Federal Court  Cour fédérale

Date: 20120523

Docket: T-1161-07
T-1357-09

Citation: 2012 FC 551

BETWEEN:

T-1161-07

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

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

AND BETWEEN:

TEVA CANADA LIMITED

Plaintiff by Counterclaim

and

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

Defendants by Counterclaim

AND BETWEEN:

T-1357-09

APOTEX INC.

Plaintiff

and

**SANOFI-AVENTIS,
SANOFI-AVENTIS DEUTSCHLAND GmbH
AND SANOFI-AVENTIS CANADA INC.**

Defendants

**PUBLIC REASONS FOR JUDGMENT
(Validity of Section 8)**

(Confidential Reasons for Judgment released May 11, 2012)

SNIDER J.

I. Introduction

[1] These Reasons for Judgment and Judgment deal with claims of invalidity of s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the *PM (NOC) Regulations* or the *Regulations*) made by Sanofi-Aventis Canada Inc. (Sanofi Canada), Sanofi-Aventis (Sanofi France) and Sanofi-Aventis Deutschland GmbH (Sanofi Germany) (collectively Sanofi). The issue of validity has been raised as a defence by Sanofi in two actions:

1. *Teva Canada Limited v Sanofi*, in Court File No. T-1161-07 (Teva Action); and

2. *Apotex Inc v Sanofi*, in Court File No. T-1357-09 (Apotex Action).

[2] In each case, Apotex Inc. (Apotex) or Teva Canada Limited (Teva), as applicable, claims compensation from Sanofi pursuant to s. 8 of the *PM (NOC) Regulations*. In brief, each of the generic plaintiffs claims that, but for the actions of Sanofi taken under the *Regulations*, it would have come to market much earlier and, because of being kept off the market, has incurred losses.

[3] Sanofi served a Notice of Constitutional Question (Notice) on the Attorney General of Canada and the Attorneys General for the provinces pursuant to s. 57 of the *Federal Courts Act*, RSC 1985, c F-7, in which Sanofi served notice of its intention to question the "constitutional validity, applicability and operability" of s. 8 of the *PM (NOC) Regulations*. None of the Attorneys General made submissions or appeared at the hearing of the validity issues.

[4] In the course of two trials of 15 days (Court File No. T-1161-07) and 13 days (Court File No. T-1357-09), this Court was presented with substantial quantities of evidence related to the issues raised by the pleadings. At the close of the two trials, the validity issues raised by Sanofi in its pleadings were not argued. Because the validity issues raised by Sanofi are so similar in both cases, it was agreed that written submissions would be made and the issues would be argued for both actions following the trials.

[5] It subsequently became apparent that the issues raised by Sanofi in the Teva Action and the Apotex Action are also identical to those raised by AstraZeneca Canada Inc. (AstraZeneca) in *Apotex v AstraZeneca*, Court File No. T-2300-05 (AstraZeneca Action). Justice Hughes, as the presiding judge in the AstraZeneca Action, has completed the trial of all but the outstanding validity questions. All of the parties were canvassed and agreed that the validity challenges in all

three cases could be argued at the same time before both judges. Written submissions were made by all parties and, on April 30, 2012 and May 1, 2012, the common validity issues were argued before me and Justice Hughes. Each judge has rendered judgment in respect of the matters for which he or she was seized. Specifically, in these Reasons and Judgment, I address the validity issues that arise in the Teva Action and the Apotex Action.

[6] These Reasons should be read together with the Reasons for Judgment in the Teva Action, with citation 2012 FC 552 (Teva Reasons), and the Apotex Action, with citation 2012 FC 553 (Apotex Reasons). Terms used in these Reasons without definition bear the same meanings as in the Apotex Reasons or the Teva Reasons, as applicable.

II. Issues

[7] In its Notice of Constitutional Question, Sanofi states that it questions the "constitutional validity, applicability and operability of Section 8 of the [*Regulations*]" and raises a number of sub-issues. The grounds for the challenge are set out in full in Appendix A to these Reasons.

[8] In summary form, Sanofi questions the constitutional validity, applicability and operability of s. 8 of the *Regulations* on the following grounds:

(a) s. 8 is unconstitutionally vague and ambiguous;

(b) s. 8 is draconian, harsh and punitive;

(c) s. 8 is unreasonable, uncertain, arbitrary, penal and confiscatory if an award can be granted even if the second person continues to infringe a valid patent;

(d) s. 8 is inconsistent with Canada's international obligations under the *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can TS 1994 No 2, 32 ILM 289 (entered into force 1 January 1994) [*NAFTA*] and the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (Marrakesh Agreement Establishing the World Trade Organization, Annex 1C) [*TRIPS*];

(e) an interpretation that allows recovery for losses before the service of a notice of allegation or the issuance of a notice of application would result in s. 8 being *ultra vires*; and

(f) an interpretation that permits recovery without proof of causation would result in s. 8 being *ultra vires*.

[9] In its written and oral submissions, Sanofi did not pursue its claims (a) and (b) in the Notice. From the written and oral submissions made during the course of the hearing of these matters, it appears that the following are the issues being argued by Sanofi:

1. Is s. 8 of the *PM (NOC) Regulations ulta vires*, as being beyond the scope of its enabling statute, s. 55.2 of the *Patent Act*, RSC 1985, c P-4 (*Patent Act* or *Act*), because:

    a) it imposes liability on the first person (Sanofi in these cases) for the period before the commencement of an application under s. 6(1) of the *PM (NOC) Regulations*;

    b) it imposes liability on a first person for the period after the issuance of a Notice of Compliance (NOC) to the second person;

    c) it imposes liability on the first person while ignoring possible competition or unapproved indications;

    d) it permits recovery in circumstances where the generic would have infringed a valid patent; or

    e) it is contrary to Canada's obligations under *TRIPS* or *NAFTA*?

