Date: 20101130

Docket: T-1161-07

Citation: 2010 FC 1210

Ottawa, Ontario, November 30, 2010

PRESENT: The Honourable Madam Justice Simpson

BETWEEN:

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

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

AND BETWEEN

TEVA CANADA LIMITED

Plaintiff by Counterclaim

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

Defendants by Counterclaim

REASONS FOR JUDGMENT AND JUDGMENT

[1] These reasons concern two motions brought pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106, both appealing an Order of Madam Prothonotary Martha Milczynski (the Prothonotary) dated February 12, 2010 (the Decision).

[2] In the first appeal, the Plaintiff by Counterclaim, Teva Canada Inc. (Teva) (formerly Novopharm Limited) appeals the Prothonotary's decision to strike the portions of its Third Amended Statement of Defence and Counterclaim dated December 10, 2008 (the Teva Counterclaim) which involved a claim for damages for permanent loss of market share.

[3] In the second appeal, Sanofi-Aventis Canada Inc. (Sanofi Canada) and Sanofi-Aventis Deutschland GmbH (Sanofi Germany) appeal the Prothonotary's refusal to dismiss the Teva Counterclaim in its entirely as against Sanofi Germany.

[4] The action is being specially managed by the Prothonotary.

[5] These appeals were heard together with a related appeal in action T-1357-09. Since the two files have not been formally consolidated, I have issued separate reasons dealing with the appeal in the other action.

THE BACKGROUND

[6] The appeals in this case arise from the regulatory scheme created by the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the Regulations). In her decision of February 22, 2010 in the related file, T-1357-09, at pages 4-5, the Prothonotary provides the following summary of this scheme. She said:

> Before selling a "new drug" in Canada, a manufacturer (be it an "innovator" or generic drug manufacturer), must make application for and obtain a Notice of Compliance ("NOC") from the federal Minister of Health. The issuance of a NOC constitutes marketing

> approval for a new drug and signifies the Minister's satisfaction that the new drug is safe and effective for human use.
>
> Under the [Regulations], an innovator drug manufacturer may submit a patent list to the Minister of Health in relation to any new drug product submissions for which the innovator has received a NOC. Such patent list may include one or more patents containing claims to the medicine contained in the drug product or its uses contained in the approved submission.
>
> Where a generic drug manufacturer seeks a NOC and has compared its drug product containing a particular medicine to the drug product of an innovator that contains the same medicine and in respect of which a NOC has already been issued, the generic must either (a) accept that the NOC will not be issued to it until the expiry of the patent(s); or (b) deliver to the innovator, a Notice of Allegation with respect to each relevant listed patent, stating that the patent has expired, that the patent is not valid or that the manufacture, use and/or marketing of the drug by the generic will not infringe any claim of the relevant patent(s).
>
> Upon receiving a Notice of Allegation, the innovator drug manufacturer may, within 45 days, commence a proceeding for an order prohibiting the Minister of Health from issuing a NOC to the generic until the expiration of the patent(s). Pending the disposition of the prohibition proceeding or the expiration of 24 months following commencement of the proceeding, whichever is earlier, the Minister cannot issue the NOC to the generic. This period of time is referred to as the "automatic stay" that prevents a generic from marketing its drug product, and to the extent an innovator is unsuccessful in the prohibition proceeding and the generic ultimately receives a NOC, a claim for damages may be commenced by the generic by virtue of section 8 of the [Regulations].

[7] In this case, Sanofi Canada filed the required new drug submissions and patent lists, and obtained an NOC to market and sell ramipril, an ACE inhibitor used to treat high blood pressure. Teva applied for its own NOC for ramipril in 2001, and in 2005, submitted Notices of Allegation.

[8] Sanofi Canada responded by bringing two prohibition proceedings against Teva. They were ultimately dismissed by the Federal Court of Appeal, which held that each constituted an abuse of process. Teva was issued its NOC on May 2, 2007.

[9] Sanofi Canada then brought an action against Teva alleging infringement of one of the relevant patents (the Infringement Action). It was eventually dismissed by Madam Justice Judith Snider in a judgment dated June 29, 2009.

