A new Canadian intellectual property right: The protection of data submitted for marketing approval of pharmaceutical drugs

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Abstract

In order to market and sell a new pharmaceutical drug in Canada, the Minister of Health requires the initial applicant to submit clinical test results demonstrating that the drug is safe and effective for human use. Subsequent applicants, who typically lack the resources to conduct expensive clinical trials, must refer to and rely upon the initial applicant's data in their applications to market a generic version of the drug.

On June 17, 2006, the federal government of Canada published a proposed data protection regulation, which would provide an initial applicant with eight years of protection for clinical test results submitted in a new drug submission. This protection would lead to an eight year period of market exclusivity for the drug associated with the clinical test data, regardless of whether that drug was protected by a Canadian patent.

In this thesis, the author first describes what data protection is on a practical level, and distinguishes data protection from other forms of intellectual property rights. Next, the author discusses how various jurisdictions choose to protect clinical test data submitted to their health authorities. Canada's international obligations pursuant to the NAFTA and the TRIPs Agreement are also examined. In this regard, the author argues that Canada is under no obligation to provide initial applicants with eight years of data protection. Furthermore, the author argues that exclusive time-limited property rights in clinical test data are difficult to justify from a theoretical perspective. Finally, the author prescribes certain legislative changes to Canada's proposed data protection regulation.

Résumé

Afin de lancer sur le marché et vendre une nouvelle drogue pharmaceutique au Canada, le ministre de la santé exige du demandeur initial de soumettre des résultats d'essai cliniques démontrant que la drogue est sûre et efficace pour l'usage humain. Les demandeurs subséquents qui ne disposent normalement pas des ressources extensives pour faire des tests cliniques dispendieux, doivent se référer et compter sur les données du demandeur initial dans leurs applications pour lancer une version générique de la drogue.

Le 17 juin 2006, le gouvernement fédéral du Canada a publié un règlement proposé de protection de données, qui fournirait à un premier demandeur huit ans de protection pour des résultats d'essai cliniques soumis dans une nouvelle demande d'autorisation de drogue. Cette protection accorderait une période de l'exclusivité de marché de huit ans pour la drogue liée aux essais cliniques, indépendamment de la protection par brevet canadien du médicament.

Dans cette thèse, l'auteur décrit d'abord la protection de données au niveau pratique, et distingue la protection de données d'autres formes de droits de propriété intellectuelle. L'auteur étudie ensuite comment les juridictions différentes protégent les essais cliniques soumis à leurs autorités sanitaires. Les engagements internationaux du Canada conformément à l'ALENA et l'ADPIC sont également discutés en détail. À cet égard, l'auteur discute du fait que le Canada n'est sous aucune obligation de fournir aux demandeurs initiaux huit ans de protection de données. Ensuite, l'auteur discute du fait qu'il est difficile de justifier les droits de propriété limités de temps exclusifs dans des essais cliniques au niveau des principes. Finalement, l'auteur suggère certains changements au règlement proposé de protection des données du Canada.

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Chapter I - What is "data protection" and how does it relate to marketing approval for pharmaceutical drugs?

Section 1 - Introduction

Virtually all of the world's developed jurisdictions regulate the marketing and distribution of pharmaceutical drugs and other health products to ensure they are safe and effective for human use. In order to obtain marketing approval for a new drug, jurisdictions such as Canada require manufacturers to submit detailed information to their health regulatory authority, including: (1) details of the methods and controls to be used in the manufacture, preparation and packaging of the new drug;[1] (2) the results of pre-clinical testing done *in vitro* and *in vivo*, to assess the drug's performance and potential toxicity;[2] and (3) the results of clinical trials involving humans to assess the drug's benefits and risks.[3]

In Canada, drug manufacturers are required to conduct three phases of human clinical trials.[4] Phase one clinical trials are first conducted on a small number of healthy volunteers, who are given the drug to determine whether it is safe for human use.[5] Next, phase two clinical trials are completed, to evaluate the efficacy of the drug in patients with medical conditions to be treated, diagnosed or prevented, and to determine the side-

[1] *Food and Drug Regulations*, C.R.C., c. 870, s. C.08.002(2)(e).
[2] Health Canada, *Product Life Cycle* (Ottawa: Health Products and Food Branch) online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/biotech/health-prod-sante/prod_life-vie_e.html>.
[3] Canadian Pharmacists Association, "Drugs: From research lab to pharmacy shelf" (January, 2005), online: <http://www.pharmacists.ca/content/hcp/resource_centre/drug_therapeutic_info/pdf/DrugApprovalProcess.pdf >.
[4] Health Canada, *Guidance for clinical trial sponsors: Clinical trial applications* (Ottawa: Health Products and Food Branch) (June 25, 2003) online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/ctdcta_ctddec_e.pdf > [Health Canada].
[5] Meir Perez Pugatch, "Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access" (October 12-16, 2004) ICTSD-UNCTAD Dialogue on ensuring policy options for affordable access to essential medicines, online at: <http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf> [*Pugatch*, Data Exclusivity].

effects and risks associated with the drug.[6] Finally, phase three clinical trials are conducted on a large number of patients (usually thousands) over a defined period of time, to gain additional safety and efficacy data needed for a risk/benefit assessment of the drug.[7]

During the past few decades, the cost of conducting the clinical trials required for obtaining marketing approval of pharmaceutical drugs has become extremely expensive. As such, clinical trial results conclusively demonstrating a drug's safety and efficacy function as a valuable asset for an "innovator",[8] and a market barrier to entry for subsequent applicants seeking to obtain regulatory approval for therapeutically equivalent versions of a new drug. Therefore, the question of whether a government allows or precludes subsequent applicants from relying upon an initial applicant's data has become an extremely important public policy decision. In fact, the protection of clinical trial data has been described as "one of the most interesting issues in the current discussion on pharmaceutical intellectual property policy-making in the global arena".[9]

At the domestic level, if a government decides to enact a "data protection"[10] regime, the initial applicant to submit conclusive safety and efficacy data and obtain a marketing authorization for a new drug is granted a term of protection for its data, thereby

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[6] Health Canada, *supra* note 4 at 3.
[7] *Ibid.*
[8] Throughout this thesis, the terms 'innovator' or 'originator' will be used interchangeably to refer to the first pharmaceutical manufacturer that obtains a marketing approval authorization for a particular drug product. Although the term 'brand-name manufacturer' is perhaps more appropriate, the terms 'innovator' and 'originator' are used within Canada's proposed data protection regulation. Therefore, for the sake of consistency, the terminology used by the federal government of Canada shall be followed in this thesis.
[9] Pugatch, *Data Exclusivity*, *supra* note 5 at 3.
[10] Throughout this thesis, the term "data protection" shall be used to encompass both data exclusivity and market exclusivity.

preventing subsequent applicants from accessing, referring to, or relying upon the submitted information. This form of data protection is referred to as 'data exclusivity', due to the fact that the initial applicant is granted an exclusive right to its information for a particular period of time. Even the health regulatory authority to which the test results are submitted is not permitted to examine or rely upon an innovator's data to approve subsequent or 'generic' applications. In this regard, it is important to distinguish between the concept of data exclusivity described above, and the related concept of 'market exclusivity'. Both data exclusivity and market exclusivity are forms of data protection. However, if data is protected by a term of market exclusivity, generic manufacturers *are* permitted to submit an application for marketing approval to the relevant government agency and to refer to an innovator's safety and efficacy data. A generic company simply has to wait for the period of market exclusivity to lapse before obtaining regulatory approval, assuming its drug is deemed to be pharmaceutically equivalent and bioequivalent to the innovator's drug. Therefore, 'data exclusivity' can be described as a stronger form of data protection than 'market exclusivity', since a generic manufacturer has to wait for the period of data exclusivity to lapse before the government authority can even consider its application.

Data protection exists regardless of whether a pharmaceutical drug is protected by a patent, although the applicable periods of exclusivity may run concurrently with each other. The fact that data protection is independent from patent protection is another reason for its importance in the current debate pertaining to intellectual property rights. Many of the discoveries in the field of biotechnology in the coming decades may be

formulations of naturally occurring substances or multi-cellular life forms, both of which are not always considered to be patentable subject matter. Hence, preventing submitted clinical trial results from being relied upon by subsequent applicants may be the only means of preventing the marketing approval of generic versions of medicinal biological products.

The United States ("US") and the European Union[11] ("EU") were the first jurisdictions in the world to enact legislative regimes providing protection for clinical trial data submitted to their health regulatory authorities in applications for marketing approval of pharmaceutical drugs. In 1984, the US enacted legislation[12] providing innovative pharmaceutical companies with a five-year period of data exclusivity for the results of clinical trials establishing a new drug's safety and efficacy.[13] Moreover, since 1987, the European Union has also provided innovators with a prescribed period of regulatory data protection for submitted clinical trial results.[14]

In contrast, Canada has yet to enact an explicit data protection regime. However, on December 11, 2004, the federal government published a proposed regulation,[15] which would have amended Canada's *Food and Drug Regulations*[16] and provided innovators

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[11] Note that the European Union was called the European Economic Community when the Council adopted the first Directive pertaining to data protection.
[12] *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) [*Hatch-Waxman Act*].
[13] 21 U.S.C. § 355(c)(3)(D)(ii) (effective for drugs approved after September 24, 1984).
[14] EC, *Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products* [1987] O.J. L. 15/36 [*Directive 87/21/EEC*].
[15] *Regulations Amending the Food and Drug Regulations (1390 – Data Protection)*, C. Gaz. 2004 I. 3712 [2004 Regulation].
[16] C.R.C., c. 870, as amended.

with an eight-year period of market exclusivity for the undisclosed test results and other data submitted for obtaining marketing approval of pharmaceutical drugs. Due to a subsequent federal election, this proposed regulation was never enacted.

On June 17, 2006 a new federal government once again published a proposed data protection regulation in Part I of the Canada Gazette.[17] The stated intent of this new '2006 Regulation' was to "allow the innovator, or originator, of the data to protect the investments made in the development of the [drug] product".[18] If brought into force, the 2006 Regulation will provide innovators with a six-year period of data exclusivity, followed by an additional two-year period of market exclusivity. The additional two-year period was stated to be "generally reflective of the period of time required to approve a [Canadian] drug submission, as well as the time required for a generic manufacturer to meet its obligations under the *Patented Medicines (Notice of Compliance) Regulations*".[19] Furthermore, the eight-year period of market exclusivity for a particular innovative drug can be lengthened by an additional six months if the innovator submits additional clinical trial results pertaining to the use of the innovative drug in relevant pediatric populations.[20]

It is the goal of this thesis to discuss and critically examine Canada's proposed data protection regulation from a number of legal and theoretical perspectives. In the remaining sections of this Chapter, Canada's current pharmaceutical drug regime will be

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[17] *Regulations Amending the Food and Drug Regulations (Data Protection)*, C. Gaz. 2006 I. 1598 online: Canada Gazette <http://canadagazette.gc.ca/partI/2006/20060617/pdf/g1-14024.pdf> [2006 Regulation].
[18] *Ibid.* at 1598.
[19] *Ibid.* at 1599.
[20] *Ibid.* at 1605, s. C.08.004.1(4).

discussed, with particular emphasis on generic drug entry. In addition, the cost of conducting human clinical trials and generating the safety and efficacy data required for the approval of pharmaceutical drugs will also be examined. In Chapter II of this thesis, the data protection regimes of various jurisdictions will be introduced, in order to provide a basis with which to compare and contrast Canada's proposed legislation. In Chapter III, Canada's international obligations pursuant to the NAFTA and the TRIPs Agreement will be introduced. Moreover, the Federal Court of Canada's decision in *Bayer v. Attorney General of Canada et al.*[21] will also be discussed. In addition, the legislative provisions of the 2006 Regulation will be critically examined. In Chapter IV of the thesis, the four justificatory theories that currently dominate scholarly debate regarding intellectual property rights will be introduced. Moreover, an attempt will be made to justify time-limited property rights in marketing approval data using these four theoretical perspectives. In Chapter V of the thesis, potential amendments to the 2006 Regulation will be proposed, so that Canada's position as a drug-importing country is taken into account in determining the proper scope and application of its data protection regime.

Section 2 - Canada's pharmaceutical drug regime

In Canada, provincial governments are responsible for, *inter alia*, administering hospital insurance plans, while the federal government is responsible for regulating the approval of medicinal drugs and other health products. Pursuant to the *Food and Drugs Act*,[22] the Therapeutics Products Directorate of Health Canada applies the provisions of the *Food*

[21] (1998), 84 C.P.R. (3d) 129 (F.C.T.D.).
[22] R.S.C., c. F-27, as amended.

and Drug Regulations to ensure that all new pharmaceutical drugs and medical devices approved for sale in Canada are safe and effective.[23]

A 'new drug' is defined in s. C.08.001.1 of the *Food and Drug Regulations* as a drug containing 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". In order to obtain government approval to market and sell a new drug, Health Canada requires an initial applicant, also called an 'innovator', to submit an application called a New Drug Submission ("NDS"). Among other requirements, the following information must be included within a NDS: (1) a list of the ingredients of the new drug;[24] (2) details pertaining to the method used to manufacture the new drug;[25] (3) the proposed dosage of the new drug;[26] (4) the claims to be made for the new drug;[27] (5) "detailed reports of the tests conducted to establish the safety of the new drug for the purpose and under the conditions of use recommended";[28] and (6) "substantial evidence of the clinical effectiveness of the new drug".[29] The 'detailed reports' establishing the safety of a new drug, and the 'substantial evidence' demonstrating the effectiveness of a new drug constitute the most important 'data' that would be protected for eight years under Canada's proposed data protection regime.

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[23] Health Canada, *Acts and Regulations*, (Ottawa: Health Products and Food Branch) online: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/acts-lois/index_e.html>.
[24] *Food and Drug Regulations*, *supra* note 16, at s. C.08.002(2)(c).
[25] *Ibid.*, s. C.08.002(2)(e).
[26] *Ibid.*, s. C.08.002(2)(k)(ii).
[27] *Ibid.*, s. C.08.002(2)(k)(iii).
[28] *Ibid.*, s. C.08.002(2)(g).
[29] *Ibid.*, s. C.08.002(2)(h).

If the Therapeutic Products Directorate is satisfied that all of the information submitted in a NDS complies with the requirements of the *Food and Drug Regulations*, the Minister of Health will issue a Notice of Compliance ("NOC") to the innovator.[30] Once an innovator receives a NOC, it is permitted to market and sell its new drug in Canada.

If the new drug turns out to be profitable, generic pharmaceutical manufacturers will inevitably want to market and sell their own versions of the new drug. In Canada, if a generic manufacturer wants to obtain a NOC to sell a generic version of a new drug, it must first submit an application to the Minister of Health called an Abbreviated New Drug Submission ("ANDS"). The information that must be included within an ANDS is not nearly as thorough as that of a NDS. Notably, a generic manufacturer does not have to submit 'detailed reports' establishing the safety of its drug, or 'substantial evidence' demonstrating the effectiveness of its drug.[31] Instead, a generic manufacturer must submit evidence from comparative studies establishing that: (1) the generic drug is the pharmaceutical equivalent of the innovative drug, meaning that both drugs contain identical amounts of the identical medicinal ingredients, in comparable dosage forms;[32] and (2) the generic drug is bioequivalent to the innovative drug, as demonstrated by bioavailability studies, pharmacodynamic studies or clinical studies.[33]

However, in addition to filing an ANDS, there are other legal and regulatory issues to resolve before a generic manufacturer can market and sell its version of an innovative

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[30] *Ibid.*, s. C.08.004(1)(a).
[31] *Ibid.*, s. C.08.002.1(2)(a).
[32] *Ibid.*, s. C.08.002.1(2)(c)(i).
[33] *Ibid.*, s. C.08.002.1(2)(c)(ii).

drug. Indeed, the legal and regulatory framework pertaining to the entry of generic pharmaceutical drugs in Canada is complex, particularly with regards to drugs whose medicinal ingredients are protected by Canadian patents.

At this point it is necessary to briefly explain what is meant by the terms 'Canadian patent' and 'patent protection'. A Canadian patent provides an inventor with time-limited exclusive rights for inventions that are found to be novel, useful and non-obvious on the date that an application for a patent is filed with the Canadian Patent Office. Pursuant to Canada's patent regime found within the *Patent Act*,[34] the exclusive rights afforded by a Canadian patent subsist for twenty years, beginning at the date of the patent application. However, it should be emphasized that the inventor to whom a patent is issued – also called the 'patentee' – is not conferred with any positive rights to exploit the invention. In other words, obtaining a patent does not necessarily provide a patentee with the means to make, use or sell the patented invention. Instead, patent protection can be best described as a bundle of 'negative rights', in that a patent prevents other legal persons in Canada from making, using, selling or importing the invention claimed in the patent. Pursuant to s. 2 of the *Patent Act*, the term 'invention' means any "new and useful art, process, machine, manufacture or composition of matter".[35] A pharmaceutical drug is considered to be a composition of matter and is therefore patentable.

Prior to March 12, 1993, Health Canada's ability to issue NOCs to drug manufacturers pursuant to the *Food and Drug Regulations* was separate and removed from Canada's

[34] R.S.C. c. P-4, as amended.
[35] *Ibid.*, s. 2.

patent regime. Therefore, even if the medicinal ingredient within a drug was protected by an innovator's patent, there was no law preventing the Minister of Health from issuing a NOC to a generic pharmaceutical manufacturer. Of course, if the generic manufacturer actually began to market and sell a drug containing a patented medicinal ingredient, the patentee would undoubtedly commence an action for patent infringement. Nevertheless, the important point here is that the Minister of Health was under no obligation to consider whether the medicinal ingredient was protected by a Canadian patent. In fact, pursuant to the compulsory licensing scheme in force prior to 1993, the Minister of Health was even permitted to rescind an innovator's patent protection for certain pharmaceutical products.[36] However, on March 13, 1993, the *Patented Medicines (Notice of Compliance) Regulations*[37] came into force, and Health Canada's ability to ignore an innovator's patents when considering a generic drug submission was laid to rest.

The *NOC Regulations* link Health Canada's ability to issue an NOC for a generic drug to the patent status of the equivalent innovative drug intended to be copied by the generic manufacturer. Pursuant to s. 4(1) of *NOC Regulations*, an innovator who files an NDS, or has been issued a NOC in respect of a drug that contains a "medicine", may submit to the Minister of Health a list of its patents that are related to the drug in question.[38] The term "medicine" is defined extremely broadly in s. 2 of the *NOC Regulations* as "a substance intended or capable of being used for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof".[39]

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[36] R.S.C., 1985, c. 33 (3rd Supp.).
[37] SOR/93-133, as amended [*NOC Regulations*].
[38] *Ibid.*, s. 4(4).
[39] *Ibid.*, s. 2.

In order to properly list a patent with the Minister of Health, the innovator's patent must "contain a claim for the medicine itself or a claim for the use of the medicine".[40] Notably, the Federal Court and Federal Court of Appeal have held that a 'claim for the medicine itself' includes claims for pharmaceutical compositions of active and inactive ingredients.[41]

Pursuant to s. 3(1) of the *NOC Regulations*, the Minister of Health is required to maintain a Patent Register, containing all of the information submitted by innovators in their patent lists. Furthermore, if a generic manufacturer files a drug submission for a NOC, and compares its drug or makes reference to a previously approved innovative drug for the purpose of demonstrating bioequivalence, the generic manufacturer must address each patent listed on the Patent Register related to the innovative drug.[42] The generic manufacturer must either accept that its NOC will not be issued until all of the innovator's patents listed on the Patent Register expire;[43] or, alternatively, the generic manufacturer must submit a Notice of Allegation ("NOA") to the innovator, alleging that the innovator's patents are not valid, or that no claim for the medicine itself would be infringed if the generic manufacturer was issued a NOC and began marketing and selling its version of the drug.[44]

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[40] *Ibid.*, s. 4(2).
[41] *Hoffman-La Roche Ltd. v. Minister of National Health and Welfare* (1995), 62 C.P.R. (3d) 58 (F.C.T.D.) at 72, aff'd. (1995), 67 C.P.R. (3d) 25 (F.C.A.).
[42] *NOC Regulations*, *supra* note 37, s. 5(1).
[43] *Ibid.*, s. 5(1)(a).
[44] *Ibid.*, s. 5(1)(b).

