Date: 20081021

Docket: T-1144-05

Citation: 2008 FC 1185

Ottawa, Ontario, October 21, 2008

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

APOTEX INC.

Plaintiff

and

MERCK & CO. INC., MERCK FROSST CANADA LTD. and MERCK FROSST CANADA & CO.

Defendants

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an action brought by the Plaintiff, Apotex Inc., under the provisions of section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (*PMNOC Regulations*), claiming recovery against the Defendants, Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. (collectively Merck). This is the first such action to proceed to trial on the merits. The parties have raised a number of preliminary issues for determination at this time, leaving the quantification of any award, if required, to a later trial.

[2] The issues required to be determined at this time are twofold. The first deals with the jurisdiction of this Court, enablement and constitutionality of section 8. The second deals with the nature and extent of the remedies afforded by section 8 of the *PMNOC Regulations*. For the reasons that follow, I find that the Federal Court has jurisdiction to hear and determine actions instituted under section 8 of the *PMNOC Regulations*, that section 8 is properly enabled and that section 8 is *intra vires* the constitutional authority of the federal Parliament. As to the second, I find that the Apotex is not entitled to disgorgement of Merck's profits, if any; that Apotex is entitled to recover its damages or its lost profits, for the period from February 3, 2004 to May 26, 2005; and, that Apotex may claim recovery of damages that occurred during said period and extended beyond that period if said damage could not have been or were not rectified in that period. No party is awarded costs.

FACTUAL BACKGROUND

[3] Counsel for the parties are to be commended for co-operating in providing an agreement as to facts and documents (Exhibit 1). The Plaintiff, Apotex Inc., is what is known colloquially as a generic drug company which manufactures and markets primarily generic versions of pharmaceuticals in Canada. In the *PMNOC Regulations*, Apotex is referred to as a "second party". The two Merck Canadian companies Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. (collectively referred to in these reasons as Merck) are the Canadian branch of a multinational organization which manufactures and markets are what are commonly referred to as "brand name" or "originator" or "innovator" pharmaceuticals and are what is referred to as "first person" under the *PMNOC Regulations*. Merck & Co. Inc., a United States company, was named as a party defendant

in this action but shortly before trial, an Order was issued, on consent, discontinuing this action against that entity.

[4] The pharmaceutical of interest in this action is a drug commonly known as alendronate which is used primarily in the treatment of osteoporosis. Merck has an interest in a patent, Canadian Patent 2,294,595 (’595) which, among other things, includes claims directed to a particular dosage regimen for the use of that known drug, alendronate, in the treatment of osteoporosis, a known use. Merck listed the ’595 patent with the Minister of Health under the provisions of the *PMNOC Regulations* which meant that any generic seeking approval to sell a generic version of alendronate in Canada for the patented dosage regimen for the treatment of osteoporosis and wanting to take advantage of simply referencing approvals already given to Merck for that drug could file an Abbreviated New Drug Submission (ANDS). In so doing a generic is required to send a notice to Merck alleging, among other things, that the ’595 patent would not be infringed or was invalid, thereby permitting Merck to commence an application in this Court to prohibit the generic from marketing its generic version of alendronate in Canada in the dosage regimen claimed in the ’595 patent.

[5] Merck received an NOC approving for sale its version of alendronate in Canada on February 4, 2002. Apotex filed an ANDS for alendronate on February 7, 2003 and sent a Notice of Allegation to Merck on April 14, 2003 alleging that the ’595 patent was invalid for a number of reasons. On May 29, 2003, Merck & Co. Inc. and Merck Frosst Canada & Co. commenced proceedings in this Court, T-884-03, to prohibit the Minister of Health from issuing a Notice of

Compliance to Apotex which otherwise would permit Apotex to sell a generic version of the alendronate drug in Canada. On February 3, 2004 the Minister send a letter to Apotex advising it that its application was approved but would be held in abeyance subject to the Court proceedings. On May 26, 2005, Mosley J. of this Court gave Reasons and an Order in T-884-03, dismissing Merck's application, finding that Apotex's allegations as to invalidity, on some but not all grounds, were justified. These Reasons are cited as 2005 FC 755. No appeal was taken. On May 27, 2005, the Minister issued a Notice of Compliance to Apotex permitting it to sell its generic version of alendronate, Apo-alendronate, in Canada.

[6] On July 5, 2005, Apotex instituted this action T-1144-05 claiming recovery against Merck under the provisions of section 8 of *PMNOC Regulations* for the period from February 3, 2004 to May 27, 2005.

[7] By Orders of this Court dated January 24, 2006 and August 14, 2008, the quantification of any amounts found to be properly recoverable in this action is a matter to be determined at a subsequent trial. The two preliminary issues previously referred to are the subject of the present trial.

ISSUES FOR DETERMINATION

1) Merck's Issues

[8] Merck submits the following issues relating to jurisdiction of this Court, enablement and, constitutionality of section 8:

a) Does the Federal Court lack jurisdiction to hear an action pursuant to section 8 of the *PMNOC Regulations*;

b) Is section 8 of the *PMNOC Regulations ultra vires* section 55.2(4) of the *Patent Act*, R.S.C. 1985 c. P-4 as amended;

c) Is section 8 outside the scope of Parliament's power to make laws in relation to patents of invention and discovery, and an unlawful intrusion into the exclusive jurisdiction of the provinces pursuant to section 92(13) of the *Constitution Act, 1867*, R.S.C. 1985, App. II, No. 5.

2) Apotex's Issues

[9] Apotex raises issues as to the nature and extent of the remedy afforded by section 8 of the *PMNOC Regulations*, in particular:

1. Is Apotex entitled to an election as between the damages which it has suffered, if any, and the profits made by Merck, if any?
2. What is the period of time in respect of which Apotex may claim recovery?
3. Is Apotex entitled to recover for damages that continue after the period expires?

[10] A number of other issues were raised in the pleadings of each of the parties but have been resolved or dropped. Merck & Co. Inc. (Merck US) is a named defendant and several issues were raised by Apotex as to the nature and degree of its participation in the events under consideration. By consent Order, this action as against Merck US was dismissed. The two remaining defendants, Merck Frosst Canada Ltd. and Merck Frosst Canada & Co. are Canadian entities only the first of

which was in existence at the time that the earlier NOC proceedings decided by Mosley J. were initiated. The second of those two entities came into existence subsequent to the institution of the NOC proceedings (T-884-03). It appears that there was a transfer of assets from the first to the second of these entities. The pleadings take issue as to this transfer and the effect thereof however, these matters are no longer of concern.

[11] In its earlier Statement of Claim, Apotex made a claim for unjust enrichment which claim was dropped at trial. By its counsel at trial, Apotex acknowledged that while during discovery some other grounds of damages were suggested none of such grounds are being pursued. Amended pleadings were filed at trial and are contained in a Trial Record (Exhibit 5). Apotex's counsel stated at trial that Apotex does not seek any relief other than that specifically claimed in the prayer for relief in its Further Amended Statement of Claim dated October 6, 2008.

Dr. Hollis

[12] Only one witness was called to appear at trial. He was Dr. Aidan Hollis called as an expert witness by Apotex. He is an associate professor of economics at the University of Calgary. Dr. Hollis' credentials were not seriously challenged by Merck. He was accepted to be an expert in economics with particular reference in pricing, competition and incentives for entering pharmaceutical markets.

[13] Merck, however, strenuously objected to the introduction of Dr. Hollis' evidence on the basis of lack of relevance or necessity. After hearing the parties in argument, I admitted Dr. Hollis'

report in the form of an affidavit sworn on September 4, 2008 together with two exhibits AH-1, a curriculum vitae, and AH-2, a published paper by Dr. Hollis and another, into evidence as Exhibit 3, subject to weight. Dr. Hollis was then cross-examined.

[14] I find that Dr. Hollis' evidence is to be given no weight. It was not referred to in any written argument submitted by any party before trial, and scarcely referred to in skeleton argument submitted at trial or in oral argument at trial by any counsel. Dr. Hollis purports to address two questions from what he describes as an "economic perspective". The first is directed to whether, under the *PMNOC Regulations,* Apotex's remedy is limited to damages or whether it could claim disgorgement of Merck's profits. Dr. Hollis is not a lawyer, and even if he were, a Canadian lawyer's opinion as to Canadian law is not admissible in evidence for the purpose of interpreting that law. Even less admissible is the evidence of an economist. An exception may exist where a statute uses wording that is meaningful to those practicing a particular profession (*Regina ex rel. Doughty* v. *Manuel* (1982), 38 O.R. (2d) 321 Ont. C.A. at 352-6). However the views of an economist as to the economic incentives or otherwise that may be provided by a regulation is not helpful in interpreting those regulations and will be given no weight.

[15] The second issue addressed by Dr. Hollis was whether Apotex's claim for damages should extend to a shortened period having regard to a delay if any, in serving the Notice of Allegation. Again, the views of an economist on this issue are not helpful. In any event, when Dr. Hollis took the stand, he made numerous corrections to his affidavit on this point, changing the period of delay to one year from two. His conclusions are summarized in paragraph 48 of his affidavit. He

admitted on cross-examination that those conclusions were "*perhaps not very well expressed*". He admitted that only in certain cases would his conclusions be accurate while in other cases they would not be accurate.

[16] I have, therefore, given Dr. Hollis' evidence no weight.

HISTORY OF THE *PMNOC REGULATIONS*

[17] The historical background to what is now the *PMNOC Regulations* has been reviewed, at least in part, in several decisions including *AB Hassle et al. v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272 (FCA); *Apotex Inc. v. Canada (Attorney General)* (2000), 6 C.P.R. (4th) 165 (FCA); *Bayer AG v. Canada (Minister of National Health and Welfare)* (1993), 51 C.P.R. (3d) 329 (FCA); and *Bristol-Myers Squibb Co. v. Canada (Attorney General)* (2005), 39 C.P.R. (4th) 449 (SCC) (*Biolyse*).

[18] Historically a number of countries, Canada among them, have been averse to extending patent monopolies to food or medicines. Canada gradually retreated from this position, allowing patents directed to processes for making food or medicine, then restricting the prohibition to only certain types of medicines and finally, lifting the restrictions entirely. Most, but not all, countries have also lifted such restrictions.

[19] Nonetheless, until 1993, Canada included a scheme in its *Patent Act* whereby an interested person could apply to the Commissioner of Patents (not the patent owner) and obtain a compulsory

licence to sell a patented medicine in Canada. Almost invariably such a licence was granted and at the rate of 4% of the net price of a finished product or 15% for the bulk ingredient. This compulsory licence system was objected to by patentees, claiming that it diminished the rights of those holding patents claiming medicines as opposed to others who may have patents for instance for bicycles.