THE TEVA COUNTERCLAIM

[10] In the meantime, on September 17, 2007, Teva had counterclaimed in the Infringement Action and named Sanofi Canada, Sanofi Germany and the Schering Corporation as Defendants by Counterclaim. Thereafter, on August 14, 2008, the Teva Counterclaim was stayed by the Prothonotary pending resolution of the Infringement Action. The stay is now lifted and the Teva Counterclaim is proceeding.

[11] The Teva Counterclaim is for damages pursuant to section 8 of the Regulations. It provides that if a "first person" applies for a prohibition order and the application is withdrawn, discontinued or dismissed, the "first person" is liable to the "second person" for any loss suffered during the period of the automatic stay. There is no dispute that Teva is the "second person" and is entitled to bring a claim against a "first person."

[12] "First person" is defined in section 2 of the Regulations as "the person referred to in subsection 4(1)." In turn, subsection 4(1) of the Regulations describes the "first person" as a person who files a new drug submission and who is entitled to submit a patent list in relation to that submission.

[13] There is no dispute that Sanofi Canada filed both a new drug submission and a patent list for ramipril, and is therefore a "first person." Further, there is no dispute that Sanofi Germany did not file either document. However, Teva submits that Sanofi Germany is liable as a "first person" because of the control it exercised over Sanofi Canada. In this respect, Teva pleads as follows at paragraph 143 A of the Teva Counterclaim:

> [Teva] 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 [Teva].

[14] Teva claims damages against Sanofi Canada and Sanofi Germany under various heads. The one which is relevant to this appeal is a claim for damages for Teva's permanent loss of market share. In this respect, Teva pleads as follows at paragraphs 135, 136 and 143 of the Teva Counterclaim:

> The commencement of the NOC Proceedings resulted in lost sales and a permanent loss of market share to [Teva] for Novo-Ramipril capsules.
>
> In addition, [Teva] 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.
>
> […]
>
> Furthermore, during the periods in which [Teva] 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 [Teva] had been approved on the same day as Apotex and Ratiopharm, [Teva] would have had a greater share in the marketplace than it currently has. Moreover, [Teva] will be unable to capture a larger percentage of the market share over time due to its late entry. Accordingly, [Teva] claims its damages for lost market share as well.

THE PROTHONOTARY'S DECISION

[15] Sanofi Canada and Sanofi Germany (collectively Sanofi) and the Schering Corporation moved seeking, *inter alia*, orders dismissing the Teva Counterclaim as against all defendants other than Sanofi Canada, and an order striking the portions of the Teva Counterclaim relating to Teva's claim for loss of market share.

[16] The Prothonotary dismissed the action against the Schering Corporation, and that part of the Decision is not being challenged. However, the Prothonotary declined to dismiss the counterclaim against Sanofi Germany, on the basis of the Federal Court of Appeal's decision in *Apotex Inc. v. Eli Lilly and Co.*, 2004 FCA 358 (*Lilly 2004*). Sanofi now appeals that aspect of the Decision (the Sanofi Appeal).

[17] As well, relying on the Federal Court of Appeal's decision in *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187, leave to appeal to the Supreme Court of Canada ref'd [2009] S.C.C.A. No. 347 (*Merck 2009*), the Prothonotary held that Teva's claim for permanent loss of market share

failed to disclose a reasonable cause of action. Accordingly, she struck the following portions of the Teva Counterclaim:

(a) The phrase "and a permanent loss of market share" in paragraph 135;

(b) The entirety of paragraph 136;

(c) The last two sentences of paragraph 143.

[18] Teva now appeals this aspect of the Decision (the Teva Appeal).

THE ISSUES

[19] The issues on the Sanofi Appeal are as follows:

(i) What is the standard of review?

(ii) Should the Teva Counterclaim proceed against Sanofi Germany?

[20] The issues on the Teva Appeal are as follows:

(i) Should Sanofi be allowed to attack Teva's Counterclaim a second time?

(ii) What is the standard of review?

(iii) Does Teva's claim for damages for permanent loss of market share disclose a reasonable cause of action?

THE SANOFI APPEAL

Issue (i) The Standard of Review

[21] The parties agree that the test to be applied on the review of a discretionary decision of a prothonotary is the one reformulated by the Federal Court of Appeal in *Merck & Co. Inc. v. Apotex Inc.*, 2003 FCA 488 (*Merck 2003*) at paragraph 19. There, the Court said:

> To avoid the confusion which we have seen from time to time arising from the wording used by MacGuigan J.A., I think it is appropriate to slightly reformulate the test for the standard of review. I will use the occasion to reverse the sequence of the propositions as originally set out, for the practical reason that a judge should logically determine first whether the questions are vital to the final issue: it is only when they are not that the judge effectively needs to engage in the process of determining whether the orders are clearly wrong. The test would now read:
>
> > Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless:
> >
> > a) the questions raised in the motion are vital to the final issue of the case, or
> > b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts.