The innovator and the Minister of Health must be served with the NOA. The innovator then has forty-five days in which to commence a judicial review application for an order prohibiting the Minister of Health from issuing a NOC to the generic manufacturer until all of the listed patents have expired.[45] The commencement of a judicial review application automatically triggers a twenty-four month statutory stay,[46] which prevents the Minister of Health from issuing a NOC, unless within that period the proceeding is disposed of by the Federal Court.[47]

At the judicial review proceeding, the onus is on the innovator to prove, on a balance of probabilities, that the generic manufacturer's allegations are not justified.[48] If the Court finds that there is no way for the generic company to manufacturer and sell its proposed drug without infringing the patent(s) listed by the innovator, then the Minister of Health is prohibited from granting a NOC for the generic drug until the patent(s) lapse. Alternatively, if the Court finds that the allegations within the NOA *are* justified, and the innovator's patents are invalid, then the Minister of Health is under no restriction from granting an NOC to the generic manufacturer.

As mentioned earlier, in order for a generic manufacturer to obtain a NOC, an ANDS must be filed with the Minister of Health. The ANDS must contain, *inter alia*, comparative studies establishing that: (1) the generic drug is the pharmaceutical equivalent of the innovative drug; and (2) the generic drug is bioequivalent to the

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[45] *Ibid.*, s. 6(1).
[46] *Ibid.*, s. 7(1)(e).
[47] *Ibid.*, s. 7(4).
[48] *Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc. et al.* (2005), 42 C.P.R. (4th) 481 (F.C.T.D.) at para. 55.

innovative drug. After bioequivalence is established, the Therapeutics Products Directorate may choose to 'examine' and 'rely' upon the data found within the applicable NDS of the innovator in order to confirm that a generic drug is safe and effective. In this regard, it is important to note that in 1995, the *Food and Drug Regulations* were amended,[49] and a provision providing for a five-year period of market exclusivity was supposedly brought into force. This data protection provision provided that if the Minister of Health examined or relied upon the safety and efficacy data submitted by an innovator in support of a generic drug submission, the Minister was prohibited from issuing a NOC to the generic manufacturer for a period of five years, beginning on the date that the innovator received its NOC.[50] However, the Therapeutics Products Directorate has always maintained that no physical examination or reliance of the innovator's data actually takes place during the review of a generic drug submission. This interpretation of the applicability of the 1995 data protection provision was upheld by the Federal Court and Federal Court of Appeal in judicial decisions which will be examined in Chapter III. The 2006 Regulation essentially overturns this judicial decision where bioequivalence forms the basis of an abbreviated new drug submission. In other words, if the 2006 Regulation is brought into force, a generic manufacturer seeking a NOC on the basis of a direct or indirect comparison of its drug with an innovative drug will be deemed to be relying upon the innovator's safety and efficacy data.

In theory, of course, generic manufacturers are free to conduct their own clinical trials in order to demonstrate the safety and effectiveness of their drug products. Thus, data

[49] SOR/95-411, s. 6.
[50] *Food and Drug Regulations*, *supra* note 16, s. C.08.004.1(1).

protection is significantly different than patent protection, which affords a patentee protection against independent invention. If an innovative drug is not protected by any applicable patents, generic manufacturers are *legally* permitted to obtain a marketing authorization for their version of the drug. However, as the next section will demonstrate, the financial resources required for conducting clinical trials and obtaining safety and efficacy data constitutes a *de facto* market barrier to entry for generic drug manufacturers.

Section 3 - The cost of generating safety and efficacy data for pharmaceutical drugs

The cost of developing innovative pharmaceutical drugs which are safe and effective for the treatment of human diseases is staggeringly expensive. In November 2001, the Tufts Centre for the Study of Drug Development conducted an in-depth study using information obtained directly from research-based pharmaceutical companies.[51] The Tufts Centre estimated that the average cost to develop a new pharmaceutical drug in the US in 2001 was $802 million.[52] Moreover, the 2001 study was an update of a previous Tufts Centre study completed in 1991, when the average cost to develop a new drug in the US was estimated to be $231 million (in 1991 US dollars).[53] According to the 2001 Tufts Centre study, the substantial increase in drug development costs from 1991 to 2001

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[51] Tufts Centre for the Study of Drug Development, "Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million", online: Tufts <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6> [Tufts Centre Study]
See also Robert Pear, "Research Costs for New Drugs Said to Soar", online: The New York Times <http://www.nytimes.com/2001/12/01/business/01DRUG.html?ex=1145592000&en=6b8831da1fb2e0bc&ei=5070>.

[52] Tufts Centre for the Study of Drug Development, "A Methodology for Counting Costs for Pharmaceutical R&D", online: Tufts <http://csdd.tufts.edu/newsevents/recentnews.asp?newsid=5> [Tufts methodology for counting costs].

[53] Tufts Centre Study, *supra* note 51.

was largely due to the increased cost of human clinical trials.[54] In fact, it was estimated that the cost of clinical trials accounts for 70% of the direct expenditures to develop a new pharmaceutical drug.

However, it should be noted that the 2001 Tufts Centre study was severely criticized by the US Generic Pharmaceutical Association and dismissed by consumer advocacy groups as being a means for the innovative pharmaceutical industry to justify its profits and to continue price-gouging the American public.[55] *Public Citizen*, a consumer advocacy group, alleged that there were two major flaws in 2001 Tufts Centre study. The first alleged flaw was that none of the clinical trials for the sixty-eight pharmaceutical drugs examined in the study were subsidized by the US government. According to *Public Citizen*, many, if not most drugs brought to market receive financial support from the US government at some stage of their discovery and development.[56] Therefore, the Tufts Centre study allegedly focused on a skewed sample of non-subsidized drugs and therefore inflated the actual cost of drug development. The second alleged flaw in the Tufts Centre study was that approximately half of the estimated $802 million cost to develop a new drug was stated to be the "opportunity cost of capital" - in other words, the amount of money that pharmaceutical companies would have made had they invested their money elsewhere.[57] Furthermore, *Public Citizen* alleged that the Tufts Centre study failed to account for the fact that pursuant to US federal tax laws, pharmaceutical

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[54] The Kaiser Family Foundation, "Daily Health Policy Report", online: Kaiser Network.org <http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=8333>.
[55] *Ibid.*
[56] Public Citizen, "Tufts drug study is skewed; True figure of R&D costs likely is 75 percent lower", online: Public Citizen <http://www.citizen.org/pressroom/release.cfm?ID=954>.
[57] *Ibid.*

companies can deduct 34% of their drug development costs. Nevertheless, even after correcting the alleged flaws in the Tufts Centre study, *Public Citizen* estimated that the actual cost of developing a new pharmaceutical drug in the US to be $110 million.

To date there have been no comprehensive studies pertaining to the actual cost of innovative drug development in Canada. However, it appears that clinical drug trials are significantly less expensive in Canada, as compared to the US. In a report published in May 2003, Industry Canada estimated that international pharmaceutical companies would save between 30%-45% on their clinical trial costs by conducting human clinical trials in Canada instead of the US.[58] However, even accounting for a 30%-45% savings on the clinical testing required to secure marketing approval for pharmaceuticals, innovative drug development in Canada is undoubtedly expensive. As the cost of clinical trials for pharmaceutical drugs increases, the test results which conclusively prove that a drug is safe and effective for human consumption become extremely valuable assets. As a result, innovators within the pharmaceutical and biotechnology industries have lobbied the federal government of Canada to provide protection for the safety and efficacy data submitted in marketing approval applications.

As mentioned above, on June 17, 2006, the federal government published a proposed data protection regulation in Part I of the Canada Gazette. The data protection regime found within the proposed 2006 Regulation would provide innovators with a six-year period of data exclusivity, followed by a two-year period of market exclusivity, for a total period of

[58] Industry Canada, "Clinical Trials in Canada: Quality with Cost Advantage", online: Industry Canada <http://www.investincanada.gc.ca/cmfiles/english_brochure45ldr-1082004-8495.pdf>.

data protection of eight years. As opposed to the current provision found in s. C.08.004.1(1) of the *Food and Drug Regulations*, the proposed scheme found within the 2006 Regulation would provide innovators with *de facto* eight-year property right in their clinical trial data. This would result in a period of protection longer than the analogous provision found within the US data protection regime. Indeed, if the 2006 Regulation is enacted and brought into force, Canada will have one of the most innovator-friendly data protection regimes in the world. Considering that Canada's innovative drug industry is quite small by international standards,[59] the question of whether a strong data protection regime constitutes prudent public policy remains to be determined. However, before passing judgment on the merits of Canada's proposed 2006 Regulation, it is important to consider the scope and application of existing data protection regimes found within other jurisdictions around the world, which is the subject of Chapter II of this thesis.

[59] Patented Medicines Prices Review Board Study Series S-0217, "A comparison of pharmaceutical research and development spending in Canada and selected countries" (December 2002), online: Patented Medicines Prices Review Board <http://www.pmprb-cepmb.gc.ca/CMFiles/ss-0217e14HCB-492003-5262.pdf>.

Chapter II – Data protection regimes in jurisdictions other than Canada

Section 1 - Introduction

In this Chapter, a number of the data protection regimes found in other jurisdictions around the world will be discussed. The United States ("US") and the European Union ("EU") will figure prominently in the following sections, since they were the first jurisdictions to enact comprehensive legislation within this area of intellectual property law. In section two, the data protection regime pertaining to the US pesticide industry will be introduced, in order to dispel the notion that marketing approval data must be protected with a time-limited property right. In section three, the US regime relating to the entry of generic pharmaceutical drugs will be introduced, with particular emphasis on the data protection scheme found within the US legislation. In section four, the protection of marketing approval data in the EU will be examined and compared with the proposed Canadian data protection regulation. Finally, in section five, the data protection regimes found within other jurisdictions will be discussed.

Section 2 - Data protection laws within the US pesticide industry

The US was the first jurisdiction in the world to introduce a legislative regime providing for protection of marketing approval data submitted to a government agency. Interestingly, this first data protection regime did not pertain to the registration of pharmaceutical drugs with the Food and Drug Administration ("FDA"); instead, it related

to the registration of pesticides with the then newly created Environmental Protection Agency ("EPA").[60]

Due to mounting public concern regarding the safety of pesticides and their effect on the environment, the US congress passed the *Federal Environmental Pesticide Control Act of 1972*[61] ("*EPCA*") which substantially amended the 1947 *Federal Insecticide, Fungicide, and Rodenticide Act*[62] ("*FIFRA*"), thereby transforming *FIFRA* from a labeling law into a comprehensive regulatory statute.[63] The *EPCA* established a '1972 *FIFRA* regime' for controlling the sale and distribution of pesticides and mandated that all pesticides containing a new "active ingredient"[64] be registered with the EPA.[65]

Pursuant to the 1972 *FIFRA* regime, an application to distribute and sell a pesticide had to include a statement of all claims to be made for the pesticide, as well as any directions for its use.[66] An application was also required to include "a full description of the tests made and the results thereof upon which the claims are based".[67] In other words, the EPA required pesticide manufacturers to submit test data to substantiate the claims that were made regarding the efficacy of their pesticides.

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[60] The EPA was established in 1970 as part of President Nixon's "Reorganization Plan of 1970", 35 Fed. Reg. 15623 (1970). See US Environmental Protection Agency "Reorganization Plan No. 3 of 1970" (July 9, 1970), online: EPA <http://epa.gov/35thanniversary/org/origins/reorg.htm>.
[61] Pub. L. No. 92-516, 86 Stat. 973 (codified as amended at 7 U.S.C. § 136a-136y) [*EPCA*].
[62] 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §136 *et seq.* [*FIFRA*].
[63] *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) at 991 [*Ruckelshaus*].
[64] 7 U.S.C. § 136 (a)(1).
[65] *Ruckelshaus*, *supra* note 63 at 992.
[66] 7 U.S.C. §136a (c)(1)(C).
[67] 7 U.S.C. §136a (c)(1)(D). Note that in 1990 subsection (c)(1)(D) was renumbered as subsection (c)(1)(F).

The 1972 *FIFRA* regime also contained a provision allowing the EPA to consider test data submitted in an original application in order to approve subsequent applications.[68] However, the subsequent (i.e. generic) applicant was required to make "an offer to compensate the original data submitter"[69] and to submit this offer to the EPA. The exact amount of compensation was to be negotiated by the original data submitter ("originator") and the generic, or, failing such an agreement, by the EPA. If the originator disagreed with the EPA's assessment, it could then apply for judicial review.[70] In effect, the 1972 *FIFRA* regime created a data-licensing scheme whereby data submitted to the EPA would be protected by a "remuneration right",[71] as opposed to an exclusive time-limited proprietary right.

The scope of the data-licensing provisions were limited, however, by a provision in the 1972 *FIFRA* regime which allowed the originator to designate certain portions of the data submitted to the EPA as "trade secrets or commercial or financial information".[72] If the EPA agreed with this 'trade secret' designation made by the originator, it was precluded from considering such data in a subsequent generic application.[73] If the EPA disagreed with the 'trade secret' designation of the originator, the originator could seek a declaratory judgment in federal district court to the effect that its submitted data should have received a 'trade secret' designation.[74]

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[68] *Ibid.*
[69] *Ibid.*
[70] *Ruckelshaus*, *supra* note 63 at 992.
[71] Trevor M. Cook, *The protection of regulatory data in the pharmaceutical and other sectors* (London: Sweet & Maxwell, 2000) at 70 [Cook].
[72] Pub. L. No. 92-516, §10(a), 86 Stat. 973 at 989.
[73] *Ibid.*, §10(b).
[74] *Ibid.*, §10(c).

Since the 1972 *FIFRA* regime did not specify standards for the designation of submitted data as "trade secrets or commercial or financial information", substantial litigation ensued.[75] The US Congress also concluded that the EPA "lacked the expertise to establish the proper amount of compensation"[76] under *FIFRA*'s data-licensing scheme. As such, in 1978 Congress enacted the *Federal Pesticide Act of 1978* ("*FPA*"), thereby amending *FIFRA* once again. The '1978 *FIFRA* regime' created by the *FPA* provided that health, safety and environmental data submitted by the originator could not obtain the 'trade secret designation'.[77] However, the 1978 *FIFRA* regime (which remains in effect as of 2006), grants originators a 10-year period of data exclusivity for data submitted to the EPA after September 30, 1978 to "support the application for the original registration of the pesticide".[78] All other data submitted after December 31, 1969 may be cited and considered in support of another application for fifteen years after the original submission if the applicant offers to compensate the original submitted. If the parties cannot agree on the amount of compensation, either may initiate a binding arbitration proceeding. If the originator refuses to participate in the negotiations or arbitration, it forfeits a claim for compensation.[79]

In addition, the 1978 *FIFRA* regime also grants a ten-year period of data exclusivity for "an application for an amendment adding any new use to the registration [of a pesticide] and that pertains solely to such new use".[80] In other words, *FIFRA* does not discriminate

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[75] *Ruckelshaus, supra* note 63 at 993.
[76] 123 Cong. Rec. 25709 (1977) (Statement of Sen. Leahy) in *Thomas v. Union Carbide Agricultural Products Co. et al.*, 473 U.S. 568 at 572..
[77] 7 U.S.C. §136h subsection (d)(1)-(3).
[78] 7 U.S.C. §136a (c)(1)(F)(i).
[79] 7 U.S.C. §136a (c)(1)(F)(iii).
[80] 7 U.S.C. §136a (c)(1)(F)(i).

between the data submitted in an application to register a pesticide containing a new active ingredient and the data submitted in an application for a new use of that same active ingredient. This policy of granting of a full period of data protection for the registration of a new use of a previously approved active ingredient is significantly different from the US regime pertaining to the registration of pharmaceutical drugs, which is the subject of the next section.

Section 3 – The US pharmaceutical drug regime

The Food and Drug Administration ("FDA") is the US government authority responsible for assuring the safety, efficacy, and security of human and veterinary drugs and biological products.[81] The FDA was first given authority to regulate pharmaceutical drugs in 1938, when Congress enacted the *Federal Food, Drug, and Cosmetic Act* ("*FDCA*").[82] The 1938 *FDCA* prohibited the marketing of any "new drug"[83] in the US prior to FDA approval of a new drug application ("NDA"), to be submitted by an initial applicant. From 1938 until 1962, a NDA simply had to include studies demonstrating that the new drug was safe for human use in order to obtain FDA approval.[84]

In 1962, the *FDCA* was substantially amended following the thalidomide disaster, which prompted the American public to demand more stringent drug regulations.[85] The 1962

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[81] US Department of Health and Human Services, "FDA's Mission Statement", online: US Food and Drug Administration <http://www.fda.gov/opacom/morechoices/mission.html>.
[82] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301-303).
[83] Pursuant to 21 U.S.C. § 321(p), "new drug" was defined as "any drug not generally recognized as safe".
[84] 21 U.S.C § 355 (1938).
[85] See *e.g.* US Department of Health and Human Services, "Milstones in US Food and Drug Law History", online: US Food and Drug Administration <http://www.fda.gov/opacom/backgrounders/miles.html>.

amendments[86] to the *FDCA* mandated that all new drugs not only be safe, but also be shown to be *effective* for their intended use.[87] An applicant was required to provide the FDA with "substantial evidence" that its drug was effective for its intended use, which meant that it had to submit "at least two 'adequate and well-controlled clinical investigations'[88] demonstrating statistically significant benefits for consumers".[89] The *FDCA* also forbid the FDA from disclosing confidential information entitled to protection under US law as a "trade secret",[90] which included the clinical trial data submitted by innovators in a NDA.[91] As such, the 1962 amendments created a legal barrier to generic market entry.

In 1970, the FDA adopted regulations establishing the first abridged procedure for the approval of generic drugs. However, the scope of this abridged procedure was limited to generic versions of new drugs approved prior to 1962 and determined by an internal FDA review process to be safe and effective.[92] In 1980, the FDA introduced a second type of generic approval procedure, which became known as the "paper-NDA", due to the fact that a generic drug's safety and efficacy could be established by referring to journal articles and other studies published in the scientific and medical literature.[93] However,

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[86] *Kefauver-Harris Amendment of 1962*, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 321, 331-32, 348, 351-53, 355, 357-60, 372, 374, 376, 381).
[87] *Ibid.*, 21 U.S.C. § 355 (1962).
[88] 35 Fed. Reg. 7,250 (1970).
[89] Elizabeth S. Weiswasser & Scott D. Danzis, "The Hatch-Waxman Act: History, Structure, and Legacy" (2003) 71:2 Antitrust L.J. 585 at 589.
[90] 21 U.S.C. § 331(j) (1982).
[91] James T. O'Reilly "Knowledge is power: Legislative control of drug industry trade secrets (1985), 54 U. Cin. L. Rev. 1 at 7.
[92] Ellen Flannery & Peter Hutt, "Balancing competition and patent protection in the drug industry: The drug price competition and patent term restoration act of 1984" (1985) 40 Food Drug Cosm. L.J. 269 at 273, in Elizabeth S. Weiswasser & Scott D. Danzis, *supra* note 89 at 592.
[93] Elizabeth H. Dickinson, "FDA's role in making exclusivity determinations" (1999) 54 Food Drug L.J. 195 at 196.

since the approval of a paper-NDA was predicated upon sufficient evidence within the scientific and medical literature, few generic drugs could be approved through this procedure. In fact, in 1984 there was congressional testimony to the effect that only fifteen paper-NDAs had been approved for generic versions of post-1962 drugs.[94] Congressional testimony also revealed that there were 150 post-1962 drugs off-patent for which no generic alternative existed, due to the fact that few generic manufacturers could afford to conduct clinical trials and obtain 'substantial evidence' that their drugs were effective.

In the late 1970s and early 1980s, consumer advocates and American legislators began to explore ways of increasing competition within the pharmaceutical industry and concluded that the disclosure of testing data was a viable means of expanding the generic drug market.[95] Several legislative initiatives failed; however in 1984, the *FDCA* and the US patent regime pertaining to pharmaceutical drugs were both substantially amended with the enactment of the *Drug Price Competition and Patent Term Restoration Act*,[96] commonly referred to as the *Hatch-Waxman Act*. The *Hatch-Waxman Act* is an extremely complex piece of legislation, due to the fact that it sought to achieve the twin goals of facilitating FDA approval of generic drugs, while at the same time protecting the innovative pharmaceutical industry's investments in drug development.

