will generate a windfall even if it is compelled to compensate Apotex for its damages flowing from its exclusion in the market. This windfall arises from the higher price charged by the Defendant for its 20 mg and 40 mg pantoprazole tablets over the price which would have been charged by Apotex for its 20 mg and 40 mg pantoprazole tablets.

23. There is no juristic reason for the Defendant to retain this windfall, namely, the excess revenues generated from sales made at a higher price than the price Apotex would have charged.

24. The Defendant thus has no entitlement to such excess revenues.

25. In the absence of a disgorgement of this unjust enrichment, every patentee would have an incentive to use the *Patent Regulations* in all cases to unjustly delay entry of every generic product at the expense of the Generic, in the knowledge that the revenues made by it would exceed the damages for which it will be liable for the delay caused to the Generic.

A-172-11

1. The Plaintiff, Apotex Inc. (“Apotex”), claims:

…

(b) disgorgement of the excess revenues realized by the Defendant by reason of the higher prices charged by it for its raloxifene tablets as a consequence of the delay in issuance to Apotex of its NOC as described in subparagraph (a);

…

22. Furthermore, by reason of the delay in Apotex obtaining its NOC for Apo-Raloxifene tablets, the Defendant was free from competition from Apotex for approximately 36 months.

23. Apotex states that, during this 36-month period, the Defendant generated revenue from sales which it would not otherwise have made.

> 24. Apotex states that the Defendant, by reason of its wrongful invocation of the *Patent Regulations*, will generate a windfall even if it is compelled to compensate Apotex for its damages flowing from its exclusion in the market. The windfall arises from the higher price charged by the Defendant for its raloxifene tablets over the price which would have been charged by Apotex for Apo-Raloxifene tablets.
>
> 25. There is no juristic reason for the Defendant to retain this windfall, namely, the excess revenues generated from sales made at a higher price than the price Apotex would have charged.
>
> 26. The Defendant thus has no entitlement to such excess revenues.
>
> 27. In the absence of a disgorgement of this unjust enrichment, every patentee would have an incentive to use the *Patent Regulations* in all cases to unjustly delay entry of every generic product at the expense of the Generic, in the knowledge that the revenues made by it would exceed the damages for which it will be liable for the delay caused to the Generic.
>
> 28. Apotex pleads and relies upon subsection 20(2) of the *Federal Courts Act*.

[4] This last plea did not form part of the statement of claim as originally filed in A-173-11. Apotex' motion to add this plea to its statement of claim in that docket was heard at the same time as the motion to strike. Prothonotary Milczynski allowed the motion to strike in its entirety, and denied leave to plead subsection 20(2) of the *Federal Courts Act*, R.S.C. 1985, c. F-7 (the *Federal Courts Act*).

[5] In docket A-172-11, Prothonotary Tabib also ordered that the above quoted paragraphs be struck in their entirety, including paragraph 28, which pled subsection 20(2) of the *Federal Courts Act*.

[6] The appeals from these decisions were heard by the Federal Court judge who dismissed them both for distinct reasons issued on the same day.

[7] In its memoranda, the appellant provides a fair description of the decisions below which I have taken the liberty to reproduce (citations omitted):

> A-172-11
>
> **The decision of Prothonotary Tabib**
>
> 10. […] The operative part of the decision of Prothonotary Tabib for present purposes reads as follows:
>
> > Counsel for Apotex further argues that even if remedies for unjust enrichment were unavailable pursuant to the restricted interpretation of section 8 of the *Regulations*, it is still not plain and obvious that an independent claim for unjust enrichment could not be asserted by Apotex against Lilly outside the scope of section 8. I disagree. What Apotex would then be asserting is a cause of action entirely based on unjust enrichment arising from the unjustified commencement and prosecution by Lilly of proceedings under the *Regulations*. The fatal flaw in Apotex' argument is that a cause of action between private parties based on unjustified enrichment or abuse of process is simply outside the jurisdiction of this Court. Outside the statutory scheme provided by the *Regulations*, there is simply no body of Federal law creating a cause of action for unjust enrichment or abuse of process between private parties.
>
> **The decision of Justice Heneghan**
>
> 11. [The Federal Court judge] dismissed Apotex's appeal from the order of Prothonotary Tabib, on the basis that there was no statutory grant of jurisdiction to

award equitable remedies in this case. She found that the cause of action arises from section 8 of the *Regulations* alone, and that this Honourable Court's decision in … *Apotex Inc. v. Merck & Co. Inc.*, (2009), 76 C.P.R. (4th) 1, lv to app ref'd, [2009] S.C.C.A. No. 347 (S.C.C.) [(*Merck F.C.A.*)], makes it "plain and obvious" that section 8 does not include a claim for unjust enrichment.

