Federal Court of Appeal | Cour d'appel fédérale

Date: 20140314

Docket: A-147-12

Citation: 2014 FCA 67

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

BETWEEN:

TEVA CANADA LIMITED

Appellant

and

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

Respondents

Heard at Toronto, Ontario, on October 16 and 17, 2013.

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

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

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REASONS FOR JUDGMENT

DISSENTING REASONS BY MAINVILLE J.A.

[1] These reasons concern an appeal (docket A-147-12) brought by Teva Canada Limited ("Teva") and a cross-appeal brought by Sanofi-Aventis Canada Inc. and Sanofi-Aventis Deutschland GmbH ("Sanofi") 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 552 and publicly released on May 23, 2012. The Liability Judgment ordered Sanofi to compensate Teva 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 2.5, 5 and 10 mg capsules of Teva's generic version of ramipril during the period commencing December 13, 2005 and ending April 27, 2007.

[2] Teva sells a generic version of ramipril in Canada. Ramipril is a drug principally used to treat hypertension, but it also has other medical uses. Sanofi asserts patent rights to this drug and to some of its uses. 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, Teva could have received its NOC from the Minister of Health to market in Canada its generic version of ramipril earlier than it actually did. It was prevented from receiving its NOC at an earlier time because of various applications by Sanofi under subsection 6(1) of the *NOC Regulations* for various 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, will be liable to a third party, such as Teva, for any loss suffered for the delay as determined in accordance with the Regulations. Teva took the view that it was entitled to such compensation and, after a long trial, the Trial Judge agreed.

[4] The issues raised by this appeal principally concern the legal framework under which compensation may be determined under section 8 of the *NOC Regulations*. This is an issue which has never previously been fully addressed by our Court.

[5] In another judgment dated May 11, 2012 and issued for reasons cited as 2012 FC 551 (the "Validity Judgment") 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 litigations were heard by the Trial Judge simultaneously, who then issued a single set of reasons. Sanofi appealed the Validity Judgment with respect to the Teva litigation in docket A-192-12. It also appealed the Validity Judgment with respect to Apotex. This Court has dismissed the appeals related to the Validity Judgment for reasons issued concurrently.

[6] It is useful to note that, concurrently with the Liability Judgment concerning Teva, the Trial Judge also issued another judgment respecting section 8 liability with respect to ramipril and involving Sanofi and Apotex cited as 2012 FC 553 (referred to herein as the "*Apotex Liability Judgment (FC)*"). Some of the issues raised in the Liability Judgment concerning Teva and in the *Apotex Liability Judgment (FC)* are similar. Moreover, this Court heard the appeal from the *Apotex Liability Judgment (FC)* two weeks after it heard this appeal involving Teva, and has issued its reasons for judgment with respect to that appeal concurrently with these reasons.

[7] There is also a related appeal involving Sanofi and Teva with respect to ramipril and concerning amendments to proceedings and to the striking out of evidence (docket A-460-11) which has been dealt with by this Court in reasons issued concurrently.

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 review of that framework follows.

[9] Prescription drugs present a particularly difficult regulatory challenge in light of the various public interest issues that 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 Canadian patients at prices that are affordable to 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* that 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 that must be followed by a manufacturer who wishes to introduce a new drug into the Canadian market.

[11] As a general rule, an innovator drug manufacturer must file a new drug submission with the Minister of Health 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 the drug is 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 of 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 includes so-called "generic" drug manufacturers who 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 with the Minister of Health an abbreviated new drug submission by which it compares its proposed "copy-cat" drug with a Canadian reference product, namely a drug in respect to 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 the drug is approved on the basis of the information provided, the Minister of Health then issues a NOC to the generic drug manufacturer in respect of 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 incur significant research and testing costs in relation to a copy-cat drug, they may sell that drug at a considerable discount on the market, at considerable savings to the Canadian public, but with significant impacts on the revenues and profits of the innovator drug manufacturer. However, innovator drug manufacturers are not without legal recourse against these generic 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 aiming 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 medications available to the public at the most affordable price, with rewarding the patentee for the research leading to the invention and other prescribed factors. 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 of 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 after 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 for 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 other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act;

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

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

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

(*e*) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (a) in circumstances where the issue

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

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

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

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

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

of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.	**de brevet.**
(5) In the event of any inconsistency or conflict between	**(5) Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.**
(*a*) this section or any regulations made under this section, and	
(*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 who files a submission for a NOC in respect of a drug (usually in the form of an abbreviated new drug submission) and who 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 that 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 which 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 the 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 drug manufacturer'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 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

(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

(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

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) 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) 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

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.	**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) 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).	**(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 relevant 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 Teva 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 that is principally used to treat hypertension, but whose medical use has expanded over the years to include heart related health

issues following the publication of a "Heart Outcomes Prevention Evaluation" ("HOPE") 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. 307. 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, including Teva, became interested in marketing their own generic versions of ramipril. 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 listings on the Patent Register": Trial Judge's Reasons at para. 30. Sanofi described these efforts as "product life cycle management", while the generic manufacturers referred to these efforts 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 31 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

Canadian Patent No.	Issue Date	Patent Register Listing	Subject Matter/Indications
1,341,206 (the '206 Patent)	March 20, 2001	April 11, 2001	The product ramipril
2,055,948 (the '948 Patent)	November 12, 2002	June 25, 2004	Use of ramipril together with a calcium antagonist for the prevention and treatment of proteinuria
2,023,089 (the '089 Patent)	January 14, 2003	November 1, 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 for the prevention of stroke, diabetes and/or congestive heart failure.

The last two patents of this list, the ‘549 and ‘387 Patents, are referred to as the “HOPE patents”.

[28] The Trial Judge also provided, at paragraph 33 of her Reasons, a useful chart that briefly summarized the steps involved in the approval under the *NOC Regulations* of Teva’s generic version of ramipril. It is useful to reproduce this chart here:

DATE	EVENT
December 24, 2001	Teva files ANDS [abbreviated new drug submission] for [Teva]-ramipril capsules. The ANDS include Form Vs, stating Teva would await expiry of the '087, '206 and '457 Patents
July 18, 2003	Teva obtains DINs for [Teva]-ramipril 2.5, 5 and 10 mg capsules
October 14, 2003	Teva is placed on “patent hold”
September 12, 2005	Notice of allegation #1 – '206 Patent
September 14, 2005	Notice of allegation #2 – '089, '948, '549 and '387 Patents
October 31, 2005	Sanofi files a Notice of Application with respect to notice of allegation #1 (Court File No. T-1965-05)
November 2, 2005	Sanofi files a Notice of Application with respect to notice of allegation #2 (Court File No. T-1979-05)