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[94] H.R. Rep. No. 98-857, pt. 1 (1984), in Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and its impact on the drug development process" (1999) 54 Food Drug L.J. 187 at 187.
[95] James O'Reilly, *supra* note 91 at 14.
[96] *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 15 U.S.C., § 68b-68c, 70b; 21 U.S.C., § 301, 355, 360cc; 28 U.S.C., sec. 2201; and 35 U.S.C., secs. 155, 155A, 156, 271, 282) [*Hatch-Waxman Act*].

The *Hatch-Waxman Act* introduced an abridged procedure for the approval of generic versions of previously approved drugs called an abbreviated new drug application ("ANDA").[97] An ANDA enables generic manufacturers to avoid conducting the expensive clinical trials required to establish the safety and effectiveness of a drug. Instead, a generic drug must be shown to be pharmaceutically equivalent, as well as "bioequivalent" to the innovative drug in order to obtain FDA approval.[98] A generic drug is considered to be bioequivalent if the rate and extent of its absorption does not show a significant difference from that of the applicable innovative drug when administered at the same dose.[99]

The *Hatch-Waxman Act* also introduced a data protection regime to the *FDCA*. Specifically, the *FDCA* now provides that if the FDA approves an innovator's NDA for a drug containing an "active ingredient" that has never been approved in the US, no subsequent applicant is permitted to submit an ANDA to the FDA for a period of five years.[100] In other words, the US regulatory regime provides for a five-year period of *data exclusivity* for pharmaceutical drugs containing new active ingredients. Furthermore, the *Hatch-Waxman Act* also provides an additional three years of *market exclusivity* for NDAs or supplements to NDAs approved by the FDA containing "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant".[101] A supplement to an NDA is

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[97] *FDCA* § 505(j), codified at 21 U.S.C. § 355(j) (2006).
[98] *FDCA* § 505 (j)(8)(B), codified at 21 U.S.C. § 355(j)(8)(B) (2006).
[99] *Ibid.*
[100] *FDCA* §§ 355(c)(3)(D)(ii), (j)(5)(D)(ii), codified at 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii) (2006).
[101] *FDCA* §§ 355(c)(3)(D)(iii), (j)(5)(D)(iii), codified at 21 U.S.C. §§ 355(c)(3)(E)(iii), (j)(5)(F)(iii) (2006).

typically filed in order to obtain marketing approval for new formulations or indications of a drug containing a previously approved 'active ingredient'.[102]

With regards to the US patent regime, the *Hatch-Waxman Act* allows innovators to submit to the FDA a list of all patents which claim the drug for which the innovator submitted their NDA.[103] The FDA is, in turn, required to compile a list of all such patents in a publication called the *Orange Book*,[104] which is analogous to the Patent Register maintained by Health Canada. The listing of a patent in the *Orange Book* has important consequences. A generic manufacturer cannot receive FDA approval for its ANDA unless it makes one of four possible "certifications" regarding any relevant patent(s) listed by an innovator in the *Orange Book*. The fourth certification, known as a 'paragraph IV certification', requires a generic manufacturer to provide notice to the innovator, and to include a "detailed statement of the factual and legal basis of the opinion of the [generic manufacturer] that the patent is invalid or will not be infringed".[105] Once an innovator receives notice of the paragraph IV certification, it has forty-five days to file an action for patent infringement against the generic manufacturer. If the innovator commences an action for patent infringement, FDA approval of the generic manufacturer's ANDA is automatically stayed for thirty months.[106] The US regulatory regime created by the *Hatch-Waxman Act* is similar to the Canadian scheme found within the *Patented Medicines (Notice of Compliance) Regulations*. However, the

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[102] Rebecca S. Eisenberg "The shifting functional balance of patens and drug regulation" (2001) 19:4 Health Affairs 119 at 123.
[103] 21 U.S.C. § 355(b)(1) (2006).
[104] Edward Hore, "A comparison of United States and Canadian laws as they affect generic pharmaceutical market entry" (2000) 55 Food Drug L.J. 373 at 378.
[105] 21 U.S.C. § 355(j)(2)(B)(iv)(II) (2006).
[106] 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2006).

Canadian regulatory regime simply provides that generic manufacturers must address an innovator's listed patents before Health Canada is permitted to issue a Notice of Compliance. By contrast, the *Hatch-Waxman Act* not only mandates that generic manufacturers address listed patents, but also stipulates that the US Patent and Trademark Office must consider the period of time that was required for the FDA to approve an innovator's NDA.

Indeed, the *Hatch-Waxman Act* also introduced a new intellectual property right called 'patent term-extension' into the US regulatory drug regime, in order to compensate patentees for the time required for the FDA to review a NDA.[107] Current US patent laws stipulate that the maximum period of patent term-extension for a new drug may not exceed five years.[108] Moreover, the total period of market exclusivity for drug product protected by a US patent cannot exceed fourteen years.[109]

Canada has never provided innovators with patent term-extension. However, as we will see in the next section, the European Union also compensates innovators for the time required to obtain marketing approval of pharmaceutical drugs by artificially extending the life of an innovator's patent.

Section 4 - The protection of marketing approval data within the European Union

The European Union ("EU") is the jurisdiction with the longest period of data protection in the world. However, it is important to note that until recently, many current members

[107] 35 U.S.C. § 156 (2006).
[108] 35 U.S.C. § 156(g)(1)(A) (2006).
[109] 35 U.S.C. § 156(c)(3) (2006).

of the EU did not even provide patent protection for medicinal drug products, let alone data protection. Therefore, it is instructive to examine how the current EU regulatory framework pertaining to pharmaceutical drugs developed.

In the 1950s, France, West Germany, Italy, Belgium, Holland and Luxembourg ratified a number of treaties, including the *EEC* Treaty,[110] which provided for the establishment of a common market, a customs union and harmonized policies in various areas of governance, including public health.[111] In 1965, a "merger treaty"[112] combined the high authorities of the three communities into a single Commission and a single Council of Ministers. The Commission is the body responsible for drafting and proposing legislation for the EEC, while the Council and the European Parliament function as executive and legislative branches, respectively. In this regard, it is important to note that the Council can adopt legislative acts called 'Directives', which mandate that certain legislative results be achieved by each Member State, but allow national governments to choose the form and method of achieving those results.[113] In contrast, a 'Regulation' adopted by the Council has general application and is binding in its entirety and directly applicable in all Member States.[114]

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[110] *Treaty establishing the European Economic Community*, 25 March 1957, 298 U.N.T.S. 11 [*EEC Treaty*].
[111] *Ibid.*, Article 129.
[112] *Treaty establishing a single council and a single commission of the European communities*, 8 April 1965, [1967] O.J. 152.
[113] *Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts*, 2 October 1997, [1997] O.J. C. 340/1, Article 249 (ex. Article 189).
[114] Article 249 (ex. Article 189).

In 1965, the Council adopted Directive 65/65/EEC,[115] which mandated that Member States enact regulatory regimes for the marketing approval of proprietary medicinal products. Specifically, Directive 65/65/EEC provided that an application for an authorization to market a medicinal product in a Member State must be accompanied by, *inter alia*, the results of: (i) physico-chemical, biological or microbiological tests, (ii) pharmacological and toxicological tests, and (iii) clinical trials.[116] In 1975, the Council adopted Directive 75/318/EEC,[117] which established standards and protocols to be used by pharmaceutical companies in respect of the tests and clinical trials required pursuant to Directive 65/65/EEC. However, it was not until the adoption of Directive 87/21/EEC[118] in December 1986 that Member States of the EEC were required to provide protection for the test data and clinical trial results submitted in marketing approval applications to their national authorities.

Directive 87/21EEC amended Directive 65/65/EEC and established an abridged procedure for the approval of medicinal products within the EEC, as well as an explicit period of data protection. In 2001, Directives 87/21/EEC, 65/65/EEC, as well as numerous others, were assembled into a single legislative text and adopted once again as

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[115] *Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products* , O.J. L 22, 09.02.1965 [*Directive 65/65/EEC*].
[116] *Ibid.*, Article 4(8)
[117] *Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, phamaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products*, O.J. L 147 09.06.1975.
[118] *Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products*, O.J. L 15, 17.01.1987, 36–37.

Directive 2001/83/EC.[119] The abridged procedure was codified in Article 10 of Directive 2001/83/EC, which provided for four possible data protection periods: (1) a six-year term of data protection for all drugs approved by Member States' national regulatory authorities, or approved pursuant to the centralized procedure managed by the European Medicines Agency ("EMEA");[120] (2) a six-year period of data protection which lapsed upon the expiry date of the patents protecting the medicinal product; (3) a mandatory ten-year period of data protection in the case of "high-technology medicinal products"[121] that were approved by the EMEA through the centralized procedure; and (4) a ten-year period of data protection for Member States that choose to protect *all* medicinal products marketed within their territory for a ten-year term. The reason why there were four data protection schemes permitted is because Directive 87/21/EEC was adopted shortly after Spain and Portugal joined the European Communities. Prior to 1992, Spain and Portugal did not even grant patents for drug products and would not have favoured the adoption of a ten year data protection period.[122]

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[119] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, O.J. L 311, 28.11.2001, 67–128.

[120] The EMEA coordinates the evaluation and supervision of medicinal products throughout the European Union ("EU"). Medicinal products approved pursuant to the centralized procedure obtain a marketing authorization valid in all Member States of the EU.

[121] High-technology products were defined in the Annex to Council Regulation 2309/93 as:

"Medicinal products developed by means of the following biotechnological processes: recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells, and hybridoma and monoclonal antibody methods";

"Medicinal products developed by other biotechnological processes which, in the opinion of the Agency, constitute a significant innovation";

"Medicinal products administered by means of new delivery systems which, in the opinion of the Agency, constitute a significant innovation";

"Medicinal products presented for an entirely new indication which, in the opinion of the Agency, is of significant therapeutic interest".

[122] Valerie Junod, "Drug marketing exclusivity under United States and European Union law", (2004) 59 Food Drug L.J. 479 at 502-503.

It is important to note that Directive 2001/83/EC was silent as to whether or not newly approved indications or formulations of a previously approved medicinal product were entitled to receive an additional term of data protection. In other words, could a generic manufacturer obtain a marketing authorization for a new indication of an innovative medicinal product, even though that new indication had not been marketed for six or ten years? The European Court of Justice ("ECJ") considered this issue in the *Generics*[123] case, and held that a generic medicinal product that is 'essentially similar' to an innovative product which has been marketed for six (or ten) years may be approved for *all* therapeutic indications and dosage forms authorized for the innovative product.[124] Importantly, the proposed Canadian data protection regulation would also allow a generic manufacturer to obtain a NOC for *all* formulations and indications of a previously approved innovative drug after the initial term of data protection is complete.

Due to the volume of litigation at the ECJ pertaining to interpretation of the term 'essentially similar', significant changes were made to the data protection regime of the European Union ("EU")[125] with the adoption of Directive 2004/27/EC[126] in 2004. Specifically, Article 10(1) of Directive 2004/27/EC provides that a generic applicant does not have to submit the results of pre-clinical tests and clinical trials if it can demonstrate that its medicinal product is a "generic of a reference medicinal product which is or has been authorized ... for not less than eight years in a Member State or in the

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[123] *Generics (UK) and Others v. The Medicines Control Agency*, C-368/96 [1998] ECR I-7967.
[124] *Ibid.* at paras. 53, 56.
[125] Pursuant to the *Treaty on the European Union*, 24 December 2002, O.J. 325, the EEC was renamed the European Community ("EC"), which became one of the three pillars of the European Union ("EU").
[126] *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 (Text with EEA relevance),* O.J. L 136, 30.4.2004, 34–57 [Directive 2004/27/EC].

Community".[127] A generic product must be bioequivalent to the reference product, and have the "same qualitative and quantitative composition in active substances" in order to be considered a "generic medicinal product".[128]

Further, a generic medicinal product that obtains an authorization after the eight year period "shall not be placed on the market until ten years have elapsed from the initial authorization of the reference product".[129] Finally, the ten year period shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the innovator obtains an authorization for one or more new therapeutic indications which are found to "bring a significant clinical benefit in comparison with existing therapies".[130] Therefore, the current EU legislation provides for an eight-year period of data exclusivity, followed by a two-year period of market exclusivity, followed by an additional one-year period of market exclusivity for a new therapeutic indication. As such, the current EU data protection scheme has been referred to as the "8 + 2 + 1 regime".[131]

Directive 2004/27/EC also stipulates that Member States shall grant a one-year period of data exclusivity for the results submitted in an application for a new indication of a "well-established substance", provided that "significant pre-clinical or clinical studies were carried out in relation to the new indication".[132] A new therapeutic indication means a new target disease, or use, for a particular medicinal product. Notably, Canada's

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[127] *Ibid.* at Article 10(1).
[128] *Ibid.* at Article 10(2).
[129] *Ibid.* at Article 10(1).
[130] *Ibid.* at Article 10(1)..
[131] Valeria Junod, *supra* note 122 at 512.
[132] Directive 2004/27/EC, *supra* note 126 at Article 10(5).

proposed regulation does not provide a period of protection for data submitted within applications to market an old medicinal ingredient for a new therapeutic use.

Furthermore, there are other important differences between the pharmaceutical drug regimes of Canada and EU. In 1992, the Council adopted Regulation 1768/92,[133] which created a new form of intellectual property within the EU called a Supplementary Protection Certificate ("SPC"). Similar to the concept of patent term extension found within the *Hatch-Waxman Act*, a SPC extends the life of a patent to compensate for the time required to obtain a marketing authorization for a patented medicinal product. Pursuant to Article 13 of Regulation 1768/92, a SPC takes effect at the end of the patent term and lasts for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the EU, minus five years. Furthermore, the duration of the SPC may not exceed five years from the date on which it takes effect. Therefore, the maximum period of combined patent and SPC protection in the EC is fifteen years, beginning on the date of the first marketing authorization.

As mentioned above, Canada has never enacted legislation extending the life of a patent to compensate for the period of time required to obtain a notice of compliance for a medicinal product. In fact, as the final section of Chapter II will demonstrate, very few nations choose to protect medicinal products with the type of intellectual property rights found within the pharmaceutical drug regimes of the US and EU.

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[133] *Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products,* O.J. L 182, 02.07.1992, 1–5.

Section 5 - Data protection in other jurisdictions around the world

In addition to the US and EU, there are a few other jurisdictions in the world that have enacted regulatory regimes providing protection for clinical trial data submitted in marketing approval applications for pharmaceutical drugs. One such jurisdiction is the Andean Community,[134] which comprises the member countries Bolivia, Columbia, Ecuador, and Peru. The Andean Community is modeled after the European Community, but has been described as "an incomplete customs union",[135] due to the fact that its free-trade area and common external tariff are still subject to a number of exceptions.

In 1993, the Andean Community adopted *Decision 344: Common Regime on Industrial Property*,[136] which mandated that member countries extend their term of patent protection to twenty years and grant patents for pharmaceutical products, which had previously been excluded from patentability.[137] Furthermore, Articles 78 and 79 of *Decision 344* provide that where member countries require experimental or other data as a condition for granting marketing approval of "pharmaceutical goods or agrochemicals involving the use of new chemicals", member countries shall protect such data for a period of not less than five years.[138]

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[134] Note that the Andean Community was known as the "Andean Group" when Decision 344 was adopted. The Andean Group changed its name to the "Andean Community" in June 1997 when the Cartagena Agreement was amended by the Trujillo Protocol.
[135] Miguel Rodriguez Mendozav, "The Andean Community in Motion: A progress report" (Washington, D.C., September 11, 1998) online: Foreign Trade Information System <http://www.sice.oas.org/geograph/south/MRod_e1.asp>.
[136] *Andean Community, Decision 344: Common Regime on Industrial Property*, online: Free Trade of the Americas <http://www.ftaa-alca.org/intprop/natleg/decisions/DEC344_e.asp>.
[137] *Ibid.* at Article 30.
[138] *Ibid.* at Articles 78, 79.

In 1994, New Zealand enacted the *Medicines Amendment Act*[139] and introduced a five-year period of data protection for "confidential supporting information" received in an "innovative medicine application". [140] Notably, the term 'innovative medicine application' is defined as "an application that refers to an active ingredient - that has not, before that application has been received by the Minister, been referred to in any other application ... as an active ingredient of a medicine".[141] In other words, the New Zealand regime does not provide a period of data protection for supporting information submitted in applications for new uses or formulations of previously approved medicinal ingredients.

Similar to New Zealand, in 1998 Australia enacted the *Therapeutic Goods Legislation Amendment Act*[142] and adopted a five-year period of data exclusivity for information submitted in an application to register therapeutic goods. Importantly, the therapeutic goods must either consist of, or contain, an "active component", defined as the substance "primarily responsible for the biological or other effect identifying the goods as therapeutic goods".[143]

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[139] N.Z., *Medicines Amendment Act 1994*, online: WIPO Database of Intellectual Property Legislative Texts <http://www.wipo.int/clea/docs_new/pdf/en/nz/nz013en.pdf#search=%22new%20zealand%20medicines%20amendment%20act%201994%22>.
[140] *Ibid.* at s. 23B.
[141] *Ibid.* at s. 23A.
[142] Austl., *Therapeutic Goods Legislation Amendment Act 1998*, online: WIPO Database of Intellectual Property Legislative Texts <http://www.wipo.int/clea/docs_new/pdf/en/au/au090en.pdf#search=%22therapeutic%20goods%20legislation%20amendment%20act%201998%22>.
[143] *Ibid.* at s. 25A(3).

In 2005, Taiwan amended its pharmaceutical laws to provide for a five-year term of protection against unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approval for their drug products.[144]

Japan also provides a period of *market exclusivity* for pharmaceutical drugs, but has never enacted an explicit data protection regime. Instead, the Japanese Ministry of Health and Welfare precludes subsequent applicants from obtaining marketing authorizations during a "re-examination period", the purpose of which is to confirm the safety and efficacy of newly approved pharmaceutical drugs.[145] Pursuant to the Japanese regulatory regime, there are three possible re-examination periods: (1) six years for "drugs containing a new chemical entity, new medicinal composition, or medicinal products with a new route of administration";[146] (2) four years for "medicinal products with new indications, or medicinal products with a new formulation"[147] or new dosage; and (3) ten years for "orphan drugs"[148] or new drugs requiring pharmaco-epidemiological study. During the prescribed re-examination period, no subsequent marketing approvals for the applicable drug may be granted, unless the subsequent applicant submits its own test data.[149]

Aside from the legislative regimes mentioned above, there is a dearth of information relating to data protection in any other jurisdictions. This is likely due to the fact that

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[144] US, *2006 Special 301 Report*, online: US Trade Representative <http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file473_9336.pdf>.
[145] Article 14(4) of the Drug Affairs Law and Director's Notice No. 725 of the Pharmaceutical Affairs Bureau of Health and Welfare, of August 1993, in Cook, *supra* note 71 at 113.
[146] *Ibid.*
[147] *Ibid.*
[148] In Japan, a drug qualifies as an "orphan drug" if it has a potential market of less than 50,000 people.
[149] Cook, *supra* note 71 at 113.

prior to the recent multilateral trade agreement pertaining to intellectual property rights, most countries did not provide any protection for clinical trial data. In fact, many countries did not even provide patent protection for medicinal drug products. However, as the next Chapter of this thesis will demonstrate, most of the world's jurisdictions are now obligated to provide some form of protection for clinical trial data submitted to their health authorities in applications for marketing approval of pharmaceutical products.

Chapter III - Canada's international obligations pertaining to data protection and the federal government's proposed regulation

Section 1 - Introduction

In Chapter III, Canada's treaty obligations pertaining to the protection of data submitted in marketing approval applications for pharmaceutical drugs will be discussed. Canada's obligations pursuant to Article 1711 of the *North American Free Trade Agreement*[150] ("NAFTA") will be examined in section two, while Canada's obligations under Article 39.3 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*[151] ("TRIPs") will be analyzed in section three. The purpose of these discussions is to determine the form and duration of protection that Canada is required to enact in order to fulfill its international commitments pertaining to data protection.