2. In the alternative, should s. 8 of the *Regulations* be "read down" to provide for an interpretation that addresses Issues 1(a) to (e)?

Although the issues were framed as “Constitutional”, I note that Sanofi does not submit that s. 8 is *ultra vires* the federal government as a matter coming within the jurisdiction of the provinces; this is not a division of powers question. Nor does Sanofi assert any argument under the *Canadian Charter of Rights and Freedoms*. The questions raised are related to the validity or *vires* of regulations enacted by the Governor in Council (GIC) pursuant to an authorizing provision of a statute.

[10] In addition, Teva and Apotex raise the following issues:

1. Is Sanofi precluded from making these validity arguments on the basis that they were not contained in its pleadings?

2. Have the issues before this Court been decided in *Apotex Inc v Merck & Co*, 2009 FCA 187, [2010] 2 FCR 389, rev’g 2008 FC 1185, leave to appeal to SCC refused [2009] SCCA No 347 [*Alendronate (FCA)*]?

[11] In these Reasons, I will consider first the two issues raised by Teva and Apotex before turning to the specific issues raised by Sanofi.

III. Adequacy of the Pleadings

[12] Apotex and Teva argue that some of the issues described in the Notice of Constitutional Question have not been pleaded by Sanofi. Specifically, they submit that the issues raised in

paragraphs (e) and (f) of the Notice have not been pleaded. These particular questions are contained in Issues 1(a), (b), (c) and (d) of the issues argued before me and summarized in paragraph [9], above.

[13] Sanofi responds with three arguments:

1. the questions of validity are merely legal issues that do not need to be pleaded;

2. in any event, on a fair reading of the pleadings, these issues of validity are encompassed in the pleadings, including in the responding pleadings of Apotex and Teva; and

3. given the amount of time that these questions have been before the parties and the fact that both Apotex and Teva have been able to respond, there is no prejudice.

[14] Apotex, in particular, acknowledges that it suffered no prejudice as a result of having to address these issues. I agree. Teva and Apotex have had considerable notice of the arguments made by Sanofi. Both are sophisticated litigants with the resources to respond to difficult legal issues. Lack of prejudice, however, is not determinative of the adequacy of pleadings.

[15] Pleadings play a critical role in the trial process. Rules 173 to 181 of the *Federal Courts Rules*, SOR/98-106 set out the requirements for pleadings. Sanofi, in its pleadings in both the Teva Action and the Apotex Action, raises the issue of the validity of s. 8. Moreover, Sanofi's

views on various aspects of validity became clear during the trials. I am prepared to take a generous approach to the pleadings and reject the arguments of Teva and Apotex. The pleadings, while not perfect, have addressed the broad issues of validity and Teva and Apotex have been able to address the arguments made by Sanofi.

IV. General Comments

[16] I begin with some overview comments about the context of the issues before me.

[17] In very general terms, the *Patent Act* is intended to provide a statutory scheme for the granting, the protection and the challenge of patents of invention. Of particular relevance to these actions, s. 55.2 of the *Act* provides that it is not an infringement of a patent for a person "to make, construct, use or sell the patented invention" for uses related to making regulatory submissions. In simple terms, before the expiry of a patent, a person may make preparations to enter the market. This is known as the "early working exception". It was a right at least partially permitted by common law and now is codified in s. 55.2 of the *Act*. As set out in s. 55.2(4), the early working exception may be further defined or restrained through regulations of the GIC:

55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada	**55.2** (1) Il n'y a pas contrefaçon de brevet lorsque l'utilisation, la fabrication, la construction ou la vente d'une invention brevetée se justifie dans la seule mesure nécessaire à la préparation et à la production du dossier d'information qu'oblige à fournir une loi fédérale, provinciale ou étrangère réglementant la fabrication, la

that regulates the manufacture, construction, use or sale of any product.

. . .

(4) The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations

(a) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

(b) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (*a*) that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;

construction, l'utilisation ou la vente d'un produit.

. . . .

(4) Afin d'empêcher la contrefaçon d'un brevet d'invention par l'utilisateur, le fabricant, le constructeur ou le vendeur d'une invention brevetée au sens du paragraphe (1), le gouverneur en conseil peut prendre des règlements, notamment :

a) fixant des conditions complémentaires nécessaires à la délivrance, en vertu de lois fédérales régissant l'exploitation, la fabrication, la construction ou la vente de produits sur lesquels porte un brevet, d'avis, de certificats, de permis ou de tout autre titre à quiconque n'est pas le breveté;

b) concernant la première date, et la manière de la fixer, à laquelle un titre visé à l'alinéa *a*) peut être délivré à quelqu'un qui n'est pas le breveté et à laquelle elle peut prendre effet;

c) concernant le règlement des litiges entre le breveté, ou l'ancien titulaire du brevet, et le demandeur d'un titre visé à l'alinéa *a*), quant à la date à laquelle le titre en question peut être délivré ou prendre effet;

(c) governing the resolution of disputes between a patentee or former patentee and any person who applies for a notice, certificate, permit or other document referred to in paragraph (*a*) as to the date on which that notice, certificate, permit or other document may be issued or take effect;

(d) conferring rights of action in any court of competent jurisdiction with respect to any disputes referred to in paragraph (*c*) and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make; and

(e) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (*a*) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.

d) conférant des droits d'action devant tout tribunal compétent concernant les litiges visés à l'alinéa *c*), les conclusions qui peuvent être recherchées, la procédure devant ce tribunal et les décisions qui peuvent être rendues;

e) sur toute autre mesure concernant la délivrance d'un titre visé à l'alinéa *a*) lorsque celle-ci peut avoir pour effet la contrefaçon de brevet.

