Federal Court of Appeal  Cour d'appel fédérale

Date: 20140314

Dockets: A-191-12
A-193-12
A-397-12
A-474-12

Citation: 2014 FCA 68

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

Docket: A-191-12

BETWEEN:

APOTEX INC.

Appellant

and

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

Respondents

Docket: A-193-12

AND BETWEEN:

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

Appellants

and

APOTEX INC.

Respondent

Docket: A-397-12

AND BETWEEN:

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

Appellants

and

APOTEX INC.

Respondent

Docket: A-474-12

AND BETWEEN:

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

Appellants

and

APOTEX INC.

Respondent

Heard at Toronto, Ontario, on October 30 and 31, 2013.

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

REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	PELLETIER J.A.
DISSENTING REASONS BY:	MAINVILLE J.A.

Federal Court of Appeal  Cour d'appel fédérale

Date: 20140114

Dockets: A-191-12
A-193-12
A-397-12
A-479-12

Citation: 2014 FCA 68

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

Docket: A-191-12

BETWEEN:

APOTEX INC.

Appellant

and

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

Respondents

Docket: A-193-12

AND BETWEEN:

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

Appellants

and

APOTEX INC.

Respondent

Docket: A-397-12

AND BETWEEN:

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

Appellants

and

APOTEX INC.

Respondent

Docket: A-474-12

AND BETWEEN:

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

Appellants

and

APOTEX INC.

Respondent

REASONS FOR JUDGMENT

DISSENTING REASONS BY MAINVILLE J.A.

[1] These reasons concern:

a) An appeal (docket A-191-12) brought by Apotex Inc. ("Apotex") from a judgment of Snider J. of the Federal Court (the "Trial Judge") dated May 11, 2012 (the "Liability Judgment") issued for reasons cited as 2012 FC 553 and publicly released on May 23, 2012, which ordered compensation to be paid to pursuant to section 8 of the *Patented Medicines*

(Notice of Compliance) Regulations, SOR/93-133 ("*NOC Regulations*") for its net lost profits in respect of 1.25, 2.5, 5 and 10 mg capsules of its generic version of the drug ramipril for the period commencing April 26, 2004 and ending December 12, 2006.

b) A separate appeal (docket A-193-12) from the Liability Judgment brought by Sanofi-Aventis, Sanofi-Aventis Deutschland GmbH and Sanofi-Aventis Canada Inc. ("Sanofi").

c) An additional appeal (docket A-397-12) brought by Sanofi from a subsequent order and direction issued by the Trial Judge dated June 22, 2012 (the "Subsequent Ramp-Ups Order") which allowed a motion for reconsideration submitted by Apotex and which resulted in an amendment to the Liability Judgment.

d) A subsequent appeal (docket A-474-12), also brought by Sanofi, from a subsequent judgment of the Trial Judge dated November 2, 2012 (the "Final Quantum Judgment") which ordered, further to the Liability Judgment, the precise amount to be paid by Sanofi to Apotex, together with post-judgment interest.

A copy of these reasons shall be placed in the Court file with respect to each of these dockets as reasons therein.

[2] Apotex sells a generic version of ramipril in Canada. Ramipril is a drug principally used to treat hypertension but which also has other medical uses. Sanofi asserts patent rights to this drug

and to some of its uses, and it has for many years held a patent monopoly over this drug which it sold in Canada under the brand name ALTACE.

[3] To market a drug in Canada, a regulatory approval known as a notice of compliance ("NOC") must first be obtained under the terms of the *Food and Drug Regulations*, C.R.C., c. 870. In certain circumstances, the issuance of a NOC may require certain steps to be followed under the *NOC Regulations*. In this case, on April 26, 2004, Apotex could have received its NOC from the Minister of Health to market in Canada its generic version of ramipril. However, it was prevented from so doing until December 12, 2006 because of various applications made by Sanofi under subsection 6(1) of the *NOC Regulations* for orders prohibiting the Minister from issuing the NOC on the ground of its patent rights. Section 8 of the *NOC Regulations* provides, *inter alia*, that if an application under subsection 6(1) is unsuccessful, a patent holder, such as Sanofi, is liable to a third party, such as Apotex, for any loss suffered for the delay as determined in accordance with the Regulations. Apotex took the view that it was entitled to such compensation and, after a long trial, the Trial Judge agreed.

[4] The issues raised by these appeals principally concern the framework under which compensation may be determined under section 8 of the *NOC Regulations*. This is an issue which has not been previously fully addressed by our Court.

[5] As a preliminary technical observation, it is useful to note that the notice of appeal submitted by Sanofi in docket A-193-12 also seeks to appeal another judgment dated May 11, 2012 and issued for reasons cited as 2012 FC 551 (the "Validity Judgment") by which the Trial Judge dismissed all

the invalidity arguments raised by Sanofi with respect to section 8 of the *NOC Regulations*. That Validity Judgment applies to the litigation involving Sanofi and Apotex in Federal Court docket T-1357-09 and to the litigation involving Sanofi and Teva in Federal Court docket T-1161-07. The validity arguments with respect to both cases were heard by the Trial Judge simultaneously, and a single set of reasons was issued by the Trial Judge. Sanofi has also appealed the Validity Judgment with respect to the Teva litigation in docket A-192-12. This Court has dismissed the appeals related to the Validity Judgment for reasons issued concurrently and cited as 2014 FCA 69.

[6] Another judgment respecting liability under section 8 of the *NOC Regulations* with respect to ramipril and involving Sanofi and Teva was issued by the Trial Judge concurrently with the Liability Judgment concerning Sanofi and Apotex: *Sanofi-Aventis Canada Inc. v. Teva Canada Limited*, 2012 FC 552 (referred to herein as the "*Teva Liability Judgment (FC)*"). Some of the issues raised in the Liability Judgment concerning Apotex and in the *Teva Liability Judgment (FC)* are similar. Moreover, this Court heard the appeal from the *Teva Liability Judgment (FC)* two weeks before it heard this appeal involving Apotex, and has issued its reasons for judgment with respect to that appeal concurrently with these reasons: 2014 FCA 67.

[7] There are also two related appeals concerning amendments to proceedings and to the striking out of evidence (dockets A-462-11 and A-27-12) which have been dealt with by this Court in reasons issued concurrently: 2014 FCA 66.

The statutory and regulatory framework

[8] The applicable statutory and regulatory framework has been discussed in other judicial decisions, notably in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 ("*Biolyse*"); *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 ("*AstraZeneca*"); and *Merck Frosst Canada Ltd. v. Apotex Inc.*, 2009 FCA 187, 76 C.P.R. (4th) 1 ("*Alendronate*"). A brief overview of this framework follows.

[9] Prescription drugs present a particularly difficult regulatory challenge in light of the various public interest issues which they raise:

(a) prescription drugs must be safe for public consumption, and the health risks associated with their use must be understood and disclosed; these public interest issues are primarily dealt with through the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the *Food and Drug Regulations*;

(b) scientific research into new and better drugs must be encouraged and properly rewarded; this is primarily dealt with through the *Patent Act*, R.S.C. 1985, c. P-4; and

(c) the drugs must be accessible to the Canadian patients at prices which are affordable for the Canadian public; these public interest issues are primarily dealt through (i) those provisions of the *Patent Act* which ensure that generic manufacturers of drugs may reasonably access the market when a patent monopoly over a drug has expired; (ii) those provisions of the *Patent Act* which allow for the control of prices for patented medicines;

and (iii) provincial regulation of drug prices such as recently described in *Katz Group Canada Inc. v. Ontario (Health and Long-Term Care)*, 2013 SCC 64.

[10] The *Food and Drugs Act* sets up a regulatory structure through the *Food and Drug Regulations* to ensure that drugs marketed in Canada meet stringent health and safety requirements. Of particular interest for this appeal is Division 8 of Part C of the *Food and Drug Regulations* which establishes the regulatory process which must be followed by a manufacturer that wishes to introduce a new drug into the Canadian market.

[11] As a general rule, an innovator drug manufacturer must file with the Minister of Health a new drug submission setting out the information and material to enable the Minister to assess the safety and effectiveness of the new drug: subsection C.08.002 of the *Food and Drug Regulations*. This generally involves providing detailed reports of the tests made to establish the safety of the new drug and substantial evidence of its clinical effectiveness for the purpose and under the conditions of use recommended. It may be very costly and time consuming for an innovator drug manufacturer to gather the evidence and to carry out the testing required to satisfy the Minister as to the safety and effectiveness of the drug. Once approved on the basis of the information provided, the Minister of Health then issues a notice of compliance (often referred to as a "NOC") to the manufacturer of the new drug in respect to the submission. This NOC allows the manufacturer to sell and advertise the new drug.

[12] A major sector of the prescription drug manufacturing industry in Canada involves so-called "generic" drug manufacturers which generally manufacture and distribute what is sometimes known

in the trade as "copy-cat" drugs. These copied drugs are similar to those researched, developed and first brought to market by innovator drug manufacturers. As a general rule, a generic drug manufacturer may file an abbreviated new drug submission with the Minister of Health by which it compares its proposed copy-cat drug with a Canadian reference product, namely a drug for which a NOC has already been issued and which is marketed in Canada by the innovator of the drug: section C.08.002.1 of the *Food and Drug Regulations*. This allows the generic drug manufacturer to meet the safety and effectiveness requirements of the copy-cat drug by demonstrating that it is the pharmaceutical equivalent of, or is bioequivalent with, the Canadian reference product. In this way, the generic manufacturer avoids the costs of lengthy clinical trials with respect to its generic drug. Once approved on the basis of the information provided, the Minister of Health then issues a NOC to the generic drug manufacturer in respect to the submission. This NOC allows the generic drug manufacturer to sell and advertise the copy-cat drug.

[13] Because generic drug manufacturers generally do not have significant research and testing costs with respect to a copy-cat drug, they may sell that drug at a considerable discount on the market, at considerable savings for the Canadian public, but with significant impacts on the revenues and profits of the innovator drug manufacturer. Innovator drug manufacturers are not however without legal recourse against these generics drug manufacturers where the copied innovator drug is subject to a monopoly resulting from the application of the *Patent Act*.

[14] The basic scheme of the *Patent Act* is conceptually simple: an inventor who discloses the workings of an invention to the public may receive a patent which ensures a 20 year monopoly on

the making, use and marketing of the invention. This basic scheme also applies to prescription drugs.

[15] In light of the importance of patented drugs with respect to human health, the *Patent Act* includes a number of provisions seeking to restrict potential abuses of the patent monopoly with respect to a drug. As an example, the Patented Medicine Prices Review Board "may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive": ss. 83(1) of the *Patent Act*.

[16] Between 1923 and 1993, Canada's policy was to make patented medicines available to generic drug manufacturers through a scheme of compulsory licensing. In determining the terms of the licence and the amount of royalties payable, the Commissioner of Patents was required to balance the desirability of making the medication affordably available to the public with rewarding the patentee for the research leading to the invention. This approach was not favoured by innovator drug manufacturers because they believed that it generally precluded recovery of important costs for the research programs required to produce a few marketable drugs from many false starts and failed research projects.

[17] In 1993, the compulsory licensing regime was repealed and replaced by the early working exception in section 55.2 of the *Patent Act*. As noted by Binnie J. in *AstraZeneca* at para. 13, the problem which section 55.2 sought to address is that if a generic drug manufacturer waits to begin its preparation of a copy-cat drug for approval under the *Food and Drug Regulations* until the

innovator's patent to the comparator drug expires, the *Food and Drug Regulations* approval process could add up to two years to the effective monopoly of the patent owner under the *Patent Act*. Without section 55.2, if the generic drug manufacturer tries to work the patented drug prior to the expiry of the patent, even if solely to satisfy the requirements of the *Food and Drug Regulations* for a NOC, it will infringe the patent, thus inviting litigation from the patent owner.

[18] Section 55.2 of the *Patent Act* reads as follows:

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 that regulates the manufacture, construction, use or sale of any product.	**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 construction, l'utilisation ou la vente d'un produit.
(2) and (3) [Repealed, 2001, c. 10, s. 2]	(2) et (3) [Abrogés, 2001, ch. 10, art. 2]
(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	(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*) 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	*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

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;

sur lesquels porte un brevet, d'avis, de certificats, de permis ou de tout autre titre à quiconque n'est pas le breveté;

(*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;

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*) 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;

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;

(*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

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*) 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.

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.

(5) In the event of any inconsistency or conflict between

(5) Une disposition réglementaire prise sous le régime du présent article

(*a*) this section or any regulations made under this section, and	prévaut sur toute disposition législative ou réglementaire fédérale divergente.
(*b*) any Act of Parliament or any regulations made thereunder, this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.	
(6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.	(6) Le paragraphe (1) n'a pas pour effet de porter atteinte au régime légal des exceptions au droit de propriété ou au privilège exclusif que confère un brevet en ce qui touche soit l'usage privé et sur une échelle ou dans un but non commercial, soit l'utilisation, la fabrication, la construction ou la vente d'une invention brevetée dans un but d'expérimentation.

[19] The *NOC Regulations* were adopted pursuant to section 55.2 of the *Patent Act*. Section 4 of these Regulations allows an innovator drug manufacturer who files a new drug submission to also submit to the Minister of Health a patent list relating to the submission. A patent on this list may then be added to a register of patents maintained by that Minister under subsection 3(2) of the Regulations.

[20] A generic drug manufacturer which files a submission for a NOC in respect of a drug (usually in the form of an abbreviated new drug submission) and which compares that drug with another drug marketed in Canada under another NOC must indicate in its submission, with respect to each patent listed on the register for the other drug, either that it accepts that it will not obtain the Minister's NOC until the patent expires, or allege (through what is known as a notice of allegation

or "NOA") that the patent is not valid or would not be infringed, and include, *inter alia*, a detailed statement of the legal and factual basis for the allegation: section 5 of the *NOC Regulations*.

[21] An innovator drug manufacturer that is served with such a notice of allegation may, within 45 days, apply to the Federal Court for an order prohibiting the Minister of Health from issuing a NOC to the generic drug manufacturer until after the expiration of a patent that is the subject of the notice: subsection 6(1) of the *NOC Regulations*. The initiation of this application for prohibition automatically triggers a 24-month delay (or "statutory freeze") that prevents the Minister of Health from issuing a NOC to the generic drug manufacturer unless, within that period, the prohibition application is finally dismissed by the court or is otherwise withdrawn or discontinued: para. 7(1)(*e*) and ss. 7(4) of the *NOC Regulations*. As noted by Binnie J. in *Biolyse* at para. 24:

> It is important to note that under this procedure, the court hearing the prohibition application has no discretion to lift the stay even if it thinks the innovator's case for interim relief is weak. Nor does the court have a discretion to leave the contending parties to their remedies under the *Patent Act*. The "second person"'s [the generic's] application for a NOC simply goes into deep-freeze until the statutory procedures have played themselves out. For these reasons, Iacobucci J. described the regime as "draconian" in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, at para. 33.