[20] In the early 1990's considerable efforts were made by the government, encouraged by lobbyists for many of the interested parties, to abolish the compulsory licence system for medicines, and to put in place a suitable system that would encourage development in the area while making medicines available to Canadians at affordable prices. The parties in this action, by agreement, filed six volumes of material said to comprise selected portions of transcripts of parliamentary committee debates, submissions by lobbyists and speeches in the House of Commons (Exhibit 2). I have not found this material to be helpful. In general, such material is not to be used in interpreting a statute or regulation (e.g. *Reference re: Validity of Regulations in Relation to Chemicals*, [1943] S.C.R. 1 per Duff CJ. at page 12). However, to get a flavour of the debate in the House of Commons, I repeat part of what was said by Hon. Pierre Blais (Minister of Consumer and Corporate Affairs and Minister of State (Agriculture) - as he then was), on December 10, 1992 in introducing Bill C-91 which Bill included amendments the *Patent Act*, including section 55.2 at issue here. He said *inter alia*:

> *On several occasions since June, I have had an opportunity to explain the main objectives of Bill C-91 and I would like to come back to them a little.*
>
> *First, Bill C-91 is meant to continue the major undertaking of modernizing Canadian intellectual property legislation, which began*

> *some years ago. In the present economic context where knowledge and innovation are the watchwords, I think that everyone will agree that it is an essential element of our competitiveness.*
>
> *Our purpose is also to align our laws with those of most of our international competitors, so that Canada can provide the same benefits and be as attractive as other countries in terms of international trade and investment.*
>
> *This bill will help us to stimulate research and development in Canada, as well as growth in a leading-edge sector.*
>
> *With Bill C-91, we also wanted to strengthen consumer protection, so that consumers can continue to obtain patented medicine at reasonable prices. I think that all Canadians are entitled to that.*

[21] Section 55.2 as passed R.S.C. 1993, c. 2, s. 4 provided that it would not be an infringement of a patent to use the invention solely for purposes of developing submissions for regulatory approval or for stockpiling. Section 55.2 was a so-called "*early working*" exception which is similar to such an exemption provided in United States legislation. However, the Canadian exception is unrestricted as to subject matter of the patent, it applies to medicines, bicycles and anything patented, and unrestricted as to any country not just Canada or province in which regulatory approval may be sought. The amendment also provided for "*stockpiling*" whereby, a person could make and stockpile patented products but not put them into the stream of commerce until the patent expired (sections 55.2(2) and (3)). These stockpiling provisions were removed in 2001. Section 55.2(4) provided a Regulation making authority. Section 55.2(5) provided that these provisions of the *Patent Act* and any Regulations passed under them, would, in the case of conflict with other provisions of the *Patent Act* or *Regulation* or any other Act or Regulations, have priority.

[22] Section 55.2(6) provided that any right to non-infringement in respect of private, non-commercial activity remained. In this last regard the decision of the Supreme Court of Canada in *SmithKline & French Inter-American Corp. v. Micro Chemicals Ltd.*, [1972] S.C.R. 506 is to be noted in which it was held that experimental use without a licence in the course of *bone fide* experiments directed to whether a person could make a patented product was not an infringement of a patent.

[23] Section 55.2 as passed in 1993 (omitting subsections (2) and (3)) remains in that form to this day and says:

Exception

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.*

Regulations

(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

Exception

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

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 of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent.

Inconsistency or conflict

(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

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.

Divergences

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

Interprétation

(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.

> *regulations made thereunder,*
>
> *this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.*
>
> *For greater certainty*
>
> *(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.*

[24] The legislation as passed in 1993 contained provisions for review of the amendments by a Statutory Committee on Industry. That review was conducted. A Report was tabled dated April, 1997. The Report indicates that many representations were made on behalf of many interested parties. It recommended, among other things, at page 40 of the Report, that in respect of proposed regulatory amendments a rigorous process for drafting, publication, and receipt of submissions on behalf of the public, be followed.

[25] The *PMNOC Regulations* first came into effect on March 12, 1993 (SOR/93-133). They were amended effective March 12, 1998 (SOR/98-166), again amended effective October 1, 1999 (SOR/99-379), against amended effective 5 October, 2006 (SOR/2006-242) and last amended effective June 12, 2008 (SOR/2008-211). It is important to note, particularly with respect to SOR/2006-242, that certain transitional provisions provide that certain amendments including some as to Section 8 do not apply to actions commenced prior to the date of coming into force of the amendments. Those amendments came into force October 5, 2006. This action was commenced

July 5, 2005. As a result, certain amendments pertaining to section 8 of the *PMNOC Regulations* made in October 2006 do not affect what is at issue in this action.

SECTION 8 – HISTORY

[26] In this action, were are concerned with section 8 of the *PMNOC Regulations* in the form in which that section stood as of the date this action was filed, July 5, 2005. As of that date, section 8 read 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 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:*	***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 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) 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	*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) ending on the date of the withdrawl, the discontinuance, the dismissal or the reversal.	*(b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.*

(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 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).

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).

(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).

[27] The history of changes to section 8 since the inception of the *PMNOC Regulations* in 1993 should be reviewed. Those changes were commented upon in the *Regulatory Impact Analyses*

Statement (RIAS) published together with the proposed amendments in the relevant Canada Gazette. The RIAS do not form part of the Regulations but have been used as an aid to interpreting the Regulations. I refer, for instance to the reasons of the Supreme Court of Canada, Binnie J. for the majority, in *Biolyse, supra*, at paragraphs 45 to 49, as well as to the reasons of Bastarache J. for the dissenting minority at paragraphs 155 to 159 in which the RIAS were accepted as an aid to interpretation of the *PMNOC Regulations*.

[28] In the *PMNOC Regulations* as they appeared originally in 1993 (SOR/93-133) section 8 read as follows:

Remedies	***Conclusions***
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).*

[29] The RIAS accompanying the publication of the 1993 *Regulations* said, *inter alia*:

Alternatives Considered	***Autres mesures envisagées***
Under the status quo patentees have the right to pursue patent infringement actions in the courts to obtain interlocutory relief and to be compensated in damages if an injunction is not granted and it turns out that there was 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.	*À l'heure actuelle, les titulaires d'un brevet ont le droit d'entamer des poursuites en contrefaçon dans le but d'obtenir un redressement interlocutoire ou des dommages-intérêts si aucune injonction n'est accordée et qu'on découvre par la suite qu'il y avait contrefaçon. En règle générale, les recours judiciaires suffisent pour régler les cas de contrefaçon. Toutefois, avec l'adoption du projet de la loi C-91, le gouvernement fait une exception dans ce domaine en permettant aux fabricants de médicaments génériques d'entreprendre les démarches nécessaires pour obtenir l'approbation réglementaire d'un produit. Par conséquent, le titulaire d'un brevet perd un droit dont il aurait pu se prévaloir pour empêcher ses concurrents de faire approuver leurs produits.*
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.	*Le présent règlement est nécessaire si on veut éviter que cette nouvelle exception en matière de contrefaçon soit mal utilisée par les fabricants de produits génériques désireux de vendre leurs produits au Canada pendant que le brevet original est encore valide. En vertu du règlement, ces fabricants peuvent toutefois*

entreprendre les démarches nécessaires pour obtenir l'approbation réglementaire et ainsi commercialiser leurs produits dès que les brevets pertinents arrivent à expiration.

[30] Section 8 was amended in 1998 (SOR/98-166) to the wording that is relevant to this action as is set out at the beginning of this portion of these Reasons. The RIAS accompanying this amendment as published in the Canada Gazette in 1998 said, *inter alia*:

The following improvements of the NOC Regulations are enacted:	*Les améliorations suivantes apportées au Règlement sur les médicaments brevetés (avis de conformité) sont promulguées) :*
…	…
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.	*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*
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.	*cas échéant, conformément aux Règles de la Cour fédérale.*
…	
Other changes are designed to reduce unnecessary litigation and streamline the litigation process: specifying the circumstances in which parties can be awarded damages and factors that may be taken into account in calculating damages;	*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.*
	…
	D'autres changements visent à réduite le nombre de….inutiles et à rationaliser le processus judiciaire, en précisant les circonstances où les parties peuvent obtenir des dommages-intérêts et les facteurs pouvant être pris en compte dans le calcul de ces dommages;

[31] The last of the changes to affect section 8 came about in 2006 (SOR/2006-242). Section 8 was amended as follows:

5. (1) Paragraph 8(1)(a) of the Regulation is replaced by the following	***5. (1) L'alinéa 8(1)a) du même règlement est remplacé par ce qui suit:***
(a) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of the Regulations, unless the court concludes that	*(a) débutant à la date attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal conclut :*
(i) the certified date was, by the operation of An Act to amend the Patent Act and the Food	*(i) soit que la date attestée est devancée en raison de l'application de la Loi*

and Drugs Act (The Jean Chrétien Pledge to Africa), chapter 23 of the Statues of Canada, 2004, earlier than it would otherwise have been and therefore a date later than the certified date is more appropriate, or	*modifiant la Loi sur les brevets et la Loi sur les aliments et drogues (engagement de Jean Chrétien envers l'Afrique), chapitre 23 des Lois du Canada (2004), et qu'en conséquence une date postérieure à celle-ci est plus appropriée,*
(ii) a date other than the certified date is more appropriate and	*(ii) soit qu'une date autre que la date attestée est plus appropriée;*
(2) Subsection 8(4) of the Regulations is replaced by the following:	***(2) Le paragraphe 8(4) du même règlement est remplacé par ce qui suit :***
(4) If a court orders a first person to compensate a second person 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.	*(4) Lorsque le tribunal enjoint à la première personne de verser à la seconde personne 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.*
(3) Section 8 of the Regulations is amended by adding the following after subsection (5):	***(3) L'article 8 du même règlement est modifié par adjonction, après le paragraphe (5), de ce qui suit :***
(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.*

[32] The transitional provisions respecting the 2006 amendments provided that these amendments do not affect actions already commenced, such as the present action. The relevant transitional provision says:

8. Subsection 8(4) of the Patented Medicines (Notice of Compliance) Regulations, as enacted by subsection 5(2) of these Regulations, does not apply to an action commenced under section 8 of the Patented Medicines (Notice of Compliance) Regulations prior to coming into force of these Regulations.	*8. Le paragraphe 8(4) du Règlement sur les médicaments brevets (avis de conformité), édicté par le paragraphe 5(2) du présent règlement, ne s'applique pas à l'action intentée en vertu de l'article 8 du Règlement sur les médicaments brevetés (avis de conformité) avant la date d'entrée en vigueur du présent règlement.*

