

Federal Court



Cour fédérale

Date: 20090717

**Docket: T-1976-06
T-2047-06**

Citation: 2009 FC 725

Halifax, Nova Scotia, July 17, 2009

PRESENT: The Honourable Mr. Justice Mandamin

Docket: T-1976-06

BETWEEN:

**CANADIAN GENERIC
PHARMACEUTICAL ASSOCIATION**

Applicant

and

**MINISTER OF HEALTH and THE
ATTORNEY GENERAL OF CANADA**

Respondents

and

**CANADA'S RESEARCH-BASED
PHARMACEUTICAL COMPANIES**

Intervener

AND BETWEEN:

APOTEX INC.

Applicant

and

**MINISTER OF HEALTH and
THE ATTORNEY GENERAL OF CANADA**

Respondents

and

ELI LILLY CANADA INC.

Intervener

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction

[1] The Applicants seek judicial review of the Governor in Council's 2006 enactment of section C.08.004.1 (the *Data Protection Regulation*) of the *Food and Drug Regulations*, C.R.C., c. 870 (the FDA Regulations). The Applicants seek a declaration that the *Data Protection Regulation* is *ultra vires* and without legal force and effect and other related remedies.

[2] The Applicant in T-1976-06 is the Canadian Generic Pharmaceutical Association (the CGPA), an association of generic drug manufacturers and their suppliers. The Respondent is Canada, as represented by the Attorney General of Canada and the Minister of Health. The Intervener is Canada's Research-Based Pharmaceutical Companies (Rx&D), an association of drug manufacturers and related companies.

[3] The Applicant in T-2047-06 is Apotex Inc. (Apotex), the largest generic drug manufacturer in Canada. The Respondent is Canada, as represented by the Attorney General of Canada and the Minister of Health. The Intervener is Eli Lilly Canada Inc. (Eli Lilly), a major Canadian drug manufacturer which participates in global pharmaceutical research and development by the Eli Lilly world-wide group of corporations.

[4] The Parties and Interveners in both applications address the same issues, the *vires* of subsection 30(3) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27 (the Act), and of the *Data Protection Regulation*. The Parties and Interveners made oral submissions at a combined hearing, parcelling out oral argument on issues amongst their respective sides. I will treat the two applications as having been joined and these reasons will apply to both proceedings, T-1976-06 and T-2047-06.

[5] Subsection 30(3) of the Act gives the Governor in Council the authority to enact regulations 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). The Governor in Council enacted the *Data Protection Regulation* on October 5, 2006.

[6] The *Data Protection Regulation* introduces a period of market exclusivity by imposing an eight year moratorium on approval for the marketing of a generic copy of a previously approved new drug.

[7] Prior to the enactment of the *Data Protection Regulation* the only restriction on a generic drug manufacturer's ability to gain approval to market a generic drug was any unexpired patent protection. After the enactment of the *Data Protection Regulation* the drug company pursuing approval for a generic copy must wait until expiry of the market exclusivity period of the new drug before its generic copy may receive approval, even if there is no existing patent protection.

[8] The issue in these two applications is whether Parliament has the constitutional power to enact subsection 30(3) of the Act and the *Data Protection Regulation* and whether the Governor in Council may enact the *Data Protection Regulation* in the present form.

[9] I have decided that subsection 30(3) of the Act and the *Data Protection Regulation* are *intra vires* as a valid exercise of the federal constitutional power under the regulation of trade and commerce, subsection 91(2) of the *Constitution Act, 1867*. I also conclude that *Data Protection Regulation* is rationally connected with subsection 30(3) of the Act and comes within the regulatory authority Parliament has given the Governor in Council.

[10] On the procedural question, I have found that the CGPA has standing on the basis of public interest.

II. Background

[11] It is useful to begin by describing the process by which approval is obtained to market drugs in Canada.

[12] Generally, a drug company obtains approval of a new drug by submitting to Health Canada a new drug submission (NDS). This submission must include extensive data establishing the safety and efficacy of the new drug. If proven to the satisfaction of the Minister of Health and his officials, the innovator drug company obtains a Notice of Compliance (NOC) approving the new medical drug. A generic manufacturer, which seeks to market a generic version of a drug previously approved by the Minister of Health, establishes that the generic drug is safe by submitting an abbreviated new drug submission (ANDS). The generic manufacturer must submit information that demonstrates that the generic drug is pharmacologically equivalent to the approved drug and has the same bioavailability. When the generic drug's safety and efficacy is proven by this comparison, the generic drug manufacturer also obtains an NOC for its generic product.

New Drug Submissions

[13] The FDA Regulations prohibit the marketing of all drugs unless the drug is proven to be both safe to consume and effective in treatment. Before a drug manufacturer can market a new drug in Canada, the drug manufacturer must be granted an NOC by the Minister of Health. The NOC indicates that the Minister is satisfied the new drug is both safe and effective. The NOC is granted pursuant to Part C, Division 8 of the FDA Regulations which states:

C.08.002. (1) No person shall sell or advertise a new drug unless

- (a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;
- (b) the Minister has issued, pursuant to section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission.

[14] The NDS contains the information required to prove the safety and efficacy of the drug. The NDS data typically identifies the drug, its benefits, adverse reactions, manufacturing processes, clinical trials on healthy volunteers, and medical clinical trials on patients and the safety and efficacy of the drug product. Justice Binnie described the process for new drug submissions in *Bristol-Myers Squibb Co. v. Canada (Minister of Health)*, 2005 SCC 26 (*Bristol-Meyers*):

13 The Food and Drug Act, R.S.C. 1985, c. F-27 (the "FDA"), sets up a regulatory structure to ensure that before drugs are allowed on the Canadian market they meet rigorous health and safety requirements. Regulatory approval culminates in the issuance of a NOC by the Minister on the advice of his officials in the Therapeutic Products Program ("TPP") of the federal Department of Health.

14 The Food and Drug Regulations, C.R.C. 1978, c. 870 ("FDA Regulations"), and departmental policies require drug manufacturers to submit different types of new drug submission for different purposes. The two principal forms of submission are the New Drug Submission ("NDS"), filed by an innovative drug manufacturer for a new drug product, and the Abbreviated New Drug Submission ("ANDS"), filed by a generic manufacturer that claims its product is the "pharmaceutical equivalent" of a previously approved "Canadian reference product" (s. C.08.002.1(1)(a)).

15 A pharmaceutical company proposing to market a new drug in Canada must include in its NDS a description of the benefits claimed, the adverse reactions experienced, the chemical composition of the ingredients and the methods of manufacture and purification in sufficient detail to enable the Minister to assess the safety and effectiveness of the new drug as therein specified. The Minister and his departmental officials then proceed to examine the material, possibly require further studies, pose questions, and generally conduct a wide-ranging inquiry, all of which may consume several years.

16 A "new drug" is defined in s. C.08.001 of the FDA Regulations as a drug which contains a substance which "has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug".

17 Eventually the Minister, if so satisfied, "shall" issue a NOC. (s. C.08.004(1)). The Minister must also be satisfied with the proposed arrangements of manufacture, quality control and so forth (s. C.08.002). The new drug may then go to market.

[15] The pre-clinical sections of the NDS consist of all the information about the numerous experiments that the innovator has conducted in the laboratory. These experiments are geared to test the action and toxicity of the drug. The clinical portions of the NDS consist of information garnered in clinical trials with volunteer subjects and/or patients to test the safety and efficacy of the new drug. Further information or studies may be required by the Minister of Health before being satisfied. The content, size, and cost of each NDS will vary. However, in general, the information required in an NDS for a new active drug is a significant undertaking by the innovator drug company and can contain as many as one to three hundred volumes of data.

[16] The Minister of Health, upon being satisfied of the new drug's safety and efficacy, issues an NOC. The drug is then listed as a Canada Reference Product and is issued a unique Drug Information Number (DIN).

Abbreviated New Drug Submissions

[17] Drug manufacturers that seek approval to market a generic copy of an approved drug proceed by way of an ANDS. The submission includes information on the composition, manufacture and studies that prove the generic drug contains the identical amount of the same medicinal ingredient in comparable dosages as the Canadian Reference Product, is pharmacologically equivalent, and has the same bioavailability as the Canadian Reference Product. Justice Hughes summarized the regulatory process to obtain approval to sell a generic

copy of an approved drug, *Sanofi-Aventis Canada Inc. v. Canada (Minister of Health)*, 2008 FC 1062:

6 Canada has provided that generic copies of approved drugs may be offered for sale in Canada, whether or not the originator consents. This happens provided that the Minister is satisfied that the copies are equally safe and effective as the original as per the Food and Drug Act and Regulations. The generic does not, however, need to provide the extensive data provided by the originator. It can simply tell the Minister that it relies upon or "references" the originator data by filing an Abbreviated New Drug Submission (ANDS). The generic must submit data on its product, largely directed to satisfying the Minister that the product is pharmalogically equivalent to the original and that the bioavailability of the active ingredient(s) is the same. Thus a generic is required to make some investment of its own in providing data.

