

Federal Court  
of Appeal



CANADA

Cour d'appel  
fédérale

**Date: 20090604**

**Dockets: A-571-08  
A-580-08**

**Citation: 2009 FCA 187**

**CORAM: NOËL J.A.  
LAYDEN-STEVENSON J.A.  
RYER J.A.**

**BETWEEN:**

**MERCK FROSST CANADA LTD.  
and MERCK FROSST CANADA & CO.**

**Appellants**

**and**

**APOTEX INC.**

**Respondent**

Heard at Toronto, Ontario, on April 21 and 22, 2009.

Judgment delivered at Ottawa, Ontario, on June 4, 2009.

**REASONS FOR JUDGMENT BY:**

**NOËL J.A.**

**CONCURRED IN BY:**

**LAYDEN-STEVENSON J.A.  
RYER J.A.**

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**REASONS FOR JUDGMENT**

**NOËL J.A.**

[1] Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. (collectively Merck) appeal from the decision of Justice Hughes (the Federal Court Judge) (2008 FC 1185), wherein he held, *inter alia*, that section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 as amended S.O.R./98-166 (*PM(NOC) Regulations*) is *intra vires* the *Patent Act*, R.S.C. 1985, c. P-4 as amended S.C. 1993, c. 2, s. 4 (*Patent Act*); within the competence of the Federal Court to

hear and determine an action brought thereunder; and within the constitutional authority of the Parliament of Canada.

[2] Also at issue were questions relating to the remedy which the Court may order pursuant to section 8 of the *PM(NOC) Regulations*. Merck challenges that aspect of the decision which held that the remedy can extend to compensation for future losses. Apotex Inc. (Apotex) for its part cross-appeals the Federal Court Judge's conclusion that it was not entitled to the disgorgement of the profits earned by Merck, but was limited to a claim for damages or its lost profits. Apotex also takes issue with the Federal Court Judge's decision not to award costs. It contends that since it was for the most part successful, costs should have been awarded in its favour.

### **THE RELEVANT FACTS**

[3] Merck received a Notice of Compliance (NOC) approving for sale in Canada its version of alendronate, used primarily in the treatment of osteoporosis, on February 4, 2002.

[4] Apotex filed an Abbreviated New Drug Submission (ANDS) for alendronate on February 7, 2003 and sent a Notice of Allegation (NOA) to Merck on April 14, 2003 alleging that Merck's Canadian Patent 2,294,595 (the '595 Patent) was invalid for a number of reasons.

[5] On May 29, 2003, Merck & Co. Inc. (a United States company) and Merck Frosst Canada & Co. commenced proceedings in the Federal Court (Court File T-884-03) to prohibit the Minister of

Health (the Minister) from issuing an NOC to Apotex which otherwise would permit Apotex to sell its generic version of alendronate (Apo-alendronate) in Canada.

[6] On February 3, 2004 the Minister sent a letter to Apotex advising it that its application for the issuance of the NOC was approved but would be held in abeyance pending the outcome of the prohibition proceedings in the Federal Court.

[7] On May 26, 2005, Mosley J. of the Federal Court dismissed Merck's prohibition application, finding that Apotex's allegations as to invalidity, on some but not all grounds, were justified (2005 FC 755). The next day, the Minister issued an NOC to Apotex permitting it to sell its Apo-alendronate in Canada.

[8] No appeal was taken from Mosley J.'s decision.

[9] On July 5, 2005, Apotex instituted an action in the Federal Court pursuant to section 8 of the *PM(NOC) Regulations* claiming damages for the period from February 3, 2004 to May 27, 2005. This is the period during which the Minister was prevented from issuing the NOC to Apotex by reason of the filing by Merck of the prohibition application eventually dismissed by Mosley J.

[10] By Order of the Federal Court dated January 24, 2006 and August 14, 2008, the quantification of amounts found to be properly recoverable in the action were left to be determined at a subsequent trial. The Federal Court Judge later agreed to consider a number of preliminary

issues submitted by the parties. He disposed of these issues by decision rendered on October 21, 2008. This is the decision now under appeal.

### **THE RELEVANT LEGAL PROVISIONS**

[11] Subsections 55.2(1) and 55.2(4) of the *Patent Act* read 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.

...

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

(a) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee

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.

[...]

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

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

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 of that notice, certificate, permit or other document might result directly or

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 de brevet.

(5) Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.

(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

indirectly in the infringement of a patent.

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.

(5) In the event of any inconsistency or conflict between (a) this section or any regulations made under this section, and (b) any Act of Parliament or any regulations made thereunder, 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.

[12] Section 8 of the *PM(NOC) Regulations* in the form in which that section stood at the time relevant to the action (i.e. on July 5, 2005) reads as follows:

8. (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the

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 ou est rejetée par le tribunal qui en est saisi, ou si

Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period:

(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 is satisfied on the evidence that another date is more appropriate; and

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

(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.

(4) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).

(5) In assessing the amount of compensation the court shall take into

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 est responsable envers la seconde personne de toute perte subie au cours de la période:

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 estime d'après la preuve qu'une autre date 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 peut, par voie d'action contre la première personne, 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 a institué ou non une action pour contrefaçon du brevet visé par la demande.

(4) Le tribunal peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts ou de profits à l'égard de la perte visée au paragraphe (1).

account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

(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 ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

[13] It is also useful to reproduce section 8 as it read when it was originally introduced in 1993:

8. (1) The first person is liable to the second person for all damage suffered by the second person where, because of the application of paragraph 7(1)(e), the Minister delays issuing a notice of compliance beyond the expiration of all patents that are subject of an order pursuant to subsection 6(1).

8. (1) La première personne est responsable envers la seconde personne de tout préjudice subi par cette dernière lorsque, en application de l'alinéa 7(1)e), le ministre report la délivrance de l'avis de conformité au-delà de la date d'expiration de tous les brevets visés par une ordonnance rendue aux termes du paragraphe 6(1).

(2) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any damage referred to in subsection (1).

(2) Le tribunal peut rendre toute ordonnance de redressement par voie de dommages-intérêts ou de profits que les circonstances exigent à l'égard de tout préjudice subit du fait de l'application du paragraphe (1).

[14] The *Regulatory Impact Analyses Statement* (RIAS) which accompanied the change to section 8 brought in 1998 explains the purpose of the amendment as follows:

...

Specifying circumstances in which damages or costs can be Awarded: A clearer indication is given to the court as to circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug, and the factors that may be taken into account in calculating damages. The court may also award costs to either a generic manufacturer or a patentee, including solicitor or client costs, as appropriate, consistent with Federal Courts Rules. The amendments reinforce the balance between providing a mechanism for the effective enforcement of patent rights and ensuring that generic drug products enter the market as soon as possible.

...

[...]

Préciser les circonstances ou des dommages-intérêts peuvent être accordés : De plus grandes précisions sont données aux tribunaux en ce qui concerne les circonstances où des dommages-intérêts pourront être accordés à un fabricant afin de le dédommager des pertes subies à cause du report de la mise en marché de son médicament générique, par ailleurs, des précisions sont aussi données sur les facteurs dont on peut tenir compte pour calculer les dommages-intérêts. Les tribunaux peuvent également accorder les dépens à l'une ou l'autre des parties (fabricant de médicaments génériques ou titulaire de brevet), y compris les honoraires professionnels, le cas échéant, conformément aux Règles de la Cour fédérale. Les modifications envisagées renforceront l'équilibre entre l'assurance d'un mécanisme qui permet de faire véritablement respecter les droits conférés par les brevets et la garantie que les médicaments génériques soient commercialisés aussitôt que possible.