[33] The RIAS accompanying the 2006 amendments as published in the Canada Gazette said, *inter alia*:

Last among the substantive changes proposed by these amendments are refinements to the section 8 damages provision. The first such change is to further specify the matters the court may take into account when calculating the period of delay for which an innovator may be held liable under that section. The second is to confirm that the Minister cannot be held liable for any delay under that section. The third is to remove the world "profits" from the provision prescribing the remedies available to a generic manufacturer seeking compensation for any loss arising from the delay. *On this last point, the Government is aware of a number of ongoing section 8 cases in which it is argued that*	*Figurant en dernier parmi les changements de fond proposes par ces modifications sont des améliorations de la disposition de l'article 8 concernant les dommages-intérêts. Le premier de ces changements vise à préciser davantage les éléments dont le tribunal peut tenir compte au moment de calculer la période de retard dont l'innovateur peut être tenue responsable en vertu de cet article. Le deuxième sert à confirmer que le ministre ne peut être tenu responsable pour tout retard en vertu de cet article. Le troisième consiste à supprimer le terme «profits» de la disposition relative aux mesures de réparation que le tribunal peut ordonner pour dédommager le fabricant de produits génériques pour les pertes encourues en raison de ce retard.*

in order for this provision to operate as a disincentive to improper use of the PM(NOC) Regulations by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovator's profits. While reserving comment on the proper interpretation of the term in these cases, which have been shielded from this change by transitional provisions, in light of the proposed tightening of this listing requirements under amended section 4, and on the introduction of the frozen register mechanism under amended section 5, the Government believes that this line of argument should no longer be open to generic companies that invoke section 8.

…

Reaction from the innovative industry was more equivocal, with the majority of companies supportive of the proposed increases in data protection but a minority strongly opposed to the proposed tightening of the patent eligibility requirements. As regards the "profits" issue, innovators were pleased with its proposed deletion, noting that there is no equivalent remedy under US law for a generic that has been delayed due to the operation of the automatic stay. For its part,

S'agissant de ce dernier changement, le gouvernement a pris connaissance d'un nombre d'affaires en cours relatives à l'article 8 dans lesquelles on avance qu'afin que cette disposition serve à décourager l'utilisation abusive du règlement de liaison par les fabricants innovateurs, le terme « profits » dans ce contexte doit s'entendre par reddition de compte de bénéfices de l'innovateur. Bien qu'il se réserve de commenter sur l'interprétation appropriée du terme dans ces affaires, ces dernières ayant été épargnées de ce changement en vertu des dispositions transitoires, à la lumière du resserrement proposé concernant les exigences relatives à l'inscription des brevets suivant l'article 4 modifié, et l'introduction du mécanisme de « gel » du registre en vertu de l'article 5 modifié, le gouvernement est d'avis que ce genre d'argument ne devrait plus être admis pour les fabricants de médicaments génériques invoquant l'article 8.

…

La réaction de l'industrie innovatrice a été plus équivoque, la majorité des entreprises appuyant la prolongation de la période de protection des données, mais

BIOTECanada urged the Government to increase the proposed term of data protection to 10 years for biologics, in light of the longer development time required to bring these protects to market.	*une minorité étant fortement opposée au resserrement proposé des exigences relatives à l'admissibilité des brevets. En ce qui a trait à la question des « profits », les innovateurs se sont dits satisfaits de la suppression proposée, notant qu'il n'y a aucun recours semblable aux États-Unis pour un fabricant de médicaments génériques ayant été retardé en raison du déclenchement de la suspension automatique. Pour sa part, BIOTECanada exhorta le gouvernement d'entendre la durée de protection des données proposées jusqu'à dix ans pour les produits biologiques, tenant compte du fait que ces derniers font l'objet d'une période de développement plus longue avant qu'ils puissent être commercialisés.*

[34] In this regard, section 45(2) of the *Interpretation Act*, R.S.C. 1985, c. I-21 is to be noted as it says that an amendment to a provision shall not be deemed to be or involve a declaration that the new provision is different from the previous version:

Amendment does not imply change in law	*Absence de présomption de droit nouveau*
(2) The amendment of an enactment shall not be deemed to be or to involve a declaration that the law under that enactment was or was considered by Parliament or other body or person by whom the enactment was enacted to	*(2) La modification d'un texte ne constitue pas ni n'implique une déclaration portant que les règles de droit du texte étaient différentes de celles de sa version modifiée ou que le Parlement, ou toute autre autorité qui l'a édicté, les*

have been different from the law as it is under the enactment as amended.	*considérait comme telles.*

JUDICIAL COMMENTARY ON SECTION 55.2 AND THE *PMNOC* REGULATIONS

[35] One of the early concerns as to the *PMNOC Regulations* was directed to process. Section 6 provided that an innovative drug company that had listed a patent under those *Regulations* could, under subsection (1), "*apply to the court*", the balance of section 6 refers to an "*application*". The Federal Court of Appeal, in 1993, in *Bayer AG v. Canada (Minister of National Health and Welfare)* (1993), 51 C.P.R. (3d) 329 determined that the most appropriate procedure to be followed was is that provided by section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 and the *Rules* governing applications. Mahoney JA. for the Court said at page 336:

> *What is authorized by s. 6(1) of the Regulations is an application "to a court of an order prohibiting the Minister from issuing" a NOC. That seems clearly to be an application within the contemplation of s. 18(1)(b) of the Federal Courts Act. The application is required by s. 18(3) to be made under s. 18.1 and the prescribed procedures are to be found in Part V.1 of the rules. The learned trial judge did not err in determining that the proceedings are governed by the Part V.1 rules.*

[36] Section 18.1 is not entirely appropriate as it largely deals with reviews of decisions of federal tribunals etc. and the *PMNOC Regulations* section 6 proceedings are not such a review. However, lacking a more appropriate template, section 18.1 and the application *Rules* of the Federal Court with adjustments such as those proposed by the December, 2007 Practice Direction of the Federal Court, have been the course followed by the Court.

[37] The manner in which section 55.2(2) of the *Patent Act* fits with the *PMNOC Regulations* as contemplated by section 55(2)(4) was considered by the Federal Court of Appeal in *Apotex Inc. v. Canada (Attorney General)* (2000), 6 C.P.R. (4th) 165. Evans JA. in his minority decision in that case, canvassed the situation and determined that subsection 55.2(4) should be construed broadly. He said at paragraphs 40 and 46:

> ***40*** *Since the words of the statutory text do not point ineluctably to one conclusion, does the statutory context resolve the ambiguity? In my opinion, the nature and subjective definition of the purpose for which the power may be exercised supports a broad interpretation: ". . . such regulations as the Governor in Council considers necessary for preventing the infringement of a patent . . .".*
>
> …
>
> ***46*** *For these reasons, and in accordance with the general directive of section 12 of the Interpretation Act , R.S.C. 1985 c. I-21, I have concluded that subsection 55.2(4) should be construed broadly, so that its application is not limited to those who have availed themselves of the benefits conferred by subsection (1) or (2) in connection with the particular medicine in dispute.*

[38] The majority disagreed with Evans JA. but on another point, they did not comment on this point.

[39] The Courts have spoken more generally as to the *PMNOC Regulations* commenting upon the unhappy union created by dealing with both Food and Drug and Patent legislation (Hugessen JA. in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)* (1994), 55 C.P.R. (3d) 302 (FCA) at page 304), and that it has created a minefield for litigants and counsel (my remarks in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2000 FC 500 at paragraph 19 and *GD Searle & Co. v. Novopharm Ltd.* (2007), 56 C.P.R. (4th) 1 at paragraph 33).

[40] The Supreme Court of Canada has on more than one occasion, considered s. 55.2 and the *PMNOC Regulations*. In *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare*, [1998] 2 S.C.R. 193, Iacobucci J. for the Court referred to as "draconian" the fact that, merely by filing a Notice of Application with the Court, an innovator (first person) could put the application by a generic for a Notice of Compliance (NOC) on hold for up to 30 (now 24) months. At paragraph 30, he said that the purpose of the *Regulations* is simply to prevent patent infringement by delaying the issuance of an NOC to a generic until such time as there would be no such infringement. At paragraphs 32 and 33 he wrote:

> ***32*** *Even if there were such a requirement, however, I would not find that the date of assessment is properly the 46th day following the issuance of the NOA. Considering the nature of the pharmaceutical industry, this seems an unduly restrictive approach, somewhat out of step with commercial reality. As Muldoon J. astutely observed in Merck Frosst Canada Inc., supra, the notion that a NOC might be granted on the 46th day after the issuance of a NOA is indeed, as Simpson J. described it, little more than "theoretical". The Regulations provide for what is, in effect, a statutory prohibition on, or injunction against, the granting of a 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.*
>
> ***33*** *There may be good policy reasons for the operation of the regulatory scheme in this fashion. However, it would be manifestly unjust to subject generic drug producers to such a draconian regime without at least permitting them to protect themselves and*

> *reduce the length of the presumptive injunction by initiating the NOC process as early as possible. As I have already said, this is not inconsistent with s. 6(2) of the Regulations, which provides only that the court shall make an order of prohibition "if it finds that none of those allegations is justified" a finding which can only be made, at the earliest, on the date of hearing. Thus, an application could properly be rejected by the Federal Court as premature if the allegation made in its support is not justified at that time. This is sufficient, in my view, to discourage inappropriately premature applications. On the other hand, to interpret the Regulations in the manner urged by the respondents would effectively be to require generic drug producers to satisfy all requirements in s. 5 and then to wait up to an additional 30 months before marketing the desired product. This cannot be what was intended by the Regulations.*

[41] In *Biolyse, supra*, Binnie J. for the majority began his reasons by addressing the "*balance*" struck by the *Patent Act*, between protection of intellectual property and constraint on health care costs. He wrote at paragraphs 1 and 2:

> ***1*** *Our Court has often spoken of "the balance struck under the Patent Act" in which the public gives an inventor the right to prevent anybody else from using his or her invention for a period of 20 years in exchange for disclosure of what has been invented. As a general rule, if the patent holder obtains a monopoly for something which does not fulfill the statutory requirements of novelty, ingenuity and utility, then the public is short-changed. See Whirlpool Corp. v. Camco Inc., [2000] 2 S.C.R. 1067, 2000 SCC 67; and Free World Trust v. Électro Santé Inc., [2000] 2 S.C.R. 1024, 2000 SCC 66.*
>
> ***2*** *In the present appeal, the Court is required to consider this "balance" in the much-litigated field of patented medicines, where Parliament is concerned not only with the balance between inventors and potential users, but between the protection of intellectual property on the one hand and, on the other hand, the desire to reduce health care costs while being fair to those whose ingenuity brought the drugs into existence in the first place.*