DATE	EVENT
December 13, 2005	'457 Patent expires
September 25, 2006	Federal Court dismisses T-1965-05 "as an abuse of process" (*Sanofi-Aventis Canada Inc v Novopharm Limited* , 2006 FC 1135, 306 FTR 56)
December 8, 2006	The Minister of Health advises that Teva was required to address the '089 and '948 Patents, but not the '549 and '387 Patents
December 15, 2006	Teva withdraws, without prejudice, portions of notice of allegation #2 relating to the '549 and '387 Patents
April 27, 2007	Federal Court of Appeal dismisses T-1979-05 (notice of allegation #2) as an abuse of process (*Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 167, rev'g 2006 FC 1547)
May 2, 2007	Teva receives an NOC for [Teva]-ramipril 2.5, 5 and 10 mg capsules

[29] The Trial Judge also noted, at paras. 34 and 35 of her Reasons, that Teva was not the only generic drug manufacturer challenging these patents. Beginning in February 2003 and continuing up to December 2006, Pharmascience Inc., Laboratoire Riva Inc. ("Riva"), Apotex, Cobalt Pharmaceuticals Inc. and Sandoz Canada Inc. also served notices of allegation. In each and every case, except for Cobalt Pharmaceuticals Inc.'s August 2006 notice of allegation, Sanofi chose to bring prohibition applications under the *NOC Regulations*. Moreover, following the issuance of Teva's NOC, Sanofi commenced an action in the Federal Court against Teva claiming that Teva had infringed the '206 Patent. In a decision dated June 29, 2009, the Federal Court dismissed that action and a companion claim against Apotex, and declared the '206 Patent to be invalid: *Sanofi-Aventis Canada Inc. v. Apotex Inc*, 2009 FC 676, 350 F.T.R. 165, aff'd 2011 FCA 300, 426 N.R. 196, leave to appeal to SCC dismissed, file 34325, [2011] 3 S.C.R. xi.

The Reasons of the Trial Judge

[30] The Trial Judge provided very detailed reasons reaching over 127 pages. The salient aspects of those reasons may be summarized as follows.

[31] Subject to the validity issues dealt with by the Trial Judge in the Validity Judgment, Sanofi acknowledged at trial that Teva was entitled to compensation pursuant to section 8 of the *NOC Regulations*: Trial Judge's Reasons at para. 3. Consequently, the debate before the Trial Judge primarily concerned how such compensation was to be determined.

[32] 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 Teva. 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 Teva would have captured if it had been able to sell its generic ramipril" during that period: Trial Judge's Reasons at para. 5 (emphasis in original).

Start and end dates of the section 8 liability period

[33] 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".

[34] 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 section 8 liability period during which the compensation should be calculated in this case.

[35] The parties agreed that the end date for the section 8 liability period was April 27, 2007 when the Federal Court dismissed Sanofi's prohibition proceedings with respect to Teva's second notice of allegation: Trial Judge's Reasons at para. 36.

[36] With respect to the commencement date, the Trial Judge noted that paragraph 8(1)(*a*) of the *NOC Regulations* establishes that it is "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 in this case agreed that the contemplated date was October 14, 2003, the so-called "patent hold" date: Trial Judge's Reasons at para. 39.

[37] 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". Both Teva and Sanofi submitted to the Trial Judge that she should exercise her discretion under that paragraph so as to set another commencement date. On the one hand, Teva urged that the commencement date be set at July 18, 2003, when it received its drug identification number ("DIN") from Health Canada, on the ground that once this DIN was received, a NOC would have been issued to it soon thereafter. On the other hand, Sanofi rather urged that the date be set at December 13, 2005 when the '457 Patent expired.

[38] With respect to Teva's submission, the Trial Judge noted that in its Form V submitted under the *NOC Regulations*, Teva had agreed to await the expiry of the '457 Patent before receiving its NOC. She also noted that Teva did not file notices of allegations until September of 2005. Consequently, the statutory stays resulting from Sanofi's prohibition proceedings under the *NOC Regulations* did not begin until October 31, 2005. As a result, the Trial Judge noted (at para. 43 of

her Reasons) that the case presented an unusual situation in which the "patent hold" date preceded the beginning of the statutory stay.

[39] The Trial Judge found, as a matter of law, that the start of the section 8 liability period cannot predate the start of the statutory stay provided for by the *NOC Regulations*: Trial Judge's Reasons at para. 60. She reached that conclusion by relying on (a) the decisions of this Court in *Apotex Inc. v. Merck & Co.*, 2011 FCA 329, 425 N.R. 279 at para. 75 ("*Norfloxacin*") and in *Alendronate* at para. 71, (b) the Regulatory Impact Statement ("RIAS") with respect to amendments to the *NOC Regulations* brought in 1993, 1998 and 2006, and (c) general principles of causality: Trial Judge's Reasons at paras. 44 to 60.

[40] Given this finding of law, the Trial Judge then proceeded to determine whether the appropriate start date should be October 31, 2005 (the commencement of the statutory stay) or December 13, 2005 (the date of the expiry of the '457 Patent). Since Teva had indicated in its abbreviated new drug submission of December 24, 2001 that it would await expiry of the '087, '206 and '457 Patents, and since it did not submit any notice of allegation with respect to the patents listed for ramipril until September, 2005 and no such notice with respect to the '457 Patent, the Trial Judge found Teva's actions consistent with a decision to await the expiry of that patent before launching its own generic version of ramipril: Trial Judge's Reasons at paras. 61 to 66. The Trial Judge found that Teva was satisfied with awaiting the outcome of the prohibition proceedings involving ramipril and other generic drug manufacturers, and was by that fact somewhat bound by the decision of Simpson J. in *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1381, 44 C.P.R. (4^{th}) 90 which prohibited the Minister of Health from issuing a NOC to Apotex until the expiry of the '457 Patent on December 13, 2005: Trial Judge's Reasons at paras. 67 to 70.

[41] The Trial Judge also considered the start date from the perspective of Teva's behaviour in the hypothetical scenario of the total absence of the *NOC Regulations*. She found that in such a scenario, Teva's behaviour was consistent with its decision not to challenge Sanofi's '457 Patent under the *Patent Act* or to risk a patent infringement action under that patent prior to launching its own generic version of ramipril: Trial Judge's Reasons at paras. 71 to 74.

[42] The Trial Judge accordingly concluded that the appropriate start date for the section 8 liability period was December 13, 2005, the date of the expiry of the '457 Patent: Trial Judge's decision at para. 75. She added that she would have reached the same conclusion even if she had found that the *NOC Regulations* allowed for the section 8 liability period to start prior to the start of the statutory stay: Trial Judge's Reasons at para. 76.

The hypothetical ramipril market

[43] Having determined the relevant section 8 liability period, the Trial Judge proceeded to assess Teva'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 Teva.

[44] Based on the expert reports and the evidence submitted, the Trial Judge adopted the analysis of Dr. Carbone to quantify both the size of the ramipril market (Trial Judge's Reasons at paras. 77 to

92) and of the generic market (Trial Judge's Reasons at paras. 93 to 105) during the section 8 liability period.