[...]

[15] Finally, reference should also be made to section 20 of the *Federal Courts Act*:

20. (1) The Federal Court has exclusive original jurisdiction, between subject and subject as well as

20. (1) La Cour fédérale a compétence exclusive, en première instance, dans les cas suivants opposant notamment

otherwise,

(a) in all cases of conflicting applications for any patent of invention, or for the registration of any copyright, trade-mark, industrial design or topography within the meaning of the *Integrated Circuit Topography Act*; and

(b) in all cases in which it is sought to impeach or annul any patent of invention or to have any entry in any register of copyrights, trade-marks, industrial designs or topographies referred to in paragraph (a) made, expunged, varied or rectified.

(2) The Federal Court has concurrent jurisdiction in all cases, other than those mentioned in subsection (1), in which a remedy is sought under the authority of an Act of Parliament or at law or in equity respecting any patent of invention, copyright, trade-mark, industrial design or topography referred to in paragraph (1)(a).

des administrés :

a) conflit des demandes de brevet d'invention ou d'enregistrement d'un droit d'auteur, d'une marque de commerce, d'un dessin industriel ou d'une topographie au sens de la *Loi sur les topographies de circuits intégrés*;

b) tentative d'invalidation ou d'annulation d'un brevet d'invention, ou d'inscription, de radiation ou de modification dans un registre de droits d'auteur, de marques de commerce, de dessins industriels ou de topographies visées à l'alinéa a).

(2) Elle a compétence concurrente dans tous les autres cas de recours sous le régime d'une loi fédérale ou de toute autre règle de droit non visés par le paragraphe (1) relativement à un brevet d'invention, un droit d'auteur, une marque de commerce, un dessin industriel ou une topographie au sens de la *Loi sur les topographies de circuits intégrés*.

### **THE FEDERAL COURT DECISION**

[16] The first set of issues addressed by the Federal Court Judge was whether section 8 is *intra vires* the *Patent Act*, within the constitutional authority of Parliament; and whether the Federal Court had the jurisdiction to hear the action. The second set of issues dealt with the nature and extent of the remedies which can be ordered pursuant to section 8 of the *PM(NOC) Regulations*.

[17] Dealing with the first set of issues, the Federal Court Judge rejected Merck's argument that the *Patent Act* does not confer on the Federal Court jurisdiction to hear actions brought pursuant to section 8 of the *PM(NOC) Regulations*. The Federal Court Judge held that Parliament has, by statute, enacted subsection 55.2(4) of the *Patent Act* which in paragraph (d) gives the authority to the Governor-in-Council to make regulations "*conferring rights of action in any court of competent jurisdiction*". The Federal Court Judge further noted that section 2 of the *PM(NOC) Regulations* defines "*court*" to mean "*the Federal Court of Canada or any other superior court of competent jurisdiction*". According to the Federal Court Judge, this has the same effect as a grant of jurisdiction made under the *Patent Act* given that subsection 12(2) of the *Patent Act* provides that "[a]ny ... regulation made by the Governor-in-Council has the same effect as if it had been enacted herein" (Reasons, paras. 63 and 64).

[18] Although he also referred to subsection 20(2) of the *Federal Courts Act*, the Federal Court Judge found that subsection 55.2(4) of the *Patent Act* and the designation of the Federal Court as a court of competent jurisdiction in section 2 of the *PM(NOC) Regulations* was the source of the Federal Court's jurisdiction (Reasons. paras. 66 and 67).

[19] The Federal Court Judge also rejected Merck's contention that section 8 of the *PM(NOC) Regulations* is *ultra vires* the *Patent Act*. Drawing an analogy, he emphasized that section 8 provides a disincentive for seeking what is in effect an interlocutory injunction. The liability created by section 8 acts like an undertaking for damages provided by the person seeking such an injunction. He held that paragraph 55.2(4)(d) specifically provides for regulations respecting

remedies and procedures in respect of disputes under paragraph (c) as to when the NOC may issue. According to the Federal Court Judge: “[t]his includes the 24-month stay on any issuance of the NOC ... and disincentives for seeking such a stay.” (Reasons, para. 74).

[20] Finally, the Federal Court Judge rejected Merck’s argument that the right of action provided pursuant to section 8 is in its pith and substance a matter respecting property and civil rights under the exclusive jurisdiction of the provinces under section 92(13) of the *Constitution Act, 1867* (Reasons, para. 76). The Federal Court Judge held that section 8 is an integral part of the scheme set out in the *PM(NOC) Regulations* as enabled by the *Patent Act*. The scheme is directed to the enforcement of rights in certain types of medicinal patents including a balanced procedure respecting such enforcement (Reasons, paras. 76 and 77).

[21] Turning to the issue of remedy, the Federal Court rejected Apotex’s contention that the disgorgement of Merck’s profit could be ordered pursuant to section 8. The Federal Court Judge noted that a section 8 order may provide for “*relief by way of damages or profits*” as set out in subsection 8(4). He further noted that there is no mention anywhere of any remedy aimed at the profit made by the first person. The entire context of section 8 is focused on compensation for loss suffered by the generic (Reasons, para. 88).

[22] The Federal Court Judge observed that the word “*profits*” appears nowhere in the *Patent Act* and that there was considerable debate as to whether the provision for an “*account*” in an infringement action, meant that a court could order disgorgement of an infringer’s profits. He noted

that the debate was laid to rest by the Federal Court of Appeal in *Beloit Canada Ltd. v. Valmet-Dominion Inc.*, [1997] 3 F.C. 497, (1997) 73 C.P.R. (3d) 321 at pages 355 to 359, where it was held that the remedy of disgorgement of an infringer's profits is authorized by paragraph 57(1)(b) of the *Patent Act*, when read with section 20 of the *Federal Courts Act* (Reasons, para. 92).

[23] However, the Federal Court Judge noted that a generic making a claim pursuant to subsection 8(4) of the *PM(NOC) Regulations* is not in the position of a patentee whose patent has been infringed. The reasonable interpretation of the words “*damages or profits*” is that the generic can seek, as a measure of its damages, in the alternative, the profits that it would have made if it had been able to market its product at an earlier time (Reasons, para. 97).

[24] Lastly, the Federal Court Judge considered Apotex's contention that during the period from February 3, 2004 to May 26, 2005, the marketplace for its alendronate product (i.e. Apoalendronate) became distorted because two other generics entered the marketplace in that period. More specifically, Apotex claimed that, were it not for Merck's prohibition application, it could have been first in the marketplace or it would have at least entered the marketplace at about the same time that the other generics did and that its market share would, thereby, have been larger than it is now. Apotex argued that a lesser market share is a matter that permanently endures and that it should be entitled to damages for lost sales and lost permanent market share beyond May 26, 2005 (Reasons, para. 120).

[25] The Federal Court Judge concluded that it is appropriate for Apotex to make the claim for losses beyond May 26, 2005 provided that the marketplace did not rectify itself or Apotex could not have remedied the marketplace disadvantage before that date. The Federal Court Judge also left the matter of quantification to the later trial (Reasons, para. 122).

### **ALLEGED ERRORS**

[26] In support of its appeal, Merck reiterates each of the arguments made before the Federal Court Judge and submits that he committed a variety of legal errors in rejecting these arguments.

[27] With respect to both the *vires* issue and the constitutional issue, Merck submits that section 8 is not necessary or integral to the overall scheme of the *PM(NOC) Regulations*. The scheme created by the *PM(NOC) Regulations* seeks to prevent patent infringement. Section 8 is not directed towards that end. Indeed, it undermines the statutory objective.

