Federal Court  Cour fédérale

Date: 20100212

Docket: T-1161-07

Citation: 2010 FC 150

Toronto, Ontario, February 12, 2010

PRESENT: Madam Prothonotary Milczynski

BETWEEN:

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

Plaintiffs

and

NOVOPHARM LIMITED

Defendant

AND BETWEEN:

NOVOPHARM LIMITED

Plaintiff by Counterclaim

and

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

Defendants by Counterclaim

REASONS FOR ORDER AND ORDER

[1] The Defendants, Sanofi-Aventis Canada Inc. ("Sanofi Canada") and Sanofi-Aventis Deutschland GmbH ("Sanofi Germany") have brought this motion for an Order:

a) striking the following paragraphs, or portions thereof, from the Third Amended Statement of Defence and Counterclaim of Novopharm Limited ("Novopharm"):

   (i) Paragraphs 76(h) and 138-140 (disgorgement of profits claim):

   (ii) Paragraph 143A and the phrases "and by Sanofi Germany" and "and Sanofi Germany" in paragraph 143B (Sanofi Germany claim); and

   (iii) The phrase "and a permanent loss of market share" in paragraph 135, and paragraphs 136 and 143 (Permanent Loss of Market Share claim).

b) directing that Novopharm amend its pleading to remove the claim related to the recovery of costs incurred during the proceedings under the *Regulations* or, alternatively, an Order striking the phrase "and expenses incurred in defending the proceedings in Court File Nos. T-1965-05 and T-1979-05 and Appeals there from to the extent not recovered in those proceeding" in paragraph 76(g) ("costs claim");

c) directing that Novopharm amend its pleading to remove the claim related to the 1.25 mg capsule, or alternatively, an Order striking the phrase "and August 2, 2006 in the case of Novo-Ramipril 1.25 mg capsules" in paragraph 76(g), and paragraph 133 ("1.25 mg capsule claim"); and

d) dismissing the action against Sanofi Germany.

[2] The Defendant by Counterclaim Schering Corporation ("Schering"), has also brought a motion, for an Order:

(a) Striking out paragraphs 76-144 of Novopharm's Third Amended Counterclaim as against Schering, and in particular, an Order removing "Schering Corporation" from the style of cause and the references to Schering in paragraphs 76(g), 76(h), and 138-143B; and

(b) Dismissing the Counterclaim against Schering;

Background

[3] This present proceeding was commenced as an action for patent infringement by Sanofi Canada, Sanofi Germany and Schering, against Novopharm Limited in respect of Novopharm's alleged infringement of Canadian Patent 1,341,206 (the "206 Patent") and the sale of its Novo-ramipril product. The 206 Patent, owned by Schering, claims the compound ramipril. Sanofi Canada sells a ramipril product in Canada, under licence, under the brand name ALTACE.

[4] In response to the Statement of Claim, Novopharm counterclaimed for, among other things, an order pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* ("*Regulations*"), requiring the Defendants by Counterclaim, to compensate Novopharm for losses suffered and/or an order for disgorgement of profits generated by the sale of ramipril during the period of time Novopharm was not in receipt of a Notice of Compliance ("NOC") due to proceedings that had been commenced under section 6 of the *Regulations*.

[5] The trial of Novopharm's section 8 counterclaim was held in abeyance pending the trial in the main action and a decision on infringement and the validity of the 206 Patent. On June 29, 2009, Justice Snider dismissed the Plaintiffs' claims and declared claims 1, 2, 3, 6 and 12 of the 206 Patent invalid. Accordingly, Novopharm's counterclaim is now proceeding.

[6] At the hearing of this motion on October 19, 2009, Novopharm advised that it has discontinued its claim for disgorgement of profits as set out in paragraphs 76(h) and 138-140 of its counterclaim, and is also seeking leave to amend the counterclaim to remove the costs claim as set out in paragraph 76(h) of the current pleading and to remove the counterclaims as they relate to the Novo-ramipril 1.25mg capsules as set out in paragraphs 76(g) and 133 of the current pleading. Novopharm is continuing to seek to recover its damages pursuant to section 8 of the *Regulations* from Sanofi Canada, Sanofi Germany and Schering.

[7] Novopharm's section 8 claim is brought in respect of several patents listed on the Patent Register pursuant to the *Regulations* and corresponding proceedings for orders of prohibition commenced by Sanofi Canada. Novopharm claims it was delayed in receiving its NOC for its Novo-ramipril product because it was required to address the listed patents and respond to the two prohibition proceedings: T-1965-05 and T-1979-05 that were commenced by Sanofi-Canada in response to the Notices of Allegations delivered by Novopharm, as required by the *Regulations*.

