Federal Court of Appeal | Cour d'appel fédérale

Date: 20101209

Dockets: A-352-09
A-360-09

Citation: 2010 FCA 334

CORAM: **NADON J.A.**
SHARLOW J.A.
LAYDEN-STEVENSON J.A.

Docket: A-352-09

BETWEEN:

APOTEX INC.

Appellant

and

THE MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA

Respondents

and

ELI LILLY CANADA

Respondent

Docket: A-360-09

BETWEEN:

CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Appellant

and

ATTORNEY GENERAL OF CANADA and
THE MINISTER OF HEALTH

Respondents

and

CANADA'S RESEARCH-BASED PHARCEUTICAL COMPANIES

Respondent

Heard at Toronto, Ontario, on June 7, 2010.

Judgment delivered at Ottawa, Ontario, on December 9, 2010.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: SHARLOW J.A.
LAYDEN-STEVENSON J.A.

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REASONS FOR JUDGMENT

NADON J.A.

[1] These are appeals from a decision of Mandamin J. (the "Judge") of the Federal Court, 2009 FC 725, dated July 17, 2009, which dismissed the judicial review applications of the appellants, Apotex Inc. ("Apotex"), appellant in Court file A-352-09, and the Canadian Generic Pharmaceutical Association (the "CGPA"), appellant in Court file A-360-09, seeking a declaration that subsection 30(3) of the *Food and Drugs Act*, R.S. 1985, c. F-25 (the "Act") and section C.08.004.1 – the *Data Protection Regulation* (the "DPR") of the *Regulations Respecting Food and Drug*, C.R.C., c. 870 (the "Regulations") – were *ultra vires* and without legal force and effect.

[2] In dismissing the applications, the Judge declared the DPR *intra vires* the federal Parliament. More particularly, he found the DPR to be *intra vires* Parliament's power to make laws respecting trade and commerce under subsection 91(2) of the *Constitution Act, 1867* ("*Constitution Act*"). He further found the provision valid because it is both rationally connected to its enabling provision, subsection 30(3) of the Act, and a permissible sub-delegation.

[3] On November 13, 2009, a Notice of Constitutional Question was filed by the CGPA. It reads as follows:

> The Appellant, the Canadian Generic Pharmaceutical Association, intends to question the constitutional validity, applicability or effect of the *Food and Drugs Act* ("FDA"), R.S.C. 1985, c. F-27, ss. 30(3), and regulations purportedly enacted

thereunder, namely the *Regulations Amending the Food and Drug Regulations (Data Protection)* (hereinafter referred to as the "2005 DP Regulations"), published October 18, 2006, in the *Canada Gazette Part II*, Vol. 140, No. 21, SOR/DORS/2006-241 at pages 1493-1494, purportedly amending the *Food and Drug Regulations*, C.R.C., c. 870, s. C.08.004.1…

[4] Subsection 30(3) of the Act and the DPR are at the heart of these appeals and they read as follows:

The Act	**La Loi**
30. (3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.	**30.** (3) Sans que soit limité le pouvoir conféré par toute autre disposition de la présente loi de prendre des règlements d'application de la présente loi ou d'une partie de celle-ci, le gouverneur en conseil peut prendre, concernant les drogues, les règlements qu'il estime nécessaires pour la mise en œuvre de l'article 1711 de l'Accord de libre-échange nord-américain ou du paragraphe 3 de l'article 39 de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'OMC.
**********	**********
"Data Protection Regulation" (DPR)	**« Règlement sur la protection des données » (RPD)**
C.08.004.1 (1) The following definitions apply in this section. "innovative drug" means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (drogue innovante) "pediatric populations" means the	**C.08.004.1** Les définitions qui suivent s'appliquent au présent article. « drogue innovante » S'entend de toute drogue qui contient un ingrédient médicinal non déjà approuvé dans une drogue par le ministre et qui ne constitue pas une variante d'un ingrédient médicinal déjà approuvé tel un changement de sel, d'ester, d'énantiomère, de solvate ou de polymorphe. (innovative drug)

following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (population pédiatrique)

« population pédiatrique » S'entend de chacun des groupes suivants : les bébés prématurés nés avant la 37e semaine de gestation, les bébés menés à terme et âgés de 0 à 27 jours, tous les enfants âgés de 28 jours à deux ans, ceux âgés de deux ans et un jour à 11 ans et ceux âgés de 11 ans et un jour à 18 ans. (pediatric populations)

(2) This section applies to the implementation of Article 1711 of the *North American Free Trade Agreement*, as defined in the definition "Agreement" in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*, and of paragraph 3 of Article 39 of the Agreement on *Trade-related Aspects of Intellectual Property Rights* set out in Annex 1C to the World Trade Organization Agreement, as defined in the definition "Agreement" in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

(2) Le présent article s'applique à la mise en œuvre de l'article 1711 de *l'Accord de libre-échange nord-américain*, au sens du terme « Accord » au paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord de libre-échange nord-américain*, et du paragraphe 3 de l'article 39 de *l'Accord sur les aspects des droits de propriété intel*lectuelle qui touchent au commerce figurant à l'annexe 1C de l'Accord sur l'Organisation mondiale du commerce, au sens du terme « Accord » au paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord sur l'Organisation mondiale du commerce.*

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,
(a) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and
(b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect

(3) Lorsque le fabricant demande la délivrance d'un avis de conformité pour une drogue nouvelle sur la base d'une comparaison directe ou indirecte entre celle-ci et la drogue innovante :
a) le fabricant ne peut déposer pour cette drogue nouvelle de présentation de drogue nouvelle, de présentation abrégée de drogue nouvelle ou de supplément à l'une de ces présentations avant l'expiration d'un délai de six ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante;
b) le ministre ne peut approuver une telle présentation ou un tel supplément et ne peut délivrer d'avis de conformité pour cette nouvelle drogue avant

of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.

l'expiration d'un délai de huit ans suivant la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante.

(4) The period specified in paragraph (3)(b) is lengthened to eight years and six months if

(a) the innovator provides the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first new drug submission for the innovative drug or in any supplement to that submission that is filed within five years after the issuance of the first notice of compliance for that innovative drug; and

(b) before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug, the Minister determines that the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in those pediatric populations and this knowledge would thereby provide a health benefit to members of those populations.

(4) Le délai prévu à l'alinéa (3)b) est porté à huit ans et six mois si, à la fois :

a) l'innovateur fournit au ministre la description et les résultats des essais cliniques concernant l'utilisation de la drogue innovante dans les populations pédiatriques concernées dans sa première présentation de drogue nouvelle à l'égard de la drogue innovante ou dans tout supplément à une telle présentation déposé au cours des cinq années suivant la délivrance du premier avis de conformité à l'égard de cette drogue innovante;

b) le ministre conclut, avant l'expiration du délai de six ans qui suit la date à laquelle le premier avis de conformité a été délivré à l'innovateur pour la drogue innovante, que les essais cliniques ont été conçus et menés en vue d'élargir les connaissances sur l'utilisation de cette drogue dans les populations pédiatriques visées et que ces connaissances se traduiraient par des avantages pour la santé des membres de celles-ci.

(5) Subsection (3) does not apply if the innovative drug is not being marketed in Canada.

(5) Le paragraphe (3) ne s'applique pas si la drogue innovante n'est pas commercialisée au Canada.

(6) Paragraph (3)(a) does not apply to a subsequent manufacturer if the innovator consents to the filing of a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission by the subsequent manufacturer before

(6) L'alinéa (3)a) ne s'applique pas au fabricant ultérieur dans le cas où l'innovateur consent à ce qu'il dépose une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations avant l'expiration du délai de six ans prévu à cet alinéa.

the end of the period of six years specified in that paragraph.	
(7) Paragraph (3)(a) does not apply to a subsequent manufacturer if the manufacturer files an application for authorization to sell its new drug under section C.07.003.	(7) L'alinéa (3)a) ne s'applique pas au fabricant ultérieur s'il dépose une demande d'autorisation pour vendre cette drogue nouvelle aux termes de l'article C.07.003.
(8) Paragraph (3)(b) does not apply to a subsequent manufacturer if the innovator consents to the issuance of a notice of compliance to the subsequent manufacturer before the end of the period of eight years specified in that paragraph or of eight years and six months specified in subsection (4).	(8) L'alinéa (3)b) ne s'applique pas au fabricant ultérieur dans le cas où l'innovateur consent à ce que lui soit délivré un avis de conformité avant l'expiration du délai de huit ans prévu à cet alinéa ou de huit ans et six mois prévu au paragraphe (4).
(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).	(9) Le ministre tient un registre des drogues innovantes, lequel contient les renseignements relatifs à l'application des paragraphes (3) et (4).
[Emphasis added]	[Non souligné dans l'original]

[5] Subsection 30(3) of the Act grants the Governor in Council authority to enact regulations, as he deems necessary, for the purpose of implementing specified data protection provisions of the *North American Free Trade Agreement* ("NAFTA") and the *Agreement on Trade-related Aspects of Intellectual Property Rights* ("TRIPS") as set out in Annex 1C to the *WTO Agreement*.

[6] The DPR introduces a period of market exclusivity for manufacturers of "innovative drug[s]" by imposing an eight-year moratorium on the approval of the marketing of generic copies of previously-approved new drugs. More particularly, paragraph (3)(a) thereof prohibits a generic manufacturer, seeking a Notice of Compliance ("NOC") for a new drug "on the basis of a direct or

indirect comparison between the new drug and an innovative drug", from filing a New Drug Submission ("NDS") "before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug". In addition, paragraph 3(b) of the DPR prohibits the Minister of Health (the "Minister") from issuing a NOC to a generic drug manufacturer "before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug". The Regulatory Impact Analysis Statement (the "RIAS"), issued with the DPR, sets out the purpose thereof as follows:

Description	Description
The amendments to section C.08.004.1 of the *Food and Drug Regulations* ("Regulations") are intended to provide new drugs with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. An additional six months period of data protection is available for innovative drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the behaviour of the drug in pediatric populations…	L'objet des modifications à l'article C.08.004.1 du Règlement sur les aliments et drogues (le « règlement ») consiste à accorder aux drogues nouvelles une position concurrentielle sur les marchés internationaux et une période d'exclusivité de marché garantie d'une durée de huit ans. Une période de six mois supplémentaires de protection des données est possible dans le cas des drogues ayant fait l'objet d'essais cliniques conçus et menés dans le but d'accroître les connaissances sur le comportement du médicament chez les populations pédiatriques…

[7] Prior to the enactment of the DPR, the only impediment to a generic drug manufacturer's ability to obtain approval of the right to market a generic drug was the existence of an unexpired patent. Since the enactment of the DPR, generic drug manufacturers cannot obtain approval for their generic drug until the period of market exclusivity of the innovative drug has expired, even where there is no patent protection for that drug.