[28] Furthermore, Merck takes issue with the analogy drawn by the Federal Court Judge between the automatic stay which the *PM(NOC) Regulations* provide, and an undertaking given in the context of an infringement action in order to obtain an interlocutory injunction. According to Merck, the Governor-in-Council could have adopted the patent litigation model, but did not. Merck submits that the Federal Court Judge erred in conducting his analysis on the basis of that analogy.

[29] With respect to jurisdiction, Merck submits that, the Federal Court Judge erred in holding that paragraph 55.2(4)(d) of the *Patent Act* when read with the definition of “*court*” in section 2 of

the *PM(NOC) Regulations* confers jurisdiction on the Federal Court. The *Patent Act* does not authorize the Governor-in-Council to confer jurisdiction by delegated legislation. Merck submits that the Federal Court Judge misinterpreted subsection 12(2) of the *Patent Act* when he held that the designation of the Federal Court in section 2 of the *PM(NOC) Regulations* amounts to a grant of jurisdiction which has the same force and effect as if it was found in a statute.

[30] With respect to the issue of remedy, Merck submits that the Federal Court Judge erred in concluding that Apotex is entitled to claim damages for lost sales and loss of permanent market share occurring outside of the period of liability defined in paragraph 8(1)(b) of the *PM(NOC) Regulations*. The language of section 8 refers to “*any loss suffered during the period*” in the past tense. Merck submits that this precludes recovery for losses suffered outside the period.

[31] By its cross-appeal, Apotex contends that the Federal Court Judge erred in finding that section 8 of the *PM(NOC) Regulations* does not allow for an award of disgorgement of profits. The ordinary and grammatical meaning of subsection 8(4) is that two forms of relief are available i.e. “*damages or profits*”. Apotex submits that given that the second person’s own lost profits are its damages, it must be the first person’s profits that are referred to as profits. Otherwise, the words “or profits” are surplusage.

[32] Apotex submits that the construction which it proposes is consistent with the balance which the *Patent Act* seeks to achieve between generics and inventors. A first person has an incentive to commence a proceeding regardless of whether there is any real possibility of infringement. Only the

risk of being compelled to disgorge its own profits can remove the incentive which a first person has to commence a prohibition proceeding for the sole purpose of extending its monopoly rights.

### **ANALYSIS AND DECISION**

[33] The first question which needs to be addressed in order to dispose of this appeal is whether section 8 of the *PM(NOC) Regulations* is *ultra vires* the *Patent Act*. The analysis which must be conducted in order to address this issue will assist in dealing with the constitutional challenge directed at section 8 and the attack on the jurisdiction of the Court.

#### *The vires issue*

[34] True questions of *vires* such as the one here in issue are to be reviewed on a standard of correctness (*Dunsmuir v. New Brunswick*, 2008 SCC 9, para. 59). The question before this Court is therefore whether the Federal Court Judge came to the correct conclusion when he held that section 8 was authorized by the *Patent Act*, and therefore validly promulgated. In my respectful view, he did.

[35] The background and the statutory authority for the *PM(NOC) Regulations* are comprehensively set out by Binnie J. in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 (*BioLyse*). Reference can also usefully be made to *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, paras. 12 to 23 (*AstraZeneca*). It is sufficient for present purposes to set out paragraphs 6 to 12, 45, 46 and 50 of *BioLyse*:

- 6 Over the years, Canada has developed a major sector of “generic drug” manufacturers described as companies that generally manufacture and distribute “drugs which were researched, developed and first brought to market by ‘innovator’ companies” (*Apotex Inc. v. Canada (Attorney General)*, [1994] 1 F.C. 742 (C.A.), at p. 751, *aff’d* [1994] 3 S.C.R. 1100). They produce what is sometimes known in the trade as “copy-cat” drugs.
- 7 The success of the generic drug manufacturers has been a source of grievance to owners of patents for pharmaceutical medicines, who view monopoly profits conferred by patents as essential to recoup the cost of their research program as well as to earn a profit on their investment. Generic drug manufacturers, who generally do not have significant research costs in relation to a drug first brought to market by an innovator company, need only turn a profit on their manufacturing and distribution facilities. Generic drugs can therefore be sold at a discount to “brand name” products in the market place, at considerable savings to the public and at considerable cost to the profits of the innovator drug companies.
- 8 Until 1993 the Minister of Health was not directly concerned with patent issues. Indeed, Parliament’s policy since 1923 had been to favour health cost savings over the protection of intellectual property by making available to generic manufacturers a scheme of compulsory licencing of an “invention intended or capable of being used for medicine or for the preparation or production of medicine” under s. 39(4) of the *Patent Act*. The compulsory licencing scheme gathered momentum after 1969 when it was extended to imported drugs. A compulsory licence could invariably be obtained from the Commissioner of Patents, and a notice of compliance (“NOC”) from the Minister of Health, providing the generic manufacturer could establish pharmaceutical equivalence of its product with the innovator drug (“the Canadian reference product”). In determining the terms of the licence and amount of royalty payable, the Commissioner of Patents was required to “have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed” (s. 39(5)). The royalty payable to the patent owner was generally fixed at 4 percent to 5 percent of the net selling price of the drug in posological form, or 15 percent of the net selling price of the drug in bulk (T. Orlhac, “The New Canadian Pharmaceutical Compulsory Licensing Provisions on How to Jump Out of the Frying Pan and Into the Fire” (1990), 6 *C.I.P.R.* 276; G. F. Takach, *Patents: A Canadian compendium of law and practice* (1993), at p. 119; and see *Imperial Chemical Industries PLC v. Novopharm Ltd.* (1991), 35 C.P.R. (3d) 137 (F.C.A.), at pp. 139-40). Linking licence fees to the cost of the “research leading to the invention” did not cover the cost of massive research programs required by the

- innovators to produce the few “winners” from the many false starts and failed research projects that never came to market.
- 9 Section 39(14) of the *Patent Act* simply required the Commissioner of Patents to notify the Department of National Health and Welfare of all compulsory licence applications.
  - 10 In a reversal of policy, Parliament in 1993 repealed the compulsory licence provisions of the *Patent Act* by what became known as Bill C-91 (S.C. 1993, c. 2) and extinguished all compulsory licences issued on or after December 20, 1991. In part, these changes flowed from international obligations accepted by Canada under the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 U.N.T.S. 299 (“TRIPS”). More immediately, perhaps, it was thought that Canada’s compulsory licensing system would be declared incompatible with Canada’s obligations under the *North American Free Trade Agreement*, Can. T.S. 1994 No. 2, in particular art. 1709(10), signed at the end of 1992.
  - 11 However, having agreed to respect the 20-year monopoly granted by patents, Parliament wished to facilitate the entry of competition immediately thereafter. It acted to eliminate the usual regulatory lag of two years or more after expiry of a patent for the generic manufacturer to do the work necessary to obtain an NOC. Parliament did so by introducing an exemption from the owner’s patent rights under which the generic manufacturers could work the patented invention within the 20-year period (“the early working exception”) to the extent necessary to obtain an NOC at the time the patent(s) expired (s. 55.2(1)) and to “stockpile” generic product towards the end of the 20-year period to await lawful market entry (s. 55.2(2)). In order to prevent abuse of the “early working” and “stockpiling” exceptions to patent protection, the government enacted the *NOC Regulations* that are at issue in this appeal.
  - 12 The patent owner’s remedies under the *NOC Regulations* are *in addition to* all of the usual remedies for patent infringement under the *Patent Act*.

...