[18] The *PM (NOC) Regulations* were enacted under the authority of s. 55.2(4) of the *Act*.

[19] Contrary to the assertions of Sanofi, the regulation-making authority granted by s. 55.2(4) is broad. Nevertheless, as observed by the Court of Appeal in *Alendronate (FCA)*, above at paragraph 52, the power of the GIC is "constrained by the wording of subsection 55.2(4) of the *Patent Act*". Of specific relevance, I observe that the GIC is permitted to enact regulations "with respect to any disputes" and "respecting the remedies" (s. 55.2(4)(d)).

[20] Sanofi takes a very narrow view of the term "disputes"; on its reading, the dispute only arises once a notice of allegation is served by the generic and a notice of application is filed in response, thus engaging the "statutory stay" of up to 24 months. In addition, Sanofi says, the dispute ends upon issuance of an NOC. This narrow interpretation ignores the reality that it is the brand company who actually starts the entire process by listing a patent on the Patent Register. Without that listing, there would be no notice of allegation and no statutory stay. Arguably, a "dispute" may arise as soon as a brand company lists a patent on the Patent Register. This is because a listing immediately requires a generic manufacturer to deal with the patent through the *PM (NOC)* Regulations rather than bring its generic product to market. The patent listing, the approval of the generic product subject to patent hold, the notice of allegation, the prohibition application, the statutory stay and the NOC proceedings are all part of the "dispute". It follows that regulations may be made "with respect to" any aspect of the dispute and "respecting the remedies" that may flow from the dispute.

[21] This broad meaning of the words “with respect to” or “respecting” is endorsed in the jurisprudence. As stated by the Supreme Court of Canada in *Nowegijick v The Queen* [1983] 1 SCR 29 at 39, 144 DLR (3d) 193:

> The words “in respect of” are, in my opinion, words of the widest possible scope. They import such meanings as “in relation to”, “with reference to” or “in connection with”. The phrase “in respect of” is probably the widest of any expression intended to convey some connection between two related subject matters.

[22] Sanofi spoke emphatically about the “balance” that is mandated by s. 55.2(4) and referred to in the jurisprudence. In Sanofi’s view, the balance that Parliament intended is between the prevention of infringement and the early market entry of cheaper generic drugs. Actually, the “balance” is more nuanced than argued by Sanofi. As described in *Alendronate (FCA)*, above at paragraph 52, the balance is “between effective patent enforcement through the use of the *PM (NOC) Regulations* and the timely market entry of lower-priced generic drugs through the use of the “*early working*” exception” (underlining added).

[23] Regardless of how the *Regulations* are worded or interpreted, one or the other of the two parties to the “dispute” will invariably believe that there is an imbalance. For example, one could argue that the *Regulations* are currently unbalanced in favour of the patentee by disallowing recovery for any damages that may have been caused by the statutory stay but incurred after the dismissal of a prohibition application. The balance will never be perfect; nor does s. 55.2(4) require such precise symmetry.

[24] In sum, s. 55.2(4) of the *Act* gives broad authority to the GIC to enact regulations that address the two aspects of the statutory scheme. Specifically, so long as the *Regulations* are

directed to both: (a) effective patent enforcement through the use of the *PM (NOC) Regulations*; and (b) the timely entry of lower-priced generic drugs through the use of the "*early working*" exception, the regulation will be validly enacted and not *ultra vires*. The "balance" spoken of by the courts does not require any perfect match or measurement, a task that would be impossible.

V. The *Alendronate* Decision

[25] Teva and Apotex assert that the issues raised by Sanofi have been considered by the Court of Appeal in *Alendronate (FCA)*, where the court considered and ruled on the authority of the Governor in Council to enact s. 8 of the *Regulations* pursuant to s. 55.2(4).

[26] Sanofi argues that the issues as to the start date, the end date, compensation/causation and patent infringement were not considered by the Court of Appeal in *Alendronate (FCA)* and, thus are issues in respect of which this Court is free to make its own determinations.

[27] The issues before the court in *Alendronate (FCA)* were truly jurisdictional or Constitutional in nature. The court was required to consider whether s. 8 is *intra vires* the *Patent Act*; within the constitutional authority of Parliament (rather than a matter which falls within exclusive provincial legislative competence); and whether the Federal Court had the jurisdiction to hear the action. The court also dealt with the nature and extent of the remedies which can be ordered pursuant to s. 8 of the *PM (NOC) Regulations*. After engaging in a careful analysis of the rights and obligations of the two parties to a "dispute" under the *Regulations*, the Court of Appeal concluded that "section 8 of the *PM(NOC) Regulations* comes within the general grant of

authority set out in subsection 55.2(4) of the *Patent Act* and that the Federal Court Judge came to the correct conclusion when he held that section 8 was validly promulgated" (*Alendronate (FCA)*, above at para 61).

[28] While I agree that the specific questions raised by Sanofi were not directly addressed in *Alendronate (FCA)*, that decision provides strong direction to this Court. In particular, the general validity of s. 8 has been determined. Any questions not explicitly addressed by the Court of Appeal must be considered in a manner that is consistent with the teachings of *Alendronate (FCA)*.

VI. Start Date

[29] The commencement date for liability under s. 8 of the *Regulations* is set out in s. 8(1)(a). Briefly stated, s. 8(1)(a) provides that the period of liability begins "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 . . . a date other than the certified date is more appropriate".