[18] The ANDS may also contain stability studies and process validation if the generic manufacturer is using a different manufacturing process or different inactive ingredients in comparison to the process employed and ingredients used by the innovator. A typical ANDS contains fewer volumes of data, typically ranging from a dozen to two dozen volumes.

[19] Once the Minister of Health is satisfied, an NOC is issued for the generic drug; the drug then also becomes a Canada Reference Product and is assigned a DIN.

[20] In either instance, in both the NDS and the ANDS, if the Minister is satisfied that the proposed new drug or generic drug is safe and effective, and otherwise complies with the requirements of the FDA Regulations, the Minister must promptly issue an NOC to the drug manufacturer, subject to patent considerations that are not relevant to these applications.

III. International Agreements and Legislation

Legislative History

[21] Section C.08.004.1 of the FDA Regulations is described in the Regulatory Impact Assessment Statement (RIAS) as a data protection provision. The Governor in Council enacted this regulatory amendment pursuant to subsection 30(3) of the Act. Subsection 30(3) itself was a statutory amendment enacted pursuant to the *World Trade Organization Agreement Implementation Act*, S.C. 1994, c. 47, s. 117. The previous version of subsection 30(3) had been enacted pursuant to the *North American Free Trade Agreement Implementation Act*, S.C. 1993, c. 44, s. 158.

[22] The wording of the present version of subsection 30(3) authorizes the Governor in Council to make such regulations as it deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement (NAFTA) and paragraph 3 of Article 39 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

NAFTA

[23] NAFTA is a trilateral North American trade agreement entered into by the governments of Canada, United States, and Mexico. NAFTA was signed on December 17, 1992. Article 1711 of NAFTA provides:

Article 1711: Trade Secrets

1. Each Party shall provide the legal means for any person to prevent trade 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.

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.

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

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 value of the trade secrets.

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 test 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.

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 shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

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.

North American Free Trade Agreement Implementation Act

[24] Parliament enacted the *North American Free Trade Agreement Implementation Act* bringing an earlier version of subsection 30(3) of the Act into effect on January 1, 1994. Prior to this enactment, section 30 of the Act only contained two subsections. This first enactment of subsection 30(3) was worded as follows:

Regulations re the North American Free Trade Agreement

(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 purpose 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 or 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.

The Data Protection Regulation as of June 9, 1995

[25] Section C.08.004.1 was enacted pursuant to subsection 30(3) of the Act and published in the Canada Gazette on June 9, 1995 under the *Regulations Amending the Food and Drug Regulations (Data Protection)*, SOR/95-411. It 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 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.

TRIPS

[26] TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. It is an international agreement administered by the World Trade Organization (WTO) and sets out minimum standards for many forms of intellectual property protection.

[27] TRIPS was signed on April 15, 1994. Article 39 of TRIPS provides:

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 in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 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.

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 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.

World Trade Organization Agreement Implementation Act

[28] Parliament amended subsection 30(3) of the Act with the passage of the *World Trade Organization Agreement Implementation Act*. This Agreement came into force on January 1, 1996. The amended section, now the current wording of subsection 30(3) of the Act reads:

Regulations re the North American Free Trade Agreement and WTO Agreement

(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, Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights 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 set out in Annex 1C to the WTO Agreement.

The Data Protection Regulation as of October 5, 2006

[29] The RIAS states that after consultation with stakeholders the FDA Regulations were amended to reflect Canada's international treaty obligations. The Governor in Council amended section C.08.004.1 and this amendment came into force on October 5, 2006 with publication in

the Canada Gazette on October 18, 2006. The earlier version from 1995 of C.08.004.1 was replaced by the following amended wording:

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 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)

(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*.

(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 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.

(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.

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

(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).

(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).
SOR/95-411, s. 6; SOR/2006-241, s. 1, effective October 5, 2006 (Can. Gaz. Pt. II, Vol. 140, No. 21, p. 1493).

IV. Related Jurisprudence

[30] Also relevant to the legislative history of section C.08.004.1 of the FDA Regulations is jurisprudence concerning the interpretation of the original wording of the provision.

[31] In *Bayer v. Canada (Attorney General)*, [1998] F.C.J. No. 1560 (*Bayer FC*), Bayer Inc. brought a motion for a declaration that the first version of C.08.004.1 provided for a five year protection period for innovators of new drugs from competition from manufacturers of similar generic drugs.

[32] In *Bayer FC* Justice Evans noted the RIAS stated that section C.08.004.1(1) was introduced to ensure compliance with Canada's obligations under NAFTA, in particular paragraphs 5 and 6 of Article 1711. After deciding that the drug in question was a new drug within the meaning of the regulation in that this was the first time approval was sought to treat humans, Justice Evans turned to the interpretation of the provision. First, Justice Evans, at para. 37 decided that "given the overall purpose of the FDA Regulations, the adverb 'indirectly' should not be read into section C.08.004.1(1) so as to broaden the scope of the verb 'relies'." Second, he decided that the text of section C.08.004.1 should be interpreted to apply when the Minister, in considering an ANDS, actually examines the data submitted in the corresponding NDS for the comparative Canadian Reference Product. Finally, he concluded that the regulation as worded and interpreted does not confer the right to a five year exclusive marketing period for Bayer since the Minister of Health does not examine the NDS information submitted by an innovator in considering a subsequent ANDS by a generic manufacturer proposing to make a generic copy.

[33] Bayer appealed the decision to the Federal Court of Appeal. In *Bayer v. Canada (Attorney General)*, [1999] F.C.J. No. 826 (*Bayer FCA*), Justice Rothstein framed the issue as:

4 The issue is whether, when a competitor of an innovator seeks approval of the safety and effectiveness of its product by comparing it

with the innovator's product, there is examination and reliance by the Minister on the confidential detailed safety reports and evidence of clinical effectiveness originally filed by the innovator with the government. If so, the innovator will be entitled to at least five years of protection from competition.

[34] Justice Rothstein confirmed Justice Evans' assessment that the Court ought not to read the words "indirectly' or some other modifier" into the regulation. He found that regulation provided for a sequence: first, filing of an ANDS; second, examination of the information filed in an earlier NDS; and third, reliance on that information by the Minister in issuing an NOC for the ANDS generic drug. Importantly, the Minister and departmental officials did not examine the original NDS data submitted nor was there an implied examination required by the wording of the then existing regulation.

[35] Justice Rothstein reviewed the NAFTA provision 1711 and concluded:

18. 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.

[36] The Governor in Council amended section C.08.004.1 after the Federal Court of Appeal decision in *Bayer FC*. The accompanying RIAS states that the amendments to the FDA Regulation are intended to clarify and effectively implement Canada's obligations under NAFTA and TRIPS "with respect to the provision 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 RIAS specifically referenced the *Bayer FC* decision noting that the previous wording of the regulation did not provide sufficient data protection. The RIAS states that the federal government believes the amendments would achieve a greater balance between the need for innovative drugs and the need for competition in the marketplace.

V. Issues

[37] The issues raised by the CGPA are:

Is the *Data Protection Regulation ultra vires* the regulation-making power conferred on the Governor in Council by subsection 30(3) of the Act?

Is the *Data Protection Regulation* and subsection 30(3) of the Act *ultra vires* the constitutional authority of the federal government?

[38] Canada responded to these two issues and raised a further issue of CGPA’s standing:

Does the CGPA have standing to seek judicial review of the *Data Protection Regulation*?

[39] The issues raised by Apotex are:

Is the *Data Protection Regulation ultra vires* the authority of the Governor in Council for not being rationally connected to the grant of authority of the Enabling Provision, which pertains to trade secrets and confidential information?

Is the *Data Protection Regulation ultra vires* federal legislative competence pursuant to s.91 of the *Constitution Act, 1867*?

Does the *Data Protection Regulation* involve an impermissible sub-delegation of treaty implementation responsibilities?

Is the *Data Protection Regulation* void for uncertainty or vagueness for the grant of discretion to the Minister as to the scope of the FDA Regulations?

[40] The Applicants agreed that there were three issues raised between the two applications since the challenge on uncertainty was not being argued. The first issue involves a constitutional challenge to subsection 30(3) of the Act and the *Data Protection Regulation*. The remaining two issues involve the validity of the *Data Protection Regulation* in relation to its governing statutory provision, subsection 30(3) of the Act: first, that the challenged regulation is not rationally connected to the enabling provision since the latter relates to trade secrets and confidential information as set out in Article 1711 of NAFTA and Article 39 of TRIPS; second, that subsection 30(3) is an impermissible sub-delegation by Parliament to the Governor in Council.