45 This Court has accepted the view that Parliament enacted Bill C-91 “with the intent of thwarting the possible appropriation by generic drug companies, such as Apotex, of the research and development initiatives of innovators, such as Merck” (*Apotex v. Canada (Attorney General)*, per Robertson J.A., at p. 752 (emphasis added), whose reasons were substantially adopted by this Court at [1994] 3 S.C.R. 1100).

46 The Regulatory Impact Analysis Statement, which accompanied but did not form part of the *NOC Regulations*, confirms that this was the intention of the regulator. It says that following the abolition of the compulsory licensing system, the government enacted the *NOC Regulations* in order to protect the right of patentees by preventing generic manufacturers from marketing their products until the expiry of all relevant patents (*Merck & Co. v. Canada (Attorney General)* (1999), 176 F.T.R. 21, at para. 51). The relevant portion of the Regulatory Impact Analysis Statement reads:

. . . As a general rule, judicial remedies are sufficient to address patent infringement. However, with the enactment of Bill C-91 the government has created an exception to patent infringement allowing generic competitors to undertake any activities necessary to work up a submission to obtain regulatory approval of a product. This removes a patent right that may have otherwise been available to patentees to prevent generic competitors from obtaining such regulatory approval of their products.

These Regulations are needed to ensure this new exception to patent infringement is not abused by generic drug applicants seeking to sell their product in Canada during the term of their competitor’s patent while nonetheless allowing generic competitors to undertake the regulatory approval work necessary to ensure they are in a position to market their products immediately after the expiry of any relevant patents. [Emphasis added.]

(Regulatory Impact Analysis Statement, SOR/93-133, *Canada Gazette*, Part II, vol. 127, No. 6, at p. 1388)

...

50 Recognizing that the “early working” and “stockpiling” exceptions could be abused, Parliament balanced creation of these exceptions with creation of a summary

procedure designed to strengthen the hand of patent owners against generic competitors *within* the 20-year patent period. This carrot and stick combination is found in s. 55.2 of the *Patent Act* (quote of s. 55.2 omitted):

[Emphasis in the original throughout the above quote]

[36] It is also useful to briefly consider what was decided by the Supreme Court in *BioLyse* and later in *AstraZeneca*. The issue in *BioLyse* was whether a “*submission*” for an NOC by a person who did not rely (i.e. piggy back) on a first person’s drug came within the ambit of the *PM(NOC) Regulations*. Binnie J., writing for the majority, recognized that the word “*submission*” in subsection 5(1.1) was on the face of it unambiguous and all inclusive (*BioLyse*, para. 43). However, the *PM(NOC) Regulations* had to be construed having regard to the *Patent Act* read as a whole and the balance which it seeks to create between the effective enforcement of patent rights through the use of the *PM(NOC) Regulations* (subsection 55.2(4)) and the timely entry of lower price generic drugs through the use of the “*early working*” exception (subsection 55.2(1)) (*BioLyse, supra*, para. 50).

[37] Viewed in that light, it became apparent that the word “*submission*” must be confined to situations where a manufacturer in fact copies from an innovator company (*BioLyse, supra*, paras. 65 and 69). Giving the word “*submission*” a wider ambit would overshoot the limited purpose for which regulations may be made and upset the balance which the *Patent Act* seeks to create.

[38] Soon after *BioLyse* was released, the Supreme Court was again called upon to apply the rationale developed in that case. In *AstraZeneca*, the issue was whether the *PM(NOC) Regulations*

applied in respect of listed patents from which the second person had not derived any advantage in making use of the “*early working*” exception.

[39] Binnie J., writing for a unanimous Court this time, noted that subsection 4(1) of the *PM(NOC) Regulations* allows the Minister to identify the precise patents relevant to the “*early working*” of a copy-cat drug (*AstraZeneca, supra*, para. 22). In order to limit the application of the *PM(NOC) Regulations* to the stated statutory objective, subsection 5(1) must be construed as requiring a patent-specific analysis restricted to the patents relevant to the comparator drug (*AstraZeneca, supra*, para. 39). Thus, the “*other drug*” referred to in subsection 5(1) can only refer to the drug to which a reference is made by second persons “*for the purpose of demonstrating bioequivalence*”. Again, to construe these words more broadly would allow the *PM(NOC) Regulations* to apply when the prevention of infringement is not in issue and would upset the balance which the *Patent Act* seeks to create (*AstraZeneca, supra*, paras. 15, 38 and 39).

[40] Against this background, I now turn to the specific language of subsection 55.2(4) of the *Patent Act*. It provides for a broad grant of authority for the making of such regulations as the Governor-in-Council “*considers necessary for preventing the infringement of a patent*” by any person who makes use of the “*early working*” exception. The specific authority outlined in paragraphs (a) to (e) is said not to limit the generality of the initial grant. The only limitation lies in the limited purpose for which regulations may be made.

[41] Paragraph (a), although drafted in much broader terms, authorizes the Governor-in-Council to impose conditions for the issuance of NOCs which, in addition to those usually imposed pursuant to the *Food and Drugs Act*, R.S.C. 1985, c. F-27 and the *Food and Drug Regulations*, C.R.C. 1978, c. 870, are aimed at the prevention of infringement. Paragraph (b) specifies that this authority to impose further conditions extends to setting the date on which NOCs can be issued.

[42] Paragraph (c) provides authority for resolving disputes as to when NOCs may be issued. For that purpose, paragraph (d) authorizes the Governor-in-Council to “*confer rights of action in any court of competent jurisdiction*” and to provide for the “*remedies*” that may be sought and the “*orders*” that may be made.

[43] Paragraph (e) provides the Governor-in-Council with the authority to provide for other measures in the event that the issuance of an NOC might result directly or indirectly in the infringement of a patent.

[44] I also note subsection 55.2(5) which provides that section 55.2 and any regulations made thereunder prevail over any Act of Parliament in the event of any inconsistency or conflict, and subsection 55.2(6) which confirms that the common law exemption for non-commercial use of patented products for the purpose of experimentation is not affected by the “*early working*” exception.

[45] Subsection 55.2(4) is the statutory authority pursuant to which the *PM(NOC) Regulations* were promulgated including section 8. In its original form section 8 did not clearly set out the circumstances entitling a second person to a remedy. In *Merck & Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (F.C.A.), [1994] F.C.J. No. 662, 55 C.P.R. (3d) 302; 169 N.R. 342, this Court stated (para. 15):

Section 8 is particularly obscure in its meaning. It appears to create a liability in the first person in the event that the Minister should comply with the 30 month prohibition in circumstances where subsection 7(2) specifically provides that that prohibition shall have ceased to apply. Fortunately, we are not required to interpret it on this appeal.

[46] Counsel advised during the hearing that there are pending actions in the Federal Court where the original section 8 is in play. I will therefore say no more about this provision as it read when it was initially promulgated.

[47] Section 8 was amended in 1998 by S.O.R./98-166. In the RIAS which accompanied the amendment, it is explained that the amendment was brought in order to provide “*a clear indication ... as to the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug*”. The amendment makes it clear that liability can be visited on a first person when a prohibition application is withdrawn, discontinued or turns out to be unsuccessful.

[48] The liability so created extends to “*any loss*” suffered by a second person during the period when an NOC could have been issued but was not by reason of the operation of the automatic stay

(paragraphs 8(1)(a) and (b)). A right of action is created in favour of second persons in order to obtain compensation for the loss in question (subsection 8(2)) and the Court is authorized to provide relief by way of “*damages or profits as the circumstances require*” (subsection 8(4)).