[22] If the innovator drug manufacturer is successful in the prohibition proceeding, the Minister of Health is prohibited from issuing to the generic drug manufacturer a notice of compliance for its generic drug until the relevant patent has expired. If the generic drug manufacturer is successful, the Minister may then issue a notice of compliance for the generic version of the drug. Whatever the outcome of the proceeding under the *NOC Regulations*, patent validity and patent infringement proceedings under the *Patent Act* may be initiated or continued by the parties before any competent court: *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129 at paras. 95-96; *Merck Frosst*

Canada Inc. v. Canada (Minister of National Health and Welfare) (1994), 55 C.P.R. (3d) 302 (F.C.A.) at pp. 319-20; *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 F.C. 588 (C.A.) at p. 600.

[23] A compensation mechanism has been set out in the *NOC Regulations* in the event that the innovator's prohibition application made under subsection 6(1) of the Regulations is withdrawn, discontinued or dismissed by the court. That mechanism is described in section 8 of the *NOC Regulations*, which is reproduced below:

8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person [the innovator] 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 [the innovator] is liable to the second person [the generic] for any loss suffered during the period	**8.** (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne [l'innovateur] ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne [l'innovateur] est responsable envers la seconde personne [le manufacturier générique] de toute perte subie au cours de la période :
(*a*) 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	*a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut :
(i) the certified date was, by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, chapter 23 of the Statutes of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or	(i) soit que la date attestée est devancée en raison de l'application de la *Loi modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique)*, chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée,

(ii) a date other than the certified date is more appropriate; and

(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

(2) A second person [the generic] may, by action against a first person [the innovator], apply to the court for an order requiring the first person [the innovator] to compensate the second person [the generic] 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 [the innovator] 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 [the innovator] to compensate a second person [a generic] 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 [innovator] or second [generic] person which contributed to delay the disposition of the application under subsection 6(1).

(ii) soit qu'une date autre que la date attestée est plus appropriée;

b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

(2) La seconde personne [le manufacturier générique] peut, par voie d'action contre la première personne [l'innovateur], demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).

(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne [l'innovateur] a institué ou non une action en contrefaçon du brevet visé par la demande.

(4) Lorsque le tribunal enjoint à la première personne [l'innovateur] de verser à la seconde personne [le manufacturier générique] une indemnité pour la perte visée au paragraphe (1), il peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts à l'égard de cette perte.

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne [l'innovateur] ou de la seconde personne [le manufacturier générique] qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

(6) The Minister is not liable for damages under this section.	(6) Le ministre ne peut être tenu pour responsable des dommages-intérêts au titre du présent article.

Background

[24] The background to the litigation and the pertinent facts are set out in the reasons of the Trial Judge and need not be repeated in full here. It suffices for the purposes of this appeal to highlight some of the most salient facts.

[25] For the purposes of this litigation, Sanofi may be considered an innovator drug manufacturer, while Apotex may be viewed as a generic drug manufacturer. Sanofi, either as a patentee or licensee, holds rights under various Canadian patents that relate to ramipril, which it sells under the brand name ALTACE. Ramipril is a drug which is primarily used to treat hypertension, but whose medical use has expanded over the years to include heart related health issues following a "Heart Outcomes Prevention Evaluation" ("HOPE") study published in the year 2000 which found that "[t]reatment with ramipril reduced the rates of death, myocardial infarction, stroke, coronary revascularization, cardiac arrest, and heart failure as well as the risk of complications related to diabetes and of diabetes itself": HOPE study at p. 150 as cited in the Trial Judge's Reasons at para. 277. The term "HOPE indications" has come to be associated with the patient profiles from the HOPE study where vascular protection was demonstrated: *Ibid*.

[26] The initial Canadian patent for ramipril was Patent No. 1,187,087 issued May 14, 1985 and which expired May 14, 2002, after 17 years of patent monopoly as the *Patent Act* then provided. With the pending expiration of this initial patent, many generic drug manufacturers became

interested in marketing their own generic versions of ramipril, including Apotex. The Trial Judge found that "Sanofi, in efforts to extend patent protection for ramipril, proceeded to obtain a further series of patents and protect those patents through listing on the Patent Register": Trial Judge's Reasons at para. 26. Sanofi described these efforts as "Altace Lifecycle Management", while the generic manufacturers referred to these as "evergreening": *Ibid*. A considerable amount of litigation under the *NOC Regulations* ensued with respect to these further patents.

[27] The Trial Judge provided a chart at paragraph 27 of her Reasons setting out the list of subsequent patents involving ramipril and its uses. It is useful to reproduce this chart here:

Canadian Patent No.	**Issue Date**	**Patent Register Listing**	**Subject Matter/Indications**
1,246,457 (the '457 Patent)	December 13, 1988 (expired December 13, 2005)	February 21, 2001	Ramipril for the treatment of cardiac insufficiency
1,341,206 (the '206 Patent)	March 20, 2001	April 11, 2001	Composition-of-matter patent
2,055,948 (the '948 Patent)	November 12, 2002	June 25, 2004	Use of ramipril together with a calcium antagonist for the treatment of proteinuria
2,023,089 (the '089 Patent)	January 14, 2003	November 10, 2003	Use of ramipril in the treatment of cardiac and vascular hypertrophy and hyperplasia
2,382,549 (the '549 Patent)	March 15, 2005	March 17, 2005	Use of ramipril in the prevention of cardiovascular events
2,382,387 (the '387 Patent)	June 21, 2005	June 28, 2005	Use of ramipril in the prevention of stroke, diabetes and/or congestive heart failure

The last two patents in this list, the '549 and '387 Patents, are referred to as the "HOPE patents".

[28] The Trial Judge also provided, at paragraph 29 of her Reasons, a useful chart briefly describing the results of the litigation under the *NOC Regulations* with respect to ramipril and involving Sanofi and Apotex. It is also useful to reproduce this chart here:

Patent No.	**Notice of Allegation**	**Notice of Application/Court File No.**	**Outcome**
'206 Patent	June 20, 2003	September 23, 2003/T-1742-03	Mactavish J. dismisses on September 20, 2005 (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283, 278 FTR 1 [*Ramipril NOC #1 (FC)*])
'457 Patent	August 20, 2003 (non-infringement)	October 8, 2003/T-1851-03	Simpson J. issues Prohibition Order until expiry of '457 Patent on October 6, 2005 [*Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1381, 44 C.P.R. (4th) 90] [*Ramipril NOC #2 (FC)*]
'457 Patent	November 10, 2003 (invalidity)	December 29, 2003/T-2459-03	Tremblay-Lamer J. dismisses on November 4, 2005 (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1504, 283 FTR 171 [44 C.P.R. (4th) 108] [*Ramipril NOC #3 (FC)*])
'089 Patent	November 17, 2003	January 5, 2004/T-11-04	von Finckenstein J. dismisses on October 27, 2005 (*Aventis Pharma Inc v Apotex Inc*, 2005 FC 1461, 283 FTR 1 [*Ramipril NOC #4 (FC)*])
'948 Patent	June 28, 2004	August 16, 2004/T-1499-04	Order of Dismissal, on Consent, dated on June 27, 2006 [*Ramipril NOC #5 (FC)*]
'549, '387 Patents (HOPE Patents)	November 29, 2005	January 17, 2006/T-87-06	By Order, Aalto P. dismisses as moot on May 2, 2008 [*Ramipril NOC #6 (FC)*]

The Reasons of the Trial Judge

[29] The Trial Judge provided detailed reasons reaching over 115 pages. The salient aspects of those reasons may be summarized as follows.

[30] Subject to the validity issues dealt with by the Trial Judge in the Validity Judgment, Sanofi acknowledged at trial that Apotex was entitled to compensation pursuant to section 8 of the *NOC Regulations*: Trial Judge's Reasons at para. 4. The debate before the Trial Judge consequently concerned primarily how such compensation was to be determined.

[31] The Trial Judge saw her task as one of assessing the compensation owed by considering what would have happened if Sanofi had not brought applications for prohibition against Apotex. The answer to this question required the Trial Judge to "construct a hypothetical, or 'but for', world during a defined period of time in the past in order to determine what share of the ramipril market Apotex would have captured if it had been able to sell its generic ramipril" during that period: Trial Judge's Reasons at para. 6 (emphasis in original).

Start and end dates of the section 8 liability period

[32] This appeal involves many issues relating to the determination of the period contemplated by paragraphs 8(1)(*a*) and (*b*) of the *NOC Regulations*. For ease of reference, I will refer to that period as the "section 8 liability period".

[33] After identifying the issues and setting out the regulatory and factual background to the litigation, the Trial Judge first dealt with the determination of the relevant section 8 liability period during which the compensation should be calculated in this case.

[34] The Trial Judge noted that paragraph 8(1)(*a*) of the *NOC Regulations* establishes the start date for the period as "the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations". The parties agreed in this case that the date certified by the Minister was April 26, 2004, the so-called "patent hold" date with respect to Apotex's generic version of ramipril: Trial Judge's Reasons at paras. 38 and 40.

[35] The Trial Judge also noted that paragraph 8(1)(*a*) nevertheless allows the court to determine if "a date other than the certified date is more appropriate". Sanofi argued that the Trial Judge should exercise her discretion in this respect so as to set the start date on December 13, 2005, which was the expiration date of Sanofi's '457 Patent concerning the use of ramipril for the treatment of cardiac insufficiency. Sanofi's argument to justify this subsequent date was founded on the existence of a prohibition order based on that patent issued by Simpson J. under subsection 6(2) of the *NOC Regulations* in *Ramipril NOC #2 (FC)*. Since the application upon which this prohibition order was based was never withdrawn, discontinued, dismissed or reversed on appeal, Sanofi submitted to the Trial Judge that Apotex had no claim to compensation under section 8 until the effect of that prohibition order ended, *i.e.* until the expiry of the '457 Patent on December 13, 2005.

[36] The Trial Judge disagreed with Sanofi, largely on the ground that less than 30 days after Simpson J. had issued the prohibition order, Tremblay-Lamer J. found the '457 Patent to be invalid

within the framework of another proceeding which dismissed another of Sanofi's prohibition applications in *Ramipril NOC #3 (FC)*. In the Trial Judge's view, the decision of Tremblay-Lamer J. effectively "unlocked" the door for Apotex to receive a NOC irrespective of the '457 Patent, with the logical result that the prohibition order issued by Simpson J. had been subsumed or "trumped" by the subsequent decision, and was therefore no longer enforceable or of any practical effect: Trial Judge's Reasons at paras. 47-48.

[37] This reasoning lead the Trial Judge to conclude that April 26, 2004, the date of Apotex's patent hold, was the appropriate date to begin the section 8 liability period in this case: Trial Judge's Reasons at para. 55.

[38] With respect to the end date of the section 8 liability period, the Trial Judge noted that paragraph 8(1)(*b*) of the *NOC Regulations* provides that the liability period ends on "the date of the withdrawal, the discontinuance, the dismissal or the reversal" of the prohibition proceeding. However, in this case, there were multiple patents registered by Sanofi under the *NOC Regulations* with respect to ramipril, and five different dismissal dates relating to five separate prohibition applications involving Sanofi and Apotex. Moreover, the Trial Judge noted that the case also presented a "very unusual situation in which the second person [Apotex] received an NOC prior to the disposition of the last prohibition proceeding": Reasons at para. 57.

[39] In light of the particular factual situation, Apotex urged the Trial Judge to conclude, on a plain reading of paragraph 8(1)(*b*), that the end of the period should be set to May 2, 2008, the date Prothonotary Aalto dismissed as moot the last prohibition proceeding involving Sanofi and Apotex

under section 6 of the *NOC Regulations* in *Ramipril NOC # 6 (FC)*. Sanofi rather favoured the date of June 27, 2006, the date it said Apotex ceased to be a "second person" with respect to the HOPE patents. The Trial Judge rejected both submissions and rather found that the appropriate date to end the section 8 liability period in this case was December 12, 2006, the date the Minister of Health issued a NOC to Apotex for its generic version of ramipril.

[40] The Trial Judge rejected Apotex's argument that the end date of the section 8 liability period should be the date of the formal dismissal of the last prohibition application on May 2, 2008. She did so on her finding that the application became moot when the NOC was issued to Apotex on December 12, 2006.

[41] The Trial Judge also rejected Sanofi's proposed end date of June 27, 2006. Sanofi had submitted that this date was that of the dismissal of the "last true" prohibition proceeding involving ramipril in *Ramipril NOC # 5 (FC)*. Sanofi had initiated prohibition proceedings against Apotex with respect to its HOPE patents; however, as a result of the decision of the Supreme Court of Canada in *AstraZeneca*, the Minister of Health took the position that Apotex did not need to address these HOPE patents since Apotex was not seeking a NOC for uses specified in these HOPE patents. As a result, for the purposes of section 8 compensation determinations, Sanofi took the position that Apotex was never a "second person" under the *NOC Regulations* with respect to the HOPE patents, and that consequently the last "valid" prohibition proceeding which was withdrawn or dismissed was in *Ramipril NOC #5 (FC)* on June 27, 2006.

[42] The Trial Judge dismissed Sanofi's argument on the ground that it was based on a misreading of *AstraZeneca* and of the decision of Hughes J. in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, [2008] 1 F.C.R. 19, aff'd 2007 FCA 276 ("*Ferring*"). In the Trial Judge's view *AstraZeneca* established that a generic drug manufacturer is not required to address patents listed by the innovator drug manufacturer after the generic drug manufacturer submits its abbreviated new drug submission, because the generic manufacturer will not have early-worked that patent. *AstraZeneca* did not decide or imply that a generic drug manufacturer would be unable to claim compensation under section 8 of the *NOC Regulations* when an innovator actually commences a prohibition proceeding in respect of a patent that the generic drug manufacturer should not have been required to address: Trial Judge's Reasons at paras. 70 and 71.