[42] Later in these reasons, Binnie J. spoke of the "*deep freeze*" into which a generic's application for a NOC is placed simply by the institution of a court application by a first party. He echoed Iacobucci J.'s comment that such a process was "*draconian*". At paragraphs 23 and 24, Binnie J. wrote:

> ***23*** *The innovator that filed the patent list may, within 45 days after being served with a Notice of Allegation, apply to the Federal Court for an order prohibiting the Minister from issuing a NOC until all of the listed patents have expired. Commencement of the application for prohibition automatically triggers a 24-month statutory freeze that stops the Minister from issuing a NOC unless within that period the prohibition application is finally disposed of by the court (see ss. 7(1)(e) and 7(4) of the NOC Regulations). In practice the prohibition proceedings can easily drag on beyond the initial 24-month period.*
>
> ***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" 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.*

[43] The Federal Court of Appeal has also considered section 55.2 of the *Patent* Act and the *PMNOC Regulations*. In *AB Hassle v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272, Stone JA. for the Court at paragraphs 5, 18 and 19 commented upon section 8 as providing for compensation to a second person for loss and the advantage provided by the *Regulations* in imposing a 24 month stay, and the disadvantage in that section 8 provides for liability for compensation:

5 *Section 8 of the Regulations renders a first person liable to compensate a second person for loss suffered by that person in the circumstances described in that section.*

…

18 *From the point of view of the patentee, the opportunity to initiate a section 6 proceeding presents advantages and disadvantages. The main advantage is that by paragraph 7(1)(e) the Minister of National Health and Welfare is not to issue the NOC for up to 24 months after receipt of proof of the making of the application for prohibition pursuant to section 6 of the Regulations. The effect, as was pointed out by Mahoney J.A. in Bayer AG, supra, at 337 "is tantamount to an interlocutory injunction" for up to the now reduced period of 24 months. This advantage, while significant, is short term. The principal disadvantage is that where the section 6 proceeding is withdrawn, discontinued or dismissed the patentee is liable to compensate the second person for its loss incurred during the period described in subsection 8(1) of the Regulations. Hence the patentee would have less reason than formerly to be tardy in prosecuting a section 6 proceeding. On the other hand, the assurance that compensation must be paid to a second person at the end of an unsuccessful section 6 proceeding is no guarantee that the second person will act with dispatch in that proceeding.*

19 *The detailed statement is not a pleading per se but represents a pivotal step in the process leading up to the issuance of an NOC. By taking that step the second person puts the patentee on notice of the grounds on which he or she considers that the making, constructing, using or selling of the drug will not infringe the second person's patent rights during the unexpired term of the patent. In theory, this procedure ought to enable the patentee to confidently decide within the 45 day time limit whether to resist the issuance of an NOC. It is to be noted that, subject to business exigencies, the second person had no obligation to make its allegation and provide its detailed statement by an imposed deadline. As much time as the second person deems necessary is available under the scheme of the Regulations.*

[44] Rothstein JA. for the Court in *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (2000), 3 C.P.R. (4th) 1 (FCA) at paragraphs 22, 27 and 28 spoke of "*relief*" available to generics in the form of "*costs, loss and damage*" in the event that ineligible patents were listed:

> ***22*** *Our second reason for not interfering with the discretion exercised by the Minister in this case relates to the scheme of the Regulations themselves. The Regulations expressly provide a process by which generic manufacturers may obtain relief in the event they are prejudiced by reason of ineligible patents being included on the Register. Subsection 6(1) and paragraph 6(5)(a) provide in relevant part:*
>
> > *6.(1) A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)(b) or (c), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the allegation.*
> >
> > *...*
> >
> > *(5) In a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application*
> >
> > > *(a) if the court is satisfied that the patents at issue are not eligible for inclusion on the register ...*
> >
> > *…*
>
> ***27*** *Paragraph 8(1)(a) specifically provides that a patent holder whose prohibition application is dismissed is liable for the loss suffered by a generic manufacturer for the delay incurred in the issuance of a Notice of Compliance to the generic by reason of the prohibition application. Under subsection 8(4), the Court has been given jurisdiction to make an award of damages or lost profits. Section 8 of the Regulations makes it apparent that the Governor in Council recognized that generic manufacturers could be subject to unjustified prohibition applications, including applications based upon ineligible patents on the Register and provided a*

> *remedy in the form of an award of damages or lost profits in such circumstances.*
>
> ***28*** *In sum, there is a comprehensive scheme provided in the Regulations which specifically addresses ineligible patents on the Register and the costs, loss and damage suffered by generic manufacturers arising from such ineligible patents being included on the Register. Having regard to the scheme and its recognition that ineligible patents may be included on the Register, it follows that there is no unlawful refusal to exercise discretion by the Minister in not deleting such patents from the Register under subsection 3(1).*

[45] In *Eli Lilly Canada Inc. v. Canada (Minister of Health)* (2003), 23 C.P.R. (4th) 289 (FCA). Sharlow JA. for the majority at paragraph 11 spoke of a claim for damages a second person may make:

> ***11*** *If prohibition proceedings are not successful, the second person may claim damages against the first person to compensate for the delay in the issuance of the notice of compliance.*

[46] Isaac CJ., in dissent, presaged Binnie J.'s later comments in *Biolyse* in referring at paragraph 74 to the balancing of the rights of patentees and generics:

> ***74*** *In my respectful opinion, my colleague's decision ignores the dual purpose of the 1998 regulatory scheme which seeks to balance the right of patentees with the intent of facilitating the entry of generic products into the market. My colleague's decision also has the effect of extending the right of the appellant under the 969 patent.*

[47] There have, of course, been numerous decisions of the Federal Court (Trial Division) commenting upon the *PMNOC Regulations* and section 55.2. I will refer only to one which deals with these Regulations and that section since those comments by Teitlebaum J. which incorporate

earlier comments by MacKay J. have not been criticized or overturned. In *Fournier Pharma Inc. v. Canada (Attorney General)* (1998), 83 C.P.R. (3d) 72, Teitlebaum J. said at paragraphs 12 to 16:

> ***12*** *The new patent scheme, which comprises the Patent Act and the Regulations, has been considered by the Federal Court, namely, in Apotex Inc. v. Canada (Attorney General) (1996), 71 C.P.R. (3d) 166, where the Court considered the validity of the Regulations.*
>
> ***13*** *In Apotex, some of the issues are virtually identical to the present case. The Court considered, inter alia, whether the Regulations were ultra vires the authority of the Governor in Council pursuant to subsection 55.2(4) of the Patent Act. Further, the Court also considered Apotex's arguments that the regulations had been enacted without necessity and for collateral or ulterior motive, and that it was discriminatory. Mr. Justice MacKay found these arguments non persuasive and dismissed the application.*
>
> ***14*** *In coming to this conclusion, Mr. Justice MacKay considered the scope of the regulatory powers conferred upon the Governor in Council by virtue of subsection 55.2(4) of the Patent Act and found that subsection 55.2(4) of the Patent Act conferred upon the Governor in Council ample discretion and authority to enact these Regulations. I have also reviewed the regulatory powers conferred upon the Governor in Council set out in subsection 55.2(4), in light of Fournier's arguments to the effect that the strict time limits are conditions which are not authorized by the enabling statute and are in effect unreasonable, unfair and unnecessary. In my view, Justice MacKay addressed some of these issues in Apotex. I quote and adopt the following passage from Justice MacKay's decision, at page 188:*
>
> > *These submissions, in my view, mistake the purport of the words "as the Governor in Council considers necessary". Those words grant discretion to the Governor in Council to which a Court defers, recognizing that Parliament has left discretion to the Governor in Council. The exercise of that discretion would only be upset if it were established, and there is no such evidence here, that the Governor in Council did not consider the Regulations necessary. There is no onus on the Governor in Council to demonstrate necessity or*

> *even that necessity was considered. The mere act of adopting regulations establishes that they were considered necessary by the Governor in Council, at least so far as this Court's review is concerned. The words used relate to a matter for determination by the Governor in Council, whose beliefs are not subject to review. The words do not raise any question of an objective standard of necessity to be met or even considered.*

15 *Mr. Justice MacKay went on to review the decision in Reference re Validity of Regulations in Relation to Chemicals, [1943] S.C.R. 1. In Chemicals (supra), the validity of the regulations had been challenged on the basis that the Governor in Council was not empowered by virtue of the enabling provision to adopt the Regulations in relation to Chemicals. The Supreme Court of Canada reviewed section 3 of the War Measures Act which conferred upon the Governor in Council authority to pass the Regulations. Section 3 stipulated that "the Governor in Council may do and authorize such acts and things, and make from time to time such orders and regulations, as he may ... deem necessary or advisable for the security, defense, peace, order and welfare of Canada". Mr. Justice MacKay in Apotex (supra), at page 188, quoted a passage from the Supreme Court of Canada's decision in Chemicals (supra), where Chief Justice Duff said, at page 12:*

> *...when Regulations have been passed by the Governor General in Council in professed fulfillment of his statutory duty, I cannot agree that it is competent to any court to canvass the considerations which have, or may have, led him to deem such Regulations necessary or advisable for the transcendant objects set forth.*

16 *In my view, the above mentioned cases clearly show that a Court should hesitate to interfere with the Governor in Council's broad discretionary powers and authority. In this respect, counsel for Fournier argued at the hearing that the strict time limits under the said subsections allow generic drug manufacturers to enter the market despite a patent or license for the said drugs, and adduced evidence by way of affidavit - Application Record, tab 3, Affidavit of Tom Brogan - to the effect that the entry of generic drugs on the market can have substantial financial and commercial repercussions, most specifically on Fournier because it only*

> *manufactures the two mentioned drugs for which registration of a patent list was refused.*

JUDICIAL COMMENTARY AS TO SECTION 8

[48] There has been little in depth judicial commentary as to section 8 of the *PMNOC Regulations* specifically. Rothstein JA, when he was sitting as a Judge of the Federal Court of Appeal in *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (2000), 3 C.P.R. (4th) 1, delivered the decision of the Court and, in discussing section 8 in the form that is at issue in the present action, wrote at paragraph 27:

> a. *Paragraph 8(1)(a) specifically provides that a patent holder whose prohibition application is dismissed is liable for the loss suffered by a generic manufacturer for the delay incurred in the issuance of a Notice of Compliance to the generic by reason of the prohibition application. Under subsection 8(4), the Court has been given jurisdiction to make an award of damages or lost profits. Section 8 of the Regulations makes it apparent that the Governor in Council recognized that generic manufacturers could be subject to unjustified prohibition applications, including applications based upon ineligible patents on the Register and provided a remedy in the form of an award of damages or lost profits in such circumstances.*

[49] It is to be noted that Rothstein JA. used the words "*lost profits*" in referring to section 8(4) even though those precise words do not appear in sub-section 8(4). Only the word "*profits*" appears in that sub-section.