[49] Subsection 8(3) makes it clear that the authority of the Court to make an order is unaffected by a patent infringement action relating to the patent in play in the failed prohibition application.

[50] Finally, in assessing the amount of compensation, the Court is required by virtue of subsection 8(5) to take into account all matters that it considers relevant, including any conduct of the first or second person which contributed to the delay in the disposition of the prohibition proceedings.

[51] I now turn to Merck’s contention that section 8 is *ultra vires* the *Patent Act*. The essence of the argument made by Merck before the Federal Court Judge and before this Court boils down to this: since the authority of the Governor-in-Council is limited to the making of regulations for the purpose of preventing infringement, a regulation which makes a first person liable for damages only by reason of being unsuccessful in asserting its patent rights in conformity with the remedy set out in the *PM(NOC) Regulations*, cannot be said to prevent infringement. As such, section 8 is *ultra vires* the *Patent Act*.

[52] I accept that, as Merck contends, the power of the Governor-in-Council is constrained by the wording of subsection 55.2(4) of the *Patent Act* according to which regulations may be made for

preventing infringement by a person who makes use of the “*early working*” exception. I also accept that this is the only purpose for which regulations may be made (*Biolyse, supra*, paras. 38, 53 and 67; *AstraZeneca, supra*, paras. 15 and 16). However, the authority to devise remedies in order to prevent infringement necessarily brings with it the power to ensure that those remedies are used by first persons for that purpose and not for some other purpose such as perpetuating their monopolies beyond the statutory period. This is particularly so when regard is had to the aforesaid balance which the *Patent Act* seeks to establish between effective patent enforcement through the use of the *PM(NOC) Regulations* and the timely market entry of lower-priced generic drugs through the use of the “*early working*” exception.

[53] The general scheme set out in the *PM(NOC) Regulations* in order to prevent infringement provides for the filing of a patent list by a first person (section 4); the right of action (application) created in favour of a first person when a second person seeks an NOC and refers to a patented drug in order to demonstrate bioequivalence (sections 5 and 6) and the resulting stay which prevents the Minister from issuing the requested NOC to the second person for 24 months (formerly 30 months). No one takes issue with the fact that these provisions are designed to achieve the statutory purpose of preventing infringement. In particular, it is clear that the Governor-in-Council formed the view that, in order to prevent patent infringement in the circumstances described in subsection 55.2(4) of the *Patent Act*, it was necessary both to provide first persons with the right to initiate prohibition proceedings in the circumstances described and prevent the issuance of the NOC to the second person for 24 months when that right is exercised.

[54] At the same time, it was readily apparent that the automatic 24-month stay was capable of being used in a manner which does not advance patent protection. In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, Iacobucci J. writing for the Court observed (at para. 32):

... The Regulations provide for what is, in effect, a statutory prohibition on, or injunction against, the granting of an NOC, commencing immediately upon the filing by a “first person” of an application for a court-imposed prohibition order and concluding only upon the earlier of the judicial determination of the application or the passage of 30 months. This prohibition takes effect automatically, without any consideration of the merits of the application; not even the ordinary requirements for an interlocutory injunction must be complied with. Under these conditions, and absent some prior indication to the contrary, I think it would be permissible for a generic producer to predict that either the patentee, the holder of a prior NOC, or both, is likely to attempt to protect or prolong their as-yet exclusive rights for as long as possible by taking advantage of the procedure set out in the Regulations.

[55] One of the more obvious concerns flowing from the automatic stay was identified by Mahoney J.A. in *Bayer AG v. Apotex Inc.*, (2001), 10 C.P.R. (4th) 151 (*Bayer*), where he noted (at para. 33) that given the scheme, it is the patentee who has both the carriage of the proceeding and the interest in its dilatory prosecution.

[56] In *AstraZeneca*, Binnie J. identified a broader concern (para. 39):

By imposing the 24-month delay called for by the *NOC Regulations*, the decision of the Federal Court of Appeal undermines achievement of the balance struck by Parliament between the objectives of the *FDA* and regulations thereunder (making safe and effective drugs available to the public) and the *Patent Act* and its regulations (preventing abuse of the “early working” exception to patent infringement). Given the evident (and entirely understandable) commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original

patent for that pioneering product has expired, the decision of the Federal Court of Appeal would reward evergreening even if the generic manufacturer (and thus the public) does not thereby derive any benefit from the subsequently listed patents.

[My emphasis]

[57] Attempts by first persons to list patents on the basis of a change in a drug name or a change in a manufacturing site, neither of which can remotely have anything to do with patent infringement, have also been noted judicially (*Apotex Inc. v. Ferring Inc.*, 2003 FCA 274, 26 C.P.R. (4th) 155 (*Ferring*); *Hoffman-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140 (*Hoffman-La Roche*)). [This last concern was directly addressed in 2006 by the addition of subsection 4(3) and the definition of “supplement to a new drug submission” in subsection 3(1) which exclude the possibility of listing a patent on the basis of an administrative submission (S.O.R./2006-242).]

[58] Section 8, by imposing on first persons a liability for the losses suffered by a second person, as a result of the operation of the automatic stay, when a prohibition application is withdrawn, discontinued or is ultimately unsuccessful, alleviates these concerns. As was noted in *AB Hassle v. Canada (Minister of National health and Welfare)*, (2000), 7 C.P.R. (4<sup>th</sup>) 272 (FCA) (*AB Hassle*) (per Stone J.A. at para. 27), the ability of the Court to order payment of damages resulting from the operation of the automatic stay suggests that a first person no longer has an exclusive interest in delaying the progress of a section 6 prohibition proceeding.

[59] By the same logic, a first person no longer has an exclusive interest in triggering the operation of the automatic stay by reference to patents which are not properly listed (*Ferring, supra*;

*Hoffman-La Roche, supra*; see also *Apotex Inc. v. Canada (Minister of National Health and Welfare)*, (2000), 3 C.P.R. (4<sup>th</sup>) 1, at paras. 27 and 28) or to “evergreen” a patented drug in order to perpetuate the benefit which the *PM(NOC) Regulations* provide (*AstraZeneca, supra*, paras. 23 and 39; *BioLyse, supra*, para. 66). As a result of section 8, a first person must focus on the issue of infringement and consider the strength of its position before initiating a prohibition proceeding.

[60] This promotes the use of the *PM(NOC) Regulations* for the purpose for which they are intended: the prevention of infringement. Significantly, it does so in a manner which is consistent with maintaining the balance alluded to in *BioLyse* and in *AstraZeneca*. It is useful to repeat that both these cases were decided on the basis that the *PM(NOC) Regulations* should be construed in a manner which goes no further than is necessary in order to prevent infringement since overshooting this objective would upset the other part of the balance which section 55.2 of the *Patent Act* seeks to achieve, namely the timely entry of cheaper generic drugs on the market. The statutory authority of the Governor-in-Council to make regulations pursuant to subsection 55.2(4) of the *Patent Act* must be construed accordingly.

[61] I therefore find that section 8 of the *PM(NOC) Regulations* comes within the general grant of authority set out in subsection 55.2(4) of the *Patent Act* and that the Federal Court Judge came to the correct conclusion when he held that section 8 was validly promulgated.

The constitutional issue

[62] Merck further contends that the Federal Court Judge erred in holding that the right of action created by section 8 of the *PM(NOC) Regulations* is within the authority of Parliament pursuant to section 91(22) of the *Constitution Act, 1867*. According to Merck, section 8 provides for an independent cause of action unconnected to the *PM(NOC) Regulations*, which falls within provincial legislative competence over property and civil rights. The standard applicable to the review of the decision of the Federal Court Judge on this point is again correctness.