[8] Schering was not a party in Court File T-1979-05 – the patents involved, Canadian Patent Nos. 2,023,089; 2,055,948; 2,382,387 and 2,382,549 were listed on the Patent Register by Sanofi Canada. In Court File T-1965-05, the 206 Patent was the patent at issue. Sanofi Germany was not a party; as the owner of the 206 Patent, Schering was a required party pursuant to section 6(4) of the *Regulations*.

[9] The application in T-1965-05 was commenced on October 31, 2005 and was dismissed by the Federal Court on September 26, 2006 (as upheld by the Federal Court of Appeal). The application in T-1979-05 was commenced on November 2, 2005 and was dismissed by the Federal Court on April 27, 2007. Novopharm received its NOC for its Novo-ramipril product on May 2, 2007.

Are Sanofi Germany and Schering Proper Parties to the Section 8 Claim?

[10] Section 8 of the *Regulations* creates a statutory cause of action whereby liability for damages may be found in circumstances where an application for an order prohibiting the Minister of Health from issuing a NOC is withdrawn, discontinued or dismissed. Section 8 provides that this liability for damages is that of a "first person", and states that prospect in the following terms:

> 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
>
> (c) 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 concludes that
>
> (i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chretien Pledge to Africa)*, chapter 23 of the Satutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or
>
> (ii) a date other than the certified date is more appropriate; and
>
> (d) ending on the date of the withdrawal, the discontinuance, the dismissal or reversal.
>
> (2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).
>
> (3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.
>
> (4) If a court orders a first person to compensate a second person under subsection (1), the court may, in respect of any loss referred to in that subsection, make any order for relief by way of damages that the circumstances require.
>
> (5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).
>
> (6) The Minister is not liable for damages under this section.

[11] Accordingly, as set out in subsection 8(2) the right of action of the "second person" for damages is only as against the "first person". Section 2 of the *Regulations* defines the "first person" as the person referred to in subsection 4(1). Section 4(1) of the *Regulations* provides that a first person is the person who filed a new drug submission ("NDS"):

> 4(1) A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.

[12] Where a "second person", usually a generic drug manufacturer, seeks to make reference to that new drug submission for the purpose of obtaining expedited regulatory approval – an NOC for its product, the "second person" must, under section 5 of the *Regulations*, address any listed patent by way of a Notice of Allegation ("NOA") delivered to the "first person". The second person may, in the NOA, allege non-infringement and/or invalidity of the patent(s). The "first person" then has a right under section 6(1) of the *Regulations*, in respect of the NOA, to commence an application for judicial review to the Federal Court for an order prohibiting the Minster of Health from issuing the NOC to the second person on the basis that the allegations of non-infringement and/or invalidity in the NOA are not justified.

[13] It is the delay arising from the time required for the application(s) commenced by the first person to be determined, in the event the second person is successful in obtaining the NOC, that gives rise to a claim for damages under section 8 of the *Regulations*. Pursuant to subsection 6(1) of the *Regulations*, the right to commence the application for an order of prohibition is exclusively that of the "first person". If such application is commenced and the "first person" is not the owner of the patent, the owner of the patent must be made a party to the application pursuant to subsection 6(4) of the *Regulations*.

[14] It is therefore only by operation of, or under the scheme of the *Regulations* that (a) any right to claim damages by a second person arises; and (b) that any such claim can only be asserted by the second person as against the first person.

[15] In the within proceeding, Novopharm is seeking damages from the three named Defendants by Counterclaim alleging each, jointly and severally, are liable as the "first person" for the purposes of section 8 damages under the *Regulations*. Each of these Defendants submit that the matter of who is the "first person" is a straightforward exercise of statutory interpretation, and that there cannot be multiple first persons under the *Regulations* as they currently read. The Defendants submit that the first person is and can only be Sanofi Canada, and it is only Sanofi Canada that can be liable under the *Regulations* to pay section 8 damages to the second person, in this case Novopharm.

[16] Novopharm submits that the definition of "first person" under section 8 of the *Regulations* ought to be read purposively and does not preclude Novopharm's claim against either Schering or Sanofi Germany. In respect of Schering, Novopharms submits that:

(i) Schering knew of, authorized and directed steps taken by Sanofi Canada in the litigation under the *Regulations;*

(ii) Schering participated fully and actively in all proceedings under the *Regulations* – "aggressively" seeking to prevent Novopharm from obtaining its NOC for its Novo-ramipril product through its filing of affidavits, and making written and oral submissions;

(iii) Schering assisted in listing the 206 Patent on the Patent Register; and

(iv) Schering's involvement had a material impact on Novopharm, causing it damages, loss and harm.