[30] In the Teva Action, Sanofi and Teva take opposing positions on the proper interpretation of s. 8 with respect to the question of the commencement of the period of Sanofi's liability. Sanofi's position is that the start date cannot be before the 24-month statutory stay imposed by s. 6 of the *Regulations*. Teva states that the period of liability must run from the date of approvability of the generic version of the drug. Neither Teva nor Sanofi argues that s. 55.2(4)

does not enable the *Regulations* to provide for a liability period that begins on the commencement of the 24-month stay. Their differences on the question of enablement arise only if there is an interpretation of s. 8 of the *Regulations* that would permit an earlier commencement date.

[31] Sanofi argues that the authority granted under s. 55.2(4) is not broad enough to encompass a regulatory provision that creates liability that begins before the grant of the 24-month stay. Teva asserts that the authority is indeed that broad.

[32] This is a question that I do not need to answer. For the reasons set out in the Teva Reasons, I have concluded that the words of s. 8 of the *Regulations* cannot be interpreted to place liability on Sanofi prior to the commencement of the 24-month statutory stay. Thus, whether s. 55.2(4) enables the imposition of such pre-stay liability is not relevant to my decision. Suffice it to say that s. 8, as I interpret the words of the provision, falls completely within the purpose of s. 55.2(4) of the *Patent Act* and is *intra vires*. I express no opinion on whether, had I interpreted the words of s. 8 more broadly, such an interpretation would have been within the authority of the GIC under s. 55.2(4) of the *Patent Act*.

[33] Even if I am wrong in my interpretation of s. 8, I have also found that, on the facts of the Teva Action, the appropriate date for the commencement of the Relevant Period is the expiry of the '457 Patent and not the approvability date. Thus, regardless of the correctness of my interpretation of s. 8, the facts for determination of Sanofi's issue are not before me.

[34] In its trial, Apotex argued that the commencement date should be April 26, 2004, the date on which it was placed on patent hold. This date is after September 23, 2003, the date of the commencement of the statutory stay in Court File No. T-1742-03. Thus, this issue is not relevant to the Apotex Action.

VII. End Date

[35] Under s. 8(1)(b) of the *Regulations*, the period of liability ends "on the date of the withdrawal, the discontinuance, the dismissal or the reversal" of the prohibition application proceedings. In *Apotex Inc v Merck & Co*, 2008 FC 1185 at paras 106-109, rev'd on other grounds 2009 FCA 187, [2010] 2 FCR 389 [*Alendronate (FC)*], Justice Hughes observed that, although s. 8(1)(a) allows the Court to choose a more appropriate date for the beginning of the liability period, s. 8(1)(b) does not give it any discretion to choose an end date other than "the date of the withdrawal, the discontinuance, the dismissal or the reversal" of the s. 6(1) prohibition application.

[36] Sanofi submits that s. 55.2(4) of the *Act* does not give authority to the GIC to impose liability on a patentee for any time after the period of a s. 6(1) prohibition application or after the issuance of an NOC. Thus, Sanofi's position is that an interpretation that would allow recovery of damages for any period of time after the issuance of an NOC would be *ultra vires*. This limitation, in Sanofi's submission, should extend to any award of discretionary damages under s. 8(5) of the *Regulations*, to the extent that such damages attempt to compensate the second person for losses that were incurred after the grant of an NOC.

[37] In my view, this is another issue that does not arise on the facts of either the Apotex Action or the Teva Action.

[38] In the Teva Action, both Sanofi and Teva submit that the end date is April 27, 2007. This was the date on which the Federal Court of Appeal dismissed the prohibition application in Court File No. T-1979-05 as an abuse of process (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167, rev'g 2006 FC 1547). Teva received its NOC permitting it to sell Novo-ramipril shortly thereafter.

[39] The situation in the Apotex Action is more complicated. The details of Apotex's lengthy path to its NOC are set out in the Apotex Reasons and I will not repeat them all here. In total, Apotex served six notices of allegation and was faced with six applications under s. 6(1) of the *Regulations* commenced by Sanofi. Of particular relevance is the following portion of the Apo-ramipril story:

- the prohibition application in Court File No. T-1499-04 (related to the '948 Patent) was dismissed by Order of Dismissal, on Consent, dated June 27, 2006;

- Apotex received its NOC on December 12, 2006, following a determination by the Minister of Health that Apotex did not have to address two patents (referred to as the HOPE Patents); and

- the prohibition application in Court File No. T-87-06 (related to the HOPE Patents) was dismissed as moot by Order of Prothonotary Aalto dated May 2, 2008.

[40] On this highly unusual sequence of events, Sanofi submits that the end date should be June 27, 2006, the date of dismissal of the last "relevant" application, and Apotex argues that the end date should be May 2, 2008, the date of dismissal of the prohibition application related to the HOPE Patents.

[41] For the reasons that I express in the Apotex Reasons, I have accepted neither of the dates argued by the parties. Rather, I have concluded that the effective date of the dismissal of the HOPE Patent litigation – December 12, 2006 – is the end date contemplated by the *Regulations*. This date happens to coincide with the issuance of the NOC for Apo-ramipril. Thus, the question of whether s. 55.2(4) authorizes the GIC to make a regulation that permits an end date that extends beyond the issuance of an NOC does not arise.

VIII. Competition and Causation

[42] Sanofi submits that a regulation that would exclude competitors from the "but for" or hypothetical world, during the period of liability, would be *ultra vires*. In the Teva Action, Teva argues that s. 8 should be interpreted in such a manner so as to exclude all competing generics including an authorized generic. Apotex, on the other hand, in the Apotex Action, acknowledges that the "but for" world may include competitors, to be determined on a case-by-case basis.

[43] Sanofi, in a related argument argues that s. 8 ought not to be capable of an interpretation that ignores the question of whether the loss claimed by the second person was caused by the first person.