[8] A brief review of the regulatory scheme enacted by Parliament with respect to the marketing of drugs in Canada and of the relevant provisions of NAFTA and TRIPS will help to facilitate an understanding of the issues raised by these appeals.

REGULATORY SCHEME

[9] It is a criminal offence in Canada to market a new drug unless the manufacturer thereof has received a NOC, i.e., the Minister's confirmation that the manufacturer has complied with the Regulations, which seek to ensure the safety and effectiveness of new drugs.

[10] The Regulations prescribe the manner in which the safety and effectiveness of the drug may be shown and they set out a process allowing manufacturers to qualify for exemption from criminality. They also set out in detail the information which a manufacturer must provide to the Minister in order to obtain a NOC. Thus, a manufacturer must obtain a NOC pursuant to Part C, Division VIII of the Regulations, failing which the selling or advertising of the drug in Canada will be subject to criminal prosecution.

[11] In order to obtain a NOC, a manufacturer must either file a New Drug Submission ("NDS") or an Abbreviated New Drug Submission ("ANDS") as required by section C.08.002.(1) of the Regulations. Generally speaking, a NDS is filed by innovator drug companies ("innovator(s)"). The information provided by innovators in a NDS serves to establish that their drug meets the regulatory requirements with regard to the safety, efficacy and quality of the drug. More particularly, the NDS

data will identify the drug, its benefits, adverse reactions, manufacturing process and the results of clinical trials on healthy volunteers and on patients.

[12] A NDS is comprised of various sections, including pre-clinical, clinical, chemistry and manufacturing sections. The pre-clinical portions thereof will consist of all the information pertaining to the experiments that the innovator has conducted in a laboratory so as to test the action and toxicity of the drug. The clinical portions of a NDS provide information with regard to clinical trials with volunteer subjects and/or patients to test the safety and efficacy of the new drug. Further information may be required by the Minister. The content, size and cost of a NDS will vary, but it can be safely said that a NDS for a new active drug, in the words of the Judge, is "… a significant undertaking by the innovator drug company and can contain as many as one to three hundred volumes of data" (Judge's Reasons, paragraph 15).

[13] Once satisfied by the information provided by the innovator, the Minister may issue a NOC. The drug will then be listed as a Canada Reference Product and will be issued a Drug Information Number ("DIN").

[14] An ANDS is available to generic drug manufacturers who wish to copy a marketed drug without having to provide the detailed reports and substantial data clinically demonstrating the safety and effectiveness of their drug. An ANDS will provide the Minister with information pertaining to the composition and manufacture of the drug, as well as studies demonstrating that the generic drug contains the identical amount of the same medicinal ingredient in comparable dosage

as the Canadian Reference Product, that it is pharmacologically equivalent and that it has the same bio-availability as the Canadian Reference Product.

[15] Thus, rather than making a direct assessment of the clinical safety or efficacy of its drug on the basis of clinical studies, a generic manufacturer uses the Canadian Reference Product to demonstrate the latter's bio-equivalence to its own product. A typical ANDS will contain fewer volumes of data in comparison to the volumes of data filed in a NDS, ranging from a dozen to two dozen volumes.

[16] Once satisfied, the Minister will issue a NOC to the generic manufacturer. The generic drug will also be listed as a Canada Reference Product and issued a DIN.

[17] I now turn to a brief review of the relevant provisions of NAFTA and TRIPS. As I indicated earlier, the purpose of subsection 30(3) of the Act is to allow the Governor in Council to enact regulations so as to implement specified data protection provisions of both NAFTA and TRIPS. More particularly, the Governor in Council is authorized to make regulations that are deemed necessary for the purpose of implementing article 1711 of NAFTA or paragraph (3) of article 39 of TRIPS.

[18]

Article 1711 of NAFTA (which was signed on December 17, 1992), provides as follows:

Article 1711: Trade Secrets	***Article 1711 : Secrets commerciaux***
1. Each Party shall provide the legal means for any person to prevent trade	1. Chacune des Parties assurera à toute personne les moyens juridiques

secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as:
(a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question;
(b) the information has actual or potential commercial value because it is secret; and
(c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.

d'empêcher que des secrets commerciaux ne soient divulgués à des tiers, acquis ou utilisés par eux, sans le consentement de la personne licitement en possession de ces renseignements et d'une manière contraire aux pratiques commerciales honnêtes, dans la mesure où :
a) les renseignements sont secrets, en ce sens que, dans leur globalité ou dans la configuration et l'assemblage exacts de leurs éléments, ils ne sont pas généralement connus de personnes appartenant aux milieux qui s'occupent normalement du genre de renseignements en question ou ne leur sont pas aisément accessibles;
b) les renseignements ont une valeur commerciale, réelle ou potentielle, du fait qu'ils sont secrets; et
c) la personne licitement en possession de ces renseignements a pris des dispositions raisonnables, compte tenu des circonstances, en vue de les garder secrets.

2. A Party may require that to qualify for protection a trade secret must be evidenced in documents, electronic or magnetic means, optical discs, microfilms, films or other similar instruments.

2. Une Partie pourra exiger que, pour faire l'objet d'une protection, un secret commercial soit établi par des documents, des médias électroniques ou magnétiques, des disques optiques, des microfilms, des films ou autres supports analogues.

3. No Party may limit the duration of protection for trade secrets, so long as the conditions in paragraph 1 exist.

3. Aucune des Parties ne pourra restreindre la durée de protection des secrets commerciaux tant que subsistent les conditions énoncées au paragraphe 1.

4. No Party may discourage or impede the voluntary licensing of trade secrets by imposing excessive or discriminatory conditions on such licenses or conditions that dilute the

4. Aucune des Parties ne pourra entraver ou empêcher l'octroi de licences volontaires à l'égard de secrets commerciaux en imposant des conditions excessives ou

value of the trade secrets.

discriminatoires à l'octroi de ces licences ou des conditions qui réduisent la valeur des secrets commerciaux.

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed tests or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

5. Lorsqu'une Partie subordonne l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des éléments chimiques nouveaux, à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées nécessaires pour déterminer si l'utilisation de ces produits est sans danger et efficace, cette Partie protégera ces données contre toute divulgation, lorsque l'établissement de ces données demande un effort considérable, sauf si la divulgation est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre toute exploitation déloyale dans le commerce.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there

6. Chacune des Parties prévoira, en ce qui concerne les données visées au paragraphe 5 qui lui sont communiquées après la date d'entrée en vigueur du présent accord, que seule la personne qui les a communiquées peut, sans autorisation de cette dernière à autrui, utiliser ces données à l'appui d'une demande d'approbation de produit au cours d'une période de temps raisonnable suivant la date de leur communication. On entend généralement par période de temps raisonnable, une période d'au moins cinq années à compter de la date à laquelle la Partie en cause a donné son autorisation à la personne ayant produit les données destinées à faire approuver la commercialisation de son produit,

shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.	compte tenu de la nature des données, ainsi que des efforts et des frais consentis par cette personne pour les produire. Sous réserve de cette disposition, rien n'empêchera une Partie d'adopter à l'égard de ces produits des procédures d'homologation abrégées fondées sur des études de bioéquivalence et de biodisponibilité.
7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.	7. Lorsqu'une Partie se fie à une approbation de commercialisation accordée par une autre Partie, la période raisonnable d'utilisation exclusive des données présentées en vue d'obtenir l'approbation en question commencera à la date de la première approbation de commercialisation.
[Emphasis added]	[Non souligné dans l'original]

[19] After the signing of NAFTA, an earlier version of subsection 30(3) of the Act was brought into effect on January 1, 1994, and an earlier version of the Regulations – section C.08.004.1 (the "first DPR") – was enacted (published in the Canada Gazette on June 9, 1995).

[20] TRIPS was signed on April 15, 1994. This was approximately one year prior to the enactment of the first DPR. However, the earlier version of subsection 30(3) of the Act which delegated this power to the Governor in Council came into effect on January 1, 1994 and thus, made no mention of TRIPS until subsection 30(3) was amended, coming into force on January 1, 1996.

[21] Article 39 of TRIPS, which reads as follows:

Article 39	***Article 39***
1. In the course of ensuring effective	1. En assurant une protection effective

protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

contre la concurrence déloyale conformément à l'article 10bis de la Convention de Paris (1967), les Membres protégeront les renseignements non divulgués conformément au paragraphe 2 et les données communiquées aux pouvoirs publics ou à leurs organismes conformément au paragraphe 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices (10) so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) has commercial value because it is secret; and
(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

2. Les personnes physiques et morales auront la possibilité d'empêcher que des renseignements licitement sous leur contrôle ne soient divulgués à des tiers ou acquis ou utilisés par eux sans leur consentement et d'une manière contraire aux usages commerciaux honnêtes , sous réserve que ces renseignements:
a) soient secrets en ce sens que, dans leur globalité ou dans la configuration et l'assemblage exacts de leurs éléments, ils ne sont pas généralement connus de personnes appartenant aux milieux qui s'occupent normalement du genre de renseignements en question ou ne leur sont pas aisément accessibles;
b) aient une valeur commerciale parce qu'ils sont secrets; et
c) aient fait l'objet, de la part de la personne qui en a licitement le contrôle, de dispositions raisonnables, compte tenu des circonstances, destinées à les garder secrets.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such

3. Lorsqu'ils subordonnent l'approbation de la commercialisation de produits pharmaceutiques ou de produits chimiques pour l'agriculture qui comportent des entités chimiques nouvelles à la communication de données non divulguées résultant d'essais ou d'autres données non divulguées, dont l'établissement demande un effort considérable, les

data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. [Emphasis added]	Membres protégeront ces données contre l'exploitation déloyale dans le commerce. En outre, les Membres protégeront ces donné es contre la divulgation, sauf si cela est nécessaire pour protéger le public, ou à moins que des mesures ne soient prises pour s'assurer que les données sont protégées contre l'exploitation déloyale dans le commerce. [Non souligné dans l'original]

[22] The RIAS, under the heading of Background, explains the obligations which signatories to NAFTA and TRIPS have agreed to:

Background The amendments to section C.08.004.1 of the *Food and Drug Regulations* are intended to clarify and effectively implement Canada's *North American Free Trade Agreement* ("NAFTA") and the *Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilizes a new chemical entity. The obligations in TRIPS require that signatories provide protection against the unfair commercial use of the data, whereas NAFTA requires that signatories provide a reasonable period of time during which a subsequent manufacturer is prohibited from relying on the originator's data for product approval. The reasonable period of time is specified as normally not being less than five years from the date on which regulatory approval was granted to the	Contexte Les modifications à l'article C.08.004.1 le règlement visent à clarifier et à mettre en oeuvre, de façon efficace, les engagements du Canada en vertu de l'Accord de libre-échange nord-américain (ALÉNA) et les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) en matière de protection des données de tests non divulgués ou d'autres données nécessaires afin de déterminer l'innocuité et l'efficacité d'un produit pharmaceutique ou agricole qui comporte une nouvelle entité chimique. Les obligations prévues aux ADPIC exigent que les signataires fournissent une protection contre l'exploitation déloyale dans le commerce des données, alors que l'ALÉNA exige que les signataires prévoient une période raisonnable pendant laquelle aucun fabricant ultérieur n'est autorisé à se fonder sur les données du premier auteur pour obtenir l'approbation du produit. La

originator of the data. In keeping with the provisions, the government has decided to provide this protection by allowing the innovator, or the originator of the data submitted for regulatory approval, to protect investments made in the development of the product by providing a period of market exclusivity.	période raisonnable est précisée et ne doit normalement pas être inférieure à cinq ans à partir de la date à laquelle la première approbation réglementaire a été accordée à l'auteur des données. Dans l'esprit de ces dispositions, le gouvernement a décidé d'accorder cette protection en permettant à l'innovateur ou au premier auteur des données soumises à l'approbation réglementaire de protéger l'investissement fait dans le développement du produit en prévoyant une période d'exclusivité du marché.

[23] The first DPR was amended in 2006 to the version at issue in these proceedings (coming into force on October 5, 2006 with publication in the Canada Gazette on October 10, 2006).

[24] Before turning to the Judge's decision, it will be useful to say a few words concerning the decisions rendered by the Federal Court and this Court in *Bayer v. Canada (Attorney General)* (1998), 84 C.P.R. (3d) 129 (FC); affirmed (1999), 87 C.P.R. (3d) 293 (FCA); leave to appeal refused, [1999] S.C.C.A. No. 386 (SCC June 15, 2000) ("*Bayer*"), upon which the appellants rely in regard to one of the questions raised by the appeals.

[25] In *Bayer*, the innovator brought a motion for a declaration that the first DPR provided a five-year protection period for innovators in respect of new drugs for which a NOC had been issued. The first DPR, under consideration in *Bayer*, read as follows:

C.08.004.1 (1) Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness	**C.08.004.1** (1) Lorsque le fabricant dépose une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations en vue de faire déterminer l'innocuité et l'efficacité de la drogue nouvelle qui en

of the new drug for which the submission or supplement is filed, and the Minister examines any information or material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer's submission or supplement, relies on data contained in the information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug.

(2) Subsection (1) does not apply where the manufacturer of a new drug for which a notice of compliance was issued pursuant to section C.08.004 gives written permission to another manufacturer to rely on the test or other data filed in respect of that new drug.

(3) Subsection (1) does not apply where the data relied upon by the Minister was contained in information or material filed by the innovator before January 1, 1994.

[Emphasis added]

est l'objet, et que le ministre examine les renseignements et le matériel présentés, dans une présentation de drogue nouvelle, par l'innovateur d'une drogue contenant une substance chimique ou biologique dont la vente comme drogue n'a pas été préalablement approuvée au Canada et s'appuie sur les données y figurant pour étayer la présentation ou le supplément du fabricant, il ne peut délivrer un avis de conformité à l'égard de cette présentation ou de ce supplément avant l'expiration du délai de cinq ans suivant la date à laquelle est délivré à l'innovateur l'avis de conformité ou l'approbation de commercialiser cette drogue, selon le cas, d'après les renseignements ou le matériel présentés par lui pour cette drogue.

(2) Le paragraphe (1) ne s'applique pas lorsque le fabricant d'une drogue nouvelle pour laquelle un avis de conformité a été délivré aux termes de l'article C.08.004 autorise par écrit un autre fabricant à se fonder sur les résultats d'essais ou d'autres données présentés au sujet de la drogue nouvelle.

(3) Le paragraphe (1) ne s'applique pas lorsque les données sur lesquelles le ministre s'appuie étaient contenues dans les renseignements et le matériel présentés par l'innovateur avant le 1er janvier 1994.

[Non souligné dans l'original]

[26] The version of subsection 30(3) of the Act at the time of *Bayer*, read as follows:

30. …	**30.** …
(3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may, for the purposes of implementing Article 1711 of the North American Free Trade Agreement, make regulations respecting the extent to which, if any, a person may, in seeking to establish the safety and effectiveness of a new drug for the purposes of any regulations made under subsection (1) or (2), rely on test or other data submitted by any other person to the Minister in accordance with such regulations.	(3) Sans que soit limité le pouvoir conféré par toute autre disposition de la présente loi de prendre des règlements d'application de la présente loi ou d'une partie de celle-ci, le gouverneur en conseil peut, pour la mise en œuvre de l'article 1711 de l'Accord de libre-échange nord-américain, prendre des règlements prévoyant dans quelle mesure, s'il y a lieu, une personne peut, lorsqu'elle tente de déterminer la sûreté ou l'efficacité d'une drogue nouvelle, pour l'application des règlements pris en vertu des paragraphes (1) ou (2), se fonder sur des essais ou d'autres données présentés au ministre, conformément à ces règlements, par une autre personne.
[Emphasis added]	[Non souligné dans l'original]

[27] Thus, the first DPR prohibited the Minister from issuing a NOC to a generic manufacturer for a period of "five years after the date of issuance to the innovator of the notice of compliance for approval to market" its new drug. However, this prohibition only applied in those instances where the Minister, in determining whether to issue a NOC to a generic manufacturer following the filing of an ANDS, examined "any information or material filed" with him in a NDS by an innovator of a drug and relied on the data contained in that information or material.

[28] The main issue before both the Federal Court (Evans J., as he then was) and this Court in *Bayer* was whether the Minister, in examining an ANDS submitted by a generic manufacturer seeking approval of the safety and effectiveness of its new drug by comparing it to that of an innovator, examined and relied on the confidential detailed safety report and evidence of clinical effectiveness filed by the innovator with its NDS. Evans J. and this Court answered the question in

the negative. Rothstein J.A. (as he then was) wrote the Reasons of this Court. He made the following remarks at paragraphs 12 and 15:

> [12] The NAFTA provisions are intended to protect trade secrets. If the generic manufacturer exercises the option of having the Minister examine the confidential information filed by the innovator in support of its application for a Notice of Compliance, it is, in effect, relying on that information within the meaning of section 6 of Article 1711. It is apparent that if confidential data is not relied upon, the trade secrets provisions of the NAFTA are not applicable. Specifically, if a generic manufacturer is able to establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the Minister having to examine and rely upon confidential data filed by the innovator, there is no reason or justification for the minimum five year protection from competition. This interpretation of subsection C.08.004.01(1) is consonant with section 5 and 6 of Article 1711 of the NAFTA.
>
> …
>
> [15] Subsection C.08.004.1(1)and sections 5 and 6 of Article 1711 of NAFTA are responsive to the requirement on innovators of pharmaceutical products of having to disclose confidential proprietary information to the government. They provide for the use of that confidential or trade secret information by the government on behalf of the generic manufacturer and when that occurs, the minimum five year protection from competition for the innovator applies. Where the government does not use that confidential or trade secret information on behalf of the generic manufacturer, the provision is not applicable.
>
> [Emphasis added]

[29] I now turn to the Judge's decision.

THE FEDERAL COURT DECISION

[30] The Judge concluded that the DPR was *intra vires* a valid exercise of the federal constitutional power respecting trade and commerce under subsection 91(2) of the *Constitution Act*. He also concluded that the DPR was rationally connected to subsection 30(3) of the Act and that it came within the regulatory authority given to the Governor in Council by Parliament.

[31] In coming to this conclusion, the Judge reviewed the process by which manufacturers of drugs gain approval to market their drugs in Canada and the legislative history of the DPR and subsection 30(3) of the Act, including the international agreements which underlay that provision. In the course of this review, the Judge also summarized the jurisprudence pertaining to the interpretation of these provisions.

[32] The Judge summarized the evidence adduced by the parties and made the following findings at paragraph 46 of his Reasons:

> [46] …
>
> 1. NDS require extensive research and clinical data on the safety and efficacy of the new drug which is compiled by innovative drug companies through considerable effort, time and cost;
> 2. ANDS for generic copies also require significant pharmacological and clinical information to prove safety and efficacy by comparison to a proven safe drug that which generic drug companies compile at significant but comparatively less development time and cost;
> 3. generic drugs are available to the public at less cost than newly approved drugs to some degree as a consequence of lower development costs;
> 4. the protection of data required by governments for the approval of new drugs is the subject of international agreements, NAFTA and TRIPS, to which Canada is signatory; and
> 5. Canada is not seen as being in compliance to the same degree with the NAFTA and TRIPS data protection requirements as other countries, notably the United States and the European Union.

[33] The Judge then turned to the question of whether the DPR was *intra vires* the federal criminal law power under subsection 91(27) of the *Constitution Act*.

[34] First, he proceeded to determine the pith and substance of the DPR. In order to make that determination, he carefully examined the DPR, its stated purpose, its legal and economic effects and

the language of NAFTA and TRIPS. He concluded that the purpose of the DPR was to implement specific provisions of NAFTA and TRIPS and that the DPR's legal effect was the protection of information submitted by innovators in their NDS. In his view, the intended effect of the DPR was the balancing of the commercial interests of both innovators and generic manufacturers, in that the DPR sought to protect the research and development costs of innovators while achieving lower drug costs by allowing the entry into the market of generic drugs.

[35] These determinations led him to conclude, at paragraph 79 of his Reasons:

> [79] I conclude that the pith and substance of the Data Protection Regulation is the balancing of commercial considerations between the protection of an innovator drug manufacturer's investments in preparing the NDS information in order to obtain an NOC for a new drug and the eventual NOC approval of generic drug manufacturer's ANDS for a lower cost generic version of the new drug.