[45] 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 one "but for" world.

[46] Teva submitted to the Trial Judge that, as a matter of law and principle, it should be considered as the only generic manufacturer of ramipril during the section 8 liability period: Trial Judge's Reasons at para. 110. On the other hand, Sanofi submitted that other generic manufacturers should be considered within a single "but for" world that should apply to all claims of all concerned generic drug manufacturers under section 8 of the *NOC Regulations*: Trial Judge's Reasons at para. 111.

[47] The Trial Judge rejected Teva's submission on the ground that it ignored (a) principles of causation, (b) the clear wording of section 8 of the *NOC Regulations* which requires that all relevant matters be considered in the assessment of the compensation amount, and (c) the principle that section 8 damages should be strictly compensatory: Trial Judge's Reasons at paras. 115 to 123.

[48] Consequently, the Trial Judge agreed with Sanofi that she must consider the presence of other generic drug manufacturers in the hypothetical generic ramipril market.

[49] However, the Trial Judge nevertheless disagreed with Sanofi's "one world" approach on the ground that the assessment of damages should be made on the facts of each case. In light of the importance of this issue for the purposes of this appeal, I reproduce here paras. 125 to 130 of the Trial Judge's Reasons where she sets out the principal reasons why she dismissed Sanofi's "one but for world" approach:

> [125] While I agree with Sanofi that the "but for" world must consider the presence 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.
>
> [126] 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.
>
> [127] A 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 Teva would have entered the market on December 13, 2005. 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 a different entry date was more appropriate. In the companion Apotex case (Court File No. T-1357-09), I have concluded that a different Relevant Period is applicable; different considerations flow from that finding. Accepting Sanofi's position would, accordingly, require that I disregard evidence in either Apotex's case or this one. Such a result is unsupportable.
>
> [128] I agree with Sanofi that the *PM (NOC) Regulations* contemplate a "multi-generic" universe. However, where I disagree with Sanofi is that the Court must develop one "universe" that accommodates each and every possible s. 8 case. By their very nature, s. 8 damages are hypothetical. It follows that estimates must be made and a market constructed that will not be perfect. 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.

> [129] 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 of 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 possibility that Sanofi's total liability would exceed the bounds of rationality, Sanofi could urge the Court to consider an adjustment pursuant to s. 8(5).
>
> [130] There may be a situation where Sanofi's fear has some merit. It certainly is not this case.

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

[51] The Trial Judge assumed that Teva would have entered the market at the beginning of the section 8 liability period on December 13, 2005. The Trial Judge also reached a number of conclusions with respect to the participation in the hypothetical generic ramipril market of Apotex, Riva and an authorized generic. These conclusions are summarized below.

Apotex

[52] The Trial Judge found that Apotex would have entered the market at the same time as Teva on December 13, 2005 when the '457 Patent expired. She came to that conclusion mainly on the ground that Apotex was subject to a prohibition order issued by Simpson J. in *Aventis Pharma Inc. v. Apotex Inc.*, above, and that the effect of that order only expired with the '457 Patent. The Trial Judge recognized that in her *Apotex Liability Judgment (FC)* she had concluded that the prohibition order of Simpson J. was unenforceable in light of the subsequent decision of Tremblay-Lamer J. in

Aventis Pharma Inc. v. Apotex Inc., 2005 FC 1504, 283 F.T.R. 171, 44 C.P.R. (4th) 108. However she found the approach she had taken in the *Apotex Liability Judgment (FC)* to be inapplicable in the proceedings concerning Teva for the following reasons (Trial Judge's Reasons at para. 150):

> In this trial, however, neither Sanofi nor Teva argues that the [Simpson J.] Prohibition Order would have been without effect or unenforceable as of November 4, 2005 [date of the Tremblay-Lamer J. decision]. Accordingly, on the record and arguments before me, I will assume that the [Simpson J.] Prohibition Order remained in place as an impediment to Apotex's market entry until December 13, 2005.
>
> (Emphasis in original)

[53] The Trial Judge also reached her conclusion with respect to Teva's market entry by applying the methodology she adopted to construct the hypothetical market. That methodology called for Teva (as a section 8 claimant) to be presumed exempt from the application of the *NOC Regulations*, while all other generic drug manufacturers, including Apotex, were to be presumed bound by the *NOC Regulations* within the hypothetical market. Consequently, the respective market entry dates of the other generic drug manufacturers (Apotex, Riva and another generic manufacturer) had to be determined, for the purposes of the hypothetical market, by taking into account the regulatory impediments established by the *NOC Regulations*: Trial Judge's Reasons at paras. 144 to 148.

Riva

[54] The Trial Judge found that Riva would not have entered the hypothetical generic ramipril market until June 21, 2007, and thus only after the section 8 liability period with respect to Teva 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. 171. She came to that conclusion by applying the same methodology she used to determine Apotex's market entry, namely that all

other generic drug manufacturers, except Teva, were to be presumed to be bound by the *NOC Regulations* in the hypothetical market, and that their respective market entry date would largely depend on how they would have navigated these Regulations.

[55] As a result, though Riva had submitted its abbreviated new drug submission for its generic version of ramipril on June 8, 2004, it had cross-referenced its own application to that of Pharmacience Inc. ("Pharmascience"): Trial Judge's Reasons at paras. 166 and 167. 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. 168 and 169. The Trial Judge therefore concluded 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. 170.

Authorized Generic

[56] 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. 173. She 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 innovator's advantage when using an authorized generic is to "recoup some of the market that has been lost to generics": Trial Judge's Reasons at para 174.

[57] Teva's submitted that section 8 of the *NOC Regulations* must be interpreted as precluding the presence of an authorized generic. The Trial Judge rejected that submission (a) by noting that

the *NOC Regulations* themselves contemplate an authorized generic in subsection 7(3), and (b) by adding 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. 180 to 184.

[58] 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. 185 to 195.

[59] The Trial Judge also found that the authorized generic would have been launched by Sanofi at the same time as Teva and Apotex would have entered the hypothetical generic ramipril market on December 13, 2005: Trial Judge's Reasons at para. 208. She reached this conclusion largely on the ground that Sanofi would have been aware of impending generic competition as a result of its litigation with Apotex under the *NOC Regulations*.

[60] Within this hypothetical generic ramipril market comprising Teva, Apotex and an authorized generic, all entering the market on December 13, 2005, the Trial Judge then proceeded to determine Teva's market share. After reviewing the expert evidence which had been submitted with respect to this issue, she accepted Dr. Carbone's analysis and concluded "that, in the 'but for' world, Teva, Apotex and the [authorized generic] would have shared the Generic Market equally": Trial Judge's Reasons at para. 217. She then determined Teva's precise share of the hypothetical ramipril market by applying an inventory adjustment: Trial Judge's Reasons at paras. 218 to 220.