[43] The Trial Judge acknowledged that the decision of Hughes J. in *Ferring* appeared to support Sanofi's view: Trial Judge's Reasons at para. 73. However, she was of the view that the issue in *Ferring* had been unnecessarily framed in terms of whether the generic manufacturer is a "second person", and that in *Ferring* "Justice Hughes was not asked to consider, nor did he consider, whether [*AstraZeneca*] would strip Apotex of its claim to damages under s. 8": Trial Judge's Reasons at para. 75.

[44] Applying her own contextual analysis to the *AstraZeneca* and *Ferring* decisions and to the overall structure of the *NOC Regulations*, the Trial Judge concluded that, in this case, Apotex was a second person in relation to the HOPE patents until December 12, 2006, when the Minister of Health decided to issue a NOC to Apotex notwithstanding the pending prohibition proceedings initiated by Sanofi with respect to those patents, thus confirming that Apotex was no longer a

second person with respect to those patents only as of that date: Trial Judge's Reasons at paras. 77 and 78. She found this approach to be consistent with the purpose of section 8 which is to "compensate a second person for the loss occasioned by the operation of the statutory stay": Trial Judge's Reasons at para. 79.

[45] The Trial Judge consequently concluded that the relevant section 8 liability period in this case was April 26, 2004 to December 12, 2006: Trial Judge's Reasons at para. 83.

The hypothetical ramipril market

[46] Having determined the relevant section 8 liability period, the Trial Judge proceeded to assess Apotex's loss of profits during that period by (a) estimating the size of the total ramipril market during the period; (b) estimating the portion of the ramipril market that would have been acquired by generic drug manufacturers during the period; and c) estimating the share of that generic market which would have accrued to Apotex: Trial Judge's Reasons at para. 84.

[47] Based on the expert reports and the evidence submitted, the Trial Judge adopted the analysis of Dr. Hollis to quantify both the size of the ramipril market as a whole (Trial Judge's Reasons at paras. 97 to 104) and of the generic ramipril market (Trial Judge's Reasons at paras. 107 and 108 and 113 to 123) during the relevant section 8 liability period.

[48] One difficult question for the Trial Judge concerned the determination of the generic ramipril market during the section 8 liability period, and particularly whether that market should be assessed on the basis of a single "but for" world. Sanofi submitted that there can be only one "but

for" world that should apply to all claims of all concerned generic drug manufacturers under section 8 of the *NOC Regulations*. In Sanofi's view, to decide otherwise would lead to overcompensation and inappropriate windfalls under section 8 for the generic drug manufacturers: Trial Judge's Reasons at paras. 128-129. In light of the importance of this issue for the purposes of this appeal, it is useful to set out fully the Trial Judge's reasons for discarding the "one but for world" approach:

> [132] I do not disagree with Sanofi's arithmetic. I also acknowledge that, if this were to happen, the result would be, if not "absurd", at least questionable. That said, Sanofi's argument contains a number of flaws.
>
> [133] The first issue that I take with Sanofi's argument is that it misrepresents Apotex's position. Apotex is not arguing that the hypothetical world under the *Regulations* must consider Apotex to be a sole-source manufacturer with no competitors throughout the Relevant Period. Rather, as I understand Apotex's argument, Apotex is submitting that other entrants in the market must be considered on a case-by-case basis.
>
> [134] While I agree with Sanofi that the "but for" world must consider the inclusion of potential competitors, I do not go so far as Sanofi asserts. In other words, I reject Sanofi's urging that I establish one "but for" world that will apply in this case and in any others involving the genericization of ramipril.
>
> [135] The assessment of damages can and should be made on the facts of each case. To the extent that there are common elements that impact on the quantification of damages, these will more likely than not come forth during the trial.
>
> [136] Another serious flaw in Sanofi's argument is that the evidence in one case may establish a different Relevant Period than in another case. This will impact on many elements of the assessment of damages. In this case, for example, I have determined that Apotex would have entered the market on April 26, 2004. This finding means that different considerations will come into play with respect to the possible entry of an authorized generic than if I had concluded that an entry date of December 13, 2005 was more appropriate. In the companion Teva case (Court File No. T-1161-07), I have concluded that a different Relevant Period is established and different considerations were relevant. Following Sanofi's urging would accordingly require that I disregard evidence in either Teva's case or this one.
>
> [137] By their very nature, damages in this action are hypothetical. It follows that estimates must be made and a market constructed that will not be perfect. As I re-write history, hypotheses must be constructed and evaluated. Those

> hypotheses will necessarily change depending on the facts of each case. I am striving to be reasonable and fair – I cannot achieve perfection. As pointed out by Lord Shaw in *Watson, Laidlaw & Co Ld v Pott, Cassels, and Williamson* (1914), 31 RPC 104 at 118 (HL):
>
> > The restoration by way of compensation is therefore accomplished to a large extent by the exercise of a sound imagination and the practice of the broad axe.
>
> [138] With respect to ramipril, Sanofi has identified only Teva, Apotex and Riva as participants in the "but for" world. I am quite certain that the damages in those three actions will not be greatly – if at all – in excess of the award of damages that would be made had the three cases been joined and one "but for" world established. Since Sanofi is the defendant in all three cases, it is well aware of the total damages being claimed. If that amount raised a real threat that Sanofi's total liability would exceed the bounds of rationality, Sanofi could urge the Court to consider an adjustment to the compensation pursuant to s. 8(5) of the *Regulations*.
>
> [139] There may be a situation where Sanofi's fear has some merit. It certainly is not this case.

[49] The Trial Judge then proceeded to determine from the evidence before her which generic drug manufacturers would enter the hypothetical market during the section 8 liability period, and the timing of their respective market entries.

[50] She assumed that Apotex would have entered the market as of the beginning of the section 8 liability period on April 26, 2004.

[51] The Trial Judge reached a number of conclusions with respect to the participation in the hypothetical market of Teva, Riva and an authorized generic. These conclusions are summarized below.

Teva

[52] The Trial Judge found that Teva would have entered the market only on August 1, 2006. Teva had filed its abbreviated new drug submission for its own generic version of ramipril on December 24, 2001, but it had also indicated pursuant to para. 5(1)(*a*) of the *NOC Regulations* that it would await the expiry of Sanofi's '457 Patent (ramipril for the treatment of cardiac insufficiency) set for December 13, 2005, and it provided no notice of allegation with respect to that patent pursuant to paragraph 5(1)(*b*) of the *NOC Regulations*. As a result, the Trial Judge found that Teva's earliest market entry date would be December 13, 2005: Trial Judge's Reasons at paras. 154-155. This date was in fact the one the Trial Judge used to determine Teva's market entry in her judgment concerning the similar section 8 compensation claims of Teva against Sanofi in the *Teva Liability Judgment (FC)* at para. 75.

[53] However, the Trial Judge did not use this date on the ground that within the context of the section 8 compensation claims of Apotex, all other generic drug manufacturers within the hypothetical market, including Teva, were to be presumed bound by the *NOC Regulations*, and that their respective market entry had to be determined, for the purposes of the hypothetical market, by taking into account the regulatory impediments established by those Regulations: Trial Judge's Reasons at para. 152.

[54] Applying this methodology, the Trial Judge reiterated that Teva had initially submitted an abbreviated new drug submission for its generic version of ramipril on December 24, 2001, and it acknowledged then that the issuance of its NOC would await the expiry of Sanofi's '206 and '457 Patents. Thus, Teva's market entry was delayed for a considerable period of time because of that

initial choice. It was not until September of 2005 that Teva submitted a notice of allegation with respect to the '206 Patent. The prohibition application that followed was dismissed on September 25, 2006: Trial Judge's Reasons at paras. 154 and 156 to 158. The Trial Judge nevertheless found that similar earlier prohibition proceedings respecting the '206 Patent and involving Laboratoire Riva Inc. ("Riva") would have concluded, hypothetically, with the dismissal of the proceedings in favour of Riva no later than July of 2006: Trial Judge's Reasons at para. 159.

[55] In the Trial Judge's view, Teva, in the hypothetical market, would have been able to rely on the Riva proceedings to seek an earlier dismissal of Sanofi's prohibition proceedings against it within days of the dismissal. As a result, the Trial Judge concluded that Teva would have been able to come to market on or about August 1, 2006: Trial Judge's Reasons at para. 160.

Riva

[56] The Trial Judge found that though Riva's "patent hold" date was June 18, 2004, it could not have entered the hypothetical generic ramipril market before June 21, 2007, and thus only after the section 8 liability period with respect to Apotex had expired. As a result, Riva would not have been a participant in the hypothetical market during the relevant section 8 liability period: Trial Judge's Reasons at para. 168. The Trial Judge came to that conclusion by applying the same methodology she used to determine Teva's market entry, namely that all other generic drug manufacturers except Apotex were to be presumed to be bound by the *NOC Regulations* in the hypothetical market, and that their respective market entry would largely depend on how they would have navigated these Regulations: Trial Judge's Reasons at para. 161.

[57] Riva had submitted its abbreviated new drug submission for its generic version of ramipril on June 8, 2004 and had a "patent hold" date of June 18, 2004. However, it had cross-referenced its own application under the *NOC Regulations* to that of Pharmacience Inc. ("Pharmascience"): Trial Judge's Reasons at paras. 163-164. Health Canada had informed Riva that it would not receive a NOC for its generic version of ramipril in advance of Pharmacience as a result of this cross-reference; Health Canada did not change its position until June 21, 2007: Trial Judge's Reasons at paras. 165 and 166. Applying her methodology requiring all other generic drug manufacturers to navigate the *NOC Regulations*, the Trial Judge concluded from these circumstances that "Riva could not have entered the ramipril market before Health Canada changed its position on Riva's cross-reference ANDS" on June 21, 2007: Trial Judge's Reasons at para. 167.

Authorized generic

[58] The Trial Judge described an "authorized generic" as a "drug that is manufactured by an innovative drug company – in this case, Sanofi – but sold by a generic company under the generic's name": Trial Judge's Reasons at para. 170. The Trial Judge noted that the approval process under the *Food and Drug Regulations* for an authorized generic is quite simple and swift. She also noted that the advantage for an innovator of using an authorized generic is to "recoup some of the market that has been lost to generics": Trial Judge's Reasons at para 171.

[59] The Trial Judge rejected Apotex's submission that section 8 of the *NOC Regulations* must be interpreted as precluding the presence of an authorized generic. She reached this conclusion by (a) accepting Sanofi's submission that the *NOC Regulations* themselves contemplate an authorized generic in subsection 7(3), and (b) noting that this issue had been considered by the Governor in

Council when adopting amendments to the *NOC Regulations* and resolved in favour of the innovators: Trial Judge's Reasons at paras. 176 to 179.

[60] The Trial Judge then found, based on the evidence submitted, that it was more likely than not that Sanofi would have decided to launch an authorized generic in the hypothetical market: Trial Judge's Reasons at paras. 181 to 190. However, the Trial Judge also found that, in the hypothetical market, Apotex would not have been impeded by the *NOC Regulations*; consequently, Apotex's launch of its generic version of ramipril would have been a surprise for Sanofi since no prior notice of proposed market entry (as required by those regulations) would have been provided to Sanofi: Trial Judge's Reasons at paras. 192 to 196. This surprise launch would have been followed within 3 months by the market entry of an authorized generic, namely by July 26, 2004: Trial Judge's Reasons at paras. 197 to 202.

[61] Within this hypothetical generic ramipril market comprising Apotex (entering as of April 26, 2004), an authorized generic (entering as of July 26, 2004) and Teva (entering as of August 1, 2006), the Trial Judge then proceeded to determine Apotex's market share taking into account the different timing for the market entrance of each generic drug manufacturer. She did not accept any of the expert evidence which had been submitted with respect to this issue (Trial Judge's Reasons at paras. 207 and 214), concluding instead that the "allocation of market share amongst the generic entrants appears to be too complex to estimate with any accuracy": Trial Judge's Reasons at para. 215. Relying on an internal Sanofi market analysis report, the Trial Judge estimated Apotex's share of the hypothetical generic ramipril market as follows (Trial Judge's Reasons at paras. 216 to 219):

> a) 100% of the hypothetical generic market for the period of April 26, 2004 to July 26, 2004 when Apotex is alone in that market;

> b) 70% of the hypothetical generic market for the short period of a few days from July 26, 2004 to August 1, 2004 when Apotex and the authorized generic are the only participants in that market;
>
> c) 50% of the hypothetical generic market for the period from August 1, 2006 to December 12, 2006 when Apotex, Teva and the authorized generic are sharing that market.

[62] The Trial Judge then addressed the methodology to calculate Apotex's lost gross sales of its generic version of ramipril, determining quite simply that it corresponded to the number of capsules it would have sold during the section 8 liability period multiplied by the prices at which it would have sold those capsules: Trial Judge's Reasons at para. 227. After discussing how drugs are priced (Trial Judge's Reasons at paras. 228 to 235), she concluded that Apotex's generic version of ramipril would be sold for a price equivalent to the following percentage of the listed price of ALTACE (the innovator version of ramipril marketed by Sanofi): (a) 70% from April 26, 2004 to July 26, 2004; and (b) 65% from July 26, 2004 to December 12, 2006: Trial Judge's Reasons at para. 236.

[63] The experts for both parties essentially agreed on the methodological approach to estimate Apotex's lost profits on these lost gross sales, except with respect to three items, namely sales returns, trade spends and cost of the active pharmaceutical ingredient: Trial Judge's Reasons at paras. 238 to 240. No issue has been raised in this appeal with respect to these concerns, and so it is not necessary to explain further the findings of the Trial Judge with respect to them.

[64] An important adjustment was requested by Apotex with respect to additional compensation for what was referred to as a "double ramp-up". The term "ramp-up" refers to the period of time that it takes a drug manufacturer to penetrate the market to its full potential. In the hypothetical market,

Apotex would have experienced a ramp-up period. However, Apotex submitted that in the real market, it also experienced a ramp-up period when it was finally authorized to sell its generic version. By taking into account a ramp-up in the hypothetical market without compensating it for the ramp-up actually experienced in the real market, Apotex suffers a loss of profits which it would not otherwise have incurred: Trial Judge's Reasons at paras. 265 to 267. These losses are not insignificant: *Ibid.* at para. 268.

[65] The Trial Judge rejected this double ramp-up claim on the ground that since it was a loss occurring after the section 8 liability period, it was precluded from compensation under section 8 of the *NOC Regulations* as a result of the principles established in *Alendronate* at paras. 99 to 102, where this Court found that section 8 does not include compensation for losses suffered outside the section 8 liability period: Trial Judge's Reasons at paras. 269 to 270.