[41] In response to the challenges, Canada submits that subsection 30(3) of the Act and the *Data Protection Regulation* are within the Parliament's constitutional competence, within the scope of the criminal law power pursuant to subsection 91(27) of the *Constitution Act, 1867*.

[42] In my view, the substantive issues to be addressed in these applications are:

1. Is the *Data Protection Regulation intra vires* the federal legislative powers pursuant to subsection 91(27) of the *Constitution Act, 1867*?
2. Is subsection 30(3) of the Act and the *Data Protection Regulation intra vires* the federal legislature powers as being enacted pursuant to the international trade agreements NAFTA and TRIPS under:
 - a) the general regulation of trade and commerce branch of subsection 91(2);
or
 - b) the national concern branch of the peace, order, and good government power (POGG)?

3. Is the *Data Protection Regulation* invalid:
 - a) for not being rationally connected to the grant of authority in subsection 30(3) of the Act; or
 - b) because the enabling provision, subsection 30(3), is an impermissible sub-delegation by Parliament of international treaty implementation responsibilities?

VI. Standard of Review

[43] The two applications by CGPA and Apotex are for judicial review of the *vires* of regulations enacted by the Governor in Council pursuant to an act of Parliament. As such they involve a question of law for which the standard of review is correctness.

Dunsmuir v. New Brunswick, 2008 SCC 9, at para. 58
Nanaimo (City) v. Rascal Trucking Ltd., [2000] 1 S.C.R. 342
Westcoast Energy Inc. v. Canada (National Energy Board), [1998] 1 S.C.R. 322

VII. Analysis

Evidence

[44] The evidence submitted by the parties in T-1976-06 consists of the following:

- 1) The CGPA submitted Affidavits from the following individuals: James Keon, Paula Rembach, and Michal Niemkiewicz.

James Keon is the president of the CGPA. In his Affidavit he discusses the importance of low cost generic drugs to drug expenditures in Canada, the health and safety approval process for generic drugs; the fact that the Minister does not rely on

the initial drug manufacturer's NDS data for an ANDS. He then surveys the power under the *Food and Drug Act* to make regulations necessary for the purpose of implementing Article 1711 of NAFTA and Paragraph 3 of Article 39 of TRIPS.

Attached to his Affidavit is a list of members of the CGPA, which includes: Cangene Corporation, Cobalt Pharmaceuticals Inc., Novopharm Limited, Nu-Pharm, Orbus Pharma Inc., Pharmascience Inc., Pro Doc Ltee, Ranbaxy Pharmaceuticals Canada Inc., ratiopharm inc., Sandoz Canada Inc., Taro Pharmaceuticals, ACIC, Debro Pharmaceuticals & Chemicals, PDi-Pharmaceuticals, Inc., Algorithm Pharma Inc., SFBC Anapharm, Viovail Contract Research, and MDS Pharma Services. Attached to his supplemental Affidavit is a table titled "Register of Innovative Drugs" dated 2006-11-02.

More specifically, Mr. Keon notes:

1. When a generic version of a drug enters the market, the price of the generic version is typically 30-50% below that of the originator drug. Thus the ability of generic manufacturers to get marketing approval for generic drugs plays a fundamental role in controlling drug expenditures in Canada.
2. The generic manufacturer in submitting an ANDS does not rely on the clinical and pre-clinical studies of the innovator to support the safety and efficacy of its generic drug. Rather, both the generic manufacturer and the Minister rely on:
 - a. the fact that an NOC has previously been issued in respect of the Canadian reference product;
 - b. the fact that the Canadian reference product is being marketed in Canada;and

- c. the information and material contained in the ANDS.
3. CGPA estimates the total lost saving to the health care system as a result of the monopolies imposed by the FDA Regulations at \$500 million dollars, as more fully set out the affidavit of Paula Rembach.

Paula Rembach is a research analyst for the CGPA. Her Affidavit contains a summary of the exhibit attached to her Affidavit; “Data Protection Analysis – Estimated Cost of 8.5 Year Ban on Generic NOC’s”.

The Affidavit of Michal Niemkiewicz contained the following documents:

- Copy of Article 1711 of the *North American Free Trade Agreement*;
- Copy of Article 39 of the *Agreement on Trade-related Aspects of Intellectual Property Rights*;
- Copy of Portions of the *North American Free Trade Agreement Implementation Act*;
- Copy of Portions of the *World Trade Organization Agreement Implementation Act*;
- Copy of the Order of the Governor in Council, SI/94-1, published on December 1, 1994 in *Canada Gazette Part II*, Vol. 128, No.1;
- Copy of the Order of the Governor in Council, SI/96-1, published on October 1, 1996 in *Canada Gazette Part II*, Vol. 130, No.1;
- Copy of Chapter 20 of the *North American Free Trade Agreement*;
- Copy of Part V of *Agreement on Trade-related Aspects of Intellectual Property Rights*
- Copy of Annex 2 of the Agreement Establishing the World Trade Organization entitled *Understanding on Rules and Procedures Governing Settlement of Disputes*
- Copy of *Food and Drug Regulations, Amendment*, SOR/95-411, published in the *Canada Gazette Part II*, Vol. 129, No. 18, pages 2489-2496 and Regulatory Impact Analysis Statement;
- Copy of *Regulations Amending the Food and Drug Regulation (Data Protection)*, SOR/2006-241 published on October 18, 2006 with Regulatory Impact Analysis Statement in *Canada Gazette Part II*, Vol. 140, No. 21;
- Copy of Section C, Division 8 of the *Food and Drug Regulations*;
- Copy of *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, published on March 24, 1993 with Regulatory Impact Analysis Statement in *Canada Gazette Part II*, Vol. 132, No.4;

- Copy of *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166, published April 1, 1998 with Regulatory Impact Analysis Statement in *Canada Gazette Part II*, Vol. 132, No. 7;
- Copy of *Regulations Amending Patented Medicines (Notice of Compliance) Regulations*, SOR/99-379, published October 13, 1999 with Regulatory Impact Analysis Statement in *Canada Gazette Part II*, Vol. 133, No. 21;
- Copy of *Regulations Amending Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242, published October 18, 2006 with Regulatory Impact Analysis Statement in *Canada Gazette Part II*, Vol. 140, No. 21; and
- Copy of report titled “Drug Expenditure in Canada 1985 – 2006” from the Canadian Institute for Health Information”

The CGPA also submitted the transcripts of the cross-examination of Anne Bowes and Declan Hamill.

- 2) Canada submitted the Affidavit of Elizabeth Bowes. She is the Associate Director at Health Canada in the Office of Patented Medicines and Liaison, Therapeutic Products Directorate. She is responsible for the administration of section C.08.004.1 of the FDA Regulations and the *Patented Medicines (Notice of Compliance) Regulations*, [S.O.R./93-133].

Ms. Bowes’ Affidavit contains an overview of the regulatory scheme, including the types of drug submissions made to the Minister of Health, and the confidential treatment of the NDSs. She goes on to discuss the legislative history of the data protection provisions.

Attached to her Affidavit are the following exhibits:

- A document without an identified source; presumably a Health Canada document titled: “Information Dissemination Procedures: Drug Submission-Related Information”;
- The Data Protection Regulations and the accompanying Regulatory Impact Statement;
- A document titled Frequently Asked Questions for New Drug Product Exclusivity, produced by the U.S. Food and Drug Administration was also submitted;
- A table titled: Register of Innovative Drugs dated 2007-02-01.

3) Rx&D submitted the Affidavit of Declan Hamill, Vice-President, Legal Affairs and Intellectual Property of Rx&D. His Affidavit described NDS and ANDS processes, referenced Article 1711 of NAFTA and paragraph 3 of Article 39 of TRIPS. He indicated the concern of Rx&D companies about lack of data protection in Canada and attached the following:

- A series of documents from the International Federation of Pharmaceutical Manufacturers and Associations titled: A Review of Existing Data Exclusivity Legislation in Selected Countries.
- A document from the Official Journal of the European Union titled “Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.
- A document submitted is from the Office of the United States Trade Representative, it is titled: Results of Bilateral Negotiations on Russia’s Accession to the World Trade Organization (WTO).
- The 2002 Annual Report of the President of the United States on the Trade Agreements Program was also submitted. This report identifies Canada’s progress towards improving its intellectual property regime with regard to patents and data protection.
- The final document submitted in the Interveners Record are Extracts from the US Special 301 Reports for the Years 2001, 2003, 2004, 2005, 2006, and 2007. These extracts include an executive summary for that year, including an overview of Canada for that respective year.

[45] The evidence submitted by the parties in T-2047-06 is:

1) Apotex submitted the following documents:

- A table titled: Register of Innovative Drugs, dated 2006-11-07.
- A table, developed by Goodmans LLP titled: “Data Protection Exclusivity Extensions, Drug Pricing”.
- A report from the Centre for Health Services and Policy Research, titled “The Canadian Rx Atlas” dated December 2005 was submitted. The key findings of the report were that Canadians spent over \$13 billion on prescription drugs in 2004. Apotex submitted this report to supplement the table developed by Goodmans LLP to demonstrate an assumption of 30% generic drug product price savings and 85% generic market penetration.