[61] The Trial Judge then quantified Teva's losses resulting from the lack of participation in this hypothetical market by multiplying the volume of lost capsules of generic ramipril it would have sold by the price at which they would have been sold, and by then deducting the expenses which Teva would have incurred to make these sales.

[62] With respect to the issues related to pricing and expenses on which the parties or their experts did not agree, the Trial Judge decided as follows. The Trial Judge dismissed Teva's claim for capital losses or for "lost business value" on the ground that this was the equivalent of a claim for loss of a permanent market share or future lost profits, a form of claim which was denied by our Court in *Alendronate*: Trial Judge's Reasons at pares. 238, 241 to 249 and 254. She also denied Teva's claim for a duplicate ramp-up adjustment (the time it takes a drug manufacturer to penetrate the market to its full potential) on the same ground: Trial Judge's Reasons at pares. 250 to 254.

[63] With respect to pricing, the Trial Judge accepted the calculations of Mr. Hamilton save in respect of pricing in the province of Quebec, for which she approved an adjustment: Trial Judge's Reasons at pares. 263 to 268.

[64] The Trial Judge further determined the level of trade spend (*i.e.* enticements to pharmacists and distributors) based on the expert evidence submitted: Trial Judge's Reasons at paras. 269 to 276. She further accepted Mr. Hamilton's approach to the pricing of the active pharmaceutical ingredient: Trial Judge's Reasons at paras. 277 to 282.

[65] The Trial Judge further rejected Teva's claim for lost profits on other products based on her prior finding that Teva would not be the first to enter the hypothetical generic ramipril market, combined with her finding of the absence of clear evidence as to how this claim could be measured: Trial Judge's Reasons at paras. 284 to 287. She further dismissed Teva's claim for lost indirect profits on the grounds that it was speculative and too remote: *Ibid.* at paras. 288 to 294.

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

[67] The Trial Judge found that, in the hypothetical market, Teva would not have included reference to HOPE indications in its product monograph, but that nevertheless some sales of that generic product would have related to those indications: Trial Judge's Reasons at paras. 302 and 310. She nevertheless refused to discard these sales from the calculation of Teva'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 Teva'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. 312.

[68] The Trial Judge concluded that, in the hypothetical market, Teva 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, Teva's losses with respect to such sales should be compensated under section 8 of the *NOC Regulations*: Trial Judge's Reasons at paras. 319 to 322. She however added "[t]hat is not to say that a second person [a generic manufacturer] may always recover for unapproved indications. Another s. 8 claim may provide a different set of facts that warrants a different finding or a downward adjustment to the second person's damages pursuant to s[s]. 8(5) of the [*NOC*] *Regulations*. But, not in this case": Trial Judge's Reasons at para. 322, emphasis in original.

The issues in appeal and the standard of review

[69] The three main issues in this appeal concern (a) the start date for the section 8 liability period, (b) the attributes of the hypothetical market during that period, and (c) whether the hypothetical sales by a generic in the hypothetical market could include sales for unapproved indications, such as the HOPE indications. Teva also raises additional issues related to the quantification of damages, including alleged errors with most of the Trial Judge's findings in this respect, including her findings concerning (i) lost business value, (ii) lost indirect profit, (iii) lost sales on other products, (iv) active pharmaceutical ingredient pricing, and (v) double ramp-up.

[70] All parties rightfully submit that the standard of review that 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 question of law cannot be extricated are reviewed on the standard of palpable and overriding error.

First Issue: Determining the start for the section 8 liability period

[71] Teva challenges the Trial Judge's finding (at para. 60 of her Reasons) that, as a matter of law, the section 8 liability period cannot begin prior to the start of the statutory stay period contemplated by paragraph 7(1)(*e*) of the *NOC Regulations*. In Teva's view, the *NOC Regulations* clearly stipulate that the start of the liability period must coincide with the date that Teva could have received its NOC for its generic version of ramipril (variously known and referred to as the "patent hold" date or the "certification date") unless the judge finds that another date is more appropriate. Teva therefore submits that the Trial Judge erred in law by finding that the start date of the section 8 liability period must correspond to the beginning of the statutory stay period. I agree with Teva on this issue.

[72] Paragraph 8(1)(*a*) of the *NOC Regulations* appears to me to be drafted in very clear and uncontroversial language:

8. (1) … the first person [the innovator drug manufacturer] is liable to the second person [the generic drug manufacturer] for any loss suffered during the period	**8. (1) […] la première personne est responsable envers la seconde personne 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 : [...]**

(ii) a date other than the certified date is more appropriate;	**(ii) soit qu'une date autre que la date attestée est plus appropriée ;**

[73] The Trial Judge's conclusion in respect to the start date of the section 8 liability period requires that the words "beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued" be substituted by the words "beginning on the date of the start of the statutory stay provided for under paragraph 7(1)(*e*) of these regulations". In my view, the Trial Judge is rewriting paragraph 8(1)(*a*) of the *NOC Regulations* rather than interpreting the plain wording of that paragraph.

[74] The Trial Judge justified her rewriting of the provision by relying on the decision of this Court in *Norfloxacin* at para. 75 where Stratas J.A. commented that section 8 compensation should be assessed "on the basis of a hypothetical question: what would have happened had [the innovator drug manufacturer] not brought an application for prohibition?" She also relied on this Court's decision in *Alendronate* at para. 71 where Noël J.A. commented that section 8 allows a generic drug manufacturer "to recover losses arising from the automatic stay triggered by a first person when the attempt to assert its patent rights fail."

[75] However, neither *Norfloxacin* nor *Alendronate* dealt with the start date of the section 8 liability period or with the interpretation of paragraph 8(1)(*a*) of the *NOC Regulations*. In many, if not most, cases the section 8 liability period will begin with the start of the statutory stay since a generic drug manufacturer will usually issue a notice of allegation concurrently with its application for a NOC or shortly thereafter. As a result, the innovator drug manufacturer will quickly initiate an application under section 6 of the Regulations with the added result of initiating the statutory stay

provided under paragraph 7(1)(*e*). Consequently, in most cases, the start date of the statutory stay will predate the patent hold date. The comments of this Court in *Norfloxacin* and *Alendronate* must be understood in that context, and not as a general statement of the law.

[76] There may indeed be circumstances, such as here, where the "patent hold" date predates the statutory stay. In such circumstances, I see no compelling legal principle which would allow a court to disregard the clear wording of paragraph 8(1)(*a*) of the *NOC Regulations*. Moreover, the Regulations themselves provide a large degree of flexibility to determine whether "a date other than the certified date is more appropriate" (sub-para. 8(1)(*a*)(ii)). Thus, as a matter of statutory interpretation, the clear wording of paragraph 8(1)(*a*) must prevail, and the start date of the section 8 liability period should be presumed to be that on which the Minister certified that a notice of compliance would have been issued to the generic drug manufacturer, subject, however, to the court's discretion to displace that date in circumstances where another date would be deemed more appropriate.