[36] Following that conclusion, the Judge indicated that he could not agree with the respondent's position that the DPR was an integral part of the overall scheme pertaining to the marketing of drugs in Canada, the essence of which is the protection of public health and safety by prohibiting all drugs except those that had been proven to be safe and effective, thus making the scheme a matter of federal legislative jurisdiction under Parliament's criminal law power found in subsection 91(27) of the *Constitution Act*.

[37] More particularly, the Judge found that the balancing of commercial considerations in respect of innovators and those in respect of generic drugs manufacturers did not form part of the scheme to protect the health and safety of the public. Thus, in his view, it could not be said that the

DPR was an integral part of the Regulations. Rather, the relationship between the DPR and the scheme was an adjunct one. At paragraph 84 of his Reasons, he made the following remarks:

> [84] The *Data Protection Regulation* is not a public safety provision so as to come within the federal criminal law powers pursuant to subsection 91(27) of the *Constitution Act, 1867* notwithstanding that the overall drug regulation scheme does. Nor is the regulation integral in that public health and safety is not enhanced without the data protection provision.

[38] The Judge thus concluded that the DPR was not *intra vires* the federal criminal law powers pursuant to subsection 91(27) of the *Constitution Act*.

[39] The Judge then went on to consider whether the Regulation might be *intra vires* by reason of another head of federal legislative jurisdiction. He looked at subsection 91(2) (the regulation of trade and commerce power) and the national concern aspect of the residual peace, order and good government power ("POGG").

[40] He first considered the question of whether the DPR could fall under the general regulation of trade and commerce branch of subsection 91(2) and began this inquiry by canvassing the relevant jurisprudence. In particular, he referred to the Supreme Court of Canada's decision in *Canada (A.G.) v. Canadian National Transportation*, [1983] 2 S.C.R. 206 ("*Canadian National Transportation*"), where the Supreme Court enunciated the criteria pursuant to which courts can distinguish between federal trade and commerce matters and provincial local matters. At paragraph 97, the Judge summarized the Court's pronouncement as follows:

> 97] In *Canada (A.G.) v. Canadian National Transportation*, [1983] 2 S.C.R. 206 (*Canadian National Transportation*), Justice Dickson, writing separate reasons, built upon Chief Justice Laskin's suggested criteria for validity under the second branch of the trade and commerce power. In addition to: (1) the provision was part

> of a general regulatory scheme; (2) the scheme was monitored by an overseeing agency; and (3) the legislation was concerned with trade as a whole rather than a particular industry, Justice Dickson included: (4) that the provinces jointly or severally would be constitutionally incapable of passing such an enactment; and (5) the failure of one or more provinces would jeopardize the successful operation in other parts of the country.

[41] The Judge then reviewed the Supreme Court's decision in *General Motors of Canada v. City National Leasing Ltd.*, [1989] 1 S.C.R. 641 ("*General Motors*"), where Dickson C.J. indicated that the principles enunciated in *Canadian National Transportation*, "represented a principled way to distinguish between federal trade and commerce matters and provincial local matters" (Judge's Reasons, paragraph 100).

[42] With those principles in mind, the Judge made a number of findings.

[43] First, he found that the Regulations established a valid regulatory drug scheme for the approval of new drugs and generic drugs, overseen by the Minister. In his view, the presence of this scheme satisfied the first two criteria of *Canadian National Transportation*.

[44] He then found that the DPR, although an adjunct rather than integral part of the regulatory scheme, rounded out a valid regulatory drug scheme established for the marketing of drugs in Canada. He said that the DPR dealt with the manufacturing and marketing of drugs which, in his view, was a local matter in a single industry. Still, he added, it "has implications of a national dimension" (Judge's Reasons, paragraph 104) in that it was enacted to comply with international treaties, NAFTA and TRIPS. Canada's implementation or failure to implement these agreements "has a national dimension that relates to Canada's ability to participate in world trade" and that the

DPR deals with a "genuine national economic concern of the kind considered by Justice Dickson in *Canadian National Transportation*" (Judge's Reasons, paragraph 105).

[45] Lastly, at paragraph 106 of his Reasons, the Judge then dealt with the last criterion enunciated in *Canadian National Transportation*:

> [106] The *Data Protection Regulation* deals with the approval of the marketing of new drugs. Provincial legislatures cannot enact legislation that delays the approval of generic drugs since provincial approvals of drugs for the market place would seriously interfere with the federal s. 91(27) criminal law power to prohibit the marketing of drugs but for exceptions where drugs are proven safe and effective. Given the inability of provincial governments to enact legislation to stage approval of generic drugs, the fifth criteria enunciated by Chief Justice Dickson, the failure of one or more provinces jeopardizing the successful operation in other parts of the country, does not arise.

[46] As a result of the above analysis, the Judge concluded that the DPR was a constitutionally valid exercise of the federal legislative power under section 91(2) of the *Constitution Act*.

[47] He then turned to the question of whether subsection 30(3) of the Act and the DPR were *intra vires* the federal legislative power under the POGG. He did not reach any conclusion on this question because he found it unnecessary to do so.

[48] The Judge then addressed the question of whether the DPR fell outside the regulatory authority of the Governor in Council for not being rationally connected to the grant of authority pertaining to trade secrets and confidential information in section 30(3) of the Act.

[49] The Judge began by summarizing the appellants' arguments at paragraphs 111 to 117 of his Reasons. He then reviewed the relevant provisions of NAFTA and TRIPS, which led him to say that the information protected by these provisions was "not necessarily 'secret' information but rather includes data that was gathered at considerable cost which is not otherwise publicly available in that assembled form" (Judge's Reasons, paragraph 120).

[50] Next, he determined that the information and material found in innovators' NDS was data that met the relevant definitions of both NAFTA and TRIPS. Although, in his view, that information may not be secret in all respects, it was, in its compilation, "unique to the innovator drug manufacturer and has value" (Judge's Reasons, paragraph 123). As a result, he concluded that the data found in the NDS came within the scope of the DPR.

[51] He then referred to paragraph 5 of article 1711 of NAFTA and to TRIPS, noting that while NAFTA identified a mechanism of market exclusivity protection, TRIPS did not outline what measures were to be taken by signatories. The content of these provisions led the Judge to state that the federal government had recognized that the first DPR was insufficient to meet its obligations under NAFTA and TRIPS. He so opined, *inter alia*, because of the comment found in the RIAS issued with the DPR. In particular, he had in mind that part of the RIAS which made reference to this Court's decision in *Bayer*. At paragraphs 126 and 127 of his Reasons, the Judge made the following comments:

> [126] The federal government recognized that the previous regulation did not satisfy its obligations under NAFTA and TRIPS as was indicated by its reference in RIAS to the Court's findings in *Bayer FC*. In enacting the current version of the *Data Protection Regulation*, the federal government is providing protection for a drug manufacturer's investment in compiling the extensive research and clinical data needed in order to obtain an NOC for a new drug by a market exclusivity

> mechanism. The regulation provides the innovator drug manufacturer the opportunity to recoup and profit by its costly investment for a period of time before others may also benefit by making generic copies of a that drug.
>
> [127] The making of a generic copy of an approved drug circumvents the need to generate the research and clinical data. The ANDS process indirectly takes advantage of the innovator drug manufacturer's production of the necessary NDS information. The result is a second stage or subsequent reliance on the innovator's work in securing an ANDS approval. In *Bristol-Myers*, Justice Binnie explained how the generic manufacturer 'relies' on the innovator drug manufacturer's approved new drug.
>
> > 21 The NOC Regulations do not use the term "generic manufacturer", but a manufacturer that obtains a NOC on the basis of pharmaceutical equivalence to a "Canadian reference product" can conveniently be called by that name.
> >
> > 22 Generally speaking, the "second person" intends to manufacture and distribute a "copy-cat" version of the active medicinal ingredient. If it copies the approved product, it can rely on the safety and efficacy data and the clinical studies submitted by the "innovator" first person. Such reliance reduces the amount of required supporting data and the approval time, and the shortened submission is therefore known as an Abbreviated NDS (ANDS).

[52] On the basis of the Supreme Court's decision in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533 ("*Bristol-Myers*"), the Judge said at paragraph 130 that "[t]he proof of the safety and efficacy of a generic drug by comparison to a previously approved [innovative drug] necessarily relies on the earlier NDS information", adding that he was satisfied that the DPR provided protection to innovators which was consistent with both NAFTA and TRIPS. Thus, in his view, by providing a period of market exclusivity for innovators, the DPR provided "an alternative to [*sic*] protection against disclosure in a manner contemplated in the two international agreements" (Judge's Reasons, paragraph 131).

[53] The Judge then turned to the last issue before him, namely, whether subsection 30(3) of the Act constituted an impermissible sub-delegation by Parliament of its international treaty implementation responsibilities. The appellant argued that Parliament's delegation to the Governor in Council, pursuant to subsection 30(3), was contrary to Parliamentary supremacy and oversight of legislation. The subsection allowed the Governor in Council to exercise sweeping peace time powers, without Parliamentary review, to determine the scope of Canada's international obligations, to undertake indeterminate obligations on Canada's behalf and to revise its regulations with new developments in international law which would be both uncertain and outside of Parliament's control. The Judge concluded that these arguments were without merit.

[54] In his view, Parliament had granted the Governor in Council "the authority to enact regulations in a narrow area specified by the boundaries of the NAFTA and TRIPS provisions" (Judge's Reasons, paragraph 134). He added that it could not be said that Parliament had left the scope of the Governor in Council's regulatory power indeterminate, in that the reference to article 1711 of NAFTA and to paragraph 3 of article 39 of TRIPS served to constrain subsection 30(3) of the Act. At paragraph 135 of his Reasons, the Judge wrote:

> [135] … The scope of the NAFTA and TRIPS drug provisions are limited. The subject matter may only deal with:
> 1. the timing of approval for proposed generic drug formulations;
> 2. situations where the initial new drug was proven safe by the assembly of data gathered with considerable effort;
> 3. the subsequent generic drug was proved safe by reliance on the prior proven safety of the innovative new drug; and
> 4. minimum time delay for generic copies for five years.

THE ISSUES

[55] There are two issues for determination in these appeals::

1. Was the DPR properly delegated by Parliament to the Governor in Council, pursuant to the permissible sub-delegation of treaty implementation responsibilities and, if so, whether the DPR is *intra vires* the authority of the Governor in Council, pursuant to subsection 30(3) of the Act (the "delegation issue")?
2. Is the DPR *intra vires* federal legislative competence, pursuant to subsections 91(2), 91(27) or the residual POGG power of the *Constitution Act* (the "constitutional issue")?