[44] Once again, Sanofi's assertion does not need to be addressed. As reflected in both the Apotex Reasons and the Teva Reasons, I am satisfied that, insofar as possible, the well-known principles of damages should apply. If it is likely that a generic would have faced competition in the "but for" world, those competitors should be accounted for. If a claimed loss, on a careful review of the hypothetical constraints of the "but for" world, cannot be shown to be probable or caused by the actions of Sanofi, the loss will not be recoverable. It may well be, in any given case, that the second person can satisfy its burden to show that it would have been alone on the market for the entire Relevant Period. That was not the case in either the Apotex Action or the Teva Action.

[45] There is no need to address Sanofi's argument beyond stating that the trial judge will be applying well-established principles of damages, including causation, to the facts before him or her. This is not a question that requires the heavy hand of a restrictive statutory interpretation.

IX. Unapproved Indications

[46] Sanofi submits that an interpretation of s. 8 that would create liability and permit recovery beyond what was approved in the second person's regulatory submissions would be *ultra vires*. In each of the Apotex Action and the Teva Action, Sanofi has argued that Apotex and

Teva are not entitled to recover damages under s. 8 for prescriptions for ramipril that might have been written to address indications for which their products were not approved, specifically, the HOPE indications.

[47] One problem for Sanofi in both actions was that it did not attempt to amend its pleadings to identify the issue related explicitly to the HOPE Patents until very late in the day. The Court declined to allow these last minute amendments to the pleadings. As a result, Sanofi was precluded from placing some factual evidence before the Court with respect to the HOPE indications. Sanofi was, however, able to present some general evidence on the HOPE Study and Patents. Further, Sanofi was able to make legal arguments on the issue of recovery in respect of unapproved indications, as that general issue was pleased. On the record that was before me in both the Apotex Action and the Teva Action, I have concluded that the generics are not prohibited from recovering for losses associated with the HOPE indications. I acknowledge that the situation might be different in another case. However, for the Apotex and Teva Actions, Sanofi's question of validity simply does not have enough facts for resolution.

X. Patent Infringement

[48] Sanofi argues that, if a generic would have infringed a valid patent during the period of liability, the generic should have no basis for recovery under s. 8 of the *Regulations*. Accordingly, Sanofi submits, any interpretation of s. 8 that permits recovery where the generic would have infringed a valid patent is *ultra vires* and s. 8 should be "read down", if necessary to avoid such a result.

[49] The first problem with Sanofi's argument on this question is that it does not arise on the facts before me in either the Apotex Action or the Teva Action. In neither case, does Sanofi argue that any patents were infringed during the period of liability. On this basis, I would decline to rule on a hypothetical situation.

[50] The second problem with Sanofi's argument on this point is that infringement can be a complex issue that can only be determined on a case-by-case basis. As was the case in *Apotex Inc v Merck & Co*, 2011 FCA 364, [2011] FCJ No 1865 [*Lovastatin (FCA)*], the facts may lead to a court finding that some but not all of a defendant's product was infringing.

[51] Moreover, this argument was made to the Court of Appeal in *Lovastatin (FCA)* and rejected. In doing so, the court made it very clear that the question of infringement is a matter that can be addressed under s. 8(5) of the *PM (NOC) Regulations*. At paragraphs 36-38, Justice Evans stated the following:

> [36] I do not accept Merck's submission that the Court should read into this provision limiting words to the effect, "unless the second person's claim is based on the loss that is has suffered by being prevented from infringing the first person's patent earlier." The presumption against reading words into a statutory text may be rebutted when demanded by context and legislative objective. In my view, it is not necessary to read an *ex turpi causa* exception into subsection 8 (1) in order to prevent patent infringers from unjustly recovering compensation from a first person.
>
> [37] This is because subsection 8(5) confers a broad discretion on the court when assessing the amount of compensation that the second person must pay. It provides that the court "shall take into account all matters that it considers relevant to the assessment of the amount," including any conduct by either party that contributed to the delay in the disposition of the first person's application for prohibition. In my view, this provision enables the Court to

> determine in its discretion whether, and to what extent, a second person's claim for compensation should be reduced, or eliminated.
>
> [38] The Court's broad discretion under subsection 8(5) allows it, when considering arguments based on *ex turpi causa*, to have regard to the factual situation in its entirety, including its nuances. In the present case, one such nuance is that not all the tablets sold by Apotex were found in the infringement action to contain lovastatin made by the infringing process. A court is likely to find it easier to apply the *ex turpi causa* principle through an exercise of judicial discretion than through the definition of liability. Discretion enables the court to assess the appropriate amount of compensation payable (including nil) in a manner that properly takes account of all the relevant facts.

[52] In conclusion on this issue, I decline to render an interpretation on s. 8 in the absence of the necessary facts and, in any event, the question is settled by the Court of Appeal in *Alendronate FCA*.

XI. *NAFTA* and *TRIPS*

[53] Sanofi complains that s. 8 of the *Regulations*, if interpreted in the manner proposed by either Apotex or Teva, would be inconsistent with Canada's obligations under two of its important international treaties – *TRIPS* and *NAFTA*. The first of these two treaties is *TRIPS*, to which Canada became a party effective January 1, 1995. Canada's commitment to *TRIPS* is reflected in the *World Trade Organization Agreement Implementation Act*, SC 1994, c 47. The second treaty is *NAFTA*, among Canada, the United States and Mexico, which came into force January 1, 1994. Canada enacted the *North American Free Trade Agreement Implementation Act*, SC 1993, c 44 with the stated objective of implementing *NAFTA*.