A-173-11

The decision of Prothonotary Milczynski

10. … The operative part of [Prothonotary Milczynski's decision] reads as follows:

> … Apotex conceded … that it can no longer advance a claim in unjust enrichment under section 8(4) of the *Regulations*. Apotex does not take a different position … but seeks leave to file an amended statement of claim that leaves the wording of the current pleading unchanged and intact, except for adding the following paragraph at the end:
>
> > 26. Apotex pleads and relies upon subsection 20(2) of the *Federal Courts Act.*
>
> …
>
> The difficulty for Apotex is that the insertion of this plea does not change the nature of its claim. Paragraph 1(b) of the statement of claim still refers to disgorgement of profits pursuant to, and for actions exclusively arising out of the *PM(NOC) Regulations* . Paragraph 25 alleges that "in the absence of disgorgement of profits, every patentee in all cases unjustly delay the entry of every generic product". Counsel for Apotex further confirmed for the Court at the hearing of the motion that Apotex does not rely on and will not plead any additional material facts in support of its claim for disgorgement of profits on the grounds that Nycomed was unjustly enriched. Apotex relies exclusively on the fact that Nycomed commenced an application for an order of prohibition

> under the *Regulations* and that that act alone caused the deprivation suffered by Apotex (the delay in the issuance of the NOC to Apotex) for which there is no juridical reason. While Apotex argues that it is relying on section 20 of the *Federal Courts Act* for its claim in equity, the claim for disgorgement is still tied to the *Regulations*, and there is no other basis for Apotex to claim that remedy.
>
> In this respect, the present case may be distinguished from the decision of Justice Kelen in *Apotex Inc. v. AstraZeneca Canada Inc.*, 2009 FC 120, where the Court allowed a claim against the Minister of Health to proceed where Apotex had commenced a section 8 claim, notwithstanding the clear statement in subsection 8(6) of the *PM(NOC) Regulations* that the Minister is not liable for any damages under section 8. Justice Kelen upheld the decision of Prothonotary Aronovitch who found that the claim against the Minister was based in negligence – not the *Regulations.*
>
> Accordingly, I am satisfied that it is plain and obvious and without doubt that Apotex cannot succeed with its claim for disgorgement of profits in the manner it was pleaded originally or in the manner proposed in its draft amended statement of claim. The claim is still tied to the *Regulations* and there is no other basis to claim the remedy. …

The decision of Justice Heneghan

11. [The Federal Court judge] dismissed Apotex's appeal from the order of Prothonotary Milczynski striking its unjust enrichment claim. She decided that the decision of this Honourable Court in … [*Merck F.C.A.*], endorsing the interpretation of section 8 as decided by the trial judge in that case [*Apotex Inc. v. Merck & Co. Inc.*, 2008 FC 1185 (*Merck F.C.*)], "makes it plain and obvious that section 8 does not include a claim for unjust enrichment, or provide this Court with the jurisdiction to grant the equitable remedy of disgorgement as a remedy on section 8 claims".

12. Justice Heneghan also found that the Prothonotary had correctly refused leave to amend, as Apotex was "trying to advance a claim of unjust enrichment in

> the context of a section 8 claim under the *Regulations*, a cause of action that does not lie within the jurisdiction of the Federal Court".
>
> 13. Finally, the motion judge concluded that, since there is no statutory grant of jurisdiction to award equitable remedies in this case, Apotex could not bring a claim for unjust enrichment independent of section 8 of the *Regulations*. This cause of action arose squarely from the Regulations, hence the only issue was whether a section 8 claim included a claim for unjust enrichment and, for the reasons previously stated, it was plain and obvious that it did not.

POSITION OF THE PARTIES

[8] Although the reasons for striking out the pleadings in A-173-11 and A-172-11 are not exactly the same, the arguments advanced by Apotex in support of the two appeals are identical.

[9] Apotex recognizes that section 8 of the *PM(NOC) Regulations* does not entitle it to any remedy other than damages computed in the manner set out in that provision. However, it contends that unjust enrichment is a different cause of action, independent of section 8, and that it is entitled to the disgorgement of the respondents' profits as a remedy which flows from this independent cause of action.