[77] The Trial Judge also relied on the Regulatory Impact Assessment Statements ("RIAS") published with the 1993, 1998 and 2006 versions of the *NOC Regulations*, but I am not convinced that the texts of the RIAS cited by the Trial Judge have the effect she ascribes. The RIAS are drafted in general terms, and do not state that the section 8 liability period must be concomitant with the period of the statutory stay. In any event, though the RIAS may serve as an interpretative tool, they cannot override the clear language of the *NOC Regulations* themselves.

[78] Finally, I am not persuaded by the Trial Judge's comment that principles of causation require that the start of the section 8 liability period be tied to the start of the statutory stay when the patent hold date precedes that date. Though ordinary principles of the law of damage have an important role to play under section 8 of the *NOC Regulations*, the liability set out under that section is purely statutory. As a result, the clear language of the Regulations (such as that set out in para. 8(1)(a)) must in all cases prevail over general principles. Moreover, I am not convinced that, in appropriate circumstances, a generic drug manufacturer would not be justified to claim compensation before the start of the statutory stay, and in fact the Regulations allow the court to determine another "more appropriate" date without any temporal restriction.

[79] Consequently, I disagree with the Trial Judge's finding of law to the effect that the section 8 liability period cannot predate the statutory stay. Rather, the section 8 liability period should begin on the date, as certified by the Minister, on which a NOC would have been issued to the generic drug manufacturer in the absence of the *NOC Regulations*, unless another preceding or subsequent date is found by the court to be more appropriate. This is what paragraph 8(1)(*a*) of the *NOC Regulations* clearly provides for, and I see no cogent reason to disregard the clear language of the Regulations in this respect.

[80] That being said, I do not agree with Teva's submission that the Trial Judge should have exercised her discretion under subparagraph 8(1)(*a*)(ii) of the *NOC Regulations* so as to set the commencement of the section 8 liability period at August 1, 2003, the date following that on which it received its drug identification number (or DIN) and was ready to launch its generic version of

ramipril. On the contrary, in the circumstances of this case, I agree with the Trial Judge's finding that the more appropriate start date is December 13, 2005, the date of the expiry of the '457 Patent.

[81] First discussing Teva's suggested start date of August 1, 2003, I note that Teva itself recognizes that the issuance of a DIN does not authorize it to market a generic drug in Canada. Only a NOC issued under the *Food and Drug Regulations* can achieve that purpose. Consequently, the fact that Teva received a DIN is immaterial to the issue of determining a more appropriate start date for the section 8 liability period. Moreover, Teva has failed to submit to this Court a single cogent argument as to why and how it could have marketed its generic version of ramipril prior to its "patent hold" date of October 14, 2003. As a result, Teva's proposed start date of August 1, 2003 should be disregarded as a "more appropriate" start date under subparagraph 8(1)(*a*)(ii) of the *NOC Regulations*.

[82] On the other hand, there is much merit to the Trial Judge's finding under subparagraph 8(1)(*a*)(ii) that a "more appropriate" start date is December 13, 2005, the date on which the '457 Patent expired. The Trial Judge came to this date for two different reasons: (a) that Teva was satisfied with awaiting the outcome of the of prohibition proceedings under the *NOC Regulations* involving ramipril and other generic drug manufacturers, and (b) from the perspective of Teva's behaviour in a hypothetical scenario of the total absence of the *NOC Regulations*, which behaviour was consistent with its decision not to challenge the '457 Patent under the *Patent Act* or to risk an infringement action under that patent prior to launching its own generic version of ramipril.

[83] I disagree with the Trial Judge's first reason, since it implies that Teva's start date is to somehow be determined with reference to its navigation of the *NOC Regulations* themselves, an approach which I believe is discouraged by the language of paragraph 8(1)(*a*) when it refers to the determination of the start date "in the absence of these Regulations". However, I agree with the Trial Judge's second test which is to analyze the conduct of Teva under the *NOC Regulations* as a proxy for the conduct it would have had in the hypothetical market in the absence of those Regulations.

[84] Specifically, Teva's conduct throughout demonstrates that it had no intention of challenging the '457 Patent under the *NOC Regulations*; as a result, the Trial Judge rightfully inferred that, in the circumstances of these proceedings, Teva would not have challenged the '457 Patent under the *Patent Act* irrespective of whether or not it had to navigate the *NOC Regulations*. Consequently, Teva's conduct shows that, in a hypothetical market where the *NOC Regulations* are non-existent, it still would not have launched its generic version of ramipril before the expiry of the '457 Patent so as to avoid potential patent infringement liability under the *Patent Act*: see Trial Judge's Reasons at paras. 71 to 76.

[85] Thus, when considered in the overall circumstances of the proceedings and as determined by the Trial Judge, a "more appropriate" date for the start of the liability period is December 13, 2005, the date of the expiry of the '457 Patent. In light of the record before us, there is no reason to believe that Teva would have risked facing a patent infringement liability action by Sanofi by launching its generic version of ramipril prior to the expiry of the '457 Patent. Put simply, Teva took a business

decision not to challenge the '457 Patent under either the *NOC Regulations* or the *Patent Act*, and it must now live with that business decision.

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

Are generic drug manufacturers excluded from the hypothetical market?

[86] Teva's submits that the hypothetical generic ramipril market should be constructed without any regard for all other potential generic market participants. Like the Trial Judge, I do not accept this submission.

[87] There is no provision in the *NOC Regulations* requiring that section 8 compensation be determined under the assumption that no other generic manufacturer would be competing within the market. On the contrary, subsection 8(5) of the *NOC Regulations* specifically provides that in assessing the amount of compensation, the court must take into account all matters which it considers relevant. Surely this includes potential third party competition.

[88] Moreover, Teva fails to identify any general principle of law or any court decision that supports its position. 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]

[89] Teva suggests that it should be entitled to the entire generic market, as would each of the other generic drug manufacturers pursuing claims related to ramipril under section 8 of the *NOC Regulations*, such as Apotex and Riva. The approach suggested by Teva would result in a windfall for itself and for each of the generic drug manufacturers pursuing similar section 8 claims since each would be compensated on the basis that they would each be holding the entire generic market for ramipril. Such an approach is illogical and contrary to basic principles of compensation.

How is the hypothetical market to be constructed?

[90] Sanofi submits that all generic drug manufacturers entering the hypothetical generic ramipril market should be subject to the same rules. Sanofi designates this as the "one world" approach to the hypothetical market. Sanofi adds that the Trial Judge erred in law by applying a methodology in constructing the hypothetical market which systematically leads to windfalls for the concerned generic drug manufacturers.