[66] A final issue dealt with by the Trial Judge concerned Sanofi's submission that Apotex's compensation under section 8 of the *NOC Regulations* cannot extend to sales of its generic version of ramipril for unapproved indications, notably the HOPE indications.

[67] The Trial Judge found that, in the hypothetical market, Apotex would not have included in its product monograph for its generic version of ramipril a reference to anything other than hypertension; nevertheless, some sales of that generic product would have related to HOPE indications: Trial Judge's Reasons at paras. 280 and 281. She refused to discard these sales from the calculation of Apotex's section 8 compensation on the grounds that (a) generic products are not promoted for specific uses, but rather sold as drug products; (b) off-label prescribing and

substitution commonly take place and there appears to be nothing illegal about this practice; (c) Sanofi has not opposed in the real world the listing of Apotex's generic version of ramipril as fully interchangeable with its own product ALTACE; and (d) the availability to Sanofi of an action for patent infringement with respect to the HOPE patents: Trial Judge's Reasons at para. 283.

[68] The Trial Judge concluded that in the hypothetical market, Apotex would have been able to make sales for HOPE indications during the section 8 liability period without any serious objection from Sanofi, and that consequently Apotex's losses in respect to such sales should be compensated under section 8 of the *NOC Regulations*: Trial Judge's Reasons at paras. 292 and 293. She however added "[t]hat is not to say that a second person [a generic manufacturer] may <u>always</u> recover for unapproved indications. Another s. 8 claim may provide a clear defence in the pleadings and a different set of facts that would warrant a different finding or a downward adjustment to the second person's damage pursuant to s[s]. 8(5) of the [*NOC*] *Regulations*. But not in this case": Trial Judge's Reasons at para. 295, emphasis in original.

<u>The issues in appeal and the standard of review</u>

[69] The principal issues in this appeal concern (a) the start and end dates of the section 8 liability period, (b) the attributes of the hypothetical market during that period, (c) how the double ramp-up of generic drug sales should be treated in the hypothetical market, and (d) whether the hypothetical sales by a generic in the hypothetical market should include sales for unapproved indications, such as the HOPE indications. Two additional issues are also raised by the parties: (e) Sanofi submits that the Trial Judge made a "calculation error" when she concluded that the authorized generic drug manufacturer's share of the generic market for ramipril would have been

30% after 24 months, while (f) Apotex submits that the Trial Judge erred in determining the date upon which Teva would have entered that market.

[70] All parties rightfully submit that the standard of review which applies is the usual standard for appellate review as described in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. Questions of law are therefore subject to review on appeal on the standard of correctness, while questions of fact, and questions of mixed fact and law from which a pure question of law cannot be extricated, are reviewed on the standard of palpable and overriding error.

First Issue: Determining the section 8 liability period

(a) The start date

[71] Sanofi submits that in light of the prohibition order issued by Simpson J. on October 6, 2005 in *Ramipril NOC #2 (FC)* with respect to the '457 Patent, the Trial Judge was precluded by law from finding any liability under section 8 *NOC Regulations* until the effect of that order was essentially set aside one month later on November 4, 2005 by the decision of Tremblay-Lamer J. in *Ramipril NOC #3 (FC)*, which found that patent invalid for the purposes of the Regulations.

[72] To support this submission, Sanofi principally relies on the decision of the English Court of Appeal in *Unilin Beheer BV v. Beery Floor NV*, [2007] EWCA Civ. 364 ("*Unilin*") and the decisions of the Federal Court which have applied *Unilin* explicitly or implicitly, notably *Eli Lilly Canada Inc. v. Apotex Inc.*, 2010 FC 952, 89 C.P.R. (4th) 332 and *Aventis-Pharma Inc. v. Pharmascience Inc.*, 2009 FC 915, 78 C.P.R. (4th) 54. Sanofi submits that *Unilin* stands for "the proposition that a subsequent declaration of invalidity of a patent will result in an order terminating

a previously granted injunction – but only with future effect. It does not allow the Court to "reach back" to the previous case and undo the award retroactively", and that this principle is important in this case "because it recognizes that a subsequent finding of invalidity, even when it is final, after trial and appeal, and even when made *in rem*, does not allow the Court to 'unwind' the past": Sanofi's Memorandum at paras. 40 and 41.

[73] Sanofi adds that the Trial Judge could not "reach behind" the prohibition order of Simpson J., which was never overturned on appeal. It adds that this Court found in *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2006 FCA 328, 53 C.P.R. (4th) 447 at para. 20 that the prohibition order of Simpson J. was in effect until the expiration of the '457 Patent. Sanofi also submits that the Trial Judge further erred in law by (a) refusing to consider November 4, 2005 (the date of the decision of Tremblay-Lamer J.) as a possible start date for the section 8 liability period, (b) engaging in an irrelevant "thought experiment" in considering what would have happened had Apotex brought a single notice of allegation against the '457 Patent rather than two, and (c) refusing to consider that the decision of Tremblay-Lamer J. was obtained by Apotex by means of an abuse of process.

[74] I do not accept Sanofi's submissions on this issue.

[75] Paragraph 8(1)(*a*) of the *NOC Regulations* clearly sets out that the section 8 liability period 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" (emphasis added). Consequently, the usual, normal or default start date is when the NOC would have been issued to the generic manufacturer had it not been for

the operation of the *NOC Regulations*, in this case April 26, 2004. It is only in circumstances where the Trial Judge deems that another date is more appropriate that this default date can be set aside.

[76] In this case, Apotex issued two notices of allegation against the '457 Patent. The first notice alleged that its generic version of ramipril did not infringe that patent (a submission which Simpson J. did not accept), while the second notice alleged that the patent was invalid (a submission which was accepted by Tremblay-Lamer J.). The segmentation of notices of allegation with respect to the same patent is a practice which has since been disapproved by our Court as an abuse of process: *AB Hassle v. Apotex Inc.*, 2006 FCA 51, [2006] 4 F.C.R. 513 at paras. 24-25 ("*AB Hassle*"). However, as noted in *AB Hassle* at para. 25, "[e]ven if it is determined that a second or subsequent notice of allegation is an abuse of process, the Federal Court nevertheless has the discretion to determine the application for a prohibition order on its merits". Moreover, at the time Apotex submitted its two notices of allegation it was not an uncommon practice to proceed in this fashion: *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (FCA) (1997), 76 C.P.R. (3d) 1; [1997] F.C.J. No. 1251 (QL) at para. 20 of the QL ed., leave to appeal refused, [1998] 1 S.C.R. viii; *Apotex Inc. v. Canada (Attorney General)* (FCA) (2000), [2000] 4 F.C. 264 at para. 44, leave to appeal refused, [2001] 1 S.C.R. v; *Eli Lilly and Co. v. Novopharm Ltd.* (FCTD) (1997), 76 C.P.R. (3d) 312, [1997] F.C.J. No. 1344 (QL) at paras. 44 to 49 of the QL ed.; *Bayer AG v. Canada (Minister of National Health and Welfare)* (FCTD) (1997), 77 C.P.R. (3d) 129, [1997] F.C.J. No. 1785 (QL) at paras. 12 to 15 of the QL ed.; *Bayer Inc. v. Canada (Minister of National Health and Welfare)* (FCTD) (1998), 82 C.P.R. (3d) 359, [1998] F.C.J. No. 1035 (QL) at paras. 9 to 14 of the QL ed.

[77] In addition, in this case Sanofi did submit its abuse of process argument to Tremblay-Lamer J., who discarded it as she was entitled to do under the principles set out in *AB Hassle* and referred to above: *Ramipril NOC #3 (FC)* at paras. 26 to 47. When this decision was brought before our Court in *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, above, Noël J.A. (at para. 14) refused to hear the appeal on the ground that it had become moot as the result of the expiry of the '457 Patent. Though Noël J.A. commented that Simpson J.'s prohibition order had remained in effect until the expiration of the '457 Patent, this comment must be understood within the entire context of the decision and with his explicit additional comment that "[b]ased on the limited record that we have, and without pre-judging the issue, if it should arise in the context of a section 8 application…" (at para. 20, emphasis added).

[78] Taking into account all of the circumstances, the question which had to be asked in this case with respect to section 8 liability (and which the Trial Judge in fact asked and addressed) was what was the overall result of the proceedings respecting the '457 Patent flowing from the notices of allegations in relation to that patent submitted by Apotex under the *NOC Regulations*? As found by the Trial Judge, in light of both the decisions of Simpson J. and of Tremblay-Lamer J., the prohibition proceedings initiated by Sanofi with respect to the '457 Patent were rejected on the ground of invalidity but not on the basis of non-infringement. The overall net result of the combined effect of both decisions in this case was that the listing of the '457 Patent on the patent register provided for under the *NOC Regulations* was found not to be an impediment to the issuance of a NOC to Apotex.

[79] Both decisions concerned the same patent, were closely tied one to the other, were rendered inside a month from one another, and should be read and understood together. For all practical purposes, and taking into account the entire context of these proceedings, the prohibition order issued by Simpson J. should be viewed as simply irrelevant for the purposes of liability determinations under section 8 of the *NOC Regulations* in light of the subsequent decision of Tremblay-Lamer J. This is particularly true when one considers that the prohibition order of Simpson J. would have never been issued had the decision of Tremblay-Lamer J. been issued first. Liability under section 8 of the *NOC Regulations* should not be made to be dependent on the largely irrelevant question of whether Simpson J. or Tremblay-Lamer J. was first to issue a decision.

[80] Consequently, I can find no fundamental error of principle in the decision of the Trial Judge with respect to the start date of the section 8 liability period.

[81] As for the *Unilin* principle on which Sanofi relies, it is telling that it has recently been set aside by the UK Supreme Court in *Virgin Atlantic Airways Limited v. Zodiac Seats UK Limited*, [2013] UKSC 46 ("*Virgin Atlantic*"). The principles set out in *Virgin Atlantic* rather strongly support the view taken by the Trial Judge in respect to the decisions of Simpson J. and Tremblay-Lamer J., and tend to confirm her overall treatment of the start date for the section 8 liability period.

[82] In *Unilin*, a patent had been granted by the European Patent Office ("EPO") with a United Kingdom ("UK") designation allowing that patent grant, pursuant to the *European Patent Convention* ("EPC"), to have the same effect as if it had been made by the UK Patent Office. The patent was then litigated in the UK, with the result that a UK court held that some of the patent

claims were valid and had been infringed, and ordered that an inquiry as to damages suffered or an account of profits be made by the infringing parties. That order eventually became an unconditional and final order in the UK. The difficulty in that case was that the EPC allowed a third party attack on a patent in the EPO called an "opposition", although such an attack was in reality for revocation of the patent. The EPC also allowed attacks on the validity of a patent in the national courts without any requirement to wait until the EPO opposition proceedings were completed. The result of this was that under the EPC system, a national court could find a patent valid by a final and conclusive decision and yet later, in opposition proceedings before the EPO, it could be determined that the patent was invalid or reduced in scope. Accordingly, the defendants in *Unilin* asked that the damages or account for profits inquiry be stayed until pending opposition proceedings relating to the patent in the EPO were finally decided. The issue in *Unilin* was which decision should prevail: the final UK court decision which had found the patent to be valid and infringed, or the eventual EPO decision which could find the patent to be invalid?

[83] Lord Justice Jacob relied on *Poulton v. Adjustable Cover,* [1908] 2 Ch. 430 ("*Poulton*") and *Coflexip v. Stolt (No. 2),* [2004] F.S.R. 34 ("*Coflexip*") for the proposition that a subsequent revocation of a patent by the UK Patent Office cannot affect any court decision previously made with respect to that patent and to which the doctrine of *res judicata* applies: *Unilin* at paras. 39 and 40, 44 to 46 and 52. Lord Jacob essentially applied the same principle to patent revocations resulting from opposition proceedings in the EPO, and thus concluded that the defendants in that case were estopped from challenging Unilin's entitlement to an account of profits, whatever the ultimate result of the opposition proceedings before the EPO: *Unilin* at paras. 88 and 92.

[84] However, *Poulton*, *Coflexip* and *Unilin* have all recently been explicitly overruled by the UK Supreme Court in *Virgin Atlantic*, where the Court held, *inter alia*, that "*Poulton* is no longer good law, and *Coflexip* was wrongly decided. It follows that *Unilin* was also wrongly decided because it proceeded on the premise of the law as stated in *Coflexip*": *Virgin Atlantic* at para. 35 (per Lord Sumption).

[85] In *Virgin Atlantic*, Virgin Atlantic Airways Ltd. claimed damages against Zodiac Seats UK Ltd. for infringement of a European Patent (UK) granted to it in May of 2007. The claim was initially dismissed, but allowed by the Court of Appeal by judgments dated October 22, 2009 and December 21, 2009 and by an order dated January 12, 2010, which declared the patent to be valid and to have been infringed, and consequently directed an inquiry as to damages. However, on September 9, 2010, a technical board of the EPO decided to amend the patent by deleting as invalid all the claims which the Court of Appeal had found to be infringed. Zodiac consequently applied to the Court of Appeal to vary its prior order, but this was refused on the ground of the *Unilin* precedent.

[86] The subsequent appeal to the UK Supreme Court was allowed on the limited question as to whether the *Unilin* decision was correct. The fundamental question raised was whether Zodiac was entitled to contend on the inquiry as to damages that there had been no damage because the patent had been retrospectively amended so as to remove the claims held to have been infringed. The answer to this question depended on whether the Court of Appeal was right to say, based on *Unilin*, that its order declaring the patent to be valid continued to bind the parties notwithstanding that the patent was later amended by the EPO.

[87] Lord Sumption held, at paras. 32 and 34 of *Virgin Atlantic* that:

> The essential fallacy in the majority's reasoning in *Coflexip* [and, by extension, in *Unilin*] lay in their view that Lord Keith in Arnold had held that cause of action estoppel was always absolute. He did not. He held that it was absolute only in relation to points actually decided on the earlier occasion. Because of this mistake, the majority had no regard to the fact that the consequences of the patent's revocation had not been decided on the earlier occasion, and could not have been because it had not happened. As for the policy considerations, they were also wrong, as it seems to me, to suppose that the court would be rehearing on the enquiry the question of validity decided by the judgment on liability. The revocation of the patent was an act in rem which determined the status of the patent as against the world. It had been revoked by the authority which had granted it and must be treated as never having existed…
>
> The truth is that the effect of the decision in *Coflexip* [and *Unilin*] is not to introduce certainty in this field but to make the outcome dependent on the wholly adventitious question which of two concurrently competent jurisdictions completes its procedures first…The fate of £49m must surely depend on more substantial and predictable considerations than these.