[56] I will first deal with the delegation issue and then with the constitutional issue. I should indicate that, not surprisingly, all parties are agreed that the standard of review for both issues is that of correctness. I see no reason to disagree with that point of view.

I. THE DELEGATION ISSUE

[57] I will first address the question of whether the DPR was properly delegated by Parliament to the Governor in Council, since, if the sub-delegation is impermissible, it is irrelevant whether the DPR as enacted is *intra vires* the regulatory authority of the Governor in Council.

[58] The appellants argue that the scope of Parliament's power to authorize the Governor in Council to make regulations was addressed by the Supreme Court in *Re Gray* (1918), 57 S.C.R. 150 ("*Re Gray*"), "a case that is now almost 100 years old, in the context of war measures". In that light, the appellants say that it is time for the courts to determine those powers "in the modern globalized era in light of Canada's position in the international community" (Apotex's Memorandum of Fact and Law, paragraph 74).

[59] In *Re Gray*, the Supreme Court dealt with section 6 of the *War Measures Act*, 1914 SC 1914 (2d Sess.), c. 2, a provision which delegated broad powers to the Governor in Council. The majority of the Court upheld the constitutional validity of section 6 even though the grant of power to the Governor in Council to make regulations was couched in very broad terms and allowed for the amending or repealing of other legislation. At pages 166-167, Duff J. referred to the provision at issue in the following terms:

> The words… are comprehensive enough to confer authority, for the duration of the war, to "make orders and regulations" concerning any subject falling within the legislative jurisdiction of Parliament – subject only to the condition that the Governor in Council shall deem such "orders and regulations" to be, by reason of the existence of real or apprehended war, etc., advisable.

[60] He then went on to make the following remarks at page 170:

> There is no attempt to substitute the executive for Parliament in the sense of disturbing the existing balance of constitutional authority by aggrandizing the prerogative at the expense of the legislature. The powers granted could at any time be revoked and anything done under them nullified by Parliament, which Parliament did not, and for that matter could not, abandon any of its own legislative jurisdiction. The true view of the effect of this type of legislation is that the subordinate body in which the law-making authority is vested by it is intended to act as the agent or organ of the legislature and that the acts of the agent take effect by virtue of the antecedent legislative declaration (express or implied) that they shall have the force of law…
>
> [Emphasis added]

[61] Anglin J., with whom Davies J. concurred, couched Parliament's power to delegate in very broad terms, at page 176:

> A complete abdication by Parliament of its legislative functions is something so inconceivable that the constitutionality of an attempt to do anything of the kind need not be considered. Short of such an abdication, any limited delegation would seem to be within the ambit of a legislative jurisdiction…

[62] He went further and said at page 182:

> … At all events all we, as a court of justice, are concerned with is to satisfy ourselves what powers Parliament intended to confer and that it possessed the legislative jurisdiction required to confer them.

[63] I have not been persuaded that there is any basis to depart from the principle enunciated by the Supreme Court in *Re Gray*, that Parliament has a broad power to delegate by way of regulations, subject to the scope of the enabling legislation. With respect, I decline the appellants' invitation to take a fresh look at Parliament's authority to delegate to the Governor in Council the power to make regulations. Recent decisions of the Federal Court and the Ontario Superior Court of Justice have relied on the principle enunciated in *Re Gray* (see *Law Society of Upper Canada v. Canada (Minister of Citizenship and Immigration)*, 2006 FC 1489, and *Canada (Attorney General) v. Giacomelli* (2010), ONSC 985). In particular, the Ontario Court of Appeal, in *R. v. J.P.*, (2003) 67 O.R. (3d) 321, at paragraphs 20 to 23, cited *Re. Gray* with approval and the Court expressly referred to the above passages from the judgments of Duff and Anglin JJ.

[64] In the present instance, subsection 30(3) of the Act grants the Governor in Council authority to "make such regulations as the Governor in Council deems necessary" so as to implement, in relation to drugs, article 1711 of NAFTA or paragraph 3 of article 39 of TRIPS. No evidence was adduced nor was any compelling argument made that subsection 30(3) negates Parliament's ability to revoke or nullify the authority given to the Governor in Council or to do the same as regards the DPR enacted pursuant to the enabling legislation.

[65] I now turn to the question of whether the DPR is *intra vires* the authority of the Governor in Council pursuant to subsection 30(3) of the Act.

[66] In summary, the appellants make the following arguments. First, they say that the DPR was enacted to implement specific provisions of NAFTA and TRIPS; second, these provisions seek to protect trade secrets and confidential information; third, the DPR seeks to provide protection to innovators without regard to whether the information disclosed in the NDS is secret or confidential. In other words, the appellants say that there is no rational connection between data submitted by innovators in their NDS and the type of data which the relevant provisions of NAFTA and TRIPS seek to protect.

[67] The appellants further say that the Judge erred in concluding that the generic manufacturers relied on the "secret" NDS information, since they do not rely on such information in seeking approval for their generic drugs. The appellants go further and say that they do not "indirectly" rely on the data found in an innovator's NDS, adding once again that generic manufacturers do not use or rely on any of the secret or confidential information found in innovators' NDS, nor does the Minister.

[68] Invoking this Court's decision in *Bayer*, the appellants say that if the Minister does not examine the confidential data found in an innovator's NDS nor rely on it in the course of approving a generic manufacturer's ANDS, the trade secrets provisions of NAFTA are not at issue. At paragraph 60 of its Memorandum of Fact and Law, Apotex says that "[i]n so holding, this

Honourable Court [in *Bayer*] determined that indirect reliance, even if it is established, is not relevant to protections sought to be established by these international treaty obligations".

[69] Finally, the appellants say that the Judge was wrong to conclude that the first DPR did not allow Canada to meet its obligations under NAFTA and TRIPS. In their view, the first DPR was in conformity with Canada's international treaty obligations and, as a result, there was no necessity for the enactment of the DPR.

[70] As indicated above, *Re Gray,* stands for the principle that Parliament has a broad power to delegate by way of regulation, subject to the scope of the enabling legislation. Subsection 30(3) allows the Governor in Council to make such regulations deemed necessary for the purpose of implementing article 1711 of NAFTA and paragraph 3 of article 39 of TRIPS.

[71] Paragraph 3 of article 39 of TRIPS is specific. It imposes a duty on Members, who require the submission of "undisclosed tests or other data, the origination of which involves a considerable effort" as a condition of approving pharmaceutical products using new chemical entities, to "protect such data against unfair commercial use". The provision also requires Members to "protect such data against disclosure… unless steps are taken to ensure that the data are protected against unfair commercial use". The provision does not specify how Members are to provide protection for the data or what steps they should take to ensure protection "… against unfair commercial use".

[72] While the entirety of article 1711 of NAFTA is referred to in subsection 30(3) of the Act, only paragraphs 5, 6 and 7 thereof appear to have inspired the DPR. These paragraphs, like

paragraph 3 of article 39 of TRIPS, deal with a Member's obligations in regard to the protection of data provided to governmental authorities as a condition of approving the marketing of pharmaceutical products. Paragraph 5 of article 1711 of NAFTA obliges Members to provide protection similar to that required under paragraph 3 of article 39 of TRIPS. Paragraph 6 of article 1711 provides that Members are to take steps to prevent generic manufacturers from relying on NDS data "… in support of an application for product approval during a reasonable period of time after their submission". The provision goes on to say that a reasonable period "… shall normally mean not less than five years" from the time when a NOC is granted to an innovator for its innovative drug.

[73] The above provisions of NAFTA and TRIPS do not, in my respectful view, pertain to the protection of trade secrets. The provisions which do pertain to the protection of trade secrets are paragraphs 1, 2 and 3 of article 1711 of NAFTA and paragraph 2 of article 39 of TRIPS. In that regard, paragraph 1 of article 39 of TRIPS makes a clear distinction between "trade secrets" and "data protection", which is the subject of paragraph 3 of article 39:

Article 39	***Article 39***
1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information [i.e., trade secrets] in accordance with paragraph 2 and data submitted to governments or governmental agencies [i.e., data protection] in accordance with paragraph 3.	1. En assurant une protection effective contre la concurrence déloyale conformément à l'article 10bis de la Convention de Paris (1967), les Membres protégeront les renseignements non divulgués conformément au paragraphe 2 et les données communiquées aux pouvoirs publics ou à leurs organismes conformément au paragraphe 3.
[Emphasis added]	[Non souligné dans l'original]

[74] The same can be said with regard to article 1711 of NAFTA, where paragraphs 1 to 4 clearly address the subject of ‘trade secrets”, whereas paragraphs 5 to 7 pertain to the protection, in respect of the marketing of pharmaceutical products that utilize new chemical entities, “… of undisclosed tests or other data necessary to determine whether the use of such products is safe and effective”. In other words, these provisions clearly seek to constrain the use by generic manufacturers of information created by innovators in relation to the approval of their “innovative drugs”.

[75] The DPR, at sub-paragraph 2 thereof, states that it applies to the implementation of article 1711 of NAFTA and to paragraph 3 of article 39 of TRIPS. It then states, at paragraph (3), that where a manufacturer, i.e. a generic manufacturer, seeks to obtain a NOC for a new drug “on the basis of a direct or indirect comparison between the new drug and an innovative drug”, the generic manufacturer may not file its ANDS prior to the expiry of six years after a NOC has been issued to the innovator in respect of its innovative drug. It further states that the Minister may not issue a NOC to the generic manufacturer before the expiry of eight years after the issuance of a NOC to the innovator.

[76] In my view, the DPR is in clear accord with the enabling provision. It is a regulation, the purpose of which is to implement, in relation to drugs, article 1711 of NAFTA and paragraph 3 of article 39 of TRIPS. Market exclusivity, conferred by the DPR on an innovator, is the means chosen by the Governor in Council to give effect to the relevant provisions of NAFTA and TRIPS. More particularly, the DPR is, in my view, a step taken by the Governor in Council “… to ensure that the data is protected against unfair commercial use”.