[54] Specifically, Sanofi argues that s. 8 of the *Regulations* must be interpreted to comply with Article 1715.2(f) of *NAFTA* and Article 48.1 of *TRIPS*. In Sanofi's view, this means that s. 8 must be interpreted to:

- require that a second person show that the first person has "abused" the automatic stay provisions of the *Regulations*;

- provide that merely bringing unsuccessful applications under the *Regulations* cannot constitute "abuse";

- limit compensation to damages suffered because of such abuse; and

- require that a causal link be established between the "injury suffered" and the patentee's use of the automatic stay.

[55] I have had the benefit of reading the draft reasons of Justice Hughes dealing with this issue, as contained in paragraphs 102-119 (2012 FC 559).

> [103] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an agreement signed by many countries. Canada became a party effective January 1, 1995. Among its objectives is:
>
> > *"the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems."*

[104] There are a number of provisions dealing with enforcement of intellectual property rights. AstraZeneca makes particular reference to two of them: Article 48(1) and Article 50(7), which I set out as follows:

Article 48

Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

. . .

SECTION 3: PROVISIONAL MEASURES

Article 50

. . .

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

[105] The North American Free Trade Agreement (NAFTA) is a treaty entered into between Canada, the United States of America and Mexico. It came into force January 1, 1994. That treaty also contains a number of provisions respecting the enforcement of intellectual property rights. AstraZeneca particularly relies on two provisions: Article 1715(2)(f) and Article 1716(7). They provide:

> *Article 1715: Specific Procedural and Remedial Aspects of Civil and Administrative Procedures*
>
> . . .
>
> *(2) Each party shall provide that its judicial authorities shall have the authority*
>
> . . .
>
> *(f) to order a party in a proceeding at whose request measures were taken and who has abused enforcement procedures to provide adequate compensation to any party wrongfully enjoined or restrained in the proceeding for the injury suffered because of such abuse and to pay that party's expenses, which may include appropriate attorney's fees.*
>
> *Article 1716: Provisional Measures*
>
> . . .
>
> *7. Each party shall provide that, where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where the judicial authorities subsequently find that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, on request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.*

[106] It is immediately apparent that these provisions of TRIPS and NAFTA are virtually identical. The first requires "abuse" on behalf of the party seeking enforcement before providing

compensation. The second provides for compensation when provisional measures are resolved or they lapse due to any act or omission by the applicant. Both treaties were entered into after the *NOC Regulations* first were established, although, those *Regulations* have been amended several times since.

[107] Canada has enacted the *World Trade Organization Agreement Implementation Act*, SC 1994, c 47, which makes reference to several treaties, such as the General Agreement on Tariffs and Trade (GATT). Specific reference is made to the *Patent Act* in sections 141 and 142 neither of which has any bearing here.

[108] It is to be noted that Article 1(1) of TRIPS specifically provides for a great deal of latitude to a member country that wishes to implement the provisions of TRIPS into its national law:

> *Article 1*
>
> *Nature and Scope of Obligations*
>
> *1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.*

[109] Canada has also enacted the *North American Free Trade Agreement Implementation Act*, SC 1993, c 44. Section 3 of that *Act* provides:

3. For greater certainty, this Act, any provision of an Act of Parliament enacted by Part II and any other federal law that implements a provision of the Agreement or fulfils an obligation of the	*3. Il est entendu que la présente loi, les dispositions d'une loi fédérale édictées par la partie II et tout autre texte législatif fédéral qui met en oeuvre une disposition de l'Accord ou vise à*

Government of Canada under the Agreement shall be interpreted in a manner consistent with the Agreement	*permettre au gouvernement du Canada d'exécuter une obligation contractée par lui aux termes de l'Accord s'interprètent d'une manière compatible avec celui-ci.*

[110] In this *Implementation Act*, a number of revisions of the *Patent Act* were implemented; but none directed to section 55.2, which is the section of interest in the present proceedings. Section 55.1 was amended by section 193 of the *Implementation Act*, but that is not relevant here. It states:

193. Section 55.1 of the said Act is repealed and the following substituted therefor:	***193. L'article 55.1 de la même loi est abrogé et remplacé par ce qui suit:***
55.1 In an action for infringement of a patent granted for a process for obtaining a new product, any product that is the same as the new product shall, in the absence of proof to the contrary, be considered to have been produced by the patented process.	*55.1 Dans une action en contrefaçon d'un brevet accordé pur un procédé relatif à un nouveau produit, tout produit qui est identique au nouveau produit est, en l'absence de preuve contraire, réputé avoir été produit par le procédé breveté.*

[111] With respect to these two treaties, TRIPS and NAFTA, I repeat what Strayer JA wrote in *Baker Petrolite Corp v Canwell Enviro-Industries Ltd*, 2002 FCA 158 at paragraph 25, that the *Implementation Acts* themselves do not give those treaties the force

of an Act of Parliament, except that they may be used to assist in interpretation of domestic legislation. The treaty cannot override the clear words used in a statute. He wrote:

> *25 I do not accept this argument for two reasons. First, article 1709(8) is a provision of the NAFTA. The NAFTA has been approved by An Act to Implement the North American Free Trade Agreement, S.C. 1993, c. 44, s. 10. However, this does not give the provisions of the NAFTA themselves the force of an Act of Parliament. I accept that an international treaty may, where relevant, be used to assist in interpreting domestic legislation. See, for example, Baker v. Canada (Minister of Citizenship and Immigration), [1999] 2 S.C.R. 817, at paragraphs 69 and 70. However, the international treaty cannot be used to override the clear words used in a statute enacted by Parliament. Section 78.4 is plain and obvious. Petrolite, I think, is relying on article 1709(8) of the NAFTA to give a restricted meaning to section 78.4 which its words cannot bear.*