Furthermore, the judicial decisions of the Federal Court and the Federal Court of Appeal in *Bayer v. Attorney General of Canada et al.* will be critically examined in section four. Finally, in section five, the specific provisions of Canada's proposed data protection regime will be examined in greater detail, in order to determine whether the 2006 Regulation merely implements Canada's international treaty obligations, or provides innovators with additional protection.

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[150] *North American Free Trade Agreement between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 & 605 (entered into force 1 January 1994) [NAFTA].

[151] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization; Annex 1C, Section 7, Article 39, 33 I.L.M. 1197-1225 (1994) [TRIPs].

With regards to treaty obligations in general, there are two major theories advanced by legal scholars to explain the relationship between international treaties and domestic law. The first theory is called 'monism', which provides that when a state ratifies an international treaty, the rights and obligations set out in the treaty are directly enforceable in that member states' domestic courts. In other words, in a 'monist' state, a ratified treaty is self-executing and does not need to be implemented into domestic law through the enactment of a statute or regulation by the monist state's national legislature or parliament. In contrast, the theory of 'dualism' provides that international treaties are not self-executing. As such, in order for an international treaty to take legal effect in a dualist state, the relevant provisions of the treaty must first be incorporated or integrated into a domestic statute or other enactment by the dualist state's legislature or parliament.

Canada is a dualist state. However, due to substantial differences in the language used to draft international treaties as compared to the language used in Canada's domestic legislation, the federal government typically does not reproduce substantial portions of a treaty when enacting an implementing statute. Instead, the implementation of international treaties is usually completed by amending Canada's pre-existing legislation pertaining to the subject matter of the treaty, or by inserting a statement in the preamble of the applicable legislation.[152] This can result in Canadian legislation containing rights and obligations that were not explicitly mandated by the international treaty. As the judicial decisions discussed in Chapter III will demonstrate, that is precisely what

[152] Stephen J. Toope, "Inside and out: The stories of international law and domestic law" (2001) 50 U.N.B.L.J. 11 at 13.

occurred when Canada amended its *Food and Drug Regulations* in 1995 in order to comply with the data protection provisions in the NAFTA.

Section 2 - The North American Free Trade Agreement

After extensive negotiations, the NAFTA was signed on December 17, 1992 and came into force on January 1, 1994.[153] The NAFTA was intended to cover virtually all aspects of international trade between Canada, the US and Mexico in order to achieve a "more efficient and integrated North American economy".[154]

The NAFTA provisions pertaining to intellectual property are found in Chapter 17 of the Agreement, beginning with Article 1701, which stipulates that each party shall, at a minimum, give effect to the Articles of Chapter 17 and to the substantive provisions of four other multilateral intellectual property law treaties.[155] Importantly, Article 1702 of the NAFTA provides that a party may implement into its domestic law "more extensive protection of intellectual property rights than is required under [the] Agreement, provided that such protection is not inconsistent with [the] Agreement".[156]

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[153] William L. Hayhurst, "When Sovereignties May Collide -- Sovereignties and the Regulation of Business in Relation to Intellectual Property: A Canadian Perspective", (1994) 20 Can-U.S. L.J. 195 at 209.
[154] Foreign Affairs and International Trade Canada, "Overview of the NAFTA" (Ottawa: September 25, 2003) online: Department of Foreign Affairs and International Trade Canada <http://www.dfait-maeci.gc.ca/nafta-alena/over-en.asp>.
[155] NAFTA, *supra* note 150 at Article 1701(2). The four multilateral intellectual property treaties are: (1) the *Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonograms*, 1971 (Geneva Convention); (2) the *Berne Convention for the Protection of Literary and Artistic Works*, 1971 (Berne Convention); (3) the *Paris Convention for the Protection of Industrial Property*, 1967 (Paris Convention); and (4) the *International Convention for the Protection of New Varieties of Plants*, 1978 (UPOV Convention).
[156] NAFTA, *supra* note 150 at Article 1702.

The NAFTA provisions pertaining to the protection of test data submitted for the approval of pharmaceutical drugs are found in paragraphs 5, 6 and 7 of Article 1711, which read as follows:

> "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.
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> 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."[157] [emphasis added]

[157] NAFTA, *supra* note 150, Article 1711(5), (6) and (7).

Therefore, pursuant to paragraph 6 of Article 1711, the minimum period of protection to be granted to innovators who submit marketing approval data to governmental authorities is five years. However, paragraph 6 also permits member states to implement 'abbreviated' or generic approval procedures based on bioequivalence and bioavailability studies. Indeed, the only barrier preventing the approval of a generic version of a drug appears to be the inability of the generic manufacturer to 'rely' on the safety and efficacy data submitted by the innovator. Importantly, paragraphs 5, 6, and 7 of Article 1711 do not conclusively state whether a generic manufacturer or a governmental agency is considered to have 'relied' on an innovator's test data when an abbreviated marketing application is filed or considered for approval. This issue was judicially considered by the Federal Court of Canada in 1995. However, before delving into Canadian case law, it is important to introduce another international treaty prescribing minimum standards for the protection of regulatory test data in the pharmaceutical industry.

Section 3 - The Agreement on Trade-Related Aspects of Intellectual Property Rights

Since the end of the Second World War, there have been numerous rounds of multilateral trade negotiations, which are typically named after the country or city in which the negotiations began. The 'Uruguay' Round of trade negotiations began in September 1986 and culminated in 1994 with the ratification of the *Marrakesh Agreement*[158] and the establishment of the World Trade Organization ("WTO").[159] The WTO, which came into existence on January 1st, 1995, is an organization that administers the global rules of

[158] *Marrakesh Agreement Establishing the World Trade Organization*, 15 April 1994, 33 I.L.M. 1144, online: World Trade Organization <http://www.wto.org/english/docs_e/legal_e/legal_e.htm> [*Marrakesh Agreement*].

[159] See World Trade Organization "What is the World Trade Organization" online: <http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm>.

trade amongst the world's countries and "customs territories".[160] The global rules of trade consist of a set of agreements that each country or customs territory must accede to prior to becoming a WTO member. In order to ensure that member states comply with the WTO agreements, the *Marrakesh Agreement* also introduced a binding system of dispute settlement and enforcement to be administered by a WTO Dispute Settlement Body.[161] As of December 11, 2005, there were 149 members of the WTO, including Canada.[162]

The three most significant WTO agreements are: the *General Agreement on Tariffs and Trade*, which pertains to the international trade of goods; the *General Agreement on Trade in Services*, which relates to certain services that member states were willing to open to foreign competition; and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPs"). These agreements, along with WTO's Dispute Settlement Body, constitute the framework of the world's multilateral trading system.

TRIPs was negotiated during the Uruguay Round, and introduced intellectual property rights into the world's multilateral trading system for the first time. TRIPs is divided into various sections, each pertaining to a different intellectual property right. For instance, Section 7 of TRIPs is entitled "*Protection of Undisclosed Information*" and encompasses Articles 39 and 40 of the Agreement. With regards to data protection, Article 39.3 of TRIPs mandates that member states provide protection for safety and efficacy data

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[160] A customs terrirtory is a jurisdiction or group of jurisdictions with a common external tariff.
[161] *Marrakesh Agreement*, part. II, Ann. 2, 33 ILM at 112. See World Trade Organization, "Understanding the WTO: Settling Disputes" (Geneva, Switzerland), online: WTO <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm>.
[162] See World Trade Organization "What is the WTO" (Geneva, Switzerland), online: WTO <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>.

submitted to their governmental agencies in applications for marketing approval of pharmaceutical and agricultural products. However, due to its ambiguous wording, the scope and application of Article 39.3 is subject to various interpretations. The full text of Article 39.3 reads as follows:

> "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 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."[163]

According to the literal wording of Article 39.3, in order for member states to become obligated to provide protection for undisclosed test or other data submitted in marketing approval applications, the following conditions must apply: (1) the member state must require such data as a condition of approving the marketing of pharmaceutical or agricultural chemical products; (2) the pharmaceutical or agricultural product must utilize a 'new chemical entity'; (3) the test data must be 'undisclosed' at the date of submission; and (4) the origination of the data must involve a 'considerable effort'. Importantly, the terms 'new chemical entity', 'undisclosed', 'considerable effort' and 'unfair commercial use' are not defined in TRIPs. This lack of clarity has resulted in disagreement amongst legal scholars regarding the scope and extent of data protection required in the domestic laws of member states in order to fulfill their treaty obligations under Article 39.3. For instance, Dr. Carlos Correa, of the University of Buenos Aires, has written that:

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[163] TRIPs, *supra* note 151, Article 39.3.

> "[T]he inclusion of test data in the TRIPs Agreement as a category of 'intellectual property' does not determine the nature of the protection conferred. In particular, it does not indicate that such data should be protected through the grant of exclusive rights".[164]

With regards to the requirement that a pharmaceutical product must utilize a 'new chemical entity', Dr. Correa is of the opinion that various interpretations of this undefined term are permissible. Specifically, Dr. Correa states that a new indication, formulation or dosage form of a pre-existing drug product may be deemed not to constitute a 'new chemical entity', since the chemical entity would already be known.[165] Moreover, according to Dr. Correa, member states may choose not to provide protection for data that was submitted in an application for a new *use* of a previously approved pharmaceutical product, since the chemical entity would not be new.[166] As we will see later on, the Canada's proposed 2006 Regulation defines the term "new chemical entity"[167] narrowly, and does not protect data submitted within an application for a new use of previously approved drug product.

The requirement that the origination of test data must involve 'considerable effort' is also the subject of serious academic debate. Dr. Correa has written that the inclusion of a 'considerable efforts' standard "suggests national regulatory authorities may request the

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[164] Carlos Maria Correa, "Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPs Agreement" (Geneva, Switzerland: The South Centre, 2002) at 14, online: The South Centre <http://www.southcentre.org/publications/protection/protection.pdf> [Correa, Data Protection].
[165] *Ibid.* at 17.
[166] *Ibid.*
[167] Note that the Canadian legislation uses the term "new medicinal ingredient" instead of "new chemical entity".

applicant prove that the information for which protection is sought is the result of considerable effort".[168] The *Trans Atlantic Consumer Dialogue*, a forum of US and EU consumer organizations which develops consumer policy recommendations, goes one step further and advocates that "companies that seek data exclusivity protections be required to disclose the costs of investments".[169]

However, the most controversial issue surrounding Article 39.3 is the scope of protection required by member states in order to fulfill the requirement of protecting undisclosed test data against 'unfair commercial use'. For instance, if a member state's health authority relies upon the test data of an innovator in order to approve a subsequent application for a generic version of the innovator's product, does that constitute 'unfair commercial use' under Article 39.3 of TRIPs? In this regard, shortly after TRIPs came into force, the Office of the US Trade Representative issued the following interpretation of the scope of data protection mandated by Article 39.3:

> "[T]he data will not be used to support, clear or otherwise review other applications or marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with the logic and the negotiating history of the provision".[170]

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[168] Correa, Data Protection, *supra* note 164 at 19.
[169] Trans Atlantic Consumer Dialogue, "Data Exclusivity and Health Registration Data" (London: December 10, 2002) online: TACD <http://www.tacd.org/cgi-bin/db.cgi?page=view&config=admin/docs.cfg&id=35>.
[170] Office of the US Trade Representative, "The protection of undisclosed test data in accordance with TRIPs Article 39.3", (1995) unattributed paper for submission in bilateral discussions with Australia in May 1995, in G.L. Skillington & E.M. Solovy, "The protection of test and other data required by Article 39.3 of the TRIPS Agreement", (2003) 24 N.W. J. Int'l L. & Bus. 1 at 33.

Therefore, according to the US interpretation of Article 39.3, a member state's reliance upon an innovator's test data in order to review and approve subsequent marketing approval applications constitutes 'unfair commercial use'.

However, this is but one interpretation of the scope and application of Article 39.3. Other interpretations are equally plausible. Dr. Correa writes that the wording of Article 39.3 gives member states flexibility in implementing domestic data protection legislation, while at the same time allowing for the approval of generic pharmaceutical products.[171] Dr. Correa is of the opinion that member states may:

> a) "require the [generic] second-entrant to produce its own testing and other data or to obtain an authorization of use from the "originator" of the data;
> b) allow the second-entrant to rely on the "originator's" data against payment of a compensation to the "originator" (when the "originator" has not given his consent for the use of the data);
> c) examine and rely upon the data submitted by the "originator" to evaluate the second-entrant application;
> d) approve a second entry marketing application without examining or otherwise relying on upon confidential information submitted by the originator."[172]

In the case of (a), member states would be providing originators with protection that can be best described as 'data exclusivity'. In the case of (b), the originator would be granted a 'remuneration right' as opposed to a property right. The case of (c) is more complicated, for a number of reasons. For one, physically examining an originator's test

[171] Correa, Data Protection, *supra* note 164 at 31.
[172] Correa, Data Protection, *supra* note 164 at 31.

data and simply relying on an originator's test data are two entirely different 'uses' of that data. Physical examination of an originator's test data by a member state's health authority for the purpose of approving a generic application would arguably constitute an 'unfair commercial use' of that data. (Admittedly, this interpretation is predicated on the notion that *governmental* use of test data falls under the rubric of the term 'unfair *commercial* use'.) In contrast, mere reliance upon the test data of an originator without physical examination would arguably not constitute 'unfair commercial use'. Indeed, due to the wording of Article 39.3, numerous interpretations of what constitutes 'unfair commercial use' are permissible.

A definitive explanation of the scope and application of Article 39.3 of TRIPs would require a decision from a WTO dispute settlement panel. When disputes arise between WTO members regarding international trade obligations, a Member State must first file a complaint with the WTOs dispute settlement body ("DSB") and request consultations with the respondent Member State. If the matter is not resolved after a period of consultations, a WTO dispute settlement panel is appointed, a hearing is held, and a panel report is then issued to the parties.[173] The decisions outlined in the panel report can then be appealed to a WTO appellate body, which subsequently issues a final report. If the respondent Member State is found to not be in compliance with its treaty obligations, it will typically propose various legislative changes that it will enact to comply with the findings of the panel report.

[173] See World Trade Organization, "Understanding the WTO: Settling Disputes - The panel process" (Geneva, Switzerland), online: WTO <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp2_e.htm>.

As of August 1, 2006, no decisions have been issued by the WTO dispute settlement panel pertaining to the issue of whether the domestic data protection legislation of a Member State (or the complete lack thereof) complies with Article 39.3 of TRIPs. However, on May 6, 1999 the US filed a complaint with the WTOs DSB and requested consultations with Argentina regarding changes that were made to Argentina's regulatory regime for marketing approval of agricultural chemical products. The US alleged that in 1998, Argentina enacted a regulation[174] that resulted in "a lesser degree of consistency with the provisions of Article 39.3 of the TRIPs Agreement",[175] contrary to Argentina's obligations as a developing country Member availing itself of the transition period afforded under TRIPs.[176] However, on May 31, 2002, the US and Argentina notified the DSB that they had reached a Mutually Agreed Solution[177] regarding all matters raised by the US in respect of its request for consultations. As such, the dispute was settled prior to the appointment of a dispute settlement panel.

The willingness of the US Trade Representative ("USTR") to settle its dispute with Argentina in May 2002 is somewhat curious, especially considering that in both 2005 and

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[174] Agentine Regulation 440/98 in Cook, *supra* note 71 at 109.

[175] *Argentina - Patent protection for pharmaceuticals and test data protection for agricultural chemicals (Complaint by the United States)* (1999), WTO Doc. WT/DS171/1 at para. 1 (Request for consultations by the United States), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds171_e.htm>.

[176] Pursuant to Article 65(2) of TRIPs, a developing country Member is entitled to delay for a period of five years, the date of application (as defined in Article 65(1)) of the provisions of the TRIPs Agreement other than Articles 3, 4 and 5. Pursuant to Article 65(5) of TRIPs, a Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 of Article 65, shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

[177] *Argentina - Patent protection for pharmaceuticals and test data protection for agricultural chemicals (Complaint by the United States)* (1999), WTO Doc. WT/DS171/3 (Notification of Mutually Agreed Solution), online: WTO <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm>.

2006, Argentina was placed on the USTR's "Priority Watch List"[178] and chastised for failing to provide "protection from unfair commercial use for confidential data submitted by research-based pharmaceutical companies".[179] Although impossible to confirm, the USTR's decision to settle its trade dispute with Argentina in May 2002 was probably due to the likelihood that a dispute settlement panel would have issued a decision favouring Argentina's position regarding Article 39.3.

Indeed, it is possible to surmise how a WTO dispute settlement panel would interpret Article 39.3 of TRIPs. In order to interpret the meaning of an undefined term in a WTO Agreement, dispute settlement panels have applied Article 31(1) of the *Vienna Convention on the Law of Treaties* ("*Vienna Convention*"). Article 31(1) provides that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".[180] Furthermore, in a 2001 panel report, a WTO dispute settlement panel held:

> "Pursuant to Article 32 of the *Vienna Convention*, a treaty interpreter may have a recourse to supplementary means of interpretation, including negotiating history,

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[178] Countries or jurisdictions on the US Trade Representative's Priority Watch List allegedly do not provide an adequate level of intellectual property rights protection or enforcement, or market access for persons relying on intellectual property protection.

[179] US Trade Representative, *2005 Special 301 Report* (Washington, D.C.: 2005) at 26, online: USTR <http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file195_7636.pdf>, and
US Trade Representative, *2006 Special 301 Report* (Washington, D.C.: 2006) at 26, online: <http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file473_9336.pdf>.

[180] *Vienna Convention on the Law of Treaties between States and International Organizations or between International Organizations*, 23 May 1969, 1155 U.N.T.S. 331 (entered into force 27 January 1980), online: <http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_2_1986.pdf#search=%22vienna%20convention%20on%20the%20law%20of%20treaties%22>.

> in order to confirm the interpretation derived after applying Article 31 of the *Vienna Convention*."[181]

Interestingly, the specific wording of TRIPs' data protection provision was vigorously negotiated for a number of years prior to the adoption of the final version of Article 39.3. As a result, there were a number of drafts proposed by member states during the Uruguay Round of trade negotiations. For instance, in the summer of 1990, three drafts were circulated, each of which would have required member states to provide protection for *all* undisclosed information submitted to governmental agencies, not simply undisclosed data submitted for the approval of pharmaceutical and agricultural products which utilize *new chemical entities*.[182] In addition, the following draft version of a data protection provision was proposed at the Ministerial Conference of the WTO in December 1990:

> "Parties, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, Parties shall] protect such data against disclosure, except where necessary to protect the public.]"[183]

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[181] *United States-Section 211 Omnibus Appropriations Act of 1998, (Complaint by the European Communities)* (2001), WTO Doc. WT/DS176/R/USA at para. 8.31 (Panel Report), online: WTO < http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds176_e.htm >.
[182] Cook, *supra* note 71at 12-13.
[183] Brussels Ministerial Conference of December 1990 in Cook, *supra* note 71 at 11.

Significantly, the December 1990 draft version explicitly prohibits government agencies from *relying* upon an innovator's test data for the approval of a generic product for a period of no less than five years. This prohibition is noticeably absent from the final text of Article 39.3. Moreover, the fact that detailed data protection obligations were included in a draft version of Article 39.3, and then subsequently removed, is an indication that WTO member states thought it best to retain substantial flexibility in their ability to draft domestic data protection legislation.

Finally, it is also important to mention that on November 14, 2001, the Ministerial Conference of the WTO, meeting in Doha, Qatar, adopted a Declaration[184] on the TRIPs Agreement and Public Health. This declaration, known as the "Doha Declaration", affirmed that the TRIPs Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all", and reaffirmed that the Agreement "provides flexibility for this purpose".[185] Therefore, it is likely that a WTO dispute settlement panel would find that Article 39.3 of TRIPs does not require member states to enact legislation providing for exclusive time-limited proprietary rights for data submitted in marketing approval applications.