[88] In his concurring opinion in *Virgin Atlantic*, Lord Neuberger of Abbotsbury further held at para. 52:

> In my view, however, it goes further than that. Absent special factors, principle, fairness and commercial sense support the view that the fact that the patent in issue had been revoked was a point which the alleged infringer should have been entitled to rely on in the assessment. It was a new, centrally important, uncontroversial fact, and to deny the alleged infringer the ability to raise it would be to give effect to a monopoly right which the patentee never should have had. Further, while not enough of a point on its own, it can fairly be said that, far from increasing litigation, permitting Zodiac to rely on the amendment of the Patent, would serve to put an end to the assessment.

[89] In my view, *Virgin Atlantic* supports the position expressed in this appeal by Apotex with respect to the start date of the section 8 liability period, as well as the Trial Judge's findings with respect to the effects of the decisions of Simpson J. and Tremblay-Lamer J. which were both reached within the context of the *NOC Regulations*.

[90] Sanofi also relies on *Apotex Inc. v. Syntex Pharmaceuticals International Inc.*, 2010 FCA 155, 84 C.P.R. (4th) 409 at para. 36 ("*Syntex*") where our Court commented that the 1993 version of section 8 of the *NOC Regulations* "was not intended to provide redress where the innovator prevailed in the prohibition proceeding, even if the generic was later successful in patent litigation." The issue in *Syntex* was whether liability under section 8 of the *NOC Regulations* could result from a declaration of patent invalidity made under regular court proceedings taken under the *Patent Act*. Since the declaration of invalidity did not result from prohibition proceedings taken under the *NOC Regulations*, both Hughes J. in the Federal Court and our Court per Dawson J.A. found that section 8 liability was not consequently triggered. With respect, Sanofi's reliance on *Syntex* is misplaced since, in this case, the declaration of invalidity flowing from the decision of Tremblay-Lamer J. did in fact result from prohibition proceedings taken under the *NOC Regulations*. *Eli Lilly Canada Inc. v. Apotex Inc.*, above, and *Sanofi-Aventis v. Pharmascience*, above, may also be distinguished on similar grounds.

(b) The end date

[91] Sanofi submits that the end date of the section 8 liability period should have been set to June 27, 2006 when the prohibition proceedings respecting the '948 Patent were dismissed on consent in *Ramipril NOC #5 (FC)*. In Sanofi's view, once that proceeding was dismissed on June 27, 2006, the HOPE patents (the '549 Patent and the '387 Patent) remained the only patents listed by Sanofi under the *NOC Regulations*. Sanofi contends that as a result of *AstraZeneca* and *Ferring*, Apotex was not a "second person" within the meaning of those Regulations with respect to the HOPE patents, and that it was consequently precluded from claiming any section 8 damages with respect to the period subsequent to June 26, 2006, which would constitute the last date of "the withdrawal, the

discontinuance, the dismissal or the reversal" referred to in paragraph 8(1)(*b*) of the *NOC Regulations*.

[92] I disagree with Sanofi's submissions on this point.

[93] The Trial Judge was confronted with two opposing arguments regarding the end date of the section 8 liability period. Apotex contended that it should be set to May 2, 2008 which was the date of the dismissal as moot of the last prohibition proceeding involving the HOPE patents, while Sanofi contended that the end date should be June 27, 2006 being the date of the dismissal of the last prohibition proceedings relating to a "relevant" (*i.e.* non-HOPE) patent. As noted above, the Trial Judge rejected both contentions and selected December 12, 2006 as the end date, being the date that the Minister of Health issued the NOC to Apotex for its generic version of ramipril.

[94] Though in this appeal Apotex appears to agree with Sanofi that it is not technically a "second person" with respect to the HOPE patents, it rightfully submits that in view of Sanofi's conduct throughout the litigation, it is precluded by the doctrines of election and estoppel from asserting that Apotex was not a "second person" for the purposes of section 8, at least until the NOC was issued to Apotex.

[95] It is important to set out the pertinent aspects of the overall litigation to understand Apotex's objection to Sanofi's submissions, as well as the Trial Judge's conclusions with respect to those submissions:

a) Apotex provided a notice of allegation with respect to the HOPE patents on November 29, 2005.

b) Sanofi responded by instituting prohibition proceedings in the Federal Court on January 17, 2006, which had the effect of triggering the statutory stay provided under paragraph 7(1)(*e*) of the *NOC Regulations*.

c) On November 3, 2006, the Supreme Court of Canada released its decision in *AstraZeneca* in which it found that the *NOC Regulations* are only concerned with patents relevant to the innovator drug actually copied by the generic drug manufacturer and not with subsequently issued and listed patents from which a generic drug manufacturer could not receive a benefit.

d) On December 8, 2006, in light of *AstraZeneca*, the Minister indicated his view that Apotex did not have to address the HOPE patents within the context of the *NOC Regulations*.

e) On December 12, 2006, the Minister of Health issued the NOC to Apotex.

f) Immediately thereafter, Sanofi commenced judicial review application proceedings in the Federal Court seeking to overturn the Minister's decision to issue the NOC to Apotex, as well as interlocutory stay proceedings.

g) On December 29, 2006, within the framework of these interlocutory stay proceedings, von Finckenstein J. issued an interlocutory stay of Apotex's NOC.

h) That stay order was itself stayed a few days later on January 8, 2007 by Sharlow J.A. pending its appeal to this Court: *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2007 FCA 7, 54 C.P.R. (4^{th}) 402.

i) On February 12, 2007, this Court allowed the appeal of the stay order issued by von Finckenstein J.: *Sanofi-Aventis Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 71, 360 N.R. 321. The Supreme Court of Canada denied leave to appeal on June 28, 2007: SCC file No. 31975, [2007] 2 S.C.R *vii*.

[96] The Trial Judge rejected Apotex's suggested end date based on her reading of *AstraZeneca* and *Ferring*, as set out at para. 76 of her Reasons:

> As I read these two decisions, the impact of *AstraZeneca (SCC)* and *Ferring* is two-fold:
>
> - in respect of newly-initiated submissions for generic drug approval under the *PM (NOC) Regulations*, a generic manufacturer is no longer required to address certain patents on the Patent Register; in which case, it will never be a second person vis-à-vis those patents; and
>
> - for prohibition applications commenced before the decisions in *AstraZeneca (SCC)* and *Ferring*, and where certain patents on the Patent Register do not now need to be addressed, the generic will immediately receive its NOC (assuming that all other relevant patents have been addressed), in which case, it will cease being a second person upon the issuance of the NOC.

> In no way do I interpret *AstraZeneca (SCC)* and *Ferring* as stripping generic manufacturers who have been kept off the market due to the actions of a brand company of their right to claim s. 8 damages.

[97] I agree with the Trial Judge's reading of *AstraZeneca*. It seems clear to me that once *AstraZeneca* was issued, all pending prohibition proceedings respecting the HOPE patents became moot, and the "withdrawal, the discontinuance, the dismissal or the reversal" of those proceedings under the meaning of paragraph 8(1)(*b*) of the *NOC Regulations* was concomitant with the issuance of the NOC to Apotex. This is sufficient to dismiss Sanofi's submissions with respect to the end date.

[98] I am also of the view that even if the effect of *AstraZeneca* were different than that found by the Trial Judge, Sanofi would still be estopped from asserting that Apotex was not a "second person" with respect to the HOPE patents for the purposes of section 8 of the *NOC Regulations* in light of its conduct under the *NOC Regulations* themselves.

[99] In this case, Sanofi listed the HOPE patents on the patent list maintained with respect to ramipril under section 4 of the *NOC Regulations* with the clear objective of forcing generic drug manufacturers (such as Apotex) which were seeking approval of copy-cat versions of ramipril to deal as "second persons" with those patents under the machinery of those Regulations. Sanofi moreover availed itself of subsection 6(1) of the *NOC Regulations* to initiate prohibition proceedings with respect to Apotex's notices of allegations concerning the HOPE patents, thus obtaining the benefit of the statutory stay provided under those Regulations. Had these prohibition proceedings not been initiated, Apotex would have received its NOC much earlier than it did. As a

result, these prohibition proceedings in fact precluded Apotex from competing earlier with Sanofi in the ramipril market. Sanofi thus obtained considerable benefits under the *NOC Regulations* by treating Apotex as a "second person" through its prohibition proceedings concerning the HOPE patents.

[100] The purpose of section 8 of the *NOC Regulations* is precisely to ensure that when an innovator drug manufacturer takes advantage of those Regulations by initiating unfounded prohibition proceedings, the generic drug manufacturer can then seek appropriate compensation for having been precluded from the market as a result. By initiating prohibition proceedings with respect to the HOPE patents and thereby precluding Apotex's market entry until December 12, 2006, Sanofi was clearly subject to section 8 compensation irrespective of whether the benefit it derived under the *NOC Regulations* was unjustified as later found in *AstraZeneca*. As a result, Sanofi cannot now claim that its own prohibition proceedings were null *ab initio* so as to deny to Apotex the benefit of section 8 compensation for the period during which those proceedings precluded it from entering the ramipril market.

Second Issue: The attributes of the hypothetical market during the section 8 liability period

[101] Sanofi submits that the Trial Judge erred in law by failing to apply the correct principles to establish the hypothetical market which would have prevailed during the section 8 liability period. More particularly, Sanofi submits that the Trial Judge erred when, for the purposes of constructing the hypothetical market, she treated Apotex's market entry without regard to the mechanics of the *NOC Regulations*, while she treated the market entry of all other generic participants as impeded by those Regulations.

[102] Sanofi further submits that this fundamental methodological error resulted in many contradictions and incongruities, including:

a) Treating Apotex as if it had no requirement to provide Sanofi with notices of allegations under the *NOC Regulations* so as to justify a finding that its market introduction of a generic version of ramipril would have been a "surprise" launch: Sanofi's Memorandum at paras. 4, 19 to 23 and 68 to 71.

b) Establishing the timing of Apotex's market entry without considerations of any *NOC Regulations* restraints, while establishing a later market entry for all the other generic manufacturers (Teva, Riva, and the authorized generic) by taking into account the constraints of those Regulations: Sanofi's Memorandum at paras. 4, 22 to 23 and 72 to 75.

c) Taking a contradictory methodological approach in the reasons issued with respect to the *Teva Liability Judgment (FC)*: Sanofi's Memorandum at para. 75.

[103] Reading the *Teva Liability Judgment (FC)* with the Liability Judgment involving Apotex, Sanofi argues that the fundamental methodological error of the Trial Judge resulted in compensation under section 8 of the *NOC Regulations* being awarded on the basis of a larger overall generic market for ramipril than what that market is in reality. Sanofi expresses this point quite clearly at para. 5 of its Memorandum:

(a) Apotex and Teva have both been granted damages for hypothetical lost sales, including in the period from December 13, 2005 – August 1, 2006.

(b) Apotex has been granted damages representing 70% of the total Canadian market for generic ramipril between December 13, 2005 – August 1, 2006.

> (c) Teva has been granted damages representing 33% of the total Canadian market for generic ramipril between December 13, 2005 – August 1, 2006.
>
> (d) In both cases it was also found as a fact that the authorized generic would have captured at least 30% of the total Canadian market for generic ramipril between December 13, 2005 – August 1, 2006.
>
> (e) Accordingly, to date, damages have been awarded during the above period on the basis that Apotex, Teva, and [the authorized generic drug manufacturer] would have sold at least 133% of the total sales available to generics in the first place.
>
> (f) Worse, the Federal Court has yet to hear or decide T-1201-08. In that case Riva claims damages for its exclusion from the market, including between January and December 2006, and any award for that period will necessarily exacerbate what is already an aggregate overcompensation.
>
> This absurdity does not result from disparate evidence between the cases; it arises from errors in the Trial Judge's approach to constructing the hypothetical world in this case.
>
> [Emphasis in original]

[104] The Trial Judge did not disagree with Sanofi's arithmetic: Trial Judge's Reasons at para. 132. She nevertheless rejected Sanofi's submissions in respect to the proper methodology on the ground that it was arguing for a single hypothetical market for all generics in all section 8 *NOC Regulations* litigations, and that such an approach was not possible in the context of separate and distinct trials where "[t]he assessment of damages can and should be made on the facts of each case" and where "the evidence in one case may establish a different 'Relevant Period' than in another case": Trial Judge's Reasons at paras. 135 and 136.

[105] Contrary to the Trial Judge, I find that there is some merit to Sanofi's argument.

[106] I agree with the Trial Judge that a single hypothetical market for all litigation involving ramipril and section 8 compensation awards may not always be a practical feasibility in light of the different relevant section 8 liability periods involved in each case, the evidence submitted at each trial, and the particular dynamics of each claim for compensation. As an example, in this case and in the proceedings leading to the *Teva Liability Judgment (FC)*, the potential participation of Pharmascience in the hypothetical ramipril market has been ignored as a result of the manner in which Sanofi prepared and managed its proceedings. A different result regarding Pharmascience's potential market participation would thus be possible in other proceedings under section 8 of the *NOC Regulations* involving another generic drug manufacturer. This could of course lead to a different division of the hypothetical generic ramipril market between generic manufacturers.

[107] Nevertheless, a methodology which strives to compensate adequately and fairly the generic manufacturers must be preferred over one that almost unavoidably leads to windfalls. The methodology used by the Trial Judge in this case is one which inherently leads to windfalls, and has in fact led to this result when considering the combined effect of the Apotex Liability Decision (FC) in this case and the *Teva Liability Judgment (FC)*.

[108] A simple example illustrates the problem with the Trial Judge's methodology. Two generic drug manufacturers seek a NOC at the same time for their respective versions of an innovator drug, each challenges at the same time the relevant patent under notices of allegation, and each is impeded from entering the market for two years as a result of unwarranted prohibition proceedings initiated by the innovator drug manufacturer. Under the methodology supported by Apotex and retained by the Trial Judge, each of the two generic drug manufacturers would be entitled to 100% of the

generic market during the two years at issue for the purposes of determining compensation under section 8 of the *NOC Regulations*. In my considered view, this is a result which could not have been contemplated by the Governor-in-Council when adopting the *NOC Regulations* and which the language of the Regulations does not allow in any event.