- 2) Canada relies on the Affidavit of Elizabeth Bowes submitted in T-1976-06.
- 3) Eli Lilly submitted three Affidavits by Jacques Gorlin, Peter Brenders and Dr. Loren Grossman.

Economist Jacque Gorlin's Affidavit included a number of reports which speak to the pharmaceutical related provisions of the TRIPS Agreement, the role of data exclusivity. These reports identify and examine the commercial and economic rational for test data confidentiality. It also lays out the current state of data protection internationally.

Peter Brenders' Affidavit explored and commented on how a strong data protection system in Canada is essential to promote biotechnology companies in Canada in order to improve the health and welfare of Canadians.

Dr. Loren Grossman's Affidavit discusses data protection with regard to the drugs Cymbalta™ and Byetta™.

[46] I draw the following general conclusions from the evidence of the parties:

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.

Is the Data Protection Regulation intra vires the federal legislative powers pursuant to section 91(27) of the Constitution Act, 1867?

[47] Protecting public health and safety is a valid exercise of the federal government's criminal law power. Canada submits that the *Data Protection Regulation* contributes to the protection of public health and safety. It submits that the *Data Protection Regulation* is integral to the operation of an overall scheme concerning the marketing of drugs in Canada. The essence of the regulatory drug scheme in the FDA Regulations is the prohibition of all drugs except for drugs that are proven to be safe and effective.

[48] Canada describes the public safety elements of the regulatory drug scheme, taken as whole as:

- i) the protection of public safety is a proper exercise of the federal government's criminal law power;

- ii) the marketing of a new drug without approval, given its inherent threat to public safety, is a criminal offence;
- iii) the FDA Regulations establish a detailed process by which a manufacturer of a new drug can obtain the exemption from criminal liability;
- iv) the FDA Regulations seek to minimize the potential for marketing unsafe drugs while maximizing the potential for safe drugs to be readily accessible in the market;
- v) the drug approval regulatory process requires exhaustive, complete and accurate information on the safety and effectiveness of the new drug;
- vi) the regulatory process also provides for an abbreviated means to prove the safety of the new drug by comparison to a proven safe drug which provides for competition, lowering the cost of safe drugs for the public and reducing the testing of human subjects;
- vii) the abbreviated drug approval process is subject to constraints to prevent reduction in innovator submissions for new drug approval; and
- viii) the constraints, while on their face relate to otherwise unfair commercial practices, are embodied in the regulations and are an integral part of the overall scheme of criminal law enacted for the protection of public safety.

[49] Canada submits that the *Data Protection Regulation* must be considered in the context of the entire drug regulation process established to protect public safety. The *Data Protection Regulation* contributes to the effectiveness of the overall scheme by allowing an abbreviated

process, while counteracting its disadvantages by providing appropriate protection to the extensive data provided by innovator drug manufacturers.

[50] Canada's argument that the protection of public health and safety is a matter of federal legislative jurisdiction under criminal law power in subsection 91(27) of the *Constitution Act, 1867* is not contested. The Supreme Court of Canada in *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1995] 3 S.C.R. 199, at para. 32 (*RJR MacDonald Inc.*), recognized this broad public health and safety jurisdiction which is circumscribed by three relatively simple requirements:

... 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;

[51] The prohibition is contained in section C.08.002 of the FDA Regulations which prohibit the sale of new drugs unless specified conditions are met. The penalty is set out in section 31 of the Act which provides for fines and imprisonment, or both, for contravention of the Act or regulations thereto.

[52] Canada asserts that while neither the prohibition nor the penalty appears in the wording of C.08.004.1, it is not independent or separable from the overall scheme. The *Data Protection*

Regulation is part of a defined exemption to the prohibition connected to ensuring the provision of safe and accessible drugs. In support of this submission Canada refers to two decisions: *Reference Re Firearms Act (Canada)*, [2000] 1 S.C.R. 783 (*Firearms Reference*), and *C.E. Jamieson & Co. (Dominion) v. Canada (Attorney General)*, [1987] F.C.J. No. 826, (*C.E. Jamieson*).

[53] In the *Firearms Reference* the Supreme Court summarized the jurisprudence as follows:

39 Alberta and the supporting interveners argued that the only way Parliament could address gun control would be to prohibit ordinary firearms outright. With respect, this suggestion is not supported by either logic or jurisprudence. First, the jurisprudence establishes that Parliament may use indirect means to achieve its ends. A direct and total prohibition is not required: see *Reference re ss. 193 and 195.1(1)(c) of the Criminal Code (Man.)*, [1990] 1 S.C.R. 1123, and *RJR-MacDonald*, *supra*. Second, exemptions from a law do not preclude it from being prohibitive and therefore criminal in nature: see *R. v. Furtney*, [1991] 3 S.C.R. 89, *Morgentaler v. The Queen*, [1976] 1 S.C.R. 616, and *Lord's Day Alliance of Canada v. Attorney General of British Columbia*, [1959] S.C.R. 497.

[54] In *C.E. Jamieson*, Justice Muldoon found that the delineation of an exemption could be part of a valid exercise of criminal law.

It seems as clear as any notion can be, that given the constitutional authority to identify and denounce human conduct by enactment of criminal law, Parliament may specifically exempt other, related, conduct from the purview of criminal law by enacting that it is not criminal. It may do so specifically, of course, and by necessary implication. To put the matter in visual terms, it may be said that because Parliament can configure the profile of a crime, it can equally carve out an exception or indentation in that profile such that it does not cover certain defined or implied conduct from the outset or which it previously covered.

[55] Canada submits that the *Data Protection Regulation* is integral to the drug regulation scheme and merely imposes additional conditions in respect of an ANDS for approval of a generic drug. The *Data Protection Regulation* serves to limit the scope of this public safety exception.

[56] Finally, Canada submits there is no encroachment on provincial authority in the constitutional sense. Even if the *Data Protection Regulation* did encroach, it is an incidental effect given the legislation is within the federal government's jurisdiction in respect of criminal law.

[57] Rx&D also submits that the *Data Protection Regulation* is *intra vires* as part of the federal criminal law power and gives support to Canada's submissions.

[58] The Intervener Eli Lilly cites *C.E. Jamieson*, focusing on the purpose of the regulation:

51 ... This Court agrees with the defendants' submission (transcript 3, page 128) that where the "legitimate" purpose -- that is, "the pith and substance" -- of the legislation is the protection of the public health and safety, supplemented by the suppression of deception and fraud, and not an attempt to protect or to suppress a particular trade or business, it is open to Parliament to legislate on the footing of criminal law.

52 When, however, it comes to the manufacturing, labelling and marketing throughout Canada of ingestible substances which, depending on the dosages could be poisonous, capable of altering moods or just plain lethal, it cannot be reasoned that regulation by the Health Protection Branch (HPB), in the protection of public health and safety including informed buying and ingestion, is too heavy a burden for valid criminal law to bear. ...

[59] Eli Lilly goes on to note that in *R. v. Wetmore et al.*, [1983] 2 S.C.R. 284 (*Wetmore*), sections 8 and 9 of the Act which prohibit the sale of food and drugs that are manufactured, packaged or sold in unsanitary conditions and the false, misleading or deceptive advertising of drugs were found to be a valid exercise of the criminal law power.

[60] Eli Lilly also pointed to the RIAS as evidence acknowledging the *Data Protection Regulation's* role in the protection of health and safety by encouraging the innovation of new medicines and in the case of pediatric data providing "health benefits to children".

Is the *Data Protection Regulation* a Valid Exercise of Federal Criminal Law Power?

[61] The submission that the *Data Protection Regulation* is part of the regulatory scheme is directed at the protection of public health and safety is an attractive argument given that the regulatory drug scheme set out in the FDA Regulations is unquestionably valid criminal law legislation. However, it must be kept in mind that the regulation of drug marketing has a very significant impact in the area of commerce.

[62] In *Labatt Brewing Co. v. Canada*, [1980] 1 S.C.R. 914 (*Labatt Brewing Co.*), Justice Estey stated there are limits to the extent of criminal law power. In *Reference re: Dairy Industry Act (Canada) S. 5(a)*, [1949] S.C.R. 1 (*Margarine Reference*), Justice Rand stated:

A crime is an act which the law, with appropriate penal sanctions, forbids; but as prohibitions are not enacted in a vacuum, we can properly look for some evil or injurious effect upon which the public against which the law is directed. That effect may be in relation to social, economic or political interests; and the legislature has in mind to suppress the evil or to safeguard the interest so threatened.

...