[22] The parties also acknowledge that the above passage referred to Mr. Justice Mark MacGuigan's decision in *R. v. Aqua-Gem Investments Ltd.*, [1993] 2. F.C. 425 (Fed. C.A.) (*Aqua-Gem*). In that case he said:

> I also agree with the Chief Justice in part as to the standard of review to be applied by a motions judge to a discretionary decision of a prothonotary. Following in particular Lord Wright in Evans v. Bartlam, [1937] A.C. 473 (H.L.) at page 484, and Lacourciere J.A. in Stoicevski v. Casement (1983), 43 O.R. (2d) 436 (Div. Ct.),

> discretionary orders of prothonotaries ought not to be disturbed on appeal to a judge unless:
>
> (a) they are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts, or
> (b) they raise questions vital to the final issue of the case.
>
> Where such discretionary orders are clearly wrong in that the prothonotary has fallen into error of law (a concept in which I include a discretion based upon a wrong principle or upon a misapprehension of the facts), or where they raise questions vital to the final issue of the case, a judge ought to exercise his own discretion de novo.

[23] The issue is whether "vitality" is to be assessed by looking at the question in the motion before the Prothonotary or by considering the Decision. In *Peter G. White Management Ltd. v. Canada*, 2007 FC 686, Mr. Justice James Hugessen concluded that, in situations (similar to the case at bar) in which the appeal is from a decision of a prothonotary dismissing a defendant's motion to strike a claim, it is not what was sought (i.e., the question before the Prothonotary) but what was ordered by the Prothonotary (i.e., the answer) which is to be analyzed to see whether it is vital to a final issue in the case. Mr. Justice Hugessen based this conclusion on his reading of *Aqua-Gem*. Several Federal Court Judges have since adopted his interpretation. A summary of the case law on this point to date is to be found in Madam Justice Anne Mactavish's decision in *Ridgeview Restaurant Limited v. The Attorney General of Canada and Steve Gibson*, 2010 FC 506 at paragraphs 20 to 24.

[24] Using Mr. Justice Hugessen's approach, the focus would be on the answer or, in other words, on the order made by the Prothonotary. In this case, because she dismissed the motion to strike, no change was made in the case – it continues to trial. In these circumstances, it cannot be said that her order was determinative of vital issues. Accordingly, review *de novo* would not be appropriate unless the Prothonotary clearly erred by exercising her discretion on a wrong principal or by misapprehending the facts and no such submission was made in this case.

[25] However, I have reviewed the Federal Court of Appeal's decisions in *Aqua-Gem* and *Merck 2003* and for the following reasons, have reached a conclusion which is contrary to that reached by Mr. Justice Hugessen.

[26] In *Aqua-Gem*, the respondent had moved to have the case dismissed for want of prosecution. The Prothonotary dismissed the motion so the action remained extant. While the question before the Prothonotary was vital in the sense that the action could be dismissed, the order was not determinative of the final issues. The judge who heard the appeal from the Prothonotary's order considered it *de novo* and the Federal Court of Appeal upheld this approach. The only possible rationale for this conclusion, in my view, is that the Court of Appeal considered the issue of vitality based on the question before the Prothonotary. This conclusion, again in my view, is borne out by a review of the Decision.

[27] On the "vitality issue", Mr. Justice MacGuigan said at paragraph 95 that "…discretionary orders of prothonotaries ought not to be distributed on appeal to a judge unless:

(a) […]

(b) they raise questions vital to the final issue of the case.

[28] The word “they” refers back to the word “orders” and indicates that one looks at the order made by the Prothonotary and only reviews it *de novo* if it has, in fact, had an impact on the trial that could be categorized as vital.

[29] The difficulty I have is that when Mr. Justice MacGuigan considered the matter, he did not actually apply the test he described. He did not look at the order. Rather, he looked at the question before the Prothonotary. He said at paragraph 98, “Another way of putting the matter would be to say that for the test as to relevance to the final issue of the case, the issue to be decided should be looked to before the question is answered by the prothonotary, ...”