[50] In *AB Hassle et al. v. Canada (Minister of National Health and Welfare)* (2000), 7 C.P.R. (4th) 272 (FCA), Stone JA. for the Court mentioned section 8 at paragraph 27 of his reasons stating that such provision served as an incentive to the patentee not to delay proceedings:

a. *I would mention a few additional considerations. The fact that the section 6 proceeding is generally to be completed within 24 months and that an award of damages awaits an unsuccessful patentee at the end of that process, should not be ignored. If a second person is always free to supplement its detailed statement in a section 6 proceeding, the proceeding itself is bound to be delayed, which could only redound to the detriment of the first person. That a longer period than the period of 24 months specified in paragraph 7(1)(e) [reduced from 30 months] may be allowed in a particular case seems to be contemplated in paragraph 7(5)(b). This Court has recognized, however, that a section 6 proceeding should be dealt with under the Rules of the Court as expeditiously as possible in order that both sides to the dispute will have their rights determined sooner rather than later. Thus in Bayer AG, supra, Mahoney J.A. stated, at 337:*

> *The court has a clear duty to deal with an application expeditiously. Given that, in the scheme of the Regulations, it is the patentee who has both the carriage of the proceeding and the interest in its dilatory prosecution, departures from the schedule imposed by the Part V.1 rules [now Part 5 of the 1998 Rules] ought not to be routine.*

The ability of the Court to order payment of damages for which an unsuccessful patentee is rendered liable under section 8 of the Regulations suggests, however, that the patentee no longer has an exclusive interest in delaying the progress of a section 6 proceeding. Moreover, the relatively short time period specified in paragraph 7(1)(e) of the Regulations and the language contained in subsection 7(5) of the Regulations, has been rightly viewed as a further indication that a section 6 proceeding should proceed expeditiously to final determination by the Court. The point was made clear in Pharmacia Inc., supra, at 215, where Strayer J.A. stated:

> *The Patented Medicines (Notice of Compliance) Regulations further indicate an intention that this particular kind of application for judicial review should be disposed of expeditiously. Section 7(1) of the regulations provides that normally a notice of compliance should not be issued until 30 months have elapsed from the filing of the application for prohibition, unless the court has in the meantime*

> *dismissed the application. Section 7(5), however, authorizes the court to abbreviate or extend the 30-month period where it has not yet reached a decision on the application but where it finds that a party to the application "failed to reasonably cooperate in expediting the application". Thus if, for example, the applicant unduly delays in bringing the matter on for hearing on the merits, the respondent can move to have the court shorten the time-limit for the issue of a notice of compliance.*

> *It is be noted as well that not only will an unsuccessful patentee in a section 6 proceeding be visited with a Court order to compensate the second person, but the patentee may also be required to pay legal costs pursuant to subsection 6(9) of the Regulations including costs "on a solicitor-and-client basis". Indeed, as provided in subsection 6(10), a factor which the Court may consider in its order as to costs is "the diligence with which the parties pursued the application". This again suggests that a section 6 proceeding was intended to be proceeded with as expeditiously as possible and not be unduly delayed by a party.*

[51] I acknowledge that these judicial comments may have been *obiter*. They are however instructive as to how the matter would strike a Court as a matter of first impression.

MERCK'S ISSUES : JURISDICTION, ENABLEMENT, CONSTITUTIONALITY

a) General

[52] Merck has raised three issues: jurisdiction, enablement and constitutionality; all three issues are directed only at section 8 of the *PMNOC Regulations*. The result, should Merck prevail on any of these, is that at least this Court, and perhaps any court, cannot entertain an action as contemplated by section 8 of the *Regulations*. Apotex points out that, in directing its challenge only to section 8, Merck is content to institute applications under section 6 in the Federal Court, enjoy the 24 month

stay afforded simply by instituting such application and, possibly gain an Order prohibiting the Minister from ever issuing an NOC to a generic so long as the patent in question remains in place.

[53] There can be no doubt that the *PMNOC Regulations* are in their pith and substance regulations dealing with patents. An innovator (first party) can only come within the *Regulations* if it has filed a new drug submissions (NDS) or supplement to that (SNDS) and lists a patent claiming a medicinal ingredient, formulation, dosage or use (section 4(1) and (2) of the *Regulations*) on a particular list supervised by the Minister of Health. A first person makes a choice, it may list or not list a patent, it is not compelled to list a patent. If a patent is listed and a generic seeks the shortcut of an abbreviated new drug submissions (ANDS) by referencing the first party's NDS or SNDS then it must make allegations sent by a notice to the first party as to invalidity, non-infringement of the patent and/or other matters as set out in section 5. The generic must then wait since the innovator again has a choice, it may do nothing in which case, after 45 days, the generic's application for an NOC proceeds or, the innovator may launch a court application to prohibit the Minister from issuing an NOC to the generic, in which case the generic's application for an NOC is put on hold for up to 24 months until the disposition of the application. One way of disposition is by Order of Prohibition directed to the Minister in which case the generic must wait until the patent expires before getting its NOC. Disposition by way of a dismissal or withdrawal is another way, in which case the generic proceeds to get its NOC almost immediately. Merck points out that if an innovator loses at the trial level, the Court of Appeal rarely entertains an appeal since the Minister issues an NOC almost immediately, making an appeal moot. Section 8 of the *Regulations*, the provision now under scrutiny, provides that a generic may commence an action for compensation

for being kept off the market by the stay afforded by the filing of the application by the innovator, if the innovator's application is dismissed, discontinued or withdrawn.

[54] In many respects, section 8 can be analogized to the undertaking usually required by a party seeking an interlocutory injunction from a Court. This Court (*Rule* 372(2)) and most other courts in this country require, unless otherwise ordered, that an undertaking as to damages be provided. An undertaking is a serious matter and the damages afforded may be substantial, although as stated by the Ontario Court of Appeal in *Debrina Corporation v. Triolet Systems Inc.* (2002), 17 C.P.R. (4th) 289 at paragraph 87, they must be reasonably foreseeable at the time of the granting of the interlocutory injunction and must be caused by ("*naturally flow from*") the injunction and not something else.

[55] Merck characterizes section 8 as providing a civil remedy without a wrong having been committed. Merck argues that the simple institution of a section 6 application and being subsequently unsuccessful cannot be said to be a "wrong" for which liability is created. This is a mischaracterization of the circumstances. Merck and others in its position have choices, a patent may be listed or not, an application may be instituted or not. Just like the institution of proceedings and seeking an interlocutory injunction, choices are made. Section 8 is a consequence of such choices. Merck and any other patentee has available to it all the remedies afforded to any patentee under the *Patent Act*, it is deprived of nothing in that regard. In seeking the advantage of section 6, it must be presumed to have done so mindfully of section 8.

[56] With these general comments, I will proceed to consider Merck's submissions as to jurisdiction, enablement, and constitutionality.

JURISDICTION

[57] Merck launched several attacks on the validity of provisions of section 8 of the *PMNOC Regulations* and the jurisdiction of the Federal Court to enforce those provisions. Not all of these attacks were pleaded however. The issue of jurisdiction is not found in Merck's pleadings. Merck argues that a Court has inherent jurisdiction to entertain issues as to its own jurisdiction.

[58] While not pleaded, the issue as to jurisdiction was fully set out in the argument of both parties; nobody has been caught by surprise. I will deal with the issue.

[59] One must start with the proposition that, in Canada's federal system, the superior courts of provinces have plenary and inherent jurisdiction to hear and decide all cases that come before them, regardless of whether the law applicable to a particular case is provincial, federal or constitutional (*Ordon Estate v. Grail* (1998), 166 D.L.R. (4th) 193 (SCC) per Iacobucci and Major JJ. for the Court at paragraph 44). Jurisdiction of the Federal Court over a matter cannot be presumed, it must be positively demonstrated (*R.W. Blacktop Ltd. v. Artec Equipment Co.* (1991), 39 C.P.R. (3d) 432 (FCTD) per Rouleau J. at 435).

[60] The essential requirements to support a finding of jurisdiction in the Federal Court have been well established by the Supreme Court of Canada in several cases such as *ITO-International*

Terminal Operators Ltd., v. Miida (1986), 28 D.L.R. (4th) 641 per McIntyre J. for the majority at page 650:

> *1. There must be a statutory grant of jurisdiction by the Federal parliament.*
>
> *2. There must be an existing body a federal law which is essential to the disposition of the case and which nourishes the statutory grant of jurisdiction.*
>
> *3. The law on which the case is based must be a "law of Canada" as the phrase is used in s. 101 of the Constitution Act, 1867.*

[61] It is upon the first of these criteria, the "statutory grant" that Merck raises much of its argument. Merck points out that jurisdiction of the Federal Court is mentioned about twenty-six times in the *Patent Act*. Many of these provisions conferring jurisdiction deal with appeals from federal tribunals and persons such as the Commissioner of Patents. A frequently used provision is section 54 which confers jurisdiction both on the Federal Court as well as the appropriate superior court of the relevant province in matters of patent infringement. Another frequently used provision is section 60 which confers exclusive jurisdiction on the Federal Court to impeach a patent. Nowhere, says Merck, in the *Patent Act* can one find a conferral of jurisdiction on the Federal Court to hear and determine actions brought under the provisions of section 8 of the *PMNOC Regulations*.

[62] I disagree.

[63] Parliament has, by statute; enacted section 55.2(4) of the *Patent Act* which in subsection (d) gives the authority to the Governor-in-Council to make regulations "*conferring rights of action in*

any court of competent jurisdiction" (emphasis added). Section 55.2(5) ensures that, with respect to any such regulation, if there is a conflict with respect to any Act of Parliament or regulations made thereunder, these regulations shall prevail. In section 12(2) of the *Patent Act* Parliament has provided that any regulation made under the provisions of the *Patent Act* have the same effect as if they were in the *Act* itself.

[64] Section 2 of the *PMNOC Regulations* defines "*court*" to mean "*the Federal Court of Canada or any other superior court of competent jurisdiction.*" This has the same effect as if it were in the *Patent Act* itself.