[77] I therefore must reject the appellants' argument that there is no rational connection between the data found in an innovator's NDS and the type of data which the relevant provisions of NAFTA and TRIPS seek to protect. It is clear that the data which article 1711 of NAFTA and paragraph 3 of article 39 of TRIPS seek to protect is precisely the type of data in regard to which the DPR offers market protection, i.e. the data found in an innovator's NDS for an innovative drug. Consequently, I can detect no error in the findings made by the Judge at paragraphs 120 and 123 of his Reasons, where he states:

> [120] It is evident from the wording of paragraphs 1 and 5 of Article 1711 of NAFTA and paragraph 3 of Article 39 of TRIPS that the information is not necessarily "secret" but rather includes data that was gathered at considerable cost which is not otherwise publicly available in that assembled form.
>
> …
>
> [123] In my view, the innovator drug manufacturers' NDS data meets the definitions in both NAFTA and TRIPS. The information may not be secret in all respects, but in its compilation, it is unique to the innovator drug manufacturer and has value. I find it is information that comes within the scope of the Data Protection Regulation.

[78] The appellants, in making their argument that the Judge erred in regard to the type of data which article 1711 of NAFTA and paragraph 3 of article 39 of TRIPS seek to protect, say that that issue was decided by this Court in *Bayer*, where Rothstein, J.A., at paragraphs 15 of his Reasons, concluded that article 1711 was meant to protect "confidential data" and that its purpose was the protection of "trade secrets".

[79] In my view, the Court in *Bayer*, did not make a determination which binds us. First, none of the issues raised by the appeal in *Bayer* pertained to the question of whether the data which article

1711 of NAFTA sought to protect was “confidential data” or “trade secrets”. Rather, as I indicated earlier, the case focused on the question of whether the Minister examined or relied upon the innovator’s NDS data in approving an ANDS. Second, because the issue now before us was not raised, the Court in *Bayer,* appears to have simply taken for granted that the type of data which gave rise to the dispute was either “confidential information” or “trade secrets”. It should also be noted that paragraph 3 of article 39 of TRIPS was not before the Court in *Bayer* and that, it goes without saying, both subsection 30(3) of the Act and the DPR were worded differently than the provisions which are at issue in these appeals.

[80] I therefore conclude that, contrary to the appellants’ assertion, the Judge’s findings at paragraphs 120 and 123 are not “directly contradictory to this Honourable Court’s interpretation of the same provisions in *Bayer*”.

[81] I now turn to the appellants’ submission that the Judge erred in concluding that the market exclusivity period granted to innovators by the DPR was an appropriate mechanism to facilitate the protection found in both NAFTA and TRIPS. The appellants say “… such a conclusion was in error since the application judge failed to appreciate that there is no reliance by a generic manufacturer on the purportedly ‘secret’ information contained in a NDS and thus there is no rational connection between a market exclusivity period and the enabling treaty provisions”.

[82] More particularly, the appellants challenge the Judge’s finding at paragraph 127 of his Reasons, where he states that generic manufacturers, by way of the ANDS process, “indirectly

take advantage of the innovator drug manufacturer's production of the necessary NDS information" and that the result "… is a second stage or subsequent reliance on the innovator's work in securing an ANDS approval". In my view, the appellants' argument is based on a misunderstanding of subsection 30(3) of the Act and of the DPR. I say this because of my view that the appellants' position fails to recognize that both subsection 30(3) of the Act and the DPR have been amended since this Court rendered its decision in *Bayer*.

[83] It is true that paragraph 6 of article 1711 of NAFTA requires Members to take steps to prevent, in respect of the data falling within the scope of paragraph 5 thereof, i.e. "undisclosed test or other data necessary to determine whether the use of such products [innovative drugs] is safe and effective", persons other than persons that submitted the data from relying "on such data in support of an application for product approval during a reasonable time after their submission". Thus, the provision seeks to prevent generic manufacturers from making use of the protected data in support of their ANDS.

[84] As to paragraph 3 of article 39 of TRIPS, it simply provides that Members shall protect such data "against unfair commercial use".

[85] Subsection 30(3) of the Act, as I have already indicated, allows the Governor in Council to make regulations which are deemed necessary to implement the relevant provisions of NAFTA and TRIPS. Thus, Parliament has left it to the Governor in Council to determine the manner in which innovators' data will be protected "against unfair commercial use". There can be no doubt that the terms of subsection 30(3) give very broad latitude to the Governor in

Council to devise the means by which the treaty provisions will be implemented. The previous version of subsection 30(3) was not as broad as the present one, in that it authorized the Governor in Council, for purposes of implementation of article 1711 of NAFTA, to "make regulations respecting the extent to which, if any, a person may… rely on test or other data" submitted by innovators.

[86] Consequently, under the authority of subsection 30(3) of the Act, the Governor in Council enacted the DPR and provided that protection would be afforded to innovators by way of market exclusivity for a determined period when a generic manufacturer sought a NOC for a new drug "… on the basis of a direct or indirect comparison between the new drug and an innovative drug". Thus, in my view, the debate which our Court addressed in *Bayer*, is not relevant for the purposes of these appeals. This is made clear by the following extract from the RIAS issued with the DPR:

Background […] Under the current Regulations [the first DPR], the data protection exclusivity period arises when the Minister of Health examines and relies on an innovator's undisclosed data in order to grant a notice of compliance to a generic manufacturer. However, to receive a notice of compliance in Canada, a generic manufacturer need only demonstrate bioequivalence by comparing its generic product to the innovator's product. Therefore, in actual practice, the Minister typically does not examine the data contained in the innovator's submission in order to grant a notice of compliance for a generic product. As a result, data protection does not arise where	*Contexte* … …..En vertu du règlement en vigueur [le premier RPD], la période de protection de l'exclusivité des données survient lorsque le ministre de la Santé examine les données non divulguées d'un innovateur et s'y fie afin de délivrer un avis de conformité au fabricant de produit générique. Cependant, pour recevoir un avis de conformité au Canada, un fabricant de produit générique doit uniquement faire la preuve de sa bioéquivalence avec le produit de l'innovateur, en comparant le produit générique à celui de l'innovateur. Par conséquent, en réalité, le ministre n'examine généralement pas les données que comporte la présentation de l'innovateur pour

bioequivalence forms the basis of a generic submission, as affirmed by the Federal Court in *Bayer Inc. v. Canada (Attorney General)*, 87 C.P.R. (3d) 293.	délivrer un avis de conformité pour un produit générique. Ainsi, la protection des données ne s'applique pas lorsque la bioéquivalence est à la base de la présentation, comme l'a confirmé la Cour fédérale d'appel dans l'affaire *Bayer Inc c. Canada (Procureur général)*, 87 C.P.R. (3d) 293.
…..<u>While the comparison necessary to demonstrate bioequivalence rarely involves an examination of the innovator's data, it does involve reliance on the innovator's product. Therefore, these amendments are being introduced to clarify that the aforementioned reliance will give rise to an exclusivity period.</u>	<u>Bien que la comparaison nécessaire pour démontrer la bioéquivalence soit rarement établie à l'aide d'un examen des données de l'innovateur, elle demande néanmoins que l'on puisse se fier à son produit. Par conséquent, ces modifications sont présentées dans le but de préciser le fait qu'une telle confiance entraîne la période d'exclusivité.</u>
[Emphasis added]	<u>[Non souligné dans l'original]</u>

[87] As is pointed out in the RIAS, the DPR, unlike the first DPR considered in *Bayer*, does not make the granting of market exclusivity conditional on the Minister having examined or relied on innovators' data. The DPR simply provides that generic manufacturers may not seek a NOC for a new drug before the expiry of a period of six years after an NOC was issued to an innovator for an "innovative drug", nor will the Minister grant a NOC before the end of a period of eight years after the granting of a NOC to an innovator where a generic manufacturer seeks its NOC "… on the basis of a direct or indirect comparison" between its new drug and an innovative drug.

[88] In other words, the test is not reliance on an innovator's data, either by the Minister or by the generic manufacturer, but rather whether there has been a <u>comparison</u>, direct or indirect,

between the generic manufacturer's new drug and an innovative drug. The RIAS puts it in different terms when it says that "…[w]hile the comparison necessary to demonstrate bio-equivalence rarely involves an examination of the innovator's data, it does involve reliance on the innovator's product".

[89] At paragraph 130 of his Reasons, the Judge concluded that the test found at paragraph (3) of the DPR was met. He put it as follows:

> [30] *Bristol-Myers* answered the question of the use of NDS information in the ANDS process. The proof of the safety and efficacy of a generic drug by comparison to a previously approved [*sic*] necessarily relies on the earlier NDS information.

[90] Those remarks should be read with the statement found at paragraph 127 of his Reasons, where he indicated that the obtaining of a NOC by a generic manufacturer, following the filing of an ANDS, "… circumvents the need to generate the research and clinical data". Thus, in his view, the ANDS process took advantage of "… the innovator drug manufacturer's production of the necessary NDS information". For that proposition, he relied on the following words of Binnie J. at paragraphs 21 and 22 of his Reasons in *Bristol-Myers*:

> 21 The NOC Regulations do not use the term "generic manufacturer", but a manufacturer that obtains a NOC on the basis of pharmaceutical equivalence to a "Canadian reference product" can conveniently be called by that name.
>
> 22 Generally speaking, the "second person" intends to manufacture and distribute a "copy-cat" version of the active medicinal ingredient. If it copies the approved product, it can rely on the safety and efficacy data and the clinical studies submitted by the "innovator" first person. Such reliance reduces the amount of required supporting data and the approval time, and the shortened submission is therefore known as an Abbreviated NDS (ANDS).