[63] It is common ground that, looked upon in isolation, section 8 creates a civil right of action which comes within the province's broad jurisdiction over property and civil rights. In *General Motors of Canada Ltd. v. City National Leasing*, [1989] 1 S.C.R. 641 (pp. 671 and 672) (*General Motors*), the Supreme Court devised a three-part test for determining the constitutional validity of federal laws which encroach on provincial heads of power: firstly, the court must determine the extent of the encroachment; secondly, the court must establish whether the act, (or a severable part of it) is valid as forming part of a valid regulatory scheme falling under federal jurisdiction; and thirdly, the court must determine whether the impugned provision is sufficiently integrated into that regulatory scheme that it can be upheld by virtue of that relationship.

[64] Dealing with the extent of the encroachment, the right of action created by section 8 is only available to a limited group of persons operating within a defined industry. Its scope of application is confined to patent controversies relating to drug products arising under the narrow conditions set out in the *PM(NOC) Regulations*. It is further limited to situations created by first persons when

they make applications pursuant to subsection 6(1). Thus, the extent of the intrusion is minor (Compare *General Motors, supra*, p. 673). It is noteworthy that despite having been duly notified, the Attorney General of the Provinces or the Territories have not seen fit to intervene.

[65] As to the second part of the test, Merck concedes that the *PM(NOC) Regulations*, including section 6 which entitles first persons to launch prohibition applications and trigger the automatic stay, were validly promulgated pursuant to the *Patent Act* and constitute a valid regulatory scheme falling within Parliament's competence over patents of invention pursuant to section 91(22) of the *Constitution Act, 1867*. The only exception is section 8. The question therefore is whether, according to the third part of the test set out in *General Motors, supra*, section 8 is sufficiently integrated into the overall scheme to become part of it. In my view, the above reasons for concluding that section 8 is *intra vires* the *Patent Act* are dispositive of this issue.

[66] I would simply add, to further highlight the extent of the connection, that an award of damages under section 8 logically flows from the section 6 prohibition proceedings and would normally be adjudicated by the judge who hears the prohibition application. I refer in particular to subsection 8(5) of the *PM(NOC) Regulations* which provides that in assessing the amount of the compensation, regard must be had to the conduct of the parties during the prohibition proceedings which contributed to the delay. It is apparent that the only reason section 8 damages are adjudicated in a separate proceeding is that regard had to be had to the right of appeal.

[67] I therefore conclude that the Federal Court Judge correctly held that section 8 comes within section 91(22) of the *Constitution Act, 1867* and is as such valid federal delegated legislation.

Jurisdiction

[68] The question to be answered with respect to jurisdiction is whether the Federal Court Judge erred in holding that he had jurisdiction to hear the section 8 action brought by Apotex. This question must again be assessed on a standard of correctness.

[69] The Federal Court derives its jurisdiction from statute. In order to support a finding of jurisdiction, the following elements must exist (*ITO – International Terminal Operators Ltd. v. Miida Electronics Inc.*, [1986] 1 S.C.R. 752 at p. 766):

- 1) There must be an express statutory grant of jurisdiction by the federal Parliament;
- 2) There must be an existing body of federal law which is essential to the disposition of the case and which nourishes the statutory grant of jurisdiction; and
- 3) The law on which the case is based must be a “law of Canada” as the phrase is used in section 101 of the *Constitution Act, 1867*.

[70] Parliament’s competence in respect of patents and the existence of a federal body of law relating to patents are not in issue. However, Merck maintains that the first condition is not fulfilled. In my respectful view, subsection 20(2) of the *Federal Courts Act* which provides the Federal Court with concurrent jurisdiction “... *in all cases ..., in which a remedy is sought under the authority of an Act of Parliament ... respecting any patent of invention ...*” is an express statutory grant of

jurisdiction which authorizes the Federal Court to hear both section 6 prohibition proceedings and section 8 actions.

[71] Proceedings instituted under section 6 and section 8 of the *PM(NOC) Regulations* come within this express grant since both provide for a remedy in respect of patents. Section 6 does so by preventing the issuance of an NOC while listed patents referred to by a second person in order to demonstrate bioequivalence remain in effect, and section 8 does so by allowing a second person to recover losses arising from the automatic stay triggered by a first person when the attempt to assert its patent rights fail.

[72] The various cases cited by Merck in support of its view that subsection 20(2) stops short of conferring jurisdiction on the Federal Court with respect to actions undertaken pursuant to section 8 are of no assistance (*R.W. Blacktop Ltd. v. Artec Equipment Co.* (1991), 39 C.P.R. (3d) 432 at p. 439 (F.C.T.D.); *Netbored Inc. v. Avery Holdings Inc.* (2005), 272 F.T.R. 131 at para. 24 (F.C.T.D.); *Aktiebolager Hassle v. Apotex Inc.* (1987), 17 C.P.R. (3d) 349 at pp. 350 to 354 (F.C.T.D.) (*Aktiebolager Hassle*); *Innotech Pty Ltd. v. Phoenix Rotary Spike Harrows Ltd.* (1997), 74 C.P.R. (3d) 275 at pp. 276 and 277 (F.C.A.)). The remedies sought in all those cases arose under the common law and were found to relate primarily to contractual or equitable rights and obligations between the parties rather than to patents of invention.

[73] We are not concerned here with the enforcement of contractual rights. What is in issue is a remedy devised by the Governor-in-Council pursuant to a regulatory scheme. The situation is closer

to that described in *Composers, Authors and Publishers Assn. of Canada Ltd. v. Sandholm Holdings Ltd.*, [1955] Ex.C.R. 244, 24 C.P.R. 58 (*Sandholm Holdings Ltd.*), where the Court held that it had jurisdiction over a dispute concerning the payment of royalties because the *Copyright Act* provided a statutory remedy to collect unpaid royalties. Significantly, in *Aktiebolager Hassle*, *supra*, a case on which Merck relies, the Federal Court Trial Division, declined jurisdiction on the basis that claims relating to the payment of license fees to a patentee were matters of contract. However, the Court explicitly distinguished at page 353 the earlier decision of the Exchequer Court in *Sandholm Holdings Ltd.* on the ground that the *Patent Act* unlike the *Copyright Act* did not provide for a statutory remedy to collect unpaid royalties.

[74] In my respectful view, both sections 6 and 8 of the *PM(NOC) Regulations* provide remedies pursuant to a regulatory scheme aimed at the prevention of infringement, and as such come within the express grant of jurisdiction conferred on the Federal Court by virtue of subsection 20(2) of the *Federal Courts Act*.

[75] Merck made the argument that the jurisdiction of the Federal Court to hear prohibition proceedings rests on paragraph 18(1)(b) of the *Federal Courts Act* rather than subsection 20(2) (Merck's Memorandum, para. 90). In this respect, Merck relies on *Bayer*, *supra*, where this Court held, in adjudicating a procedural matter, that a prohibition application pursuant to section 6 comes within the jurisdiction conferred by paragraph 18(1)(b) of the *Federal Courts Act* since it contemplates relief against a federal board. Merck makes the point that the jurisdiction so conferred must be confined to section 6 applications since section 8 actions do not involve a federal board.

[76] No doubt that is so. However, the fact that jurisdiction to hear prohibition proceedings can be found in paragraph 18(1)(b) of the *Federal Courts Act* because it contemplates relief against the Minister, as was held in *Bayer, supra*, does not alter or diminish the grant of jurisdiction made pursuant to subsection 20(2) with respect to patents of invention. Nothing in that decision suggests that paragraph 18(1)(b) operates to exclude the jurisdiction conferred by subsection 20(2).