[91] As discussed in the appeal reasons issued concurrently and concerning section 8 compensation with respect to ramipril involving Sanofi and Apotex (2014 FCA 68), the methodology which should be applied to construct the hypothetical market must be one which is concordant 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 the Regulations; rather, the compensation owed is purely compensatory:

> … A contextual reading of section 8 of the *PM(NOC) Regulations* indicates that "*compensation*" for the loss resulting from the operation of the automatic stay is to

> be computed by reference to the loss suffered by the second person by reason of the stay or the profits that it would have made during the period when it was prevented from going to the market. The claim by Apotex that it should be entitled to all the remedies available to a patentee whose patent has been infringed ignores the plain fact that it is not in that position. The compensation provided is for prejudice actually suffered by a second person by reason of the operation of the stay.
>
> [Emphasis added]

[92] In my view, a construction of a hypothetical market in which Teva enters the market free of the regulatory constraints of the *NOC Regulations*, while the market entry of other potential generic manufacturers is not considered or is impeded by these Regulations, invariably ensures that there will be a windfall for Teva and the other generic manufacturers prevailing themselves of section 8 of those Regulations in their respective proceedings.

[93] 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 Teva 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.

[94] The proper methodology is to construct a hypothetical market that most resembles a real market. In the real market, competition between various generic drug manufacturers occurs. Moreover, once a generic drug manufacturer has received a NOC for a copy cat drug, and save rare exceptions, another generic drug manufacturer can reasonably expect to secure a NOC for its own version of the copy cat drug.

[95] 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 and 36 and 37, a case involving ramipril, Sexton J.A. found that once an innovator has 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 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 Regulations themselves:

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.**

[96] 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. This necessarily implies that the compensation for all concerned should be established based on a same methodology which tends to avoid a windfall for the generic drug manufacturers involved taken as a whole.

[97] 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 the Regulations were non-existent ("in the absence of these Regulations"), then competition from other generic drug manufacturers should be considered. In this respect, it should further be assumed that, save rare exceptions, these other generic drug manufacturers will be in a position to receive a NOC subject only to the delays and timelines set out in the *Food and Drug Regulations*.

[98] Put otherwise, 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.

[99] This approach constructs a hypothetical market that reflects a level regulatory playing field in that market.

The treatment of an authorized generic in the hypothetical market

[100] Teva further submits that, as a matter of principle, authorized generic drug manufacturers should not be considered in the hypothetical market. Again, I cannot support this submission.

[101] First, the *NOC Regulations* themselves contemplate the possibility of authorized generic drug manufacturers in its subsection 7(3), which renders inapplicable the statutory stay provisions "if the owner of the patent has consented to the making, constructing, using and selling of the drug in Canada by the second person [the generic drug manufacturer]."

[102] Second, as aptly noted by the Trial Judge herself at para. 182 of her Reasons:

> Generic drug companies have raised the allegation of inequities caused by AGs [authorized generics] in the past. The 2006 RIAS, above at 1525, contains the following remarks:
>
> > As a final note, certain generic drug companies also argued very forcefully that the Government should incorporate measures in these amendments to address what they perceive as diminishing market incentives in their industry. More specifically, they contend that innovators are increasingly entering into licencing arrangements with willing generic companies (so-called "authorized generics") in order to pre-empt genuine generic competitors and retain market share past patent expiry. This practice, which is also said to be prevalent in the US, is currently being studied by the US Federal Trade Commission. While the Government is of the view that there is insufficient information on the impact of this practice on market dynamics in the industry to support regulatory action at this time, it will be examining this practice more closely in response to these concerns.

[Emphasis added]

> At that time, the Governor in Council was aware that there was an issue surrounding AGs and chose not to make amendments to exclude consideration of AGs in a claim under s. 8. In the absence of clear statutory language, I cannot simply, as urged by Teva, exclude the AG from the s. 8 assessment.

[103] After reviewing the evidence and considering the Trial Judge's Reasons, Teva has failed to convince me that the Trial Judge committed a palpable and overriding error in reaching her factual conclusions with respect to the market participation of an authorized generic drug manufacturer.

The participation of Apotex and Riva in the hypothetical market

[104] Teva also submits that all generic drug manufacturers participating in the hypothetical market (except itself) are required to navigate the *NOC Regulations*: Teva's Memorandum at para. 69. As a result, the Trial Judge should have found that Apotex's participation in the hypothetical market could not have occurred prior to December 15, 2006 when the Minister of Health determined that it did not have to address the HOPE Patents. As I have noted above and in the reasons issued concurrently concerning Apotex's section 8 claims against Sanofi with respect to ramipril (2014 FCA 68), the participation of all generic drug manufacturers in the hypothetical market should not be determined with reference to the *NOC Regulations*.

[105] Teva also adds that Sanofi failed to adduce enough evidence to demonstrate that Apotex could have entered the hypothetical generic ramipril market. However, Teva fails to clearly identify the alleged errors, largely limiting itself to the general statement that the Trial Judge's findings are based on conjecture: Teva's Memorandum at para. 70. After reviewing the evidence and

considering the Trial Judge's Reasons, Teva has failed to convince me that the Trial Judge committed a palpable and overriding error in reaching her factual conclusions with respect to Apotex's capacity to enter the generic ramipril market.

[106] A more relevant submission is made by Sanofi with respect to Apotex's and Riva's market participation.

[107] Had the Trial Judge taken into account the proper approach to construct the hypothetical generic ramipril market, an approach that is described above and which allows for a level playing field in the hypothetical market by treating all market participants on an equal footing with respect to their regulatory environment, she would have certainly reached different conclusions with respect to the market entry dates of Apotex, Riva and an authorized generic.

[108] As an example, in this case involving Teva, the Trial Judge found that Apotex would enter the hypothetical generic ramipril market on December 13, 2005 on the ground that it was precluded from entering earlier as a result of the decision of Simpson J. in *Aventis Pharma Inc. v. Apotex Inc.*, above: Trial Judge's Reasons at para. 148. Yet, in the *Apotex Liability Judgment (FC)*, the Trial Judge found that the Simpson J. order could be disregarded in light of the subsequent decision of Tremblay-Lamer J. in *Aventis Pharma Inc. v. Apotex Inc.*, above, leading her to conclude that Apotex's market entry would be its "patent hold" date of April 26, 2004.

[109] Moreover, as Teva has rightfully pointed out, in the *Apotex Liability Judgment (FC)* the Trial Judge considered that the market participation of an authorized generic drug manufacturer

would have followed a surprise launch by Apotex on April 24, 2004, leading her to conclude that the authorized generic would enter the market 90 days later on July 26, 2004. However, in the Liability Judgment involving Teva, she determined that the authorized generic drug manufacturer would enter the market at the same time as all other generics since the application of the *NOC Regulations* (which, through the notice of allegation, require an advance notice of intended market entry) would have precluded a surprise launch.