... to give trade protection to the dairy industry in the production and sale of butter; to benefit one group of persons as against competitors in business in which, in the absence of the legislation, the latter would be free to engage in the province. To forbid the manufacture and sale to such an end is *prime facie* to deal directly with civil rights or individuals in relation to particular trade within the provinces.

Determining the Pith and Substance

[63] The Supreme Court of Canada has set out the process for determining the pith and substance of impugned legislation. The pith and substance doctrine is used to determine which head of power a piece of legislation falls under. The analysis may concern the legislation as a whole, or certain provisions. The pith and substance analysis has two parts: first, the provision at issue is characterized by its most dominant feature, and second, the subject matter to which the legislation relates is identified. The law is categorized as either a federal or provincial legislative power enumerated in section 91 or 92 of the *Constitution Act, 1867*.

[64] Most recently, in *Chatterjee v. Ontario (Attorney General)*, 2009 SCC 19, Justice Binnie wrote:

16 The first step in a constitutional challenge is to determine "the matter" (to track the language of the Constitution Act, 1867) in relation to which the impugned law is enacted. What is the essence of what the law does and how does it do it? "[T]wo aspects of the law must be examined: the purpose of the enacting body, and the legal effect of the law" (Reference Re Firearms Act, at para. 16). This exercise is traditionally known as determining the law's "pith and substance". It may include not only the impugned Act but also external material surrounding its passage, including Hansard. In principle this assessment should be made without regard to the head(s) of legislative competence, which are to be looked at only once the "pith and substance" of the impugned law is determined. Unless the two steps are kept distinct there is a danger that the whole exercise will become blurred and overly oriented towards results.

[65] The Court is not bound by a purpose clause when considering the *vires* of a constitutional enactment. Nevertheless the statement of legislative intent is useful. *Chatterjee*, at para. 18.

[66] Section 117 of the *World Trade Organization Agreement Implementation Act* reads:

117. Subsection 30(3) and (4) of the *Food and Drugs Act* are replaced by the following:

(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 Intellectual Property Rights set out in Annex 1C to the WTO Agreement.

(4) In subsection (3), “North American Free Trade Agreement” has the meaning given to the word “agreement” by subsection 2(1) of the *North American Free Trade Implementation Act*,

“WTO Agreement” has the meaning given to the word “Agreement” by subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

(emphasis added)

[67] The RIAS accompanying the *Data Protection Regulation* sets out the federal government’s declared purpose. It reads in part:

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 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.

(emphasis added)

[68] When the wording of the *Data Protection Regulation* is examined, it is apparent that it is intended to implement Article 1711 of NAFTA and Paragraph 3 of Article 39 of TRIPS by providing a period of market exclusivity for drug manufacturers that obtain approval for new drugs by means of NDS submissions.

[69] The purpose of the *Data Protection Regulation* is stated by Parliament in the governing legislation, enacted by the Governor in Council in the regulation, and explained by the federal government in the RIAS as the implementation of Article 1711 of NAFTA and Paragraph 3 of Article 39 of TRIPS by providing a period of market exclusivity. In this way, drug manufacturers secure protection of their substantial investment in research and medical information they must prepare and submit to the Minister of Health and his officials as a requirement in the process of obtaining an NOC approval.

[70] The next step in assessing the pith and substance is to examine the effects of the challenged legislation. Justice Binnie, in *Chatterjee*, at para. 19 held:

the Court in determining its pith and substance will look at "how the legislation as a whole affects the rights and liabilities of those subject to its terms" (*R. v. Morgentaler*, [1993] 3 S.C.R. 463, at p. 482).

A reviewing court will also look beyond the legal effect to examine the predicted effect of the legislation.

[71] The *Data Protection Regulation* has three specific legal consequences. First is the six year prohibition of any filing of an ANDS by a drug manufacturer for a generic copy after an NOC has issued for a new drug. Second is the eight year preclusion of Ministerial issuance of an NOC for an ANDS from the date of the NOC first issued for the new drug which is being copied. Third is a further six month delay in the issuance of an NOC if pediatric clinical studies were conducted and the results provided to the Minister's satisfaction.

[72] Looking beyond the direct legal effects, the RIAS states in the Benefits and Costs Section that:

The government believes that these amendments, including changes resulting from stakeholders' comments, will achieve a greater balance between the need for innovative drugs and the need for competition in the marketplace in order to facilitate accessibility of those drugs.

...

The net effect of the amendments to the data protection provisions in these Regulations, concurrent with amendments to the PM(NOC) Regulations, will be to provide a balanced, stable regime that encourages innovation while at the same time ensuring Canadians have access to affordable medicines.

(emphasis added)

The CGPA has submitted evidence it claims demonstrates that, if the *Data Protection Regulation* is valid, the effect would be a cost to Canada's health care system by delaying the introduction of less expensive generic drugs to market. The CGPA estimate this cost is in the order of \$500

million for an eight and a half year span. The Interveners contend such measures are necessary in order to protect the substantial investment drug manufacturers must expend in order to satisfy the extensive information required in the NDS for a new drug.

[73] The longer deferral of eight years is predominant and guides any determination of the effect of the *Data Protection Regulation*. While it is true the RIAS refers to an additional six month incentive for information concerning clinical pediatric studies, the imposition of the more substantive eight year deferral for approval of generic drugs has the overall effect of bestowing a commercial benefit to innovator drug manufacturers rather than a safety benefit to the public.

[74] In *Bayer FC* Justice Evans noted that the predecessor regulation had the effect of suspending the very drug regulation scheme intended for public safety. In *Bayer FCA* Justice Rothstein, after referring to the NAFTA provisions as an aid in the interpretation of the regulation, found the regulation was intended to protect trade secrets. The current *Data Protection Regulation* follows much the same track. It also suspends the approval of generic drugs that would otherwise be eligible for an NOC. The *Data Protection Regulation* addresses commercial considerations rather than public safety concerns.

[75] One may also look to international agreements as an aid to interpretation of a legislative provision as Justice Rothstein did in *Bayer FCA* when he referred to NAFTA. The language of section Paragraph 3 of Article 39 of TRIPS also points to the protection of intellectual property in a commercial setting:

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 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)

[76] The *Data Protection Regulation* does not directly add to public safety since it postpones the introduction of lower cost generic drugs. The RIAS states that the *Data Protection Regulation* is to encourage innovator drug manufacturers, or at least allow them to recover their investment, and thereby foster innovators to develop new drugs. However, 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.

[77] The *Data Protection Regulation* is part of the regulatory scheme which contains a prohibition, an overall drug regulation scheme, and a penalty. However, that is not enough. The legislation must serve a “criminal law” objective and safeguard the public. In the case of the drug regulations, the mischief of the legislation is directed to and must be related to public health and safety matters. As I noted above from para. 32 of *RJR-MacDonald*: “the legislation ... must be directed at a legitimate public health evil.”

[78] Considering the *Data Protection Regulation*, the stated purpose, its legal and economic effects, and the language of NAFTA and TRIPS, I conclude that the purpose of the *Data Protection Regulation* is the implementation of the specific provisions of NAFTA and TRIPS. The legal effect is the protection of the NDS information submitted by innovator drug companies

and its intended effect is the balancing of commercial considerations, protecting the research and development costs for new drugs by innovator drug manufacturers on one hand and achieving lower drug costs by the eventual introduction of generic drugs by generic drug manufacturers on the other hand.

[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.

[80] As the final step in the pith and substance analysis, I find the subject matter of the *Data Protection Regulation* does not accord with the public health and safety aspect of the federal criminal law power in subsection 91(27).

Is the *Data Protection Regulation* Integral to the Drug Regulatory Scheme?

[81] It is not disputed that the regulatory drug regime in the Act is a measure enacted for public health and safety purposes within the federal criminal law power. If an impugned provision is integral to a valid statutory scheme it may be valid even if it would otherwise be invalid.

[82] In *Kirkbi AG v. Ritvik Holdings Inc.*, 2005 SCC 65 (*Kirkbi*), at para. 35, the Supreme Court of Canada held that s. 7(b), codifying the common law tort of passing off is sufficiently

integrated with *Trade-marks Act*, R.S.C. 1985 c. T-13, as its pith and substance is directly connected with the legislative protection of trade marks.

[83] While it is true that the RIAS refers to the benefit derived from the six month extension upon the satisfactory conduct of pediatric studies, I have found the dominant feature of the *Data Protection Regulation* is the balancing of commercial considerations between the protection of an innovator drug manufacturer's investment in preparing the NDS information for an NOC for a new drug and the eventual approval of a generic drug company's ANDS submission for an NOC for a lower cost generic copy of the new drug. The balancing is of commercial considerations, not public health and safety. While the *Data Protection Regulation* is related to the regulatory drug scheme in the Act, I would characterize the relationship as adjunct rather than integral to the FDA Regulations.

[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.

[85] I conclude that the *Data Protection Regulation* is not *intra vires* by reason of the subsection 91(27) federal criminal law power.