[65] The Supreme Court of Canada has dealt with similar provisions on at least two occasions. In *The King v. Singer*, [1941] S.C.R. 111, Rinfret J. for the majority at pages 115 and 116 reviewed provisions in several federal statutes which gave the Regulations made under these statutes the effect of the statute itself. He clearly appears to have approved of such a technique since he criticized the *Regulations* that he was considering in that case for not having such provision made in the enabling statute.

[66] In *Canadian Pacific Ltd. v. Matsqui Indian Band* (1995), 122 D.L.R. (4th) 129, the Supreme Court dealt with provisions in the *Indian Act*, R.S.C. 1985, c. I-5, section 83(3) which permitted an Indian Band to make by-laws providing for an appeal procedure as to tax assessments on lands in an Indian reserve. The by-law as passed by the Band provided for an appeal to the Federal Court – Trial Division. Lamer CJ. and Cory J. concurring, held at paragraph 52 that the Indian Bands,

having been authorized by statute to create by-laws, was entitled to take advantage of jurisdiction already existing in the Federal Court under section 24(1) of the *Federal Court Act*. Section 24(1) has since been repealed however that is not material to the present case. Under section 20(2) of the *Federal Courts Act* the Federal Court has jurisdiction in respect of "*all cases…in which a remedy is sought under authority of an Act of Parliament…respecting any patent of invention…*"

[67] Thus, under section 20(2) of the *Federal Courts Act* the Federal Court may accept jurisdiction in a patent matter as being made "*under authority*" of a federal statute. The *Patent Act*, section 55.2(4) authorizes regulations to be made, such as the *PMNOC Regulations*, conferring jurisdiction on "*<u>any</u> court of competent jurisdiction*" (emphasis added). Section 2 of *PMNOC Regulations* names Federal Court as such a court. Section 12(2) of the *Patent Act* gives the *PMNOC Regulations* the same effect as a statute.

[68] As to the two other criteria for jurisdiction as set out in *ITO, supra*, namely (2) an existing body of federal law, it is clear that both of the *Patent Act* and *Federal Courts Act* are such bodies of federal law and (3) that the law must be a law of Canada, it is clear that the *Patent Act* and *Federal Courts Act* are existing laws and laws of Canada. Both criteria are satisfied.

[69] I conclude that the Federal Court has jurisdiction to hear this action.

ENABLEMENT

[70] As its second argument, Merck argues that section 8 of the *PMNOC Regulations* is not enabled by an express grant of power in subsection 55.2(4) of the *Patent Act*. It argues that the opening words of subsection 55.2(4) "*necessary for the preventing of the infringement of a patent*" are words of constraint and that any regulation passed under that provision must be directed to such prevention and not otherwise. Merck argues that section 8 creates a new cause of action not directed to patent infringement but to punishment of an unsuccessful innovator in an NOC application.

[71] Again, I disagree.

[72] The *Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended and its *Regulations* create a benefit for its generics; they can avoid costly testing by simply referencing an innovator's approved product. However, unless the innovator owns or has rights in respect of a patent, there is no patent infringement.

[73] The *PMNOC Regulations* confer a benefit on a particular class of persons who own or have rights in respect of patents pertaining to medicines, their formulation, dosages and uses. Such a benefit is not available to anyone else. The benefited innovator person may choose to list its patents under the *Regulations* and, if notified by a generic that it is seeking an NOC possibly impacted by such a patent, the innovator may choose to launch an application to prohibit the grant of an NOC to the generic. In this way, the innovator having such a patent and electing to make such choices has

an advantage in being given the right to commence a particular application, the mere commencement of which puts the generic application in a 24 month "*deep freeze*". If successful, an innovator will preclude the generic from getting an NOC at all which of course precludes the risk of patent infringement. Thus the regulations are directed to "*patent infringement*".

[74] The *PMNOC Regulations* must be considered as a whole. Section 8 provides, just as in any ordinary court proceeding, a disincentive for seeking what is in effect an interlocutory injunction. It is like an undertaking given by a person seeking such injunction. It is part of a "*balance*" to use the words of the Supreme Court of Canada in *Biolyse*, *supra*, of the *Regulations*. It is a normal and expected balance having regard to undertakings given in Court proceedings such as those for patent infringement when interlocutory injunctions are sought. Subsection 55.2(4)(d) specifically provides for regulations respecting remedies and procedures in respect of disputes under subsection (c) as to when the NOC may issue. This includes the 24 month stay on any issuance of the NOC provided by section 7(1)(e) of the *PMNOC Regulations* and disincentives for seeking such a stay.

[75] I find that section 8 is properly enabled by section 55.2(4) of the *Patent Act*.

CONSTITUTIONALITY

[76] Merck argues that section 8 creates a civil cause of action between individuals for recovery of damages and, as such, is in its pith and substance a matter respecting property and civil rights thus a matter for exclusive jurisdiction in the provinces under section 92(13) of the *Constitution Act, 1967*.

[77] Again, I disagree. Section 8 is an integral part of a scheme set out in the *PMNOC Regulations* as enabled by the *Patent Act* which scheme is directed to the enforcement of rights in certain types of medicinal patents including a balanced procedure respecting such enforcement.

[78] The Supreme Court of Canada in *General Motors of Canada Ltd. v. City National Leasing* (1989), 34 C.P.R. (3d) 417 considered similar circumstances. There the question was whether, under the *Combines Investigation Act* as it then was the federal government could, under its powers respecting trade and commerce, provide for a civil cause of action which could be taken by one individual against another for breach of certain provisions of that *Act*. The unanimous decision of the Court was delivered by Dickson J. At page 436, he recognized that in a federal system it is inevitable that, in pursuing valid objectives, the legislation of each level of government will impact occasionally on the sphere of power of the other level of government; overlap of legislation is to be expected and accommodated in a federal state. He encouraged judicial restraint in proposing strict tests which would result in striking down such legislation.

[79] At page 438, Dickson J. summarized a three step process of analysis:

> (1) First, the court must determine whether the impugned provision can be viewed as intruding on provincial powers and, if so, to what extent;
>
> (2) Second, the court must establish whether the Act, or severable part, is valid as forming part of a regulatory scheme falling under federal competence; and
>
> (3) Third, is the impugned provision sufficiently integrated into the regulatory scheme.

[80] As to the first of these criteria, Dickson J. at page 439 set out three further criteria to be considered:

> (1) Is the provision remedial and serving to enforce the substantive provisions of the *Act*;
>
> (2) Is the action created of limited scope as opposed to a general cause of action; and
>
> (3) It is to be recognized that the federal government is not constitutionally precluded from creating rights of civil action where such measures can be shown to be warranted.

[81] The right to take an action created by section 8 of the *PMNOC Regulations* is of limited scope. It only arises if an innovator chooses to commence an action under those *Regulations* in respect of a patent which it has chosen to list under those *Regulations* and is ultimately unsuccessful. The action is part of the overall scheme of the Regulations so as to create a balance, similar to an undertaking given by one seeking an interlocutory injunction. Section 8 is well integrated into the regulatory process.

[82] Overall, section 8 is nourished by the *Patent Act* and patents are clearly a subject within the exclusive competence of the federal Parliament.

[83] Section 8 of the *PMNOC Regulations* meets all the criteria required for valid federal legislation.

APOTEX'S ISSUES: NATURE AND EXTENT OF SECTION 8 REMEDIES

Loss-Damages or Profits

[84] Apotex argues that it is entitled, by way of relief in this action, to an election that would include either Apotex's damages or Merck's profits during the relevant period. It does so for a number of reasons:

1. Section 8(4) of the *PMNOC Regulations* provides for "*relief by way of damages or profits*" thus entitling Apotex to claim Merck's profits;
2. An award of profits accords with the scheme of the *Patent Act* and the *PMNOC Regulations*; and
3. Section 20(2) of the *Federal Court Act*, provides that this Court can give a remedy at law or in equity respecting a patent.

1) Section8(4) of the Regulations

[85] It has been established by the Supreme Court of Canada on several occasions such as *Biolyse*, *supra*, at paragraphs 470 and 473 and *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559 at paragraphs 26 and 27 that the words of a statute or regulation are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the statute or regulation, the object of the statute or regulation, and the intention of Parliament.

[86] The object of the *PMNOC Regulations* has been reviewed earlier in these reasons with reference to cases such as *Biolyse* and the expression of intent of Parliament has been given in the words of Minister Blais, as he then was, cited earlier. It is to create a kind of "*balance*" between the

rights of patentees and access by the Canadian public to affordable drugs. It is not said that the balance is exact or perfectly even, but a sense of balance must exist. A person having certain kinds of patents relating to medicines is given a right to delay and possibly preclude a generic from getting rather easy access to the market by copying and referencing a patentee's innovations and testing, the generic is given a right, section 8, to compensation if the delay is unwarranted.

[87] With this background, the whole of the relevant subsections of section 8 of the *PMNOC Regulations* can be examined:

i. Section 8(1) provides that if a first person is unsuccessful or terminates its application to provide an NOC to the generic, the first person:

> "*…is liable to the second person (generic) for any loss suffered during the period*"

ii. Section 8(2) provides that a generic may institute an action (such as the present case) against a first person:

> "*…for an order requiring the first person to compensate the second person (generic) for the loss referred to in subsection (1)*"

iii. Section 8(4) states, in its entirety:

> "*The court may make <u>such order</u> for relief by way of damages or profits as the circumstances require <u>in respect of any loss referred to in subsection (1)</u>*". (Emphasis added)

iv. Section 8(5) provides a discretion in the Court:

> "*In assessing the amount of compensation…*"

[88] It is clear from the context of the whole of section 8 that what is provided for is that the Court may make an Order compensating a generic for loss in the prescribed circumstances. The Order may provide for "relief by way of damages or profits" as set out in subsection 8(4). There is no mention anywhere, except as is argued by Apotex, of any remedy in section 8 of disgorgement of any profit made by the first party such as Merck. The entire context of section 8 is focused on compensation for loss suffered by the generic. A reasonable, if not perfect, "balance" has been achieved. Here, the generic was, as it turns out, wrongfully delayed from entering the marketplace; it is compensated for loss occasioned by that delay. It is a reasonable balance.

[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.

[90] The *Patent Act*, section 55(1) provides that a person who infringes a patent is liable to the patentee and others "for all damages". Subsection 55(2) provides for "reasonable compensation" before a patent was granted, a matter examined by Snider J. of this Court in *Jay-Lor International Inc. v. Penta Farm Systems Ltd.*, 2007 FC 358; this a relatively new concept applicable to patents granted from applications filed after October 1, 1989 and not relevant to the present discussion.

[91] Section 57 provides that the Court may, in an infringement action grant an injunction and, in subsection (b) may grant an order "*…for and respecting an inspection or account*".