[109] The methodology which should be applied to construct the hypothetical market must be one which is consistent with general principles of compensatory damages and with the prior jurisprudence of this Court. As noted by Noël J.A. in *Alendronate* at para. 89, section 8 of the *NOC Regulations* does not seek to impose punitive damages on innovator drug manufacturers which avail themselves of these Regulations; rather, the compensation owed is compensatory. Moreover, it is a fundamental principle of tort law that an injured person should be compensated for the full amount of its loss, but no more: *Ratych v. Bloomer*, [1990] 1 S.C.R. 940 at p. 962. As noted in that case by McLachlin J. (as she then was) at p. 962:

> The plaintiff is to be given damages for the full measure of his loss as best that can be calculated. But he is not entitled to turn an injury into a windfall. In each case the task of the Court is to determine as nearly as possible the plaintiff's actual loss…The award is justified, not because it is appropriate to punish the defendant or enrich the plaintiff, but because it will serve the purpose or function of restoring the plaintiff as nearly as possible to his pre-accident state or alternatively, where this cannot be done, providing substitutes for what he has lost.
>
> [Emphasis in original]

[110] In my view, the Trial Judge's construction of a hypothetical market in which Apotex enters the market free of the regulatory constraints of the *NOC Regulations*, while the market entry of other potential generic manufacturers is impeded by these Regulations, almost invariably ensures

that there will be a windfall for Apotex and the other generic manufacturers availing themselves of section 8 of the Regulations in their respective proceedings. This is particularly clear in this case.

[111] The Trial Judge came to diametrically contradictory findings with respect to many aspects of the hypothetical market in the Liability Judgment involving Apotex (which I will also refer to herein as the "*Apotex Liability Judgment (FC)*" as compared to the *Teva Liability Judgment (FC)*:

a) In the *Apotex Liability Judgment (FC)*, the Trial Judge determined (at paras. 41 to 55) that Apotex's market entry would have been April 26, 2004, the date of its "patent hold", while in the *Teva Liability Judgment (FC)*, she determined (at paras. 143 to 154) that Apotex's market entry would rather have been December 13, 2005 based on the effects of the Simpson J. prohibition order in *Ramipril NOC #2 (FC)*, a prohibition order which she however found to be of no effect in the *Apotex Liability Judgment (FC)*.

b) In the *Apotex Liability Judgment (FC)*, the Trial Judge determined (at paras. 151 to 160) that Teva's market entry would have been on or about August 1st, 2006 even though its "patent hold" date was October 14, 2003, while in the *Teva Liability Judgment (FC)*, she determined (at paras. 61 to 76) that Teva's market entry would rather have been December 13, 2005.

c) In the *Apotex Liability Judgment (FC)*, the Trial Judge determined (at paras. 191 to 202) that an authorized generic drug manufacturer's market entry would have been July 26, 2004 following a surprise launch by Apotex, while in the *Teva Liability Judgment (FC)*, she

determined (at paras. 196 to 208) that an authorized generic drug manufacturer's market entry would rather coincide with Teva's market launch on December 13, 2005.

[112] The Trial Judge explained these inconsistent findings by referring to the different evidence submitted in both cases, on the different section 8 liability periods at issue, and on the "broad axe" approach to compensation determinations made in a hypothetical world: Trial Judge's reasons in the *Apotex Liability Judgment (FC)* at paras. 135 to 139 reproduced above; *Teva Liability Judgment (FC)*, at paras. 127 to 130. Though I recognize that the evidence submitted in each case and the different section 8 liability periods could lead to different conclusions in the ramipril liability proceedings involving Apotex and Teva under section 8 of the *NOC Regulations*, I am nevertheless of the view that these elements alone do not explain these inconsistencies.

[113] For the most part, the relevant evidence in both cases was the same on the important issues affecting market entry, in particular the litigation history of each NOC proceedings involving Sanofi and the concerned generics. The inconsistencies cannot therefore simply be explained away by differences in evidence. Rather, they largely flow from the methodology used by the Trial Judge in constructing the hypothetical market, and particularly from her view that the market entry of the generic drug manufacturer claiming under section 8 is determined with little or no regard to the *NOC Regulations* themselves, while the market entry of the other generic drug manufacturers is largely dependent on their navigation of those Regulations. In my view this approach is wrong.

[114] The proper methodology is to construct a hypothetical market that most resembles a real market. In the real market, save rare exceptions, once a generic drug manufacturer has received a

NOC for a generic version of an innovator drug, another generic drug manufacturer can reasonably expect to secure a NOC for its own generic version of that drug.

[115] In this respect, in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd. (F.C.A.)*, 2007 FCA 163, [2008] 1 F.C.R. 174 at paras. 26, 36 and 37, a case involving ramipril, Sexton J.A. found that once an innovator drug manufacturer had failed to secure a prohibition order with respect to a generic drug manufacturer's notice of allegation concerning a given patent on its patent list, it may not litigate again the same issues repeatedly in other prohibition proceedings involving other generic drug manufacturers. Moreover, paragraph 6(5)(*b*) of the *NOC Regulations* (introduced in 1998 through SOR/98-147 and amended in 2006 through SOR/2006-242) has made this principle part of the *NOC Regulations*:

6. (5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part	**6.** (5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :
…	[…]
(*b*) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.	*b*) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

[116] Furthermore, the compensation contemplated by section 8 of the *NOC Regulations* is to provide the generic drug manufacturer relief by way of damages for the loss suffered during the section 8 liability period. When more than one generic drug manufacturer is involved with respect to the same innovator drug, there is no reason not to apply the same principle to all concerned

generic drug manufacturers seeking compensation under section 8 of the *NOC Regulations*. This necessarily implies that the compensation for all concerned should be established based on a methodology which is internally consistent between the claims and consistent with general principles of law relating to the determination of compensatory damages.

[117] Consequently, in the hypothetical world, once a generic drug manufacturer is deemed to have been issued a NOC under paragraph 8(1)(*a*) of the *NOC Regulations* as if these Regulations were non-existent ("in the absence of these Regulations"), then other generic drug manufacturers should be assumed to be in a position to receive a NOC subject only to the delays and timelines set out in the *Food and Drug Regulations*.

[118] In other words, for the purposes of constructing the hypothetical market, once a NOC is deemed to have been issued to the claimant under paragraph 8(1)(*a*) of the *NOC Regulations*, those Regulations should be disregarded not only with respect to the claimant generic drug manufacturer, but also with respect to any other generic drug manufacturer that is found, on a balance of probabilities, to also be a market participant. The regulatory hurdles of the *NOC Regulations* are therefore disregarded, but the other regulatory and legislative restraints flowing notably from the *Food and Drug Regulations* and the *Patent Act* are considered for each participating generic drug manufacturer individually.

[119] This approach constructs a hypothetical market reflecting a level regulatory playing field in that market.

[120] I therefore conclude that the findings of the Trial Judge with respect to the entry of Teva, Riva and an authorized generic into the hypothetical market should be set aside. I would therefore return the matter to the Federal Court for a new hearing applying the methodological approach described above.

Third Issue: The double ramp-up

[121] Apotex has also submitted, in its notice of appeal and in oral argument, that in the circumstances of this case, the hypothetical market should have been constructed without any reference to a ramp-up period.

[122] The term "ramp-up" refers to the period of time that it takes a drug manufacturer to penetrate the market to its full potential. In the hypothetical market, Apotex would in theory have experienced a ramp-up period. However, Apotex submits that in the real market, it actually experienced a ramp-up period when it was finally authorized to sell its generic version of ramipril. By taking into account a ramp-up in the hypothetical market without taking into account the ramp-up actually experienced in the real market, Apotex suffers a loss of profits which it would not otherwise have incurred.

[123] The Trial Judge rejected this ramp-up claim on the ground that since it was a loss occurring after the relevant section 8 liability period, it was precluded from compensation under section 8 of the *NOC Regulations* as a result of the principle established in *Alendronate* at paras. 99 to 102, where this Court found that section 8 does not include compensation for losses suffered outside the section 8 liability period.

[124] It is useful to note that the question of the eligibility of a claim for compensation under section 8 of the *NOC Regulations* for the double ramp-up is the subject of some controversy in the Federal Court. In this case and in the *Apotex Liability Judgment (FC)*, the Trial Judge was of the view that such a claim was precluded by the principle set out in *Alendronate*. However, both Hughes J. in *Apotex Inc. v. Merck Canada Inc.*, 2012 FC 1235, 105 C.P.R. (4th) 399 and Phelan J. in *Apotex Inc. v. Takeda Canada Inc.*, 2013 FC 1237 have taken a different approach.

[125] In *Apotex Inc. v. Merck Canada Inc.*, above at para. 85, Hughes J. noted that the Trial Judge had declined to award compensation for the double ramp-up based on her view of the decision of our Court in *Alendronate*. However, he also noted (at paras. 86 and 87) that he was not satisfied that our Court had this situation in mind when it reached its decision in *Alendronate*, particularly in light of the common view of accounting experts that, normally, compensation would be made to prevent a double ramp-up loss. Nevertheless, in the interest of comity, Hughes J. adopted the view of the Trial Judge in this case and thus did not allow compensation for double ramp-up.

[126] In *Apotex Inc. v. Takeda Canada Inc.*, above at paras. 129 to 131, Phelan J. noted the positions of the Trial Judge and of Hughes J. with respect to the double ramp-up, but determined that he should not resolve the issue on the basis of comity. He noted, at para. 136 to 138, that in *Alendronate* this Court was dealing with a claim for future losses, while the claim for double ramp-up was of a different nature, being one for a loss of revenue being double counted against the successful generic drug manufacturer. As a result, Phelan J. did not read the *Alendronate* decision as endorsing the proposition that compensation under section 8 of the *NOC Regulations* is to be determined without regard to double-counting. Relying on subsection 8(5) of the *NOC Regulations*

(which allows the court to take into account all matters that it considers relevant in assessing the amount of compensation) he concluded at para. 146 that "[t]here is nothing in law and certainly nothing in equity which requires the Court to ignore the factor of double counting and to adjust the compensation accordingly."

[127] I agree with the approach adopted by Phelan J.

[128] First, this Court's decision in *Alendronate* must be understood within the context of the claim which was at issue in that case. As noted by Hughes J. in the trial decision which was the subject of that appeal and reported as *Apotex Inc. v. Merck & Co. Inc. et al*, 2008 FC 1185, [2009] 3 F.C.R. 234 (*Alendronate (FC)*) at para. 9, the issue was whether Apotex was "entitled to recover for damages that continue after the [liability] period expires". Indeed, the claim at issue was for "loss sales and permanent market share": *Alendronate (FC)* at para. 118. It is this claim which was rejected by our Court in *Alendronate* on the basis of the following principle set out by Noël J.A. at para. 102 of that decision:

> 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.

[129] The claims which are excluded by this principle are those losses which occur beyond the section 8 liability period, such as those losses which occur as a result of the loss of a future market share. This principle does not however mean that a claim for compensation should be reduced as a

result of double counting. By denying the double ramp-up claim in this case, Sanofi benefits from a windfall because the ramp-up period is considered twice. In such circumstances, it is appropriate for a court to exercise its discretion under paragraph 8(5) of the *NOC Regulations* and to consider as a relevant factor the actual ramp-up period which occurred in the real market so as to avoid double counting it in the hypothetical market. This approach is entirely consistent with the overall purpose of section 8 of the *NOC Regulations*, and it does not violate the principle of excluding future losses set out in *Alendronate*.

[130] As a necessary implication, I would also therefore allow the appeal from the Subsequent Ramp-Ups Order which amended the Liability Judgment with respect to the ramp-up effect that would have affected all the generic drug manufacturers participating in the hypothetical market.

Fourth Issue: Liability for hypothetical sales in the hypothetical market related to unapproved indications, such as the HOPE indications

[131] Sanofi further submits that since Apotex removed the HOPE indications from its product monograph to secure its NOC, and since the uses of ramipril for the HOPE indications are subject to Sanofi's HOPE patents, Apotex should not be entitled to be compensated for any losses incurred in the hypothetical market and resulting from sales of its generic version of ramipril associated with the HOPE indications.

[132] For Sanofi, the "question is whether the 'loss' referred to in s. 8 can extend to a category of sales that is necessarily predicated on an infringing use by patients. Properly interpreted, s. 8 does not contemplate recovery by a second person for such sales": Sanofi's Memorandum at para. 84. It adds that while "Apotex itself may not be *infringing* in relation to the HOPE sales, all such sales

during the section 8 liability period would have necessarily resulted in an infringement of Sanofi's rights by others and a lost sale to Sanofi at a time when it enjoyed patent exclusivity in respect of HOPE uses. Given the well-understood purpose of s. 8 to *prevent patent infringement* on the part of generics, it should not be read to extend to lost sales that necessarily result in an infringement of the patentee's rights, by anyone": Sanofi's Memorandum at para. 86, emphasis in original.

[133] In the factual circumstances of these proceedings, I do not accept Sanofi's submissions. In the real market, Sanofi has taken no measure to enforce its HOPE patents, and has not opposed the listing of generic versions of ramipril as substitutes to ALTACE for any indication. If Sanofi is not enforcing its HOPE patents in the real market, and is allowing the sale of generic versions of ramipril for HOPE indications in the real market without any serious opposition, I fail to understand why the situation should be deemed different in the hypothetical market. To the extent the hypothetical market is intended to reflect the real market, sales in the hypothetical market should be treated in the same way as sales in the real market.

[134] Moreover, this Court has already found that in such circumstances a generic drug manufacturer cannot be held responsible for patent infringement on the basis of the theory of "contributory infringement": *Apotex Inc. v. Nycomed Canada Inc.*, 2011 FC 1441, 100 C.P.R. (4th) 1 at paras. 18 to 28, aff'd 2012 FCA 195, 105 C.P.R. (4th) 16 at para. 3, leave to appeal to SCC refused file 34873 [2012] 3 S.C.R. xiv.

[135] In light of all of the above, I can find no reviewable error with in the Trial Judge's findings and conclusions with respect to the HOPE indications.

Fifth Issue: Alleged calculation error in the Trial Judge's conclusion that the authorized generic drug manufacturer's market share would have been 30% of the generic ramipril market after 24 months

[136] Sanofi further submits that the Trial Judge made a palpable and overriding error when she concluded that an authorized generic drug manufacturer's share of the generic market for ramipril would have been 30% after 24 months. Sanofi alleges that the evidence relied upon by the Trial Judge (the market analysis report to which Mr. Gravel testified, referred to at para. 216 of the Trial Judge's Reasons) made clear that a 30% market share for an authorized generic applied to a market in which there were 5 participants, while the hypothetical market constructed by the Trial Judge had only 3 participants. Sanofi concludes from this that the Trial Judge's finding that an authorized generic would have had a 30% share of the generic market to be erroneously low for the first 24 months of the hypothetical market, thus unjustifiably increasing the compensation owed to Apotex.