[110] By applying a level regulatory playing field in the hypothetical market, it should be assumed that the *NOC Regulations* would not apply, and that consequently Sanofi would not have obtained an advance notice of the decision of Apotex to enter the generic ramipril market. Consequently, I see no reason why the entry of an authorized generic drug manufacturer should have been treated differently in the Liability Judgment involving Teva than in *Apotex Liability Judgment (FC)*.

[111] Similar considerations apply to the market entry of Riva.

[112] As a result, I conclude that the findings of the Trial Judge with respect to the entry of Apotex, 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: Liability for hypothetical sales in the hypothetical market related to unapproved indications, such as the HOPE indications

[113] In its cross-appeal, Sanofi submits that since Teva 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, Teva 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.

[114] For Sanofi, the question is "whether the 'loss' referred to in section 8 can extend to a category of sales that are inextricably associated with an infringing use. Properly interpreted, section 8 does not contemplate recovery by a second person for such sales": Sanofi's Memorandum at para. 129. It adds that while "Teva may not be *infringing* in relation to HOPE sales, all such sales during the relevant period would have resulted in an infringement of Sanofi's rights 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 section 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, particularly when the generic party took intentional steps to avoid any claim of infringement": Sanofi's Memorandum at para. 132, emphasis in original.

[115] In the factual circumstances of these proceedings, I do not agree with Sanofi's submissions. The simple fact of the matter is that, 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.

[116] 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.

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

Fourth Issue: Alleged errors in the quantification of damages

[118] Teva also raises additional issues related to the quantification of damages, including the Trial Judge's findings concerning (i) lost business value, (ii) lost indirect profit, (iii) lost sales on other products, (iv) active pharmaceutical ingredient pricing, and (v) double ramp-up.

Lost Business Value

[119] The claim related to lost business value is essentially a claim for lost future profits which is precluded by the decision of this Court in *Alendronate*. As noted by Noël J.A. at paras. 101 and 102 of that decision:

> [101] In this case, we have the advantage of knowing that in 1998 the Governor-in-Council focused on this very issue, and chose to limit the measure of the losses which can be compensated by way of damages to those suffered during the period. No issue of principle flows from this. The Governor-in-Council could

> have extended the measure of the losses to include those caused during the period, regardless of when they are suffered. However, it did not do that.
>
> [102] The Governor-in-Council's clearly expressed intent must be given effect to. This excludes compensation for losses occurring in future years since such losses cannot be said to have been suffered during the period. It follows, for instance, that Apotex's entitlement to damages for lost sales resulting from the alleged decrease in its market share must be confined to sales that can be shown to have been lost within the period. In order to be compensated, the losses must be shown to have been incurred during the period. I therefore conclude that the appeal should be allowed on this limited point.
> [Emphasis in original]

[120] As a result, the Trial Judge made no error of principle in rejecting Teva's claim with respect to lost business value.

Lost Indirect Profit

[121] Teva also submits that the Trial Judge erred by failing to award it compensation for the lost opportunity to reinvest the profits that it would have made resulting from its sales of generic ramipril during the section 8 liability period. I disagree.

[122] The Trial Judge found, as a matter of fact, that "there is simply no evidence on the record, beyond the bare assertions … that Teva would have made such investments. The claim is too vague and unsubstantiated to be allowable on the facts of this case": Trial Judge's Reasons at para. 292. Teva has failed to convince me that the Trial Judge made a palpable and overriding error in reaching these findings.

[123] Moreover, as a matter of law, to the extent that Teva has lost an opportunity to invest the profits it would have made during the liability period, the Trial Judge was correct in concluding that

pre-judgment interest was the accepted method for compensating this loss unless there is clear and non-speculative evidence of a lost opportunity that would exceed the interest otherwise payable: Trial Judge's Reasons at para. 293, citing *V.K. Mason Construction Ltd. v. Bank of Nova Scotia*, [1985] 1 S.C.R. 271 at p. 286.

Lost sales on other products

[124] Teva further submits that the Trial Judge erred in dismissing its claim for compensation allegedly resulting from the loss of its ability to generate additional business as a consequence of its presence in the generic ramipril market during the section 8 liability period. Teva asserts that the Trial Judge recognized these losses, but refused to allow compensation in light of the difficulty in quantifying the losses.

[125] The Trial Judge rather found that Teva's claim was largely dependent on its assumption that it would be the sole generic supplier of ramipril during the section 8 liability period; since this assumption was rightfully discarded by the Trial Judge, the evidentiary basis supporting the claim in a multi-generic market environment was thus found to be highly speculative: Trial Judge's Reasons at paras. 284-285.

[126] In any event, the Trial Judge also found that the evidence submitted by Teva to support this claim was nothing more than "vague statements": Trial Judge's Reasons at para. 286.

[127] Consequently, the Trial Judge's decision to disallow this claim was not based on a refusal to quantify the amount of compensation, but rather resulted from the lack of an evidentiary foundation to support the claim. Teva has failed to convince me that the Trial Judge committed a palpable and

overriding error in reaching her factual conclusions about the quality of the evidence supporting this claim.

Active pharmaceutical ingredient pricing

[128] In addition, Teva submits that the Trial Judge made a palpable and overriding error of fact in determining the price for its acquisition of the active pharmaceutical ingredient for its generic version of ramipril. I disagree. The Trial Judge's factual finding was based on the ample expert evidence before her and on her decision to adopt the approach of Mr. Hamilton (Sanofi's expert) over that of Ms. Loomer (Teva's expert).

[129] In this appeal, Teva is essentially asking this Court to review anew the expert evidence so as to substitute a new finding of fact which would be more favourable to its position. Re-weighing expert evidence is not the role of an appellate court. Since Teva has failed to explain in what manner the findings of the Trial Judge would constitute a palpable and overriding error, its appeal with respect to the pricing of the active pharmaceutical ingredient must fail.

Double ramp-up

[130] 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, Teva would in theory have experienced a ramp-up period. However, Teva 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, Teva suffers a loss of profits which it would not otherwise have incurred.

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

[132] 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.

[133] 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.

[134] 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 paras. 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."

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

[136] 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.*, 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 [section 8 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 principle set out by Noël J.A. at para. 102 of that decision reproduced above in these reasons.

[137] 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 entirely 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 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*.

[138] I would consequently allow Teva's appeal on the issue of the double ramp-up.

Conclusions

[139] I would allow in part the appeal and the cross-appeal by confirming the Trial Judge's judgment in all aspects except with respect to sub-paragraph 2(a) and to paragraph 3 of that judgment, which I would set aside.

[140] I would also refer the matter back to the Chief Justice of the Federal Court for a continuance of the trial by the Trial Judge or another judge in light of the reasons of this Court with respect to (a) the construction of an hypothetical generic market for ramipril in which a level regulatory playing field applies, and (b) the double ramp-up.