[10] Apotex acknowledges that the decision of this Court in *Merck F.C.A.* on which the Federal Court judge relied has determined the scope of the damages available to second persons under section 8, but says that this decision is silent on whether disgorgement of profits may be obtained by independent action.

[11] Keeping in mind the stringent test applicable on a motion to strike, Apotex submits that it is not plain and obvious that its claim is doomed to fail, or does not exhibit a "scintilla of success" (*Apotex v. Wellcome Foundation Ltd. (1996)*, 113 F.T.R. 241). In this respect, Apotex relies on the decisions of the Ontario Superior Court (Divisional Court) in *Apotex Inc. v. Abbott Laboratories Limited et al.*, 2010 ONSC 6909. (2010), 89 C.P.R. (4th) 141 and *Apotex Inc. v. Laboratoires Fournier S.A. et al.*, 2010 ONSC 6947, where attempts to strike claims for unjust enrichment in the context of a claim pursuant to section 8 of the *PM(NOC) Regulations* were dismissed.

[12] Apotex submits that the Prothonotaries and the Federal Court judge proceeded on wrong principle when they held that the outcome of its claim for unjust enrichment was clear and beyond doubt and struck the paragraphs asserting this claim.

[13] The respondents for their part submit that the Federal Court judge correctly dismissed the appeals, and essentially stand by the reasons given by the Federal Court judge and the Prothonotaries.

ANALYSIS AND DECISION

[14] There is no dispute as to the standard of review. Although a decision on a motion to strike is discretionary, it may be reversed on appeal if, as alleged, it is based on an error of law or principle (*Domtar Inc. v. Canada*, 2009 FCA 218).

[15] Before turning to the alleged errors, it is useful to first identify the precise claims advanced by the two statements of claims and the material facts advanced in support of these claims. A good starting point is the prayer for relief which in each seeks:

> a) damages suffered by Apotex in respect of the delay in issuance to Apotex of a Notice of Compliance (NOC) for [the relevant] tablets by reason of the [*PM(NOC) Regulations*];
>
> b) disgorgement of the excess revenues realized by the Defendant by reasons of the higher prices charged by it for its [relevant] tablets as a consequence of the delay in issuance to Apotex of this NOC as described in subparagraph (*a*)*;*
>
> [My emphasis]

[16] Paragraphs 22 of the statement of claim in A-173-11 and 24 of the statement of claim in A-172-11, each allege that "… the defendant by reason of its wrongful invocation of the *Patent Regulations*, will generate a windfall …" to which it is not entitled [my emphasis]. The only material fact advanced in support of the characterization of the defendant's conduct as "wrongful" is that the prohibition proceedings initiated by the respondents were eventually dismissed (para. 16 in file A-173-11 and paras. 16 to 18 in file A-172-11) with the result that the issuance of the relevant Notices of Compliance to Apotex were delayed by reason of the regulatory stay which operates in favour of the respondents (paras. 18 and 20 to 25 in file A-173-11; paras. 20 and 22 to 27 in file A-172-11). These are the requirements which underlie a first person's liability under section 8 and indeed the identical allegation is made in support of the claim for damages under that provision (paras. 18 and 19 in file A-173-11; paras. 20 and 21 in file A-172-11). Significantly, no other "wrongful" act is alleged to have been committed (compare *Apotex Inc. v. Laboratoires Fournier*

S.A., [2006] O.J. No. 4555, 54 C.P.R. (4th) 241 (O.H.C.J.) at para. 25 where the constituent elements of the tort of abuse of process as set out in *R. Cholkan & Co. v. Brinker* (H.C.J.), [1990] O.J. No. 1, 71 O.R. (2d) 381 as well as conspiracy to commit this tort were also alleged).

[17] It follows that as found by Prothonotary Milczynski in the above quoted passage (para. 7 above), while Apotex relies on the Federal Court's jurisdiction to provide equitable relief under subsection 20(2) of the *Federal Courts Act* for its claim for disgorgement of profits, this claim is tied to the *PM(NOC) Regulations* since entitlement is said to flow from the fact that the prohibition proceedings initiated by the respondents were ultimately dismissed, as contemplated by section 8, and nothing more. Given this, the question which arises is whether Apotex can have any hope of successfully invoking subsection 20(2) of the *Federal Courts Act* to obtain the additional remedy which it seeks.