[137] I disagree with Sanofi. In my view, the Trial Judge committed no such error.

[138] Sanofi essentially isolates some of the evidence submitted with respect to the market share which an authorized generic drug manufacturer would have secured, and ignores the totality of the evidence before the Trial Judge, as well as the reasoning which lead her to conclude that a 30% market share was appropriate. It is clear from the Trial Judge's Reasons that in determining market shares, she considered the reports and testimonies of Dr. Carbone (Trial Judge's Reasons at paras. 205 to 207), of Dr. Hollis (*ibid.* at paras. 208 to 214) as well as the market analysis report to which Mr. Gravel testified and on which Sanofi relies (*ibid.* at para. 216).

[139] Furthermore, the Trial Judge recognized the difficulties she faced in allocating market shares between generic entrants (Trial Judge's Reasons at para. 215) and further recognized the limitations of the market analysis report to which Mr. Gravel testified (*ibid.* at para. 217). She also acknowledged that her "conclusions as to the market shares, unfortunately, do not match any of the scenarios modeled by the experts" (*ibid.* at para. 220). It is therefore clear from her Reasons that the Trial Judge determined the market share of an authorized generic drug manufacturer based on the totality of the evidence before her. I can find no palpable and overriding error with respect to that finding.

[140] That being said, the Trial Judge's findings with respect to the market share of the authorized generic drug manufacturer will need to be adjusted in light of the correct methodology adopted to construct that market and discussed above.

Sixth Issue: Did the Trial Judge make an error in determining the date upon which Teva would have entered the generic ramipril market

[141] In appeal docket A-191-12, Apotex submits that the Trial Judge erred in finding that Teva would have entered the hypothetical market on August 1, 2006. Rather, in Apotex's view, the Trial Judge should have found that Teva would have only entered the generic ramipril market at the end of October 2007, thus after the end of Apotex's section 8 liability period.

[142] For Apotex, the Trial Judge erred in finding that Teva could have leveraged Riva's success in its prohibition proceedings under the *NOC Regulations* involving the '206 Patent and thus entered the market on August 1, 2006. Apotex rather submits that the Trial Judge should have considered the decision of the Federal Court in the prohibition proceedings involving Riva and the

‘206 Patent as if the basis on which that decision was made was non-existent, *i.e.* that the declaration of invalidity of the ‘206 Patent made in the prohibition proceedings involving Apotex and Sanofi in *Ramipril NOC #1 (FC)* should be deemed never to have occurred.

[143] Apotex’s submissions are entirely rooted on the methodology used by the Trial Judge to construct the hypothetical market. As already noted above, that methodology requires that Apotex’s market entry be determined without regard to the *NOC Regulations*, while the market entry of all other generic participants must be determined as if these Regulations applied, *i.e.* section 8 compensation must be assessed in a hypothetical market where Apotex is deemed not to be subject to the *NOC Regulations*, but all its generic competitors are so subject. As noted by Apotex in its Memorandum in appeal docket A-191-12 at para. 17:

> Justice Snider properly determined that Apotex’s commencement date in respect of its damage period was on the date it was approved by the Minister “in the absence of the *PMNOC Regulations*”. However, insofar as other generic drug manufacturers were considered, the *PMNOC Regulations* remained an obstacle. As a result, while Apotex did not have to address the ‘206 Patent in the hypothetical world, other generic companies still faced the ‘206 Patent and were required to address same but without the benefit of Apotex’s success in T-1742-03 [*Ramipril NOC #1 (FC)*]. In other words, other generics could not “unlock” the regulatory door by following in the footsteps of Apotex.

[144] As already discussed above, that methodological approach is wrong and should be discarded. Apotex’s submissions in appeal docket A-191-12 further demonstrate the fundamental error in the Trial Judge’s construction of the hypothetical market for the purposes of section 8 of the *NOC Regulations*. They exemplify the artificial nature of the methodology and the inherent bias this methodology has towards providing windfalls to generic drug manufacturers.

[145] As a result, though I have found that the Trial Judge did err in setting Teva's market entry at August 1, 2006, I disagree with Apotex's suggested market entry date for Teva at the end of October 2007.

Conclusions

[146] I would allow in part the appeals in docket A-193-12 and A-191-12 by confirming the Trial Judge's judgment in Federal Court docket T-1357-09 in all aspects except with respect to paragraph 2d) and subparagraphs 2f)(i), 2f)(ii) and 2f)(iv), which I would set aside.

[147] I would further allow the appeal in docket A-397-12 and set aside the Subsequent Ramp-Ups Order.

[148] I would also allow the appeal from the Final Quantum Judgment in docket A-474-12 and set aside that judgment.

[149] I would refer the matter back to the Chief Justice of the Federal Court for a new determination by the Trial Judge or another judge of that Court in light of the reasons of this Court with respect to (a) a hypothetical market in which a level regulatory playing field applies, and (b) the double ramp-up.

[150] Insofar as Sanofi's notice of appeal seeks to challenge the Validity Judgment, I would dismiss that appeal for the reasons given in 2014 FCA 69, which are adopted hereunder *mutatis mutandis*.

[151] Finally, in light of the divided results, I would make no order as to costs.

"Robert M. Mainville"

J.A.

SHARLOW J.A.

[152] I agree with the following conclusions reached by my colleague Justice Mainville, substantially for the reasons he has given:

a) The Trial Judge made no error in concluding that the section 8 liability period began on April 26, 2004 and ended on December 12, 2006.

b) The Trial Judge made no error in concluding that Apotex was entitled to compensation for lost sales of its generic version of ramipril associated with the HOPE indications.

c) The Trial Judge made no error in concluding that an authorized generic drug manufacturer would have achieved a 30% share of the hypothetical generic ramipril market after 24 months.

[153] However, for the reasons explained below, I respectfully disagree with Justice Mainville's proposed disposition of these appeals.

[154] I differ from Justice Mainville with respect to the methodology for determining the date on which the potential competitors of Apotex would have entered the hypothetical market, and with respect to the double ramp-up. I would reverse the Trial Judge on only one point, namely, her conclusion that Teva would have entered the hypothetical market during the section 8 liability period.

Determining the date of entry of competitors in the hypothetical market

[155] Sanofi submits that the Trial Judge erred when, for the purposes of constructing the hypothetical market, she treated Apotex as having entered the hypothetical market unimpeded by the *NOC Regulations*, while she treated the market entry of all other generic participants as impeded by the *NOC Regulations*. Sanofi submits that this methodology inevitably results in systematic overstatement of section 8 damages when all potential claimants are taken into account, and that it has resulted in specific factual errors relating to the date of entry on which the Apotex competitors could have entered the market. Justice Mainville agreed with Sanofi's argument. I do not agree, for the following reasons.

[156] Sanofi points out that the combined effect of the decisions of the Trial Judge in this case and in the *Teva Liability Judgment (FC)* is that the hypothetical market for the period December 13, 2005 to August 1, 2006 (the overlapping portion of the section 8 liability periods for Apotex and Teva) exceeds the size of the actual generic ramipril market. As a result, according to Sanofi, its total liability to Apotex and Teva for section 8 damages is overstated. Sanofi argues that because this overstatement is the inevitable result of the methodology adopted by the Trial Judge for determining the characteristics of the hypothetical market, the methodology must be wrong in principle. Sanofi advocates a methodology in which each potential competitor is assumed to enter the hypothetical market free of the constraints of the *NOC Regulations* – I will refer to this as the "open season methodology".

[157] The machinery of the *NOC Regulations* always takes time. She assumed that in the hypothetical world, the *NOC Regulations* exist and the competitors of a section 8 damages

claimant would act as they did in the real world in relation to the *NOC Regulations*, except to the extent that there is evidence upon which the trier of fact can reasonably conclude that they would have acted differently. The open season methodology assumes the *NOC Regulations* away for the purpose of constructing the hypothetical market. For each claimant for section 8 damages, that would result in more competitors entering the hypothetical market at an earlier date than they could have done if the *NOC Regulations* were assumed to be in force. That would reduce the amount of the section 8 damages in every case in which the claimant has a potential competitor, and therefore it would reduce the aggregate liability of the first person (the innovator drug manufacturer, in this case Sanofi) in all such cases involving the same generic drug. That would undoubtedly be an advantage to the first person, but it could be unfairly prejudicial to a particular claimant because it is not possible to determine whether the open season methodology necessarily would result in reasonable compensation to each claimant or to all claimants collectively.

[158] The Trial Judge rejected the open season methodology, largely because it is inconsistent with the requirement that each claim for section 8 damages must be determined on its own merits based on the evidence presented. She assumed that in the hypothetical world, the competitors of a section 8 damages claimant are bound by the *NOC Regulations*, and that those competitors would act as they did in the real world in relation to the *NOC Regulations* except to the extent that there is evidence upon which the trier of fact can reasonably conclude that they would have acted differently.

[159] I agree with the Trial Judge's reasons for rejecting the open season methodology. I would add that in my view, the methodology she adopted is more consistent with the language and purpose of the *NOC Regulations* than the open season methodology.

[160] The *NOC Regulations* are silent on the specific question of whether the determination of a claim for section 8 damages must be based on the assumption that potential generic competitors of the claimant in the hypothetical market are subject to the *NOC Regulations*. However, paragraph 8(1)(*a*) expressly requires the *NOC Regulations* to be disregarded in constructing one element of the hypothetical generic market. It provides that the beginning of the section 8 liability period is the date "as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations" (unless another date is found to be more appropriate by virtue of subparagraph 8(1)(*a*)(i) or (ii)).

[161] Since the *NOC Regulations* say that their existence must be disregarded for one specific purpose, it seems to me that to disregard the *NOC Regulations* for some other purpose would be tantamount to judicially amending section 8. I conclude, therefore, that each claim for section 8 damages is intended to be determined on the basis that the hypothetical world is one in which there are *NOC Regulations*.

[162] It follows that in the hypothetical market, the behaviour of competing generic drug manufacturers must be determined on the basis that the *NOC Regulations* exist, and each generic drug manufacturer will conduct itself accordingly.

[163] The result, as between this case and the *Teva Liability Judgment (FC)*, is that the Trial Judge constructed two hypothetical worlds that are not the same. But inconsistencies are inevitable when each claim is determined on its own merits, based on the evidence presented in respect of that claim, following a particular litigation history that is influenced by the parties' own litigation tactics.

[164] One such inconsistency is that Apotex is assumed to have the first entrant advantage in the hypothetical market in this case, but not in the *Teva Liability Judgment (FC)*. However, that inconsistency is inherent in the scheme of section 8 of the *NOC Regulations*. If that is a problem that requires a remedy, the remedy lies with Parliament or the Governor-in-Council, not this Court.

[165] I turn now to the arguments relating specifically to the entry into the hypothetical market of ratiopharm inc., Riva and Teva.

i. Ratiopharm and the "surprise launch"

[166] In 2003, in the real world, Apotex served Sanofi with four notices of allegation challenging the validity of the patents listed against Sanofi's ramipril product. That gave Sanofi substantial warning of the potential patent challenges. That warning enabled Sanofi to ensure that when Apotex received its NOC in December of 2006, Sanofi's authorized generic drug manufacturer, ratiopharm inc., could immediately launch its competing generic product.

[167] However, the Trial Judge held that in the hypothetical world, Sanofi would have been surprised by the launch of the Apotex generic product on April 26, 2004 because in the hypothetical world it must be assumed that Apotex would have served no notices of allegation on Sanofi. She also concluded that the steps required before an authorized generic product could be introduced would take three months. Therefore, the Trial Judge found that the launch of the authorized generic product would have occurred on July 26, 2004.

[168] Sanofi argues that the Trial Judge erred at the first step in this analysis because the obligation to file notices of allegation exists in the hypothetical world. Prior to the hypothetical approval of its generic product on April 26, 2004, Apotex would have done exactly as it did in the real world, which was to serve notices of allegation at various times in 2003, including those alleging the invalidity of the 206 and 457 patents. Therefore, in the hypothetical world Sanofi would have known before April 26, 2004, that Apotex was seeking to enter the generic market and it could and would have prepared for an immediate launch. (Sanofi's Memorandum at paras. 4, 19 to 23 and 68 to 71).

[169] Apotex argues that the Trial Judge, in constructing the hypothetical world, was obliged to assume that Apotex would serve no notices of allegation. This argument relies primarily on paragraph 8(1)(*a*) of the *NOC Regulations* which, subject to certain exceptions that are not relevant here, provides that the beginning of the section 8 liability period is the date "as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations". Apotex argues that this should be taken as a signal that the hypothetical world is

intended to be one in which its position (the position of the party claiming section 8 damages) is not constrained in any way by the *NOC Regulations*.

[170] Paragraph 8(1)(*a*) does not say or suggest that the hypothetical world has no *NOC Regulations*, much less that the hypothetical world has no *NOC Regulations* that are binding on the section 8 damages claimant, in this case Apotex. It says only that the *NOC Regulations* are to be disregarded in determining the beginning of the section 8 liability period, as long as neither of the stated exceptions applies. For that reason, I do not accept the rationale of Apotex for confirming the Trial Judge's conclusion as to the date on which the authorized generic would have entered the market.

[171] In my view, Apotex should be treated as having served the same notices of allegation in the hypothetical world just as it did in the real world. The *NOC Regulations* require that a drug manufacturer wishing to obtain a NOC for a generic version of an existing drug before the expiry of the patents listed against the existing drug must address those patents by serving a notice of allegation in which it alleges that the patent is invalid or will not be infringed by the generic product. There is no reason why that legal requirement should be ignored in the hypothetical world.

[172] However, that does not undermine the Trial Judge's conclusion that the authorized generic, ratiopharm, inc., would not have been ready to launch on April 26, 2004. I reach that conclusion for the following reason. In the real world, Sanofi commenced six prohibition applications against Apotex, four of them before April 26, 2004, of which two challenged the

validity of a listed patent. The first of those, relating to the 206 patent, was dismissed on September 20, 2005. Given Sanofi's consistent pattern of commencing prohibition applications at every opportunity, it seems to me improbable that in the hypothetical world, Sanofi would have prepared for the launch of an authorized generic product before it lost even the first of its prohibition applications.