[141] In light of the divided result, I would make no order as to costs.

"Robert M. Mainville"

J.A.

SHARLOW J.A.

[142] 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 December 13, 2005 and ended on April 27, 2007.

(b) The Trial Judge made no error in concluding that Teva 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 authorized generic drug manufacturers are not excluded from the hypothetical market.

(d) The Trial Judge made no error in her findings with respect to lost business value, lost indirect profit, lost sales on other products, and the pricing of the active medicinal ingredient.

[143] However, for the reasons explained below, I respectfully disagree with Justice Mainville's proposed disposition of this appeal. I differ from Justice Mainville with respect to the methodology for determining the date on which the potential competitors of Teva would have entered the hypothetical market, and with respect to the double ramp-up. For the reasons that follow, I would dismiss the appeal and cross-appeal.

Determining the date of entry of competitors in the hypothetical market

[144] Sanofi submits that the Trial Judge erred when, for the purposes of constructing the hypothetical market, she treated Teva 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. Justice Mainville agreed with Sanofi's argument. I do not agree, for the reasons explained more fully in the reasons issued concurrently concerning Apotex's section 8 claims against Sanofi with respect to ramipril (2014 FCA 68).

[145] My view, in summary, is that in the hypothetical world constructed for the purposes of determining section 8 damages, the NOC Regulations should not be assumed away except to the extent required by paragraph 8(1)(a), that is, for the purpose of determining the beginning of the section 8 liability period. For all other purposes, the NOC Regulations should be assumed to exist in the hypothetical world, and all steps that were actually taken under the NOC Regulations should be assumed to have been taken in the hypothetical world unless there is evidence upon which the trier of fact may reasonably conclude that different steps would have been taken.

[146] This methodology led the Trial Judge to conclude that in the Teva hypothetical world, Apotex and an authorized generic would have entered the hypothetical market on the date of the expiry of the 457 patent, December 13, 2005, the same day that she had previously determined to be the day on which Teva would have entered the hypothetical market, which was also the beginning of the section 8 liability period.

[147] Teva argues that the Trial Judge erred in finding that Sanofi would and could have arranged to have an authorized generic ready to launch on December 13, 2005. That is a factual finding that must stand absent an error in principle or a palpable and overriding factual error. I can discern no such error. I note that in the real world, Sanofi had ensured that an authorized generic was ready to launch almost simultaneously with the issuance of the NOC to Apotex on December 12, 2006. Given the history of the ramipril litigation and the various challenges to the validity of the relevant patents before 2005, it was reasonably open to the Trial Judge to conclude that Sanofi could have achieved in December of 2005 what it actually achieved in December of 2006.

[148] Both Sanofi and Teva argue that the Trial Judge erred in determining that Apotex also would have entered the hypothetical market on December 13, 2005. Sanofi argues for an earlier entry date for Apotex, and Teva argues for a later entry date.

[149] Sanofi argues that the Trial Judge should have chosen an earlier date for the entry of Apotex into the hypothetical market because that is what she did in the Apotex Liability Judgment (FC). In the Apotex case, the Trial Judge decided as she did largely because the only prohibition order ever made against Apotex in relation to ramipril (the order of Simpson J. issued on October 6, 2005 in respect of the allegation of non-infringement of the 457 patent) was rendered ineffective by the later decision of Tremblay-Lamer J. (November 4, 2005) when she dismissed the prohibition application in respect of the allegation that the 457 patent was invalid. The Trial Judge declined to reach the same conclusion in this case for the reasons she explained at paragraph 150 of her reasons (quoted above in the reasons of Justice Mainville and repeated here for ease of reference):

> In this trial, however, neither Sanofi nor Teva argues that the [Simpson J.] Prohibition Order would have been without effect or unenforceable as of November

> 4, 2005 [date of the Tremblay-Lamer J. decision]. Accordingly, on the record and arguments before me, I will assume that the [Simpson J.] Prohibition Order remained in place as an impediment to Apotex's market entry until December 13, 2005. (Emphasis in original)

[150] It might well have been open to the Trial Judge to conclude in this case, as she did in the Apotex Liability Judgment (FC), that the order of Tremblay-Lamer J. effectively caused the earlier prohibition order of Simpson J. to lose its legal effect against Apotex. However, given the arguments made by Sanofi and Teva, she was not compelled to reach the same conclusion in this case. On the contrary, given the arguments put to her, it was open to her to conclude, as she did, that in the hypothetical world the order of Simpson J. should be assumed to have been in effect. To reverse her conclusion on that point now because of Sanofi's revised position in this Court would be tantamount to saying that the Trial Judge erred in law by failing to accept an argument that was never put to her. In my view, that is not an appropriate basis for reversing what is essentially a factual conclusion in relation to the hypothetical market. I would reject Sanofi's argument for an early entry date for Apotex.

[151] Teva argues that it was not open to the Trial Judge to conclude that Apotex would have entered the market on December 13, 2005 because there was not sufficient evidence that Apotex could have entered the market at that time. The Trial Judge explained her conclusion at paragraphs 145 to 154 of her reasons, addressing specifically all of the arguments Teva made in support of its position that Apotex could not have entered the market on December 13, 2005. She rejected all of those arguments. Her conclusions are supportable on the evidence and arguments presented, and I can discern no error in principle. I would reject Teva's argument for a later entry date for Apotex.

Double ramp-up

[152] As explained by my colleague Justice Mainville, Teva submitted 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. Justice Mainville accepted this argument. I do not, for the reasons explained more fully in the reasons issued concurrently concerning Apotex's section 8 claims against Sanofi with respect to ramipril (2014 FCA 68).

[153] In summary, I agree with the Trial Judge, who rejected the double ramp-up argument on the authority of Alendronate (at paras. 99 to 102). It is not possible, in my view, to reach the contrary conclusion without implicitly reversing the principle in Alendronate. I am unable to accept that this case justifies a reversal of that principle.

Conclusion

[154] I would dismiss the appeal and the cross-appeal. In view of the divided success, I would award no costs.

"K. Sharlow"

J.A.

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

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS: A-147-12

APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT DATED MAY 11, 2012, COURT FILE NO. T-1161-07

STYLE OF CAUSE:	TEVA CANADA LIMITED v. SANOFI-AVENTIS CANADA INC. and SANOFI-AVENTIS DEUTSCHLAND GmbH
PLACE OF HEARING:	TORONTO,ONTARIO
DATE OF HEARING:	October 16 AND 17, 2013
REASONS FOR JUDGMENT BY:	SHARLOW J.A.
CONCURRED IN BY:	DAWSON J.A.
DISSENTING REASONS BY:	MAINVILLE J.A.
DATED:	MARCH 14, 2014

APPEARANCES:

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