[112] In any event, the "paramouncy" clause provided in subsection 55.2(5) of the *Patent Act* resolves any doubt; the wording of the *Patent Act* and *NOC Regulations* is paramount:

55.2 (5) In the event of any inconsistency or conflict between *(a) this section or any regulations made under this section, and* *(b) any Act of Parliament or any regulations made thereunder,*	*55.2 (5) Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.*

> *this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.*

[113] AstraZeneca argues that, even though the relevant provisions of TRIPS and NAFTA were not directly implemented into Canadian legislation or regulations, they should "inform" the interpretation of the *Patent Act* and *NOC Regulations*. In so doing, they rely on *National Corn Growers Assn v Canada (Import Tribunal)*, [1990] 2 SCR 1324. Gonthier J for the majority wrote at page 1371:

> *The first comment I wish to make is that I share the appellants' view that in circumstances where the domestic legislation is unclear it is reasonable to examine any underlying international agreement. In interpreting legislation which has been enacted with a view towards implementing international obligations, as is the case here, it is reasonable for a tribunal to examine the domestic law in the context of the relevant agreement to clarify any uncertainty. Indeed where the text of the domestic law lends itself to it, one should also strive to expound an interpretation which is consonant with the relevant international obligations.*

[114] The legislation in question in *Corn Growers*, supra, was legislation specifically designed to implement certain of Canada's treaty obligations respecting subsidization of imported grain. The Supreme Court was not making a pronouncement of such general application that, wherever a treaty may be found, even if not implemented in domestic legislation, it can "inform" the interpretation of that legislation.

[115] In any event, even if one were to take the position that the TRIPS and NAFTA treaties are to "inform" section 55.2 of the *Patent Act*, and section 8 of the *NOC Regulations*, AstraZeneca has been less than clear in its argument as to what should be the result. At best, as discussed with its Counsel in oral argument, it seems to be that the obligation to pay under section 8(1) is only triggered if there is an "abuse". There is no jurisprudence to assist as to what TRIPS or NAFTA considers an "abuse" to be. AstraZeneca argues that only an abuse of process would trigger an obligation to pay

and that simply to commence and follow through with an application for prohibition under section 6 of the *NOC Regulations* is not an “abuse”.

[116] I reject this argument. The *Corn Growers* decision, even if applicable, states that reference to a treaty is only to be made if the legislation is unclear. Here, section 8(1) is not unclear. It does not include the word “abuse” or anything referencing an activity that could be considered abusive. AstraZeneca wants to read in a word that is not there and a word that would fundamentally change the meaning of that provision. There is no merit to the argument.

[117] The Federal Court of Appeal recently considered a similar argument in *Fraser v Janes Family Foods Inc*, 2012 FCA 99 in dealing with whether the obligation to post security for costs under Federal Courts Rule 416 was contrary to certain NAFTA and TRIPS provisions. The Court held that NAFTA cannot override the clear provisions of the Rule. Nöel J for the Court wrote at paragraphs 19 and 22:

> *19 In my view, "interpreting" Rule 416(1)(a) as not applying in these circumstances would amount to "overriding" its application. The proposition set out by Justice Cromwell in Merck is simply that where a legislative enactment is open to two constructions, one which is consistent with Canada's treaty obligation and one which is not, the former should be preferred. It does not put into question the conclusion reached in Baker Petrolite that the NAFTA cannot "override" a clear legislative enactment.*
>
> . . .
>
> *22 Again as was stated in Baker Petrolite and Pfizer, the fact that a treaty is approved by an Act of Parliament does not give the provisions of the treaty the force of law. The only way in which Rule 1.1(2) could assist the appellants is if they could show that Rule 416(1)(a) is inconsistent with the Implementing Acts themselves.*

> [118] The only effect that TRIPS and NAFTA had respecting the *NOC Regulations* is that the compulsory licensing provisions relating to pharmaceuticals were repealed, and the present *NOC Regulations* were put in place. Binnie J wrote in *Biolyse, supra* at paragraph 10:
>
> > *10 In a reversal of policy, Parliament in 1993 repealed the compulsory licence provisions of the Patent Act by what became known as Bill C-91 (S.C. 1993, c. 2) and extinguished all compulsory licences issued on or after December 20, 1991. In part, these changes flowed from international obligations accepted by Canada under the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 299 ("TRIPS"). More immediately, perhaps, it was thought that Canada's compulsory licensing system would be declared incompatible with Canada's obligations under the North American Free Trade Agreement, Can. T.S. 1994 No. 2, in particular art. 1709(10), signed at the end of 1992.*
>
> [119] Thus, I find that neither TRIPS nor NAFTA are of any assistance to AstraZeneca in this case.

I agree with the analysis and conclusion of Justice Hughes and adopt these reasons as my own. In sum, Sanofi has not persuaded me that s. 8 is contrary to Canada's obligations under *TRIPS* or *NAFTA*.

XII. Conclusion

[56] In conclusion, I accept that, on a very liberal reading, the questions raised by Sanofi in this portion of the Teva and Apotex Actions have been properly (albeit indirectly) pleaded. However, I am not persuaded that any of the validity arguments raised by Sanofi should succeed. More specifically and in summary form, my conclusions are as follows:

(a) The question of whether s. 8 imposes liability on the first person prior to the commencement of a prohibition application is inapplicable to the facts of the Apotex Action, where Apotex does not seek any such recovery. With respect to the Teva Action, I have concluded that s. 8 does not permit recovery before the commencement of the statutory stay and, in any event, the appropriate date for the commencement of the period of liability (December 13, 2005) does not fall before the imposition of the statutory stay. Thus Sanofi's question does not arise on the facts before me.