As mentioned previously, no WTO dispute settlement panel has issued a decision pertaining to the interpretation of Article 39.3 of TRIPs. However, in the next section of

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[184] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Doc. WT/MIN (01)/DEC/2 (20 November 2001), online: WTO <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> [*Doha Declaration*].
[185] *Ibid.* at para. 4.

Chapter III, we will examine a Federal Court of Canada decision which considered the scope and extent of data protection required pursuant to Article 1711 of the NAFTA.

Section 4 - The Federal Court of Canada's decision in *Bayer*

In 1995, Canada amended its regulatory framework for the approval of pharmaceutical drugs in order to implement Article 1711 of the NAFTA into domestic Canadian law.[186] The amending regulations[187] added a new provision pertaining to the protection of regulatory data to Part C, Division 8 of Canada's *Food and Drug Regulations*.[188] It should be noted that prior to 1995, Canada had no legislation whatsoever protecting the data submitted to the Therapeutics Products Directorate in applications for marketing approval of a "new drug".[189] The 1995 data protection provision, codified in section C.08.004.1(1) of the *Food and Drug Regulations*, read as follows:

> "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

[186] It appears that Health Canada did not consider Article 39.3 of TRIPs when the amendments to the *Food and Drug Regulations* were drafted.
[187] S.O.R. / 95-411.
[188] C.R.C. c. 870 (1978) as amended.
[189] *Food and Drug Regulations*, *supra* note 16, s. C.08.001.

> 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".

The literal wording of s. C.08.004.1(1) appears to grant the innovator of a new drug a five-year period of data protection for the information contained in a New Drug Submission ("NDS"), provided the following events occur: (1) the Minister examines any information in the NDS; and (2) the Minister relies on the data contained in the information to approve a generic manufacturer's Abbreviated New Drug Submission ("ANDS") or Supplement to an ANDS.

However, it is important to note that unlike the initial five-year period of *data exclusivity* granted to American innovators, s. C.08.004.1(1) appears to grant a five-year period of *market exclusivity* to Canadian innovators. In other words, s. C.08.004.1(1) does not prevent generic manufacturers from filing an ANDS or a supplement to an ANDS with Health Canada and referencing the test results and other data contained in a NDS of an innovator. Section C.08.004.1(1) simply prohibits the Minister from issuing a Notice of Compliance ("NOC") for the generic version of a drug for five years.

However, despite what the literal wording of s. C.08.004.1(1) may suggest, the scope and application of the provision was considered by the Federal Court of Canada in a case entitled *Bayer v. Attorney General of Canada et al.*[190] In *Bayer*, a motion for summary judgment was brought by Bayer, an innovative pharmaceutical company, who had

[190] (1998), 84 C.P.R. (3d) 129 (F.C.T.D.) [*Bayer*].

previously filed a NDS with the Minister of Health in respect of drug X.[191] Bayer was the innovator of drug X, which was not protected by any Canadian patents.[192] Due to the lack of patent protection for drug X, executives from Bayer met with representatives of Health Canada to seek assurances that if a NOC was issued to Bayer in respect of drug X, a subsequent NOC would not be issued to a generic manufacturer of an equivalent drug until five years after the issuance of Bayer's NOC.[193] The representatives of Health Canada did not agree that Bayer's drug should be granted a five year period of market exclusivity. As a result, Bayer commenced litigation and asked the Federal Court for declaratory relief against the Minister of Health in relation to the interpretation and application of s. C.08.004.1(1). Counsel for Bayer formulated a number of questions of law that he asked the Federal Court to answer, including the following:

> "QUESTION 2: After the issuance of the Notice of Compliance for Drug X for use in the treatment of Disease X, would the Minister of Health (the "Minister") need to rely on data contained in or derived from the Plaintiff's New Drug Submission for Drug X, to establish the safety and effectiveness of a drug product of a second manufacturer who files an Abbreviated New Drug Submission or Abbreviated Supplemental New Drug Submission comparing its drug product to the Plaintiff's Drug X?
>
> ...
>
> QUESTION 4: Is the Minister prohibited from issuing a Notice of Compliance to a second manufacturer who files an Abbreviated New Drug Submission or Abbreviated Supplemental New Drug Submission comparing its drug product to the Plaintiff's Drug X, until five years after the issuance of the

[191] Note that in *Bayer*, an order of the Federal Court provided for the confidentiality of the names of the drugs referred to above by letters, as well as their active ingredients and the diseases for which they were used or were proposed to be used.
[192] *Bayer*, *supra* note 190 at para. 16.
[193] *Bayer*, *supra* note 190 at para. 18.

Notice of Compliance for Drug X for use in the treatment of Disease X to the Plaintiff?"[194]

With respect to Question 2, the Federal Court acknowledged that in granting a generic manufacturer marketing approval for a product that is the "functional equivalent of a drug for which the Minister has already issued a NOC on the basis of the information supplied by the innovator, the Minister is indirectly, at least, 'relying' on that information to establish the safety and effectiveness of the generic drug manufacturer's product".[195]

However, the Federal Court expressed reservations about granting a five-year period of market exclusivity for unpatented drug products and held that s. C.08.004.1(1) was "not intended to create a protection analogous to a patent for the benefit of nearly all innovators of new drugs who have obtained a NOC".[196] The Court further stated that "[g]iven the overall purpose of the Regulations, the adverb 'indirectly' should not be read into s. C.08.004.1(1) so as to broaden the scope of the verb 'relies'".[197]

In addition, the Court held that s. C.08.004.1(1) should "be read in the context of the overall [regulatory] scheme, which is to facilitate the approval process for new drugs when sought by manufacturers other than the innovators, and thus to reduce the cost of drugs to provincial governments and members of the public".[198] As such, the Federal Court answered Question 2 in the negative and rejected the argument that the Minister of Health 'relies' on an innovator's test data when deciding whether to issue a NOC on the

[194] *Bayer*, *supra* note 190 at para. 20.
[195] *Bayer*, *supra* note 190 at para. 33.
[196] *Bayer*, *supra* note 190 at para. 37.
[197] *Bayer*, *supra* note 190 at para. 37.
[198] *Bayer*, *supra* note 190 at para. 34.

basis of an ANDS.[199] The Federal Court also found that "in most cases, the Minister is asked to issue a NOC solely on the basis of the information contained in the ANDS".[200]

Next, the Federal Court considered whether, for the purpose of s. C.08.004.1(1), the Minister 'examines' the data and other information in Bayer's NDS when considering an ANDS submitted by a generic manufacturer. In answering this question, the Court stated:

> "The use of the present tense of both verbs, "examines" and "relies", indicates that the person who drafted s. C.08.004.1 envisaged that each would occur in the course of the Minister's considering the same submission, namely, the ANDS".[201]

In other words, the Federal Court held that the five-year period of data protection prescribed by s. C.08.004.1 will only arise if the Minister actually examines an innovator's test data *at the time* it considers a generic manufacturer's ANDS. The fact that the Minister previously examined the innovator's test data at the time the innovator filed its NDS was found to be irrelevant. However, this interpretation of the scope and application of s. C.08.004.1 serves to render the provision nugatory.

Counsel for Bayer also argued that the Court should consider the wording of Article 1711(6) of the NAFTA, which does not include a requirement that the information submitted by an innovator be 'examined' at the time a generic submission is being

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[199] *Bayer*, *supra* note 190 at para. 37.
[200] *Bayer*, *supra* note 190 at para. 43.
[201] *Bayer*, *supra* note 190 at para. 42.

considered.[202] In responding to this argument, the Federal Court held that Article 1711(6) "appears to contemplate a situation in which a competitor 'relies' on the data submitted by a manufacturer to obtain marketing approval".[203] However, the Court found that a generic manufacturer will not 'rely' on an innovator's data to obtain an NOC for a drug that is bioequivalent to the innovator's drug. Rather, the Court held that the generic will only rely on its comparative studies and bioavailability tests and stated:

> "Article 1711 does not confer the right to five years' exclusive marketing of a new drug from the date of the issue of a NOC on the basis of the test data contained in the innovator's NDS in a situation such as that in issue in this case".[204]

The trial decision in *Bayer* was upheld by Canada's Federal Court of Appeal.[205] Rothstein J.A., writing for the Court of Appeal, stated that s. C.08.004.1(1) "contemplates that the Minister [of Health] may or may not examine and rely upon confidential information filed by the innovator" when considering an ANDS filed by a generic manufacturer. [206] Rothstein J.A. held that there was "no implied examination or reliance"[207] on the confidential information submitted by the innovator in its NDS and that "words cannot be read into the regulation".[208] Instead, Rothstein J.A. found that s. C.08.004.1(1)

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[202] *Bayer*, *supra* note 190 at para. 44.
[203] *Bayer*, *supra* note 190 at para. 54.
[204] *Bayer*, *supra* note 190 at para. 53.
[205] *Bayer Inc. v. Attorney General of Canada et al.* (1999), 87 C.P.R. (3d) 293 (F.C.A.) [*Bayer (FCA)*].
[206] *Ibid.* at para. 9.
[207] *Ibid.* at para. 13.
[208] *Ibid.* at para. 12.

> "provides for a sequential process; first, the filing of the ANDS by the generic manufacturer; second, and after the filing of the ANDS, examination of the information filed by the innovator; and third, reliance by the Minister on that information in issuing a Notice of Compliance to the generic manufacturer. Only if all three steps are applicable, does the minimum five-year market protection provided by the regulation apply".[209]

The Federal Court of Appeal also considered whether its interpretation of the scope and application of s. C.08.004.1(1) was consistent with Canada's treaty obligations pursuant to Article 1711 of the NAFTA. In answering this question, Rothstein J.A. stated that:

> "[I]f a generic manufacturer is able to establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the Minister having to examine and rely upon confidential data filed by the innovator, there is no reason or justification for the minimum five-year protection from competition. This interpretation of subsection C.08.004.1(1) is consonant with section 5 and 6 of Article 1711 of the NAFTA".[210]

As was seen in the trial decision, the Federal Court of Appeal appeared to conflate the concepts of patent protection and data protection. Indeed, Rothstein J.A. stated that "[i]f a generic manufacturer compares its product to an innovator's product solely on the basis of public information, providing the innovator with protection from competition for a minimum of five years is tantamount to granting it the protection a patent would provide".[211] Rothstein J.A. further intoned that the words of s. C.08.004.1(1) could not "be construed to yield such a result".[212]

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[209] *Ibid.* at para. 13.
[210] *Ibid.* at para. 15.
[211] *Ibid.* at para. 16.
[212] *Ibid.* at para. 16.

Both the Federal Court and the Federal Court of Appeal were clearly perturbed by the prospect of having to enforce five-year exclusivity rights on the basis of confidential information submitted in applications to Health Canada. However, the literal wording of s. C.08.004.1(1) does appear to provide an innovator with protection from competition analogous to that which a patent provides. Moreover, the federal government of Canada apparently contemplated a data protection regime with exclusivity rights analogous to those provided by Canadian patents. The Regulatory Impact Analysis Statement ("RIAS") accompanying the 1995 amendments to the *Food and Drug Regulations* provides the following example of an application of s. C.08.004.1(1):

> "The patent on an innovator's product A expires in 1997. The NOC for product A is issued in 1995 and contains a new chemical or biological substance. An abbreviated new drug submission is filed in 1996 for a second entry product B. If in order to assess the safety, efficacy and quality of product B, the Minister relies upon information contained in the innovator's submission for product A, a NOC for product B would not be issued until the year 2000, thus giving the innovator an additional 3 years market protection for product A."

A RIAS is a pre-ambulatory statement which accompanies but does not form part of regulations enacted by the Federal government. A RIAS typically contains information as to the purpose and effect of the proposed regulation. The Supreme Court of Canada has held that "the use of the RIAS to determine both the purpose and the intended application of a regulation has been frequent in this Court and others, and this across a

wide range of interpretive settings".[213] However, even though the Federal Court judge in *Bayer* cited the RIAS accompanying the 1995 amendments, both the Federal Court and The Federal Court of Appeal remained adamant that the Minister of Health does not actually 'rely' on an innovator's test data when considering an ANDS.

Largely as a result of the judicial decisions in *Bayer*, the federal government proposed to enact a regulation amending s. C.08.004.1 of the *Food and Drug Regulations*. On December 11, 2004 this proposed regulation (the "2004 Regulation") was published in Part I of the Canada Gazette.[214] Part I of the Canada Gazette contains all public notices, official appointments and proposed regulations from the Federal government.[215] In other words, a regulation published in Part I of the Canada Gazette does not necessarily reflect the enacted version of that particular regulation. Typically, the Federal government will publish a proposed regulation in Part I of the Canada Gazette and then invite comments from interested parties and stakeholders during a consultation period. Regulations are then often revised to reflect the concerns and suggestions received from various stakeholders. In contrast, Part II of the Canada Gazette consists of all regulations that have been enacted by the Federal government, as well as other classes of statutory instruments, such as orders in council and proclamations.[216]

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[213] *Biolyse Pharma Corporation v. Bristol-Myers Squibb Company et al.* (2005), 39 C.P.R. (4th) 449 (SCC) at para. 157.
[214] *Regulations Amending the Food and Drug Regulations (1390 – Data Protection)*, C. Gaz. 2004 I. 3712, online: Canada Gazette <http://canadagazette.gc.ca/partI/2004/20041211/pdf/g1-13850.pdf> [2004 Regulation].
[215] See Canada Gazette, "Learn more about the Canada Gazette" (Ottawa: 6 July 2006) online: Government of Canada <http://canadagazette.gc.ca/learn-e.html#i1>.
[216] *Ibid.*

The 2004 Regulation provided that proposed amendments to s. C.08.004.1 would codify more clearly Canada's data protection commitments pursuant to the NAFTA and the TRIPs Agreement. However, due to the federal election on January 23, 2006, the 2004 Regulation was never enacted. On June 17, 2006 the federal government published a new proposed regulation (the "2006 Regulation"), which would once again amend s. C.08.004.1 of the *Food and Drug Regulations*.[217] In the next section of Chapter III, the proposed data protection schemes of both the 2004 Regulation and the 2006 Regulation will be discussed in greater detail.

Section 5 - Canada's proposed data protection regulation

The data protection regulation published in the Canada Gazette Part I on December 11, 2004, provided that s. C.08.004.1 of the *Food and Drug Regulations* was to be replaced with a new s. C.08.004.1 consisting of seven subsections. The scope and length of data protection was prescribed by subsection (3) of the new provision, and read as follows:

> "(3) The Minister shall not issue a notice of compliance to a manufacturer, in respect of a new drug that the manufacturer compares to an innovative 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 if
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> *(a)* the manufacturer, in its new drug submission, abbreviated new drug submission, supplement to a new drug submission or supplement to an abbreviated new drug submission, directly or indirectly, compares the new drug to the innovative drug and the innovative drug contains

[217] 2006 Regulation, *supra* note 17.

a medicinal ingredient that had not been approved in Canada before the first notice of compliance was issued to the innovator;

(b) the comparison forms the basis on which the manufacturer seeks the issuance of a notice of compliance; and

(c) the medicinal ingredient in the new drug is identical to the medicinal ingredient in the innovative drug."[218]

As a starting point, it is important to note that subsection (3) of the proposed s. C.08.004.1 prescribed an eight-year period of data protection leading to market exclusivity, not data exclusivity. Therefore, the 2004 Regulation would not have prevented generic companies from submitting an abbreviated new drug submission to Health Canada which referred to, or relied upon, an innovator's test data. The 2004 Regulation would simply have prevented Health Canada from *issuing* a notice of compliance for the generic drug for a period of eight years. Indeed, subsection (7) of the proposed provision provided that "[n]othing in this section prevents any manufacturer from filing a submission or supplement with the Minister before the end of the period specified in subsection (3)".[219]

In addition to the eight-year period of market exclusivity prescribed by subsection (3), subsection (4) would have granted innovators an additional six months of market exclusivity in respect of a new drug submission that "contained pediatric studies relating to pediatric age groups for which the drug may be used".[220] Finally, subsection (5) of the proposed s. C.08.004.1 provided that the eight-year period of market exclusivity would

[218] 2004 Regulation, *supra* note 214, at 3716.
[219] *Ibid.* at 3717.
[220] *Ibid.* at 3717.

no longer apply if an innovator obtained a notice of compliance but subsequently withdrew its approved drug from the Canadian market.

It is extremely important to note that the 2004 Regulation defined the term 'innovative drug' as "a drug in respect of which an innovator has received a notice of compliance and includes a drug referred to in paragraph (*a*) of the definition 'Canadian reference product' in section C.08.004.1".[221] This definition of 'innovative drug' is extremely broad, since a notice of compliance ("NOC") may be obtained for a drug that is simply a minor alteration of a previously approved drug. For instance, if a company wants to market alternative indications, formulations, or dosage forms of a previously approved drug, it can apply for, and obtain, additional NOCs. Therefore, the 2004 Regulation would have allowed innovators to obtain multiple terms of data protection by obtaining new NOCs for different indications or formulations of a previously approved drug. In other words, the 2004 Regulation would have provided a period of market exclusivity for drugs that were not at all 'innovative'.

Moreover, pursuant to subsection (3)(*c*) of the proposed provision, the medicinal ingredient in the generic drug had to be 'identical' to the medicinal ingredient in the innovative drug for the eight-year period of market exclusivity to apply. The term 'identical' was not defined in the proposed legislation. However, from the perspective of innovators, this requirement might have created a data protection regime that was incredibly narrow in scope, and likely would have resulted in substantial litigation

[221] *Ibid.* at 3716.

pertaining to the issue of whether a particular innovative drug and generic drug were 'identical'.

Therefore, the 2004 Regulation suffered from two significant flaws: the first being the overly broad definition of 'innovative drug', which could have provided a period of market exclusivity for minor variations of previously approved drugs; and the second being the difficulty in assessing whether a generic drug is 'identical' to an innovative drug, for the purpose of determining whether the eight-year period of exclusivity actually applied.

The 2004 Regulation was never enacted as an official regulation and therefore was never brought into force. However, on June 17, 2006, the Federal government published another proposed data protection regulation[222] (the "2006 Regulation") in Part I of the Canada Gazette. The 2006 Regulation replaces the 2004 Regulation, but contains significant legislative changes that merit further discussion.

The 2006 Regulation would amend s. C.08.004.1 of the *Food and Drug Regulations* and replace it with a new s. C.08.004.1 containing eight subsections. The prescribed period of data protection is once again found in subsection (3) of the proposed provision, and reads as follows:

[222] 2006 Regulation, *supra* note 17.

"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."[223]

It is important to note that subsection (3) of the proposed s. C.08.004.1 prescribes a six-year period of *data exclusivity*, during which time a generic drug submission may not be filed with Health Canada, followed by a two-year period of *market exclusivity*. The RIAS accompanying the 2006 Regulation provides that the additional two-year period is "generally reflective of the period of time required to approve a drug submission, as well as the time required for a generic manufacturer to meet its obligations under the *Patented Medicines (Notice of Compliance) Regulations*".[224]

In addition, the 2006 Regulation alters the scope and application of the six-month extension for pediatric studies. Specifically, subsection (4) of the new provision provides that the period of market exclusivity is lengthened to eight-years and six months if an

[223] *Ibid.* at 1604.
[224] *Ibid.* at 1599.

innovator submits the results of clinical trials in pediatric populations to the Minister of Health within five years after the issuance of the first notice of compliance. Further, the Minister of Health must determine that the clinical trials were "designed and conducted for purpose of increasing knowledge of the use of the innovative drug in those pediatric populations".[225]

However, the two most significant differences in the 2006 Regulation is the change to the definition of 'innovative drug', and the absence of the requirement that the medicinal ingredient in the generic drug and the innovative drug must be identical for the period of market exclusivity to apply. In the 2006 Regulation, 'innovative drug' is defined as

> "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".[226]

In other words, pursuant to the 2006 Regulation, 'innovative drug' is defined very narrowly, thereby preventing minor variations of previously approved drugs from receiving an additional term of data protection.