[18] In my respectful view, the answer to this question is no. Parliament, through the delegated authority of the Governor-in-Council, has considered the question whether a remedy should be available to second persons in the circumstances alleged by the statements of claim and the extent of that remedy. It did so in an attempt to strike a balance between the need for patent protection on the one hand and the timely entry of lower priced drugs on the market, on the other. Section 8 fits within this compromise (see *Merck F.C.A.* at paras. 45 to 61; *Bristol Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 at paras. 6 to 12, 45, 46 and 50; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 at paras. 12 to 23).

[19] Compromises by their nature fall short of fully responding to the competing interests at stake with the result that no one was happy with section 8. Innovative companies did not believe that they ought to be visited with damages for simply availing themselves of the procedure devised by Parliament to ensure patent protection (*Merck F.C.A.* at para. 51). Generic companies argued, as Apotex does here, that the balance struck did not provide a sufficient disincentive to first persons when regard is had to the negative impact which the "automatic stay" has on the access to cheaper drugs.

[20] Prior to the 2006 amendment, section 8 was ambiguous as it provided for an entitlement to "damages or profits". However, the reference to "profits" was eventually determined to refer to a second person's lost profits rather than to profits earned by the first person during the regulatory stay period (see *Merck F.C.* at para. 97 as confirmed by *Merck F.C.A.* on this point at paras. 88 to 91).

[21] Any doubt in this regard was removed by the 2006 amendment which deleted the reference to the word "profits" in section 8. The Regulatory Impact Analysis Statement (RIAS) which accompanied this amendment explained the change as follows:

> The Government is aware of a number of ongoing section 8 cases in which it is argued that in order for this provision to operate as a disincentive to improper use of the *PM(NOC) Regulations* by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovator's profits …

After referring to the introduction of related measures, the RIAS concluded:

> … The Government believes that this line of argument should no longer be open to generic companies that invoke section 8.
>
> [My emphasis]

[22] When regard is had to this amendment, and the decision of this Court in *Merck F.C.A.*, the matter could not be any clearer. Parliament, through the auspices of the Governor-in-Council, has considered whether generic companies should be entitled to the disgorgement of first persons' profits in the circumstances contemplated by section 8, and has excluded this remedy. It did so in the context of the above-noted balance which is sought to be achieved by the *PM(NOC) Regulations*. This is a legislative policy issue with respect to which the will of Parliament is paramount.

[23] It follows that whatever jurisdiction the Federal Court has under subsection 20(2) of the *Federal Courts Act* to provide equitable relief, it cannot be used to grant a remedy which section 8 was intended to exclude (compare *Radio Corp. of America v. Philco Corp. (Delaware)* (1966), 48 C.P.R. 128 at 136 (SCC); see also *Zaidan Group Ltd. v. London (City)* (1990), 71 O.R. (2d) 65 at 69 (C.A.), aff'd [1991] 3 S.C.R. 593), unless a cause of action independent of the operation of section 8 is alleged. Here, no such cause of action has been pled. The result is that Apotex' claim for disgorgement of profits cannot possibly succeed.

[24] Counsel for Apotex did not place before us the statements of claim which are the subject matter of the two decisions of the Ontario Superior Court (Divisional Court) on which he relies (see para. 11 above). It is therefore difficult to comment on these decisions. However, if as here, Apotex

claimed to be entitled to the disgorgement of the first persons' profits simply because the prohibition applications which it initiated were ultimately dismissed as contemplated by section 8, I respectfully disagree with the conclusion reached in these cases.

[25] This suffices to dispose of the appeals, which I would dismiss with costs, in each case.

"Marc Noël"
J.A.

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

"I agree.
Johanne Trudel J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-172-11
APPEAL FROM AN ENDORSEMENT AND ORDER OF THE HONOURABLE MADAM JUSTICE HENEGHAN DATED APRIL 18, 2011, DOCKET NO. T-656-09.	
STYLE OF CAUSE:	APOTEX INC. and ELI LILLY CANADA INC.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	December 12, 2011
REASONS FOR JUDGMENT BY:	Noël J.A.
CONCURRED IN BY:	Dawson J.A. Trudel J.A.
DATED:	December 16, 2011

APPEARANCES:

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FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-173-11

APPEAL FROM AN ENDORSEMENT AND ORDER OF THE HONOURABLE MADAM JUSTICE HENEGHAN DATED APRIL 18, 2011, DOCKET NO. T-1786-08.

STYLE OF CAUSE:	APOTEX INC. and NYCOMED CANADA INC. and NYCOMED GmbH
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	December 12, 2011
REASONS FOR JUDGMENT BY:	Noël J.A.
CONCURRED IN BY:	Dawson J.A. Trudel J.A.
DATED:	December 16, 2011

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