[30] In my view, the restatement of the *Aqua-Gem* test in *Merck 2003* gives effect to the approach Mr. Justice MacGuigan actually adopted.

[31] *Merck 2003* was a case in which Apotex sought to make fundamental amendments to its Statement of Defence. The motions judge who reviewed the Prothonotary’s decision to allow the amendment declined to treat the proposed amendments as vital and did not conduct a *de novo* review. He upheld the Prothonotary’s decision to allow the Apotex amendments.

[32] The Court of Appeal found that the proposed amendments were vital and conducted its own *de novo* review. In the end, it declined to permit the amendments. The importance of this decision for present purposed is that the restatement and the Court’s subsequent analysis makes it clear that,

as Sanofi submits, it is the question before the Prothonotary that is the focus of the "vitality" analysis.

[33] In 2006, the Federal Court of Appeal again dealt with the question of vitality. In *Peter G. White Management Ltd. v. The Queen*, 2006 FCA 190, the Court considered, *inter alia*, an appeal from the decision of a Federal Court motions judge on an appeal from a Prothonotary's order. Before the Prothonotary, the Crown had moved to strike the claim against the individual defendants who were a Minister of the Crown and three public servants. The Prothonotary allowed the motion. The motions judge dismissed the appeal without considering the matter *de novo*.

[34] At paragraph 33 and following, the Court of Appeal considered the standard of review and concluded that the motions judge had erred in concluding that the motion to dismiss was not vital to the final issue in the case. The Court of Appeal noted that the causes of action against the individual defendants were separate and distinct from those asserted against the Crown and found that removing the defendants put an end to the Plaintiff's causes of action against them in Federal Court.

[35] In conducting its analysis, the Court of Appeal looked at the question in the motion before the Prothonotary and concluded that it was vital. It therefore held that the motions judge ought to have determined the matter *de novo*.

[36] In view of these cases, I must next consider whether the questions before the Prothonotary in this case can be said to be vital.

[37] On this issue, I have concluded that questions dealing with the presence or absence of a defendant will be vital if something essential is taken from a plaintiff if a defendant is excluded. In this case, without Sanofi Germany, the Plaintiffs cannot argue that there could be joint liability because Sanofi Germany controlled Sanofi Canada. I therefore conclude that the removal of the defendants is a vital matter. Accordingly, the decision not to dismiss the Teva Counterclaim against Sanofi Germany will be reviewed *de novo*.

Issue (ii) Should the Teva Counterclaim proceed against Sanofi Germany?

[38] A pleading should not be struck unless it is "plain and obvious" that it discloses no reasonable cause of action: *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 at page 980.

[39] Sanofi takes the position that, on a plain reading of subsection 4(1) of the Regulations, Sanofi Canada is the only "first person" since it was the only Defendant to file a new drug submission or a patent list in relation to ramipril. It said that, since section 8 of the Regulations only creates a right of damages against a "first person", the Teva Counterclaim fails to disclose a reasonable cause of action against Sanofi Germany.

[40] In *Lilly 2004*, the Federal Court of Appeal considered a similar argument. A generic drug manufacturer brought a section 8 claim against two innovator drug manufacturers: a Canadian subsidiary which had filed a new drug submission and patent list, and its American parent which had not done so. The parent sought summary judgment on the basis that it was not a "first person".

As is the case here, the generic's claim against the foreign company was based on the degree of control it exercised over the Canadian company.

[41] The Court of Appeal described the issue in *Lilly 2004* as follows at paragraph 9:

> The question in dispute, therefore, is whether [the parent] can be said to have submitted the patent list to the Minister pursuant to subsection 4(1), even though the list was submitted in the name of [the subsidiary].

In my view, this is precisely the issue in the case at bar.

[42] The Court held, at paragraphs 11-13 of its decision, that common law concepts such as agency might be relevant to statutory interpretation. The Court illustrated this point saying that, if a parent exercised sufficient control over a subsidiary such that the subsidiary could be said to be acting as an agent, the subsidiary's actions "might be regarded as actions taken by both [the subsidiary and the parent]. Thus, [the parent] might be a "first person", and therefore a proper defendant […]."

[43] It is noteworthy that the Court added, at paragraph 14:

> 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 its subsidiary is a sufficiently difficult legal question to require a trial.