(b) The question of whether s. 8 imposes liability on a first person for the period after the issuance of an NOC does not arise before me on the Teva Action, where the parties are agreed that the end date is the issuance of the NOC. In the Apotex Action, I have concluded that the effective dismissal of the last operative prohibition application was the same date as the issuance of the NOC to Apotex. Thus, the question of validity does not arise on the facts before me.

(c) The question of whether s. 8 imposes liability on the first person, while ignoring possible competition or unapproved indications, is a matter to be addressed on a fact-specific basis. In both the Teva Action and the Apotex Action, I agree with Sanofi that the "but for" world must include a consideration of whether it is more probable than not that other generics, including an authorized generic, would have entered the market during the period of liability. I have also concluded that, on the facts of both cases, there is no bar to Apotex or Teva recovering damages for the indications set out in the HOPE Patents. Sanofi's question need not be addressed, other than to say that well-understood principles of damages calculations will be applicable to the assessment of liability under s. 8.

(d) The Court of Appeal, in *Alendronate (FCA)*, responded completely to Sanofi's argument that recovery should not be permitted in circumstances where the generic would have infringed a valid patent.

(e) Adopting the reasoning of my colleague Justice Hughes, I conclude that s. 8 of the *Regulations* is not contrary to Canada's obligations under *TRIPS* or *NAFTA*.

[57] Costs of this portion of each of the Teva Action and Apotex Action will be awarded to Teva and Apotex as applicable. If the parties are unable to agree on costs, the matter will be dealt with together with and in the same manner set out in the Teva Reasons and the Apotex Reasons.

POSTSCRIPT

[1] These Reasons for Judgment are un-redacted from confidential Reasons for Judgment which were issued on May 11, 2012 pursuant to the Direction dated May 11, 2012.

[2] The Court canvassed counsel for the parties whether they had concerns if the reasons were issued to the public without redactions. On May 18, 2012, counsel for the Apotex Inc. (the plaintiff in T-1357-09) advised that there are no portions of the confidential Reasons for Judgment that should be redacted. No other party responded.

"Judith A. Snider"
Judge

Ottawa, Ontario
Public Reasons for Judgment May 23, 2012
Confidential Reasons for Judgment May 11, 2012

Extract from Notices of Constitutional Question

Sanofi questions the constitutional validity, applicability and operability of section 8 of the *Regulations.* In particular and without limiting the generality of the foregoing:

(a) Section 8 of the *Regulations* is unconstitutionally vague and ambiguous. Section 8 exposes a first person to losses suffered during a defined period but which losses may have no relationship to any activity of the first person. A vague regulation is unconstitutional because it forces the court to depart from its judicial role of interpreting legislation to that of legislator when the court attempts to give meaning to the legislation.

(b) Section 8 of the *Regulations* is draconian, harsh and punitive because the first person may have no control over the period of liability. The liability period is subject to manipulation by the second person. By its role in the regulatory process, the second person can affect the date when its drug submission is approvable by the Minister. In addition, the second person selects the date when a notice of allegation is made.

(c) Section 8 is invalid legislation delegated by Parliament to the Governor General in Council because Parliament could never have contemplated a regulation which is unreasonable, uncertain, and arbitrary. Particularly, section 8 imposes an absolute liability and is penal and confiscatory if there is

no requirement that fault be proven and/or an award under s. 8 can be granted even if the second person continues to infringe a valid patent. Thus, s. 8 can reward unlawful conduct.

(d) Section 8 of the *Regulations* is inoperative and of no force or effect because it is inconsistent with and contrary to Canada's treaty obligations under the North American Free Trade Agreement ("NAFTA") and the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") (Annex 1C to the Agreement Establishing the World Trade Organization) and the statutes implementing the treaties, the North American Free Trade Agreement Implementation Act, S.C. 1993, c. 44 (assented to June 23, 1993) and The World Trade Organization Agreement Implementation Act, S.C. 1994, c. 47 (assented to December 15, 1994). These statutes were implemented after the coming into force of s. 55.2(4) of the *Patent Act*, under which the *Regulations* were purportedly made. NAFTA and TRIPS require that Canada provide adequate and effective protection and enforcement of patent rights. Section 8 derogates from and is inconsistent with those requirements. In particular, while the *Regulations* were enacted to prevent abuse of the regulatory use exception provided by s. 55.2(1) of the *Patent Act*, s. 8 imposes potentially harsh remedies against a patentee, absent proof that the generic was improperly delayed market entry, namely, a finding that the patent is invalid and/or would not be infringed, so as to discourage reliance on the scheme provided by the *Regulations.*

(e) An interpretation of section 8 that permits recovery for losses before (i) the service of a notice of allegation or (ii) the issuance of a notice of application would result in the *Regulations* being *ultra vires*. In that regard, subsections 55.2(4) (c) and (d) of the *Patent Act* speak to disputes between patentees and those seeking a notice of compliance. No dispute arises until an application has been commenced so any remedy conferred for a time period before the commencement of an application is *ultra vires*.

(f) An interpretation of section 8 that permits recovery for losses without the proof of causation would result in the *Regulations* being *ultra vires*. The Governor in Council had no authority to exclude causation as a relevant element of the statutory cause of action created by section 8. To be valid legislation, section 8 must require that the second person prove that the first person caused all losses for which recovery is sought by the second person.

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET:	T-1161-07
STYLE OF CAUSE:	SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION AND SANOFI-AVENTIS DEUTSCHLAND GmbH v TEVA CANADA LIMITED
DOCKET:	T-1357-09
STYLE OF CAUSE:	APOTEX INC. v. SANOFI-AVENTIS et al
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	April 30, 2012 and May 1, 2012
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T-1161-07

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T-1357-09

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