[17] In respect of Sanofi Germany, Novopharm submits:

a. Sanofi Germany exercises complete control over the actions of Sanofi Canada and that all of Sanofi Canada's actions were directed, required or otherwise controlled by Sanofi Germany using Sanofi Canada as its "instrument";

b. Sanofi Germany participated fully and actively as a co-applicant in the proceedings under the *Regulations* – "actively" seeking to prevent Novopharm from obtaining its NOC for its Novo-ramipril product; and

c. Sanofi Germany benefited from the delay in Novopharm's market entry.

[18] The Third Amended Counterclaim pleads Novopharm's allegations as follows:

> 143A Novopharm states that Sanofi Germany exercises complete control over the actions of Sanofi Canada and states that the aforementioned actions were all directed, required or otherwise controlled by Sanofi Germany utilizing Sanofi Canada as its instrument. The actions of Sanofi Canada and Sanofi Germany were all part of a common enterprise carried out by Sanofi Canada pursuant to the direction and on behalf of Sanofi Germany. Accordingly, the actions of Sanofi Canada must in law and in equity be treated as the acts of Sanofi Germany which, therefore, is also liable to Novopharm.

[19] The same is not said of Schering:

> 143B Novopharm further states that all steps taken by Sanofi Canada and by Sanofi Germany were carried out with the

> knowledge, authority and directions of Schering, such as to make Schering liable for any unlawful actions committed by Sanofi Canada and Sanofi Germany.

[20] The issue on this motion then is whether it is "plain and obvious" that the interpretation of "first person" advanced by Novopharm is not available, and that it is certain that liability for section 8 damages can only attach to the person who filed the NDS and patent list.

[21] Novopharm submits that a broader interpretation of "first person" to include persons other than the person that filed the NDS and patent list is consistent with Justice Evans' reasons in *Apotex Inc. v. Eli Lilly and Company*, 2004 FCA 358, who at para. 14 stated:

> In my respectful opinion, therefore, the Motions Judge erred in law in the exercise of her discretion when she said that whether Lilly U.S. controlled Lilly Canada as alleged in Apotex' pleadings could not be relevant to whether Lilly U.S. was a "first person" because of the statutory nature of Apotex' cause of action. Whether, for the purpose of section 8, a "first person" includes the corporation who directed the submission of the patent list in the name of the subsidiary is a sufficiently difficult legal question to require a trial.

[22] The moving parties submit that this decision must be put in its proper context – that it was applicable when the potential for recovery of the first person's profits, as opposed to only the second person's damages was as yet undecided. It is in that scenario that might lead to a broader interpretation of the term "first person" or a need to include companies related to the first person to "follow the money". As it is now settled, however, that the recovery of a first person's profits is not available in an action under section 8 of the *Regulations*, (*Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. v. Apotex Inc.*, 2009 FCA 187, leave to SCC denied January 28, 2010), the

moving parties submit Sanofi Germany and Schering are no longer proper or necessary parties and that as against them, there is no cause of action.

[23] Justice Evans' comments, however, are not clearly and without doubt, restricted to the possible relevance of findings of agency and control solely for the purposes of following a money trail to determine profits. At paras. 11-13, Justice Evans noted:

> That common law concepts, such as agency, for example, are never relevant to the interpretation of legislation is a very broad proposition, for which no supporting authority was advanced. Indeed, it is clear from the cases relied upon by Apotex that, in some circumstances at least, whether a wholly owned subsidiary has acted, in effect, as the agent of its shareholder corporation may be relevant in determining the liability of the parent under a taxing statute…
>
> In my opinion, the assertions of complete corporate control in Apotex's pleadings go beyond asserting the kind of relationship between Lilly U.S. and Lilly Canada that inevitably exists between a corporation and its sole shareholder. It might emerge on discovery that the degree of control exercised by Lilly U.S. over Lilly Canada was such as to make Lilly U.S. a "first person".

[24] At paragraph 15 of his reasons, Justice Evans refers to the relevance of such inquiry and fact finding, <u>for example</u>, to the extent profits might be recoverable. At paragraph 16 of the reasons, he states to the effect that <u>if</u> notions of agency or control are relevant to determining whether someone other than the person filing the NDS and patent list is the "first person", findings of fact will be required that can only properly be made in the context of a trial in order to determine the degree of control exercised over the purported nominal first person.