[77] Nevertheless, Merk's interpretation of the *Bayer* decision seems to have led the Federal Court Judge to look for an express grant of jurisdiction elsewhere than in subsection 20(2) of the *Federal Courts Act*. He found that the authority given to the Governor-in-Council under paragraph 55.2(4)(d) of the *Patent Act* to make regulations “*conferring rights of action in any court of competent jurisdiction*” (his emphasis) allows the Governor-in-Council to confer jurisdiction on “*any court*” by way of regulations and that section 2 of the *PM(NOC) Regulations* which defines “*court*” to mean the Federal Court of Canada or Superior Courts of competent jurisdiction constitutes such a grant (Reasons, paras. 63 and 64).

[78] In my respectful view, while paragraph 55.2(4)(d) gives the Governor-in-Council the power to make regulations “*conferring rights of action*”, it does not empower the Governor-in-Council to confer jurisdiction on courts not already possessed with such jurisdiction. What subsection 55.2(4) envisages is that the Governor-in-Council may, amongst the courts which are competent to hear such actions, designate the court(s) of its choice. That is what the definition of the word “*court*” in section 2 of the *PM(NOC) Regulations* achieves by identifying the Federal Court (which has statutory jurisdiction pursuant to subsection 20(2) of the *Federal Courts Act*) and the Superior

Courts of Provinces (which have inherent jurisdiction) as courts of competent jurisdiction to hear matters arising under the *PM(NOC) Regulations*.

[79] The Federal Court Judge further held that even if the Governor-in-Council is not empowered to grant jurisdiction on courts by way of regulations, the designation of the Federal Court in section 2 of the *PM(NOC) Regulations* amounts to a statutory grant of jurisdiction. In this respect, he relied on subsection 12(2) of the *Patent Act*, which provides that regulations made under the provisions of the Patent Act have the same effect as if they were made under the Patent Act itself and subsection 55.2(5) of the *Patent Act* which provides that in the case of a conflict between the *PM(NOC) Regulations* and the *Patent Act*, the regulations shall prevail (Reasons, paras. 63 and 64).

[80] In my respectful view, this reasoning is incorrect. To the extent that paragraph 55.2(4)(d) of the *Patent Act* does not authorize the Governor-in-Council to confer jurisdiction by way of regulation, subsections 12(2) and 55.2(5) of the *Patent Act* cannot possibly be construed as validating a grant of jurisdiction made pursuant to a regulation (Compare *The Minister of Health v. The King, Ex p. Yaffe*, [1931] A.C. 494 at pp. 501 and 502 per Viscount Dunedin (*Yaffe*); *Trans-Canada Pipe Lines Ltd. v. Provincial Treasurer of Saskatchewan*, (1968), 67 D.L.R. (2d) 694 at pp. 700 to 703 (Sask. Q.B.) (*Trans-Canada*); *Biolyse, supra*, at para. 55).

[81] That said, for the reasons given, the Federal Court Judge had to look no further than to subsection 20(2) of the *Federal Courts Act* to hold that the Federal Court has jurisdiction to hear

and dispose of both the section 6 prohibition proceedings and the section 8 actions. I therefore conclude that the Federal Court Judge correctly held that he had jurisdiction over the action brought by Apotex pursuant to section 8 of the *PM(NOC) Regulations*.

### Remedy

[82] Two issues arise with respect to remedy. The more significant is the one raised by Apotex by way of cross-appeal as to whether the Federal Court Judge properly rejected the contention that it was entitled to compensation by way of a disgorgement of Merck's profits. In this regard, Apotex relies on the plain and grammatical meaning of the words of section 8 and argues that the Federal Court Judge failed to recognize that the disgorgement of profits wrongly made during the stay period is consistent with the scheme and object of the *Patent Act* and the *PM(NOC) Regulations*. This issue is one of pure statutory construction which stands to be reviewed on a standard of correctness.

[83] The words of section 8 must be read in their entire context and in their grammatical and ordinary sense, harmoniously with the scheme of the *PM(NOC) Regulations*, their object, and the intention of Parliament (*Bell ExpressVu Limited Partnership v. Rex*, 2002 SCC 42, [2002] 2 S.C.R. 559 at paras. 29 and 30, as applied in *Biolyse, supra*, at para. 43). Where regulations are concerned, the purpose of the enabling statute must also be considered (*Biolyse, supra*, para. 47).

[84] The debate turns on the words in subsection 8(4) which authorize the Court to provide “*for relief by way of damages or profits*”. The Federal Court Judge identified the issue as follows

(Reasons, para. 89):

Why then are the words “*or profits*” appearing in subsection 8(4). Apotex argues that they cannot be redundant with “*damages*” thus they must mean something else and that something else is Merck’s profits. This requires an examination as to how the word “*profits*” has been used in a patent context.

[85] After reviewing the *Patent Act* and considering the authorities, the Federal Court Judge noted that a patentee whose patent has been infringed is entitled to an election which can call into play two different measures of profit (Reasons, para. 96):

Thus, where a patent has been infringed, a patentee is entitled to seek, by way of remedy an account (meaning disgorgement of an infringer’s profit) as an equitable remedy, or damages as a legal remedy. If damages are selected, one way of measuring damages, if the patentee makes or sells the patented product, is to determine the patentee’s lost profit.

[Emphasis in the original]

[86] However, he went on to note that a second person claiming compensation pursuant to subsection 8(4) of the *PM(NOC) Regulations* is not in the position of a patentee (Reasons, para. 97):

Turning to section 8(4) of the *PMNOC Regulations* it is immediately apparent that the generic is not a patentee, in fact it escaped charges of infringement of somebody else’s patent by demonstrating that the patent was invalid (as in the present case) or not infringed. The generic cannot claim damages or an account of profits for infringement. What the generic can claim is “compensation” for “loss” having been kept off the market for a period of time. That “compensation” takes the form of “damages or profits”. The reasonable interpretation of those words “damages or profits” is that the generic can seek,

as a measure of its damages in the alternative, the profits that it would have made if it had been able to market its product at an earlier time.

[Emphasis in the original]

[87] Apotex argues that this construction requires that the word “*lost*” be read in the contested phrase as in “*damages or lost profits*”. According to Apotex, the Federal Court Judge had to take the language of the provision as it is, and the words “*damages or profits*” do not warrant the narrow scope which he gave to these words.

[88] The Federal Court Judge confronted this argument (Reasons, paras. 98 to 101). In particular, he referred to Professor Ruth Sullivan’s 5<sup>th</sup> Edition of *Sullivan on the Construction of Statutes*, 2008 LexisNexis Canada, and endorsed the view that “*reading down*” as opposed to “*reading in*” is a legitimate technique of statutory interpretation to the extent that a contextual interpretation indicates that a narrow scope was intended. In this case adding the word “*lost*” narrows the scope of the expression “*damages or profits*” and therefore “reads down” the provision in a manner that is consistent with the intent of Parliament.

[89] I can detect no error in this reasoning. 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.

[90] In so holding, I reject Apotex's assertion that the disgorgement of Merck's profit is necessary in order to achieve the balance which underlies section 55.2 of the *Patent Act*. In my view, a measure which compels a first person to place the second person in the position in which it would have been, if the operation of the stay had not been triggered, fits well within the contemplated balance.

[91] I therefore conclude that the Federal Court Judge came to the correct conclusion when he held that section 8 of the *PM(NOC) Regulations* does not envisage the disgorgement of a first person's profit.