[173] The Trial Judge's conclusion that it would have taken three months for all the steps required to launch the generic product of ratiopharm, inc. was reasonably open to her on the record. Therefore, her conclusion that the authorized generic would have entered the hypothetical market on July 26, 2004 must stand.

(ii) Entry of Riva and Teva

[174] The Trial Judge concluded that Riva would not have entered the hypothetical market at all during the section 8 liability period (April 26, 2004 to December 12, 2006), and Teva would have entered the hypothetical market on August 1, 2006. For the following reasons, I have concluded that the Trial Judge should have determined that neither Riva nor Teva would have entered the hypothetical market during the section 8 liability period.

1. Riva

[175] Riva initially was barred from receiving a NOC because of a particular policy of the Minister of Health in respect of the application of the *NOC Regulations*. The reference product for Riva's abbreviated new drug submission was a generic ramipril product of another generic drug manufacturer, Pharmascience. The Minister informed Riva that its NOC could not be issued

until Pharmascience received its NOC. That delayed Riva's market entry from June 18, 2004 until June 21, 2007, when the Minister's policy was reversed. The Trial Judge found no reason to conclude that the Minister's policy would have been reversed in the hypothetical world on any earlier date. Therefore, Riva would not have entered the hypothetical market until after the end of the section 8 liability period. In my view, that conclusion was reasonably open to the Trial Judge on the evidence.

2. Teva

[176] The Trial Judge concluded that Teva would have entered the hypothetical market to compete with Apotex on August 1, 2006, so that Apotex would have had Teva as a competitor in the hypothetical market from that date until December 12, 2006, the end of the section 8 liability period. That conclusion is based on two separate findings.

[177] First, the Trial Judge noted that in the real world, Teva voluntarily kept itself off the market from 2001 until December 13, 2005, when the 457 patent expired, by agreeing that the issuance of its NOC would await the expiry of that patent. The Trial Judge concluded that this voluntary delay would have occurred in the hypothetical world as well, so that Teva could not have entered the hypothetical market until at least December 13, 2005. Neither party challenges that conclusion.

[178] Second, the Trial Judge noted that there was a further delay in the real world because Teva did not serve notices of allegation until September of 2005. The last of the prohibition applications in respect of those patents was dismissed in the real world in April of 2007, based

on the dismissal of parallel prohibition proceedings against Apotex in June of 2006. That would suggest that Teva could not have entered the market until after December 12, 2006, the end of the section 8 liability period.

[179] However, the Trial Judge concluded that in the hypothetical world, Teva would have entered the hypothetical market on August 1, 2006. She reached that conclusion on the basis that in the hypothetical world, Teva could and would have taken steps much earlier to obtain a dismissal of Sanofi's prohibition applications against it. That is because in the hypothetical world Riva would have taken steps much earlier to obtain the dismissal of Sanofi's prohibition applications against it based on Apotex's successful defence of the prohibition applications against it. Then, Teva could have relied on Riva's success to obtain its own summary dismissal.

[180] Both Sanofi and Apotex (in A-191-12) challenge that conclusion, for different reasons. Sanofi argues that Teva would have entered the market earlier, so that Apotex would have had Teva as a competitor for a longer period within the section 8 liability period. Apotex argues (in A-191-12) that Teva would have entered the market later, so that Apotex would not have had Teva as a competitor at all during the section 8 liability period.

[181] To consider these arguments, it is necessary to understand the position of Riva in the real world, relative to the position of Apotex and Teva:

a) In June of 2004, Riva served Sanofi with a notice of allegation with respect to the 457, 206 and 089 patents. Riva alleged among other things that the 206 patent was invalid

for want of sound prediction and that it would not infringe the 089 patent. On July 23, 2004, Sanofi responded with a prohibition application (T-1384-04).

b) In September of 2004, Riva served Sanofi with a second notice of allegation, this time alleging non-infringement of the 948 patent. On October 22, 2004, Sanofi responded with a second prohibition application (T-1888-04).

c) In September and December of 2005, two prohibition applications by Sanofi against Apotex were dismissed. The first dealt with an allegation that the 206 patent was invalid for want of sound prediction (2005 FC 1283). The second dealt with an allegation that the 457 patent was invalid for obviousness (2005 FC 1504).

d) On December 13, 2005, the 457 patent expired.

e) On May 8, 2006, a prohibition application by Sanofi against Teva relating to the 206 patent was dismissed by a prothonotary as an abuse of process because Sanofi was raising the same issues it had raised against Apotex in a prohibition application dismissed on September 20, 2005 (affirmed by a judge of the Federal Court (2006 FC 1135) and this Court in *Novopharm*, cited above).

f) On April 27, 2007, another prohibition application by Sanofi against Teva relating to the remaining patents (except the 457 patent) was dismissed as an abuse of process because Sanofi's challenge to the non-infringement allegation could not succeed (2007

FCA 167, citing *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 229 (June 21, 2006) and *Novopharm*).

g) On May 17, 2007 (2007 FC 532), Harrington J. dismissed both of Sanofi's prohibition applications against Riva. However, he said that he would have granted the prohibition application relating to the 206 patent, except that he was bound by *Novopharm* to find that application an abuse of process. He said in his reasons that, but for the *Novopharm* case, he would have granted the prohibition application in respect of the 206 patent (T-1384-04) because he found that Riva's allegation of invalidity was not justified.

[182] Sanofi argues that the Trial Judge should have asked herself what Teva would have done in the hypothetical world once Apotex received its NOC on April 26, 2004. If she had considered that question, according to Sanofi, she would have concluded that once Apotex was on the market, Teva would have promptly sought a summary decision that would have enabled it to enter the market very quickly after April 26, 2004 (although no specific date is suggested). In my view, the question posted by Sanofi cannot be answered in Sanofi's favour unless, on April 26, 2004, there was some legal basis upon which Teva could have obtained an order from the Federal Court dismissing all of Sanofi's prohibition applications against it.

[183] The difficulty for Sanofi is that in the real world, none of Sanofi's prohibition applications responding to an invalidity allegation had been dismissed by April 26, 2004. Therefore, there is no basis for concluding that on or shortly after April 26, 2004 in the

hypothetical world, Teva would have had a legal basis for a summary proceeding (such as a motion to dismiss for abuse of process) that would have led to the issuance of its NOC. I conclude that there is no merit to Sanofi's ground of appeal on this point.

[184] Apotex argues that the Trial Judge erred in concluding that in the hypothetical world, Riva would have had a basis for an abuse of process motion. That conclusion is based on the assumption that in the hypothetical world, there never were any prohibition applications against Apotex, and therefore no prohibition applications that could have been dismissed. It follows that Riva would have had no basis for a motion for summary judgment. Even if Riva had taken steps to hasten the hearing of Sanofi's prohibition application, Sanofi would have been successful in its prohibition application relating to the allegation of invalidity of the 206 patent. It is clear from the reasons of Harrington J. that in the absence of the dismissal of the prohibition application against Apotex, he would have granted that prohibition application.

[185] If the prohibition application against Riva in respect of the 206 patent had not been dismissed, there would have been no basis for an abuse of process motion in respect of the prohibition application against Teva in respect of the 206 patent. In the absence of a dismissal of the Riva prohibition applications in respect of the 206 patent, Teva would have had no basis for its abuse of process motion. Therefore, Teva's prohibition application in respect of the 206 patent could not have been dismissed summarily on September 25, 2006. Instead, it would have been heard on the merits after December of 2006.

[186] As explained above, I do not consider it correct to assume that there are no *NOC Regulations* in the hypothetical world, or that the *NOC Regulations* are not binding on the section 8 claimant (except for the purpose of determining the beginning of the section 8 liability period). Therefore, it appears to me that in the hypothetical world as well as in the real world, the prohibition applications against Apotex would have been dismissed just as they were in the real world. Each such dismissal gave Apotex a right to claim damages under section 8 of the *NOC Regulations*. But at the same time, each dismissal based on an invalidity allegation potentially put at risk any other Sanofi prohibition applications based on the same allegation, including the invalidity allegations made by Teva and Riva.

[187] Given that, it seems to me that Riva and Teva would have behaved in the hypothetical world just as they did in the real world, which was to seek summary dismissal as soon as they considered they had a fair chance of success. And in the real world, the last of the prohibition applications against Riva and Teva relating invalidity allegations was not dismissed until after December 16, 2006. I see no reason to conclude that either Riva or Teva could or would have achieved that result in the hypothetical world any earlier than they did in the real world.

[188] I conclude that the Trial Judge erred in principle in concluding that Teva would have entered the hypothetical market on August 1, 2006. In my view, the only reasonable conclusion on this record is that Teva would not have entered the hypothetical market during the section 8 liability period. Therefore, I would allow the Apotex appeal (A-191-12). The result is that the only competitor of Apotex in the hypothetical market during the section 8 liability period would have been the authorized generic, ratiopharm, inc.

Double ramp-up

[189] As explained by Justice Mainville, Apotex submitted in its notice of appeal and in oral argument that the hypothetical market should have been constructed without any reference to a ramp-up. Apotex argues that it is unfair to reduce the number of hypothetical lost sales during the ramp-up in the hypothetical world without compensating it for its actual lost sales during the ramp-up in the real world.

[190] The Trial Judge rejected the double ramp-up argument on the authority of *Alendronate* (at paras. 99 to 102). She concluded that in the hypothetical market, a ramp-up would have occurred that would have resulted in lower lost sales during the section 8 liability period. But she also concluded that any reduction in sales during the actual ramp-up period was a loss occurring after the section 8 liability period, and therefore it is a loss that cannot be the basis of a claim for damages under section 8.

[191] I agree with the Trial Judge on this point. It is not possible, in my view, to reach the contrary conclusion without implicitly reversing *Alendronate*. The principle in that case has been confirmed twice by this Court: *Teva Canada Limited v. Sanofi-Aventis Canada Inc.*, 2011 FCA 149, and *Teva Canada Ltd. v. Nycomed Canada Inc.*, 2012 FCA 129 (leave to appeal was refused in all three cases). I am unable to accept that this case justifies a reversal of the principle.

[192] I recognize the force of the submission of Apotex that not recognizing the double ramp-up represents a windfall for Sanofi. Indeed, it may well represent a windfall for other innovator drug companies in future cases. However, in my view that is the inevitable consequence of the

decision of the Governor-in-Council to limit section 8 damages to losses incurred within the section 8 liability period. The consequence of that decision cannot be avoided by this Court.

[193] In A-397-12, Sanofi argues that the Trial Judge erred in making her order dated June 22, 2012. In that order, the Trial Judge granted the motion of Apotex to reconsider her initial judgment to reflect a ramp-up in respect of each new entrant to the generic market. I have not been persuaded that the Trial Judge erred in principle in exercising her discretion to grant that motion. Therefore, I would dismiss this appeal of the reconsideration order. Given that I would allow the Apotex appeal (A-191-12), the parties must redetermine Apotex's Lost Volumes during the section 8 liability period. In that redetermination, the parties must take into account the ramp-up effect that would have affected Apotex beginning on April 26, 2004 and the authorized generic beginning on June 26, 2014.

Conclusion

[194] For these reasons, I would allow the Apotex appeal in A-191-12, I would dismiss Sanofi's appeals in A-193-12 and A-397-12, and I would allow Sanofi's appeal in A-474-12 solely to facilitate the redetermination of the quantum of damages. I would award Apotex its costs in A-191-12, A-193-12 and A-397-12. I would award no costs in A-474-12.

"K. Sharlow"

J.A.

"I agree.
J.D. Denis Pelletier J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-191-12

(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED MAY 11, 2012, FEDERAL COURT FILE NO. T-1357-09.)

STYLE OF CAUSE:	APOTEX INC. v. SANOFI-AVENTIS et al
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 30 AND 31, 2013
REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	PELLETIER J.A.
DISSENTING REASONS BY:	MAINVILLE J.A.
DATED:	MARCH 14, 2014

APPEARANCES:

Harry Radomski Nando DeLuca Ben Hackett	FOR THE APPELLANT
Andrew Reddon Steven Mason David Tait Sanjaya Mendis	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Goodmans LLP Toronto, Ontario	FOR THE APPELLANT
McCarthy Tétrault LLP Toronto, Ontario	FOR THE RESPONDENTS

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-193-12

(APPEAL FROM THE JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED MAY 11, 2012, FEDERAL COURT FILE NO. T-1357-09.)

STYLE OF CAUSE:	SANOFI-AVENTIS et al v. APOTEX INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 30 AND 31, 2013
REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	PELLETIER J.A.
DISSENTING REASONS BY:	MAINVILLE J.A.
DATED:	MARCH 14, 2014

APPEARANCES:

Andrew Reddon Steven Mason David Tait Sanjaya Mendis	FOR THE APPELLANTS
Harry Radomski Nando DeLuca Ben Hackett	FOR THE RESPONDENT

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Toronto, Ontario	FOR THE APPELLANTS
Goodmans LLP Toronto, Ontario	FOR THE RESPONDENT

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-397-12

(APPEAL FROM THE ORDER AND DIRECTION OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED JUNE 22, 2012, FEDERAL COURT FILE NO. T-1357-09.)

STYLE OF CAUSE:	SANOFI-AVENTIS et al v. APOTEX INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 30 AND 31, 2013
REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	PELLETIER J.A.
DISSENTING REASONS BY:	MAINVILLE J.A.
DATED:	MARCH 14, 2014

APPEARANCES:

Andrew Reddon Steven Mason David Tait Sanjaya Mendis	FOR THE APPELLANTS
Harry Radomski Nando DeLuca Ben Hackett	FOR THE RESPONDENT

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Toronto, Ontario	FOR THE APPELLANTS

Goodmans LLP Toronto, Ontario	FOR THE RESPONDENT

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-474-12

(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED NOVEMBER 2, 2012, FEDERAL COURT FILE NO. T-1357-09.)

STYLE OF CAUSE:	SANOFI-AVENTIS et al v. APOTEX INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 30 AND 31, 2013
REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	PELLETIER J.A.
DISSENTING REASONS BY:	MAINVILLE J.A
DATED:	MARCH 14, 2014

APPEARANCES:

Andrew Reddon Steven Mason David Tait Sanjaya Mendis	FOR THE APPELLANTS
Harry Radomski Nando DeLuca Ben Hackett	FOR THE RESPONDENT

SOLICITORS OF RECORD:

McCarthy Tétrault LLP Toronto, Ontario	FOR THE APPELLANTS

Goodmans LLP Toronto, Ontario	FOR THE RESPONDENT