Is subsection 30(3) of the Act and the Data Protection Regulation intra vires the federal legislative powers under the general regulation of trade and commerce branch of subsection 91(2)?

[86] The next question is whether the *Data Protection Regulation* may be *intra vires* by reason of another head of federal legislative jurisdiction such as subsection 91(2), the regulation of trade and commerce or the national concern aspect of the residual peace, order and good government power (POGG). Both of the respective Applicants oppose these possibilities.

[87] Apotex begins its submission by stating that although the federal government has the power to sign international treaties but does not have plenary constitutional power to implement international treaty obligations. Legislative authority must be found in a head of power enumerated in s. 91 of the *Constitution Act, 1867: Canada (A.G.) v. Ontario (A.G.)*, [1937] A.C. 326 (P.C.), (the Labour Conventions Case).

[88] Apotex contends that the valid exercise of the federal trade and commerce power must satisfy the criteria set out in *Kirkbi* at para. 17:

- (i) the impugned legislation must be part of a regulatory scheme;
- (ii) the scheme must be monitored by the continuing oversight of a regulatory agency;
- (iii) the legislation must be concerned with trade as a whole rather than with a particular industry;
- (iv) the legislation should be of a nature that provinces jointly or severally would be constitutionally incapable of enacting; and
- (v) the failure to include one or more provinces or localities in a legislative scheme would jeopardize the successful operation of the scheme in other parts of the country (*City National Leasing*, at pp. 662-63).

[89] Apotex argues the *Data Protection Regulation* fails this test. First, it argues that it is an adjunct to the regulatory drug approval scheme. Secondly, the *Data Protection Regulation* is directed to a single industry, and finally, there is no evidence provincial governments would be unable to enact or cooperate to address the subject matter since provincial legislatures already

have legislation that provide for prescribing generic drugs in place of brand-name drugs: *Drug Interchangeability and Dispensing Fee Act*, R.S.O. 1990 c. P-23; *Ontario Drug Benefit Act*, R.S.O. 1990, O-10.

[90] Finally, Apotex submits that the need for uniformity across Canada in the matter of drug approvals by itself cannot justify use of the trade and commerce power: *Labatt Brewing Co.*; *Reference Re Anti-Inflation Act*, [1976] 2 S.C.R. 373.

General Regulation of Trade Affecting the Whole Dominion

[91] No challenge is posed to the constitutional validity of the Act or the regulatory drug scheme. Imbedded legislation need not concern the same subject matter as the legal regime in which it is lodged: *John Deere Plow v. Wharton* (1914), 18 D.L.R. 353.

[92] Earlier courts have narrowly construed the scope of the federal trade and commerce power because of the potential for interference with provincial powers, particularly property and civil rights. In *Citizens Insurance v. Parsons* (1881), 7 App.Cas. 96 (*Parsons*), the Privy Council found that s. 91(2), the regulation of trade and commerce power, was composed of two elements: the first branch being political arrangements regulating inter-provincial trade; the second branch being the general regulation of trade affecting the dominion as a whole. However, that power did not extend to a particular business in a single province. Lord Smith stated:

25 Construing therefore the words "regulation of trade and commerce" by the various aids to their interpretation above suggested, they would include political arrangements in regard to trade requiring the sanction of parliament, regulation of trade in matters of interprovincial concern, and it may be that they would include general regulation of trade affecting the whole dominion. ... It is enough for the decision of

the present case to say that, in their view, its authority to legislate for the regulation of trade and commerce does not comprehend the power to regulate by legislation the contracts of a particular business or trade, such as the business of fire insurance in a single province.

[93] The regulation of trade and commerce power has also been constrained in the area of international agreements. In the Labour Conventions Case the Privy Council held the legislation was *ultra vires* because that Parliament did not have the constitutional authority to implement labour standard conventions. Lord Atkin stated:

[t]here is no existing constitutional ground for stretching the competence of the Dominion Parliament so that it becomes enlarged to keep pace with the enlarged functions of the Dominion executive ... In other words, the Dominion, cannot, merely by making promises to foreign countries, clothe itself with legislative authority inconsistent with the constitution that gave it birth.

[94] In *MacDonald v. Vapour Canada Ltd.*, [1977] 2 S.C.R. 134 (*Vapour*), Chief Justice Laskin considered the scope of the federal legislative power in relation to the regulation of trade and commerce as set out in *Parsons*. He began by reiterating Lord Smith's articulation of the two branches to s. 91(2). Chief Justice Laskin considered whether subsection 7(e) of the *Trade-marks Act*, R.S.C. c.T-10, which prohibited acts contrary to honest business practices, could be said to be part of a regulatory scheme under the oversight of a regulatory agency concerned with trade as a whole. He stated that:

Section 7 is, however, nourished for federal legislative purposes in so far as it may be said to round out regulatory schemes prescribed by Parliament in the exercise of its legislative power in relation to patents, copyrights, trade marks and trade names. The subparagraphs of s. 7, if limited in this way, would be sustainable...

However, Chief Justice Laskin found that subsection 7(e) of the *Trade Marks Act* could not be sustained as valid because it was not directed to patents, copyrights, trade marks and trade names.

[95] Chief Justice Laskin also decided where it was open for Parliament to legislate the implementation of international treaties in a manner consistent with federal powers; it must be done clearly so that the matter is not left to inference. He set out the following precondition:

In my opinion, assuming Parliament has power to pass legislation implementing a treaty or convention in relation to matters covered by treaty or convention which would otherwise be for provincial legislation alone, the exercise of that power must be manifested in the implementation legislation and not left to inference.

[96] In *Labatt Brewing Co.*, Justice Estey held that the offending regulation dealt with the regulation of a single industry and was not legislation that affected industry in “a sweeping general sense” as contemplated in *Parsons*.

[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.

[98] Justice Dickson qualified that the five elements were neither exhaustive nor was the presence or absence of any of the five determinative:

The above does not purport to be an exhaustive list, nor is the presence of any or all of these indicia necessarily decisive. The proper approach to the characterization is still the one suggested in *Parsons*, a careful case by case assessment. Nevertheless, the presence of such factors does at least make it far more probable that what is being addressed in a federal enactment is genuinely national economic concern and not just a collection of local ones.

(emphasis added)

[99] In *General Motors of Canada v. City National Leasing Ltd.*, [1989] 1 S.C.R. 641 (*City National Leasing*), the Supreme Court of Canada gave effect to the developing indicia for a valid exercise of the federal trade and commerce power. Chief Justice Dickson recognized the continuing need to restrain the federal trade and commerce powers so as to not erode the provincial jurisdiction for property and civil rights. He stated at para. 30:

The true balance between property and civil rights and the regulation of trade and commerce must lie somewhere between an all pervasive interpretation of s. 91(2) and an interpretation that renders the general trade and commerce power to all intents vapid and meaningless.

[100] He then traced the development of specific criteria in *Vapour* and *Canadian National Transportation*. The Chief Justice concluded his discussion with the observation that the five principles enumerated in *Canadian National Transportation* represented a principled way to distinguish between the federal trade and commerce matters and provincial local matters.

[101] The FDA Regulations establish a valid regulatory drug scheme for the approval of both new and generic drugs. The regulatory scheme is overseen by the Minister of Health and officials. The presence of a constitutionally valid federal scheme subject to the oversight of the Minister of Health satisfies the first two criteria.

[102] The *Data Protection Regulation*, although adjunct rather than integral, can be said to “round out” the valid federal regulatory drug scheme established for marketing drugs in Canada much in the manner as described by Chief Justice Laskin in *Vapour*. It brings the mechanism by which generic copies of new drugs are approved into conformity with Canada’s obligations in NAFTA and TRIPS.

[103] In *Vapour* the Court stated that if Parliament had the power to legislate the implementation of a treaty the exercise of that power must be expressly manifested in the legislation. This requirement is satisfied since Parliament expressed the intention to implement NAFTA Article 1711 and Paragraph 3 of Article 39 of TRIPS in the *World Trade Organization Agreement Implementation Act* and repeated that intention in the very wording of subsection 30(3) of the Act and in the *Data Protection Regulation* itself.

[104] The *Data Protection Regulation* deals with the manufacture and marketing of drugs, a local matter in a single industry. However, the evidence also demonstrates that this regulation has implications of a national dimension. It was enacted in compliance with NAFTA and TRIPS. NAFTA involves Canada, the United States and Mexico. The TRIPS agreement involves many countries around the world, most of which participate to some degree or other in

the TRIPS scheme for the protection of new drug research investment through market exclusivity mechanisms.

[105] Canada's implementation or failure to implement such international trade agreements has a national dimension that relates to Canada's ability to participate in world trade. In this sense, the *Data Protection Regulation* deals with a genuine national economic concern of the kind considered by Justice Dickson 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.