[92] The other issue relating to remedy pertains to the claim for damages set out in subparagraph 1(a)(ii) of the Respondent's Further Amended Statement of Claim (Reasons, para. 118):

...

(a) damages suffered by Apotex in respect of the drug alendronate by reason of the commencement of a proceeding by the Defendants pursuant to the Patented Medicines (Notice of Compliance) Regulations (the "Patent Regulations"), in respect of:

...

(ii) lost sales and permanent market share due to the fact that launch by Apotex of its alendronate product was unjustly delayed with the result that two other generic manufacturers, Novopharm Limited ("Novopharm") and Cobalt Pharmaceuticals Inc. ("Cobalt"), launched their

alendronate products essentially simultaneously, thus denying Apotex the opportunity to establish as permanent market share advantage in advance of any generic competitor.

[93] The Federal Court Judge, while recognizing that catchwords are not entirely accurate, characterized the claim as being for “future losses” (Reasons, para. 119). He described the precise purport of the claim as follows (Reasons, para. 120):

As I understand Apotex’s claim, it is saying that during the period from February 3, 2004 to May 26, 2005, the marketplace for this particular product became distorted because two other generics entered the marketplace in that period. Apotex claims that, were it not for Merck’s NOC application against Apotex, Apotex could have been first in the marketplace or at least entered the marketplace at about the same time that the other generics did and that Apotex’s market share would, thereby, have been larger [than] it now is. Apotex argues that such lesser market share is a matter that permanently endures and is a matter of permanent loss. The loss, says Apotex, may be quantified by experts at the later trial.

[94] In assessing whether the claim came within the ambit of section 8, the Federal Court Judge drew an analogy with the situation where a person suffers an injury by the tortious act of another (Reasons, para. 121):

... For instance, a person may be injured in the leg so that, for the rest of that person’s life, that person suffers a leg disability. The leg may heal, the person perhaps ought to have sought, but did not, medical attention or remedial therapy. These are matters of quantification and not a matter of injury itself.

[95] Relying on this analogy, the Federal Court Judge held that the claim for lost sales and lost permanent market share beyond May 26, 2005 (i.e. beyond the period contemplated by section 8)

was properly advanced, subject to Apotex showing that such losses were not rectified and could not have been rectified within the period. The exact wording of the judgment is as follows (para. 2c.):

Apotex Inc. is entitled to claim damages for lost sales and lost permanent market share as claimed in paragraphs 1 (a)(ii) of its Further Amended Statement of Claim dated October 6, 2008 for a period beyond May 26, 2005 provided it is shown in evidence that such loss was not rectified and could not have been rectified before that date;

[My emphasis]

[96] Merck submits that in so concluding the Federal Court Judge gave to section 8 an effect that is clearly not intended. In particular, Merck insists that subsection 8(1) only makes a first person liable for any loss “*suffered*” during the period. The decision of the Federal Court Judge extends the remedy to damages suffered outside the period.

[97] No one takes issue with the Federal Court Judge’s characterization of the claim made by Apotex in its Further Amended Statement of Claim. The issue is therefore whether the claim as construed by the Federal Court Judge comes within the words of subsection 8(1). This again gives rise to a pure question of statutory interpretation which stands to be reviewed on a standard of correctness.

[98] As has already been noted, section 8 in its original form was somewhat obscure (see para. 45 above). The RIAS which accompanied the 1998 amendment to section 8 indicates that the change was brought in order to provide a clearer indication as to the circumstances in which damages can be awarded. In this respect, the amended version of section 8 makes it clear that:

[T]he first person “is liable to the second person for any loss suffered during the period

- (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 is satisfied on the evidence that another date is more appropriate; and
- (b) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

[...] la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :

- 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 estime d’après la preuve qu’une autre date 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.

[My emphasis]

[99] According to the analysis of the Federal Court Judge, the losses claimed by Apotex were caused during the period since that is when Apotex was prevented from occupying the market and obtaining the market share which, based on its claim, it would otherwise have had. No one takes issue with this reasoning. The question is whether the decrease in sales which occurs in future years as a result of this decreased market share comes within section 8. The Federal Court Judge, by allowing the claim for losses “beyond May 26, 2005” to proceed, answered this question in the affirmative.

[100] When regard is had to the broad grant of authority conferred by subsection 55.2(4) of the *Patent Act*, it seems clear that the measure of the compensation which can be awarded under the

*PM(NOC) Regulations* is a matter within the discretion of the Governor-in-Council. It is also clear that in keeping with the purpose of the *PM(NOC) Regulations* and the balance which the *Patent Act* seeks to achieve, a range of compensation was open to the Governor-in-Council in the exercise of this discretion.

[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.

### Costs

[103] Finally, Apotex also challenges by way of its cross-appeal the Federal Court Judge's decision not to award costs in its favour. The Federal Court Judge held that the parties should

assume their respective costs. The reason given is that both had “largely” failed to succeed on the issues asserted by them (Reasons, para. 12).

[104] Decisions pertaining to costs are discretionary in nature and will only be overturned when the Trial Judge failed to give sufficient weight to all relevant considerations, erred in law, or misapprehended the facts (*Schmeiser v. Monsanto Canada Inc.*, 2002 FCA 449, (2002), 22 C.P.R. (4<sup>th</sup>) 455 at para. 2 (F.C.A.)).

[105] Apotex argues that the Federal Court judge misapprehended the facts when he held that success in the action before him was divided. The suggestion appears to be that success should be assessed by counting the issues on which it was successful and as it succeeded on most issue, costs should have been awarded in its favour.

[106] The Federal Court Judge obviously did not evaluate the degree of success that way. He viewed the issue of remedy, and in particular, Apotex’s contention that it was entitled to the disgorgement of Merck’s profits as a significant part of the debate before him. While there may be different ways to evaluate success, it has not been shown that the Federal Court Judge committed a reviewable error in assessing success as he did.

[107] Apotex also contends that the Federal Court Judge erred by failing to give it an opportunity to be heard on the issue of costs. However, there is no suggestion that Apotex did not have the opportunity to make representations on the issue of costs at the close of the hearing. When a party

fails to avail itself of that opportunity, there is no positive obligation to invite submissions on the issue of costs. I see no reason for interfering with the Federal Court Judge's decision on the issue of costs.

[108] For the above reasons, I would dismiss Apotex's cross-appeal with costs computed at the mid-level of Column III of Tariff B. I would allow the appeal in part, set aside paragraph 2 (c) of the judgment rendered by the Federal Court Judge, and giving the judgment which he ought to have given, I would hold that Apotex's claim for damages for lost sales and lost permanent market share must be confined to such losses which can be shown to have been incurred during the section 8 period. I would grant the costs of the appeal in favour of Merck but given the limited success, I would direct that the costs be computed at the mid-level of Column I of Tariff B.

“Marc Noël”

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J.A.

“I agree.  
Carolyn Layden-Stevenson J.A.”

“I agree.  
C. Michael Ryer J.A.”

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

**DOCKETS:** A-571-08 and A-580-08

**(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE HUGHES  
DATED OCTOBER 21, 2008, NO. T-1144-05.)**

**STYLE OF CAUSE:** MERCK FROSST CANADA LTD. and  
MERCK FROSST CANADA & CO. and  
APOTEX INC.

**PLACE OF HEARING:** Toronto, Ontario

**DATE OF HEARING:** April 21 and 22, 2009

**REASONS FOR JUDGMENT BY:** Noël J.A.

**CONCURRED IN BY:** Layden-Stevenson J.A.  
Ryer J.A.

**DATED:** June 4, 2009

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