[44] Further, at paragraph 15 the Court said:

> Its resolution may depend, <u>for example</u>, on whether the "profits" recoverable under section 8 are the profits from the drug in question made by the "first person" during the period of the delay

> or the profits *not* made during that period by the "second person" from its version of the drug. If the intent of section 8 is to enable the "second person" to elect to recover the "first person's" profits, rather than merely its own lost profits, that might support an interpretation of "first person" which includes the corporation that controlled all relevant actions of the corporation in whose name the application for an NOC was made, the patent list was submitted and an NOC was issued. Otherwise, the second person may be unable to recover the innovator's profits and, if the statutory purpose is to enable the recovery of the profits of the directing mind of the person whose name appears on the documents listed in subsection 4(1), that statutory purpose will have been thwarted. This is because it is conceivable that intercorporate arrangements may have ensured that profits from the sale of the drug in Canada show up on the books of the parent company, not its Canadian subsidiary.
>
> [My emphasis]

[45] Sanofi's main submission, relying on paragraph 15 of *Lilly 2004*, is that the Court of Appeal's decision was based on the availability of a disgorgement of profits as a remedy under section 8. The Court held that a cause of action for disgorgement of profits is only meaningful if the plaintiff can implead all parties who might have earned the profits. Thus, a broad interpretation of "first person" was required. However, in *Merck 2009*, the Federal Court of Appeal held that disgorgement of profits is not available as a remedy under section 8. For this reason, Sanofi says that the rationale behind *Lilly 2004* has been extinguished and there is no longer any reason to give a broad or elastic interpretation to "first person."

[46] However, I am not persuaded that the decision in *Lilly 2004* was premised entirely on the existence of a claim for profits. As noted above, the Court made several general statements supporting the possibility of section 8 liability on the part of a company which controlled and directed the person who actually submitted the new drug submission and patent list. For example,

the Court stated that common law agency principles might apply in the section 8 context and that actions of a subsidiary might be regarded as the actions of its parent.

[47] Paragraph 15 of *Lilly 2004* simply presents disgorgement of profits as an example of a situation in which a broad definition of "first person" may be appropriate. In my view, the reference to profits was only an illustration and was not intended to be exhaustive. In other words, I think it likely that the Court in *Lilly 2004* would have reached the same conclusion about the need for a trial to decide the meaning of "first person" even if disgorgement of profits had not been available as a remedy. Accordingly, the question of whether a "first person" includes a controlling corporation in the context of a section 8 claim for damages remains open.

[48] During the hearing, Sanofi made several arguments about how to resolve the statutory interpretation question. For example, both paragraph 4(4)(d) and subsection 6(4) of the Regulations refer to the owners of relevant patents, but subsection 4(1) does not refer to any additional parties. This suggests that the drafter of the Regulations intended to exclude the parties other than the one who filed the new drug submission and patent list from the definition of "first person" in subsection 4(1).

[49] However, it is not my role to decide the question. My role is only to determine whether it is plain and obvious that Teva's interpretation of "first person" must fail. In light of *Lilly 2004*, I have concluded that such a result is not plain and obvious.

[50] For these reasons, I have reached the same conclusion as the Prothonotary, and the Sanofi Appeal will therefore be dismissed with costs to Teva in any event of the cause.

THE TEVA APPEAL

Issue (i) Should Sanofi be allowed to attack Teva's Counterclaim a second time?

[51] In its written submissions, Teva alleged that the Prothonotary should not have entertained Sanofi's motion to strike its claim for permanent loss of market share, because (i) Sanofi challenged the same pleading in 2007 and (ii) because Sanofi filed a defence to the Teva Counterclaim.

[52] Although Teva did not pursue these submissions at any length in oral argument, I will address them briefly. In my view, Sanofi was entitled to bring a second motion to strike Teva's Counterclaim because the Federal Court of Appeal's decision in *Merck 2003* was released after Sanofi's first motion to strike. This constitutes a "special reason" or "relevant change of circumstances" justifying a second motion to strike: see *Pawar v. Canada* (1997), 132 F.T.R. 44 (Proth.) aff'd 137 F.T.R. 231 (F.C.T.D.); *Harris v. Canada*, 2001 FCT 758 at para. 24. As well, filing a defence does not preclude a motion to a strike pleading for failure to disclose a reasonable cause of action: see, for example, *Coca-Cola Ltd. v. Pardhan* (1997), 139 F.T.R. 223 (F.C.T.D.), affirmed (1999), 85 C.P.R. (3d) 489, leave to appeal to the Supreme Court of Canada ref'd [1999] S.C.C.A. No. 338 (QL) at para. 8.