[107] I conclude that the *Data Protection Regulation* is *intra vires* as a constitutionally valid exercise of the federal legislative power under the s. 91(2) regulation of trade and commerce as it meets the criteria required for the second branch of the federal trade and commerce legislative power.

Is subsection 30(3) of the Act and the Data Protection Regulation intra vires the federal legislature powers under the national concern branch of the peace, order, and good government power (POGG)?

[108] Apotex also submits the Data Protection Provision does not satisfy the national concern requirement referred to in *Crown Zellerbach Canada Ltd.*, [1988] 1 S.C.R. 401, (*Crown Zellerbach*) at para 33, that the residual POGG power to enact legislation can only be exercised if the legislation has:

... a singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern and a scale of impact on provincial jurisdiction that is reconcilable with the fundamental distribution of legislative power under the Constitution, ...

[109] There is another aspect that must first be considered. In *Crown Zellerbach*, the Supreme Court set out the test for the national concern doctrine. Justice Le Dain listed:

1. the national concern doctrine is separate ...
2. it applies to new matters which did not exist at confederation and matters which since became matters of national concern;
3. it must have a singleness, distinctiveness, and indivisibility that distinguishes it from local matters and its impact on provincial jurisdiction is reconcilable with the distribution of constitutional power; and
4. in determining 3, what would the effect of provincial failure to effectively deal with the regulation of the matter on extra provincial interests.

(emphasis added)

[110] It may be said that international trade agreements of the kind represented by NAFTA and TRIPS are new matters that did not exist at confederation which have since become matters of national concern. This question was not fully engaged in argument. Accordingly, I do not propose to go further in consideration of this question.

Is the Data Protection Regulation 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 Food and Drugs Act?

[111] Apotex submits that the *Data Protection Regulation* was enacted pursuant to the international treaty provisions of NAFTA and TRIPS which govern the protection of “trade secrets” or “confidential information” respectively. Since the treaty provisions were incorporated by reference in subsection 30(3) of the Act, the limitations in the treaties restrict the Governor in Council’s authority to enact regulations.

[112] Apotex submits the *Data Protection Regulation* is not rationally connected to the protection of trade secrets or confidential information because subsection 30(3) of the Act and the *Data Protection Regulation* derive their purpose from the sections concerning trade secrets in NAFTA and undisclosed information in TRIPS: *Canadian Wheat Board v. Canada (Attorney General)*, 2007 FC 807, at paras. 35-39 The *Data Protection Regulation* operates without regard to whether the information or data in NDS submissions:

- a) are secret or undisclosed, and have been subject to reasonable steps to protect their secrecy;
- b) are of actual or potential commercial value;
- c) originate from considerable effort or expenditures; and
- d) must be disclosed to protect the public.

[113] Apotex also argues that the *Data Protection Regulation*:

- a) operates without regard to whether the Minister's reliance upon the information or data, or whether approval of the generic submission, would be contrary to honest commercial practices;
- b) applies regardless of whether anyone reviews, utilizes or discloses trade secrets or otherwise undisclosed information;
- c) applies regardless of whether review, reliance, utilization or disclosure of trade secrets or otherwise undisclosed information is required to file a generic drug submission; or to grant an NOC in respect of a generic drug submission.

[114] Apotex argues that the *Data Protection Regulation* protects trade secrets by, in effect, granting an injunction on behalf of a innovative drug manufacturer enjoining generic manufacturers from submitting ANDS and the Minister of Health from granting an NOC for a generic drug during specific periods of time. Apotex further submits the period of protection under the *Data Protection Regulation* bears no relationship to the value of the data in question, the maintenance of confidence in the regulatory scheme, or whether the data was developed in another country. The market exclusion period is fixed for all eligible drugs. The *Data Protection Regulation* simply provides market exclusivity without regard to the protection of the NDS data.

[115] The CGPA also argues that the *Data Protection Regulation* is beyond the scope of subsection 30(3) of the Act. Permitted regulations must not restrict the authority conferred elsewhere in the Act, they must only apply to trade secrets or undisclosed data, and must affect only the person who "relies on" such data, and only for a "reasonable period", normally five

years. The *Data Protection Regulation* exceeds these limitations; it creates a new intellectual property regime without statutory authority.

[116] Apotex submits that the *Data Protection Regulation* seriously encroaches on the exclusive legislative competence of the provinces. CGPA also submits that the *Data Protection Regulation* is not within the power of the federal government as it is directed at subject matter within the exclusive jurisdiction of the provinces. The regulation's purpose is to implement treaty obligations concerning trade secrets and confidential information in order "to protect investments made in the development of the product by providing a period of market exclusivity." RIAS p. 1495.

[117] Apotex and the CGPA note that the language and purpose in NAFTA and TRIPS is very similar to that of the *Trade-marks Act*, subsection 7(e) which provided:

7. No person shall

(e) do any other act or adopt any other business practice contrary to honest industrial or commercial usage in Canada.

In *Vapour* at paras. 23, 36-37 and 46 the Supreme Court of Canada struck down subsection 7(e) of the *Trade-marks Act* as being *ultra vires* federal legislative competence which was a provision concerned with provincial and civil rights.

[118] Justice Rothstein found in *Bayer FCA* at para 7:

When a generic manufacturer files an ANDS, the safety and effectiveness of the generic product may be demonstrated by showing that the product is the pharmaceutical and bioequivalent of the innovator's product. If the generic manufacturer is able to do so solely by comparing its product with

the innovator's product which is being publicly marketed, the Minister will not have to examine or rely upon confidential information filed as part of the innovator's NDS.

[119] The provisions of NAFTA and TRIPS reference data, that is secret or undisclosed, that was the subject of reasonable steps to ensure secrecy; that was the product of considerable effort and with commercial values, which equates with the criteria for trade secrets/ confidential information at common law. Justice Cumming, in *CPC International Inc. v. Seaforth Creamery Inc.*, [1996] O.J. No. 3393 (Ont. Gen. Div.), stated at para. 22:

“Trade secrets” and “confidential information” are not easily definable with exhaustive precision, but once ascertained constitute proprietary rights. A useful description as to what is to be considered in determining what is and what is not a trade secret or privileged confidential information is seen in *Software Solutions Inc. v. Depow* (1989), 25 C.P.R. (3d) 129 (N.B.Q.B.) at 138-139. To constitute a trade secret, the information must not be of a general nature, but must be specific. The specific information must not be generally known to the public but it may be acquired from materials available to the public with the expenditure of time and effort. The owner of that specific information must treat it as confidential and it must be clear that the owner regards the information as secret. The information should only be communicated to an employee on a need-to-know basis and within the constraint that the owner shows his/her intention to maintain the secrecy of the information. If there is disclosure to a third party beyond the employment relationship, the owner should require of that party that there cannot be disclosure or use in any way not authorized expressly by the owner.

(emphasis added)

[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.

[121] Article 1711 of NAFTA defines the protection information as: “where the origination of such data involves considerable effort”. The information, as defined in NAFTA, is:

...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;

[122] Paragraph 3 of Article 39 of TRIPS defines the information as “the origination of which involves a considerable effort” which corresponds to the definition by Justice Cumming: “The specific information must not be generally known to the public but may be acquired from materials available to the public with the expenditure of time and effort” rather than explicitly secret.

[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*.

[124] Both NAFTA and TRIPS provide for member countries to protect data that has been assembled with considerable effort. NAFTA Article 1711, paragraph 5 states: “the Party shall protect against disclosure ... or unless steps are taken to ensure that the data is protected against unfair commercial use.” TRIPS, paragraph 3 of Article 39 states: “...as a condition of approving the marketing ... Members shall protect such data against disclosure, ... or unless steps are taken to ensure that the data are protected against unfair commercial use.”

[125] NAFTA identifies a market exclusivity protection mechanism. TRIPS does not specify what measures are to be taken. It is for the federal government to decide what measures it would implement to satisfy its international obligations.

[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-Meyers*, 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).

(emphasis added)

[128] The market exclusivity period may not arise in every instance. Subsection 2 of the *Data Protection Regulation* expressly references the NAFTA and TRIPS provisions. Both qualify when the protective measures are required:

NAFTA: s. 1711 (in part)

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.

TRIPS: paragraph 3 Article 39

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.

(emphasis added)

[129] It seems to me that the limitations implied by the above emphasized phrases in the international agreements expressly referenced in the *Data Protection Regulation* may arise in certain situations such that the protective market exclusivity mechanism may not have application. However, such questions would be dependent on the specific facts of a given case and do not arise in the matters that are before me.

[130] *Bristol-Meyers* 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 necessarily relies on the earlier NDS information.

[131] I am also satisfied that the *Data Protection Regulation* provides for the protection consistent with both NAFTA and TRIPS. In my view, by establishing a market exclusivity period, the *Data Protection Regulation* provides an alternative to protection against disclosure in a manner contemplated in the two international agreements.