Furthermore, the 2006 Regulation does not provide that the medicinal ingredient in the generic drug must be identical to the medicinal ingredient in the innovative drug for data protection to arise. Instead, data protection is triggered when a manufacturer seeks marketing approval for a generic version of a drug on the basis of direct or indirect

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[225] *Ibid.* at 1605.
[226] *Ibid.* at 1604.

comparison with an innovative drug. Therefore, the 2006 Regulation restricts the number of 'innovative' drugs that qualify for data protection, while at the same time ensuring that data protection is triggered whenever a generic manufacturer applies for a NOC on the basis of a direct or indirect comparison with an innovative drug.

The proposed 2006 Regulation does not provide a coherent explanation for why an *eight-year* period of market exclusivity is required, particularly when Canada's international obligations pursuant to the NAFTA are to provide a five-year period of protection. The Regulatory Impact Analysis Statement accompanying the 2006 Regulation simply states that the intent of the prescribed protection is to "allow the innovator, or originator, of the data to protect the investments made in the development of the product by allowing a period of market exclusivity".[227] This statement suggests that the federal government is attempting to provide a utilitarian justification for the adoption of an eight-year period of market exclusivity for regulatory data. In other words, the federal government is implicitly stating that if data protection is not provided to innovators, future investments in the development of new drug products may not occur in Canada. However, this statement could also be construed to mean that innovators *deserve* to have their investments protected, due to the substantial resources expended in order to prove that a new drug product is safe and effective. In any event, justifying an eight-year period of exclusivity for marketing approval data is not an easy task, particularly when an innovator already receives a reward for submitting such data to the Minister of Health in the form of a marketing approval authorization. However, in the next Chapter of this thesis, the theoretical grounds upon which legal scholars justify intellectual property

[227] *Ibid.* at 1598.

rights will be introduced, and an attempt will be made to provide a justification for the eight-year period of data protection prescribed by the 2006 Regulation.

Chapter IV - Theoretical justifications for granting property rights for the data submitted in marketing approval applications

Section 1 - Introduction

If brought into force, the proposed data protection regime within the 2006 Regulation will create a new property right within the Canadian legal landscape; namely, an eight-year property right in safety and efficacy data, leading to an eight-year period of market exclusivity for pharmaceutical drugs. While the enactment of new intellectual property rights regimes is becoming common in developed jurisdictions, justifying these new property rights from a theoretical perspective can be problematic. In Chapter IV, the four legal theories that currently dominate scholarly debate regarding intellectual property rights will be examined, to determine whether they can provide a coherent theoretical justification for the enactment of an eight-year property right in clinical trial data.

A property right - or simply the term 'property' - is a complex legal concept which is difficult to define cogently and coherently. Moreover, the legal conception of property has undergone substantial change over the past few centuries. Eighteenth century legal scholar William Blackstone famously defined property as "that sole and despotic dominion which one man claims and exercises over the external things of the world, in total exclusion of the right of any other individual in the universe".[228] In other words, according to Blackstone's definition, property consisted of physical things that a particular owner could exclude from the rest of the world and control absolutely.

[228] William Blackstone, *Commentaries on the Laws of England* (Chicago: Chicago University Press, 1979), vol. 2 at 2.

Blackstone considered property rights to be rights *in rem* which were so absolute and sacrosanct that the common law would not permit property rights to be infringed, even for the benefit of society at large.[229]

However, as contemporary legal scholars have noted, Blackstone's "physicalist" and "absolutist" conceptions of property could only be maintained through a set of legal fictions.[230] In the case of incorporeal hereditaments, choses in action or business goodwill, where no 'thing' actually existed, Blackstone simply pretended that a physical thing existed and was owned absolutely. By the early twentieth century, legal scholars began to examine the concept of property more closely. In a journal article published in 1913, Wesley Newcomb Hohfeld rejected Blackstone's conception of property as being the absolute dominion over external objects and instead argued that "all legal interests are 'incorporeal' – consisting, as they do, of more or less limited aggregates of *abstact* legal relations".[231] In other words, according to Hohfeld, the concept of property could no longer simply be considered as tangible realty or personalty. In a later article published in 1917, Hohfeld took his argument one step further and stated that even if a physical thing does exist and an individual exerts physical control over that thing, "physical relations are wholly distinct from jural relations",[232] and "all rights *in rem* are against

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[229] William Blackstone, *Commentaries on the Laws of England* (Chicago: Chicago University Press, 1979), vol. 1 at 135 in Kenneth J. Vandevelde, "The new property of the nineteenth century: The development of the modern concept of property" (1980) 29 Buff. L. Rev. 325 at 332.
[230] Kenneth J. Vandevelde, "The new property of the nineteenth century: the development of the modern concept of property" (1980) 29 Buff. L. Rev. 325 at 332.
[231] Wesley Newcomb Hohfeld, "Some fundamental legal conceptions as applied in judicial reasoning" (1913) 23 Yale L.J. 16 at 24.
[232] Wesley Newcomb Hohfeld, "Fundamental legal conceptions as applied in judicial reasoning" (1917) 26 Yale L.J. 710 at 721.

persons".[233] In other words, Hohfeld argued that property consists of a set of rights between legal persons in relation to things, as opposed to rights over things, and that all rights *in rem* are simply bundles of rights *in personam*.[234] Hohfeld's work in the early twentieth century resulted in a paradigm shift in the understanding of the nature of property and the substance and form of property rights. Indeed, contemporary property law scholarship is imbued with the notion that property consists of a "bundle of sticks",[235] with each stick representing a different type of relationship between a rights-holder and other legal persons.[236]

Hohfeld's analysis of property begs the following two questions: (1) if there is no 'physicality' requirement for property, what sorts of interests or resources ought to be judicially or legislatively categorized as property?; and (2) what set of *in personam* rights ought to be considered as the necessary incidents of property once a particular interest or resource has been categorized as property? It is submitted that these two questions are inextricably intertwined. In other words, the conceptual question of what property *is* can never be fully divorced from the issue of what sort of property rights ought to be recognized. And by removing the physicality requirement for property, Hohfeld expanded the concept of what property *is*, yet at the same time shrunk Blackstone's absolute conception of property rights.

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[233] *Ibid.* at 722.
[234] James E. Penner, *The idea of property in law* (Clarendon Press, Oxford, 1997) at 177.
[235] Craig A. Arnold, "The reconstitution of property: Property as a web of interests" (2002) 26 Harv. Envtl. L. Rev. 281 at 284-86.
[236] James E. Penner, "The 'bundle of rights' picture of property" (1996) 43 UCLA L. Rev. 711 at 713.

In the decades since Hohfeld's publications, legal scholars have debated the meaning of the term "property right". Lawrence Becker has written that property rights "are the rights of ownership",[237] which is itself a highly ambiguous term. In *Oxford Essays in Jurisprudence*,[238] A.M. Honoré published a paper entitled "*Ownership*", in which he listed eleven elements which he described as necessary for full, liberal ownership of an item or resource. Notably, Honoré's eighth element was defined as the "absence of term", meaning that full ownership rights must be of indefinite duration. Therefore, at this point we can already conclude that according to Honoré, an *eight-year* period of protection for clinical trial data would not constitute full, liberal ownership of that data. However, regardless of how 'ownership' is defined, it is clear that an ownership right or 'property right' gives a legal person the right to use, the right to sell or transfer, and most importantly, the right to exclude others from the item or resource that is owned.

Returning to the question of what interests or resources ought to be categorized as property, it is important to recognize that the changing conception of property during the twentieth century has resulted in the 'propertization' of many new interests and resources. For instance, in the past few decades, Canadian courts have expanded the rubric of 'property' in cases dealing with everything from government entitlements [239] to algorithms and computer hardware.[240] The concept of property has also expanded within the field of patent law in recent years, particularly in the US where the Supreme Court

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[237] Lawrence C. Becker, *Property rights: Philosophical foundations* (London: Routledge and Kegan Paul, 1977) at 18 [Becker, *Property Rights*].
[238] A.M. Honoré, "Ownership" in *Oxford Essays in Jurisprudence*, A.G. Guest ed. (Oxford, Clarendon Press, 1961) at 107-47.
[239] *Re Webb and Ontario Housing Corporation*, (1978) 22 O.R. (2d) 257 (C.A.).
[240] *Re Motorola Inc. Patent Application No. 2,085,228*, (1998) 86 C.P.R. (3d) 71 (P.A.B.).

has held that transgenic animals, stem cells and "everything under the sun made by man" is patentable.[241] Meanwhile, the EU recently adopted a novel legislative regime aimed at protecting compilations of data, thereby creating a new category of intellectual property.[242] Indeed, it is extremely easy for judiciaries and legislatures to expand the scope of the term property and begin treating new interests and resources as property. Furthermore, strengthening the protection surrounding an interest or resource is also fairly simple. For instance, over the past two decades the US congress has significantly strengthened American copyright laws.[243]

However, it is a much more difficult task to provide a coherent theoretical justification for treating new interests, resources or things as property, and for justifying new laws that strengthen existing property rights regimes. In the following sections of Chapter IV of this thesis, the four legal theories typically used to justify intellectual property rights - namely, utilitarianism, personality theory, labour theory and social-contract theory - will be introduced and discussed. At this point, it is important to state that this thesis will not delve into a philosophical discussion of whether the concept of private property itself can be justified, or whether there ought to be *any* private property rights at all. In other words, Chapter IV will not address the issue that legal scholar Lawrence Becker calls the problem of a "*general* justification"[244] of private property. Instead, Chapter IV of this thesis will consider whether any of the aforementioned legal theories can provide a

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[241] *Diamond v.Chakrabarty*, 447 U.S. 303 (1980) at 308-9.
[242] EC, *Council Directive 96/9/EC of the European Parliament of 11 March 1996 on the Legal Protection of Databases*, [1996] O.J. L. 77/20, online: Eur-Lex <http://europa.eu.int/ISPO/infosoc/legreg/docs/969ec.html>.
[243] *Sonny Bono Copyright Term Extension Act*, Pub. L. No. 105-298, 112 Stat. 2827 (1998) (codified as amended in scattered sections of 17 U.S.C.).
[244] Becker, *Property Rights*, *supra* note 237 at 3.

"*specific* justification"[245] for the enactment of a specific *type* of property right; namely, an eight-year period of exclusivity for clinical trial data submitted in marketing approval applications for pharmaceutical drugs.

Section 2 - Utilitarianism

The theory of utilitarianism was first described and defended by the nineteenth century English philosophers Jeremy Bentham and John Stuart Mill.[246] In the *Principles of Morals and Legislation*, Jeremy Bentham wrote that "[a]n action then may be said to be conformable to the principle of utility, or, for shortness sake, to utility, (meaning with respect to the community at large) when the tendency it has to augment the happiness of the community is greater than any it has to diminish it".[247] Due to the fact that Bentham's philosophy is solely concerned with the *consequences* of particular actions and with increasing the happiness of society, utilitarianism has been described as both a consequentialist and hedonistic philosophical doctrine.[248]

However, because certain acts conformable with the principle of utility are morally and ethically questionable, twentieth century philosophers and legal theorists generally distinguish between two categories of utilitarianism: act-utilitarianism and rule-utilitarianism. While Bentham's act-utilitarianism is solely concerned with the total goodness or badness of the consequences of particular actions, rule-utilitarianism provides that "rules will be established by reference to the principle of utility, and

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[245] *Ibid.*
[246] James Rachels, *The elements of moral philosophy* 3rd ed. (New York: Random House, 1986) [Rachels].
[247] Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation* (Oxford: Clarendon Press, 1876) at 3 [Bentham].
[248] Rachels, *supra* note 246 at 109-110.

individual acts will then be judged right or wrong by reference to those rules".[249] Therefore, if we wanted to demonstrate that Canadian patent rights are justified on the basis of rule-utilitarianism, it would be unnecessary to prove that each and every patent issued by the Patent Office increases Canada's economic growth or general welfare; instead, we would need to demonstrate that the *regime* of granting twenty-year property rights for novel, non-obvious inventions results in a net increase in economic growth and social welfare greater than what would occur without the regime.

In liberal democracies, rules are typically established by the judiciary in the form of legal opinions, and regimes are introduced by governments in the form of legislation and executive decisions. Indeed, one author has stated that "utilitarianism can be seen almost as built into a contract of government".[250] Bentham himself attempted to include government action into his utilitarian philosophy when he wrote that "[a] measure of government (which is but a particular kind of action, performed by a particular person or persons) may be said to be conformable to or dictated by the principle of utility, when in like manner the tendency which it has to augment the happiness of the community is greater than any which it has to diminish it".[251]

If we consider the proposed 2006 Regulation, a utilitarian justification or rationale for such government action would require us to establish that Canadian society would benefit from treating clinical test data as property, and from granting innovators an eight-year

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[249] *Ibid.* at 118.
[250] J.J.C. Smart & Bernard Williams, *Utilitarianism: For and against* (Cambridge: Cambridge University Press, 1973) at 136.
[251] Bentham, *supra* note 247 at 3.

period of exclusivity for data submitted in marketing approval applications. In this regard, political philosopher Alan Ryan has written that the utilitarian justification of property rights is, in general, "a matter of showing how a system of legally defined and enforced rights and duties best promotes the general welfare".[252] Innovators would argue that by enacting a Canadian data protection regime and enforcing an eight-year term of market exclusivity, the federal government is encouraging companies to conduct clinical trials on unpatentable drugs, such as naturally occurring substances and biologics, thereby ensuring that such drugs are brought to market. This rule-utilitarian rationale has also been used to argue for a broader definition of the term "invention" under section 2 of Canada's *Patent Act*.[253] In a dissenting opinion in the Supreme Court of Canada decision in *Harvard College v. Canada (Commissioner of Patents)*,[254] Binnie J., stated that "it is indisputable that vast amounts of money must be found to finance biomedical research. It is necessary to feed the goose if it is to continue to lay golden eggs".[255]

Law and economics scholars also adhere to the notion that intellectual property rights ensure that limited resources are utilized most efficiently. For instance, in an influential article pertaining to copyright law, William Landes and Richard Posner wrote that "without copyright protection, authors, publishers, and copiers would have inefficient incentives with regard to the timing of various decisions", and that "there would be a shift toward the production of works that are difficult to copy".[256] Moreover, in an article

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[252] Alan J. Ryan, "Utility and Ownership" in *Utility and Rights*, ed. Frey, Blackwell/University of Minnesota Press, 1985).
[253] *Patent Act*, *supra* note 34, s. 2.
[254] [2002] 4 S.C.R. 45 [*Harvard College*].
[255] *Ibid.* para. 25.
[256] William Landes, Richard Posner, "An Economic Analysis of Copyright Law" (1989) 18 J. Leg. Stud. 325 at 332.

relating to the economic efficiencies of trade-mark protection, Landes and Posner stated that "trademarks lower search costs and foster quality control rather than create social waste and consumer deception".[257] The benefit conferred on the public in return for a monopoly in a trade-mark is "in assuring consumers that they are buying from the source from whom they think they are buying and receiving the quality which they associate with that particular trade-mark".[258] In fact, out of all the established intellectual property rights regimes in developed jurisdictions, trademark law may be the most amenable to a utilitarian justification.

On the other hand, utilitarianism does not seem to provide a compelling justification for treating clinical test data as a new form of intellectual property. In the absence of empirical evidence to the contrary, it is difficult to imagine how granting innovators an additional means of preventing cheaper generic drugs from coming to market would promote the general welfare of Canadians. As philosopher Edwin C. Hettinger has written, establishing the right to restrict the current availability and use of existing intellectual products for the purpose of increasing the future availability and use of new intellectual products is a paradoxical approach.[259] In this regard, granting innovators an eight-year term of data protection will not necessarily result in the production of more of Binnie J.'s "golden eggs". In fact, data protection may actually retard the discovery and production of truly innovative drug products; namely, those that are patentable. If the 2006 Regulation is brought into force, Canadian pharmaceutical companies may begin to

[257] William Landes & Richard Posner, "Trademark law: An economic perspective" (1987) 30 J. Law and Econ. 265 at 270.
[258] *Mattel. Inc. v. 3894207 Canada Inc.*, 2006 SCC 22 at para. 21.
[259] Edwin Hettinger, "Justifying Intellectual Property" (1988) 18(1) Philolsophy and Public Affairs 31 at 48.

focus their attention on producing unpatentable drug products such as biologics and naturally occurring substances, or "me-too" drugs protected by weak patents of questionable validity. The research costs required to produce such products are typically far less than the cost of discovering and conducting research on new chemical compounds. Moreover, the Regulatory Impact Analysis Statement accompanying the 2006 Regulation does not even pretend that the proposed legislation will promote the general welfare of Canadians. Rather, the federal government states that the intent of this new data protection is to allow an innovator to protect the investments made in its drug product. Therefore, justification of the data protection regime embodied within the 2006 Regulation must be grounded upon some other theoretical approach.

Section 3 - Personality theory

The personality theory of property was first articulated by eighteenth century German philosopher Georg Wilhelm Frederick Hegel. In part one of his most famous work, *Philosophy of Right*, Hegel discussed the connections between free will, personality and the appropriation of private property. In a subsection of part one entitled "*Property*" Hegel wrote that "[p]ersonality is the first, still wholly abstract, determination of the absolute and infinite will".[260] Moreover, Hegel stated that "[p]ersonality is that which struggles to lift itself above [the restriction of being only subjective] and to give itself reality, or in other words to claim that external world as its own".[261] With regards to the appropriation of resources or things in the external world as property, Hegel wrote:

[260] Georg Wilhelm Friedrich Hegel, *Philosophy of Right*, translated by T.W. Knox (Chicago: William Benton Publisher, 1952) at para. 41.
[261] *Ibid.* at para. 39.

> "A person has as his substantive end the right of putting his will into any and every thing and thereby making it his, because it has no such end in itself and derives its destiny and soul from his will. This is the absolute right of appropriation which man has over all 'things'."[262]

Therefore, the Hegelian theory of the property acquisition revolves around the following syllogism: (1) a person has a free will; (2) a person has the substantive right to incorporate his or her free will into external 'things'; (3) due to the fact that external things have no will of their own, when a person incorporates his or her will into an external thing, that person has thereby appropriated that thing.

However, appropriation or acquisition of an external thing does not necessarily constitute a private property right in that thing. It could just mean that a person has a right of possession in that thing. Hegel addressed this issue in later paragraphs of the subsection on property when he wrote that "[s]ince my will, as the will of a person ... becomes objective to me in property, property acquires the character of private property".[263] Therefore, according to Hegel, private property is justified as an expression of a person's will or personality.