[91] The appellants say that the Judge was wrong to rely on *Bristol-Myers*. I disagree. While it is true that the Minister does not usually examine the information provided by innovators in granting a NOC to a generic manufacturer following the filing of an ANDS on the basis of bio-equivalence, there cannot be much doubt that the ANDS process involves, at the very least, indirect reliance on the safety and efficacy information derived from innovators' NDS. In other words, a generic manufacturer relies on the information found in an innovator's NDS in that: (i) that information provides the actual knowledge about the safety and efficacy of the drug and its conditions of use; (ii) without that knowledge, it would not be possible for a generic manufacturer to produce its new drug without conducting extensive non-clinical and clinical studies (see the Affidavit of Ann Elizabeth Bowes, Appeal Book, Vol. II, page 472). It is in that sense that a generic manufacturer relies upon the data provided by an innovator in its NDS. The following extract from the RIAS is apposite and I reproduce it:

Triggering Mechanism	Mécanisme déclencheur
The triggering mechanism is intended to capture generic and second entrant manufacturers that are seeking to rely on direct or indirect comparison between their drug and the innovative drug. As was observed by the Supreme Court of Canada in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, such direct or indirect comparisons would exclude submissions in which the submission sponsor does not rely on another manufacturer's safety and efficacy data in seeking approval under the *Food and Drug Regulations*. This is consistent with Article 1711 of NAFTA and paragraph 3, Article 39 of TRIPS, since there would be no unfair commercial use of data on the reliance on such data for the approval	Le mécanisme déclencheur vise à assujettir les fabricants de médicaments génériques et les deuxièmes fabricants qui tentent de se fonder sur la comparaison directe ou indirecte entre leur drogue et une drogue innovante. Comme l'an mentionné la Cour suprême du Canada, dans l'affaire *Bristol-Myers Squibb Co. c. Canada (Procureur général)*, 2005 CSC 26, de telles comparaisons directes ou indirectes excluraient les présentations dans lesquelles le parrain de la présentation ne se fie pas aux données d'innocuité et d'efficacité d'un autre fabricant afin d'obtenir une approbation en vertu du règlement. Cela est conforme à l'article 1711 de l'ALÉNA ainsi qu'au paragraphe 3 de l'article 39 des

of the product. The mechanism is intended to capture both submissions that fall under the abbreviated new drug submission provisions and submissions that are filed under the new drug submission provisions, so long as there is a direct or indirect comparison with the innovative drug. [Emphasis added]	ADPIC, du fait qu'il n'y aurait pas d'utilisation déloyale de ou de fondement sur ces données pour obtenir l'approbation du produit. Le mécanisme cherche à englober les présentations assujetties aux dispositions qui s'appliquent aux présentations abrégées de drogues nouvelles et à celles qui sont soumises en vertu des dispositions visant les drogues nouvelles, dans la mesure où l'on a établi une comparaison, qu'elle soit directe ou indirecte, avec la drogue innovante. [Non souligné dans l'original]

[92] Finally, I need not deal with the appellants' argument that the Judge was wrong to conclude that the first DPR did not allow Canada to meet its obligations under NAFTA and TRIPS. Whether the appellants are right or wrong on this point is of no relevance to the issues raised in these appeals. However, what this argument clearly shows is that the appellants do not approve of the means chosen by the Governor in Council to implement the relevant provisions of NAFTA and TRIPS.

[93] In my respectful view, that position is untenable. Parliament, by way of subsection 30(3) of the Act, gave the Governor in Council the power to implement the treaty obligations "as the Governor in Council deems necessary". Consequently, the Governor in Council is the sole judge as to the means necessary to implement the treaty obligations. In these circumstances, unless bad faith is established – which it is not – this Court cannot and will not question the means found advisable by the Governor in Council to implement the treaty obligations.

[94] I therefore conclude that the DPR was properly delegated by Parliament to the Governor in Council and that it is *intra vires* the authority of the Governor in Council.

II THE CONSTITUTIONAL ISSUE

[95] The first step in a constitutional challenge such as the one now before us is to determine the "pith and substance" or essential character of the impugned law. In other words, we must identify the law's dominant or most important characteristics. Courts will also consider the effects of the impugned law – how it changes the rights and liabilities of those who are subject to it. Peter W. Hogg, in *Constitutional Law of Canada*, 5th Ed. Supplemented (Toronto: Thomson Reuters, 2007), updated in 2009, explains the process in which a Court must engage at Volume I, page 15-13:

> The process of characterization is not a technical, formalistic exercise, confined to the strict legal operation of the impugned law… the fact that a provincial law levies a tax (for example) is not decisive of its classification as a taxing measure. The Court will look beyond the direct legal effects to inquire into the social or economic purposes which the statute was enacted to achieve. If the Court concludes that the purpose of the ostensible tax is to regulate or destroy the banks, then the law will be characterized as being in relation to banking and will be held to be invalid.

[96] Once the pith and substance of the law has been determined, the next step is to classify it by reference to the heads of power under the *Constitution Act*. If the pith and substance falls within federal legislative authority, incidental effects on provincial jurisdiction will be allowed (see: *Canadian Western Bank v. Alberta*, 2007 SCC 22 at pages 25-31).

[97] I now turn to the pith and substance of the DPR.

[98] The appellants argue that the pith and substance concerns commercial considerations, not public safety. They claim that the DPR is *ultra vires* the trade and commerce power and is not validly enacted under any other head of federal power. To the contrary, they submit that the protection of trade secrets and confidential information is a matter of property and civil rights under provincial jurisdiction (section 92(10) of the *Constitution Act*.

[99] The respondents claim that the pith and substance is directed towards public health and safety and does not intrude upon any provincial head of power. The Crown maintains that the DPR is a scheme falling under criminal law power. The other respondents agree, but contend that it is also valid under the regulation of trade and commerce and the POGG powers.

[100] The Judge found the pith and substance of the DPR to be "the balancing of considerations between the protection of an innovator drug manufacturer's investments in preparing the NDS information in order to obtain a NOC for a new drug and the eventual NOC approval of a generic drug manufacturer's ANDS for lower cost generic version of the new drug" (Judge's Reasons, paragraph 79).

[101] Following that determination, the Judge went on to classify the DPR's pith and substance by way of reference to a head of power in the *Constitution Act*. He concluded that the DPR did not fall within the federal legislative criminal law power, but rather under the trade and commerce power.

[102] I respectfully disagree with the Judge's conclusion that the DPR is, in its pith and substance, an exercise of the trade and commerce power. In my view, it is wrong in principle to determine the pith and substance of the DPR by referring to the language of the regulation itself and its enabling legislation, without situating the DPR within the overall scheme of which it became a part. My reasons for reaching this conclusion are explained in more detail below. At this point, it suffices to say that it is important to note that Parliament chose not to enact subsection 30(3) of the Act as a stand-alone statute, but as an amendment to the Act, an existing statute that has long been accepted as constitutionally valid. Thus, the critical question was whether subsection 30(3), and thus the DPR, was a valid exercise of the constitutional authority for the Act.

[103] I have already briefly described the regulatory scheme prescribed by the Regulations. That scheme provides that it is a criminal offence for a person to market a new drug unless that drug has been found by the Minister to be safe and effective. If the drug is safe and effective, the Minister will issue a NOC to the manufacturer of the drug, confirming that the Regulations have been complied with.

[104] In order to obtain a NOC for a new drug and thus be exempt from the prohibition that new drugs not be put on the market, a manufacturer must comply with the many terms and conditions set out in the Regulations. In particular, the Regulations require that those seeking to obtain a NOC for their new drug file either a NDS or an ANDS.

[105] It cannot be disputed that a prohibition without any exceptions would certainly protect the public from unsafe drugs. However, that effort would be self-defeating in that no new drug would ever enter the market. Hence, public health and safety would suffer because efforts to discover and market new drugs would not materialize. Consequently, an exception was created so as to counter the negative effects of a total ban on new drugs whereby. Under the exception, drug manufacturers are permitted to demonstrate to the Minister that their new drug is safe and effective by submitting a NDS or an ANDS. In other words, the Government has attempted to balance it duty to protect Canadians from unsafe drugs and its duty to provide Canadians with safe and effective new drugs.

[106] Until recently, the Regulations were primarily concerned with “innovators” who invest considerable sums of money into research to discover new, safe and effective drugs. I have already explained the NDS process pursuant to which innovators seek a NOC for their new drug. As found by the Judge at paragraph 46 of his Reasons, it is a very costly and time-consuming process.

[107] More recently, the Regulations were amended to allow generic manufacturers to qualify for exemption from the prohibition. Through the ANDS process, they may demonstrate that their new drug is safe and effective. This process, as the Judge found at paragraph 46 of his Reasons, also requires considerable effort in time and investment, but not to the same extent as for innovators. The difference in effort exists because generic manufacturers can obtain a NOC for their new drug by demonstrating that it is pharmaceutically equivalent, i.e., that their generic

drug contains the identical amount of the identical medicinal ingredient as the Canadian Reference Product of an innovator, in comparable dosage form.

[108] As a result, generic manufacturers are not required to make a direct assessment of the clinical safety and efficacy of their drug on the basis of clinical studies. Rather, they use the innovators' new drug to demonstrate its bioequivalence to their own. In that sense, generic manufacturers, as I have already explained, are in effect relying, at least indirectly, on the information and data provided by innovators in their NDS.

[109] The ANDS process, by allowing generic manufacturers to market their new drugs, permits the entry of more new drugs on the Canadian market at, generally, prices lower than those of "innovative drugs". However, the entry of generic new drugs at lower prices may constitute a disincentive for innovators with regard to their efforts to discover new "innovative drugs" for Canadians. More particularly, unless innovators are able to recover their expenses and make a reasonable profit on the sale of their new drugs, they will have no incentive to pursue research to find new drugs.

[110] With that concern in mind, the DPR was introduced to implement article 1711 of NAFTA and paragraph 3 of particle 39 of TRIPS, which seek to provide protection to innovators in respect of "undisclosed tests or other data" that they must provide to government entities in order to obtain approval for their new drugs.

[111] It is with that context in mind that I now turn to the pith and substance of the DPR.

[112] As the RIAS makes clear, the Government intended, in enacting the DPR, to "achieve a greater balance between the need for innovative drugs and the need for competition in the marketplace in order to facilitate the accessibility of those drugs" [Emphasis added]. To find the source of this proposition, one must examine the DPR in the context of the comprehensive scheme of law found in the Regulations.

[113] In my view, what the entire context reveals is that the DPR is a mechanism deemed necessary to balance the effects of the regulatory scheme set forth in the Regulations, the purpose of which is to protect public health and safety. In particular, the DPR plays an important role with regard to the ANDS process by counteracting, or reducing, the negative aspects thereof. More particularly, by granting innovators a period of market protection for eight years, the DPR puts in place a regime which provides incentives for innovators to continue their search for "innovative drugs". Ultimately, the DPR exists to encourage the development of new drugs which, there cannot be much dispute, constitutes a valid public health and safety purpose.

[114] Although it is true, as the Judge found at paragraph 79 of his Reasons, that the DPR seeks to balance "commercial considerations between the protection of an innovator drug manufacturer's investments… and the eventual NOC approval of a generic drug manufacturer's ANDS", the Judge erred, in my respectful view, in failing to consider the entire context in which the DPR finds itself. The true purpose of the DPR is not to balance the commercial interests of innovators and generic drug manufacturers, but rather to ensure that Canadians have reasonable access, at reasonable prices, to new, safe and effective drugs. In other words, the Regulations as

a whole encourage the research and development of new medicines that save lives, prevent diseases, heal and cure and improve the health of Canadians, who can only benefit from the discovery and development of new medicines after the information and data generated in extensive pre-clinical and clinical trials demonstrate the "innovative drug's" safety and efficacy to the satisfaction of the Minister. The DPR plays an important part in this regulatory scheme.