[92] Nowhere does the word "*profits*" appear in the *Patent Act*. There was considerable scholarly debate as to whether the provision for an "*account*" meant that a Court, in an infringement action, could, as an alternative to awarding damages to a patentee, order disgorgement of an infringer's profits. That debate was laid to rest by the Federal Court of Appeal in *Beloit Canada Ltée v. Valmet Dominion Inc.* (1997), 73 C.P.R. (3d) 321. Stone JA. for the Court discussed the question at pages 355 to 359 of the reported reasons and concluded that the remedy of disgorgement of an infringer's profits is expressly provided for in section 57(1)(b) of the *Patent Act*, *supra*, when read together with section 20 of the *Federal Court Act*.

[93] Lederman J. of the Ontario Superior Court in *Bayer AG v. Apotex Inc.* (2001), 10 C.P.R. (4th) 151 (aff'd 16 C.P.R. (4th) 417 Ont. C.A.) and as cited by Snider J. in *Jay-Lor*, *supra*, at paragraph 114, said at paragraph 12 of *Bayer*:

> ***12*** *The remedy of an accounting of profits is equitable in origin and its goal is compensatory. The purpose is not to punish the defendant for its wrongdoing: Beloit Canada Ltd. v. Valmet Oy (1994), 55 C.P.R. (3d) 433 at 455 (F.C.T.D.), var'd on other grounds (1995), 61 C.P.R. (3d) 271 (F.C.A.); Lubrizol Corp. v. Imperial Oil Ltd. (1996), 71 C.P.R. (3d) 26 at 33 (F.C.A.). Like an award of damages, an accounting of profits is designed to compensate the patentee for the wrongful use of its property. While the goal of each remedy is the same, the underlying principles are very different. An award of damages seeks to compensate the plaintiff for any losses suffered by the plaintiff as a result of the infringement. The amount of profits earned by the infringing party is irrelevant. An accounting of profits, on the other hand, aims to disgorge any profits improperly received by the defendant as a*

> *result of its wrongful use of the plaintiff's property. Such profits, having been earned through the use of the plaintiff's property, rightly belong to the plaintiff. The aim is to remedy the unjust enrichment of the defendant by transferring these profits to their rightful owner, the patentee: Beloit Canada Ltd. v. Valmet Oy (1994), supra, at p. 455 (F.C.T.D.).*

[94] Heald J., sitting as a Deputy Judge of the Federal Court, discussed the principles governing the calculation of damages in a patent infringement claim in *AlliedSignal Inc. v. DuPont Canada Inc.* (1998), 78 C.P.R. (3d) 129 (aff'd 86 C.P.R. (3d) 324 F.C.A.) at paragraphs 17 to 23:

> ***17*** *During the eleven days required to hear this Reference, counsel for the parties made extensive submissions as to the proper approach for determination of the measure of damages in the circumstances of this case. Before turning to a detailed analysis, I think it instructive to set out the general principles governing the calculation of damages in a patent infringement claim.*
>
> ***18*** *Subsection 55(1)(a) is the relevant provision of the Patent Act. It states:*
>
> > *55. (1) Any person who infringes a patent is*
> >
> > > *(a) liable to the patentee and to all persons claiming under the patentee for all damages sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement;*
>
> ***19*** *In addition, the common law has developed a number of principles in relation to the measure of damages. Firstly, due regard must be given to the statement of Lord Wilberforce in General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.:*
>
> > *The general rule at any rate in relation to "economic" torts is that the measure of damages is to be, so far as possible, that sum of money which will put the injured party in the same position as he would have been in if he had not sustained the wrong (Livingstone v. Rawyards Coal Co., 5 A.C. 25, per Lord Blackburn at 39.)*

> *In the case of infringement of a patent, an alternative remedy at the option of the plaintiff exists by way of an account of profits made by the infringer.... The respondents did not elect to claim an account of profits: their claim was only for damages. There are two essential principles in valuing that claim: first, that the plaintiffs have the burden of proving their loss; second, that the defendants being wrongdoers, damages should be liberally assessed but that the object is to compensate the plaintiffs and not punish the defendants (Pneumatic Tyre Co. Ltd. v. Puncture Proof Pneumatic Tyre Co. (1899), 16 R.P.C. 209 at 215.)*

20 *In the words of Lord Buckley in Meters Ltd. v. Metropolitan Gas Meters Ltd., the valuation of the claim is "one that is not capable of being mathematically ascertained by any exact figure." However, it is ultimately necessary to arrive at an exact figure that fairly represents the compensation due to the plaintiff. Accordingly, courts have developed a number of "practical working rules which have seemed helpful to judges in arriving at a true estimate of the compensation which ought to be awarded against an infringer to a patentee."*

21 *Where the patentee does not normally license use of its invention, it is entitled to the profits on the sales it would have made but for the presence of the infringing product in the market. For those sales made by the infringer that the patentee would not have made, the patentee is entitled to a reasonable royalty: Colonial Fastener Co. v. Lightning Fastener Co., Watson, Laidlaw & Co. v. Pott, Cassels & Williamson.*

22 *It should be noted that where the patentee has licensed its invention in the past, it is "almost a rule of law" to assess damages in terms of a reasonable royalty; i.e., according to what the infringer would have paid if it had entered into a legitimate licensing agreement with the patentee: Meters Ltd. v. Metropolitan Gas Meters Ltd.; Catnic Components Ltd. v. Hill & Smith Ltd. This does not apply to the case at bar because the plaintiff has consistently manufactured and sold its own film, and there is no evidence of a license ever being issued for their patented technology.*

23 *In addition to lost profits due to lost sales, the patentee may also claim lost profits due to price suppression if it can establish that it necessarily reduced its prices because of the competition of*

> *the infringer: Colonial Fastener Co. v. Lighting Fastener Co., American Braided Wire Co. v. Thomson.*

[95] In considering "damage" suffered by a patentee because of an infringer's wrongful activity, one may speak in terms of "profits" lost where the patentee is engaged in the manufacture or sale of the patented goods. Where the patentee only licenses its rights, then losses are calculated in terms of lost royalties. Where a patentee does neither, then a Court may assess a "reasonable royalty". I quote in part from *Terrell on the Law of Patents* (16th ed.) London, Sweet & Maxwell, 2006 at paragraphs 13-32 to 13-35:

> ***Principle on which damages assessed***
>
> *The principle to be applied in assessing damages is that the plaintiff should be restored by monetary compensation to the position which he would have occupied but for the wrongful acts of the defendant, provided always that such loss as he proves is (i) foreseeable, (ii) caused by the wrong and (iii) not excluded from recovery by public or social policy.*
>
> ...
>
> *Where the patentee grants licences*
>
> *Patentees derive their remuneration in respect of their inventions either by utilizing their monopoly rights to enable them to obtain increased profits as manufacturers, or by permitting others to use their inventions under licence in consideration of royalty payments. In the latter case, the determination of the damages accruing from infringements is usually a relatively simple matter, it being generally assumed that the damage is equal to the amount which the infringer would have had to pay had he had a licence upon the terms normally granted by the patentee.*

> *Reasonable royalty*
>
> *Where the patentee does not grand licences and cannot prove any loss as manufacturer, the court may assess the damages upon a reasonable royalty basis.*
>
> *Where the patentee manufactures*
>
> *Where the patentee makes his profits as manufacturer (whether or not he grants licences in addition) rather more difficult questions arise, such as whether the infringement has deprived him of manufacturer's profits equivalent to those which he would have made had he had the sale of the infringing goods, and what, if any, other damage may have been occasioned to him by their unauthorized sale.*

[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.

[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.

[98] In so reading, section 8(4), I appreciate that it may be said that I am reading the word "*lost*" to modify the word "*profits*" just as Rothstein J. and others have done before. In this regard, I refer to Professor's Sullivan's 5th edition of "*Sullivan on the Construction of Statues*", 2008, LexisNexis Canada Inc., where, at pages 172 and 173, she refers to what she characterizes as the "Presumption of Perfection":

> ***Presumption of perfection.*** *Legislation is presumed to be accurate as well-drafted; it is presumed that the legislature does not make slips of the pen. In Commissioners for Special Purposes of the Income Tax v. Pemsel, Lord Halsbury wrote:*
>
> > *…I do not think it is competent to any Court to proceed upon the assumption that the legislature has made a mistake. Whatever the real fact may be, I think a Court of Law is bound to proceed upon the assumption that the legislature is an ideal person that does not make mistakes"*
>
> *In theory, this idealization of the legislative drafter's work can be justified.*
>
> …
>
> *Because mistakes inevitably occur, the presumption of perfection should be readily rebutted. It is a normal part of the judicial function to review the work of drafters and in appropriate cases make necessary corrections.*

[99] At pages 165 to 168, Professor Sullivan discusses how a Court may "read down" or "read in" in respect of a statute. At page 165 she says:

> ***Reading down vs. reading in.*** *The terms "reading down" and "reading in" are used in both statutory interpretation and Charter application. In statutory interpretation, they refer to interpretative techniques designed to give effect to the intended scope of legislation; in Charter application, they refer to remedies designed to adjust the intended scope because the legislation as enacted violates*

> *guaranteed rights or freedoms in a way that cannot be justified under s. 1. In both contexts, however, reading down refers to narrowing the scope of the legislative text, while reading in refers to expanding its scope.*
>
> *The point to be made here is that reading down and reading in both require the interpreter to add words to legislative text. The different lies in the effect of the additional words: reading down adds words of restriction or qualification, whereas reading in ads words that expand the reach of the legislation.*

[100] Later at pages 167 and 168, Professor Sullivan reviews the decision of the Supreme Court of Canada in the *Biolyse*, *supra*, approving of the majority decision. At page 168, she criticized the minority's approach to the *PMNOC Regulations* and concluded that "reading down" is a legitimate interpretive technique. She said:

> *The dissent's failure to distinguish words of limitation from words of expansion invites confusion – as evidenced by the following:*
>
> > *Contextual interpretation does not justify departures from ordinary rules of statutory interpretation; in particular, reading in words cannot be justified in the absence of a demonstrable ambiguity.*
>
> *In so far as this passage suggests that adding qualifying words to a text is inappropriate save in cases of demonstrable ambiguity, it is inconsistent with Driedger's modern principle. Contextual interpretation is the very tool required to determine whether reading down is permissible, that is, to determine whether it can be justified as interpretation or must be condemned as amendment. Furthermore, in so far as the passage suggests that reading in (as defined here) is permissible given a demonstrable ambiguity, it is seriously misleading.*
>
> *To summarize, while reading in may on occasion be justified as a constitutional remedy, it is not a legitimate interpretive technique. It amounts to amendment rather than paraphrase. Reading down, on the other hand, is a legitimate interpretive technique provided the reasons for narrowing the scope of the legislation can be justified in terms of ordinary interpretive techniques.*

[101] Having regard to all of the foregoing discussion, including but not limited to what Professor Sullivan has said, I conclude that the proper interpretation of section 8(4) of the *PMNOC Regulations* is to find that the words "damages or profits" are to be interpreted to include only "compensation" for the "loss", if any, suffered by a generic, and that those words do not provide for a right of a generic to elect for a disgorgement or account of a first person's profits.