The Hegelian personality theory of property has been criticized from a number of fronts. Lawrence Becker suggests that Hegel is conflating the personal *need* to acquire and appropriate external things with the separate issue of the *right* to private property. In a direct rebuke to Hegel's theory, Becker writes that "[i]t cannot follow simply from the

[262] *Ibid.* at para. 44.
[263] *Ibid.* at para. 46.

fact that I have a right to put my will into something (i.e. appropriate it) that I have the right to indefinite possession and capital".[264]

Professor Margaret Jane Radin writes that since the personality theory "depends partly on the subjective nature of the relationships between person and thing, it makes more sense to think of a continuum that ranges from a thing indispensable to someone's being to a thing wholly interchangeable with money".[265] Moreover, professor Radin states that the personality theory of property "generates a hierarchy of entitlements: [t]he more closely connected with personhood, the stronger the entitlement.[266] In a similar vein, intellectual property scholar Justin Hughes writes that "personality is manifested to varying degrees in different objects", and then asks the following question: "[d]oes more personality warrant more property protection?"[267]

In this author's opinion, the Hegelian personality theory is largely unsuitable as the basis of a *general* justification for property rights. However, if we consider enacting a *specific* intellectual property rights regime, or consider providing protection for *particular* things or resources, then the answer to Justin Hughes's question should be a resounding 'yes'; the more closely connected with personality, the greater the property protection. In this regard, legal scholars have noted that works such as sculptures, poems, novels and musical works are uniquely amenable to a personality justification.[268] Indeed, it would seem that certain items protected by copyright law fit most comfortably within Hegel's

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[264] Becker, *Property Rights*, *supra* note 237 at 30.
[265] Margaret Jane Radin, "Property and personhood" (1982), 34 Stan. L. Rev. 957 at 987.
[266] *Ibid.* at 986.
[267] Justin Hughes, "The philosophy of intellectual property" (1988), 77 Geo. L.J. 287 at 339 [Hughes].
[268] *Ibid.* at 340.

personality theory. Canada's *Copyright Act*,[269] which has been influenced by the legal traditions and theories of continental Europe, includes provisions that protect an author's moral rights. Furthermore, the Supreme Court of Canada has described an author's moral rights as follows:

> "Moral rights, by contrast, descend from the civil law tradition. They adopt a more elevated and less dollars and cents view of the relationship between an artist and his or her work. They treat the artist's oeuvre as an extension of his or her personality, possessing a dignity which is deserving of protection".[270]

More specifically, section 14.1 of Canada's *Copyright Act* provides that "[t]he author of a work has ... the right to the integrity of the work", while subsection 28.2(1) provides that the author's right to the integrity of a work is infringed if the work is "distorted, mutilated or otherwise modified" to the prejudice of the honour or reputation of the author.[271] Furthermore, in the case of paintings, sculptures or engravings – which can be described as works that are highly personal – the prejudice referred to in subsection 28.2(1) of the *Copyright Act* is deemed to have occurred as a result of *any* distortion, mutilation or other modification of the work.[272]

However, the necessary corollary to the assertion that more personality warrants stronger property protection is that less personality, or no connection to personhood whatsoever, ought to result in little or no property protection. In this regard, Justin Hughes has written that "difficult problems for the personality justification are posed by

[269] R.S.C. 1985, c. C-42, as amended [*Copyright Act*].
[270] *Théberge v. Galerie d'Art du Petit Champlain Inc.* (2002), 17 C.P.R. (4th) 161 (SCC).
[271] *Copyright Act*, *supra* note 269, s. 28.2(1).
[272] *Ibid.*, s. 28.2(2).

copyrightable computer software and other technological categories of intellectual property: patents, microchip masks, and engineering trade secrets".[273]

Similarly, clinical test data submitted in marketing approval applications would also pose significant justification problems for the personality theory of property. Innovative pharmaceutical companies do not search for clinical test results that reflect their personalities; rather, they are searching for data that demonstrates that their drug product is safe and effective for human consumption. As one legal scholar has argued, at some point the "external constraints" on a particular form of intellectual property may be "too great to permit meaningful expressions of personality".[274] In this regard, I would submit that innovators would be hard pressed to argue that their personalities have been incorporated or are reflected in their clinical test results. In fact, if anyone has a personality claim to data derived from clinical trials, it would be the human subjects who actually took part in the clinical trials. As such, the personality theory cannot provide a coherent justification for granting innovators an eight-year property right in data submitted in marketing approval applications to the Minister of Health.

Section 4 – Labour theory

While the personality theory of property focuses on the individual creativity that a person incorporates into an item or resource, the labour theory of property considers the value that is added to an item or resource through labour, as well as the degree of effort expended. The labour theory of property acquisition was first articulated by seventeenth

[273] Hughes, *supra* note 267 at 341.
[274] Hughes, *supra* note 267 at 343.

century English philosopher John Locke in Chapter V of the second *Treatise of Civil Government*.[275] Locke's labour theory begins with the initial proposition that:

> "The earth and all that is therein ... belong to mankind in common, as they are produced by the spontaneous hand of nature; and nobody has originally a private dominion exclusive of the rest of mankind in any of them as they are thus in their natural state".[276]

Locke then states that "there must of necessity be a means to appropriate"[277] the earth and all the fruits it naturally produces. The remaining paragraphs of Chapter V of the second *Treatise of Civil Government* consist of Locke's various justifications for "how labour could at first begin a title of property in the common things of nature".[278]

Property scholar Lawrence Becker has written that there are two basic Lockean justifications for why labour entitles a person to a property right in an item or resource: (1) the notion that labour has added something of value to an item, such that the labour and item become mixed or joined together; and (2) the notion that property rights are required as a return for the labourer's pains and effort.[279] Within Locke's first justification there are two variants, the first of which has been described as follows:

> (a) "Whenever someone, by his labour, changes a thing from its natural state";[280]

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[275] John Locke, *Treatise of Civil Government and a Letter Concerning Toleration*, Charles L. Sherman ed. (New York: Irvington Publishers Inc., 1965) [*Treatise of Civil Government*].
[276] *Treatise of Civil Government*, ch. 5, para. 26.
[277] *Ibid.*, ch. 5, para. 26.
[278] *Ibid.*, ch. 5, para. 51.
[279] Becker, *Property Rights*, *supra* note 237 at 36.
[280] *Treatise of Civil Government*, *supra* note 275 at ch. 5, para. 27 in Becker, *Property Rights*, *supra* note 237 at 33.

(b) "he has 'mixed' his labour with it – that is joined to it something that is his own";[281]

(c) "He 'thereby makes it his property', for it hath, by this labour something annexed to it that excludes the common right of other men".[282]

(d) "For this labour being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough, and as good left in common for others".[283]

The concept of mixing one's labour with a particular thing and thereby acquiring a property right in that thing has been severely criticized. Philosopher Robert Nozick has asked why one should gain a property right in an item or resource rather than lose the investment of one's labour.[284] Nozick uses the example of someone emptying a can of tomato juice into the ocean to demonstrate the absurdity of granting property rights on the basis of mixing one's labour with things in their natural state.[285] Indeed, the conclusion can be made that certain resources or things are simply not appropriable no matter how much labour is annexed or mixed with them. In this regard, property scholar Seana Shiffrin has written that in order to justify a person's appropriation of a thing through labour, the following conditions must be met: "First, things *of that sort* must be susceptible to justified private ownership. Second, the person must satisfy the conditions necessary to appropriate that specific thing".[286] However, as professor of law Wendy

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[281] *Treatise of Civil Government*, *supra* note 275 at ch. 5, para 27 in Becker, *Property Rights*, *supra* note 237 at 33.
[282] *Treatise of Civil Government*, *supra* note 275 at ch. 5, para 27. in Becker, *Property Rights*, *supra* note 237 at 33.
[283] *Treatise of Civil Government*, *supra* note 275 at ch. 5, para 27. in Becker, *Property Rights*, *supra* note 237 at 33.
[284] Robert Nozick, *Anarchy, State and Utopia* (New York: Basic Books, 1974) at 174-175.
[285] *Ibid.* at 175.
[286] Seana Valentine Shiffrin, "Lockean arguments for private intellectual property" in Stephen R. Munzer ed., *New essays in the legal and political theory of property* (Cambridge: Cambridge University Press, 2001) 138 at 143.

Gordon has noted, "Locke himself offered no precise definition of the kind of appropriative labour that could give rise to a property claim".[287]

If we apply Seana Shiffrin's conditions to the proposed 2006 Regulation, the conclusion can be made that pharmaceutical drug products containing new medicinal ingredients are the 'sort of things' susceptible to justified private ownership. After all, these drug products may already be protected to Canadian patents. Moreover, through the laborious task of conducting clinical trials and obtaining safety and efficacy data, innovators change pharmaceutical products from their natural 'unmarketable' state into drugs that can be sold to the Canadian public. However, can we conclude that innovators engage in the kind of appropriative labour necessary to give rise to an eight-year period of market exclusivity simply by conducting clinical trials and submitting their results to the Minister of Health? Considering that innovators are *already* required to submit safety and efficacy data in order to obtain a notice of compliance to market and sell their pharmaceutical products, it does not appear that Shiffrin's second condition for justifying the appropriation of a thing has been met.

Furthermore, there is also the issue of the Lockean proviso, which provides that after the appropriation of private property, there must be "enough, and as good left in common for others".[288] Property rights scholars have noted that with regards to patent protection, if a patented article is something which society would not have eventually enjoyed if no

[287] Wendy J. Gordon, "A property right in self-expression: Equality and individualism in the natural law of intellectual property", (1993), 102 Yale L.J. 1533 at 1547 [Gordon].
[288] *Treatise of Civil Government*, *supra* note 275 at ch. 5 at para. 27.

patent regime existed, then the inventor's monopoly hurts nobody.[289] However, if we consider clinical data protection, the pharmaceutical drug products protected by such regimes would have been enjoyed by society regardless of a period of market exclusivity. After all, innovators are in the business of developing and marketing new pharmaceutical drugs, and have done so in Canada for some time without the benefit of a data protection regime. Therefore, granting an innovator a time-limited monopoly in its data would increase health care costs and hurt certain individuals within Canadian society, particularly those who cannot afford to buy prescription drugs for which there are no generic alternatives. In addition, generic pharmaceutical companies would also be precluded from obtaining marketing authorizations for their bio-equivalent products for a period of eight years. As such, we can conclude that the data protection regime within the 2006 Regulation does not satisfy the Lockean 'enough and as good' proviso, and is therefore not justified by Locke's first argument for the appropriation of private property.

The second variant of Locke's first argument has been described as follows:

(a) "That labour put[s] a distinction between [the thing worked on] and [what is held in] common".[290]

(b) "[t]he distinction is that labour 'added something to [the thing] more than nature...had done' ".[291]

(c) "The thing labour adds – the difference it makes – is value"[292]..."and labour is responsible for nine-tenths or perhaps ninety-nine hundredths of the value of the products of the earth".[293]

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[289] Gordon, *supra* note 287 at 1566.

[290] *Treatise of Civil Government*, *supra* note 275, ch. 5 at para. 28 in Becker, *Property Rights*, *supra* note 237 at 34.

[291] *Treatise of Civil Government*, *supra* note 275, ch. 5 at para. 28 in Becker, *Property Rights*, *supra* note 237 at 34.

(d) "Therefore one's labour entitles one to property in the thing laboured on".[294]

The second variant of Locke's first argument has been referred to as the "value-added" theory or the "labour-desert" theory of property acquisition.[295] This variant is a consequentialist legal theory, due to the proposition that labouring and adding value to an item or thing results in a property right in that item or thing.

If we consider the data protection scheme found within the 2006 Regulation, the labour involved in obtaining safety and efficacy data is, in fact, responsible for a substantial percentage of the value of a pharmaceutical drug that has obtained marketing approval from the Minister of Health. After all, in the absence of safety and efficacy data, a pharmaceutical drug can not be marketed or sold in Canada. In this sense, the labour involved in conducting clinical trials does 'put a distinction' between drug products that are simply being tested in laboratories, as compared to drug products that have obtained marketing approval and can be sold to the Canadian public.

However, even if we accept the preceding analysis, can we conclusively state that the *consequences* of demonstrating that a pharmaceutical drug is safe and effective is that an innovator is granted an eight-year exclusive right to market and sell that drug? Moreover, can we say innovators are entitled to an eight-year property right if they can demonstrate a drug's safety and effectiveness?

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[292] *Treatise of Civil Government*, *supra* note 275, ch. 5 at para. 28 in Becker, *Property Rights*, *supra* note 237 at 34.
[293] *Treatise of Civil Government*, *supra* note 275, ch. 5 at para. 40 in Becker, *Property Rights*, *supra* note 237 at 34.
[294] Becker, *Property Rights*, *supra* note 237 at 34.
[295] Hughes, *supra* note 267 at 305-06.

One property law scholar has written that the labour-desert argument "will only support the award of property rights unequivocally if: (i) property rights are the only alternative a fully informed labourer would accept as fitting; and (ii) such an award is not a disproportionate sacrifice for others".[296] If we consider the labour involved in conducing clinical trials, fully informed innovative pharmaceutical companies have long since accepted the award of a notice of compliance to market and sell their drug products as a return for including safety and efficacy data in their drug submissions. Of course, as discussed in Chapter I of this thesis, the cost of conducting the clinical trials required to obtain such data has become extremely expensive. However, a more fitting alternative to the award of data protection leading to an eight-year period of market exclusivity might be a remuneration right, which would allow innovators the opportunity to recoup the costs of conducting clinical trials. The Regulatory Impact Analysis Statement ("RIAS") accompanying the 2006 Regulation provides support for the alternative of a remuneration right. Indeed, in the section of the RIAS entitled "*Background*", the federal government writes that "[t]he intent of this [data] protection is to allow the innovator, or originator, of the data to protect the investments made in the development of the product by allowing a period of market exclusivity".[297] Furthermore, the award of an eight-year exclusivity right may constitute a disproportionate sacrifice for individual Canadians, particularly if the drug for which the period of market exclusivity applies is a life-saving medicine. Therefore, although conducting clinical trials and obtaining safety and efficacy data adds significant value to a pharmaceutical drug, it is difficult to conclude that such labour

[296] Lawrence C. Becker, "Deserving to own intellectual property" (1993) 68 Chi.-Kent L. Rev. 609 at 626.
[297] 2006 Regulation, *supra* note 17 at 1598.

entitles an innovator to an eight-year property right in the drug that was laboured upon, or that an innovator deserves an eight-year property right. As such, we must consider Locke's second justification.

Locke's second justification for the acquisition of private property is initially identical to the second variant of the first justification, although there is the new concept of the state having to prevent the rest of society from benefiting from a person's 'painful' labour. Locke's second justification has been described as follows:

> "appropriation in most cases involves labour which would not be undertaken except for the expected benefits; to let others have the 'benefits of another's pains' would clearly be unjust".[298]

Justin Hughes has referred to this justification as the "avoidance view of labour",[299] due to the fact that since people would rather avoid engaging in labour, the government becomes obliged to grant property rights in order to get people to labour upon items or recourses in the commons. This argument is not so much that people *deserve* property rights in the fruits of their labour; rather, the second justification is predicated on the proposition that no else should benefit from another person's hard work. This justification for property rights is also found within Blackstone's observation that no one

[298] *Treatise of Civil Government*, *supra* note 275, ch. 5 at para. 34 in Becker, *Property Rights*, *supra* note 237 at 35.
[299] Hughes, *supra* note 267 at 302-03.

would take the initiative to work and cultivate if other people could simply "seise upon and enjoy the product of his industry, art, and labour".[300]

However, as with the first justification discussed above, Locke's second justification has been challenged by philosophers and property scholars alike. For example, Pierre Joseph Proudhon has posed the following rhetorical question: how can someone demand a property right for labour that the rest of society did not impose upon them, or for value that they were not asked to create.[301]

If we consider the 2006 Regulation, the second justification requires us to ask whether the act of conducting clinical trials and obtaining evidence of a drug's safety and efficacy justifies the creation of duties and responsibilities on the part of the federal government. In this regard, it is important to note that the federal government does, in fact, impose labour upon innovative pharmaceutical companies through the requirement of having to demonstrate a drug's safety and efficacy. In effect, the Minister of Health asks innovators to create value through labour. However, can the conclusion be made that the federal government has a *duty* to prevent generics from using or referring to an innovators safety and efficacy data for a period of eight years? Or, alternatively, is the jural relationship between innovators, generics and the Minister of Health more akin to what Hohfeld described as a "power-liability" relationship, as opposed to a "right-duty"

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[300] William Blackstone, *Commentaries on the Laws of England* (Chicago: Chicago University Press, 1979), vol. 2 at 7 in Carol M. Rose, "Canons of property talk, or, Blackstone's anxiety" 108 Yale L.J. 601 at 607.
[301] Pierre J. Proudhon, *What is property?: An enquiry into the principle of right and government* (New York, Howard Fertig, 1966) at 84 in Lawrence C. Becker "Deserving to own intellectual property" (1993), 68 Chi.-Kent L. Rev. 609 at 624-25.

relationship?[302] If that is the case, then innovators would simply have certain *powers* with respect to the clinical trial data they submit to the Minister of Health, and innovators would not be awarded with eight-year property rights that the federal government has a duty to uphold.

At the end of the day, the fundamental problem with justifying Canada's proposed data protection scheme with the Lockean labour theory of property is that innovators are already receiving the reward of a notice of compliance for submitting their clinical test results to the Minister of Health. Moreover, it is simply not realistic to say that innovators will refrain from conducting clinical trials if they are not awarded with an eight-year period of data protection. In fact, the only additional 'labour pains' that innovators have experienced in recent years are the rapidly escalating costs of conducting clinical trials. But this is not a sufficient reason for creating new rights in data that would result in the 'propertization' of unpatentable pharmaceutical drugs. Therefore, Locke's second version of the labour theory is simply not a coherent justification for the data protection regime found within the 2006 Regulation.

Section 5 - Social contract theory

The last of the four theoretical approaches used to justify intellectual property rights is the social contract theory, which is typically described as either a political theory or a theory of moral philosophy.[303] From a political perspective, social contract theory is said to provide a justification for representative government, in that human beings are able to

[302] Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning,* (New Haven: Yale University Press, 1919) at 23.
[303] Rachels, *supra* note 246 at 128-131.

escape from an uncivilized state of nature only if they agree to give up their unconditional freedom and abide by a set of rules and conventions.[304] A central government or authority is required in order to enforce the set of rules and conventions agreed upon by the human beings that make up the polity. This tacit agreement of governance is referred to as the 'social contract'. Therefore, the social contract theory of government is predicated on the consent of the polity, rather than on the natural or hereditary rights of a sovereign ruler.[305] And as a result of the reciprocal nature of the social contract of governance, the state forms and develops in a manner that serves to protect the interests of its members.[306]

In addition to being a political theory, a number of moral philosophers have written that social contract theory also explains the nature of morality.[307] For example, James Rachels has defined the social contract conception of morality as follows:

> "Morality consists in the set of rules, governing how people are to treat one another, that rational people will agree to accept, for their mutual benefit, on the condition that others follow those rules as well".

We can also see elements of the social contract within the Lockean proviso that each individual must ensure that there is 'enough and as good left in common for others' as there was before an appropriation of private property. In this sense, Locke's theory of

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[304] J.J. Rousseau *The social contract or principles of political right*, trans. by G.D.H. Cole, in *Great books of the western world*, Robert Maynard Hutchins ed. (Chicago: William Benton Publisher, 1952) at book 1, ch. 8.
[305] Shubha Ghosh, "Patents and the regulatory state: Rethinking the patent bargain metaphor after *Aldred*, (2004) 19 Berkeley L.J. 1315 at 1321.
[306] *Ibid.* at 1322.
[307] Rachels, *supra* note 246 at 128.

property can be described as both a natural rights theory and as a social contract theory of property.

With regard to intellectual property rights, the Supreme Court of Canada has intimated that in addition to utilitarianism, the concept of a social contract provides a further justification for Canada's patent regime. In the dissent in *Harvard College*, Binnie J. wrote that "[t]he *Patent Act* embodies the public policy that those who directly benefit from an invention should be asked, through the patent system to pay for it, at least in part".[308] Moreover, legal historians have written that between the years 1600 and 1800, there was a fundamental change in patent law in England, in that patents went from being viewed as "contracts between the crown and the patentee to [being viewed] as a social contract between the patentee and society".[309]

Social contract theory is not without its limitations however, since the scope and content of the laws to be enforced by a central government are predicated upon the type of society that is desired. As many scholars have noted, even if social contract theorists could articulate a vision of a just society, the process of formulating and enacting determinate laws and regulations in accordance with such a vision remains problematic. Social contract theorists also tend to borrow from a diverse collection of other political

[308] *Harvard College*, *supra* note 254 at para. 25.
[309] Edward C. Waltersheid, "The early evolution of the United States Patent Law: Antecedents (Part 3) (1995) 77 J. Pat. & Trad. Off. Socy. 771 at 793.

and legal theories.[310] As a result, the social contract theory suffers from the problem of indeterminacy.

Moreover, the social contract theory of governance suggests that the central government ought to perform some affirmative duties in return for the consent and acquiescence of the polity. As one author has written:

> "If the power to tax engenders a correlative right, it is sensible that this right is one to services, or at least to a voice in how tax money is spent. If citizens have a duty to refrain from private violence, there ought to be a correlative government duty to protect them".[311]

If we consider the proposed 2006 Regulation, social contract theory suggests that there ought to be a correlative government duty in return for the consent from individual Canadians to enact such a data protection regime. After all, Canadian consumers will undoubtedly have to spend more of their disposable income to obtain pharmaceutical drugs that are protected by an eight-year period of market exclusivity. In this regard, it would seem sensible for the federal government to mandate that innovators submit additional information in their drug submissions in return for the statutory grant of a new property right protecting that information. One possibility would be for the Minister of Health to insist that clinical data submitted by innovators in a drug submission not only demonstrates that a particular pharmaceutical product is safe and effective for human

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[310] William Fisher "Theories of intellectual property", in S.R. Munzer ed., *New Essays in the legal and political theory of property*, (Cambridge: Cambridge University Press, 2001) at 172.
[311] Susan Bandes, "The negative constitution: A critique" (1990), 88 Mich. L. Rev. 2271 at 2238-39.

consumption, but that the drug is *safer* and *more effective* than previously approved drugs used to treat the same malady or disease.