Is subsection 30(3) of the Act an impermissible sub-delegation by Parliament of international treaty implementation responsibilities?

[132] Apotex submits that, in the alternative, if subsection 30(3) permits the Governor in Council to enact subordinate legislation dealing with the same subject matter that goes beyond the limits of the NAFTA and TRIPS provisions, it is an impermissible sub-delegation and abdication of legislative functions to the Governor in Council. Such a delegation is contrary to Parliamentary supremacy, and oversight of legislation. In such circumstance, subsection 30(3) would permit:

- (a) the Governor in Council to exercise sweeping peace-time powers without Parliamentary review,
- (b) the Governor in Council to determine the scope of Canada's international obligations, and undertake indeterminate obligations on Canada's behalf; and
- (c) The Governor in Council to revise its regulations with new developments in international law which would be both uncertain and outside of Parliament's control.

[133] The CGPA also contends that subsection 30(3) of the Act is an impermissible sub-delegation of Parliament's responsibility for implementation of international agreements.

[134] In my view these submissions have little merit. Parliament has given the Governor in Council the authority to enact regulations in a narrow area specified by the boundaries of the NAFTA and TRIPS provisions.

[135] Parliament has not left the scope of the Governor in Council's regulatory power indeterminate. Subsection 30(3) of the Act is constrained by its internal reference to NAFTA 1711 and TRIPS paragraph 3 of Article 39. 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.

[136] The suggestion that subsection 30(3) of the Act allows the Governor in Council to make future revisions unsupervised by Parliament upon new developments in NAFTA or TRIPS does not arise on the facts before the Court. Should this unlikely event arise in the future it can be examined at that time.

[137] Given the above limitations to the Governor in Council's power to regulate, I do not find the Parliamentary delegation to exceed the bounds of what is permissible.

Does the CGPA have standing to seek judicial review of the Regulation?

[138] Canada submits that the CGPA does not have standing to bring this application for judicial review. It relies on section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, which provides that no person may seek judicial review in the Federal Court unless that person is "directly affected by the matter in respect of which relief is sought".

[139] Canada submits that the *Data Protection Regulation* imposes limitations on drug manufacturers seeking an ANDS for a generic version of an approved new drug. The CGPA, as an association of generic drug manufacturers and related companies, is not itself a drug manufacturer and does not make any applications for a NOC for a generic or other drug. The CGPA is not a party that is "directly affected" by the regulation within the meaning of section 18.1 of the *Federal Courts Act*. *Independent Contractors and Business Association v. Canada (Minister of Labour)*, [1998] F.C. J. No. 352, at para. 30

[140] Canada also submits that the CGPA does not have public interest standing. In *Canadian Council of Churches v. Canada (Minister of Employment and Immigration)*, [1992] 1 S.C.R. 236, at para. 30 Justice Cory laid out the three requirements a party seeking public interest standing must show:

1. there is a serious issue to be tried;
2. the party has a direct interest or a genuine interest in the matter; and

3. there can be no other reasonable and effective way to bring the issue to the Court.

[141] Canada submits that the third requirement is fundamental to grant public interest standing. *Hy and Zel's Inc. v. Ontario (Attorney General)*, [1993] 3 S.C.R. 675 at para 16.

Canada submits that there is a more reasonable and effective means of bringing the matter to the Court, namely the challenge brought by Apotex in T-2047-06. Public interest standing is not granted when a private litigant is available to challenge the matter: *Canadian Council of Churches, above* at para. 36.

[142] The CGPA application is a challenge to the *vires* of the *Data Protection Regulation*. *Vires* challenges do not necessarily require a fact specific situation in order to proceed. As such, facts concerning a specific attempted application for an ANDS would not be relevant.

[143] Canada previously brought a motion to strike CGPA's application on the basis that the CGPA had no standing. In *CGPA v. Canada*, 2007 FC 154, Justice Harrington concluded that it was not plain and obvious that the CGPA did not have standing in its own right or on the basis of public interest and dismissed the motion to strike without prejudice to the question of standing being raised again. He also granted Rx&D intervener status observing that their presence helped to complete the picture. On appeal, Justice Sexton held that there was a serious issue to be tried and the CGPA had a direct or genuine interest in the matter.

[144] There is no question or debate that the CGPA application involves a serious issue. The *Data Protection Regulation* delays introduction of generic drugs, and this delay has implications for both the Canadian health system and generic drug companies.

[145] The CGPA, as an association representing the generic drug manufacturers and their suppliers, clearly has a genuine interest in the matter. The CGPA is not an “officious inter-meddlers” as discussed in *Moresby Explorers Ltd. v. Canada (Attorney General)*, 2006 FCA 144.

[146] In respect of the third requirement, that there must be no other reasonable and effective way to bring the issue to the Court, Justice Sexton stated:

This conclusion is in no way diminished by the result in the companion case to this appeal ... where this Court held that it was not plain and obvious that Apotex did not have standing to contest the *vires* of the New Data Protection Regulations. Since there has been no final ruling on whether Apotex has standing to contest the *vires* of the New Data Protection Regulations, it cannot be said it is plain and obvious that there is another manner in which to bring this issue to the Court. (emphasis in original)

The companion case, *Apotex v. Canada (Governor in Council)*, 2007 FCA 374 was also remitted to the judicial review hearing without prejudice. Canada did not renew its challenge to Apotex’s standing. The result is that no final ruling was sought on Apotex’s standing leaving the CGPA in much the same position as it was when the motion appeal was heard.

[147] At the time the CGPA commenced its application Apotex had not yet filed its application. In my view, at the time the CGPA commenced its application, it was entitled to public interest standing. Since Canada has not provided any jurisprudence that sets out the proposition that a

party that was entitled to standing at the commencement of its application loses that standing because another party commences an application on the same issue, I see no reason to decide the CGPA lost that public interest standing when Apotex commenced its own application.

[148] Finally, with regard to the style of cause in *Apotex v. Canada*, T-2047-06, Canada has asked that Governor in Council be struck from the style of cause since section 48 of the *Federal Courts Act* provides that the “Attorney General of Canada” is named in proceedings against the Federal Government. Justice Harrington granted the same application in *CGPA v. Canada*, 2007 FC 154. He also added the Minister of Health. I adopt the same approach. I will strike out the “Governor in Council” as a respondent and add the Minister of Health so that all directly interested participants are present.

Conclusion

[149] I conclude that the *Data Protection Regulation* is *intra vires* the federal government legislature powers by subsection 91(2) the regulation of trade and commerce of the *Constitution Act, 1867*.

[150] The *Data Protection Regulation* was not *intra vires* by reason of subsection 91(27) the criminal law power because the pith and substance of the regulation was directed at balancing commercial considerations between innovative drug manufacturers and generic manufacturers arising from the implementation of international trade agreements. The *Data Protection Regulation* is not saved as being integral to the valid drug regulatory scheme since this regulation operates to suspend the drug regulatory scheme.

[151] The *Data Protection Regulation* comes within the second branch of the s. 91(2) regulation of trade and commerce power as this provision meets the criteria set out by the Supreme Court of Canada in *National City Leasing* for being a matter of genuine national economic concern. The *Data Protection Regulation* rounds out the valid federal drug regulatory scheme, has a national economic dimension because of Canada's obligations pursuant to international trade agreements NAFTA and TRIPS, and is a matter which the provinces cannot address legislatively individually or collectively.

[152] The *Data Protection Regulation* is not beyond the regulatory power of the Governor in Council in that the regulation is properly concerned with data protection for innovator drug companies which are required to provide confidential commercially valuable data to secure a NOC to introduce new drugs to the Canadian market. This is consistent with the requirement in the NAFTA and TRIPS provisions.

[153] Finally, the *Data Protection Regulation* is a permissible sub-delegation by Parliament to the Governor in Council since the delegated regulatory power is constrained by the limitations in the NAFTA and TRIPS agreements.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that:

1. The Canadian Generic Pharmaceutical Association has standing to bring the application T-1976-06.
2. The style of cause in application T-2047-06 is amended to remove the Governor in Council as a Respondent.
3. The *Data Protection Regulation* is declared to be *intra vires* the federal Parliament.
4. The applications for judicial review, T-1976-06 and T-2047-06 are dismissed.
5. Costs are awarded to Canada in each respective application. No costs are awarded to the Interveners, the Research-Based Pharmaceutical Association and Eli Lilly Canada Inc.

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1976-06 and T-2047-06

STYLE OF CAUSE: CANADIAN GENERIC PHARMACEUTICAL
ASSOCIATION v. THE MINISTER OF HEALTH ET
AL.

APOTEX INC. v. GOVERNOR IN COUNCIL ET AL.

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: DECEMBER 16, 2008

**REASONS FOR JUDGMENT
AND JUDGMENT BY:** MANDAMIN, J.

DATED: JULY 17, 2009

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