[102] Section 20(2) of the *Federal Courts Act* does not expand upon the remedies afforded by section 8 of the *PMNOC Regulations*. It enables the Regulations to include equitable remedies, but such remedies must be found in the Regulation. As I have stated above, I cannot find such a remedy in the *PMNOC Regulations.*

DELAY

[103] Merck argues that Apotex "delayed" in serving its Notice of Allegation for 66 days, therefore it argues that the period for which compensation to Apotex is to be calculated should be reduced to 66 days.

[104] I disagree.

[105] Subsections 8(1)(a) and (b) provide for the period over which compensation for loss may be provided:

> ***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 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 withdrawl, the discontinuance, the dismissal or the reversal.*

[106] With respect to subsection 8(1)(a) there is no provision for "*certification*" as such by the Minister or any definition in the *PMNOC Regulations* or elsewhere as to what such "*certification*" may mean. The parties have agreed, however, and I find that is reasonable to conclude that the date "*as certified by the Minister on which a notice of compliance would have been issued*", is the date of the letter sent by the Minister to the generic Apotex stating that the examination of its ANDS application has been completed but an NOC will not be issued until the requirements of the *PMNOC Regulations* are met, that is, until the then outstanding Court application T-844-03 is determined or withdrawn. In this case, that letter (Exhibit 1, Tab 7) is dated February 3, 2004. Thus, according to subsection 8(1)(a), the beginning date from which Apotex can claim compensation "*unless the court is satisfied on the evidence that another date is more appropriate*" is February 3, 2004.

[107] Subsection 8(1)(a) provides that the period of compensation shall end, in this case, on the date of dismissal. Here that date is May 26, 2005, the date that this Court in T-844-03 dismissed

Merck's application. There was no appeal. No provision is made in that subsection for any discretion in the Court to choose another date.

[108] Thus the presumptive period over which compensation may be sought by Apotex is from February 3, 2004 to May 26, 2005.

[109] The discretion that I am given in respect of that period is only with respect to the first date, February 3, 2004, the date that, to use the vernacular, the Minister has written to the generic to say that its application for an NOC is approved subject to "patent hold". I can only exercise my discretion under subsection 8(4)(a) if I am satisfied on the evidence that another date is more appropriate.

[110] The evidence that Merck refers to in argument is found in the agreed fact and documents, Exhibit 1. Merck points out that Apotex's ANDS was submitted to the Minister on February 7, 2003, that Apotex's Notice of Allegation (Exhibit 1, Tab 5) is dated February 25, 2003, but apparently was not received by Merck until April 14, 2003. No excerpts from the discovery of Apotex were put in evidence that deal with these dates or the "delay", if any, in serving the notice of allegation.

[111] Merck's argument as to the so-called delay refers to the period between February 7, 2003 the date Apotex filed its ANDS (Exhibit 1, Tab 5) and the agreed date of service April 14, 2003 (Agreed Facts, paragraph 12, Exhibit 1, Tab A). Merck argues that, had the Notice of Allegation

been served on the date that Apotex filed its ANDS, February 7, 2003 (Agreed Facts, paragraph 17) or very shortly thereafter, Merck would have been obliged by the *PMNOC Regulations* to file its Application with the Court within 45 days from the date of service and, had it done so, the disposition of these proceedings by the Court would have occurred some 66 days earlier than it did, therefore Merck's exposure to liability, given that the date of "certification", February 4, 2004 remains the same, would have been some 66 days less.

[112] I find all of this improbable and, in any event, irrelevant to the considerations that I have to take into account under subsection 8(1)(a).

[113] Subsection 8(1)(a) requires that the Court look at the date that the Minister says that the generic's application is approved subject to any outstanding *PMNOC Regulations* matters such as, in this case, application T-884-03. Here the date of such a letter is February 3, 2004. I can consider some other date where the evidence persuades me that I should. There is absolutely no evidence before me that the Minister would have sent the letter of February 3, 2004 at some earlier or later date having regard to some event or some conduct of some person or otherwise.

[114] Here, the only evidence is that possibly, but not probably, Apotex should have served its Notice of Allegation some 66 days earlier. There is nothing to suggest that the Minister knew about or even cared when the Notice of Allegation was served or that the date of service would have in any way impacted upon the date of the letter of February 3, 2004. The Minister's letter of February

3, 2004 appears to reflect considerations as to Apotex's ANDS submission having regard only to the *Federal Drug Act* and *Regulations*. The letter states:

> *"Please consider this letter as notice that the examination of the above submission has been completed as of February 3, 2004. …"*

[115] The "above submission" is Submission # 082561 which was the ANDS filed by Apotex on February 7, 2003. The "examination" was conducted under the *Food and Drug Act* and *Regulations* and had nothing to do with the *PMNOC Regulations* or Apotex's Notice of Allegation.

[116] There is no relevant evidence before this Court upon which any discretion afforded by section 8(1)(a) of the *PMNOC Regulations* can be exercised. The relevant starting date for the period of compensation will remain as February 3, 2004. The termination date is May 26, 2005.

FUTURE LOSSES

[117] Merck characterizes a claim made by Apotex in respect of certain damages as a claim for "*future losses*". While perhaps not entirely accurate as catchwords, it is convenient to refer to that claim as such.

[118] Apotex's claim is set out in paragraph 1. (a)(ii) of its Further Amended Statement of Claim as follows:

> *1. The Plaintiff, Apotex Inc. ("Apotex"), claims:*
>
> *(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.*

[119] Excerpts from the discovery of Apotex were put in evidence at trial (Exhibit 4) in which there was the following exchange between counsel (Tab 1, pages 21 & 22), Markwell for Merck and Crowfoot for Apotex:

> *Mr. Markwell: Sorry, to clarify your last statement. The damages that flow from those losses at law, what do you mean by that?*
>
> *Mr. Crowfoot: Well, the damages that flow from that period because they were kept off the market during that period. The damages may incorporate things like lost market share which is a present value calculation.*
>
> *Mr. Markwell: So it's not correct, then that your loss is restricted to the 16-month period, that it could be for the longer period of time?*
>
> *Mr. Crowfoot: No, the losses in respect of the 16-month period being off the market. The calculation of that loss may involve the present value calculation of a lesser market share than Apotex otherwise would have had.*
>
> *Mr. Markwell: During those 16 months or beyond those 16 months?*
>
> *Mr. Crowfoot: The loss of market share occurs once they enter the market, and they only have an X percent market share instead of a Y percent market share. That loss is incurred as of the date that they entered the market because they cannot acquire the market share they should have. So the losses still occurred within the period, but calculating it may involve looking forward.*

> *Mr. Markwell: So what would be the time frame for those future losses?*
>
> *Mr. Crowfoot: The loss of market share would be perpetual, but it's the present value calculation that are the further out you get, the less financial impact it has. It's all a matter of expert evidence. I don't know how long it would be.*
>
> *Mr. Markwell: So it's Apotex's position that there may, in fact, be a perpetual loss that would be calculated as of the date of the Notice of Compliance taking into account factors that will be subject of expert evidence?*
>
> *Mr. Crowfoot: Yes.*

[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 that 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.

[121] I analogize the situation to one of an injury that a person may have suffered by the tortious activity of another person. 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.

[122] Therefore, I find that it is appropriate for Apotex to make the claim, provided that the marketplace did not rectify itself or Apotex could not have remedied the marketplace disadvantage before May 26, 2005. The matters of quantification are left to the later trial.

COSTS

[123] The success, or lack thereof, in respect of this portion of the trial is divided, each of the parties having largely failed to succeed on the issues asserted by them. This trial was greatly simplified by an agreement as facts and documents and the conduct of counsel during trial. Their co-operation with each other and the Court was exemplary. I find that it is most appropriate not to award any costs to any party for this portion of the trial.

JUDGMENT

For the Reasons provided herein:

THE COURT ADJUDGES that:

1. Section 8 of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 as amended (SOR/98-166) effective until 2006 is:
    a. within the competence of the Federal Court to hear and determine an action brought thereunder;
    b. enabled by the *Patent Act*, R.S.C. 1985, c. P-4 as amended S.C. 1993, c. 2, s. 4; and
    c. *intra vires* the constitutional authority of the federal Parliament of Canada

2. In this action brought under the provisions of said section 8:
    a. Apotex Inc. is not entitled to elect an account or the disgorgement of the profits of the Respondent, Merck Frosst Canada Ltd. or Merck Frosst Canada & Co.;
    b. Apotex Inc. is entitled to claim damages or its lost profits for the period from February 3, 2004 to May 26, 2005; and
    c. 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;

3. The quantification of the damages or lost profits referred to in paragraph 2 above shall be the subject of the further trial as set out in the Order of this Court dated August 14, 2008. Any party is entitled to seek case management by the Prothonotary assigned to this action for directions as to the procedure to be followed in respect of said trial;

4. No party is entitled to costs of this present portion of the trial of this action.

"Roger T. Hughes"
Judge

FEDERAL COURT

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1144-05
STYLE OF CAUSE:	**APOTEX INC. and MERCK & CO., INC., MERCK FROSST LTD. and MERCK FROSST CANADA & CO**.
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	October 6, 2008
REASONS FOR JUDGMENT and JUDGMENT:	Hughes, J.
DATED:	October 21, 2008

APPEARANCES:

Andrew Brodkin Ken Crowfoot Jerry Topolski	FOR THE PLAINTIFF APOTEX INC.
Patrick Kierans Jason C. Markwell Kristin E. Wall Andres Garin	FOR THE DEFENDANTS MERCK & CO. et al.

SOLICITORS OF RECORD:

Goodmans LLP 250 Younge Street, Suite 2400 Toronto, ON M5B 2M6 Fax: (416) 979-1234	FOR THE PLAINTIFF APOTEX INC.
Ogylvie Renault LLP Suite 3800, P.O. Box 84 200 Bay Street Royal Bank Plaza, South Tower Toronto, ON M5J 2Z4 Fax: (416) 216-3930	FOR DEFENDANTS MERCK & CO et al.