However, according to the provisions of the proposed 2006 Regulation, the federal government will not be enacting any correlative government duties if an eight-year period of data protection is brought into force. In other words, the newly proposed data protection scheme does not conform to the concept of a bargain or a social contract at all. Therefore, the conclusion can be made that the social contract theory of intellectual property does not provide a robust theoretical justification for the proposed data protection scheme found within the 2006 Regulation.

Section 6 – Conclusion

None of the four theoretical perspectives currently used by legal scholars to justify intellectual property rights can be said to provide a cogent justification for data protection leading to an eight-year period of market exclusivity for pharmaceutical drugs. However, due to the nature of the property right we are attempting to justify, this is perhaps not surprising. Clinical test data submitted to government agencies in marketing approval applications is definitely located at the outer margins of what can realistically be considered 'intellectual property'. A more accurate definition of clinical test data is that of "gathered information".[312] And Anglo-American common law has always struggled with claims for property rights in gathered information, largely due to the fact that existing intellectual property rights regimes serve to protect non-obvious inventions or tangible expressions of ideas, as opposed to compilations of facts. As such, a *sui generis*

[312] Hughes, *supra* note 267 at 292.

right must be legislatively or judicially created if a claim for a property right in gathered information is to be sustained. For example, in the 1918 decision in *International News Service v. Associated Press*,[313] the US Supreme Court struggled with the issue of whether a company that expends time and effort in gathering news worldwide for the purpose of publication in the US ought to be granted a time-limited property right in its news. Although a majority of the US Supreme Court held that contemporaneous news "must be regarded as *quasi* property",[314] and that a *sui generis* property right was warranted in order to prevent a competing company from reaping where it had not sown, there were two lengthy dissenting opinions in *INS*, and the majority decision remains controversial to this day.

In many ways, the current problem of attempting to provide a justification for a property right in clinical trial data mirrors the submission in *INS* that contemporaneous or 'hot' news constitutes quasi property that ought to be protected by a *sui generis* property right. In both instances, either the legislature or the judiciary must decide to categorize gathered information as property, and then assign a particular form of protection as a result of that categorization. In *INS*, the US Supreme Court justified its decision to categorize hot news as quasi property by relying upon the labour-desert theory,[315] as well as an incentive-based justification akin to utilitarianism.[316] However, is important to note that in *INS*, the US Supreme Court held that the period of protection to be afforded to hot news was to last only "until its commercial value as news to the complainant and all of

[313] 248 U.S. 215 (1918) [*INS*].
[314] *INS* at 236.
[315] *INS* at 239.
[316] *INS* at 241.

[its competitors] has passed away".[317] Therefore, although the US Supreme Court categorized hot news as quasi property that was capable of being misappropriated, the specific type of property right granted in *INS* was extremely limited in duration. Hence, the particular form of protection afforded to hot news in *INS* was, in substance, at the outer margins of what can be realistically be considered a property right.

The unique solution formulated by the US Supreme Court in *INS* should not be lost upon the federal government of Canada in its attempt to provide protection for clinical trial data submitted by innovators. Alternative forms of protection less akin to a property right could aid in the justification of the 2006 Regulation, from both a theoretical and a practical perspective. Regarding this issue, in the final Chapter of this thesis, I will explore various alternatives to protecting clinical trial data with an eight-year property right, and suggest possible amendments to the 2006 Regulation.

[317] *INS* at 245.

Chapter V - Potential amendments to Canada's proposed data protection regulation

Section 1 - Introduction

In Chapter V, I will propose an alternative legal mechanism for protecting marketing approval data in lieu of an eight-year property right. In section two, Canada's innovative pharmaceutical industry will be examined in greater detail. In section three, the concept of protecting clinical trial data with a remuneration right, as opposed to an eight-year exclusivity right will be introduced. Finally, in the last section of this thesis, I will suggest that an appropriate balance needs to be struck between innovators and generics regarding the protection of marketing approval data.

Section 2 – The Canadian perspective regarding data protection

The protection of clinical trial and other test data is rapidly becoming a "North-South" issue, pitting the interests of the US, EU and other drug-exporting countries against the interests of the world's less developed countries. [318] Despite the US Trade Representative's insistence that Article 39.3 of TRIPs *already* requires WTO Member States to grant exclusivity rights to the originator of marketing approval data, the US has begun to pressure its trading partners to accept explicit five-year data protection provisions in bilateral trade agreements. These five-year data protection provisions were included in recent US trade agreements with Singapore,[319] Chile,[320] Australia,[321] and

[318] Pugatch, *Data Exclusivity*, *supra* note 5 at 18.
[319] *US-Singapore Free Trade Agreement*, United States and Singapore, 15 January 2003, art. 16.8(1), online: US Trade Representative <http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/asset_upload_file708_4036.pdf>.

Bahrain.[322] Notably, the inclusion of an explicit data protection provision in a bilateral trade agreement has multilateral effects. Pursuant to Article 4 of TRIPs, any advantage, favour or privilege granted by a Member State of the WTO to the nationals of any other country must be accorded immediately and unconditionally to the nationals of all other Members.[323] Therefore, drug-exporting countries other than the US, such as Japan, Switzerland and the EU will all benefit from the trade concessions made by a WTO Member to the US in a bilateral trade agreement. One commentator has referred to this US tactic as a "divide and conquer strategy of isolating developing countries",[324] thereby "homogenizing data exclusivity ... on terms favourable to intellectual property exporting WTO members".[325]

Canada is not an innovative drug-exporting WTO member. In 1996, Canada had the second largest trade deficit in pharmaceuticals out of the 29 OECD countries.[326] In addition, most of Canada's innovators are subsidiaries of American and European multinational pharmaceutical companies. Hence, from a Canadian perspective, it is

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[320] *US-Chile Free Trade Agreement*, United States & Chile, 3 April 2003, art. 17.10(1), online: US Trade Representative <http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/asset_upload_file912_4011.pdf>.

[321] *US-Australia Free Trade Agreement*, United States & Australia, 18 May 2004, art. 17.10(1)(a), online: US Trade Representative <http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file469_5141.pdf>.

[322] *US-Bahrain Free Trade Agreement*, United States & Bahrain, 14 September 2004, art. 14.9(1)(a), online: US Trade Representative <http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Bahrain_FTA/final_texts/asset_upload_file211_6293.pdf> [*US-Bahrain FTA*].

[323] TRIPs, *supra* note 151, art. 4.

[324] Aaron Xavier Fellmeth, "Secrecy, monopoly, and access to pharmaceuticals in international trade law: Protection of marketing approval data under the TRIPs Agreement", (2004) 45 Harv. Int'l L.J. 443 at 456.

[325] *Ibid.*

[326] Joel Lexchin, "Intellectual property rights and the Canadian pharmaceutical marketplace: Where do we go from here?" (2005) 35:2 Int'l J. Health Services 237 at 239.

submitted that the federal government ought to consider whether the creation of an eight-year period of data protection will actually result in increased innovation from Canada's pharmaceutical industry.

In this regard, it is instructive to consider a report published by the Patented Medicines Prices Review Board in December 2002,[327] which found that total research and development ("R&D") spending in Canada by innovative pharmaceutical companies rose from $626 million in 1995 to $945 million in 2000, an increase of 51%.[328] However, the same report also noted that total drug *sales* by pharmaceutical patentees rose by almost 75% over the same period, and reached $9.3 billion in 2000. Therefore, the ratio of R&D spending to domestic sales in Canada actually *decreased* from 11.7% in 1995 to 10.1% in 2000.[329] By contrast, the ratio of R&D spending to domestic sales in the US held steady at 18.4% from 1995 to 2000, and was approximately 19% in 2000 for the European countries included within the report.[330] Therefore, it is abundantly clear that innovative pharmaceutical companies in Canada were not reinvesting a proportionate amount of their increased revenues into pharmaceutical drug research. In addition, the period from 1995 to 1999 coincides with the first number of years that the *Patented Medicines (Notice of Compliance) Regulations* were in effect in Canada, which gave innovators a new *procedural* right to prevent generic drugs from coming to market.

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[327] Patented Medicines Prices Review Board, Study Series S-0217, "A comparison of pharmaceutical research and development spending in Canada and selected countries (2002)", online: PMPRB <http://www.pmprb-cepmb.gc.ca/CMFiles/ss-0217e14HCB-492003-5262.pdf>.
[328] *Ibid* at 5.
[329] *Ibid* at 13.
[330] *Ibid* at 13.

If the 2006 Regulation is brought into force, innovators will be given a new *substantive* right to prevent generic drugs from obtaining marketing approval authorizations from Health Canada. As such, the federal government ought to consider whether the creation of this new property right will increase the availability and use of new pharmaceutical drugs more than that of any alternative mechanism.

Admittedly, the federal government's ability to enact alternatives to the 2006 Regulation is circumscribed by Canada's treaty obligations pursuant to the NAFTA and TRIPs Agreement. However, as discussed in Chapter III, the ambiguous wording of both Article 1711 of the NAFTA and Article 39.3 of TRIPs means that a number of interpretations of the scope and applicability of these provisions are plausible. Furthermore, pursuant to the interpretive principle of *in dubio mitius*,[331] widely recognized in international law as a supplementary means of interpretation, sovereign states cannot be assumed to have intended to impose more onerous obligations upon themselves (as opposed to less burdensome obligations) where the language of a treaty is ambiguous. Therefore, it is submitted that we should not automatically conclude that Article 1711 of the NAFTA and Article 39.3 of TRIPs impose upon the Canadian government the onerous obligation of enacting a five-year (let alone an eight-year) period of data protection, leading to market exclusivity. Article 1711(6) simply provides that no person other than the Party who submitted the marketing approval data can "rely on such data in support of [a subsequent] application for product approval during a reasonable

[331] *European Communities – Measures Concerning Meat & Meat Products*, WT/DS26/AB/R, WT/DS48/AB/R (Appellate Body Report) January 16, 1998, at para. 165 and footnote 154.

period of time after [the original submission]".[332] Nowhere in Article 1711 is the health regulatory authority of a Party to the NAFTA explicitly precluded from granting a marketing approval authorization to a subsequent applicant. By contrast, the data protection provisions included in bilateral trade agreements that the US recently ratified with Chile, Singapore, Australia and Bahrain all contain language explicitly precluding marketing approval authorizations for subsequent applicants for a period of five years. For instance, the data protection provision found within the recently ratified *US-Bahrain Free Trade Agreement* reads as follows:

> "Article 14.9: Measures Related To Certain Regulated Products
>
> 1. (a) If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on:
>
> (i) the safety or efficacy information submitted in support of the marketing approval; or
>
> (ii) evidence of the marketing approval;
>
> for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the Party."[333]

Therefore, it is submitted that the language found in Article 1711 of the NAFTA cannot be interpreted so as to require the Canadian government to reward innovators with a five-year (or an eight-year) property right in marketing approval data. However, it is also

[332] NAFTA, *supra* note 150, art. 1711(6).
[333] *US-Bahrain FTAt*, *supra* note 322, art. 14.9(1).

facile to suggest that Canada has no obligations whatsoever regarding the protection of innovators' marketing approval data, which was the Federal Court's finding in the *Bayer* decision. As discussed in Chapter III, Article 39.3 of the TRIPs Agreement allows for flexibility in the implementation of a minimum standard of data protection. In the next section, a more flexible data protection regime will be introduced, which would allow for increased generic market entry and at the same time effectively implement Canada's international treaty obligations.

Section 3 – A Canadian compromise regarding data protection

The federal government has written that the legislative intent behind the 2006 Regulation is to protect an innovator's investment in the development of a drug product by allowing for a period of market exclusivity.[334] However, the grant of a time-limited exclusive property right is only one mechanism for protecting investments. In this section, an alternative means of protecting clinical trial data will be introduced.

Property rights are the form of protection giving rise to the least amount of state intervention once they have been awarded.[335] For example, pursuant to the proposed data protection scheme within the 2006 Regulation, only an innovator can consent to the issuance of a notice of compliance to a generic manufacturer before the end of the eight-year period of market exclusivity.[336] Even if the generic offers to compensate the innovator for its consent to market a pharmaceutical drug before the period of data

[334] 2006 Regulation, *supra* note 17 at 1598.
[335] Guido Calabresi & A. Douglas Melamed, "Property rules, liability rules, and inalienability: One view of the cathedral" (1972) 85:6 Harv. L.Rev. 1089 at 1092 [Calabresi & Melamed].
[336] 2006 Regulation, *supra* note 17, s. C.08.004.1(6).

protection expires, the innovator's property right constitutes a veto to reject all offers. Health Canada will not be permitted to assess the value of the data protection entitlement and will not have the authority to order the innovator to consent to the issuance of a notice of compliance for a prescribed amount of compensation. As professor Guido Calabresi and Douglas Melamed aptly wrote, "[p]roperty rules involve a collective decision as to who is to be given an initial entitlement but not as to the value of the entitlement".[337] By contrast, whenever the government or a third party can revoke or rescind an initial entitlement by paying an "objectively determined value for it, an entitlement is protected by a liability rule",[338] giving rise to a right to remuneration.

As discussed in Chapter II, the first data protection regime enacted in the US pertained to the pesticide and insecticide industries and the submitted data was protected by a remuneration right, not a property right. Also recall that this inaugural data protection regime was short-lived, due to the ambiguous wording of *FIFRA*, and because the US Environmental Protection Agency was ill-equipped to determine the appropriate amount of compensation to be awarded to an innovative pesticide manufacturer under *FIFRA*'s data-licensing scheme. Indeed, if the decision is made to protect clinical trial data with a remuneration right, we must also consider which institutions and procedures are most suitable for determining the value of the entitlement. For instance, if the Canadian government sought to enact a compulsory licensing regime for marketing approval data submitted to Health Canada in new drug submissions, it would also have to give an institution or tribunal the ability to assess the value of the submitted data.

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[337] Calabresi and Melamed, *supra* note 335 at 1092.
[338] *Ibid.*

In Canada, there is already a quasi-judicial agency called the Patented Medicines Prices Review Board ("PMPRB") which regulates the prices that pharmaceutical manufacturers may sell patented medicines to wholesalers, such as pharmacies. The PMPRB was created in 1987 as part of the amendments to the *Patent Act* restricting compulsory licensing of pharmaceuticals under patent protection.[339]

The PMPRB is mandated by the *Patent Act* to ensure that the price of patented medicines in Canada is not excessive.[340] Pursuant to federal regulations,[341] patentees must submit to the PMPRB information regarding the quantity of the medicine sold and either the average price per package or the net revenue from sales of each dosage form.[342] Subsequently, the PMPRB reviews the pricing information of patented drug products on an on-going basis and has the authority to conduct factual investigations. If the PMPRB conducts an investigation and finds that the price of a patented drug product is excessive, the PMPRB may make a binding order directing the patentee to "cause the maximum price at which the patentee sells the medicine ... to be reduced to such level as the Board considers not to be excessive and as is specified in the order".[343]

In other words, the exclusive twenty-year right to make, use and sell a pharmaceutical drug product claimed in a valid Canadian patent is circumscribed by the PMPRB. Likewise, if the 2006 Regulation is enacted, the federal government should also create a

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[339] *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41.
[340] *Patent Act*, *supra* note 34, s. 83(1).
[341] *Patented Medicines Regulations, 1994*, SOR/94-688.
[342] *Ibid.*, s. 4(1)(e).
[343] *Patent Act*, *supra* note 34, s. 83(1).

quasi-judicial body circumscribing an innovator's right to the exclusive use of clinical trial data submitted to the Minister of Health. For instance, the federal government could enact a regime similar to that found within the 1972 *FIFRA* regime in the US. As such, generic manufacturers would be able to submit an offer to compensate an innovator for its consent to market a particular pharmaceutical drug during the applicable period of data protection. If the innovator refused the offer, the generic manufacturer could then apply to a quasi-judicial body for a determination of an appropriate licensing fee to be paid to the innovator.

Innovators would likely argue that the amount of any licensing fee ought to be tied to the market value of the drug associated with the clinical trial data. However, it is submitted that this would be an erroneous method of valuation. After all, the rationale for protecting clinical trial data in the first place is to protect innovators' investments in the development of drug products, not the profits accruing from the sale of pharmaceutical drugs. Therefore, clinical trial data relating to a drug that possesses an enormous market and profit potential should not be valued higher than equivalent data associated with a poorly-selling drug. Arguably, it would be prudent public policy if the quasi-judicial body simply considered the investments made in the development of drug products when determining the appropriate licensing fee. If that were the case, innovators would likely attempt to drive up the cost of their clinical trials as much as possible in order to increase the applicable licensing fee. Innovators may even choose to substantially increase the sample sizes used in their human clinical trials, which would provide Health Canada with more in-depth clinical trial data. This could result in an increased awareness of the

potential side-effects associated with a particular drug. Of course, the quasi-judicial body would also have to be wary of attempts by innovators to unnecessarily drive up the costs of clinical trials. For instance, the payment of exorbitant 'consulting' fees to the individuals managing an innovator's clinical trials would need to be excluded from the calculation of the amount invested in the development of the applicable drug product. As such, the members appointed to the quasi-judicial body would have to be well-versed in accounting principles.

The amount of the licensing fee payable to the innovator should also be tied to the length of time remaining on the data protection period. For instance, if a generic manufacturer sought an innovator's consent to apply for a notice of compliance in the first year of the data protection term, it would be required to pay a greater licensing fee than in the last year of the data protection term. I would suggest that generic manufacturers be required to pay 50% of the total costs of an innovator's pre-trial testing and clinical trials if an offer is made in the first year of the data protection term; 40% in the second year; 30% in the third year; 20% in the fourth year; and 10% in the fifth year. After the fifth anniversary of an innovator's original marketing authorization, no data protection would subsist and the Minister of Health would be free to issue a notice of compliance to subsequent applicants who submit the appropriate bio-equivalency data. As such, my proposed data protection term would last for a period of five years. Furthermore, if a second generic manufacturer submitted an offer to an innovator after the first generic had already paid the applicable licensing fee, the second generic would also be required to pay a licensing fee to the innovator, calculated on the scale described above.

Sections 4 – Conclusion

In Canada, there has always been an intense competition between innovative and generic pharmaceutical companies for market share. From 1969 until 1987, generic manufacturers were able to receive compulsory licenses to sell patented drug products almost as of right.[344] In 1987, the federal government restricted the ability of generics to apply for compulsory licenses, and in 1993, Canada's compulsory licensing regime was completely abolished.[345] Indeed, in the past few decades, the federal government's policy with regards to pharmaceutical drugs has been tilted in favour of innovators.

However, a balance needs to be struck between the interests of innovative pharmaceutical companies and their generic counterparts. Due to the escalating costs of human clinical trials, innovators require some form of protection for their investments in medicinal drug products in addition to patent protection. Indeed, patents can be said to provide protection for the investments made in the discovery of the compounds that make up the medicinal ingredient found in a pharmaceutical drug. However, generic manufacturers, as well as ordinary Canadian citizens, should not be unduly burdened by unjustifiable intellectual property rights or a severe term of data exclusivity.

Despite the federal government's insistence that there is a need to harmonize the "[data] protection offered in Canada with the protection offered in comparable jurisdictions",[346] it should be remembered that Canada's innovative pharmaceutical industry is not

[344] Randy Marusyk & Dr. Margaret Swain, "Price control of patented medicines in Canada" (1993) 10 C.I.P.R. 159 at 162.
[345] *Supra* note 37.
[346] 2006 Regulation, *supra* note 17 at 1601.

'comparable' to those of the US and EU. A unique Canadian compromise is required with regards to the enactment of a regime aimed at protecting innovators' investments in clinical trials. As such, the federal government ought to enact a data protection regime providing innovators with a five-year right to remuneration, instead of an eight-year exclusive property right.

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