Issue (ii) The Standard of Review

[53] The above discussion of this issue applies here (see paragraphs 21 to 32 above). The question before the Prothonotary dealt with whether Teva could claim damages for permanent loss of market share. This is a question which is vital to the case and, accordingly, a *de novo* review will be undertaken.

Issue (iii) Do Teva's claims for damages for permanent loss of market share disclose a reasonable cause of action?

[54] Section 8 of the Regulations permits the second person, in this case Teva, to claim damages from the first person "for any loss suffered during the period" defined in the Regulations. The period at issue is the period of operation of the automatic stay and the issue is whether permanent loss of market share can be said to have been a loss suffered during the period.

[55] In the Federal Court decision which was reviewed by the Court of Appeal in *Merck 2009*, Mr. Justice Roger Hughes, dealing with a section 8 claim involving loss of market share, held that losses are "suffered" at the time they are caused. Hence, in his view, losses caused during the period were also suffered during the period even if they were experienced at a later date. See *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2008 FC 1185.

[56] However, in *Merck 2009*, the Federal Court of Appeal reversed Mr. Justice Hughes. It held that losses are only "suffered during the period" if the losses themselves are incurred during the

period. Thus, losses caused during the period, but incurred later, cannot be claimed under section 8.

The Court of Appeal concluded as follows at paragraphs 101-102:

> In this case, we have the advantage of knowing that in 1998 the Governor-in-Council 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.
>
> 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. I therefore conclude that the appeal should be allowed on this limited point. [Emphasis in original].

[57] In my view, the Federal Court of Appeal's reasons are clear. A second person may claim damages resulting from a loss of market share, but only for losses actually incurred within the period. Section 8 does not provide any entitlement to damages in respect of losses incurred outside the period.

[58] In oral argument, counsel for Teva indicated that the paragraphs of the Teva Counterclaim which the Prothonotary struck relate to damages incurred both within and beyond the period. Sanofi acknowledges that Teva should be allowed to claim damages incurred within the period. Consequently, on consent, an Order will issue reinstating those paragraphs to the extent that they refer to damages incurred within the period.

[59] However, Teva also seeks to reinstate its claim for damages incurred outside the period. In my opinion, the Federal Court of Appeal's decision in *Merck 2009* makes it plain and obvious that this claim is hopeless and discloses no reasonable cause of action.

[60] Teva attempted to distinguish *Merck 2009* on the ground that the Court of Appeal was considering an earlier version of the Regulations. However, there are no material differences between the two versions. The provision of the Regulations, subsection 8(1), which includes the requirement that damages be "suffered during the period," has not changed.

[61] Teva also criticized the *Merck 2009* decision itself. It said that the Federal Court of Appeal only provided one possible interpretation of "suffered during the period," and that this interpretation is inconsistent with the purpose of the Regulations, with Teva's ability to make itself whole, and with approaches to the assessment of damages used in tort law. However, since the Supreme Court of Canada refused to grant leave to appeal the *Merck 2009* decision, the Federal Court of Appeal's interpretation must be considered settled law.

[62] For these reasons, I have reached the same conclusion as the Prothonotary and the Teva Appeal will be dismissed with respect to Teva's claims for damages incurred outside the relevant period.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The Sanofi Appeal is dismissed;
2. On consent, the Teva Appeal is allowed in part;
3. The portions of paragraphs 135, 136 and 143 of the Teva Counterclaim which were struck in the Decision are hereby reinstated to the extent that they refer to claims for damages incurred within the relevant period;
4. Teva shall, within twenty days of the date of this Judgment, serve and file an amended counterclaim consistent with this Order, including language clarifying that the claims for permanent loss of market share in paragraphs 135, 136 and 143 refer only to claims for damages incurred within the relevant period.
5. Costs of the Sanofi Appeal are payable by Sanofi Canada to Teva in any event of the cause, and costs of the Teva Appeal are payable by Teva to Sanofi Canada in any event of the cause.

"Sandra J. Simpson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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