[25] Novopharm raises reasons other than following the trail of profits to argue why such findings could be relevant and necessary so as to apply the purposive interpretation it urges to

include parent, related or other companies in the definition of "first person". For example, there may be issues of recovery and the ability to satisfy an award of damages. Business operations may be organized such that "first persons" may be only nominal entities with insufficient assets.

[26] Whether or not there are problems of nominal or first persons unable to satisfy an entire damage award in the within case is not the issue on this motion - the issue is whether there is any resolution of the proper interpretation of the *Regulations.* In that regard, and having regard to the Court of Appeal decision in *Lilly*, it is settled law that contentious issues of statutory interpretation or legal argument should not be dealt with on motions to strike pleadings, but rather should be left for determination at trial.

[27] Whether a "first person" under the *Regulations* may include persons other than the person who filed the NDS and patent list (or cannot include them without amendment to the *Regulations*) has not yet been fully canvassed at trial, and has yet to be finally determined. Thus, it is clear that this issue ought not to be decided on a motion to strike, where sufficient material facts have otherwise been pleaded to support the claim. Novopharm has done so in respect of Sanofi Germany. However, even if Novopharm's broader interpretation of "first person" is accepted, the allegations as against Schering fail to meet the requirement of pleading sufficient material facts that if proven, would enable a Court to make a finding that Sanofi Canada was an agent, acting as nominal first person, directed and controlled by Schering. Schering and Sanofi Canada are unrelated parties. Novopharm has not pleaded that Schering is a "first person" that exercises "complete control" over Sanofi Canada. I am satisfied that in any event of the disposition of the

first person issue, it is plain and obvious that Novopharm's claim for section 8 damages against Schering is clearly doomed to fail.

Permanent Loss of Market Share

[28] Novopharm concedes at paragraph 50 of its written representations that the allegations set out in paragraphs 135, 136 and 143 of the Third Amended Counterclaim relate to the future and permanent loss of market share and may not give rise directly to an award of damages. Yet Novopharm resists the motion to strike those paragraphs on the grounds that they clearly demonstrate the nature and the extent of the harm that has been caused to Novopharm, and that it is relevant to the Court's assessment of Novopharm's damages. However, whatever damages Novopharm may be entitled to shall be determined on the basis of the window of recovery provided by section 8 of the *Regulations* – those damages are restricted to compensation for the loss suffered during the period of operation of the automatic stay.

[29] Reference to permanent loss of market share and the alleged denial of an opportunity to enhance Novopharm's reputation affecting the introduction of new products in advance of competitors and sales of non-ramipril products is not relevant to the calculation of damages under section 8 of the *Regulations* in this action. As noted by the Court of Appeal in *Apotex v. Merck & Co*. (2009), 76 CPR (4th) 1 (FCA) at paragraphs 101- 102:

> 101...the Governor General focused on this very issue, and chose to limit the measure of the losses which can be compensated by way of damages to those suffered during the period. No issue of principle flows from this. The Governor-in-Council could have extended the measure of the losses to include those caused during the period, regardless of when they are suffered. However, it did not do that.

> 102 The Governor-in-Council's clearly expressed intent must be given effect to. This excludes compensation for losses occurring in future years since such losses cannot be said to have been suffered during the period. It follows, for instance, that Apotex's entitlement to damages for lost sales resulting from the alleged decrease in its market share must be confined to sales that can be shown to have been lost within the period. In order to be compensated, the losses must be shown to have been incurred during the period.

[30] Accordingly, it is appropriate to strike the impugned paragraphs as they are not relevant and do not disclose a reasonable cause of action.

ORDER

THIS COURT ORDERS that:

1. The Third Amended Counterclaim as against Schering Corporation is struck and hereby dismissed.
2. The phrase "and a permanent loss of market share" in paragraph 135; the whole of paragraph 136; and the sentences "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" in paragraph 143 are struck.
3. Novopharm shall, within twenty days of the date of this Order, serve and file a Fourth Amended Counterclaim consistent with the reasons and this Order, including an amendment to the style of cause to remove reference to Schering Corporation.
4. The balance of the motion filed by Sanofi-Aventis Canada Inc., and Sanofi-Aventis Deutschland GmbH is dismissed.
5. In the event the parties cannot agree on costs, each may submit written submissions, no longer than three pages in length, within twenty days of the date of this Order.

"Martha Milczynski"
Prothonotary

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1161-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION and SANOFI-AVENTIS DEUTSCHLAND GmbH v. NOVOPHARM LIMITED
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	October 19, 2009
REASONS FOR ORDER AND ORDER BY:	Milczynski P.
DATED:	February 12, 2010

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