[115] At paragraph 76 of his Reasons, the Judge questioned the statement found in the RIAS that the DPR was enacted to encourage innovators and/or to allow them to recover their investments, thus fostering the development of new drugs. In his view, "the evidence on this point is more of a logical assertion than a clear demonstration that innovators are not or will not bring forward new drugs for approval without the provision". In my respectful view, that statement is mistaken in that in determining the pith and substance of a law, courts are not to be concerned with the efficacy of the law or whether it does, in fact, achieve the intended goal. In his dissenting Reasons in *RJR-MacDonald*, La Forest J., at pages 257-258, explained this proposition in the following terms:

> … Once it is conceded, as I believe it must be, that tobacco consumption has detrimental health effects and that Parliament's intent in enacting this legislation was to combat these effects, then the wisdom of Parliament's choice of method cannot be determinative with respect to Parliament's power to legislate. The goal in a pith and substance analysis is to determine Parliament's underlying purpose in enacting a particular piece of legislation; it is not to determine whether Parliament has chosen that purpose wisely or whether Parliament would have achieved that purpose more effectively by legislating in other ways:…
>
> [Emphasis added]

[116] This statement was reiterated by a unanimous Supreme Court in *Reference re Firearms Act (Can.)*, [2000] 1 S.C.R. 783 at page 797:

> Determining the legal effects of a law involves considering how the law will operate and how it will affect Canadians. The Attorney General of Alberta states that the law will not actually achieve its purpose. Where the legislative scheme is relevant to a criminal law purpose, he says, it will be ineffective (e.g., criminals will not register their guns); where it is effective it will not advance the fight against crime (e.g., burdening rural farmers with pointless red tape). These are concerns that were properly directed to and considered by Parliament. Within its constitutional sphere, Parliament is the judge of whether a measure is likely to achieve its intended purposes; efficaciousness is not relevant to the Court's division of powers analysis…
>
> [Emphasis added]

[117] I therefore conclude that the pith and substance of the DPR is to implement article 1711 of NAFTA and paragraph 3 of article 39 of TRIPS so as to encourage the development of new drugs, a valid public health and safety purpose.

[118] I now turn to the question of whether the pith and substance of the DPR falls within federal legislative authority under the *Constitution Act*. In my view, the DPR constitutes a valid exercise of the federal criminal law power under subsection 91(27) of the *Constitution Act*.

[119] In *RJR-MacDonald Inc. v. Canada*, the Supreme Court, in emphasizing the absolute nature of the federal legislative criminal law power under subsection 91(27) of the *Constitution Act*, circumscribed that power at page 246, where La Forest J. (although dissenting on the result, his view on this point was supported by a majority) wrote:

> Given the "amorphous" nature of health as a constitutional matter, and the resulting fact that Parliament and the provincial legislatures may both validly legislate in this area, it is important to emphasize once again the plenary nature of the criminal law power. In the *Margarine Reference, supra*, at pp. 49-50, Rand J. made it clear that the protection of "health" is one of the "ordinary ends" served by the criminal law, and that the criminal law power may validly be used to safeguard the public from any "injurious or undesirable effect". The scope of the federal power to create criminal legislation with respect to health matters is broad,

> and is circumscribed only by the requirements that the legislation must contain a prohibition accompanied by a penal sanction and must be directed at a legitimate public health evil. If a given piece of federal legislation contains these features, and if that legislation is not otherwise a "colourable" intrusion upon provincial jurisdiction, then it is valid as criminal law; see *Scowby, supra*, at pp. 237-38.
>
> [Emphasis added]

[120] In my view, the test enunciated by the Supreme Court in *RJR-MacDonald*, is met. First, with regard to a prohibition, section C.08.002 of the Regulations provides that no person shall sell or advertise a new drug unless the conditions set out therein are met, i.e., *inter alia*, the filing of a NDS and the issuance of a NOC. Second, with respect to a requirement that there be a penal sanction, section 31 of the Act provides a penalty in the following terms:

31. Subject to section 31.1, every person who contravenes any of the provisions of this Act or of the regulations made under this Part is guilty of an offence and liable (a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both; and (b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.	**31.** Sous réserve de l'article 31.1, quiconque contrevient à la présente loi ou aux règlements pris sous le régime de la présente partie commet une infraction et encourt, sur déclaration de culpabilité : a) par procédure sommaire, pour une première infraction, une amende maximale de cinq cents dollars et un emprisonnement maximal de trois mois, ou l'une de ces peines et, en cas de récidive, une amende maximale de mille dollars et un emprisonnement maximal de six mois, ou l'une de ces peines; b) par mise en accusation, une amende maximale de cinq mille dollars et un emprisonnement maximal de trois ans, ou l'une de ces peines.

[121] There remains to be addressed the third requirement of the test enunciated by La Forest J. that the law be directed at a legitimate public health evil. In my view, that requirement is met in the present circumstances.

[122] There cannot be any dispute, in my view, that the legislative scheme found in the Regulations contributes to the protection of public health and safety, one of the "ordinary ends" of the criminal law (see: *Standard Sausage Co. v. Lee* (1934), 1 W.W.R. 81 (BCCA); *R. v. Wetmore*, [1983] 2 S.C.R. 284). In other words, the Regulations exist to protect the public from the sale of unsafe and/or ineffective drugs while, at the same time, making sure that the public has access to safe and effective drugs.

[123] As the Judge states at paragraph 81 of his Reasons, there is no dispute between the parties that the protection of public health and safety is a matter clearly falling within the federal legislative criminal law power and that the Act and Regulations constitute a valid scheme for regulating public health and safety. What is at issue, however, is whether the DPR, in the Judge's words, "is integral to a valid statutory scheme".

[124] It is important to remember that the Judge held that the DPR was not an integral part of the Regulations, but rather an adjunct part (Judge's Reasons, paragraph 83). However, at paragraph 102 of his Reasons, he indicated that the DPR, "although adjunct rather than integral, can be said to 'round out" the valid federal regulatory drug scheme established for marketing drugs in Canada".

[125] In my view, the DPR is clearly not separable from the overall scheme of criminal law found in the Regulations to which, as I have already explained, it contributes. The Judge, as I have also explained, erred in confining his determination of the pith and substance to the

language only of the DPR and its enabling legislation, without regard to the overall scheme. As a result, he was unable to appreciate that the DPR contributes to and, thus, forms an integral part of the overall scheme to protect public health and safety.

[126] Other than the prohibition preventing the marketing of new drugs under section C.08.002(1) of the Regulations and the exception provided for those who satisfy the Minister of the safety and efficacy of their new drug and are issued a NOC, the remainder of the legislative scheme, which includes the DPR, pertains to the terms and conditions of the exemption from criminal prosecution. In my view, there cannot be a serious debate in regard to the proposition that an exemption from a criminal law prohibition, which necessarily includes all the terms and conditions of the exemption, constitutes an exercise of the criminal law power, in the same way that the prohibition itself constitutes an exercise of that power (see: *Reference re Firearms Act*, at page 807).

[127] Thus, to the extent that the exemption from the prohibition can be linked to the criminal law ends of the legislation, the exemption constitutes an exercise of the criminal law power. Here, the criminal law ends of the legislation is ensuring that only safe drugs are made available to Canadians (see: *C.E. Jamieson v. Attorney General of Canada* (1948), 46 D.L.R. (4^{th}) 601).

[128] To put the matter in full context, subsection C.08.002(1) of the Regulations prescribes the prohibition against the marketing of new drugs and sets out the exemption thereto, i.e., the filing of a NDS resulting in the issuance of a NOC. Subsections C.08.002(2) and (3) provide the specifics surrounding the filing of a NDS and, more particularly, the information that must be

provided to demonstrate the safety and effectiveness of the new drug. Section C.08.002.1, in turn, provides the specifics with regard to an ANDS and sets out the information required in order to satisfy the Minister of the new drug's safety and effectiveness. Section C.08.003.1 sets out certain information that the Minister may examine, although not provided by the manufacturer in his NDS or ANDS submission, in determining whether the drug's safety and effectiveness have been demonstrated. Sections C.08.004 sets out the duty of the Minister to either issue a NOC or advise the manufacturer otherwise following a review of a NDS or an ANDS submission. Finally, the DPR sets out further conditions that must be met in connection with the filing of an ANDS and the issuance of a NOC in regard thereto. Together, these provisions define the exemption from criminal prosecution for the marketing of a new drug.

[129] I am satisfied that the DPR meets the requirements of the tripartite test set out by the Supreme Court in *RJR-MacDonald.*

[130] I should also say that I am satisfied that the DPR in no way encroaches on matters of provincial jurisdiction, since provinces have no role whatsoever to play with respect to the approval of the safety and effectiveness of new drugs. Further, the DPR does not interfere with provincial jurisdiction to authorize generic manufacturers to commercially market their drugs. At paragraph 106 of his Reasons, the Judge states:

> [106] The Data Protection Regulation deals with the approval of the marketing of new drugs. Provincial legislatures cannot enact legislation that delays the approval of generic drugs since provincial approvals of drugs for the market place would seriously interfere with the federal s. 91(27) criminal law power to prohibit the marketing of drugs but for exceptions where drugs are proven safe and effective…

[131] Thus, the conditions imposed by the DPR on generic manufacturers and the Minister in regard to the filing of an ANDS and the issuance of a NOC in regard thereto do not encroach on provincial jurisdiction, in the constitutional sense.

[132] In conclusion, the DPR is, in my opinion, rationally and functionally connected to the federal legislative scheme for new drug approval and clearly contributes to balancing the effects of a process established by the Government to protect public health and safety through its jurisdiction to legislate in respect of the criminal law. In view of this conclusion, I need not address the question of whether the DPR falls under another head of federal legislative jurisdiction such as subsection 91(2) of the *Constitution Act* or the POGG

DISPOSITION

[133] I would dismiss the appeals with one set of costs in favour of the respondents.

"M. Nadon"
J.A.

"I agree.
K. Sharlow J.A."

"I agree.
Carolyn Layden-Stevenson J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-352-09
STYLE OF CAUSE:	APOTEX INC. v. AGC ET AL
PLACE OF HEARING:	Toronto, Ontario
DATE OF HEARING:	June 7, 2010
REASONS FOR JUDGMENT BY:	NADON J.A.
CONCURRED IN BY:	SHARLOW J.A. LAYDEN-STEVENSON J.A.
DATED:	December 9, 2010

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FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-360-09
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